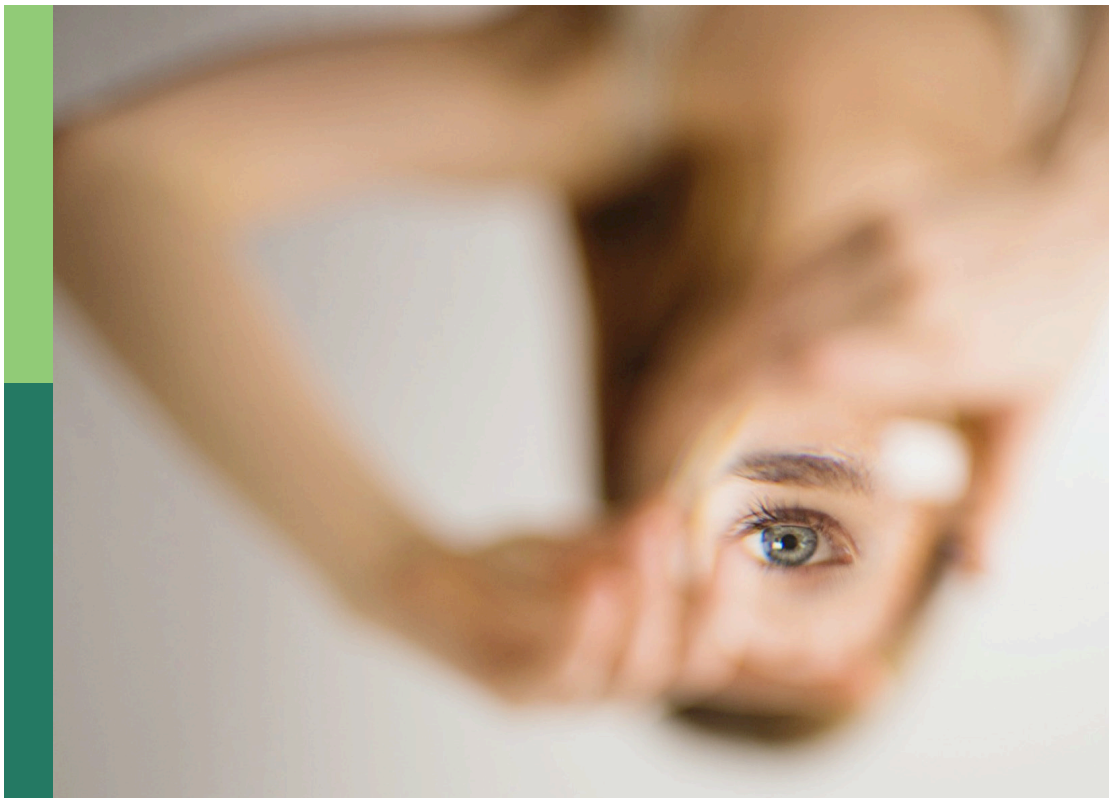
frontiers | Research Topics

Non-pharmacological interventions for mental disorders

Edited by
Lara Guedes De Pinho, César Fonseca, Manuel Lopes, Brooke Schneider and Łukasz Gawęda

Published in
Frontiers in Psychology
Frontiers in Public Health



ISSN 1664-8714
ISBN 978-2-8325-4708-3
DOI 10.3389/978-2-8325-4708-3

About Frontiers

Frontiers is more than just an open access publisher of scholarly articles: it is a pioneering approach to the world of academia, radically improving the way scholarly research is managed. The grand vision of Frontiers is a world where all people have an equal opportunity to seek, share and generate knowledge. Frontiers provides immediate and permanent online open access to all its publications, but this alone is not enough to realize our grand goals.

Frontiers journal series

The Frontiers journal series is a multi-tier and interdisciplinary set of open-access, online journals, promising a paradigm shift from the current review, selection and dissemination processes in academic publishing. All Frontiers journals are driven by researchers for researchers; therefore, they constitute a service to the scholarly community. At the same time, the *Frontiers journal series* operates on a revolutionary invention, the tiered publishing system, initially addressing specific communities of scholars, and gradually climbing up to broader public understanding, thus serving the interests of the lay society, too.

Dedication to quality

Each Frontiers article is a landmark of the highest quality, thanks to genuinely collaborative interactions between authors and review editors, who include some of the world's best academicians. Research must be certified by peers before entering a stream of knowledge that may eventually reach the public - and shape society; therefore, Frontiers only applies the most rigorous and unbiased reviews. Frontiers revolutionizes research publishing by freely delivering the most outstanding research, evaluated with no bias from both the academic and social point of view. By applying the most advanced information technologies, Frontiers is catapulting scholarly publishing into a new generation.

What are Frontiers Research Topics?

Frontiers Research Topics are very popular trademarks of the *Frontiers journals series*: they are collections of at least ten articles, all centered on a particular subject. With their unique mix of varied contributions from Original Research to Review Articles, Frontiers Research Topics unify the most influential researchers, the latest key findings and historical advances in a hot research area.

Find out more on how to host your own Frontiers Research Topic or contribute to one as an author by contacting the Frontiers editorial office: frontiersin.org/about/contact

Non-pharmacological interventions for mental disorders

Topic editors

Lara Guedes De Pinho — University of Evora, Portugal
César Fonseca — University of Evora, Portugal
Manuel Lopes — University of Evora, Portugal
Brooke Schneider — University Medical Center Hamburg-Eppendorf, Germany
Łukasz Gawęda — Institute of Psychology, Polish Academy of Sciences, Poland

Citation

De Pinho, L. G., Fonseca, C., Lopes, M., Schneider, B., Gawęda, Ł., eds. (2024). *Non-pharmacological interventions for mental disorders*. Lausanne: Frontiers Media SA. doi: 10.3389/978-2-8325-4708-3

Table of contents

frontiers | Frontiers in Psychology

TYPE Editorial
PUBLISHED 22 March 2024
DOI 10.3389/fpsyg.2024.1363348

OPEN ACCESS

EDITED AND REVIEWED BY
Gianluca Castelnuovo,
Catholic University of the Sacred Heart, Italy

*CORRESPONDENCE
Brooke C. Schneider
b.viertel@uke.de

RECEIVED 30 December 2023
ACCEPTED 01 March 2024
PUBLISHED 22 March 2024

CITATION
Pinho LG, Fonseca C, Gawęda Ł, Lopes M and Schneider BC (2024) Editorial: Non-pharmacological interventions for mental disorders. *Front. Psychol.* 15:1363348. doi: 10.3389/fpsyg.2024.1363348

Editorial: Non-pharmacological interventions for mental disorders

Lara Guedes de Pinho[1,2], César Fonseca[1,2], Łukasz Gawęda[3], Manuel Lopes[1,2] and Brooke C. Schneider[4]*

[1]Nursing Department, University of Évora, Évora, Portugal, [2]Comprehensive Health Research Centre (CHRC), University of Évora, Évora, Portugal, [3]Experimental Psychopathology Lab, Institute of Psychology, Polish Academy of Sciences, Warsaw, Poland, [4]Department of Psychiatry and Psychotherapy, University Medical Center Hamburg-Eppendorf, Hamburg, Germany

KEYWORDS

mental health, depression, psychosis, lifespan perspective, scalability, wellbeing, psychotherapy

Editorial on the Research Topic
Non-pharmacological interventions for mental disorders

International evidence-based treatment guidelines recommend non-pharmacological interventions as gold standard approaches for the treatment of most mental disorders. Despite this, a large treatment gap exists such that many individuals suffering from mental disorders receive only medication or no treatment at all (Kazdin, 2017). The World Health Organization has declared improving mental health a top priority for worldwide sustainability (World Health Organization, 2019) and recommended several transformations of world mental health practices to improve access for all individuals (World Health Organization, 2022). Inspired by this, in this Research Topic, we sought to support dissemination of research on all types of non-pharmacological interventions for mental health and thus, highlight possible avenues for closing the mental health treatment gap and improving mental health care.

Promotion of cost-effective preventative approaches is necessary to promote good mental health globally and to prevent the onset of mental disorders (World Health Organization, 2022). The systematic umbrella review by Saijonkari et al. aimed to evaluate the effectiveness of interventions for the promotion of mental health and mental wellbeing, as well as for the primary prevention of mental health disorders. This review found evidence primarily for interventions that utilize cognitive-behavioral therapy (CBT) and promote resilience, mindfulness or healthy lifestyles. Interventions such as motivational interviewing to reduce alcohol consumption in young adults, parenting interventions and workplace interventions are also covered.

Primary treatment approaches for anxiety include psychotherapy as well as pharmacotherapy; however, the use of alternative treatment approaches may help reach more individuals suffering from symptoms, especially treatments which can be administered by professionals without specialized training in mental healthcare. The meta-analysis by Hong et al. evaluated the efficacy of electroacupuncture (EA) for patients with anxiety, concluding that this intervention significantly reduced patients' anxious symptomatology, suggesting it as an effective therapeutic option.

Development of sustainable long-term care models for treatment of severe mental illness is necessary to reduce healthcare costs and support symptom stability. Yet, little is known about patients' perceptions of these programs. Rohenkohl et al. examined patients' preferences in relation to integrated care provided in the "Hamburg Model (ACCESS)," a multimodal integrated care concept in which treatment is adapted to an individual patient's needs by a therapeutically oriented community treatment team. Having an assigned long-term therapist with whom the patient developed a trusting therapeutic relationship and having 24/7 telephone contact for crises were factors considered by patients to be the most useful and important.

Empirically-based concepts for psychological care during acute inpatient stays for individuals with psychosis are lacking (American Psychiatric Association, 2021). Fischer et al. report a pilot study on the feasibility, acceptability and safety of Metacognitive Training for patients with psychosis in a psychiatric acute care setting (MCT-Acute). Although MCT-Acute represents a promising non-pharmacological approach for improving treatment of acute psychosis, controlled trials are needed to confirm its efficacy.

The WHO Mental Health report calls for increased dissemination of community-based programs (2022). Machorrinho et al. present data on an 8-week psychomotor therapy program for victims of intimate partner violence. The Feel-Own-Move (FOM) intervention was administered in shelter homes to victims of intimate partner violence (IPV). The authors conclude that FOM appears to be a viable psychomotor therapy intervention for female victims of IPV living in shelters and leads to reduced body dissociation among participants, which is suggested to prospectively contribute to improved mental health and quality of life.

Modulation of dysfunctional brain activation via transcranial electrical stimulation is emerging as a possible new treatment for attention-deficit hyperactivity disorder (ADHD). In their study Kannen et al. aimed to reduce symptoms and improve attention in adults with ADHD by enhancing alpha band power via transcranial alternating current stimulation (tACS). Participants received active and sham stimulation on distinct days. The authors concluded that the study did not provide clear evidence of an increase in alpha power induced by tACS, so observed improvements in attention could not be attributed to intervention-related effects. Despite this, the authors discuss limitations to their work and provide suggestions for improving future studies exploring whether alpha power enhancement via tACS could be a therapeutic option for ADHD.

Higher education students are a group at risk of developing mental health problems, and these problems worsened with the COVID-19 pandemic, with college students reporting increased rates of depression and anxiety (Li et al., 2021). In this Research Topic, Zuo and Zhang report an RCT on a CBT-based intervention for university students with maladaptive perfectionism. In line with the authors' hypothesis, the intervention led to improvements in maladaptive aspects of perfectionism, concern about mistakes and doubts about actions, as well as symptoms of anxiety and depression compared to a wait-list control group.

Expanding research to improve understanding of the effectiveness of empirically based treatments outside of strictly controlled trials is essential for transforming mental healthcare. Wallsten et al. assumed a transdiagnostic approach to examining the effects of a group rumination-focused CBT (RF-CBT) vs. a wait-list control in a primary care setting utilizing a sample of patients with depression, anxiety and/or insomnia as well as other comorbidities. RF-CBT led to significant improvements in insomnia, whereas improvement in depression was detected only at 2-month follow-up and no significant group differences were found for rumination. It remains unclear which mechanisms may have contributed to improvements in insomnia and depression, but this study suggests a need for further examination of the impacts of RF-CBT on insomnia.

Schneider et al. report mediators of depression reduction in Metacognitive Training for depression in older adults (MCT-Silver), a CBT-based group intervention. In line with WHO recommendations for mental health transformations, due to its structured format, MCT-Silver can be administered by individuals without advanced training in mental health and is easily scalable (www.uke.de/mct-silver). In a recently published RCT, MCT-Silver led to significant reductions in depression and rumination compared to an active control group (Schneider et al., 2024).

Language and cultural adaptations of empirically-based psychological interventions are necessary to increase dissemination and promote worldwide mental health care. Pinho et al. report details of a planned RCT on a translated and culturally-adapted version of MCT-Silver in Portugal. Promotion of mental healthcare treatment for late life depression is especially important as depression in older adults often goes undetected and is undertreated (Horackova et al., 2019).

The WHO's Sustainable Development Goals (SDGs) set reduction of suicide as an international priority by aiming to reduce the suicide mortality rate by a third by 2030 (World Health Organization, 2022). Particularly frontline medical works faced enormous psychological stress during the COVID-19 pandemic and represent a vulnerable group (Ghebreyesus, 2020). In an uncontrolled pilot trial, Robles et al. report the implementation and effects of a brief, remote manualized crisis intervention and suicide risk management intervention for COVID-19 healthcare workers in Mexico. In their study, frontline workers were invited to contact a free 24-h helpline. Trained psychologists and psychiatrists provided up to 12 crisis intervention sessions either online or by telephone utilizing empirically based techniques (EBTs). Helpline users demonstrated significant improvements in Clinical Global Impression (CGI) severity score and self-rated distress. This intervention provides initial evidence of the feasibility of a low-threshold intervention for crisis management.

In a final study on the treatment of affective disorders, in an uncontrolled pilot study, Oaks-Cornellissen et al. examined effects of a 10-week multimodal lifestyle intervention for improving the mental health of individuals with an affective disorder in South Africa. Differing from other approaches, the program focused on promotion of healthy lifestyle behaviors as well as positive psychology practices. Significant improvements in many domains, including overall mental health, depression, anxiety and vitality are reported. This work provides evidence of the feasibility and acceptance of the intervention in patients with clinical diagnoses.

Finally, reflecting the need for improved treatments across the lifespan (World Health Organization, 2022), three studies examined interventions in children and/or their families.

Reduction of repetitive and off task behaviors is a major goal in the treatment of many children with autism spectrum disorder (ASD); however, it remains unclear to what extent some sensory integration therapies, and specifically compression (Trembath et al., 2023), may lead to reduction of problematic behaviors. In a study by Grandits et al., nine children with ASD were randomly assigned to wear compression clothing for either their first five or last five sessions of Applied Behavioral Analysis. Compression clothes failed to increase task participation or reduce repetitive behaviors so that it could not be identified as an effective add-on approach to treatment of ASD.

Children with learning disorders (LDs) have higher rates of emotional disorders and may be at a greater risk for poorer self-concepts compared to typically developing peers (Huang, 2011). Martínez-Briones et al. examined the effect of neurofeedback (NFB) on self-concept among 34 children ages 8–11 years with a learning disorder vs. a sham-NFB or a waiting-list control group. Supporting the author's hypotheses, NFB led to significant increases in several domains of self-concept suggesting that NFB may represent a promising new path to improving treatment for children with LDs.

Targeting parenting practices and strengthening resources for families are key areas of mental health transformations (World Health Organization, 2022). In a final study for this Research Topic, Marlotte et al. adapted a trauma-informed, resilience skill-building family intervention for adolescents ages 12–18 years old with depression and a participating caregiver. Twenty-five pairs were randomized to either the adapted intervention [Families Over Coming Under Stress for Families with Adolescent Depression (FOCUS-AD)] or usual care (CBT) delivered in school-based health clinics. FOCUS-AD was found to be feasible and acceptable; however, depressive symptoms declined significantly in both groups. Contrary to expectations, family functioning was not significantly improved in either intervention. Although this study contributes to research indicating that skills-based interventions may improve depressive symptoms particularly in minority and under-resourced youth and families, it remains unclear how important outcomes such as family functioning may be better targeted.

Author contributions

LP: Writing—review & editing. CF: Writing—review & editing. ŁG: Writing—review & editing. ML: Writing—review & editing. BS: Writing—review & editing, Writing—original draft.

Funding

The author(s) declare financial support was received for the research, authorship, and/or publication of this article. This research was funded by the Federal Ministery of Education and Research (Bundesministerium für Bildung und Forschung; #57610786) and by Foundation for Science and Technology (FCT: Fundação para a Ciência e Tecnologia), by the Programme for Cooperation in Science between Portugal and German (reference: 2021.09647.CBM).

Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

The author(s) declared that they were an editorial board member of Frontiers, at the time of submission. This had no impact on the peer review process and the final decision.

Publisher's note

References

American Psychiatric Association (2021). *The American Psychiatric Association Practice Guideline for the Treatment of Patients With Schizophrenia, 3rd Edn.* New York, NY: American Psychiatric Association. doi: 10.1176/appi.books.9780890424841

Ghebreyesus, T. A. (2020). Addressing mental health needs: an integral part of COVID-19 response. *World Psychiatry* 19:129. doi: 10.1002/wps.20768

Horackova, K., Kopecek, M., Machu, V., Kagstrom, A., Aarsland, D., Motlova, L. B., et al. (2019). Prevalence of late-life depression and gap in mental health service use across European regions. *Eur. Psychiatr.* 57, 19–25. doi: 10.1016/j.eurpsy.2018.12.002

Huang, C. (2011). Self-concept and academic achievement: a meta-analysis of longitudinal relations. *J. School Psychol.* 49, 1–14. doi: 10.1016/j.jsp.2011.07.001

Kazdin, A. E. (2017). Addressing the treatment gap: a key challenge for extending evidence-based psychosocial interventions. *Behav. Res. Ther.* 88, 7–18. doi: 10.1016/j.brat.2016.06.004

Li, Y., Wang, A., Wu, Y., and Han, N. (2021). Impact of the COVID-19 pandemic on the mental health of college students: a systematic review and meta-analysis. *Front. Psychol.* 12:669119. doi: 10.3389/fpsyg.2021.669119

Schneider, B. C., Veckenstedt, R., Karamatskos, E., Ahlf-Schumacher, J., Gehlenborg, J., Schultz, J., et al. (2024). Efficacy and moderators of metacognitive training for depression in older adults (MCT-Silver). *J. Aff. Disorders* 345, 320–334. doi: 10.1016/j.jad.2023.10.118

Trembath, D., Varcin, K., Waddington, H., Sulek, R., Bent, C., Ashburner, J., et al. (2023). Non-pharmacological interventions for autistic children: an umbrella review. *Autism* 27, 275–295. doi: 10.1177/13623613221119368

World Health Organization (2019). *The WHO Special Initiative for Mental Health (2019-2023): Universal Health Coverage for Mental Health (No. WHO/MSD/19, 1.).* Geneva: World Health Organization.

World Health Organization (2022). *World Mental Health Report: Transforming Mental Health for All.* Geneva: World Health Organization.

frontiers | Frontiers in Psychology

TYPE Original Research
PUBLISHED 25 January 2023
DOI 10.3389/fpsyg.2023.1127068

OPEN ACCESS

EDITED BY
Lara Guedes De Pinho,
University of Evora,
Portugal

REVIEWED BY
Tânia Correia,
University of Porto,
Portugal
Yaoyao Sun,
Shandong University,
China

*CORRESPONDENCE
Darren P. Morton
✉ darren.morton@avondale.edu.au

SPECIALTY SECTION
This article was submitted to Psychology for Clinical Settings, a section of the journal Frontiers in Psychology

RECEIVED 19 December 2022
ACCEPTED 10 January 2023
PUBLISHED 25 January 2023

CITATION
Oakes-Cornellissen A, Morton D, Rankin P and Renfrew M (2023) Efficacy of a multimodal lifestyle intervention (The Lift Project) for improving the mental health of individuals with an affective mood disorder living in South Africa.
Front. Psychol. 14:1127068.
doi: 10.3389/fpsyg.2023.1127068

Efficacy of a multimodal lifestyle intervention (The Lift Project) for improving the mental health of individuals with an affective mood disorder living in South Africa

Amanda Oakes-Cornellissen, Darren Morton*, Paul Rankin and Melanie Renfrew

Lifestyle Medicine and Health Research Centre, Avondale University, Cooranbong, NSW, Australia

Background: Affective disorders are becoming more pervasive worldwide, including in Southern Africa, where treating patients with these conditions is challenging due to social and financial constraints. A variety of non-pharmacological approaches including lifestyle medicine (e.g., exercise, nutrition, sleep) and positive psychology practices (e.g., gratitude, service), are effective for treating mental health (MH) conditions.

Methods: Twenty-six individuals from South Africa with a diagnosed MH condition participated in a 10-week multimodal intervention incorporating a diverse range of non-pharmacological strategies for improving MH. MH metrics were assessed pre-and post-intervention, including general MH, vitality/energy (VIT), depression, anxiety, stress, and satisfaction with life. MH and VIT were also measured weekly.

Results: Improvements were observed in all mental metrics from pre-to post-intervention: MH (59%, $p<0.001$, Cohen's $D=1.36$), VIT (110%, $p<0.001$, Cohen's $D=1.71$), depression (–46%, $p<0.001$, Cohen's $D=-1.06$), anxiety (–48%, $p<0.001$, Cohen's $D=-1.21$), stress (–36%, $p<0.001$, Cohen's $D=-1.08$) and life satisfaction (23%, $p<0.001$, Cohen's $D=0.66$). Significant improvements in MH and VIT were observed after only 1 week of the intervention and progressively increased until the seventh week, after which further improvements were not statistically significant.

Conclusion: The findings of this cohort study indicate that a multimodal intervention that incorporates lifestyle and positive psychology practices may benefit individuals living with an affective disorder. Non-pharmacological, multimodal interventions might offer a stigma-free way of providing MH promotion and treatment at a population level.

KEYWORDS

lifestyle, intervention – behavioral, depression, anxiety, stress, affective disorder, lifestyle medicine, positive psychology

1. Introduction

The most common psychological conditions reported globally are depression and anxiety (Albert, 2015; Laborde-Lahoz et al., 2015). According to the World Health Organization (WHO) World Mental Health Survey, South Africa ranks among the highest mid-to-low-income countries in the lifetime prevalence of Common Mental Disease (CMD; Stein et al., 2008). It has been

postulated that South Africa's hostile history, which resulted in social inequality, conflict, and trauma, has contributed to the high prevalence of psychological distress (Das-Munshi et al., 2016; Harriman et al., 2022). Studies indicate that within South Africa, affective disorders are especially common in low socioeconomic areas (Mungai and Bayat, 2019) and in communities with high levels of social dysfunction, crime rates, and gangsterism (Tomita et al., 2015).

Despite the high prevalence of affective disorders in South Africa, mental health (MH) conditions are underdiagnosed and underreported, leading to poor health outcomes for those living with untreated mental illnesses (Meyer et al., 2019). Indeed, at an international level, expenditure on MH services in many countries is estimated at 5% or less of overall healthcare budgets (Gupta et al., 2016). With the immense financial strain that South Africa's public health sector is experiencing, clients with CMD often fail to receive the necessary care, or any care at all (Kagee, 2008). Hence, novel approaches to addressing the MH burden are required.

The treatment of affective disorders is increasingly predicated on pharmacological protocols, yet the prevalence of MH conditions continues to rise (Mojtabai and Jorm, 2015; Jorm et al., 2017), raising questions regarding the efficacy of anti-depressant medication for curbing the escalating rates of mental distress (Khan and Brown, 2015). Further, while pharmacological approaches have benefits, they may complicate the disease profile with unpleasant side effects (Huhn et al., 2014) such as "feeling emotionally numb," detached from reality, drowsiness, sexual dysfunction, and suicidal ideation, to name a few (Read and Williams, 2018).

There is increasing interest in the use of non-pharmacological approaches for improving MH (Manger, 2019). Indeed, there is strong evidence showing the MH benefits of interventions that promote healthy lifestyle behaviors such as exercise (Josefsson et al., 2014; Keating et al., 2018), healthy eating (Jacka et al., 2017; Owen and Corfe, 2017; Firth et al., 2020); sleep (Freeman et al., 2020; Scott et al., 2021), and exposure to nature (Taniguchi et al., 2022). In addition, positive psychology practices have been shown to improve MH (Seligman and Csikszentmihalyi, 2014; Carr et al., 2021), including expressing gratitude (Wong et al., 2018; Waters et al., 2022); identifying and using one's signature strengths (Macfarlane, 2019); and engaging in service activities (Walsh, 2011). Notably, the implementation of lifestyle and positive psychology therapies comes with minimal to no deleterious side effects, which highlights their utility (Marx et al., 2022). However, while the benefits of these lifestyle and positive psychology strategies have been demonstrated, they are often applied as single modality interventions. The emerging discipline of "Lifestyle Psychiatry" is calling for a broader, multimodal approach (Noordsy, 2019).

A multimodal intervention that has been shown to improve participants' MH and wellbeing is "The Lift Project" (Morton et al., 2020; Przybylko et al., 2021b,c; Renfrew et al., 2021b). The Lift Project is a positively oriented 10-week education program that experientially engages participants in wellbeing-enhancing strategies from the disciplines of lifestyle medicine and positive psychology. The Lift Project was initially designed as a mental wellbeing program for generally healthy cohorts, and numerous studies, including randomized controlled trials, have reported positive outcomes among this target population (Przybylko et al., 2021a; Renfrew et al., 2021a). However, stratified analyses have indicated that while the intervention adopts a positive orientation, participants with the lowest baseline MH metrics may benefit the most (Morton et al., 2020). This may suggest that promoting the positive may negate the negative, even among individuals with poor MH.

This study aimed to examine the potential benefits of The Lift Project intervention for adults with a diagnosed affective mood disorder living in a community in South Africa that exhibits high levels of mental distress. If efficacious, non-pharmacological interventions like The Lift Project that are positively oriented and adopt a multimodal approach may provide a useful tool for supporting individuals who suffer from affective disorders, and thereby offer a helpful solution for addressing the MH burden.

2. Methodology

2.1. Study design

The objective of this study was to pilot-test the efficacy of a 10-week intervention for improving quantitative MH metrics among adults living with a diagnosed affective mood disorder. Hence, a single-arm, pre-post cohort design was selected as a precursor to a larger randomized controlled trial, pending the study showing beneficial outcomes. The 10-week intervention commenced in August and concluded in October 2022. Ethical clearance for the study was obtained by the Avondale University Human Ethics Committee (approval no: ETH.2022.009).

2.2. Study participants

The study was promoted to patients from a General Practice in Kathu, a small mining town in the Northern Cape of South Africa with a population of approximately 14,000 residents as reported at the 2016 census. This location was selected as the community is underserved and has a high prevalence of mental distress. It was rationalized that if benefits were observed in this challenging context, it might represent a novel approach for addressing mental distress in other high-need, poorly funded communities.

The inclusion criteria for the study were:

1. Males and females between the ages of 18 and 65 years. Affective disorders in South Africa are prevalent among both males and females and within this broad age range and hence, the intervention was made available to all adults with a MH diagnosis (as defined below).
2. Currently taking either anti-depressant, anxiolytic, or mood stabilizing medication for an affective mood disorder.
3. A score of ≤56 on the MH scale or ≤45 on the vitality scale (VIT) of the SF-36 health assessment (Ware and Sherbourne, 1992). The literature indicates that the MH is a good predictor of MH disorders, including depression, anxiety, and affective disorders generally (Berwick et al., 1991). A MH score ≤56 is considered indicative of major depression. A VIT score of ≤45 represents clinically significant fatigue (Donovan et al., 2008).

The exclusion criteria were:

1. Pregnant or lactating.

2. Scheduled to be taken off prescribed medication for their relevant mood disorder(s) during the scheduled 10-week period of the intervention.

Thirty-one participants applied to participate in the study. The data for five individuals were excluded from the study due to their MH or VIT scores exceeding those specified in the inclusion criteria above, however, these individuals were allowed to participate in the intervention. Three participants exited the study within the first week as they did not want to participate in the intervention. The remaining 23 participants (mean age = 41.2 ± 10.8 years, 19 females/4 males) constituted the study cohort.

2.3. "The Lift Project" intervention

The intervention was conducted over 10 weeks and explored evidence-based, non-pharmacological strategies for increasing hedonic and eudemonic wellbeing. Each week, the subjects participated in a 60-min group session hosted at a local General Practice clinic. Three group sessions were offered each week for the participants to choose from (Monday, Tuesday, or Wednesday evenings), with a maximum of ten participants in a group. Participants who were not able to attend either of the three sessions for that week were given the option to attend a catch-up session, but these remained small as most participants were able to attend one of the three scheduled sessions. All 23 participants successfully completed all of the 10 lessons of the intervention over the 10 weeks and hence received and applied all the content as set out in Table 1. Five participants attended the intervention *via* Zoom due to an inability to attend in person. All the group sessions were conducted by the same facilitator who was trained and resourced to deliver the program through an online portal that included: an overview of the program and its rationale, weekly lesson plans, and ideas for conducting the program. The facilitator was also given full access to the program to become familiar with the content of each lesson.

The intervention utilized a pedagogical framework abbreviated as LETS—Learn, Experience, Think, and Share. At each session, the participants viewed an educational video that presented the evidence-base for the topic (i.e., "Learn"). The video presentations were approximately 15 min in duration and were presented in a positive tone. Arising from the video presentation, the participants were issued with challenges for the upcoming week that involved them personally putting the learnings into practice (i.e., "Experience"). These were issued as "challenge by choice," but with the reminder that the more they engaged with challenges the more benefit they would likely experience. The participants were then encouraged to reflect on what they were learning and experiencing (i.e., "Think") by completing a workbook/journal that was provided to them. The workbook reinforced the key messages of the lessons and provided the participants with space to reflect on what they were learning and experiencing. Finally, the participants were encouraged to "Share" their learnings and experiences through group discussion activities, as well as share with others from within their sphere of influence.

An overview of the topics covered in the intervention and the associated challenges are shown in Table 1.

TABLE 1 Overview of The Lift Project intervention.

Week	Topic
1	Title: Speak positively. Synopsis: Introduction to the emotional brain (the Limbic system) and the influence of language on emotion. Challenges: Compliment others; memorize inspirational literature.
2	Title: Move dynamically. Synopsis: The influence of physical activity on mental health. Challenges: Daily step challenge; engage in resistance exercises.
3	Title: Immerse in an uplifting physical environment. Synopsis: Environmental influences on mental health. Challenges: 30 min daily outdoor time; view the sunrise.
4	Title: Immerse in an uplifting social environment. Synopsis: The impact of relationships on mental wellbeing and strategies for nurturing positive relationships. Challenges: Engage the love languages; make a new friend in person or forgive a friend/family member.
5	Title: Look to the positive. Synopsis: The mental health benefits of focusing on the positive in the past, present and future. Challenges: Daily journal of "what went well;" perform the "Gratitude Visit."
6	Title: Eat nutritiously. Synopsis: The influence of a whole food, plant-based diet on mental health. Challenges: 8 daily serves of plant foods; prepare and share a healthy plant-based meal.
7	Title: Rest – sleep well. Synopsis: The influence of good sleep on mental health. Challenges: Restrict screen usage before bed; spend an evening by firelight.
8	Title: Rest - destress. Synopsis: Positive strategies for managing stress. Challenges: 10 min of daily mindfulness; take a guilt free day off.
9	Title: Serve. Synopsis: The value of service on mental health and how to serve using signature strengths. Challenges: Random acts of kindness; recognize and apply unique signature strengths for good.
10	Title: Flourish Synopsis: Highlighting the PERMA framework for enhancing overall wellbeing (positive emotion, engagement, relationships, meaning, and achievement). Challenges: Engage in activities that are enjoyable; set goals, and work toward achieving them.

2.4. Measurements

The participants completed a health and wellbeing questionnaire at the beginning and end of the 10-week intervention. The questionnaire took approximately 15–20 min to complete and used validated instruments, explained below, to assess: General MH, vitality/energy (VIT), Depression, Anxiety, Stress, and Satisfaction with Life. In addition, MH and VIT were assessed at the beginning of each weekly lesson, which took approximately 2 min to complete.

2.4.1. MH and vitality (VIT)

Two subscales from the 36-item Short Form Health Survey (Contopoulos-Ioannidis et al., 2009) were used in this study to assess general MH (5 items) and vitality/energy (VIT, 4 items) pre-and

post-intervention as well as every week throughout the 10-week intervention.

Each item in the MH and vitality subscales has six response options ranging from "All of the time" to "None of the time." The standard procedure was used to calculate a score between 0 to 100 for MH and VIT (Ware et al., 2000), with higher scores indicating better MH and vitality. Studies have reported a Cronbach alpha of 0.90 for the MH scale and 0.87 for the VIT scale, indicating good internal consistency (Jenkinson et al., 1994). In the present study, Cronbach alphas of 0.84 and 0.83 were recorded for MH and vitality, respectively.

2.4.2. Depression, anxiety, and stress scale

The 21-item Depression, Anxiety, and Stress Scale (DASS-21), which is appropriate for use in both clinical and nonclinical populations (Osman et al., 2012), was administered pre-and post-intervention to assess depression, anxiety, and stress (7 items per subscale). The 21-items of the DASS-21 are assessed on a 4-point Likert scale, asking respondents to rank their symptoms of depression, anxiety, and stress as "Never," "Sometimes," "Often," and "Almost always." Scores for each of the three domains were converted to a total score out of 100, with higher scores indicating worsening symptoms. Good internal consistency has been reported for the three domains of the DASS-21, with Cronbach alphas ranging from 0.76 to 0.91 (Le et al., 2017). The present study observed a Cronbach alpha of 0.85 for depression, 0.75 for anxiety and 0.83 for stress.

2.4.3. Satisfaction with life scale

The 5-item SWLS is extensively used as a measure of overall life satisfaction (Pavot et al., 1991). It involves five questions measured on a 6-point Likert scale with responses ranging from "Strongly disagree" to "Strongly agree." The Cronbach alpha was 0.85, which is higher than that reported (Vassar, 2008) in a meta-analysis of the instrument (Cronbach alpha = 0.78).

2.5. Sample size calculation and statistical analyses

The required sample size was calculated using data from previous studies that have utilized the same intervention (Morton et al., 2020) and was based on the following assumptions: a change in MH scores of 20%; 80% power and significance level of 0.05 (95% confidence interval); a moderate effect size (i.e., 0.5); an attrition rate of 30%.

The data were entered and screened using Microsoft Excel (version 16) before being imported into IBM SPSS statistical software package (version 28) for analysis. Descriptive statistics, including mean and standard deviation, were used to present the data. Paired *t*-tests were used to determine differences in the outcome measures from baseline to post-intervention. As six outcome measures were analyzed, a Bonferroni correction was applied, resulting in the adoption of a level of significance of 0.008 (i.e., 0.05/6). Effect size (Cohen's D) was calculated as the mean change in the outcome measure divided by the standard deviation of the subjects' mean difference scores. Repeated-measures ANOVA with *post-hoc* analyses were used to examine changes in the weekly MH and VIT measures.

3. Results

As shown in Table 2, significant improvements were observed in all outcome measures (at the 0.008 level), with large effect sizes. Based on scores reported by the participants at the conclusion of the study, approximately two-thirds (i.e., 15 of the 23) would not have met the study inclusion criteria (i.e., a MH score of ≤56 or a VIT score of ≤45).

The mean changes in the weekly MH and VIT scores are illustrated in Figures 1, 2, respectively. The ANOVA indicated significant changes over time for both MH (F ratio = 15.4, $p \leq 0.001$, Partial Eta Squared = 0.412) and VIT (F ratio = 20.5, $p \leq 0.001$, Partial Eta Squared = 0.483). *Post-hoc* analyses indicated that significant improvements were reported after only 1 week in both MH ($p = 0.005$) and VIT ($p = 0.015$), after which the reported MH and VIT scores were significantly higher than baseline at the <0.001 level for all subsequent weeks. As can be observed in Figures 1, 2, there was a trend for incremental improvement in the MH and VIT scores over the 10 weeks of the intervention.

Two participants made changes to their prescriptions over the duration of the study. Thyroid medication was added to one participant's medication list in week 9 of the intervention and another participant had their anti-depressant medication reduced to half during week 4.

4. Discussion

The findings of this pilot study suggest that positively oriented MH interventions that incorporate an array of lifestyle medicine and positive psychology strategies may support and improve the MH of individuals with diagnosed affective disorders. Previous studies have demonstrated that The Lift Project intervention used in this study is efficacious and acceptable among healthy cohorts, but the outcomes of this study suggest that the intervention might benefit people across the MH spectrum. These findings may have important implications as they suggest that interventions similar in design to that used in the current study might offer a stigma-free way of providing MH promotion and treatment at a population level, using a universal prevention approach.

TABLE 2 Changes in the outcome measures from baseline to post-intervention.

Measure	Pre-test	Post-test	Change	% Change	*t* Statistic	*p* value	Cohen's *D*
	Mean (SD)	Mean (SD)					
Mental health (MH)	43.6 (22.1)	69.4 (15.9)	25.9	59.3	8.39	<0.001	1.36
Vitality/energy (VIT)	29.8 (21.8)	62.9 (16.8)	33.0	110.8	8.01	<0.001	1.71
Depression	51.7 (26.8)	27.8 (18.4)	−23.9	−46.3	−6.75	<0.001	−1.06
Anxiety	44.3 (19.0)	23.1 (16.1)	−21.2	−47.9	−5.52	<0.001	−1.21
Stress	55.2 (20.9)	35.5 (15.5)	−19.7	−35.7	−5.00	<0.001	−1.08
Life satisfaction	55.1 (19.8)	68.3 (20.0)	13.2	23.9	3.37	0.002	0.66

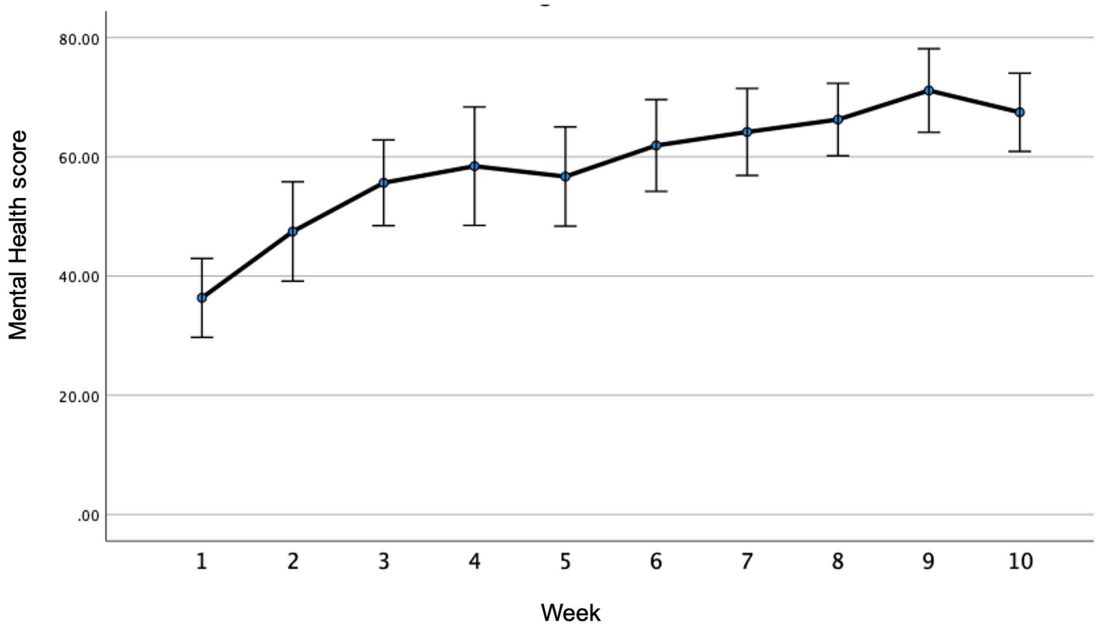


FIGURE 1
Weekly mental health (MH) scores throughtout the intervention.

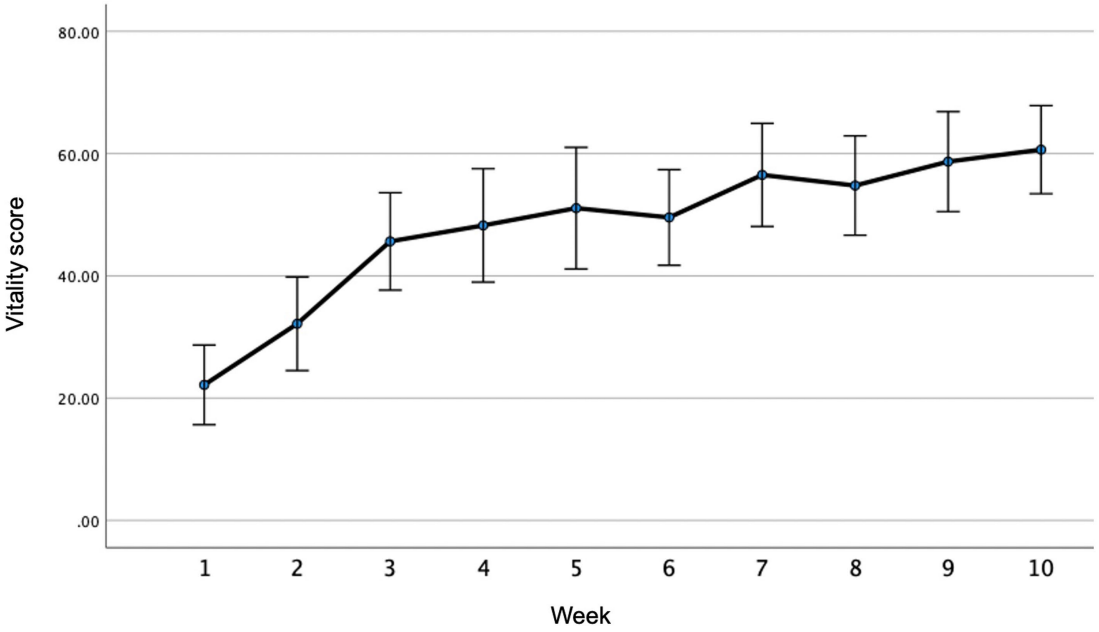


FIGURE 2
Weekly vitality/energy (VIT) scores throughtout the intervention.

The effect sizes observed in this study were substantially larger than those observed in other studies that have utilized the same intervention among relatively healthy cohorts. For example, in a randomized controlled trial involving 425 general community members from Australasia, effect sizes of 0.42 and 0.45 were observed for change in MH and VIT, respectively (Przybylko et al., 2021a). The very large effect sizes observed in the present study (i.e., >1.0) are encouraging, although it is recognized that the individuals have more scope of improvement when starting from a lower baseline. Indeed, in a study of The Lift Project intervention among College students, the greatest improvements were observed among those with the poorest baseline MH scores (Morton et al., 2020).

This is the first study of The Lift Project to document weekly changes in MH and VIT throughout the duration of the 10-week intervention. The observation that significant improvements in MH and VIT were recorded after only 1 week is notable, but the impetus for such rapid improvements warrants investigation. It is hypothesized that the act of engaging with an intervention might instill hope, which alone is mood-enhancing, independent of the "challenges" issued to the participants as

part of the intervention. Indeed, hope is an important MH determinant (Van Gestel-Timmermans et al., 2010; Schrank et al., 2012). While further studies are required to ascertain the potential contributors to the observed rapid improvements in MH and VIT, these measures continued to increase incrementally throughout the duration of the intervention which suggests that the intervention did not merely instill "false hope," but that the activities were beneficial.

While the week-by-week MH and VIT data showed a progressive upward trend over the 10 weeks of the intervention, further studies are required to confirm these observations and to determine causality. Understanding the time-course of potential improvements in MH metrics as well as "plateauing" may help inform the design of interventions with regard to optimal duration. Shorter interventions may be administered more cost-effectively, although interventions of longer durations might better support long-term behavior change. A study involving a lifestyle intervention targeting cardiovascular disease found that an 8 or 16 sessions intervention produced similar outcomes in the short-term (Morton et al., 2017), but longer interventions might better cement behavior change and result in more sustained benefits. Indeed, there is a need to further investigate the relative merits of shorter and longer interventions, especially with regard to long-term benefits. While the current pilot study only examined pre-to post-intervention changes, a randomized controlled trial using the same intervention observed sustained benefits at 3-month follow-up (Przybylko et al., 2021a). Longer-term follow-up should be included in future studies.

4.1. Limitations

There are several limitations of this study. Firstly, several factors affect the generalizability of the findings. As the study involved a relatively small cohort it was not possible to explore the influence of covariates such as age, sex, and group. Further, the participants were self-selecting and therefore may have presented to the study with a high readiness for change. Certainly, the low attrition rate (<10%) would suggest that the participants in the study were prepared to take action, as framed by the Transtheoretical Model of Behavior Change (Prochaska et al., 2009). Further affecting the generalizability of the findings is the strong female participation bias, which is commonly observed in lifestyle interventions (Pot et al., 2019; Przybylko et al., 2021b). A second limitation relates to the absence of a control group. As a result, it is not possible to determine the influence of confounders, such as seasonal variation, on the outcomes observed in the study. Future studies should also capture details about the extent to which the participants engage in the weekly challenges to investigate the association between adherence to the intervention and the benefits obtained. Certainly, the findings of this pilot study warrant a rigorous clinical trial.

5. Conclusion

The findings of this pilot study indicate that a positively oriented, multimodal intervention that incorporates lifestyle medicine and positive psychology strategies may benefit individuals living with an affective disorder. Given that interventions like The Lift Project have also shown to be efficacious among non-clinical cohorts, it may support the use of such interventions at a population level as a universal MH prevention strategy.

Data availability statement

The datasets presented in this article are not readily available because Ethical clearance to share the data set has not been granted. Requests to access the datasets should be directed to darren.morton@avondale.edu.au.

Ethics statement

The studies involving human participants were reviewed and approved by Avondale University Human Research Ethics committee. The patients/participants provided their written informed consent to participate in this study.

Author contributions

AO-C was responsible for conceiving the study, conducting the intervention, data collection and collation, and writing the paper. DM led the development of the intervention and assisted with data analyses. DM, MR, and PR contributed to the study design and provided editorial input on the paper. All authors contributed to the article and approved the submitted version.

Funding

Publication costs were provided by the Lifestyle Medicine and Health Research Centre at Avondale University.

Acknowledgments

The authors would like to thank G. Cornellissen, R. Combrinck, and A. Vermeulen for their assistance in screening and referring patients to be part of this study.

Conflict of interest

DM is the founding director of a profit-for-purpose trust that owns the intervention used in this study. He has received no financial reimbursement.

The remaining authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

References

Albert, P. R. (2015). Why is depression more prevalent in women? *J. Psychiatry Neurosci.* 40, 219–221. doi: 10.1503/jpn.150205

Berwick, D. M., Murphy, J. M., Goldman, P. A., Ware, J. E., Barsky, A. J., and Weinstein, M. C. (1991). Performance of a five-item mental health screening test. *Med. Care* 29, 169–176. doi: 10.1097/00005650-199102000-00008

Carr, A., Cullen, K., Keeney, C., Canning, C., Mooney, O., Chinseallaigh, E., et al. (2021). Effectiveness of positive psychology interventions: a systematic review and meta-analysis. *J. Posit. Psychol.* 16, 749–769. doi: 10.1080/17439760.2020.1818807

Contopoulos-Ioannidis, D. G., Karvouni, A., Kouri, I., and Ioannidis, J. P. (2009). Reporting and interpretation of SF-36 outcomes in randomised trials: systematic review. *BMJ* 338:a3006. doi: 10.1136/bmj.a3006

Das-Munshi, J., Lund, C., Mathews, C., Clark, C., Rothon, C., and Stansfeld, S. (2016). Mental health inequalities in adolescents growing up in post-apartheid South Africa: cross-sectional survey, SHaW study. *PLoS One* 11:e0154478. doi: 10.1371/journal.pone.0154478

Donovan, K. A., Jacobsen, P. B., Small, B. J., Munster, P. N., and Andrykowski, M. A. (2008). Identifying clinically meaningful fatigue with the fatigue symptom inventory. *J. Pain Symptom Manag.* 36, 480–487. doi: 10.1016/j.jpainsymman.2007.11.013

Firth, J., Gangwisch, J. E., Borsini, A., Wootton, R. E., and Mayer, E. A. (2020). Food and mood: how do diet and nutrition affect mental wellbeing? *BMJ* 369:m2382. doi: 10.1136/bmj.m2382

Freeman, D., Sheaves, B., Waite, F., Harvey, A. G., and Harrison, P. J. (2020). Sleep disturbance and psychiatric disorders. *Lancet Psychiatry* 7, 628–637. doi: 10.1016/S2215-0366(20)30136-X

Gupta, S., Methuen, C., Kent, P., Chatain, G., Christie, D., Torales, J., et al. (2016). Economic development does not improve public mental health spending. *Int. Rev. Psychiatry* 28, 415–419. doi: 10.1080/09540261.2016.1210582

Harriman, N. W., Williams, D. R., Morgan, J. W., Sewpaul, R., Manyaapelo, T., Sifunda, S., et al. (2022). Racial disparities in psychological distress in post-apartheid South Africa: results from the SANHANES-1 survey. *Soc. Psychiatry Psychiatr. Epidemiol.* 57, 843–857. doi: 10.1007/s00127-021-02175-w

Huhn, M., Tardy, M., Spineli, L. M., Kissling, W., Foerstl, H., Pitschel-Walz, G., et al. (2014). Efficacy of pharmacotherapy and psychotherapy for adult psychiatric disorders: a systematic overview of meta-analyses. *JAMA Psychiat.* 71, 706–715. doi: 10.1001/jamapsychiatry.2014.112

Jacka, F. N., O'Neil, A., Opie, R., Itsiopoulos, C., Cotton, S., Mohebbi, M., et al. (2017). A randomised controlled trial of dietary improvement for adults with major depression (the 'SMILES' trial). *BMC Med.* 15, 1–13. doi: 10.1186/s12916-017-0791-y

Jenkinson, C., Wright, L., and Coulter, A. (1994). Criterion validity and reliability of the SF-36 in a population sample. *Qual. Life Res.* 3, 7–12. doi: 10.1007/BF00647843

Jorm, A. F., Patten, S. B., Brugha, T. S., and Mojtabai, R. (2017). Has increased provision of treatment reduced the prevalence of common mental disorders? Review of the evidence from four countries. *World Psychiatry* 16, 90–99. doi: 10.1002/wps.20388

Josefsson, T., Lindwall, M., and Archer, T. (2014). Physical exercise intervention in depressive disorders: meta-analysis and systematic review. *Scand. J. Med. Sci. Sports* 24, 259–272. doi: 10.1111/sms.12050

Kagee, A. (2008). Symptoms of depression and anxiety among a sample of south African patients living with a chronic illness. *J. Health Psychol.* 13, 547–555. doi: 10.1177/1359105308088527

Keating, L. E., Becker, S., McCabe, K., Whattam, J., Garrick, L., Sassi, R. B., et al. (2018). Effects of a 12-week running programme in youth and adults with complex mood disorders. *BMJ Open Sport Exerc. Med.* 4:e000314. doi: 10.1136/bmjsem-2017-000314

Khan, A., and Brown, W. A. (2015). Antidepressants versus placebo in major depression: an overview. *World Psychiatry* 14, 294–300. doi: 10.1002/wps.20241

Laborde-Lahoz, P., El-Gabalawy, R., Kinley, J., Kirwin, P. D., Sareen, J., and Pietrzak, R. H. (2015). Subsyndromal depression among older adults in the USA: prevalence, comorbidity, and risk for new-onset psychiatric disorders in late life. *Int. J. Geriatr. Psychiatry* 30, 677–685. doi: 10.1002/gps.4204

Le, M. T. H., Tran, T. D., Holton, S., Nguyen, H. T., Wolfe, R., and Fisher, J. (2017). Reliability, convergent validity and factor structure of the DASS-21 in a sample of Vietnamese adolescents. *PLoS One* 12:e0180557. doi: 10.1371/journal.pone.0180557

Macfarlane, J. (2019). Exploring how awareness of character strengths can benefit mental health nurses. *Br. J. Ment. Health Nurs.* 8, 145–152. doi: 10.12968/bjmh.2019.8.3.145

Manger, S. (2019). Lifestyle interventions for mental health. *Aust. J. Gen. Pract.* 48, 670–673. doi: 10.3316/informit.677910465132419

Marx, W., Manger, S. H., Blencowe, M., Murray, G., Ho, F. Y.-Y., Lawn, S., et al. (2022). Clinical guidelines for the use of lifestyle-based mental health care in major depressive disorder: world Federation of Societies for biological psychiatry (WFSBP) and Australasian Society of Lifestyle Medicine (ASLM) taskforce. *World J. Biol. Psychiatry* 6, 1–54. doi: 10.1080/15622975.2022.2112074

Meyer, J., Matlala, M., and Chigome, A. (2019). Mental health care-a public health priority in South Africa. *S. Afr. Fam. Pract.* 61, 25–30. doi: 10.4102/safp.v61i5.4946

Mojtabai, R., and Jorm, A. F. (2015). Trends in psychological distress, depressive episodes and mental health treatment-seeking in the United States: 2001–2012. *J. Affect. Disord.* 174, 556–561. doi: 10.1016/j.jad.2014.12.039

Morton, D. P., Hinze, J., Craig, B., Herman, W., Kent, L., Beamish, P., et al. (2020). A multimodal intervention for improving the mental health and emotional well-being of college students. *Am. J. Lifestyle Med.* 14, 216–224. doi: 10.1177/1559827617733941

Morton, D. P., Kent, L., Rankin, P., Mitchell, B., Parker, K., Gobble, J., et al. (2017). Optimizing the intensity of lifestyle medicine interventions: similar outcomes for half the sessions. *Am. J. Lifestyle Med.* 11, 274–279. doi: 10.1177/1559827615612420

Mungai, K., and Bayat, A. (2019). An overview of trends in depressive symptoms in South Africa. *S. Afr. J. Psychol.* 49, 518–535. doi: 10.1177/0081246318823580

Noordsy, D. L. (2019). *Lifestyle Psychiatry*. Washington, D.C: American Psychiatric Pub.

Osman, A., Wong, J. L., Bagge, C. L., Freedenthal, S., Gutierrez, P. M., and Lozano, G. (2012). The depression anxiety stress scales—21 (DASS-21): further examination of dimensions, scale reliability, and correlates. *J. Clin. Psychol.* 68, 1322–1338. doi: 10.1002/jclp.21908

Owen, L., and Corfe, B. (2017). The role of diet and nutrition on mental health and wellbeing. *Proc. Nutr. Soc.* 76, 425–426. doi: 10.1017/S0029665117001057

Pavot, W., Diener, E., Colvin, C. R., and Sandvik, E. (1991). Further validation of the satisfaction with life scale: evidence for the cross-method convergence of well-being measures. *J. Pers. Assess.* 57, 149–161. doi: 10.1207/s15327752jpa5701_17

Pot, G. K., Battjes-Fries, M. C., Patijn, O. N., Pijl, H., Witkamp, R. F., de Visser, M., et al. (2019). Nutrition and lifestyle intervention in type 2 diabetes: pilot study in the Netherlands showing improved glucose control and reduction in glucose lowering medication. *BMJ Nutr. Prev. Health* 2, 43–50. doi: 10.1136/bmjnph-2018-000012

Prochaska, J., Johnson, S., and Lee, P. (2009). "The transtheoretical model of behavior change" in *The Handbook of Health Behavior Change*. eds. S. A. Shumaker, J. K. Ockene and K. A. Reikert (Heidelberg, Germany: Springer Publishing Company), 59–83.

Przybylko, G., Morton, D., Kent, L., Morton, J., Hinze, J., Beamish, P., et al. (2021a). The effectiveness of an online interdisciplinary intervention for mental health promotion: a randomized controlled trial. *BMC Psychol.* 9, 1–11. doi: 10.1186/s40359-021-00577-8

Przybylko, G., Morton, D. P., Morton, J. K., Renfrew, M. E., and Hinze, J. (2021b). An interdisciplinary mental wellbeing intervention for increasing flourishing: two experimental studies. *J. Posit. Psychol.* 17, 573–588. doi: 10.1080/17439760.2021.1897868

Przybylko, G., Morton, D. P., and Renfrew, M. E. (2021c). Addressing the COVID-19 mental health crisis: a perspective on using interdisciplinary universal interventions. *Front. Psychol.* 12:1102. doi: 10.3389/fpsyg.2021.644337

Read, J., and Williams, J. (2018). Adverse effects of antidepressants reported by a large international cohort: emotional blunting, suicidality, and withdrawal effects. *Curr. Drug Saf.* 13, 176–186. doi: 10.2174/1574886313666180605095130

Renfrew, M. E., Morton, D. P., Morton, J. K., and Przybylko, G. (2021a). The influence of human support on the effectiveness of digital mental health promotion interventions for the general population. *Front. Psychol.* 12:716106. doi: 10.3389/fpsyg.2021.716106

Renfrew, M. E., Morton, D. P., Northcote, M., Morton, J. K., Hinze, J. S., and Przybylko, G. (2021b). Participant perceptions of facilitators and barriers to adherence in a digital mental health intervention for a nonclinical cohort: content analysis. *J. Med. Internet Res.* 23:e25358. doi: 10.2196/25358

Schrank, B., Bird, V., Rudnick, A., and Slade, M. (2012). Determinants, self-management strategies and interventions for hope in people with mental disorders: systematic search and narrative review. *Soc. Sci. Med.* 74, 554–564. doi: 10.1016/j.socscimed.2011.11.008

Scott, A. J., Webb, T. L., Martyn-St James, M., Rowse, G., and Weich, S. (2021). Improving sleep quality leads to better mental health: a meta-analysis of randomised controlled trials. *Sleep Med. Rev.* 60:101556. doi: 10.1016/j.smrv.2021.101556

Seligman, M. E., and Csikszentmihalyi, M. (2014). "Positive psychology: an introduction" in *Flow and the Foundations of Positive Psychology* (Dordrecht, Netherlands: Springer), 279–298.

Stein, D. J., Seedat, S., Herman, A., Moomal, H., Heeringa, S. G., Kessler, R. C., et al. (2008). Lifetime prevalence of psychiatric disorders in South Africa. *Br. J. Psychiatry* 192, 112–117. doi: 10.1192/bjp.bp.106.029280

Taniguchi, K., Takano, M., Tobari, Y., Hayano, M., Nakajima, S., Mimura, M., et al. (2022). Influence of external natural environment including sunshine exposure on public mental health: a systematic review. *Psychiatry Int.* 3, 91–113. doi: 10.3390/psychiatryint3010008

Tomita, A., Labys, C. A., and Burns, J. K. (2015). A multilevel analysis of the relationship between neighborhood social disorder and depressive symptoms: evidence from the south African national income dynamics study. *Am. J. Orthopsychiatry* 85, 56–62. doi: 10.1037/ort0000049

Van Gestel-Timmermans, H., Van Den Bogaard, J., Brouwers, E., Herth, K., and Van Nieuwenhuizen, C. (2010). Hope as a determinant of mental health recovery: a psychometric evaluation of the Herth Hope index-Dutch version. *Scand. J. Caring Sci.* 24, 67–74. doi: 10.1111/j.1471-6712.2009.00758.x

Vassar, M. (2008). A note on the score reliability for the satisfaction with life scale: an RG study. *Soc. Indic. Res.* 86, 47–57. doi: 10.1007/s11205-007-9113-7

Walsh, R. (2011). Lifestyle and mental health. *Am. Psychol.* 66, 579–592. doi: 10.1037/a0021769

Ware, J., Kosinski, M., and Dewey, J. (2000). How to Score Version 2 of the SF-36® Health Survey (Standard & Acute Forms) Lincoln. RI: Quality Metric Incorporated.

Ware, J. E., and Sherbourne, C. D. (1992). The MOS 36-item short-form health survey (SF-36). *Med. Care* 30, 473–483. doi: 10.1097/00005650-199206000-00002

Waters, L., Algoe, S. B., Dutton, J., Emmons, R., Fredrickson, B. L., Heaphy, E., et al. (2022). Positive psychology in a pandemic: buffering, bolstering, and building mental health. *J. Posit. Psychol.* 17, 303–323. doi: 10.1080/17439760.2021.1871945

Wong, Y. J., Owen, J., Gabana, N. T., Brown, J. W., McInnis, S., Toth, P., et al. (2018). Does gratitude writing improve the mental health of psychotherapy clients? Evidence from a randomized controlled trial. *Psychother. Res.* 28, 192–202. doi: 10.1080/10503307.2016.1169332

frontiers | Frontiers in Psychology

TYPE Original Research
PUBLISHED 22 March 2023
DOI 10.3389/fpsyg.2023.1153377

OPEN ACCESS

EDITED BY
María Roncero,
University of Valencia,
Spain

REVIEWED BY
Lisa Amalia Denza Webster,
Leeds Trinity University,
United Kingdom
David Rosenbaum,
University of Tübingen,
Germany

*CORRESPONDENCE
Brooke C. Schneider
b.viertel@uke.de

SPECIALTY SECTION
This article was submitted to Psychology for Clinical Settings, a section of the journal Frontiers in Psychology

RECEIVED 29 January 2023
ACCEPTED 02 March 2023
PUBLISHED 22 March 2023

CITATION
Schneider BC, Veckenstedt R, Karamatskos E, Pinho LG, Morgado B, Fonseca C, Moritz S and Jelinek L (2023) Negative cognitive beliefs, positive metacognitive beliefs, and rumination as mediators of metacognitive training for depression in older adults (MCT-Silver). *Front. Psychol.* 14:1153377. doi: 10.3389/fpsyg.2023.1153377

Negative cognitive beliefs, positive metacognitive beliefs, and rumination as mediators of metacognitive training for depression in older adults (MCT-Silver)

Brooke C. Schneider[1]*, Ruth Veckenstedt[1], Evangelos Karamatskos[1], Lara Guedes Pinho[2,3], Bruno Morgado[4], César Fonseca[2,3], Steffen Moritz[1] and Lena Jelinek[1]

[1]Department of Psychiatry and Psychotherapy, University Medical Center Hamburg-Eppendorf, Hamburg, Germany, [2]Nursing Department, University of Évora, Évora, Portugal, [3]Comprehensive Health Research Centre (CHRC), University of Évora, Évora, Portugal, [4]University Rovira i Virgili, Tarragona, Spain

Background: Metacognitive Training for Depression in older adults (MCT-Silver; www.uke.de/mct-silver) is a cognitive-behavioral based group intervention that aims at reducing depression by targeting (meta)cognitive beliefs and rumination. In the present study, it was examined whether negative cognitive beliefs, positive metacognitive beliefs and/or rumination may be implicated as mediators of MCT-Silver's effects on depression.

Materials and methods: We conducted a secondary analysis of a randomized controlled trial comparing MCT-Silver to an active control intervention (cognitive remediation) including 66 older adults (60years and older) with complete baseline data. Clinician-rated (Hamilton Depression Rating Scale) and self-reported (Beck Depression Inventory-II) depression, negative cognitive beliefs (Dysfunctional Attitudes Scale-18B), positive metacognitive beliefs (positive beliefs subscale; Metacognition Questionnaire-30) and rumination (10-item Ruminative Response Scale) were assessed before (pre) and after 8weeks of treatment (post), as well as 3months later (follow-up). It was examined whether change in depression (pre- to follow-up) was mediated by change in negative cognitive beliefs, positive metacognitive beliefs and/or rumination (pre- to post-assessment).

Results: Mediation results differed for self-reported vs. clinician-rated depression. The effect of MCT-Silver on reduction in clinician-rated depression was mediated by a reduction in self-reported rumination, whereas reduction in self-reported depression was mediated by a reduction in negative cognitive beliefs. Positive metacognitive beliefs were not a significant mediator for either outcome.

Conclusion: The current study provides initial evidence for the roles of negative cognitive beliefs and rumination in the treatment of depression in later life with MCT-Silver. Given the divergence of findings and lack of causal precedence, mechanisms of change for MCT-Silver cannot yet be equivocally identified.

KEYWORDS

metacognitive training, rumination, negative cognitions, older adults, intervention, depression, metacognitive beliefs

1. Introduction

Depression is a common mental health disorder in later life such that that up 21.1% older adults (60 years and older) in Europe have clinically relevant depressive symptoms (Hu et al., 2022). Depression is a major cause of disability (Santomauro et al., 2021) and represents a risk factor for dementia (Wu et al., 2020). Underscoring the importance of prompt treatment, depression in older adults has a longer time to remission and is more likely to become chronic compared to depression in younger adults (Schaakxs et al., 2018). Although psychotherapy for depression in older adults is effective ($g = 0.66$; Cuijpers et al., 2014, 2020) and cognitive-behavioral (CBT), interpersonal, reminiscence and problem-solving therapies are recommended by treatment guidelines for depression in older adults (Hinrichsen et al., 2014; DGPPN, 2017), the mediators and mechanisms of change through which these therapies "work" remain unclear (Kazdin, 2007; Cuijpers, 2019). Improved understanding of mediators and mechanisms of change is essential to understanding why and how treatments for depression may work and to improving efficacy of these interventions (Ehring et al., 2022).

Metacognitive Training-Silver (MCT-Silver; www.uke.de/mct-silver) is a low-threshold, CBT-based group intervention developed for older adults with depression. It is based on Metacognitive Training for psychosis (MCT; Moritz et al., 2014), which inspired the development of further MCTs for depression among young and middle-aged adults (D-MCT; Jelinek et al., 2015, 2016, 2019), obsessive–compulsive disorder (Miegel et al., 2021), borderline personality disorder (Schilling et al., 2018), pathological gambling (Gehlenborg et al., 2021), and bipolar disorder (Haffner et al., 2018). Several other metacognition-based interventions have been developed over the past years in addition to MCT (for a review see Moritz et al., 2018). Metacognitive Training adopts the metacognitive perspective ("thinking about thinking") with the aim of increasing participants' awareness for cognitive biases, which are the result of depressive information processing styles (e.g., mood-congruent memory such as an older adult focusing exclusively on situations in which they completed a task slower or with more effort). Associated negative cognitive beliefs also represent a target of MCT ("I should not cook anymore if I cannot do it all by myself"). In addition, Metacognitive Training for depression (i.e., D-MCT and MCT-Silver) also addresses problematic coping skills (e.g., rumination about declining ability levels) and metacognitive beliefs about thinking styles (e.g., rumination helps to solve problems). Metacognitive Training utilizes a structured multimedia presentation to convey the content of the intervention and also addresses disorder-specific thought content. Thus, through psychoeducation and interactive exercises, D-MCT and MCT-Silver to improve patients' awareness of cognitive biases in everyday life. Patients are invited to critically reflect upon thought content and coping skills, which contribute to and maintain depression, and it is discussed how such thoughts and behaviors can be changed. Based on the content of the training, we hypothesize that MCT-Silver could exert its effects on depression through negative cognitive beliefs, positive metacognitive beliefs and/or rumination.

1.1. Negative cognitive beliefs

Cognitive theories of depression postulate that a cognitive vulnerability to depression leads to activation of negative cognitive schemas in times of stress and encourages automatic cognitive biases (Beck et al., 1979; Beck and Haigh, 2014). Such biases include, for example, increased attention to and a memory preference for negative information (e.g., mood congruent memory bias) and negative interpretations of ambiguous situations (Mathews and MacLeod, 2005; Moritz et al., 2008). These biases then lead to subsequent endorsement of negative cognitive beliefs about oneself, the world and the future (Nieto et al., 2020). Although cognitive beliefs have been shown to be relatively stable, they are also malleable (Faissner et al., 2018) and the results of several RCTs on CBT interventions have provided evidence of their effects on negative cognitive beliefs (Cristea et al., 2015; Lorenzo-Luaces et al., 2015; Jelinek et al., 2017; Normann and Morina, 2018). However, the role of negative cognitive beliefs in depression treatment has not been equivocally proven. For example, the extent to which changes in such beliefs may occur because of a specific (e.g., CBT-based intervention) versus general (e.g., supportive therapies) treatment or through natural remission of depressive symptoms is unclear (Cristea et al., 2015). Moreover, relatively few studies have examined change in negative cognitive beliefs due to a psychological intervention among older adults.

1.2. Positive metacognitive beliefs

MCT-Silver sets a focus on examining one's thinking processes on the "meta" level. Indeed, it has been suggested that all CBT-based therapies address metacognitive processes as they involve challenging negative thoughts and not accepting thoughts as facts and thus encourage "thinking about one's thinking" (Moritz et al., 2018). Additionally, Wells has proposed a series of maladaptive metacognitive beliefs about thinking that occur transdiagnostically (Wells and Cartwright-Hatton, 2004). Like negative cognitive beliefs, metacognitive beliefs have also been implicated in the formation and reoccurrence of depression (Papageorgiou and Wells, 2009; Weber and Exner, 2013; Faissner et al., 2018). Differing from negative cognitive beliefs, metacognitive beliefs are focused, for example, on the usefulness, dangerousness and/or controllability of thinking rather than thought content. The Metacognition Questionnaire-30 (Wells and Cartwright-Hatton, 2004) is often used to assess metacognitive beliefs on five subscales: cognitive confidence, positive beliefs about worry, cognitive self-consciousness, negative beliefs about the uncontrollability of thoughts and danger, and beliefs about the need to control thoughts. Specifically, positive metacognitive beliefs refer to beliefs regarding the usefulness of rumination in solving problems and overall coping. We hypothesize that among Wells' metacognitive domains, positive cognitive beliefs would be implicated in the effects of MCT-Silver as the training content directly addresses assumptions regarding the usefulness of rumination. Moreover, paying more attention to thoughts (e.g., to reframe them) and reducing confidence in (negative) beliefs and biases (e.g., mood-congruent memory) or catastrophic assumptions (e.g., jumping to conclusions) is rather encouraged in MCT-Silver and, therefore, is not in line with Wells' concept.

1.3. Rumination

Rumination has been conceptualized in varying ways. According to the Response Styles Theory (Nolen-Hoeksema, 1987), rumination represents a transdiagnostic emotion regulation (ER) strategy involving repetitively and passively focusing on negative feelings, symptoms of distress and their meaning and consequences (Aldao et al., 2010). ER has been defined as a conscious or unconscious and automatic or controlled attempt to increase or decrease an emotional experience (for a review see Braunstein et al., 2017) in order to appropriately respond to environmental demands (Campbell-Sillis and Barlow, 2007; Berking and Wupperman, 2012). Thus, rumination may be described as an automatic ER response conditioned to triggering stimuli, such as low mood (Watkins and Nolen-Hoeksema, 2014), which involves self-reflection and self-focused attention (Lyubomirsky and Nolen-Hoeksema, 1993). Goals of rumination may include attempts at problem-solving or gaining clarity regarding symptoms (e.g., "Why do I have these symptoms?"). Although metacognitive beliefs are associated with rumination, several additional causal factors must be considered when understanding which patients use it as an emotion regulation strategy. For example, learning processes based on experiences with parents who demonstrate passive coping styles, as well as an overly critical and controlling parental style have been associated with increased use of rumination. Also, cognitive (e.g., evaluation of discrepancies between actual and desired states), genetic and neurocognitive factors (e.g., reduced cognitive control) are implicated in rumination (for a review see Watkins and Roberts, 2020).

Rumination is linked to a plethora of negative psychological consequences, including increasing the severity of and prolonging negative mood and associated negative thinking, and impairing problem-solving and engagement in positive behaviors (Watkins and Roberts, 2020). Supporting its role as a (primarily maladaptive) ER strategy separate from depressive symptoms, rumination predicts the onset of major depressive episodes (Nolen-Hoeksema, 2000; Watkins and Roberts, 2020) and rumination following a stressor is associated with greater depression severity, in both cases also after accounting for baseline levels of depressive symptoms (Michl et al., 2013). Moreover, in a study utilizing ecological momentary assessment, rumination mediated longitudinal relationships between stress and both negative affect and depressive symptoms for stressful events occurring in daily life (Ruscio et al., 2016).

Whereas repetitive thinking in and of itself may not worsen mood (Emery et al., 2020), particularly a repetitive focus on negative thoughts, such as those involved in Beck's cognitive triad, are implicated in reduced mood due to rumination (Ehring and Watkins, 2008; Poerio et al., 2014). CBT has moderate effects on rumination (Hedge's $g = 0.57$; Spinhoven et al., 2018); however, rumination has been less frequently included as an outcome in RCTs. Although rumination has also been implicated in depression among older adults (Tang et al., 2022), older adults ruminate less frequently than their younger counterparts (Nolen-Hoeksema and Aldao, 2011; Ricarte et al., 2016) and age-related differences in ER have been well documented (Carstensen et al., 1999; Emery et al., 2020). Thus, findings from studies with younger or middle-aged adults should not be generalized to older adults. Evidence for the effects of psychological interventions on rumination in older adults remains insufficient (Spinhoven et al., 2018). We found only one study examining the effects of a CBT-based intervention on rumination among older adults (Ekkers et al., 2011).

1.4. Empirical findings on metacognitive training for depression

MCT-Silver represents an age-adapted version of D-MCT and while there is significant overlap between the content of the two treatments (Jelinek et al., 2015), MCT-Silver includes unique content, which is described below. An initial RCT on D-MCT yielded medium to large effects on clinician- and self-reported depressive symptoms, as well as small to medium effects on negative cognitive beliefs following the intervention as well as after 6-months among young and middle-aged adults participating in an outpatient rehabilitation program (Jelinek et al., 2016). Moreover, D-MCT had moderate to large effects on metacognitive beliefs immediately following the intervention (Jelinek et al., 2017). There is also evidence of maintenance of these changes after 3 years (Jelinek et al., 2019). In separate studies, a superior effect of D-MCT as an add-on intervention among patients completing an intensive inpatient program was found for negative cognitive beliefs (Hauschildt et al., 2022) and in a study with outpatients, significantly greater reductions in rumination and metacognitive beliefs were found in the D-MCT group compared to a wait-list control (Özgüç and Tanriverdi, 2022). In an initial examination of the relative contributions of metacognitive vs. cognitive processes to depression reduction in D-MCT, Jelinek et al. (2017) compared negative cognitive beliefs with three subscales of the Metacognitive Questionnaire (MCQ; 'need for control', 'negative beliefs', 'positive beliefs'). Only improvement on the 'need for control' subscale of the MCQ significantly mediated D-MCT's effect on reduction in depressive symptoms at a medium effect.

The acceptance and feasibility of metacognitive training with older adults was confirmed in a pilot study in which D-MCT groups were offered as an add-on treatment to older adults participating in an intensive inpatient treatment program (Schneider et al., 2018). In a revision phase, based on patient feedback and empirical findings on depression in later life, select modules and exercises were revised. Specifically, a D-MCT module on self-esteem was altered to address negative attitudes about aging (Chachamovich et al., 2008; Laidlaw et al., 2018) and an imagery rescripting exercise regarding self-image replaced several D-MCT exercises. A second module was partially revised to integrate concepts from acceptance and commitment therapy (ACT) in the context of accepting negative feelings with a focus on age-related changes (e.g., mobility limitations, illness, loss of significant others). Finally, a new module was developed to address (re-)defining values later in life (e.g., due to changing roles and priorities). All case examples were revised as necessary for older adults and the format was edited to improve the clarity and presentation of the content based on patient feedback. Therefore, MCT-Silver is best conceptualized as a "modern" CBT-based intervention, which integrates traditional CBT with third-wave techniques and theories utilizing an overarching metacognitive approach.

In a recently completed RCT comparing MCT-Silver to an active control group (cognitive remediation; Schneider et al., *under review*), both groups had large and significant reductions on the primary outcome (Hamilton Depression Rating Scale; HDRS) from baseline to post ($t1$) and follow-up ($t2$; $d_{MCT\text{-}Silver} = 1.26–1.42$; $d_{CR} = 1.05–1.12$).

However, there were no significant group differences ($\eta_p^2 = 0.001–0.002$). For self-reported depression (Beck Depression Inventory – II; BDI-II) and rumination (Ruminative Response Scale; RRS), MCT-Silver yielded significant moderate to large effects compared to CR immediately following the intervention (*t*1) and after 3 months (*t*2; BDI-II: $\eta_p^2 = 0.075–0.135$; RRS: $\eta_p^2 = 0.087–0.127$). A significant moderate effect was found for positive metacognitive beliefs (MCQ-PB) at post-assessment (*t*1; $\eta_p^2 = 0.067$), but group differences did not reach significance at follow-up (*t*2: $\eta_p^2 = 0.027$). The MCT-Silver group had small to moderate reductions in negative cognitive beliefs (Dysfunctional Attitudes Scale-18B) at post- and at 3-month follow-up ($d_{MCT\text{-}Silver} = 0.24–0.30$), whereas negative cognitive beliefs remained stable in the CR group ($d_{CR} = -0.06–0.06$).

1.5. Aim of the present study

The mediators through which MCT-Silver exerts its effects have not yet been examined. By including negative cognitive beliefs, positive metacognitive beliefs and rumination as mediators, we sought to explore whether MCT-Silver's impacts on depression relative to an active control condition (i.e., cognitive remediation; MyBrainTraining©; NeuroCare GmbH) may be due to specific (meta) cognitive mechanisms (e.g., changes in negative cognitive beliefs or positive metacognitive beliefs), to improvement in an ER strategy (e.g., rumination) or both. To this end, we conducted a secondary analysis of data from our recent RCT on the effectiveness of MCT-Silver. In line with the previously presented theoretical models and work on the effects of CBT and metacognitive-based interventions, we expected that a better outcome at 3-month follow-up after MCT-Silver treatment would be mediated by an improvement in negative cognitive beliefs (DAS-18B), positive metacognitive beliefs (MCT-PB) and rumination (RRS) from baseline to post-intervention. Although the RCT did not yield significant between-group differences for clinician-rated depression, based on current recommendations regarding probing for mediation effects in the absence of group differences (MacKinnon et al., 2007; Hayes, 2022, p. 123), we examined mediators of reduction in both clinician-rated and self-reported depressive symptoms. Due to links between late-onset depression and neurodegenerative changes (Leyhe et al., 2017), we sought to control for possible confounds by additionally examining models including covariates (late / early onset of depression as indicated by self-reported depressive symptoms prior to age 60 and number of depressive episodes).

2. Materials and methods

2.1. Design

The present study represents a secondary analysis of data from an RCT comparing group MCT-Silver for older adults with depression to an active control (e.g., cognitive remediation). All participants were assessed at three time points: baseline (*t*0), post (*t*1; 8 weeks) and follow-up (*t*2; 3 months after post). After t0, participants were randomized to one of the two groups. Study leads performed the randomization using a randomization plan developed by a statistician (1,1 allocation rule). Raters were blinded to group allocation. To ensure rater blindness throughout the study, raters reminded participants at the beginning of the post- and follow-up assessments not to disclose their group assignment. Informed consent was obtained before the interview from all participants. Participants were given 20€ upon completion of each assessment as compensation for their time and travel costs. The study received ethical approval and was registered at Clinical Trials.gov (NCT03691402). The trial was conducted in accordance with the Declaration of Helsinki.

2.2. Participants and procedure

We recruited participants *via* Google AdWords, articles in a senior magazine, posters, brochures, advertisements, as well as through depression, anxiety and memory outpatient clinics. Prior to the baseline examination, potential participants were screened for eligibility in a telephone interview and then an appointment was made for the baseline examination. Before participants attended interviews, they completed measures of secondary outcomes sent *via* post. The Mini International Neuropsychiatric Interview (MINI; German version, 7.0.2; Sheehan et al., 1998) was used to assess for a current major depressive episode, recurrent depression and/or dysthymia (inclusion criteria). Additionally, participants had to (1) be at least 60 years old, (2) provide consent to participate in MCT-Silver as well as in the diagnostic interviews, (3) be available for weekly group sessions, (4) be eligible for group therapy (ability to generally comply with group rules was assessed during the screening interview), (5) have sufficient German language skills, and (6) score within the intact range (≥17 points) on a telephone version of the Mini Mental State Examination (ALFI-MMSE; Roccaforte et al., 1992). Exclusion criteria were as follows: (1) current or lifetime psychotic symptoms, (2) current or lifetime mania, (3) severe neurological disease (e.g., Parkinson's disease, multiple sclerosis), (4) current substance dependence, (5) visual or hearing impairment, which prevented group participation and/or testing, and/or (6) current acute suicidality. Current substance use or abuse was tolerated. Concurrent outpatient psychotherapy or pharmacological treatment did not lead to exclusion from the study but was carefully documented.

2.3. Implementation of interventions

2.3.1. Experimental intervention: Metacognitive training–Silver

One MCT-Silver session was administered per week over a period of 8 weeks (*ca.* 60 min per session). MCT-Silver groups were conducted by licensed psychotherapists as well as psychologists with master's degrees who were currently undergoing postgraduate training in psychotherapy. Two trainers led each group. All trainers received training in MCT-Silver prior to their participation in the study and were regularly supervised by one of the study leads (BS, RV for an MCT-Silver and D-MCT Online Training see www.uke.de/e-dmct). All MCT-Silver modules were presented as slides that contain the training content. The number of participants in MCT-Silver groups ranged from three to eight; due to the open format of MCT-Silver, participants could join at any time. The modules cover topics including negative cognitive beliefs,

metacognitive beliefs, rumination and depressive behaviors, which are supported by significant research on depression: Modul 1: Mental filter (Carver and Ganellen, 1983; Gotlib and Joormann, 2010); Module 2: Mood-congruent memory / false memories (Mathews and MacLeod, 2005; Moritz et al., 2008), Module 3: "Should" statements (Graham et al., 2010; Egan et al., 2011) and disqualifying the positive (Cane and Gotlib, 1985; Elliott et al., 1997) as well as acceptance of negative feelings (Hayes et al., 1996; Butler and Ciarrochi, 2007); Module 4: Values (Isaacowitz and Seligman, 2002; Hayes et al., 2006; Wrosch et al., 2013); Module 5: Exaggeration/Minimization (Garber and Hollon, 1980; Hoehn-Hyde et al., 1982; Cane and Gotlib, 1985; Wenzlaff and Grozier, 1988) as well as Attribution Style (Carver and Ganellen, 1983; Wenzlaff and Grozier, 1988), Module 6: Rumination and Withdrawal (Rood et al., 2009; Seidel et al., 2010; Wells, 2011); Module 7: Jumping to Conclusions (Strunk et al., 2006; Miranda et al., 2008), and Module 8: Self-Worth in Later Life (Davey et al., 2004; Orth et al., 2009; Holmes et al., 2016).

2.3.2. Control intervention: Cognitive remediation

An active control condition was administered to match the treatment group in terms of therapeutic effort. Participants in the control group completed MyBrainTraining© exercises on a computer once a week for up to 60 min. Although participants often completed the training in groups of 2–3, some sessions were individually scheduled. Training sessions were conducted in the hospital where the study took place. Psychologists were present to mark attendance, monitor for worsening of symptoms and help with possible computer problems, but did not administer any structured intervention. Log-in information was not given to participants to prevent practice at home.

2.4. Measures

Two outcomes were investigated. The primary outcome measure was the total score of the Hamilton Depression Rating Scale (HDRS, 17-item version; Hamilton, 1960). The secondary outcome measure was self-rated depression as measured by the Beck Depression Inventory-II (BDI-II; Beck et al., 1996).

2.4.1. Potential cognitive mediators

2.4.1.1. Dysfunctional Attitudes Scale-18B (DAS-18B)

The Dysfunctional Attitudes Scale is a self-report questionnaire designed to assess and identify dysfunctional attitudes, thoughts, and schemas associated with depression. For the present study, the German DAS-18B (Rojas et al., 2015) was used, which consists of 18 items answered on a seven-point Likert scale (1 = total agreement to 7 = total disagreement). A higher total score indicates a greater presence of dysfunctional attitudes. Internal consistency for our study was good (Cronbach's $\alpha = 0.85$).

2.4.1.2. Positive beliefs subscale, Metacognitions Questionnaire-30 (MCQ-30)

The Metacognitions Questionnaire-30 is a self-rating questionnaire developed by Wells and Cartwright-Hatton (2004). The questionnaire has good psychometric properties with a retest reliability of $r = 0.75$ and internal consistency of $\alpha = 0.72$. Internal consistency of the positive beliefs subscale in the current sample was acceptable (Cronbach's $\alpha = 0.79$).

2.4.1.3. 10-item Ruminative Response Scale

The 10-item Ruminative Response Scale (Treynor et al., 2003) is a subscale of the Response Style Questionnaire (Nolen-Hoeksema and Morrow, 1991), which assesses ruminative tendencies. The scale contains only items unconfounded with depression. The RRS-10 has demonstrated high internal consistency and test–retest reliability (Treynor et al., 2003). Internal consistency in our study was also good (Cronbach's $\alpha = 0.82$).

2.5. Strategy of data analysis

IBM SPSS 27.0 software was used for all analyzes. A subsample of participants with complete baseline data were included for this secondary analysis ($N = 66$). Participants with missing baseline data did not differ from those with complete baseline data regarding demographic or clinical characteristics (age, gender, education, number of depressive episodes, baseline scores on the HDRS or BDI-II). There were also no significant differences for change on depression measures over the study period ($t0$-$t2$) or mediators ($t0$-$t1$). Missing outcome data (post, follow-up) were imputed by the expectation–maximization (EM) algorithm trimmed to fall between the minimum and maximum of possible values. Although various cutoffs have been defined for determining early- and late-onset of depression in the literature, we defined early-onset depression as self-reported depressive symptoms prior to age 60. For mediation analysis, MCT-Silver was coded as 1 and CR as 0. A treatment effect in the analyses thus refers to effects of MCT-Silver above and beyond CR. To capture change in depression (HDRS and BDI-II), standardized residualized change scores using a simple linear regression model in which baseline scores predicted follow-up scores ($t0$ to $t2$) were calculated. To capture change in the mediators (DAS-18B, MCQ-PB and RRS), standardized residualized change scores were calculated in which baseline scores predicted post-assessment scores ($t0$ to $t1$). Greater declines in the respective variable is indicated by more positive standardized residualized change scores. The mediation analysis thus determines to what extent change in depression from $t0$ to $t2$, i.e., from baseline to 3-month follow-up, that was brought about by MCT-Silver above and beyond CR can be explained by change in the mediator variables in the treatment period, i.e., from baseline to end of treatment 8 weeks later ($t0$-$t1$). We expected that the mediation analysis would yield positive beta values for path a (group to mediator), which would indicate that MCT-Silver led to a greater reduction in the mediator versus CR. Path b would also result in a positive beta value (mediator to HDRS) indicating that a reduction in the mediator led to a reduction in depression. The mediation analysis was conducted using an SPSS macro PROCESS developed by Hayes (2022). The analysis allows delineation of the effects of each of the proposed mediators separately while controlling for the others. It thus presents a rather conservative test for estimating individual mediation effects. To correct for potential biases of non-normality in the sample, results were bootstrapped 5,000 times. When the effect range (LL = lower limit to UL = upper limit) of the 95% CI does not include zero, the null hypothesis is considered rejected.

3. Results

Groups were similar on psychopathological and sociodemographic data as well as medication (see Table 1). Most participants ($n = 56$; 84.9%) met criteria for a current depressive episode. Six (9.1%) participants fulfilled criteria for recurrent depression without a current major depressive episode or dysthymia (all also met the HDRS cutoff for at least mild depression according to the HDRS [≥9]; DGPPN, 2017). Approximately one-third of participants (34.9%; $n = 23$) had a single depressive episode whereas 60.6% ($n = 40$) had recurrent depressive episodes. Half ($n = 33$; 50.0%) fulfilled criteria for dysthymia. Spearman correlations between change in all variables over the different time points (*t*0-*t*1; *t*0-*t*2) are displayed in Table 2. As expected, correlations were highest within the same constructs over time (change on BDI-II from t0-t1 and t0-t2) but change in DAS-18B, RRS and MCQ-PB were also significantly correlated. Change in MCQ-PB was not significantly correlated with change in depression at any time point.

Mediation was tested separately for the HDRS and BDI-II (Table 3). Consistent with the main RCT results, MCT-Silver elicited long-term reduction in depression only on the BDI-II ($b = 0.70$, SE = 0.22, $p = 0.002$, BootLLCI = 0.26, BootULCI = 1.14), whereas the treatment group effect was not significant for the HDRS ($b = -0.03$, SE = 0.24, $p = 0.902$, BootLLCI = −0.50, BootULCI = 0.45). Treatment with MCT-Silver elicited a greater reduction on the MCT-PB and RRS as well as the DAS-18B at post-intervention. Mediation results differ for the two depression measures: For the HDRS, the indirect effect of treatment on reduction in clinician-rated depression was significant *via* RRS ($b = 0.18$; BootSE = 0.12; BootLLCI = 0.01, BootULCI = 0.46) with a non-significant effect of treatment on reduction in depression of −0.14 (SE = 0.25, $p = 0.570$, BootLLCI = −0.63, BootULCI = 0.35). For the BDI-II, the indirect effect of treatment on reduction in self-reported depression was significant *via* DAS-18B ($b = 0.19$, BootSE = 0.10, BootLLCI = 0.02, BootULCI = 0.41) with a remaining significant effect of treatment on reduction in depression of 0.51 (SE = 0.22, $p = 0.022$, BootLLCI = 0.08, BootULCI = 0.95). For the non-significant indirect effects of the MCQ-PB for both depression measures as well as the DAS-18B and RRS for the HDRS and BDI-II, please see Table 4.

With regard to the covariates early−/late-onset and number of depressive episodes, participants reporting early-onset of depressive symptoms (prior to age 60) had, on average, 5.25 (SD = 4.59) depressive episodes, whereas those with late-onset had 2.48 (SD = 2.39) depressive episodes ($t(46.99) = 3.01$; $p < 0.004$). Mediation was again tested separately for the HDRS and BDI-II when including the covariates age of onset and number of depressive episodes. Indirect effects of mediators were not substantially changed. For the HDRS, the indirect effect of treatment on reduction in clinician-rated depression remained significant only *via* RRS ($b = 0.21$; BootSE = 0.13; BootLLCI = 0.01, BootULCI = 0.53) with a non-significant effect of treatment on reduction in depression of −0.14 (SE = 0.26, $p = 0.60$, BootLLCI = −0.66, BootULCI = 0.39). For the BDI-II, the indirect effect of treatment on reduction in self-reported depression remained significant only *via* DAS-18B ($b = 0.16$, BootSE = 0.09, BootLLCI = 0.01, BootULCI = 0.36) with a significant effect of treatment on reduction in depression of 0.48 (SE = 0.22, $p = 0.033$, BootLLCI = 0.04, BootULCI = 0.93).

TABLE 1 Baseline sociodemographic and clinical characteristics: Means (SD) or frequencies.

Variable	MCT-Silver (*n*=34)	CR (*n*=32)	Statistics (MCT-Silver vs. CR)
Age (years)	72.29 (6.41)	71.53 (7.40)	$t(64) = 0.60$, $p = 0.655$
Sex (female/male)	26/8	22/10	$\chi^2 = 0.50$, $p = 0.482$
Formal education (years)	10.21 (1.82)	10.53 (1.76)	$t(64) = 0.74$, $p = 0.464$
Marital status (single/married/separated or divorced/widowed)	7/6/12/9	5/8/11/8	Cramer's $V = 0.10$, $p = 0.882$
Number of MDE (incl. current)	3.85 (4.45)[a]	3.93 (3.28)[b]	$t(61) = 0.44$, $p = 0.932$
Onset of depression (early vs. late)*	19/15	16/16	$\chi^2 = 0.29$, $p = 0.632$
Medication (antidepressant/benzodiazepine/combination/none/other)	8/2/3/20/1	14/1/0/16/1	Cramer's V = 0.29, $p = 0.252$
Comorbidity (MMD only/MDD and comorbid disorder)	24/10	21/11	$\chi^2 = 0.19$, $p = 0.665$
Psychopathology			
HDRS-17	17.30 (4.75)	15.44 (4.06)	$t(64) = 0.81$, $p = 0.096$
BDI-II	29.88 (9.38)	27.57 (10.04)	$t(64) = 0.97$, $p = 0.336$
DAS-18B	62.06 (21.02)	54.84 (17.40)	$t(64) = 0.29$, $p = 0.135$
RRS	24.75 (5.65)	23.25 (5.25)	$t(64) = 0.60$, $p = 0.267$
MCQ-PB	12.55 (4.27)	11.44 (3.37)	$t(64) = 1.17$, $p = 0.245$

*Early-onset depression was defined as self-reported depressive symptoms prior to age 60. BDI-II = Beck Depression Inventory-II; CR = Cognitive remediation; DAS-18B = Dysfunctional Attitudes Scale, Version 18-B; HDRS = Hamilton Depression Rating Scale; MCQ-PB = Metacognition Questionnaire-Positive Beliefs subscale; MDE = Major depressive episodes; RRS = Ruminative Response Scale; [a] $n = 33$, [b] $n = 30$.

TABLE 2 Pearson's correlations between change in self-reported and clinician-rated depression with change in negative cognitive beliefs, positive metacognitive beliefs and rumination (N=66).

	1.	2.	3.	4.	5.	6.	7
1. ΔBDI-II, t0-t1	--	0.415***	0.508***	0.488***	0.103	0.698***	0.313*
2. ΔHDRS, t0-t1		--	0.247*	0.402***	0.047	0.403**	0.642**
3. ΔDAS-18B, t0-t1			--	0.434***	0.368**	0.433***	0.057
4. ΔRRS, t0-t1				---	0.281*	0.323**	0.297*
5. ΔMCQ-PB, t0-t1					---	0.084	−0.023
6. ΔBDI-II, t0-t2						---	0.403***
7. ΔHDRS, t0-t2							---

BDI-II = Beck Depression Inventory-II; DAS-18B = Dysfunctional Attitudes Scale, Version 18-B; HDRS = Hamilton Depression Rating Scale; RRS = Ruminative Response Scale; MCQ-PB = Metacognition Questionnaire-Positive Beliefs subscale. *$p < 0.05$; **$p < 0.01$; ***$p < 0.001$.

TABLE 3 Direct effects of treatments on mediators and of mediators on clinician-rated and self-reported depression.

	Mediators ($t0$-$t1$)						Outcomes ($t0$-$t2$)			
	DAS-18B		RRS		MCQ-PB		HDRS		BDI-II	
	b	SE	b	SE	b	SE	b	SE	b	SE
Treatment group	**0.57***	**0.24**	**0.51***	**0.24**	**0.50***	**0.23**	−0.14	0.25	**0.51***	**0.22**
DAS-18B							−0.04	0.13	**0.33****	**0.12**
RRS							**0.35***	**0.13**	0.14	0.12
MCQ-PB							−0.09	0.13	−0.15	0.12
R^2	0.08		0.07		0.07		0.11		0.29	

BDI-II = Beck Depression Inventory-II; DAS-18B = Dysfunctional Attitudes Scale, Version 18-B; HDRS = Hamilton Depression Rating Scale; RRS = Ruminative Response Scale; MCQ-PB = Metacognition Questionnaire-Positive Beliefs subscale. **$p < 0.01$; *$p < 0.05$. Treatment group coded as MCT-Silver = 1 and active control = 0. Higher scores on the mediators and outcomes indicate greater reductions. Bold indicates that the 95% confidence interval does not encompass zero.

4. Discussion

Our study provides first evidence of how MCT-Silver may exert its effects on depression. In this secondary analysis of our RCT data, MCT-Silver led to a significant reduction in rumination, positive metacognitive beliefs and negative cognitive beliefs above and beyond CR. However, our results regarding mediation are not fully conclusive. Whereas rumination mediated reduction in clinician-rated symptoms, negative cognitive beliefs mediated the effect of MCT-Silver on reduction in self-reported depression. Conclusions regarding causal mechanisms for MCT-Silver are also limited by the lack of causal precedence given that there was an overlap in the measurement of mediators and outcomes. Thus, although our findings support significant statistical mediation, causation remains unclear (Kazdin, 2007). We first discuss the overall findings with regard to their relevance as possible mechanisms of change in MCT-Silver and then address possible reasons for the discrepancy between the BDI-II and HDRS.

Consistent with the results from our recent RCT on MCT-Silver, we did not find a direct effect of MCT-Silver on the main outcome–reduction in clinician-rated depressive symptoms (HDRS). However, the indirect effect of MCT-Silver *via* RRS on depressive symptoms was significant. Failure to test for indirect effects despite the absence of significant total or direct effects in mediation models may lead to an under analysis of data and missed identification of meaningful mediation effects (Hayes, 2022, p. 123). Given the significant impairment associated with rumination, this ER strategy represents an important target for psychological interventions. Our findings indicate that the reduction in rumination from pre- to post-assessment due to MCT-Silver significantly mediated the reduction in depressive symptoms for clinician-assessed depression from pre-assessment to the 3-month follow-up. In other words, MCT-Silver exerted its effect on reduction in clinician-rated depression symptoms only *via* reduced ruminations.

Given that the overarching goal of MCT-Silver is gaining insight into thought processes (e.g., "thinking about one's thinking"), it is likely that several of the cognitive and metacognitive techniques (e.g., questioning the usefulness of rumination, challenging negative thoughts that serve as ruminative content, not treating thoughts as facts) and general psychoeducation (e.g., differences between problem-solving and rumination) presented in MCT-Silver contributed to reduced ruminations (Papageorgiou and Wells, 2009; Hawley et al., 2014). In addition, MCT-Silver integrates other approaches, which may have impacted rumination. For example, with the aim of increasing awareness of cognitive biases, MCT-Silver Module 2 "Memory" specifically addresses a tendency to remember situations from the past overly positively or negatively. Patients are then encouraged to seek more specific, accurate memories and to remain "fair" when comparing their current life with the past. Thus, increased awareness of mood-congruent memory biases may lead to

TABLE 4 Indirect effects of potential mediators on self-reported and clinician-rated depression.

	HDRS (*t*0-*t*2)				BDI-II (*t*0-*t*2)			
	Effect	BootSE	BootLLCI	BootULCI	Effect	BootSE	BootLLCI	BootULCI
DAS-18B	−0.02	0.08	−0.20	0.13	**0.19**	**0.10**	**0.28**	**0.40**
RRS	**0.18**	**0.12**	**0.01**	**0.45**	0.07	0.07	−0.04	0.25
MCQ-PB	−0.04	0.08	−0.23	0.10	−0.08	0.08	−0.25	0.06
Total	0.11	0.13	−0.14	0.38	0.18	0.12	0.44	−0.02

BDI-II = Beck Depression Inventory-II; DAS-18B = Dysfunctional Attitudes Scale, Version 18-B; HDRS = Hamilton Depression Rating Scale; RRS = Ruminative Response Scale; MCQ-PB = Metacognition Questionnaire-Positive Beliefs subscale. Bold indicates that the 95% confidence interval does not encompass zero.

reduced ruminations. Alternatively, similar to reminiscence therapy, training patients to search for more specific autobiographical memories may improve specificity of information processing (Hamlat, 2018). Moreover, integrating concepts from third-wave treatments, in Module 3, increasing acceptance for negative feelings is presented. It is then discussed that acceptance of and giving up fighting negative thoughts and feelings can lead to improved mood. This would then fit well with Nolen-Hoeksema's et al. (2008) concept of shifting attention away from negative thought content.

Although our findings on rumination are promising, the literature is not equivocal regarding to what extent rumination may be best conceptualized as an ER strategy versus as a component of an emotional reaction to an ongoing emotional conflict (e.g., depressive symptoms and their causes). Similar to other components of emotional reactions (e.g., physiological, cognitive), rumination begins automatically and involuntarily. Thus, its measurement *via* self-report measures has been criticized as it is unclear to what extent individuals can accurately self-report on such strategies as reflecting upon one's emotion regulation requires significant insight and metacognitive ability (Aldao et al., 2010; Berking and Wupperman, 2012). Moreover, the experience of rumination may be confounded with cognitive-emotional aspects of depression itself (e.g., negative thoughts associated with depression or thinking about feelings of sadness; Aldao et al., 2010). Studies demonstrating qualitative differences in depressed and non-depressed individuals regarding rumination may provide supporting evidence for this view. For example, depressed individuals have more thoughts regarding hopelessness while ruminating and feel more sadness during rumination than non-depressed individuals (Rosenbaum et al., 2020). To increase specificity of measurement of depression versus rumination in our study, we used the 10-item RRS which was developed to reduce overlap between rumination and depressive symptoms (Treynor et al., 2003).

To date, the effects of D-MCT on rumination has only been considered in two studies (Jelinek et al., 2013; Özgüç and Tanriverdi, 2022), which yielded significant reductions in rumination at small (Cohen's $d = 0.32$) and large ($\eta 2 = 0.229$) effects, respectively. Further work is needed to examine whether these findings can be replicated in future studies and specifically for MCT-Silver in older adults. Taken together, in line with general CBT concepts for depression treatment, our study adds further evidence that rumination represents an important treatment target also for older adults with depression, is malleable and can mediate a reduction in depressive symptoms among this patient group.

In line with cognitive models of depression, reduction in negative cognitive beliefs because of MCT-Silver mediated reduction in self-reported depression. As a CBT-based intervention, MCT-Silver aims to improve participants' awareness of negative thought patterns and cognitive biases. In a second step, participants are taught over several modules how such negative thoughts can be challenged and modified to be more realistic and "fair." The impact of these negative thoughts on mood is also highlighted in the training. The current study thus provides further support for the malleability of negative cognitive beliefs among older adults, which to date has been shown to be important for depression recovery primarily within younger and middle-aged adults (Cristea et al., 2015; Faissner et al., 2018).

Our results differ somewhat from previous work on D-MCT, in which the DAS did not emerge as a significant mediator; rather the 'cognitive control' subscale of the MCQ-30 was the only significant mediator (Jelinek et al., 2017). Given that we did not include the same MCQ subscales in the current study, these mediation models cannot be directly compared. Although MCT-Silver includes content similar to D-MCT, specific treatment content does differ (e.g., the inclusion of components drawn from ACT in MCT-Silver). Therefore, it is not surprising that the mediators through which the treatments affect depression also differ (at least with regard to the DAS-18B). It is also unclear to what extent age-related differences, for example, in emotion processing or attentional biases, may impact the (purported) mechanisms through which D-MCT and MCT-Silver work.

The discrepant findings between self- and clinician-reported depression, prohibits a conclusive statement regarding mediators of the effects of MCT-Silver on depressive symptoms. Moreover, given the overlap of measurement periods for outcomes and mediators, causality of these associations also cannot be equivocally established. Therefore, our study provides initial evidence that MCT-Silver may work through reduction of specific cognitive processes (e.g., reduction of negative cognitive beliefs) as well as through improving ER strategies (e.g., rumination). Discrepancies between the BDI-II and HDRS are not uncommon. Change on the BDI-II and HDRS in our study were significantly correlated ($r \approx 0.40$); however, correlations between the BDI-II and HDRS have been shown to vary widely ($r = 0.20$–0.89; Schneibel et al., 2012). Moreover, the HDRS has been criticized for underestimating cognitive symptoms of depression (Zimmerman et al., 2005), which in our study is reflected by the smaller and non-significant associations between change on the DAS-18B and the HDRS at post and follow-up, respectively (see Table 2). Thus, the specific content of the DAS-18B may better correspond to the cognitive aspects of depression measured by the BDI-II.

Finally, our findings were unchanged after controlling for possible effects of late−/early-onset of depression as well as number of depressive episodes. This is broadly in line with studies indicating

that effects of depression treatment do not differ based on age of onset (Kozel et al., 2008; Tunvirachaisakul et al., 2018). However, older adults with both late-onset and recurrent depression may take longer to achieve remission (Driscoll et al., 2005). Given that our measures were based on self-report data, future work utilizing neuroimaging data may better rule out effects of neurodegenerative processes.

4.1. Limitations

The current study has several strengths (e.g., RCT, blinded assessors, confirmed diagnoses, analyses controlled for possible confounding variables) and sheds further light on mediators of reduction in depressive symptoms within older adults, but it is not without its limitations. First, it is important to emphasize that this study represents an analysis of a subsample of our RCT participants. Thus, our conclusions only pertain to this specific sample and there were some minor differences on secondary outcomes (e.g., significance of between-group reductions in DAS-18B at post-assessment). Next, as previously mentioned, we cannot draw equivocal conclusions given that mediators differed for self-reported versus clinician-rated depression. Third, participants had mild to moderate depressive symptoms, and it is unclear whether our findings may apply to patients with more severe depression. Interestingly, self-rated depression on the BDI-II was more severe compared to clinician ratings of depressive symptoms. Patients reported having on average four depressive episodes and half ($n = 33$) met criteria for dysthymia. This suggests that many participants were experiencing perhaps milder yet chronic symptoms.

Although our study's mediation models represent methodological standards for mediation (Hayes, 2022), future work should seek to provide further support for MCT's mechanisms of change (Kazdin, 2007). The ideal test of mediation would include intermediate measurements during treatment as well as a manipulation of these mediators (Ehring et al., 2022). For example, it would be ideal to measure changes in possible mediators following each session or at intermediate points throughout treatment (e.g., Lemmens et al., 2017). Given that our study only included three time points and the period of measurement of mediators and outcomes overlapped, this prohibits the investigation of causal relationships between rumination, negative cognitive beliefs and metacognitive beliefs with each other as well as with regard to change in depressive symptoms. Our study examined reductions in depressive symptoms at follow-up, which also captures maintenance of intervention effects. Finally, it is important to point out that mediation only provides evidence regarding which of the tested variables account for change due to treatment and do not exclude the possibility that other factors (e.g., also including common factors, other ER strategies, knowledge) contributed to the observed reductions in depressive symptoms. Specifically, we did not include measures associated with the integrated ACT techniques.

4.2. Conclusion

Taken together this study provides initial evidence for negative cognitive beliefs and rumination as mechanisms of change in MCT-Silver. These findings underscore the importance of targeting negative cognitive beliefs and rumination when treating depression among older adults, however, given the divergent outcomes for self-reported and clinician-rated outcomes as well as the lack of casual precedence, MCT-Silver's mechanisms of change have yet to be conclusively identified.

Data availability statement

The raw data supporting the conclusions of this article will be made available upon reasonable request without undue reservation.

Ethics statement

The studies involving human participants were reviewed and approved by Local Psychology Ethics Commission (Lokale Psychologische Ethikkomission) of the Center for Psychosocial Medicine at the University Medical Center Hamburg-Eppendorf. The patients/participants provided their written informed consent to participate in this study.

Author contributions

BS: conceptualization, methodology, formal analysis, writing the original draft, and funding acquisition. RV: supervision, investigation, conceptualization, and project administration. EK: writing–review and editing, methodology, and resources. LP, BM, and CF: writing–review and editing, and resources. SM and LJ: conceptualization, methodology, resources, and writing–review and editing. All authors contributed to the article and approved the submitted version.

Funding

The study was funded by a grant to BS from the UKE Stiftung. This research was also funded by FEDER, Programa Interreg VA España-Portugal (POCTEP), Instituto Internacional de Investigação e Inovação em Envelhecimento–Capitaliza "0786_CAP4ie_4_P". The funding sources had no role in the preparation of the data or manuscript.

Acknowledgments

We would like to thank Celine Nguyen, Josephine Gehlenborg, Marie Kuhl, Jan Lehmbeck, Jakob Scheunemann, Marcel Riehle, Malin Steinbach, Francesa Bohn, Birgit Hottenrott, and all CR trainers for their support of this study.

Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

References

Aldao, A., Nolen-Hoeksema, S., and Schweizer, S. (2010). Emotion-regulation strategies across psychopathology: a meta-analytic review. *Clin. Psychol. Rev.* 30, 217–237. doi: 10.1016/j.cpr.2009.11.004

Beck, A. T., and Haigh, E. A. P. (2014). Advances in cognitive theory and therapy: the generic cognitive model. *Annu. Rev. Clin. Psychol.* 10, 1–24. doi: 10.1146/ANNUREV-CLINPSY-032813-153734

Beck, A. T., Rush, A. J., Shaw, B. F., and Emery, G.. (1979). *Cognitive Therapy of Depression*. New York: Guilford Press.

Beck, A. T., Steer, R. A., and Brown, G. K.. (1996). *Beck Depression Inventory-II*. San Antonio, TX: Psychological Corporation.

Berking, M., and Wupperman, P. (2012). Emotion regulation and mental health: recent findings, current challenges, and future directions. *Curr. Opin. Psychiatry* 25, 128–134. doi: 10.1097/YCO.0b013e3283503669

Braunstein, L. M., Gross, J. J., and Ochsner, K. N. (2017). Explicit and implicit emotion regulation: a multi-level framework. *Soc. Cogn. Affect. Neurosci.* 12, 1545–1557. doi: 10.1093/scan/nsx096

Butler, J., and Ciarrochi, J. (2007). Psychological acceptance and quality of life in the elderly. *Qual. Life Res.* 16, 607–615. doi: 10.1007/s11136-006-9149-1

Campbell-Sillis, L., and Barlow, D. (2007). "Incorporating emotion regulation into conceptualizations and treatments of anxiety and mood disorders" in *Handbook of Emotion Regulation*. ed. J. J. Gross (New York: The Guilford Press), 542–559.

Cane, D. B., and Gotlib, I. H. (1985). Depression and the effects of positive and negative feedback on expectations, evaluations, and performance. *Cognit. Ther. Res.* 9, 145–160. doi: 10.1007/BF01204846

Carstensen, L. L., Isaacowitz, D. M., and Charles, S. T. (1999). Taking time seriously: a theory of socioemotional selectivity. *Am. Psychol.* 54, 165–181. doi: 10.1037/0003-066X.54.3.165

Carver, C. S., and Ganellen, R. J. (1983). Depression and components of self-punitiveness: high standards, self-criticism, and overgeneralization. *J. Abnorm. Psychol.* 92, 330–337. doi: 10.1037/0021-843X.92.3.330

Chachamovich, E., Fleck, M., Laidlaw, K., and Power, M. (2008). Impact of major depression and subsyndromal symptoms on quality of life and attitudes toward aging in an international sample of older adults. *Gerontologist* 48, 593–602. doi: 10.1093/geront/48.5.593

Cristea, I. A., Huibers, M. J. H., David, D., Hollon, S. D., Andersson, G., and Cuijpers, P. (2015). The effects of cognitive behavior therapy for adult depression on dysfunctional thinking: a meta-analysis. *Clin. Psychol. Rev.* 42, 62–71. doi: 10.1016/j.cpr.2015.08.003

Cuijpers, P. (2019). Targets and outcomes of psychotherapies for mental disorders: an overview. *World Psychiatry* 18, 276–285. doi: 10.1002/wps.20661

Cuijpers, P., Karyotaki, E., Eckshtain, D., Ng, M. Y., Corteselli, K. A., Noma, H., et al. (2020). Psychotherapy for depression across different age groups: a systematic review and meta-analysis. *JAMA Psychiat.* 77, 694–702. doi: 10.1001/jamapsychiatry.2020.0164

Cuijpers, P., Karyotaki, E., Pot, A. M., Park, M., and Reynolds, C. F. (2014). Managing depression in older age: psychological interventions. *Maturitas* 79, 160–169. doi: 10.1016/j.maturitas.2014.05.027

Davey, A., Halverson, C. F., Zonderman, A. B., and Costa, P. T. (2004). Change in depressive symptoms in the Baltimore longitudinal study of aging. *J. Gerontol. B Psychol. Sci. Soc. Sci.* 59, P270–P277. doi: 10.1093/geronb/59.6.P270

DGPPN, BÄK, KBV, AWMF. (2017). *(Hrsg.) für die Leitliniengruppe Unipolare Depression. S3-Leitlinie/Nationale Versorgungs Leitlinie Unipolare Depression–Langfassung. Guideline Group Unipolar Depression. S3-Guideline/National Disease Management Guideline Unipolar Depression–Short Version, 2.* Auflage. Version 5, doi: 10.6101/AZQ/000364

Driscoll, H. C., Basinski, J., Mulsant, B. H., Butters, M. A., Dew, M. A., Houck, P. R., et al. (2005). Late-onset major depression: clinical and treatment-response variability. *Int. J. Geriatr. Psychiatry* 20, 661–667. doi: 10.1002/gps.1334

Egan, S. J., Wade, T. D., and Shafran, R. (2011). Perfectionism as a transdiagnostic process: a clinical review. *Clin. Psychol. Rev.* 31, 203–212. doi: 10.1016/j.cpr.2010.04.009

Ehring, T., Limburg, K., Kunze, A. E., Wittekind, C. E., Werner, G. G., Wolkenstein, L., et al. (2022). (When and how) does basic research in clinical psychology lead to more effective psychological treatment for mental disorders? *Clin. Psychol. Rev.* 95:102163. doi: 10.1016/j.cpr.2022.102163

Ehring, T., and Watkins, E. R. (2008). Repetitive negative thinking as a transdiagnostic process. *Int. J. Cogn. Ther.* 1, 192–205. doi: 10.1521/ijct.2008.1.3.192

Ekkers, W., Korrelboom, K., Huijbrechts, I., Smits, N., Cuijpers, P., and Van Der Gaag, M. (2011). Competitive memory training for treating depression and rumination in depressed older adults: a randomized controlled trial. *Behav. Res. Ther.* 49, 588–596. doi: 10.1016/j.brat.2011.05.010

Elliott, R., Sahakian, B. J., Herrod, J. J., Robbins, T. W., and Paykel, E. S. (1997). Abnormal response to negative feedback in unipolar depression: evidence for a diagnosis specific impairment. *J. Neurol. Neurosurg. Psychiatry* 63, 74–82. doi: 10.1136/jnnp.63.1.74

Emery, L., Sorrell, A., and Miles, C. (2020). Age differences in negative, but not positive, rumination. *J. Gerontol.* 75, 80–84. doi: 10.1093/geronb/gbz109

Faissner, M., Kriston, L., Moritz, S., and Jelinek, L. (2018). Course and stability of cognitive and metacognitive beliefs in depression. *Depress. Anxiety* 35, 1239–1246. doi: 10.1002/da.22834

Garber, J., and Hollon, S. D. (1980). Universal versus personal helplessness in depression: belief in uncontrollability or incompetence? *J. Abnorm. Psychol.* 89, 56–66. doi: 10.1037/0021-843X.89.1.56

Gehlenborg, J., Bücker, L., Berthold, M., Miegel, F., and Moritz, S. (2021). Feasibility, acceptance, and safety of metacognitive training for problem and pathological gamblers (gambling-MCT): a pilot study. *J. Gambl. Stud.* 37, 663–687. doi: 10.1007/s10899-020-09975-w

Gotlib, I. H., and Joormann, J. (2010). Cognition and depression: current status and future directions. *Annu. Rev. Clin. Psychol.* 6, 285–312. doi: 10.1146/annurev.clinpsy.121208.131305

Graham, A. R., Sherry, S. B., Stewart, S. H., Sherry, D. L., McGrath, D. S., Fossum, K. M., et al. (2010). The existential model of perfectionism and depressive symptoms: a short-term, four-wave longitudinal study. *J. Couns. Psychol.* 57, 423–438. doi: 10.1037/a0020667

Haffner, P., Quinlivan, E., Fiebig, J., Sondergeld, L. M., Strasser, E. S., Adli, M., et al. (2018). Improving functional outcome in bipolar disorder: a pilot study on metacognitive training. *Clin. Psychol. Psychother.* 25, 50–58. doi: 10.1002/cpp.2124

Hamilton, M. (1960). A rating scale for depression. *J. Neurol. Neurosurg. Psychiatry* 23, 56–62. doi: 10.1136/jnnp.23.1.56

Hamlat, E. J. (2018). Autobiographical memory as a target of intervention: increasing specificity for therapeutic gain. *Pract. Innov.* 3, 227–241. doi: 10.1037/pri0000075

Hauschildt, M., Arlt, S., Moritz, S., Yassari, A. H., and Jelinek, L. (2022). Efficacy of metacognitive training for depression as add-on intervention for patients with depression in acute intensive psychiatric inpatient care: a randomized controlled trial. *Clin. Psychol. Psychother.* 29, 1542–1555. doi: 10.1002/cpp.2733

Hawley, L. L., Schwartz, D., Bieling, P. J., Irving, J., Corcoran, K., Farb, N. A. S., et al. (2014). Mindfulness practice, rumination and clinical outcome in mindfulness-based treatment. *Cogn. Ther. Res.* 38, 1–9. doi: 10.1007/s10608-013-9586-4

Hayes, A. F.. (2022). *Introduction to Mediation, Moderation, and Conditional Process Analysis*. New York, United States: Guilford Press.

Hayes, S. C., Luoma, J. B., Bond, F. W., Masuda, A., and Lillis, J. (2006). Acceptance and commitment therapy: model, processes and outcomes. *Behav. Res. Ther.* 44, 1–25. doi: 10.1016/J.BRAT.2005.06.006

Hayes, S. C., Wilson, K. G., Gifford, E. V., Follette, V. M., and Strosahl, K. D. (1996). Experiential avoidance and behavioral disorders: a functional dimensional approach to diagnosis and treatment comparing syndromal and functional classification. *J. Consult. Clin. Psychol.* 64, 1152–1168. doi: 10.1037/0022-006X.64.6.1152

Hinrichsen, G. A., Brickman, A. M., Edelstein, B., VachaHhaase, T., Hiroto, K., and Zweig, R. (2014). Guidelines for psychological practice with older adults.. *Am. Psychol.* 69, 34–65. doi: 10.1037/a0035063

Hoehn-Hyde, D., Schlottmann, R. S., and Rush, A. J. (1982). Perception of social interactions in depressed psychiatric patients. *J. Consult. Clin. Psychol.* 50, 209–212. doi: 10.1037/0022-006X.50.2.209

Holmes, E., Blackwell, S. E., Burnett Heyes, S., Renner, F., and Raes, F. (2016). Mental imagery in depression: phenomenology, potential mechanisms, and treatment implications. *Annu. Rev. Clin. Psychol.* 12, 249–280. doi: 10.1146/annurev-clinpsy-021815-092925

Hu, T., Zhao, X., Wu, M., Li, Z., Luo, L., Yang, C., et al. (2022). Prevalence of depression in older adults: a systematic review and meta-analysis. *Psychiatry Res.* 311:114511. doi: 10.1016/j.psychres.2022.114511

Isaacowitz, D. M., and Seligman, M. E. P. (2002). Cognitive style predictors of affect change in older adults. *Int. J. Aging Hum. Dev.* 54, 233–253. doi: 10.2190/J6E5-NP5K-2UC4-2F8B

Jelinek, L., Faissner, M., Moritz, S., and Kriston, L. (2019). Long-term efficacy of metacognitive training for depression (D-MCT): a randomized controlled trial. *Br. J. Clin. Psychol.* 58, 245–259. doi: 10.1111/bjc.12213

Jelinek, L., Hauschildt, M., and Moritz, S. (2015). "Metakognitives training bei depression (D-MKT)" in *Metacognitive Training for Depression (D-MCT)*. ed. H. Starvemann (Weinheim: Beltz)

Jelinek, L., Hauschildt, M., Wittekind, C. E., Schneider, B. C., Kriston, L., and Moritz, S. (2016). Efficacy of metacognitive training for depression: a randomized controlled trial. *Psychother. Psychosom.* 85, 231–234. doi: 10.1159/000443699

Jelinek, L., Otte, C., Arlt, S., and Hauschildt, M. (2013). Identifying and correcting cognitive biases: a pilot study on the metacognitive training for depression (D-MCT). *Z. Psychiatr. Psychol. Psychother.* 61, 247–254. doi: 10.1024/1661-4747/a000167

Jelinek, L., Van Quaquebeke, N., and Moritz, S. (2017). Cognitive and metacognitive mechanisms of change in metacognitive training for depression. *Sci. Rep.* 7, 1–8. doi: 10.1038/s41598-017-03626-8

Kazdin, A. E. (2007). Mediators and mechanisms of change in psychotherapy research. *Annu. Rev. Clin. Psychol.* 3, 1–27. doi: 10.1146/annurev.clinpsy.3.022806.091432

Kozel, F. A., Trivedi, M. H., Wisniewski, S. R., Miyahara, S., Husain, M. M., Fava, M., et al. (2008). Treatment outcomes for older depressed patients with earlier versus late onset of first depressive episode. *Am. J. Geriatr. Psychiatry* 16, 58–64. doi: 10.1097/JGP.0b013e31815a43d7

Laidlaw, K., Kishita, N., Shenkin, S. D., and Power, M. J. (2018). Development of a short form of the attitudes to ageing questionnaire (AAQ). *Int. J. Geriatr. Psychiatry* 33, 113–121. doi: 10.1002/gps.4687

Lemmens, L. H. J. M., Galindo-Garre, F., Arntz, A., Peeters, F., Hollon, S. D., DeRubeis, R. J., et al. (2017). Exploring mechanisms of change in cognitive therapy and interpersonal psychotherapy for adult depression. *Behav Res Ther.* 94, 81–92. doi: 10.1016/j.brat.2017.05.005

Leyhe, T., Reynolds, C. F., Melcher, T., Linnemann, C., and Kl, S. (2017). A common challenge in older adults: classification, overlap, and therapy of depression and dementia. *Alzheimer Dement.* 13, 59–71. doi: 10.1016/j.jalz.2016.08.007

Lorenzo-Luaces, L., German, R. E., and DeRubeis, R. J. (2015). It's complicated: the relation between cognitive change procedures, cognitive change, and symptom change in cognitive therapy for depression. *Clin. Psychol. Rev.* 41, 3–15. doi: 10.1016/j.cpr.2014.12.003

Lyubomirsky, S., and Nolen-Hoeksema, S. (1993). Self-perpetuating properties of dysphoric rumination. *J. Pers. Soc. Psychol.* 65, 339–349. doi: 10.1037/0022-3514.65.2.339

MacKinnon, D. P., Fairchild, A. J., and Fritz, M. S. (2007). Mediation analysis. *Annu Rev Psychol.* 58, 593–614. doi: 10.1146/annurev.psych.58.110405.085542

Mathews, A., and MacLeod, C. (2005). Cognitive vulnerability to emotional disorders. *Annu. Rev. Clin. Psychol.* 1, 167–195. doi: 10.1146/ANNUREV.CLINPSY.1.102803.143916

Michl, L. C., Mclaughlin, K. A., Shepherd, K., and Nolen-Hoeksema, S. (2013). Rumination as a mechanism linking stressful life events to symptoms of depression and anxiety: longitudinal evidence in early adolescents and adults. *J. Abnorm. Psychol.* 122, 339–352. doi: 10.1037/a0031994

Miegel, F., Moritz, S., Hottenrott, B., Demiralay, C., and Jelinek, L. (2021). Metacognitive training for obsessive-compulsive disorder: a randomized controlled trial. *J. Obsessive. Compuls. Relat. Disord.* 30:100647. doi: 10.1016/j.jocrd.2021.100647

Miranda, R., Fontes, M., and Marroquín, B. (2008). Cognitive content-specificity in future expectancies: role of hopelessness and intolerance of uncertainty in depression and GAD symptoms. *Behav. Res. Ther.* 46, 1151–1159. doi: 10.1016/j.brat.2008.05.009

Moritz, S., Andreou, C., Schneider, B. C., Wittekind, C. E., Menon, M., Balzan, R. P., et al. (2014). Sowing the seeds of doubt: a narrative review on metacognitive training in schizophrenia. *Clin. Psychol. Rev.* 34, 358–366. doi: 10.1016/j.cpr.2014.04.004

Moritz, S., Lysaker, P. H., Hofmann, S. G., and Hautzinger, M. (2018). Going meta on metacognitive interventions. *Expert. Rev. Neurother.* 18, 739–741. doi: 10.1080/14737175.2018.1520636

Moritz, S., Voigt, K., Arzola, G. M., and Otte, C. (2008). When the half-full glass is appraised as half empty and memorised as completely empty: mood-congruent true and false recognition in depression is modulated by salience. *Memory* 16, 810–820. doi: 10.1080/09658210802282708

NeuroCare GmbH. *MyBrainTraining*. Available at: http://www.mybraintraining.com

Nieto, I., Robles, E., and Vazquez, C. (2020). Self-reported cognitive biases in depression: a meta-analysis. *Clin. Psychol. Rev.* 82:101934. doi: 10.1016/J.CPR.2020.101934

Nolen-Hoeksema, S. (1987). Sex differences in unipolar depression: evidence and theory. *Psychol. Bull.* 101, 259–282. doi: 10.1037/0033-2909.101.2.259

Nolen-Hoeksema, S. (2000). The role of rumination in depressive disorders and mixed anxiety/depressive symptoms. *J. Abnorm. Psychol.* 109, 504–511. doi: 10.1037/0021-843X.109.3.504

Nolen-Hoeksema, S., and Aldao, A. (2011). Gender and age differences in emotion regulation strategies and their relationship to depressive symptoms. *Pers. Individ. Dif.* 51, 704–708. doi: 10.1016/j.paid.2011.06.012

Nolen-Hoeksema, S., and Morrow, J. (1991). Factor analysis of posttraumatic stress disorder in children experienced earthquakes in Turkey. *J. Pers. Soc. Psychol.* 61, 115–121. doi: 10.1037/0022-3514.61.1.115

Normann, N., and Morina, N. (2018). The efficacy of metacognitive therapy: a systematic review and meta-analysis. *Front. Psychol.* 9:2211. doi: 10.3389/fpsyg.2018.02211

Nolen-Hoeksema, S., Wisco, B. E., and Lyubomirsky, S. (2008). Rethinking rumination. *Perspect Psychol Sci.* 3, 400–424. doi: 10.1111/j.1745-6924.2008.00088.x

Orth, U., Robins, R. W., Trzesniewski, K. H., Maes, J., and Schmitt, M. (2009). Low self-esteem is a risk factor for depressive symptoms from young adulthood to old age. *J. Abnorm. Psychol.* 51, 52–66. doi: 10.1016/j.advwatres.2012.07.003

Özgüç, S., and Tanriverdi, D. (2022). Effects of metacognitive training (D-MCT) on metacognition and ruminative thought levels of major depression patients. *Int. J. Ment. Health Addict.* 1, 1–12. doi: 10.1007/s11469-022-00869-z

Papageorgiou, C., and Wells, A. (2009). A prospective test of the clinical metacognitive model of rumination and depression. *Int. J. Cogn. Ther.* 2, 123–131. doi: 10.1521/IJCT.2009.2.2.123

Poerio, G. L., Totterdell, P., and Miles, E. (2014). Mind-wandering and negative mood: does one thing really lead to another? *Conscious. Cogn.* 22, 1412–1421. doi: 10.1016/j.concog.2013.09.012

Ricarte, J., Ros, L., Serrano, J. P., Martínez-Lorca, M., and Latorre, J. M. (2016). Age differences in rumination and autobiographical retrieval. *Aging Ment. Health* 20, 1063–1069. doi: 10.1080/13607863.2015.1060944

Roccaforte, W. H., Burke, W. J., Bayer, B. L., and Wengel, S. P. (1992). Validation of a telephone version of the Mini-Mental State Examination. *J. Am. Geriatr. Soc.* 40, 697–702. doi: 10.1111/j.1532-5415.1992.tb01962.x

Rojas, R., Geissner, E., and Hautzinger, M. (2015). DAS-18 form A and form B: development and psychometric evaluation of two short and comparable versions of the dysfunctional attitudes scale. *Diagnostica* 61, 173–183. doi: 10.1026/0012-1924/a000123

Rood, L., Roelofs, J., Bögels, S. M., Nolen-Hoeksema, S., and Schouten, E. (2009). The influence of emotion-focused rumination and distraction on depressive symptoms in non-clinical youth: a meta-analytic review. *Clin. Psychol. Rev.* 29, 607–616. doi: 10.1016/j.cpr.2009.07.001

Rosenbaum, D., Veen, I. I., Kroczek, A., Hilsendegen, P., Schurian, K. V., Bihlmaier, I., et al. (2020). Amplitude of low frequency fluctuations (ALFF) of spontaneous and induced rumination in major depression: an fNIRS study. *Sci. Rep.* 10:21520. doi: 10.1038/s41598-020-78317-y

Ruscio, A. M., Gentes, E. L., Jones, J. D., Hallion, L. S., Coleman, E. S., and Swendsen, J. (2016). Rumination predicts heightened responding to stressful life events in major depressive disorder and generalized anxiety disorder. *J. Abnorm. Psychol.* 124, 17–26. doi: 10.1037/abn0000025.Rumination

Santomauro, D. F., Mantilla Herrera, A. M., Shadid, J., Zheng, P., Ashbaugh, C., Pigott, D. M., et al. (2021). Global prevalence and burden of depressive and anxiety disorders in 204 countries and territories in 2020 due to the COVID-19 pandemic. *Lancet* 398, 1700–1712. doi: 10.1016/S0140-6736(21)02143-7

Schaakxs, R., Comijs, H. C., Lamers, F., Kok, R. M., Beekman, A. T. F., and Penninx, B. W. J. H. (2018). Associations between age and the course of major depressive disorder: a 2-year longitudinal cohort study. *Lancet Psychiatry* 5, 581–590. doi: 10.1016/S2215-0366(18)30166-4

Schilling, L., Moritz, S., Kriston, L., Krieger, M., and Nagel, M. (2018). Efficacy of metacognitive training for patients with borderline personality disorder: preliminary results. *Psychiatry Res.* 262, 459–464. doi: 10.1016/j.psychres.2017.09.024

Schneibel, R., Brakemeier, E., Wilbertz, G., Dykierek, P., Zobel, I., and Schramm, E. (2012). Sensitivity to detect change and the correlation of clinical factors with the Hamilton Depression Rating Scale and the Beck Depression Inventory in depressed inpatients. *Psychiatry Res.* 198, 62–67. doi: 10.1016/j.psychres.2011.11.014

Schneider, B. C., Bücker, L., Riker, S., Karamatskos, E., and Jelinek, L. (2018). A pilot study of metacognitive training (D-MCT) for older adults with depression. *Z. Neuropsychol.* 29, 7–19. doi: 10.1024/1016-264x/a000210

Seidel, E. M., Habel, U., Finkelmeyer, A., Schneider, F., Gur, R. C., and Derntl, B. (2010). Implicit and explicit behavioral tendencies in male and female depression. *Psychiatry Res.* 177, 124–130. doi: 10.1016/j.psychres.2010.02.001

Sheehan, D. V., Lecrubier, Y., Sheehan, K. H., Amorim, P., Janavs, J., Weiller, E., et al. (1998). The Mini International Psychiatric Interview (M.I.N.I.): the development and validation of a structured diagnostic psychiatric interview for DSM-IV and ICD-10. *J. Clin. Psychiatry* 59 Suppl 20, 22–33. PMID: 9881538

Spinhoven, P., Klein, N., Kennis, M., Cramer, A. O. J., Siegle, G., Cuijpers, P., et al. (2018). The effects of cognitive-behavior therapy for depression on repetitive negative thinking: a meta-analysis. *Behav. Res. Ther.* 106, 71–85. doi: 10.1016/j.brat.2018.04.002

Strunk, D. R., Lopez, H., and DeRubeis, R. J. (2006). Depressive symptoms are associated with unrealistic negative predictions of future life events. *Behav. Res. Ther.* 44, 861–882. doi: 10.1016/j.brat.2005.07.001

Tang, T., Jiang, J., and Tang, X. (2022). Psychological risk and protective factors associated with depression among older adults in mainland China: a systematic review and meta-analysis. *Int. J. Geriatr. Psychiatry* 37:5637. doi: 10.1002/gps.5637

Treynor, W., Gonzalez, R., and Nolen-Hoeksema, S. (2003). Rumination reconsidered: a psychometric analysis. *Cogn. Ther. Res.* 27, 247–259. doi: 10.1023/A:1023910315561

Tunvirachaisakul, C., Gould, R. L., Coulson, M. C., Ward, E. V., Reynolds, G., Gathercole, R. L., et al. (2018). Predictors of treatment outcome in depression in later life: a systematic review and meta-analysis. *J. Affect. Disord.* 227, 164–182. doi: 10.1016/j.jad.2017.10.008

Watkins, E. R., and Nolen-Hoeksema, S. (2014). A habit-goal framework of depressive rumination. *J. Abnorm. Psychol.* 123, 24–34. doi: 10.1037/a0035540

Watkins, E. R., and Roberts, H. (2020). Reflecting on rumination: consequences, causes, mechanisms and treatment of rumination. *Behav. Res. Ther.* 127:103573. doi: 10.1016/j.brat.2020.103573

Weber, F., and Exner, C. (2013). Metacognitive beliefs and rumination: a longitudinal study. *Cogn. Ther. Res.* 37, 1257–1261. doi: 10.1007/s10608-013-9555-y

Wells, A.. (2011). *Metacognitive Therapy for Anxiety and Depression*. New York: The Guilford Press.

Wells, A., and Cartwright-Hatton, S. (2004). A short form of the metacognitions questionnaire: properties of the MCQ-30. *Behav. Res. Ther.* 42, 385–396. doi: 10.1016/S0005-7967(03)00147-5

Wenzlaff, R. M., and Grozier, S. (1988). Depression and the magnification of failure. *J. Abnorm. Psychol.* 97, 90–93. doi: 10.1037/0021-843X.97.1.90

Wrosch, C., Scheier, M. F., and Miller, G. E. (2013). Goal adjustment capacities, subjective well-being, and physical health. *Soc. Personal. Psychol. Compass* 7, 847–860. doi: 10.1111/spc3.12074

Wu, J. J., Wang, H. X., Yao, W., Yan, Z., and Pei, J. J. (2020). Late-life depression and the risk of dementia in 14 countries: a 10-year follow-up study from the Survey of Health, Aging and Retirement in Europe. *J. Affect. Disord.* 274, 671–677. doi: 10.1016/j.jad.2020.05.059

Zimmerman, M., Posternak, M. A., and Chelminski, I. (2005). Is it time to replace the Hamilton Depression Rating Scale as the primary outcome measure in treatment studies of depression? *J. Clin. Psychopharmacol.* 25, 105–110. doi: 10.1097/01.jcp.0000155824.59585.46

frontiers | Frontiers in Psychology

TYPE Original Research
PUBLISHED 15 May 2023
DOI 10.3389/fpsyg.2023.1167961

OPEN ACCESS

EDITED BY
Lara Guedes De Pinho,
University of Evora, Portugal

REVIEWED BY
Li Zhang,
Shanghai University of Sport, China
Malahat Akbarfahimi,
Iran University of Medical Sciences, Iran

*CORRESPONDENCE
Thalía Fernández
✉ thaliafh@yahoo.com.mx
Juan Silva-Pereyra
✉ jsilvapereyra@gmail.com

†These authors share first authorship
‡These authors share senior authorship

RECEIVED 17 February 2023
ACCEPTED 24 April 2023
PUBLISHED 15 May 2023

CITATION
Martínez-Briones BJ, Flores-Gallegos R, Cárdenas SY, Barrera-Díaz BE, Fernández T and Silva-Pereyra J (2023) Effects of neurofeedback on the self-concept of children with learning disorders.
Front. Psychol. 14:1167961.
doi: 10.3389/fpsyg.2023.1167961

Effects of neurofeedback on the self-concept of children with learning disorders

Benito Javier Martínez-Briones[1†], Rodrigo Flores-Gallegos[1†], Sonia Y. Cárdenas[1,2], Bertha Elena Barrera-Díaz[1], Thalía Fernández[1*‡] and Juan Silva-Pereyra[3*‡]

[1]Departamento de Neurobiología Conductual y Cognitiva, Instituto de Neurobiología, Universidad Nacional Autónoma de México Campus Juriquilla, Querétaro, Mexico, [2]Universidad Pedagógica Nacional, Querétaro, Mexico, [3]Facultad de Estudios Superiores Iztacala, Universidad Nacional Autónoma de México, Tlanepantla, Estado de México, Mexico

Children with learning disorders (LDs) often have a lower self-concept than their typically developing peers. Neurofeedback (NFB) treatments seem to improve the cognitive and academic performance of these children, but the effects on self-concept have not been studied. In this exploratory study, 34 right-handed children (8–11 y.o.) with LD and delayed electroencephalographic maturation responded to the Piers–Harris Children's Self-Concept Scale. One group received NFB (n=20), and another group (n=14) served as control, which included 9 children treated with sham-NFB and 5 on a waiting-list. A nonparametric permutation approach was used to compare the academic performance and self-concept difference (postscores – prescores) between the NFB and control groups. Given the smaller size of the control subgroups, a comparison of the percent changes between sham-NFB and the waiting-list was performed with the non-overlap of all pairs (NAP) technique. In the NFB group, the scores of reading, math, and global self-concept increased significantly, highlighting the self-concept subdomains of physical appearance, nonanxiety, popularity, and happiness. Additionally, the sham-NFB subgroup showed better outcomes than the waiting-list subgroup, perhaps due to noncontrolled factors. We found improved academic performance and self-concept in children with LDs who received NFB treatment. This study is an important exploratory step in studying a relevant treatment that seems to ameliorate symptoms of LDs such as anxiety and low self-concept.

KEYWORDS

self-concept, self-esteem, neurofeedback, learning disorder, children, EEG biofeedback

1. Introduction

With a prevalence range of 5–20%, learning disorders (LDs) are the most common neurodevelopmental problems afflicting school-age children (Shaywitz et al., 1999; Altarac and Saroha, 2007; Lagae, 2008; American Psychiatric Association, 2013). According to the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Text Revision (DSM-5-TR) (American Psychiatric Association, 2022), a specific LD is diagnosed in individuals with persistent difficulties (at least 6 months) during their development (Criterion C) in learning the basic academic skills of reading, writing, or mathematics (Criterion A), with performance scores in standardized tests substantially below those expected for their age, causing significant interference with academic performance or with activities of daily living (criterion B). The

learning difficulties are not better explained by intellectual disabilities, uncorrected visual or hearing acuity, other neurological or psychiatric disorders, or inadequate educational instruction (Criterion D).

Compared with children with typical development, students with LD have higher rates of emotional disorders such as anxiety, depression (Willcutt and Pennington, 2000; Carroll et al., 2005; Nelson and Gregg, 2012), and an affected sense of self-esteem or self-concept (both concepts being often conflated; Cooley and Ayres, 1988; Smith and Nagle, 1995; Gans et al., 2003; McArthur et al., 2016, 2020; Huang et al., 2021). Self-esteem is a rather general and emotionally loaded value that people assign to themselves, while self-concept is a psychological construct of how people perceive themselves based on a multifaceted set of relatively stable self-perceptions, formed through experience and influenced by the judgments of others, which includes a sense of social worth and thoughts about one's physical characteristics, abilities, and academic skills (Epstein, 1973; Marsh, 1990; Piers and Herzberg, 2002; Zeleke, 2004; McArthur et al., 2020). Self-concept is "essentially phenomenological in nature"; therefore, it heavily depends on the self-report of the individual to describe and evaluate him or herself (Marsh, 1990; Piers and Herzberg, 2002). Since school is considered the main social environment for young people, individuals who are receiving failing grades are more at risk of developing negative self-concepts, anxiety, and depression. Reduced self-esteem is in itself an important risk factor for depression in the young (Sowislo and Orth, 2013; Choi et al., 2019; Hards et al., 2020); it has a bidirectional relationship with anxiety (Sowislo and Orth, 2013; Francis et al., 2019), and teens with LDs show three times more suicidal ideations and attempted suicides than their peers (Daniel et al., 2006). LDs have significant societal impacts in the form of school dropout and higher levels of poverty, with most juvenile delinquents showing low academic performance (Kutner et al., 2006); thus, it is important to explore the emotional and identity dimensions of individuals with LDs and the impact of treatments to ameliorate their symptoms.

The current research on self-concept impairments in LDs either focuses on heterogeneous samples of academic impairments, mostly working with the formerly known learning disorder not otherwise specified (LD-NOS) (American Psychiatric Association, 2000), or on the dyslexia subtype (Snowling et al., 2007; Terras et al., 2009; Huang et al., 2021), with meta-analyses showing people with dyslexia (compared to controls) having an affected sense of global self-concept together with an impaired self-perception of academic skills (McArthur et al., 2016) and anxiety (Francis et al., 2019; McArthur et al., 2020). In samples with heterogeneous types of LDs, self-esteem has been found to be affected (Lahane et al., 2013), with specific impairments in the self-concept subdomains of academic skills and conduct (Cooley and Ayres, 1988; Gans et al., 2003), including affected perceptions of intellectual ability and social acceptance (Smith and Nagle, 1995).

The main interventions to treat the academic symptoms of LDs are special education classes and remedial programs in reading, writing, or mathematics (Swanson and Hoskyn, 1998; National Reading Panel, 2000; Shaywitz and Shaywitz, 2020). It is assumed that a child's self-concept would be indirectly improved by successfully treating their main academic impairments, due to supporting their ability to perform at school, coupled with the positive feedback from their achievements and encouragement from others (McArthur et al., 2016). However, it is not common practice to report self-concept improvements, or even general improvements in well-being, in treatments that focus on academic domains, but two studies do stand out. On the one hand, Block (1993) reported improved self-esteem together with reading improvements in children who went through a literature-based reading program; on the other hand, a meta-analysis of educational interventions found a moderate effect of treatments on the self-concept of children with LDs (Swanson and Hoskyn, 1998).

Regarding the effects of noneducational types of treatment on the self-concept of people with LDs, MacMahon and Gross (1987) treated LD children with an aerobic exercise program and found that their self-concept improved compared to a control group. Similarly, Musetti et al. (2019) found that teenagers with LDs who underwent psychosocial treatment improved their self-concept compared with healthy or untreated teens with LDs.

An EEG-based neurofeedback (NFB) treatment is also a relevant therapeutic approach. An NFB treatment is an operant conditioning training program that aims to modify brain activity for therapeutic or performance-enhancing purposes (Budzynski et al., 2009; Gruzelier, 2014; Sitaram et al., 2017). NFB treatments have an experimental treatment status (Thibault and Raz, 2016), with ongoing research of their effects on disorders such as ADHD (Lubar et al., 1995; Simkin et al., 2014, 2016), anxiety disorders (Hammond, 2006; Abdian et al., 2021), epilepsy (Egner and Sterman, 2006; Sterman and Egner, 2006; Morales-Quezada et al., 2019), and LDs (Fernández et al., 2003; Becerra et al., 2006; Breteler et al., 2010; Nazari et al., 2012; Martínez-Briones et al., 2021). Children with LD often exhibit an abnormally slower resting-state EEG than children with typical development, characterized by an excess of theta activity and a deficit of alpha activity (Chabot, 2001; Fernández et al., 2002; Fonseca et al., 2006). The research of NFB effects on LD shows that attempting to normalize the EEG by reducing the theta/alpha ratio seems to facilitate EEG maturation and, as a consequence, can boost cognitive performance (Fernández et al., 2003, 2016; Martínez-Briones et al., 2021) and improve EEG resting-state patterns (Fernández et al., 2003, 2007), with treatment effects lasting at least 2 years (Becerra et al., 2006). NFB treatments may also benefit those with LDs by improving spelling ability, which may be associated with increased EEG connectivity of the alpha-band (Breteler et al., 2010), and by improving reading and phonological awareness, with such effects possibly being related to the normalization of EEG connectivity measures (Nazari et al., 2012). However, to our knowledge, there is no evidence of an improved self-concept after NFB treatment in LD children. Three of the abovementioned studies state that most parents subjectively reported a boost in their child's self-esteem (Becerra et al., 2006; Fernández et al., 2007, 2016), but this was not captured with a direct and objective assessment that considered self-concept as a multidomain construct. Thus, this study aimed to explore the effects of NFB treatments on the self-concept of children with LDs.

The LD sample of this study was heterogeneous, with impairments in the academic domains of reading, writing, and/or mathematics. We adhered to an examination of a global self-concept derived from the following subdomains or specific perceptions of self-concept: behavior, intellectual or academic skills, physical appearance, freedom from anxiety, popularity, and happiness or life satisfaction (Alexopoulos and Foudoulaki, 2002; Flahive et al., 2015). Hence, this is an exploratory study of the possible effects of NFB treatment on six aspects of self-concept in children with LDs.

Several researchers conceive cognitive achievement as the result of self-esteem or self-concept (Marsh, 1990; Núñez Pérez and Solís, 1995; González-Pienda et al., 2000; Tobia et al., 2017); however,

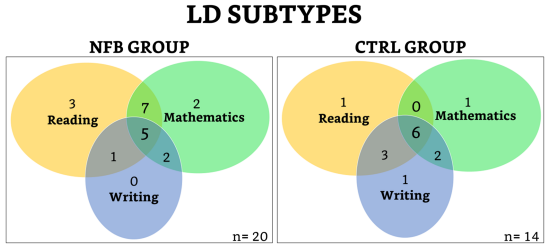


FIGURE 1
Venn diagrams of the distribution of academic impairments.

Baumeister et al. (2003) views a high self-concept as partly the result of good school performance. In a meta-analysis based on the analysis of 105 studies involving a sample of more than 58,000 participants from the world over, Huang (2011) concluded the relationship between self-concept and academic performance as bidirectional. Since the children in this study come from primary schools, it is essential to recognize the relationship between academic performance and self-concept as stronger in elementary than in high school (Huang, 2011). Thus, because the NFB treatment aims to improve cognitive performance, an increased self-concept may be an emergent result of this study.

2. Materials and methods

The Ethics Committee of the Instituto de Neurobiología, Universidad Nacional Autónoma de México (UNAM), approved the experimental protocol (INEU/SA/CB/146). This protocol complies with the Ethical Principles for Medical Research Involving Human Subjects established by the Declaration of Helsinki (World Medical Association, 2013). Informed consent was signed by all children and their parents.

2.1. Participants

The necessary sample size for this study was calculated with G*Power 3.1 software[1] using the effect size of a difference between two groups (NFB vs. sham-NFB; Martínez-Briones et al., 2021). We used the following values: a Cohen's *d* effect size of 1.15, a 1:1 size ratio between the two groups, a one-tailed type 1 error rate of 0.05, and a power of 0.9. Accordingly, at least 28 participants (14 per group) were needed.

Forty right-handed children aged 8–11 years diagnosed with LD were selected from a larger sample of children referred by teachers and social workers from several elementary schools in Querétaro, México. All children fulfilled the following inclusion criteria: (1) a normal neurological and psychiatric assessment (except for the LD diagnostic requirements, as stated below), without language impairments or visual/ hearing acuity problems (those with visual problems used correcting glasses); (2) an intelligence quotient (IQ) of at least 75 [Wechsler Intelligence Scale for Children 4th Edition, WISC-4 (Wechsler, 2010)], used to exclude children with intellectual disability; (3) without severe socioeconomic disadvantages, that is, a mother (or tutor in her absence) with at least a completed elementary school education and a *per capita* income greater than 50 percent of the minimum wage; and (4) an abnormally high EEG resting-state theta/alpha ratio compared to a normative database (Bosch-Bayard et al., 2020b). The EEG of children with LDs often has more theta and less alpha activity than typical children; thus, we obtained the *z* values of the theta/alpha ratio and selected children with *z* values greater than 1.645 (one-tailed distribution, $p = 0.05$) in at least one lead of their EEG spectra.

In addition, all children had an LD diagnosis. The LD diagnosis was based on the following three criteria: (a) poor academic achievement reported by teachers and parents; (b) percentiles of 10 or lower in the subscales of reading, writing, or mathematics of the Infant Neuropsychological Scale for Children (Matute et al., 2014); and (c) the final decision of LD was delivered by a psychologist according to the DSM-5 criteria for LD (American Psychiatric Association, 2013). A few children failed to complete different items of the attentional evaluation, but they did not meet the DSM-5 criteria of ADHD (American Psychiatric Association, 2013), as others have reported (Holcomb et al., 1986; Silva-Pereyra et al., 2003).

All children were randomly assigned to either an NFB treatment that reinforced a reduction in the theta/alpha ratio (NFB group) or a sham-NFB treatment (control group). The treatment (NFB or sham) was delivered via the lead with the highest abnormal *z* value.

Eleven children were impaired in all three domains (reading, writing, and mathematics); four children were impaired in reading and writing; seven children were impaired in reading and mathematics; four children were impaired in writing and mathematics; four children were impaired in reading; one child was impaired in writing; and three children were impaired in mathematics (Figure 1). It can be noted that our sample of children with LDs was heterogeneous in its distribution of academic impairments, yet both groups were reasonably similar (see Table 1 and Figure 1) for comparison in further analyses.

All children were randomly assigned to either an NFB treatment that reinforced a reduction in the theta/alpha ratio (NFB group; $n = 20$, 9 females) or a sham-NFB treatment (control group). The treatment (NFB or sham) was delivered via the lead with the highest abnormal z value. However, only 9 children in the control group received sham-NFB treatment; the remaining 11 could not receive any treatment due to COVID-19 pandemic-related lockdowns. Nonetheless, we were able to carry out the evaluations for 5 of them after a period of waiting. Therefore, the control group (Ctrl group; $n = 14$, 6 female) was made up of two subgroups of children: a sham subgroup ($n = 9$) and another subgroup, which we considered to be a waiting-list group (WL group; $n = 5$).

2.2. Instruments

2.2.1. Neuropsychological scale for children (ENI)

The Neuropsychological Scale for Children (ENI: Escala Neuropsicológica Infantil; Matute et al., 2014) is standardized by age for the Mexican population. Three ENI domains are evaluated, namely, reading, writing, and mathematics, with several variables

1 https://www.psychologie.hhu.de/arbeitsgruppen/allgemeine-psychologie-und-arbeitspsychologie/gpower

TABLE 1 Descriptive data for the neurofeedback (NFB) and control (CTRL) groups.

	NFB n=20	CTRL n=14	Statistical differences between groups	
	Mean (SD)	Mean (SD)	t	p
Age	9.05 (1.05)	9.00 (1.52)	0.11	0.91
Female/male ratio	9/11	6/8	$X^2 = 0.15$	0.90
WISC-4: Full Scale IQ	92.55 (11.06)	93.07 (9.14)	−0.15	0.89
Reading	30.62 (20.87)	21.16(20.48)	1.36	0.26
Writing	38.68 (21.07)	28.82(17.80)	1.52	0.20
Mathematics	32.57 (20.79)	41.01(21.78)	−1.17	0.31
Global self-concept	53.15 (11.90)	59.79(8.36)	−1.96	0.04
z score (theta/alpha)	2.62 (1.001)	2.19(0.57)	1.22	0.18

assessed for each domain (reading: accuracy, comprehension, and speed; writing: accuracy, narrative composition, and speed; mathematics: counting, number management, calculus, and logical reasoning). Raw scores were transformed to percentiles according to the scale attributes. Reading and writing speeds were measured in terms of the time needed to read a text and write a composition; the correct responses were measured for the other subdomains of the three ENI domains.

2.2.2. Piers–Harris children's self-concept scale

All participants responded to the Piers–Harris Children's Self-Concept Scale, a self-report questionnaire chosen for its multidimensional structure, which allows the categorization of self-perceptions of different domains of experience. The scale's items describe real scenarios with which the children could feel identified. Participants were instructed to answer yes or no to a list of 80 statements about how they think and feel about themselves. A psychologist clarified the confidentiality of the test and explained the importance of giving truthful answers. The psychologist was also present during the performance of the scale to assist with children's doubts.

The scale gives a global score as a general measure of self-concept taken from 6 specific subdomains: behavior, academic competence, physical appearance, freedom from anxiety, popularity, and happiness. A higher score indicates a more positive self-evaluation in the measured subdomain. In this study, the Piers–Harris 2 was used. It was standardized by scholastic grade with a U.S. sample of 1,387 children (49.7% male and 50.3% female) ranging from 7 to 18 years. We considered that the sample may be slightly underrepresentative of a Hispanic or Latino population; however, it has been recognized as appropriate in research, educational, and clinical settings (Alexopoulos and Foudoulaki, 2002; Review of the Piers-Harris Children's Self-Concept Scale 2nd Edition, 2011; Flahive et al., 2015).

2.3. Neurofeedback and sham treatments

A resting-state EEG was recorded during an eyes-closed condition while the child was seated in a dimly lit, faradized, and soundproofed room using 19 leads of the 10–20 International System (ElectroCap™ Inc., Eaton, OH, United States) referenced to linked earlobes (A1A2). For this purpose, we used a Medicid™ IV system and Track Walker™ v2.0 software (Neuronic Mexicana, SA, Mexico City, Mexico). The amplifier bandwidth was set from 0.5 to 50 Hz. All electrode impedances were a maximum of 10 kΩ, and the signal was amplified with a gain of 20,000. EEG data were sampled with a frequency of 200 Hz and edited offline. On average, 24 artifact-free segments of 2.56 s were used for analysis.

To obtain the theta(θ)/alpha(α) (θ/α) ratio, first, the absolute power (AP) of the broad-band model was calculated in the frequency domain, and then θ/α was obtained as the ratio of AP(θ) to AP(α) for each lead. Here, we used the theta and alpha frequency bands in their traditional definitions: theta comprises the frequencies of 3.6–7.5 Hz, and alpha comprises the frequencies of 7.6–12.5 Hz (Fernández et al., 2003), with a frequency resolution of 0.39 Hz.

To calculate the z value of the theta/alpha ratio (z[θ/α]), we obtained the population age-dependent mean [μ(age)] and standard deviation (σ) for the eyes-closed resting-state EEG for each lead used in our study. This was performed by calculating the θ/α index in each lead for all subjects of the Cuban normative database (Bosch-Bayard et al., 2020b) and 2nd-order polynomial age-dependent regressions of those indices to obtain μ(age) and σ (Bosch-Bayard et al., 2001, 2020a).

The NFB treatment was applied at the lead with the highest z(θ/α) using a neurofeedback program adapted by Fernández et al. (2003) for the Medicid IV recording system. Every 20 ms, this program automatically selects a 1,280 ms segment and calculates the θ/α ratio. This ratio is compared to the threshold value previously established by the therapist; only if the θ/α ratio is lower than the threshold value is a tone of 500 Hz at 60 dB (positive reinforcer) emitted. This process is repeated until the EEG recording finishes, using overlapped 1,280 ms segments. The child is told to keep the sound going because it means their brain is working well; in this way, the tone assumes a positive value. The criterion for establishing this threshold the first time was using the subject's value in their resting-state EEG recorded in the sample selection phase, but this was adjusted by trial and error until the tone was delivered approximately 70% of the time. Later (every 3 min), it was verified whether the percentage of time remained between 60 and 80% of the 3 min period, and if so, the threshold was not modified further. If the tone appeared for more than 80% of the time, the most common situation, the therapist changed the threshold to a lower value. Likewise, if the tone appeared less than 60% of the time, the threshold was increased.

The sham treatment was identical to the NFB treatment, except that it was noncontingent with the EEG activity of the child. The goal of a sham-NFB treatment is that the individual has the "feeling" of receiving a real treatment; for this, the same rewarding stimulus of the real NFB is given, but this is not related to their brain activity. There are several ways to obtain this kind of fake stimulus: one is by using the stimulus produced by recording a real NFB treatment of another participant, and the other is by randomly emitting the stimulus with a given frequency, such as between 60 and 80% of the time. The latter approach was used in this study. In other studies, some participants who received the sham treatment reported "finding the feedback confusing and ineffective" (Angelakis et al., 2007); no child in our sham group reported anything of that nature. In this study, none of the

participants knew which condition they were in, nor did they know that there were both experimental and control conditions.

Each subject received 30 training sessions three times a week over 10–12 weeks, with a duration of 30 min per session. At the beginning of each session, the children were told that they would receive candy at the end of the session according to their performance. To motivate the child, a learning curve plot was updated for each session showing the last successful θ/α ratio.

All children were examined with the ENI and self-concept scales in both pre- and posttreatment conditions.

2.4. Data analysis

2.4.1. Pretreatment comparison between groups

A non-parametric permutation *t*-test (5,000 permutations) was applied for the comparison between groups in terms of age, *z* score of the theta/alpha ratio, academic performance (reading, writing, and mathematics), and global self-concept using a statistical tool from eLORETA software (Pascual-Marqui et al., 2011). This nonparametric technique does not require a theoretical distribution since the null-hypothesis distribution of statistical tests is iteratively generated by shuffling processing of the data and does not need corrections for multiple comparisons when several time points are assessed. A chi-square analysis was performed to assess whether the sex distribution was homogenous between groups using SPSS (version 25).

2.4.2. Pre- vs. posttreatment comparison between and within groups

Z score of theta/alpha ratio after treatment: A non-parametric permutation t test (5,000 permutations) was performed to compare the difference (postscores – prescores) between the NFB group and the sham subgroup. This analysis was not applied to the waiting-list subgroup, given its lack of postevaluation.

Academic performance after treatment: The academic performance was analyzed using the same permutation t test described before to compare the NFB and Ctrl groups' percentile score differences (postscores – prescores) in the reading, writing, and mathematics domains. A similar analysis was applied to observe the differences within groups.

Self-concept after treatment: The permutation t test was performed to compare the differences (postscores – prescores) between the NFB and Ctrl groups in the global self-concept score. The same statistical analysis was applied to the self-concept subdomains (behavior, academic skills, physical appearance, non-anxiety, popularity, and happiness).

2.4.3. Sham vs. waiting-list

Given that the Ctrl group consisted of two subgroups (sham and waiting-list), we were interested in analyzing possible between-group prepost changes in academic performance and global self-concept. Due to their small sample size, a qualitative comparison based on the percent changes was performed with the nonoverlapping all pairs (NAP) technique (Parker and Vannest, 2009) using the web-based NAP calculator from Vannest et al. (2016). With this, each variable of the pre- and postconditions was computed from the scaled scores of the respective subscales of each variable. For example, reading depends on reading accuracy, reading comprehension, and reading speed, while global self-concept depends on the following subdomains: behavior, academic skills, physical appearance, nonanxiety, popularity, and happiness. A similar description of the technique is given by Parker et al. (2011) and Flores-Gallegos et al. (2022).

3. Results

3.1. Pretreatment comparison between groups

In the comparison between the NFB and Ctrl groups, no significant differences were found in age, gender distribution, intelligence coefficient (IQ), academic performance, or z scores of theta/alpha ratio. The Ctrl group had a higher global self-concept than the NFB group, as shown in Table 1.

3.2. Pre vs. posttreatment comparison between and within groups

3.2.1. Theta/alpha ratio

There was no significant difference between the NFB group (mean difference = −0.64, SD = 1.05) and the sham subgroup (mean difference = −0.45, SD = 0.45) in the theta/alpha ratio change (postscores – prescores) ($t = -0.52$, $p = 0.34$, $d = -0.24$). The within-group analyses showed a significant decrease in the theta/alpha ratio after treatment for both the NFB group and the sham subgroup (Table 2).

3.2.2. Academic performance

There was a significant gain for the NFB group (mean difference = 7.74, SD = 15.75) in mathematics ($t = 2.86$, $p = 0.01$, $d = 0.80$) compared to the Ctrl group (mean difference = −8.78, SD = 18.89), with 14/20 subjects of the NFB group improving compared to 5/14 controls, as Figure 2 shows. The within-group analyses showed a significant improvement in reading for the NFB group ($t = 3.46$, $p = 0.005$, $d = 0.59$), with 17/20 subjects improving, while there were no significant differences posttreatment for the Ctrl group (Figure 2B). Additional data can be found in the Supplementary Tables S1–S3.

3.2.3. Self-concept

There was a significant gain for the NFB group (mean difference = 7.90, SD = 7.91) in the global self-concept difference (postscore – prescore) ($t = 1.69$, $p = 0.05$, $d = 0.59$) in comparison to the Ctrl group (mean difference = 2.14, SD = 11.48), with 17/20

TABLE 2 Within groups pre vs. post *z* score (theta/alpha) differences for NFB and sham.

	n	Mean pre (SD)	Mean post (SD)	*t*	*p*	Cohen's *d*
NFB	20	2.62 (1.01)	1.98 (1.16)	−2.70	0.00	0.58
Sham	9	2.19 (0.57)	1.74 (0.51)	−2.98	0.01	0.83

subjects improving in the former group compared to 9/14 in the latter (including 3/5 subjects in the waiting-list subgroup).

The within-group analysis (Figure 3) indicated significant increases ($p < 0.05$) in self-concept for the NFB group in the following subdomains: physical appearance (12/20 subjects), nonanxiety (15/20), popularity (12/20), and happiness (12/20). There were no significant differences for the Ctrl group. Additional data can also be found in the Supplementary Tables S4, S5.

3.3. Sham vs. waiting-list

In the comparison between the sham and waiting-list subgroups, there were no significant differences in the gender distribution ($X^2 = 0.93$, $p = 0.33$) or intellectual coefficient (IQ, $t = -1.23$, $p = 0.27$) before treatment. There was a significant difference in age between subgroups ($t = 5.81$, $p = 0.001$), but this did not affect the qualitative analysis.

The sham subgroup had a higher percent change in NAP value over the waiting-list subgroup in the academic performance domains of reading, writing, and mathematics, as shown in Table 3.

There was also a higher NAP value for global self-concept in the sham subgroup (NAP = 0.55, SD = 0.12, $z = 4.76$, CI 90% [0.36–0.74]) compared to the waiting-list subgroup (NAP = 0.48, SD = 0.16, $z = 3.06$, CI 90% [0.22–0.73]), as shown in Figure 4.

4. Discussion

The main objective of this study was to explore the indirect effects of NFB on the self-concept of children with LDs. We expected the children in the NFB group to show an improved self-concept compared to the Ctrl group. Additionally, since it has been reported that NFB treatments have a direct effect on the EEG activity of LD children (Fernández et al., 2003), with a concomitant positive impact on academic performance (Breteler et al., 2010; Nazari et al., 2012), we also expected the NFB group to show a larger theta/alpha ratio decrease and better academic performance. As discussed below, these expectations were mostly met.

Regarding the changes produced by each respective treatment in the theta/alpha ratio, no significant differences were found between the NFB and sham groups. However, the within-group analyses did show significant ratio reductions for both groups. In the NFB group, this was an expected and desired result, since this reduction is an index of the operant learning involved in NFB treatments. For the sham group, some reduction in any case would be anticipated due to expectation (Schönenberg et al., 2021), the placebo effect (Geuter et al., 2017), and meta-cognitive mechanisms (Huang et al., 2020). However, above all, since the comparison was made between the NFB group and the sham subgroup (9 children) of the Ctrl group, the statistical power could not have been optimal to detect a proper difference due to the sample size.

Regarding the academic performance comparison, our heterogeneous sample of children with LDs was mainly affected in terms of reading and mathematics abilities; a corresponding improvement was observed only for the NFB group and only in those domains. A boost in reading ability has been previously found in children with LDs after receiving an NFB treatment (Breteler et al., 2010; Nazari et al., 2012), but, to our knowledge, the present study is the first that also reported an improvement in mathematics after an NFB treatment.

Concerning the main self-concept results, the impaired domains reported in the field of dyslexia are the global self-concept and the subdomains of academic skills (McArthur et al., 2016) and anxiety (Francis et al., 2019; McArthur et al., 2020). In heterogeneous LD populations such as ours, specific impairments have been found in the subdomains of academic skills, behavior (Cooley and Ayres, 1988; Gans et al., 2003), intellectual ability, and social acceptance (Smith and Nagle, 1995). Thus, after the NFB treatment, we would expect improvements in the self-concept perceptions of academic skills,

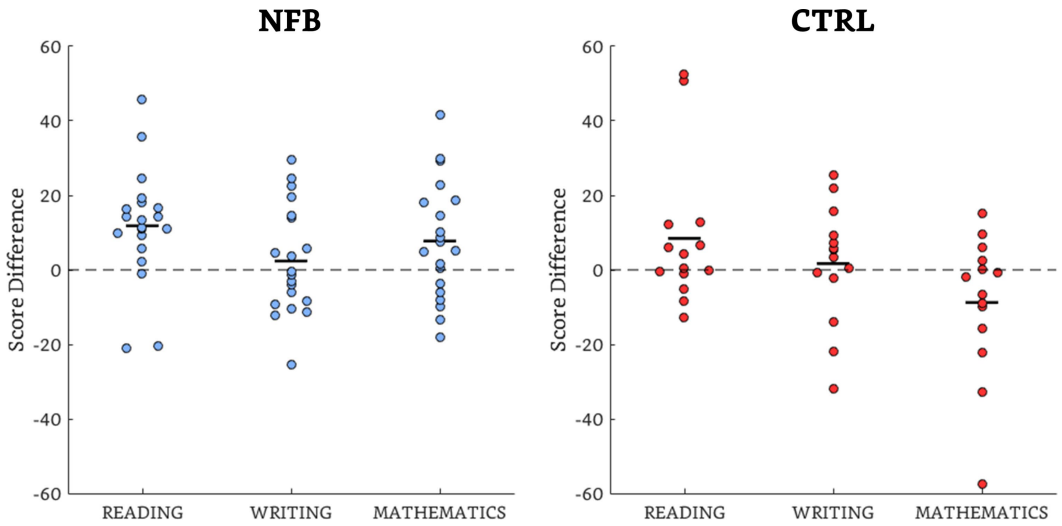


FIGURE 2
Scatterplots of the percentile difference scores (post − pretreatment)of the academic performance for the NFB and Ctrl groups. The majority of observations are above the unity (dotted) line, showing overall group effects in all but the writing domain of the NFB group and the mathematics domain of the Ctrl group. The black dashes indicate the mean values.

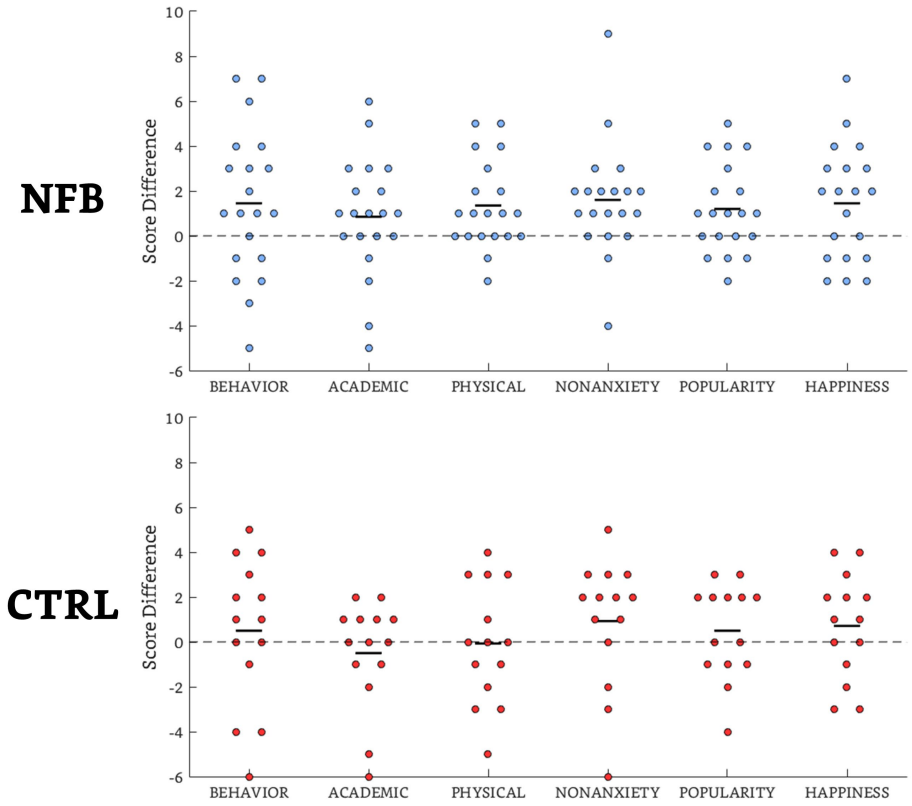


FIGURE 3
Scatterplots of the difference scores (post-pretreatment) of the self-concept subdomains for the NFB group and Ctrl groups. The majority of observations are above the unity (dotted) line, showing overall group effects in all but the subdomains of academic skills and physical appearance of the Ctrl group. The black dashes indicate the mean values.

TABLE 3 Non-overlap of all pairs (NAP) assessment of academic performance for sham and waiting-list subgroups.

Variable	Group	NAP average (SD)	z	Confidence Interval 90%	Above 50% of NAP
Reading	Sham	0.50 (0.06)	7.96	0.40–0.61	66.67%
	WL	0.50 (0.08)	5.86	0.36–0.64	60.00%
Writing	Sham	0.44 (0.08)	5.21	0.30–0.58	22.22%
	WL	0.41 (0.11)	3.65	0.23–0.60	20.00%
Mathematics	Sham	0.43 (0.09)	4.85	0.28–0.57	44.44%
	WL	0.23 (0.12)	2.07	0.05–0.44	0.00%

behavior, and popularity (as an index of social acceptance) on the Piers–Harris scale. In this study, we found that the NFB group showed an improved global self-concept, highlighting improvements in the following subdomains: physical appearance, nonanxiety, popularity, and happiness. It has been reported that NFB treatments can positively affect anxiety (Mennella et al., 2017; López-Pinar et al., 2020; Chen et al., 2021) and depression (Choi et al., 2010; López-Pinar et al., 2020), findings that are congruent with our increased self-concept perceptions of non-anxiety and happiness. In the Piers–Harris scale, the global self-concept directly depends on the significantly affected subdomains. According to our results, the nonanxiety dimension had the largest effect size and may have exerted the most influence over the other subdomains. These results are congruent with previous findings of a prominent role of anxiety and its possible bidirectional relationship with self-concept (Sowislo and Orth, 2013).

Although the sample sizes of the Ctrl subgroups differed, the NAP analysis over each participant represented a percent change that reduced the limitation of the low statistical power. This analysis revealed that the academic performance and global self-concept in the sham subgroup improved more than in the waiting-list subgroup, which indicates a treatment effect that may be due to placebo. The placebo effect of a sham-NFB treatment arises from the technological context (e.g., noticing the signals from the EEG in a computer) and the encouragement and verbal information from the researchers and parents around the training sessions (Colloca and Miller, 2011; Schönenberg et al., 2021), which are factors that, by causing an expectation of improvement, end in a placebo response in the person. Moreover, the placebo effect could be linked to endorphin and dopamine increases that may affect the EEG alpha activity (Thornton, 2018), a finding that could also explain the lack of difference between

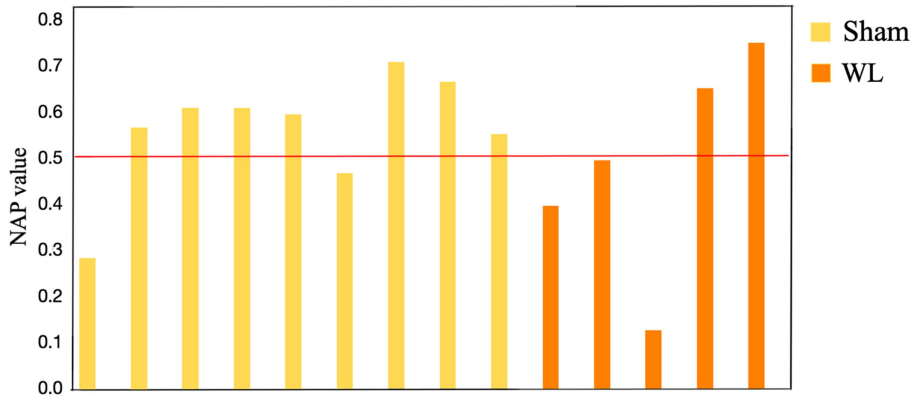


FIGURE 4
Non-overlap of all pairs (NAP) assessment of global self-concept for participants in the sham subgroup (7/9 above 0.5 NAP) and waiting-list subgroup (2/5 above 0.5 NAP).

the NFB and sham's theta/alpha ratio change, with both groups showing a significant ratio decrease. In the sham subgroup, the placebo effect seemed to have affected the academic performance and global self-concept, with larger improvements above the waiting-list subgroup. A similar finding was reported by Qiu et al. (2022), where a placebo group with explicitly detailed information about the self-esteem and fitness benefits of a physical training session was compared to a simpler placebo group (with less explicit information) and a control group, with the placebo group improving over the control group but not as much as the explicit placebo. Thus, a placebo effect would explain some of the academic performance and self-concept improvements in our groups.

Although the previous analysis indicated that 14 individuals per group were required for a statistical power of 0.9 with an error rate of 0.05, we realize that the sample sizes are small and make generalization difficult. However, these recent times of transition are not ideal for increasing sample sizes or conducting new experiments that include children with LD, as the diagnosis is based on pre-pandemic norms, and this period was characterized by poor school instruction (Lewis et al., 2021). Also, social isolation had negative psychological effects, promoting anxiety, depression, and other factors that could affect self-concept (Orgilés et al., 2020; Xie et al., 2020).

5. Conclusion

Neurofeedback treatments have previously been used to ameliorate the academic impairments of children with LDs. Since a child's self-concept might be indirectly improved by treating such impairments, this is the first exploratory study that aimed to investigate the effects of NFB on the self-concept of children with LDs. We found a positive effect of NFB on the global self-concept of these children, possibly due to the improved perceptions of physical appearance, nonanxiety, popularity, and happiness. Future studies could attempt to replicate these findings with a larger sample of children with LDs and delayed EEG maturation.

Data availability statement

The datasets presented in this study can be found in online repositories. The names of the repository/repositories and accession number(s) can be found at: https://data.mendeley.com/datasets/s3dtfw96cx.

Ethics statement

The studies involving human participants were reviewed and approved by Comité de Ética del Instituto de Neurobiología, UNAM. Written informed consent to participate in this study was provided by the participants' legal guardian/next of kin.

Author contributions

SC and TF: conceptualization. BM-B, RF-G, and JS-P: methodology and formal analysis. BM-B and RF-G: software, writing – original draft preparation, and visualization. BM-B, RF-G, SC, BB-D, and TF: investigation. BM-B, RF-G, and TF: resources. BM-B, RF-G, SC, and BB-D: data curation. BM-B, RF-G, SC, BB-D, TF, and JS-P: writing – review and editing. TF and JS-P: supervision and project administration. All authors contributed to the article and approved the submitted version.

Funding

This research was supported by CONACYT under the grant CB-2015-1-251309, and by grant IN207520 from PAPIIT, DGAPA-UNAM, Mexico. BM-B is thankful for a CONACYT scholarship (477474) and a DGAPA-UNAM scholarship (B22298), which supported the realization of this work. RF-G (scholarship recipient: 917148) was the beneficiary of a CONACYT scholarship (720424).

Acknowledgments

The authors are grateful for the cooperation of the children and parents who participated in this study. The authors also acknowledge the technical support of Ana C. Piñón, Claudia C. Gutiérrez, Eliseo Islas, Héctor Belmont, Lourdes Cubero, Lucero Albarrán-Cárdenas, María Elena Juárez, Marisa Oar Eola, Mauricio Cervantes, Milene Roca-Stappung, Minerva B. Rojas, Mónica Carlier, Paulina Rodríguez Leis, Saulo Hernández, and Thalía Harmony.

Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

Supplementary material

The Supplementary material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpsyg.2023.1167961/full#supplementary-material

References

Abdian, H., Rezaei, M., Eskandari, Z., Ramezani, S., Pirzeh, R., and Dadashi, M. (2021). The effect of quantitative electroencephalography-based neurofeedback therapy on anxiety, depression, and emotion regulation in people with generalized anxiety disorder. *Basic Clin. Neurosci.* 12, 281–290. doi: 10.32598/BCN.12.2.2378.1

Alexopoulos, D. S., and Foudoulaki, E. (2002). Construct validity of the Piers-Harris Children's self-concept scale. *Psychol. Rep.* 91, 827–838. doi: 10.2466/pr0.2002.91.3.827

Altarac, M., and Saroha, E. (2007). Lifetime prevalence of learning disability among US children. *Pediatrics* 119, Suppl 1, S77–S83. doi: 10.1542/peds.2006-2089L

American Psychiatric Association (2000). *Diagnostic and statistical manual of mental disorders, (4th ed., text rev.).*

American Psychiatric Association (2013). *Diagnostic and statistical manual of mental disorders (5th ed.).* doi: 10.1176/appi.books.9780890425596

Angelakis, E., Stathopoulou, S., Frymiare, J. L., Green, D. L., Lubar, J. F., Kounios, J., et al. (2007). EEG neurofeedback: a brief overview and an example of peak alpha frequency training for cognitive enhancement in the elderly. *Clin. Neuropsychol.* 21, 110–129. doi: 10.1080/13854040600744839

American Psychiatric Association. (2022). *Diagnostic and statistical manual of mental disorders (5th ed., text rev.).* doi: 10.1176/appi.books.9780890425787

World Medical Association. (2013). World medical association declaration of Helsinki: ethical principles for medical research involving human subjects. *JAMA* 310, 2191–2194. doi: 10.1001/jama.2013.281053

Baumeister, R. F., Campbell, J. D., Krueger, J. I., and Vohs, K. D. (2003). Does high self-esteem cause better performance, interpersonal success, happiness, or healthier lifestyles? *Psychol. Sci. Public Interes.* 4, 1–44. doi: 10.1111/1529-1006.01431

Becerra, J., Fernández, T., Harmony, T., Caballero, M. I., Garcia, F., Fernández-Bouzas, A., et al. (2006). Follow-up study of learning-disabled children treated with neurofeedback or placebo. *Clin. EEG Neurosci.* 37, 198–203. doi: 10.1177/155005940603700307

Block, C. C. (1993). Strategy instruction in a literature-based reading program. *Elem. Sch. J.* 94, 139–151. doi: 10.1086/461756

Bosch-Bayard, J., Aubert-Vazquez, E., Brown, S. T., Rogers, C., Kiar, G., Glatard, T., et al. (2020a). A quantitative EEG toolbox for the MNI neuroinformatics ecosystem: normative SPM of EEG source spectra. *Front. Neuroinform.* 14:33. doi: 10.3389/fninf.2020.00033

Bosch-Bayard, J., Galan, L., Aubert Vazquez, E., Virues Alba, T., and Valdes-Sosa, P. A. (2020). Resting state healthy EEG: the first wave of the cuban normative database. *Front. Neurosci.* 14:555119 doi: 10.3389/fnins.2020.555119

Bosch-Bayard, J., Valdés-Sosa, P., Virues-Alba, T., Aubert-Vázquez, E., John, E. R., Harmony, T., et al. (2001). 3D statistical parametric mapping of EEG source spectra by means of variable resolution electromagnetic tomography (VARETA). *Clin. EEG Neurosci.* 32, 47–61. doi: 10.1177/155005940103200203

Breteler, M. H. M., Arns, M., Peters, S., Giepmans, I., and Verhoeven, L. (2010). Improvements in spelling after QEEG-based neurofeedback in dyslexia: a randomized controlled treatment study. *Appl. Psychophysiol. Biofeedback* 35, 5–11. doi: 10.1007/s10484-009-9105-2

Budzynski, T. H., Budzynski, H. K., Evans, J. R., and Abarbanel, A. (2009a). "Introduction," in *Introduction to quantitative EEG and neurofeedback (Second Edition)*, eds. T. H. Budzynski, H. K. Budzynski, J. R. Evans and A. Abarbanel (San Diego: Academic Press), xxi–xxii. doi: 10.1016/B978-0-12-374534-7.00020-4

Carroll, J. M., Maughan, B., Goodman, R., and Meltzer, H. (2005). Literacy difficulties and psychiatric disorders: evidence for comorbidity. *J. Child Psychol. Psychiatry Allied Discip.* 46, 524–532. doi: 10.1111/j.1469-7610.2004.00366.x

Chabot, R. J. (2001). The clinical role of computerized EEG in the evaluation and treatment of learning and attention disorders in children and adolescents. *J. Neuropsychiatr.* 13, 171–186. doi: 10.1176/appi.neuropsych.13.2.171

Chen, C., Xiao, X., Belkacem, A. N., Lu, L., Wang, X., Yi, W., et al. (2021). Efficacy evaluation of neurofeedback-based anxiety relief. *Front. Neurosci.* 15:758068. doi: 10.3389/fnins.2021.758068

Choi, S. W., Chi, S. E., Chung, S. Y., Kim, J. W., Ahn, C. Y., and Kim, H. T. (2010). Is alpha wave neurofeedback effective with randomized clinical trials in depression? A pilot study. *Neuropsychobiology* 63, 43–51. doi: 10.1159/000322290

Choi, Y., Choi, S. H., Yun, J. Y., Lim, J. A., Kwon, Y., Lee, H. Y., et al. (2019). The relationship between levels of self-esteem and the development of depression in young adults with mild depressive symptoms. *Medicine (Baltimore)* 98:e17518. doi: 10.1097/MD.0000000000017518

Colloca, L., and Miller, F. G. (2011). How placebo responses are formed: a learning perspective. *Philos. Trans. R. Soc. B Biol. Sci.* 366, 1859–1869. doi: 10.1098/rstb.2010.0398

Cooley, E. J., and Ayres, R. R. (1988). Self-concept and success-failure attributions of nonhandicapped students and students with learning disabilities. *J. Learn. Disabil.* 21, 174–178. doi: 10.1177/002221948802100310

Daniel, S. S., Walsh, A. K., Goldston, D. B., Arnold, E. M., Reboussin, B. A., and Wood, F. B. (2006). Suicidality, school dropout, and reading problems among adolescents. *J. Learn. Disabil.* 39, 507–514. doi: 10.1177/00222194060390060301

Egner, T., and Sterman, M. B. (2006). Neurofeedback treatment of epilepsy: from basic rationale to practical application. *Expert. Rev. Neurother.* 6, 247–257. doi: 10.1586/14737175.6.2.247

Epstein, S. (1973). The self-concept revisited. Or a theory of a theory. *Am. Psychol.* 28, 404–416. doi: 10.1037/h0034679

Fernández, T., Bosch-Bayard, J., Harmony, T., Caballero, M. I., Díaz-Comas, L., Galán, L., et al. (2016). Neurofeedback in learning disabled children: visual versus auditory reinforcement. *Appl. Psychophysiol. Biofeedback* 41, 27–37. doi: 10.1007/s10484-015-9309-6

Fernández, T., Harmony, T., Fernández-Bouzas, A., Díaz-Comas, L., Prado-Alcalá, R. A., Valdés-Sosa, P., et al. (2007). Changes in EEG current sources induced by neurofeedback in learning disabled children. An exploratory study. *Appl. Psychophysiol. Biofeedback* 32, 169–183. doi: 10.1007/s10484-007-9044-8

Fernández, T., Harmony, T., Fernández-Bouzas, A., Silva, J., Herrera, W., Santiago-Rodríguez, E., et al. (2002). Sources of EEG activity in learning disabled children. *Clin. EEG Neurosci.* 33, 160–164. doi: 10.1177/155005940203300405

Fernández, T., Herrera, W., Harmony, T., Díaz-Comas, L., Santiago, E., Sánchez, L., et al. (2003). EEG and behavioral changes following neurofeedback treatment in learning disabled children. *Clin. EEG Neurosci.* 34, 145–152. doi: 10.1177/155005940303400308

Flahive, M. H. W., Chuang, Y. C., and Li, C. M. (2015). The multimedia piers-Harris children's self-concept scale 2: its psychometric properties, equivalence with the paper-and-pencil version, and respondent preferences. *PLoS One* 10:e0135386. doi: 10.1371/journal.pone.0135386

Flores-Gallegos, R., Rodríguez-Leis, P., and Fernández, T. (2022). Effects of a virtual reality training program on visual attention and motor performance in children with reading learning disability. *Int. J. Child Comput. Interact*. 32:100394. doi: 10.1016/j.ijcci.2021.100394

Fonseca, L. C., Tedrus, G. M. A. S., Chiodi, M. G., Cerqueira, J. N., and Tonelotto, J. M. F. (2006). Quantitative EEG in children with learning disabilities: analysis of band power. *Arq. Neuropsiquiatr.* 64, 376–381. doi: 10.1590/S0004-282X2006000300005

Francis, D. A., Caruana, N., Hudson, J. L., and McArthur, G. M. (2019). The association between poor reading and internalising problems: a systematic review and meta-analysis. *Clin. Psychol. Rev.* 67, 45–60. doi: 10.1016/j.cpr.2018.09.002

Gans, A. M., Kenny, M. C., and Ghany, D. L. (2003). Comparing the self-concept of students with and without learning disabilities. *J. Learn. Disabil.* 36, 287–295. doi: 10.1177/002221940303600307

Geuter, S., Koban, L., and Wager, T. D. (2017). The cognitive neuroscience of placebo effects: concepts, predictions, and physiology. *Annu. Rev. Neurosci.* 40, 167–188. doi: 10.1146/annurev-neuro-072116-031132

González-Pienda, J. A., Núñez, J.C., González-Pumariega, S., Álvarez, L., Roces, C., García, M., et al. (2000). Autoconcepto, proceso de atribución causal y metas académicas en niños con y sin dificultades de aprendizaje. *Psicothema* 12, 548–556.

Gruzelier, J. H. (2014). EEG-neurofeedback for optimising performance. I: a review of cognitive and affective outcome in healthy participants. *Neurosci. Biobehav. Rev.* 44, 124–141. doi: 10.1016/j.neubiorev.2013.09.015

Hammond, D. C. (2006). Journal of neurotherapy: investigations in neuromodulation, neurofeedback and applied neuroscience. *J. Neurother.* 10, 25–36. doi: 10.1300/J184v03n01

Hards, E., Ellis, J., Fisk, J., and Reynolds, S. (2020). Negative view of the self and symptoms of depression in adolescents. *J. Affect. Disord.* 262, 143–148. doi: 10.1016/j.jad.2019.11.012

Holcomb, P. J., Ackerman, P. T., and Dykman, R. A. (1986). Auditory event-related potentials in attention and reading disabled boys. *Int. J. Psychophysiol.* 3, 263–273. doi: 10.1016/0167-8760(86)90035-8

Huang, C. (2011). Self-concept and academic achievement: a meta-analysis of longitudinal relations. *J. Sch. Psychol.* 49, 505–528. doi: 10.1016/j.jsp.2011.07.001

Huang, A., Sun, M., Zhang, X., Lin, Y., Lin, X., Wu, K., et al. (2021). Self-concept in primary school student with dyslexia: the relationship to parental rearing styles. *Int. J. Environ. Res. Public Health* 18:9718. doi: 10.3390/ijerph18189718

Huang, C., Zhang, H., Huang, J., Duan, C., Kim, J. J., Ferrari, M., et al. (2020). Stronger resting-state neural oscillations associated with wiser advising from the 2nd- but not the 3rd-person perspective. *Sci. Rep.* 10:12677. doi: 10.1038/s41598-020-69507-9

Kutner, M., Greenberg, E., Jin, Y., and Paulsen, C. (2006). The health literacy of America's adults: results from the 2003 national assessment of adult literacy. *(NCES 2006–483). U.S. Department of Education*. Washington, DC: National Center for Education Statistics

Lagae, L. (2008). Learning disabilities: definitions, epidemiology, diagnosis, and intervention strategies. *Pediatr. Clin. N. Am.* 55, 1259–1268. doi: 10.1016/j.pcl.2008.08.001

Lahane, S., Shah, H., Nagarale, V., and Kamath, R. (2013). Comparison of self-esteem and maternal attitude between children with learning disability and unaffected siblings. *Indian J. Pediatr.* 80, 745–749. doi: 10.1007/s12098-012-0915-5

Lewis, K., Kuhfeld, M., Ruzek, E., and McEachin, A. (2021). Learning during COVID-19: reading and math achievement in the 2020–21 school year. *NWEA*. Available at: https://www.nwea.org/uploads/2021/07/Learning-during-COVID-19-Reading-and-math-achievement-in-the-2020-2021-school-year.research-brief-1.pdf

López-Pinar, C., Martínez-Sanchís, S., Carbonell-Vayá, E., Sánchez-Meca, J., and Fenollar-Cortés, J. (2020). Efficacy of nonpharmacological treatments on comorbid internalizing symptoms of adults with attention-deficit/hyperactivity disorder: a Meta-analytic review. *J. Atten. Disord.* 24, 456–478. doi: 10.1177/1087054719855685

Lubar, J. F., Swartwood, M. O., Swartwood, J. N., and O'Donnell, P. H. (1995). Evaluation of the effectiveness of EEG neurofeedback training for ADHD in a clinical setting as measured by changes in T.O.V.a. scores, behavioral ratings, and WISC-R performance. *Biofeedback Self Regul.* 20, 83–99. doi: 10.1007/BF01712768

MacMahon, J. R., and Gross, R. T. (1987). Physical and psychological effects of aerobic exercise in boys with learning disabilities. *J. Dev. Behav. Pediatr.* 8, 274–277. doi: 10.1097/00004703-198710000-00006

Marsh, H. W. (1990). A multidimensional, hierarchical model of self-concept: theoretical and empirical justification. *Educ. Psychol. Rev.* 2, 77–172. doi: 10.1007/BF01322177

Martínez-Briones, B. J., Bosch-Bayard, J., Biscay-Lirio, R. J., Silva-Pereyra, J., Albarrán-Cárdenas, L., and Fernández, T. (2021). Effects of neurofeedback on the working memory of children with learning disorders-an EEG power-spectrum analysis. *Brain Sci.* 11: 957. doi: 10.3390/brainsci11070957

Matute, E., Inozemtseva, O., Gonzalez, A. L., and Chamorro, Y. (2014). La Evaluación Neuropsicológica Infantil (ENI): Historia y fundamentos teóricos de su validación, un acercamiento práctico a su uso y valor diagnóstico. Available at: http://revistaneurociencias.com/index.php/RNNN/article/view/44

McArthur, G., Castles, A., Kohnen, S., and Banales, E. (2016). Low self-concept in poor readers: prevalence, heterogeneity, and risk. *PeerJ* 4:e2669. doi: 10.7717/peerj.2669

McArthur, G. M., Filardi, N., Francis, D. A., Boyes, M. E., and Badcock, N. A. (2020). Self-concept in poor readers: a systematic review and meta-analysis. *PeerJ* 8:e8772. doi: 10.7717/peerj.8772

Mennella, R., Patron, E., and Palomba, D. (2017). Frontal alpha asymmetry neurofeedback for the reduction of negative affect and anxiety. *Behav. Res. Ther.* 92, 32–40. doi: 10.1016/j.brat.2017.02.002

Morales-Quezada, L., Martinez, D., El-Hagrassy, M. M., Kaptchuk, T. J., Sterman, M. B., and Yeh, G. Y. (2019). Neurofeedback impacts cognition and quality of life in pediatric focal epilepsy: an exploratory randomized double-blinded sham-controlled trial. *Epilepsy Behav.* 101:106570. doi: 10.1016/j.yebeh.2019.106570

Musetti, A., Eboli, G., Cavallini, F., and Corsano, P. (2019). Social relationships, self-esteem, and loneliness in adolescents with learning disabilities. *Clin. Neuropsychiatry* 16, 165–172.

National Reading Panel (2000). Teaching children to read: an evidence-based assessment of the scientific research literature on reading and its implications for reading instruction. Available at: http://www.nichd.nih.gov/publications/nrp/upload/smallbook_pdf.pdf

Nazari, M. A., Mosanezhad, E., Hashemi, T., and Jahan, A. (2012). The effectiveness of neurofeedback training on EEG coherence and neuropsychological functions in children with reading disability. *Clin. EEG Neurosci.* 43, 315–322. doi: 10.1177/1550059412451880

Nelson, J. M., and Gregg, N. (2012). Depression and anxiety among transitioning adolescents and college students with ADHD, dyslexia, or comorbid ADHD/dyslexia. *J. Atten. Disord.* 16, 244–254. doi: 10.1177/1087054710385783

Núñez Pérez, J. C., González Pumariega, S., and González Pienda, J. A. (1995). Autoconcepto en niños con y sin dificultades de aprendizaje. *Psicothema* 7, 587–604.

Orgilés, M., Morales, A., Delvecchio, E., Mazzeschi, C., and Espada, J. P. (2020). Immediate psychological effects of the COVID-19 quarantine in youth from Italy and Spain. *Front. Psychol.* 11:579038. doi: 10.3389/fpsyg.2020.579038

Parker, R. I., and Vannest, K. (2009). An improved effect size for single-case research: nonoverlap of all pairs. *Behav. Ther.* 40, 357–367. doi: 10.1016/j.beth.2008.10.006

Parker, R. I., Vannest, K. J., and Davis, J. L. (2011). Effect size in single-case research: a review of nine nonoverlap techniques. *Behav. Modif.* 35, 303–322. doi: 10.1177/0145445511399147

Pascual-Marqui, R. D., Lehmann, D., Koukkou, M., Kochi, K., Anderer, P., Saletu, B., et al. (2011). Assessing interactions in the brain with exact low-resolution electromagnetic tomography. *Philos. Trans. R. Soc. A Math. Phys. Eng. Sci.* 369, 3768–3784. doi: 10.1098/rsta.2011.0081

Piers, E. V, and Herzberg, D. S. (2002). Piers-Harris Children's self-concept scale: manual. Western Psychological Corporation. Available at: https://books.google.com.mx/books?id=-S12zQEACAAJ

Qiu, Y., Mao, Z., and Yun, D. (2022). Can the add-on placebo effect augment the physical and mental health outcomes of exercise? A meta-analysis. *Appl. Psychol. Heal. Well-Being* 14, 483–498. doi: 10.1111/aphw.12315

Review of the Piers-Harris Children's Self-Concept Scale 2nd Edition (2011). Community-university Partnersh. Available at: (https://www.ualberta.ca/community-university-partnership/media-library/community-university-partnership/resources/tools-assessment/piers-harris-2may-2012.pdf).

Schönenberg, M., Weingärtner, A. L., Weimer, K., and Scheeff, J. (2021). Believing is achieving - on the role of treatment expectation in neurofeedback applications. *Prog. Neuro-Psychopharmacology Biol. Psychiatry* 105:110129. doi: 10.1016/j.pnpbp.2020.110129

Shaywitz, S. E., Fletcher, J. M., Holahan, J. M., Shneider, A. E., Marchione, K. E., Stuebing, K. K., et al. (1999). Persistence of dyslexia: the Connecticut longitudinal study at adolescence. *Pediatrics* 104, 1351–1359. doi: 10.1542/peds.104.6.1351

Shaywitz, S., and Shaywitz, J. (2020). *Overcoming dyslexia: completely revised and updated. 2nd* New York: Alfred A. Knopf

Silva-Pereyra, J., Rivera-Gaxiola, M., Fernández, T., Díaz-Comas, L., Harmony, T., Fernández-Bouzas, A., et al. (2003). Are poor readers semantically challenged? An event-related brain potential assessment. *Int. J. Psychophysiol.* 49, 187–199. doi: 10.1016/S0167-8760(03)00116-8

Simkin, D. R., Arnold, L. E., and Lubar, J. (2016). Neurofeedback in attention-deficit/hyperactivity disorder: evaluation difficulties. *J. Am. Acad. Child Adolesc. Psychiatry* 55, 1090–1091. doi: 10.1016/j.jaac.2016.09.494

Simkin, D. R., Thatcher, R. W., and Lubar, J. (2014). Quantitative EEG and neurofeedback in children and adolescents. Anxiety disorders, depressive disorders, comorbid addiction and attention-deficit/hyperactivity disorder, and brain injury. *Child Adolesc. Psychiatr. Clin. N. Am.* 23, 427–464. doi: 10.1016/j.chc.2014.03.001

Sitaram, R., Ros, T., Stoeckel, L., Haller, S., Scharnowski, F., Lewis-Peacock, J., et al. (2017). Closed-loop brain training: the science of neurofeedback. *Nat. Rev. Neurosci.* 18, 86–100. doi: 10.1038/nrn.2016.164

Smith, D. S., and Nagle, R. J. (1995). Self-perceptions and social comparisons among children with LD. *J. Learn. Disabil.* 28, 364–371. doi: 10.1177/002221949502800607

Snowling, M. J., Muter, V., and Carroll, J. (2007). Children at family risk of dyslexia: a follow-up in early adolescence. *J. Child Psychol. Psychiatry Allied Discip.* 48, 609–618. doi: 10.1111/j.1469-7610.2006.01725.x

Sowislo, J. F., and Orth, U. (2013). Does low self-esteem predict depression and anxiety? A meta-analysis of longitudinal studies. *Psychol. Bull.* 139, 213–240. doi: 10.1037/a0028931

Sterman, M. B., and Egner, T. (2006). Foundation and practice of neurofeedback for the treatment of epilepsy. *Appl. Psychophysiol. Biofeedback* 31, 21–35. doi: 10.1007/s10484-006-9002-x

Swanson, H. L., and Hoskyn, M. (1998). Experimental intervention research on students with learning disabilities: a meta-analysis of treatment outcomes. *Rev. Educ. Res.* 68, 277–321. doi: 10.3102/00346543068003277

Terras, M. M., Thompson, L. C., and Minnis, H. (2009). Dyslexia and psycho-social functioning: an exploratory study of the role of self-esteem and understanding. *Dyslexia* 15, 304–327. doi: 10.1002/dys.386

Thibault, R. T., and Raz, A. (2016). When can neurofeedback join the clinical armamentarium? *Lancet Psychiatry* 3, 497–498. doi: 10.1016/S2215-0366(16)30040-2

Thornton, K. E. (2018). Perspectives on placebo: the psychology of neurofeedback. *NeuroRegulation* 5, 137–149. doi: 10.15540/nr.5.4.137

Tobia, V., Riva, P., and Caprin, C. (2017). Who are the children Most vulnerable to social exclusion? The moderating role of self-esteem, popularity, and nonverbal intelligence on cognitive performance following social exclusion. *J. Abnorm. Child Psychol.* 45, 789–801. doi: 10.1007/s10802-016-0191-3

Vannest, K. J., Parker, R. I., Gonen, O., and Adiguzel, T. (2016). *Single case research: Web-based calculators for SCR analysis, Version 2.0*. College Station, TX: Texas A&M University

Wechsler, D. (2010). WISC-IV, Escala de inteligencia de wechsler para Niños-IV. Manual técnico y de interpretación. TEA Ediciones, S.A. Available at: https://books.google.com.mx/books?id=AH8rPQAACAAJ.

Willcutt, E. G., and Pennington, B. F. (2000). Psychiatric comorbidity in children and adolescents with reading disability. *J. Child Psychol. Psychiatry Allied Discip.* 41, 1039–1048. doi: 10.1017/S0021963099006368

Xie, X., Xue, Q., Zhou, Y., Zhu, K., Liu, Q., Zhang, J., et al. (2020). Mental health status among children in home confinement during the coronavirus disease 2019 outbreak in Hubei Province. *China JAMA Pediatr.* 174, 898–900. doi: 10.1001/jamapediatrics.2020.1619

Zeleke, S. (2004). Self-concepts of students with learning disabilities and their normally achieving peers: a review. *Eur. J. Spec. Needs Educ.* 19, 145–170. doi: 10.1080/08856250410001678469

frontiers | Frontiers in Psychology

TYPE Original Research
PUBLISHED 06 July 2023
DOI 10.3389/fpsyg.2023.1154385

OPEN ACCESS

EDITED BY
Gianluca Castelnuovo,
Catholic University of the Sacred Heart, Italy

REVIEWED BY
Glenna Tinney,
Independent Researcher, Alexandria,
United States Minor Outlying Islands
Claudia Emck,
VU Amsterdam, Netherlands

*CORRESPONDENCE
Joana Machorrinho
✉ jipm@uevora.pt

RECEIVED 30 January 2023
ACCEPTED 19 June 2023
PUBLISHED 06 July 2023

CITATION
Machorrinho J, Marmeleira J, Veiga G and Santos GD (2023) Feel-Own-Move: a psychomotor therapy program for victims of intimate partner violence living in shelter homes. Feasibility and effects on mental health, bodily dissociation, and quality of life. *Front. Psychol.* 14:1154385. doi: 10.3389/fpsyg.2023.1154385

Feel-Own-Move: a psychomotor therapy program for victims of intimate partner violence living in shelter homes. Feasibility and effects on mental health, bodily dissociation, and quality of life

Joana Machorrinho[1,2]*, José Marmeleira[1,2], Guida Veiga[1,2] and Graça Duarte Santos[1,2]

[1]Comprehensive Health Research Center, Universidade de Évora, Évora, Portugal, [2]Departamento de Desporto e Saúde, Escola de Saúde e Desenvolvimento Humano, Universidade de Évora, Évora, Portugal

Introduction: Intimate partner violence (IPV) is a worldwide concern, impacting victims' mental health, physical health, and quality of life. High rates of posttraumatic stress disorder (PTSD), depression, anxiety, bodily dissociation, and somatic symptoms have been found in victims of IPV, with an important impact on the chronicity of impairments and on the outcomes of psychological interventions. Therapeutic interventions available in shelter homes for victims are scarce in addressing their body–mind needs therefore asking for better empirical research. Thus, the aim of this study was to evaluate the feasibility and effects of Feel-Own-Move (FOM), an 8-week psychomotor therapy program for victims of IPV, on their mental health, levels of bodily dissociation, and general quality of life.

Methods: A within-subject repeated measures design was used to evaluate the intervention effects, and feasibility results were analyzed.

Results: Seventeen women completed the program (mean age 42.8 years, range 21–64). Results showed a significant decrease in levels of bodily dissociation, with FOM having a large effect size. The intervention also had a large effect size at increasing the environment domain of quality of life, although no statistically significant differences were found. FOM ended with excellent rates of reach, adherence, acceptability, and satisfaction. A positive retention rate was also found.

Discussion: In conclusion, FOM seems to be a feasible psychomotor therapy intervention for female victims of IPV living in shelters. Importantly, this program showed to be effective in reducing bodily dissociation among participants, which is suggested to prospectively contribute to their mental health and quality of life.

KEYWORDS

psychomotor therapy, intimate partner violence, women, health, quality of life, bodily dissociation, intervention

Introduction

Intimate partner violence (IPV) refers to any physical, psychological, sexual or economic act of violence perpetrated to a victim in the context of an intimate relationship (World Health Organization, 2021). IPV is a widespread social concern that affects about one-third of women worldwide (World Health Organization, 2021). Victims extensively report symptoms of anxiety,

depression, posttraumatic stress (PTSD), and altered patterns of sleep and eating (Lagdon et al., 2014). Research has also found a high prevalence of reported pain, neuromuscular, and gastrointestinal symptoms, which were associated with the severity of symptoms of PTSD and depression, and with health-related quality of life (Kelly, 2010).

Mental health, physical health, and behavior are intertwined. Some of the internal processes necessary for self-regulation, knowledge, and self-growth, rely on information arouse from the psychophysical awareness, namely the awareness of bodily sensations and the connection to the body (Price, 2007). Aligned with this, an alarming prevalence of self-injury and suicidal behaviors, along with symptoms of body disownership [the sense of not owning one's body (Ataria, 2018)] and bodily dissociation [the feeling of being separate from one's body and emotions; an "avoidance of internal experience" (Price, 2007)] have been found among victims of IPV (Machorrinho et al., 2021a,b). Importantly, body disownership and bodily dissociation have been pointed out as responsible for the development of PTSD symptoms, the restriction of treatment outcomes, and the prognoses of IPV victims (Ataria, 2018; Tschoeke et al., 2019). Bodily dissociation can include difficulty with the identification and expression of emotions, and also represents a risk factor for the development of anxiety and depression symptoms in female victims of IPV (Machorrinho et al., 2021b). Dissociation often emerges as a defense psychological mechanism, to protect the bodily self and to cope with pain and trauma (Price, 2007). It has a particularly higher prevalence among victims of physical and sexual IPV, for whom it is negatively associated with health-related quality of life (Costa et al., 2015).

Support centers, shelter homes and primary social and health care services strive to increase the reach and effectiveness of programs to prevent IPV and reduce its consequences (Arroyo et al., 2017). Shelter homes (also called transitional supportive housing, TSH) represents a tertiary prevention strategy that aims to reduce mortality or disability (Coker, 2004). In this regard, shelters commonly deliver advocacy support, Cognitive Behavioral Therapy (CBT) and social assistance while providing a safe home, food, education, and employment opportunities for a limited period (6–12 months; Klein et al., 2021). By being physically secure and distant from the violent environment, shelter homes might represent a valuable place for therapeutic interventions targeted at victims' recovery of health and reconstruction of life and identity (Arroyo et al., 2017). Although some advocacy and psychoeducation interventions have shown positive effects, mostly on healthcare use and mental health symptoms, the broad and complex consequences of IPV on women's health and identity require extensive research and consideration of body–mind interventions (Eckhardt et al., 2013; Arroyo et al., 2017; Ogbe et al., 2020).

The lasting effects of trauma on the body and on the body–mind relationship, have brought growing interest to the development of effective therapeutic interventions (Classen et al., 2021). Traumatic experiences dysregulate neurochemical and psychophysiological usual responses to stress (Shepherd and Wild, 2014; Payne et al., 2015; Van der Kolk, 2015). In victims of recurrent violence and stress, among the major consequences of this chronic dysregulation, desensitization to stress triggers and numbing, or hyper-arousal chronic states have been reported as two possible extreme responses (Van der Kolk, 2015; Van de Kamp and Hoven, 2019). Hence, increasing research recommends a bottom-up approach as a starting point in the therapeutic work with trauma victims to facilitate arousal and affect regulation (Ogden et al., 2006; Van der Kolk, 2015; Van de Kamp and Hoven, 2019). Diverse body–mind-oriented interventions have shown moderate to large effects on decreasing PTSD symptomatology in adults with diverse trauma origins (Van de Kamp et al., 2019). Examples can be Yoga (Van der Kolk, 2015), Sensorimotor psychotherapy (Classen et al., 2021), Somatic Experiencing (Payne et al., 2015; Andersen et al., 2017), Dance/movement therapy (Dieterich-Hartwell, 2017) and Psychomotor therapy (PmT; Bieleveldt, 2019; Rekkers et al., 2021). These approaches reclaim bottom-up sensations and regulation processes to address traumatic imprints and regulate arousal (Van de Kamp et al., 2019).

PmT is a movement and body-oriented therapy that provides that bottom-up approach and explores embodied emotional, cognitive and relational identity processes (European Forum of Psychomotricity, 2012). PmT acts upon complex bodily dimensions, namely the real body, the imaginary body, the functional body, the body schema and the body image (Potel, 2019; Fernandes et al., 2022). The awareness and processing of those bodily dimensions are promoted through movement, breathing, and self-expression, as a vehicle to enhance the adaptive functioning of the individual (Llaurado, 2008; Lebre et al., 2020). Distinctively, solving problematic behaviors (namely disruptive behaviors) is not the primary goal for a PmT therapist. Instead, he/she works at the expression of anguishes embedded in the body, allowing for new representations of the Self, the others, and the world, with an indirect impact on behavior (Emck and Scheffers, 2019; Lebre et al., 2020; Marmeleira et al., 2023).

The psychomotor therapist has a complex graduated training (as part of the bachelor's degree in psychomotricity) that allows him/her an in-depth experience in the holistic understanding and facilitation of bodily expression and movement, as well as promoting body awareness and regulating arousal. His/her therapeutic accompaniment is characterized by a consistent, comprehensive, responsive, and encompassing attitude (Llaurado, 2008; Potel, 2019), also revealed at the level of resonance and kinesthetic empathy. These principles and attitudes are the basis of an approach that is proposed to be consistent in the work on revalidating sensations and supporting the participants' verbal and non-verbal expression (Llaurado, 2008).

Feel-Own-Move (FOM) is a PmT program specifically designed to be implemented in shelter homes, and its therapeutic mechanisms have been recently described (Marmeleira et al., 2023). Upon a safe, empathic and cohesive investment of the therapeutic space and of the therapeutic relationship, participants are invited to (i) experience interoceptive and proprioceptive sensations, (ii) become aware of bodily internal sensations and representations with a non-judgmental approach, (iii) experience and learn relaxation techniques, and (iv) express, through movement, writing, drawing and verbal and non-verbal communication, their body knowledge, insecurity, fears and desires (Caldwell and Victoria, 2011; Payne et al., 2015; Van de Kamp and Hoven, 2019; Björkman and Ekblom, 2022; Machorrinho et al., 2022; Marmeleira et al., 2023). FOM thus allows victims of IPV the safe embodiment of new internal and external representations.

FOM is an 8-week PmT program that integrates the benefits of group sessions and individual sessions, apart from being implemented in a short period of time. It considers the minimum time needed for a therapeutic process to occur, and the short periods of time that most victims actually stay in the shelter home (Arroyo et al., 2017). However, the effectiveness and feasibility of FOM was not empirically

examined yet. In this regard, the aim of the present study was twofold. First, the feasibility (reach, adherence, retention and acceptability) of FOM was assessed in a sample of female victims of IPV living in three different shelter homes. Second, the effects of FOM on quality of life and mental health indicators, such as bodily dissociation, anxiety, depression and PTSD of women victims of IPV living in shelters was examined.

Methods

Study design

A non-random within-group repeated measures design was used to evaluate the effects and feasibility of FOM on female victims of IPV living in shelter homes. Participants were tested at week 1 (T1) and week 5(T2) before the intervention, to monitoring of the control period. Participants were again tested at week 13, after the 8-week intervention (T3). The study was previously approved by the University ethics committee and conducted in accordance with the Declaration of Helsinki (General Assembly of the World Medical Association, 2014). From June 2021 to November 2022, this intervention research was proposed to the managing entities of three Portuguese shelters for victims of IPV. Upon agreement, women victims who were currently living in each shelter were invited by the managing entities to attend a brief presentation session in the shelter. The study procedures (assessments needed) and characteristics of the intervention (length, frequency of the sessions, therapist and types of activities) were presented by the therapist of FOM to the women who attended this session and who were considered eligible to participate in the study. The inclusion criteria were being 18 years or older and having suffered IPV in the first person. Ninety-four percent of the women showed an interest in participating ($N = 30$), as represented in Figure 1.

Participants

Thirty women accepted to enroll in this study. Due to incompatible schedules (considering work and mothering tasks), 6 women could not engage in the program. Of the 24 initial participants, seventeen (mean age 42.8 years, sd = 11.1; range 21–64) completed the program. Those reported that they had suffered physical (71%), psychological (94%), and sexual (59%) violence for a mean duration of 16 years and 3 months (sd = 16.5 years; range 2–48 years) and were free from violence for a mean of 6 months (sd = 0.53 years; range: 1–18 months). In Table 1 we can see that, at baseline, 82% ($n = 14$) of the participants were unemployed or retired, and 71% ($n = 12$) were living in the shelter with one or more children. In the sociodemographic survey, the most reported symptoms were sleep problems (65%), chronic pain (41%), and anxiety attacks (29%).

Procedures

After signing the informed consent form, the baseline assessment session was scheduled. Participants completed a sociodemographic survey about general health symptoms, medical diagnosis of posttraumatic stress disorder, anxiety and depression, use of psychiatric medication, leisure activities or therapeutic practices, and the types of violence they have suffered, for how long, and since when they were free from the violent relationship. Participants completed the PTSD Checklist (Marcelino and Gonçalves, 2012), the Hospital Anxiety and Depression Scale (HADS; Pais-Ribeiro et al., 2007), Scale of Body Connection (SBC, Neves et al., 2017), and World Health Organization Quality of Life checklist (WHOQoL-bref; Vaz Serra et al., 2006). Assessment sessions took about 60 min, and occurred at baseline (T1), after 4 weeks of control time (pre-intervention, T2), and after 8 weeks of intervention (post-intervention, T3).

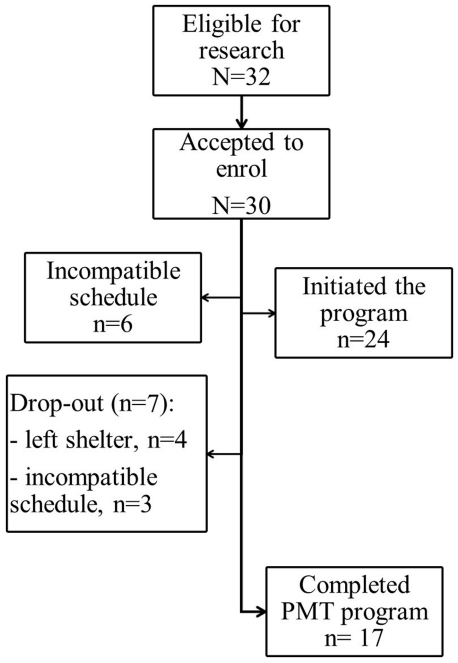


FIGURE 1
Flow diagram of recruitment and participation.

Instruments

Posttraumatic stress disorder checklist

Posttraumatic Stress Disorder symptoms in the last 2 months were evaluated using the PTSD Checklist–civilian version (PCL; Weathers et al., 1994). This self-report questionnaire can differentiate the three PTSD clusters from the DSM-IV medical diagnostic manual: experiencing, avoidance, and hypervigilance. A Likert scale, from zero (nothing) to five (extremely) was used to score the frequency of each symptom. The sum of the scores for each cluster was analyzed. The Portuguese version includes 17 items and has good psychometric properties (Cronbach's alpha = 0.94; Marcelino and Gonçalves, 2012).

Hospital anxiety and depression scale

Hospital Anxiety and Depression Scale (HADS; Zigmond and Snaith, 1983) enables health professionals to assess anxiety and depression levels at a brief and objective way (Herrmann, 1997). It is a self-report questionnaire with 14 items, seven assessing anxiety and seven assessing depression symptoms. Each item is rated in a 0–3 scale and classifies the symptom as feeling equal to times before or a lot

TABLE 1 Descriptive statistics of demographic and health information.

Sociodemographic variables	*N*=17		
	N (%)	Mean (SD)	Range
Age (years)		42.8 (11.1)	21–64
Body Mass Index (kg/m^2)		27.7 (5.1)	18.7–37.6
Types of violence			
Psychological only	4 (24)		
Psychological and Physical	3 (18)		
Psychological, Physical and Sexual	10 (59)		
Duration of violence (years)		16.3 (16.5)	2.0–48.0
Time since violence ended (years)		2.4 (6.1)	0.1–30.0
Health			
Sleep problems	11 (65)		
Anxiety attacks	5 (29)		
Migraines	4 (24)		
Memory difficulties	2 (12)		
Chronic pain	7 (41)		
Gastrointestinal problems	4 (24)		
Hypertension	2 (12)		
Medical diagnosis			
Posttraumatic stress disorder	1 (6)		
Anxiety disorder	5 (29)		
Depression disorder	9 (53)		
Behavior			
Self-injury	5 (29)		
Suicidal ideation	9 (53)		

M, mean; SD, standard deviation.

worse than before. Scores higher than 7 in each subscale, indicate clinically relevant levels of anxiety or depression, and results can be analyzed through the sum of the items of each subscale, ranging from 0 to 21. Snaith (2003) suggests scores of 0–7 to be considered "normal," between 8 and 10 being suggestive of the presence of the state of anxiety or depression, and above 11 to be indicative of the presence of that state. The most recent study found the Portuguese version to have good internal consistency (Cronbach's alpha_anxiety scale = 0.76; Cronbach's alpha_depression scale = 0.81; Pais-Ribeiro et al., 2007).

Scale of body connection

Bodily Dissociation (the sense of separation from the body) was assessed through the Scale of Body Connection (SBC; Price and Thompson, 2007), a self-report Likert scale that measures body awareness and bodily dissociation. Mean scores higher than 2 suggest a significant presence of bodily dissociation symptoms. The adaptation from Neves et al. (2017) confirmed the reliability and validity of this scale for the Portuguese population (Cronbach's alpha = 0.73).

World health organization quality of life checklist

The WHOQoL is a self-administered Likert scale that allows the assessment of the perceived quality of life in four domains: Physical health (domain 1; e.g. dependence on medical aids, mobility, pain, work capacity), Psychological health (domain 2; e.g. negative and positive feelings, self-esteem, body image, personal beliefs, learning and memory), Social relationships (domain 3; e.g. personal relationships, social support, sexual activity) and Environment (domain 4; e.g. freedom, physical safety, accessibility to health and social care, opportunities for acquiring new information and to participate in recreative activities, transport). The Portuguese version of the WHOQoL-bref includes 26 items and shows good reliability and validity scores, except for domain 3 (Cronbach's alphas ranging from 0.64 for domain 3 and 0.87 for domain 1; Vaz Serra et al., 2006), which was thus removed from analysis in this study (Tavakol and Dennick, 2011).

The Feel-Own-Move psychomotor therapy program

Psychophysiology of trauma

Neural circuits involved in interoception (integration and processing of visceral bodily sensations) and emotional regulation, as the insula, the amygdala and the prefrontal cortex seem to be disrupted as a result of trauma experiences (Bruce et al., 2013; Nicholson et al., 2015). In fact, not only depression and anxiety, but also PTSD reflects impairments in emotional and arousal regulation (Shepherd and Wild, 2014). Acknowledging those impairments and their chronic dysregulation among victims of trauma, Payne et al. (2015) proposed a therapeutic somatic restoration of the Core Response Network (CRN), a brain network connecting the limbic, autonomic, motor and arousal systems. The authors state that people with PTSD are stuck with a dysregulated CRN, translating into hypo or hyper-arousal chronic states (Levine, 2010; Payne et al., 2015). Further research has also found that for victims of trauma, chronic stress "inhibits the effectiveness of the stress response and induces desensitization" (Van der Kolk, 2022, p. 15). With this in mind, (i) exercise- and movement-based interventions aiming to recover access to internal bodily sensations, and (ii) breathing and meditation techniques aiming to promote emotional regulation abilities in both a psychophysiological and behavioral axis, have been studied (Caldwell and Victoria, 2011; Rosenbaum et al., 2015; Taylor et al., 2020; Björkman and Ekblom, 2022).

The Feel-Own-Move rationale

Based on the exposed literature, FOM was developed to allow victims of IPV to regain awareness of bodily sensations, to integrate sensations and emotions into the senses of body ownership and agency, and to train abilities of arousal regulation. Through movement, expression, breathing, and relaxation techniques, the aim of each session was twofold. On the one hand, to progressively promote and deepen a non-judgmental awareness of bodily sensations and of sensation-emotion relationships, strengthening the mind–body connection. On the other hand, the second aim was to increase self-regulation, as a path to weaken mental health symptoms, and indirectly increase the quality of life. The program combined individual sessions and group sessions.

The individual sessions had an approximate length of 40 min and allowed for personalized attention to the bodily sensations, representations, and expressions of each participant. This individualization offered a specific therapeutic space and time, for a deepened exploration and integration of each insight. In addition, group sessions (4–6 participants), with approximately 60 min each, allowed for an empathetic expression of each participant, offering a

meeting of different ways of embodied being. The encounters promoted by group sessions aimed for a widening of images, sensations, and representations into the therapeutic process of each participant.

Overall, both individual and group sessions included three sequential moments: an initial warming-up activity, a second moment with body awareness and grounding activities and a final relaxation moment.

Warming-up

The activation of proprioceptive (muscular) and interoceptive (visceral) sensations in the initial moments of each session was accomplished through aerobic exercises and strength training (Powers et al., 2015; Rosenbaum et al., 2015; Björkman and Ekblom, 2022). The benefits of exercise, especially aerobic exercise, in the treatment of PTSD-related symptoms is hypothesized as being due to the elevation of brain-derived neurotrophic factor, related with synaptic plasticity (Powers et al., 2015). In FOM, the exacerbation of neutral bodily sensations through exercise has the aim of facilitating awareness in cases of bodily dissociation and hypo-arousal states (Machorrinho et al., 2022). Distinctively, these activities are frequently accompanied by bodily metaphors and movement imagery to increase connection to the body and the feeling of empowerment. Importantly, exercise has to be proposed with an attuned approach, i.e., process-oriented, highlighting safety sensations and a joyful experience (Calogero et al., 2019). This attunement with exercise and a careful adjustment to participant's capacities, ensures for optimal effectiveness, promotes motivation and reduces dropouts (Louková et al., 2015; Calogero et al., 2019; Van de Kamp and Hoven, 2019). This exacerbation of bodily sensations serves as a starting point to the reclaiming of ownership and agency toward the body, enhanced in the following moment of the session (MacLaren, 2016).

Body awareness and grounding

It is important for patients with dissociative symptoms to also improve sensory awareness in a slow, integrative and non-judgmental approach (Ogden et al., 2006; Van der Kolk, 2015). The integration of bodily sensations and of the body–mind connection is frequently enhanced in yoga and grounding techniques as a path to stabilization and peaceful reconnection to the body (Brand et al., 2012; O'Shea Brown, 2021). In FOM, the therapist facilitates the transition to a second moment of slow movements, using therapeutic touch, imagery, or guided sensations (saying, for example, "Focus on the weight of the body against the wall," or asking "Where in your body do you feel strength/ resistance/ movement/ stillness?") as mediators. These mediators aim to reinforce the body–mind connection and the feelings of body ownership and agency (Kirmayer and Gómez-Carrillo, 2019). Body schema activities are also promoted in these moments to surpass the segmentation of the body and promote its wholeness (Louková et al., 2015; Marmeleira et al., 2023).

Relaxation

The regulation of arousal seems to be a crucial element to account for when intervening in trauma-related disorders (Van de Kamp and Hoven, 2019). Relaxation and breathing techniques are frequently delivered with the intent of reducing patients' excessive physiological arousal and promoting emotional regulation skills. In FOM, sessions end with physiologic-driven relaxation techniques such as Jacobson's progressive muscle relaxation and active-passive relaxation proposed by Wintrebert (Guiose, 2003). Progressive muscle relaxation is used in the initial phase, as a present-focused and active relaxation, which can be easily translated to quick practices for patients' use in daily life (Hazlett-Stevens and Fruzzetti, 2021). Once the participants can autonomously endorse general progressive relaxation, the active-passive relaxation method is implemented. In the last sessions of FOM, participants are invited to train mindfulness meditation techniques to address daily arousal regulation needs.

Implementation

The program consisted of an 8-week Psychomotor Therapy (PmT) with 24 three-weekly sessions, combining 16 individual sessions with 8 group sessions. The intervention was delivered by two therapists with more than 12 years of clinical experience in body–mind-oriented interventions. The program was developed, structured, and conceptualized by one of them (as part of the research team), who also holds a bachelor's and master's degree in psychomotricity. A manual guide and protocol of implementation for the FOM program were previously developed and trained by the therapists to ensure maintenance of the FOM's purpose and delivery. Both therapists had permanent intervision and mutual monitoring of the process, struggles experienced, and qualitative achievements. Both therapists also had weekly supervision with a third therapist from the research team that developed FOM, with more than 20 years of experience in body-psychotherapeutic practice and supervision.

Feasibility and acceptability

The reach of the program and adherence of the participants was assessed to examine its feasibility. To examine acceptability and satisfaction with the PmT intervention, a 9-item survey developed by the authors of this study was administrated to the participants who completed the program. Following recommendations of Bowen and colleagues (Bowen et al., 2009), each item was classified on a Likert scale, between zero (nothing) and four (extremely), and covered topics related to perceived personal impact, sense of trust and respect and comfort regarding the sessions, the therapist, and the assessments.

Data analysis

A descriptive analysis of sociodemographic and health variables was performed. The normality of data was checked through the Shapiro–Wilk test. A one-way repeated measures ANOVA was used to examine within-group changes between T1 and T2, and T2 and T3. Significance levels were adjusted using the Bonferroni correction, considering significance if $p < 0.05$. Mean and standard deviations are reported. Effect sizes are provided as partial eta-squared (η_p^2) and interpreted as: 0.01–0.06, small effect, 0.06–0.14, medium effect, and ≥ 0.14, large effect (Cohen, 1988). Results of non-parametric variables are presented as median and interquartile range (IQR). Friedman tests were carried out to examine changes in non-parametric variables, using *post hoc* pairwise comparisons (Wilcoxon Signed-Rank test) and a Bonferroni adjustment was applied. Significance levels were considered at $p < 0.017$. Effect sizes were calculated using Kendall's W Value, and interpreted as <0.3, small effect, 0.3–0.5, moderate effect, and >0.5, large effect (Tomczak and Tomczak, 2014). The delta value (Δ%) of proportional change between each moment

(T1, T2, and T3) was calculated using the formula: Δ% = [(momentY – (momentY−1))/(momentY-1)] x 100.

Statistical analyzes were performed, using SPSS version 24.0 software (IBM Corp, 2017).

Results

Overall, the results suggested good feasibility of the program. Regarding reach, it was measured as the rate of women who accepted to participate in the study, from all the ones who were invited to. Thirty out of 32 agreed to participate (94%). The two women who declined had just arrived at the shelter (2 or 3 days before the invitation) and claimed not to be prepared to initiate a therapeutic process yet. Due to schedule incompatibilities, 6 women were not able to integrate the program. In those cases, women had intense and rotating schedules, added to house and mothering chores. Twenty-four women initiated the program, and seven drop-out, representing a retention rate of 71%. Considering adherence, among participants who completed the program, they attended 86% of the individual sessions and 75% of the group sessions. Results showed strong acceptability and satisfaction with the program, as detailed in Table 2 (all positive questions ≥3.5).

Results show a significant decrease in levels of bodily dissociation over time [$F(2) = 4.517$, $p = 0.029$, $\eta_p^2 = 0.376$]. *Post hoc* analysis with Bonferroni adjustment revealed that bodily dissociation decreased from pre ($M = 2.3$, SD = 0.8) to post-intervention ($M = 2.0$, SD = 0.7) (Δ% = 12,4%). Scores of the environmental quality of life showed a non-significant increase between assessments, although a large effect size was found [$F(2) = 1.543$, $p = 0.246$, $\eta_p^2 = 0.171$]. The results of all dependent variables are shown in Table 3.

TABLE 2 Acceptability and satisfaction with FOM.

Questions	Mean (SD)	Range
Do you feel satisfied with the program you have participated in?	3.9	3–4
Do you feel yourself different from before initiating the program?	3.5	2–4
Do you feel that this program brought positive things to you?	0.8	2–4
Were the activities of the sessions interesting?	3.7	2–4
Did you felt respected in the sessions?	3.9	3–4
Do you feel that this program brought negative things to you?	0.0	0
Did you felt that you could trust in the therapist?	4.0	4
Did you felt yourself safe during the sessions?	3.9	3–4
Did you felt bothered/ disturbed with the assessments?	1.2	0–4

Values ranging from zero (nothing) to four (extremely).

Discussion

The study of the associations between mental health and embodiment-related variables among victims of IPV has gained paramount importance (Machorrinho et al., 2021b, 2022). Although there is increasing research on therapeutic and preventive interventions for victims of trauma, highlighting body–mind interactions and their influence on victims' health, trauma recovery, and quality of life, the necessary adaptations for victims of IPV were yet scarcely attended (Van der Kolk, 2015; Marmeleira et al., 2023). The aim of the present study was to examine the effects of a Psychomotor Therapy "Feel-Own-Move" (FOM) program delivered in shelter homes for victims of IPV. The FOM program was shown to be effective at decreasing the values of bodily dissociation in victims, also with a suggested effect on increasing quality of life.

The recruitment and retention of participants in IPV-related research have been a longstanding concern (Dutton et al., 2003). In this study, the attractiveness of the body–mind program, the schedules flexibility and adaptation to participants' possibilities, the close positive recommendation of the shelters' managing entities, and the empathic attitude of the PmT therapist, might have been important factors to the excellent reach of the program (94% of women accepted to enroll in the study; Dutton et al., 2003). Nevertheless, 7 of the 24 participants (29%) did not complete the program, mostly because they have left the shelter to rebuild their lives in another city or to move to another shelter with more adequate social-economic support. Although this is a positive retention rate compared with other IPV research (Hansen et al., 2014; Arroyo et al., 2017), it is important to note that the study design here implemented may have influenced the retention rate of the program, since it compelled participants to a 4-week control period before initiating the intervention. Without this control period, inherent to the research, we can hypothesize that more participants would be able to complete the program, since its short duration is in accordance with current recommendations of interventions to be delivered in shelter homes (Arroyo et al., 2017). Moreover, to surpass the schedule constraints pointed out by 13% of the initial participants who dropped out, we suggest that in the future the FOM should provide a set of videotaped sessions that participants can easily watch and perform individually at any time. Although these would imply close supervision from the psychomotor therapist, we believe that it could be advantageous for the feasibility of the FOM program.

IPV is equally prevalent across all age groups, and shelter homes welcome adult women with no age grouping. Thus, as expected, our sample included women in a wide age range. More than half (59%) have suffered the three types of violence (sexual, physical and psychological), which is known to increase the repercussions of trauma on mental health and quality of life (Campbel, 2002). At baseline, participants mostly reported symptoms of chronic pain, difficulty falling asleep and staying asleep, and anxiety attacks. Adding to this, self-reported measures at baseline revealed clinically relevant levels of anxiety, bodily dissociation and PTSD (avoidance cluster), but only normal to light levels of depressive symptoms. Conversely, depressive disorder was the most medically diagnosed in this sample ($n = 9$; 53%), whereas only 5 participants (29%) had a previous diagnosis of anxiety disorder, and only one (6%) of PTSD. This finding suggests an underdiagnosis of trauma-related mental health problems, possibly due to women not having any medical/ psychological check-ups after they have exposed their IPV victimization. Suicidal ideation and self-injury behaviors, which are commonly an expression of depressive feelings and of a disconnection from the body, were highly reported in this sample (You et al., 2012; Hielscher et al., 2019; Polskaya and Melnikova, 2020). It is also noteworthy the high levels of body mass index (BMI), which were recently suggested as an indicator of weaker

TABLE 3 Scores on dependent variables at baseline (T1), pre-intervention (T2) and post-intervention (T3).

	Baseline	Pre-intervention	Post-intervention	*p*	Δ%	Effect size
PTSD						
Reexperiencing[a]	12.6 (6.0)	12.2 (6.0)	11.0 (13.0)	0.808		
Hyper-vigilance[b]	12.9 (5.2)	12.2 (5.2)	12.3 (5.3)	0.749		
Avoidance[a]	15.0 (8.0)	14.0 (15.0)	14.0 (11.5)	0.345		
Anxiety[b]	9.9 (4.1)	9.3 (5.1)	9.0 (5.5)	0.762		
Depression[a]	7.0 (5.0)	6.0 (5.0)	7.0 (5.5)	0.405		
Bodily dissociation[b]	2.3 (0.8)	2.3 (0.8)	2.0 (0.7)	0.029	T3 < T2 (12.4%)	.376[d]
Quality of life						
Physical[a]	3.2 (0.9)	3.3 (1.0)	3.1 (0.8)	0.939		
Psychological[b]	3.7 (0.6)	3.5 (0.7)	3.6 (0.6)	0.467		
Environment[b]	3.1 (0.5)	3.0 (0.5)	3.3 (0.5)	0.246	T3 > T2 (10.0%)	.171[d]

PTSD, Posttraumatic Stress Disorder; [a]data reported as median (interquartile range); [b]data reported as mean (standard deviation); Δ%, proportional change; [c]effect size reported as Kendall'sW value; [d]effect size reported as partial eta-squared, η_p^2.

self-care behaviors and health-promoting attitudes in IPV victims, mediating the associations between IPV and physical health problems (Weaver and Resnick, 2004; Machorrinho et al., 2022).

Prior to intervention, a control period allowed for important monitoring of each variable evolution, since the shelter home, as a preventive and supportive strategy for victims, can have a positive impact on their well-being and mental health (Yakubovich et al., 2022). However, none of the variables have shown significant differences between baseline and pre-intervention assessments, which highlights the lack of effective short-term therapeutic interventions at these shelters.

The FOM program allowed women to reconnect with their bodies in a trustworthy relational atmosphere. Along with the relevant decreases in bodily dissociation levels, participants ended up being extremely satisfied with the program, reporting feelings of safety, respect and trust toward the setting and the therapist. These results corroborate research that suggests both physical and relational safety as a primary step for effective intervention with trauma clients (Baylin and Winnette, 2016).

While bodily dissociation is importantly related with poorer quality of life and physical and mental health, its improvement through therapeutic approaches is yet scarcely studied (Price, 2007; Price et al., 2012; Cheng et al., 2022). Bodily dissociation acts through a disregard of internal experience, an avoidance of sensations and emotions, thus interfering with one's monitoring of health and self-care behaviors (Price and Thompson, 2007). The avoidance or dissociation from bodily experience is part of the concept of psychophysical awareness, linked to the internal processes necessary for self-regulation and self-knowledge (Price and Thompson, 2007). Bodily dissociation thus causes significant impairments in daily life and impoverishes the possible outcomes of psychological therapeutic processes (Price et al., 2017).

While various body–mind interventions have shown to be effective at increasing body awareness (the awareness of body sensations, also part of psychophysical awareness), impacting bodily dissociation has shown to be more difficult, especially when considering short-term interventions (Classen et al., 2021; Cheng et al., 2022). A possible explanation mechanism for the positive effect of this Psychomotor therapy program on bodily dissociation is the inclusion of cardiovascular and strength activities with an attuned approach (Louková et al., 2015; Calogero et al., 2019; Marmeleira et al., 2023). These activities were delivered with joyful, safe and process-oriented instruction, again embedded in an empathic and encompassing therapeutic setting. By (i) increasing biological sensations of movement, rhythm, and vitality, while (ii) emphasizing the connections between sensations and emotions, and (iii) delivering words of agency toward the body, these activities aimed to facilitate awareness and reconnect female victims of IPV with their living bodies, allowing them to regain their sense of body ownership (Machorrinho et al., 2022; Marmeleira et al., 2023). This mechanism might also explain the large effect size of the intervention on the environmental domain of quality of life. This domain refers to senses of safety, mobility, autonomy and opportunity to participate in leisure activities, which corroborates the rationale of the Psychomotor therapy intervention where some of the short-term objectives are to activate movement, to regain pleasure in physical activity, and to increase vitality and strength (Marmeleira et al., 2023). On the other hand, research has shown benefits of exercise on symptoms of PTSD, anxiety and depression, especially for aerobic exercise, yoga practices and general physical activity (Cabral et al., 2011; Hallgren et al., 2016; Frederiksen et al., 2021). Rosenbaum et al. (2015) specifically found that adding exercise augmentation through motivational tools to decrease sedentary behavior, and resistance training, is more effective at reducing PTSD than treatment as usual only. Through a systematic review with meta-analysis, Björkman and Ekblom (2022) corroborated the overall benefits of adding exercise to the usual treatment of PTSD. The hypothesis of why FOM did not had similar significant positive results on PTSD is twofold. First, because, although FOM included an initial exercise moment with the aim of augmenting interoceptive and proprioceptive sensations, this was not the main or only goal of FOM, justified by the inclusion of two other important moments in each session. Second, the majority of the interventions revised by Björkman and Ekblom (2022) were implemented for at least 12 weeks, with 2–3 sessions per week. Due to the retention concerns inherent to the IPV shelter context, FOM had a shortened duration of 8 weeks, which can possibly have a limiting effect on its results, specifically on effectively reducing PTSD symptoms.

Overall, results suggest that FOM has an impact on reconnecting women victims of IPV with their bodies, diminishing their bodily dissociation and promoting their willingness to move more and autonomously engage in activities. This program had, however, no

significant effects on reducing anxiety, reexperiencing, or hyper-vigilance, nor on their perceived quality of life in terms of physical, social, or psychological healthcare. It is thus important to notice that many of those women were on a waiting list for physical therapy, reconstruction surgery, or general medical and psychological assistance related to serious sequelae from the violent assaults. Additionally, as time goes by in shelter homes, each woman is under increased pressure to leave, find a job, and provide children enough social and economic autonomy, which can increase their feelings of anxiety and fear of being somehow a victim again.

Limitations

One factor that limits the generalizability of the results of FOM is the small sample size. Efforts were made to attend to different shelters and balance participants' heterogeneity in order to enrich the depth of results. However, the sample size was negatively impacted due to the loss of participants from the shelters. This loss was due, not only by women leaving the shelter or finding occupying jobs, but also by the therapeutic-groups design, that required the ending of one program before initiating another one, which delayed the inclusion of new participants in the study, possibly extending its costs. One other factor that might have limited the impact of FOM, was the poor conditions of the shelter to effectively implement the relaxation moments during sessions. In general, the small, cold and loud rooms made available for therapy were not adequate to practice relaxation and hindered the therapist's efforts to counterbalance such limitations. Also, some sessions' length had to be shortened due to women not having no one in the house to take care of the children. This can reveal an important concern when reflecting on the feasibility of FOM's implementation. Future FOM implementations might benefit from having a contingency plan with appropriate conditions to the relaxation activities, and plan for parallel activities for the children.

IPV is a complex problem that requires extensive research on various psychological, physical and social dimensions. Acknowledging the intertwining of most of those dimensions, it would be important to account for confounding variables in this research. This was not possible to perform in the current study due to the non-normal distribution of some of the dependent variables, which prevented us from supporting a reliable covariance statistical analysis. In this regard, the account for confounding variables is recommended for future studies. Also, a multidimensional assessment of variables that can impact trauma experience and adherence to support is also recommended, as it is the example of attachment security.

We further encourage future research to examine the evolution of FOM's results on follow-up assessments. Additionally, we suggest exploring the effectiveness of FOM on reoccurrence rates, acknowledging that bodily dissociation was recently hypothesized as playing an important role in revictimization numbers (Zamir et al., 2018). Considering the positive effects found in the present study, it could be important to adapt FOM to be extended to other levels of IPV prevention, such as primary support centers and healthcare settings.

In conclusion, FOM, an 8-week Psychomotor therapy program seems to be a feasible and highly accepted therapeutic intervention for female victims of IPV living in shelters. Most importantly, this program showed to be effective in reducing bodily dissociation among participants, which is suggested to prospectively contribute to their mental health and quality of life (Machorrinho et al., 2021b).

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Ethics statement

The studies involving human participants were reviewed and approved by Ethics Committee of the University of Évora. The patients/participants provided their written informed consent to participate in this study.

Author contributions

JM, GS, GV, and JMar contributed to the design and conception of this study. JM and GS cautiously designed the intervention program, which was critically revised by GV and JMar. JM collected data, which was analyzed by JM and JMar. JM wrote the first draft of the manuscript. GS, GV, and JMar revised the final manuscript. All authors contributed to manuscript revision, read, and approved the submitted version.

Funding

This research was funded by Fundação para a Ciência e Tecnologia, IP National support through Comprehensive Health Research Centre, CHRC (UI/BD/150985/2021). Also, this work is funded by national funds through the Foundation for Science and Technology, under the project UIDP/04923/2020.

Acknowledgments

The authors would like to thank all the managing entities of the shelter homes who embraced this study and facilitated its presentation to participants and implementation. A warm acknowledgment to Ema Inácio, the highly dedicated and professional therapist who embraced FOM and the embodied lives of the participants in shelter homes. We finally endorse a special thanks to all the women who accepted to know more about FOM and about the state of their body-mind connection, and to the ones who embraced this therapeutic journey.

Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

References

Andersen, T. E., Lahav, Y., Ellegaard, H., and Manniche, C. (2017). A randomized controlled trial of brief somatic experiencing for chronic low back pain and comorbid post-traumatic stress disorder symptoms. *Eur. J. Psychotraumatol.* 8:1331108. doi: 10.1080/20008198.2017.1331108

Arroyo, K., Lundahl, B., Butters, R., Vanderloo, M., and Wood, D. S. (2017). Short-term interventions for survivors of intimate partner violence: a systematic review and meta-analysis. *Trauma Violence Abuse* 18, 155–171. doi: 10.1177/1524838015602736

Ataria, Y.. (2018). *Body disownership in complex posttraumatic stress disorder*. New York, US: Palgrave Macmillan.

Baylin, J., and Winnette, P.. (2016). *Working with traumatic memories to heal adults with unresolved childhood trauma: Neuroscience, attachment theory and Pesso Boyden system psychomotor psychotherapy*. London: Jessica Kingsley Publishers.

Bieleveldt, S.. (2019). *Psychomotor therapy and recovery of intimacy: the importance of raising body awareness and to increase a positive experience of intimacy and sexuality*. ESTSS Symposium, pp. 2–4.

Björkman, F., and Ekblom, Ö. (2022). Physical exercise as treatment for PTSD: a systematic review and meta-analysis. *Mil. Med.* 187, e1103–e1113. doi: 10.1093/milmed/usab497

Bowen, D. J., Kreuter, M., Spring, B., Cofta-Woerpel, L., Linnan, L., et al. (2009). How we design feasibility studies. *Am. J. Prev. Med.* 36, 452–457. doi: 10.1016/j.amepre.2009.02.002

Brand, B. L., Myrick, A. C., Loewenstein, R. J., Classen, C. C., Lanius, R., McNary, S. W., et al. (2012). A survey of practices and recommended treatment interventions among expert therapists treating patients with dissociative identity disorder and dissociative disorder not otherwise specifed. *Psychol. Trauma Theory Res. Pract. Policy* 4:490500, 490–500. doi: 10.1037/a0026487

Bruce, S. E., Buchholz, K. R., Brown, W. J., Yan, L., Durbin, A., and Sheline, Y. I. (2013). Altered emotional interference processing in the amygdala and insula in women with post-traumatic stress disorder. *Neuroimage Clin.* 2, 43–49. doi: 10.1016/j.nicl.2012.11.003

Cabral, P., Meyer, H. B., and Ames, D. (2011). Effectiveness of yoga therapy as a complementary treatment for major psychiatric disorders: a meta-analysis. *Prim. Care Companion CNS Disord.* 13:1068. doi: 10.4088/PCC.10r01068

Caldwell, C., and Victoria, H. K. (2011). Breathwork in body psychotherapy: towards a more unified theory and practice. *Body Mov. Dance Psychother.* 6, 89–101. doi: 10.1080/17432979.2011.574505

Calogero, R., Tylka, T., McGilley, B., and Pedrotty-Stump, K. (2019). "Attunement with exercise (AWE)" in *Handbook of positive body image and embodiment: Constructs, protective factors, and interventions*. ed. T. L. Tylka (New York: Oxford Academic)

Campbel, J. C. (2002). Health consequences of intimate partner violence. *Lancet* 359, 1331–1336. doi: 10.1016/S0140-6736(02)08336-8

Cheng, S. C., Thompson, E. A., and Price, C. J. (2022). The scale of body connection: a multisample study to examine sensitivity to change among mind–body and bodywork interventions. *J. Integr. Complement. Med.* 28, 600–606. doi: 10.1089/jicm.2021.0397

Classen, C. C., Hughes, L., Clark, C., Hill, M. B., Woods, P., and Beckett, B. (2021). A pilot RCT of a body-oriented group therapy for complex trauma survivors: an adaptation of sensorimotor psychotherapy. *J. Trauma Dissoc.* 22, 52–68. doi: 10.1080/15299732.2020.1760173

Cohen, J. (1988). *Statistical power analysis for the behavioral sciences, 2nd Edn.*. Hillsdale: Lawrence Erlbaum.

Coker, A. L. (2004). Primary prevention of intimate partner violence for Women's health. *J. Interpers. Violence* 19, 1324–1334. doi: 10.1177/0886260504269686

Costa, D., Hatzidimitriadou, E., Ioannidi-Kapolou, E., Lindert, J., Soares, J., Sundin, Ö., et al. (2015). Intimate partner violence and health-related quality of life in European men and women: findings from the DOVE study. *Qual. Life Res.* 24, 463–471. doi: 10.1007/s11136-014-0766-9

Dieterich-Hartwell, R. (2017). Dance/movement therapy in the treatment of post traumatic stress: a reference model. *Arts Psychother.* 54, 38–46. doi: 10.1016/j.aip.2017.02.010

Dutton, M. A., Holtzworth-Munroe, A., Jouriles, E., McDonald, R., Krishnan, S., McFarlane, J., et al. (2003). *Recruitment and retention in intimate partner violence research*. Rockville, US: US Department of Justice.

Eckhardt, C. I., Murphy, C. M., Whitaker, D. J., Sprunger, J., Dykstra, R., and Woodard, K. (2013). The effectiveness of intervention programs for perpetrators and victims of intimate partner violence. *Partn. Abus.* 4, 196–231. doi: 10.1891/1946-6560.4.2.196

Emck, C., and Scheffers, M. (2019). "Psychomotor interventions for mental health: an introduction" in *Psychomotor interventions for mental health–adults*. eds. J. De Lange, O. Glas, J. Van Busschbach, C. Emck and T. Scheewe (Los Angeles, CA: Boom), 162–179.

European Forum of Psychomotricity. (2012). *Psychomotrician professional competences in Europe*. Ljubljana: European Forum of Psychomotricity.

Fernandes, J., Veiga, G., and Gutierres, F. P. (2022). Psicomotricidade e paradigma da complexidade. *Psicol. Saúde Debate* 8, 363–377. doi: 10.22289/2446-922X.V8N1A21

Frederiksen, K. P., Stavestrand, S. H., Venemyr, S. K., Sirevag, K., and Hovland, A. (2021). Physical exercise as an add-on treatment to cognitive behavioural therapy for anxiety: a systematic review. *Behav. Cogn. Psychother.* 49, 626–640. doi: 10.1017/S1352465821000126

General Assembly of the World Medical Association (2014). World medical association declaration of Helsinki: ethical principles for medical research involving human subjects. *J. Am. Coll. Dent.* 81, 14–18.

Guiose, M. (2003). "Fondements théoriques et techniques de la relaxation," in *Rapport, medicine faculty de. ed. Faculté de médecine Pierre et Marie Curie* (Paris: Paris-VI University), 21–23.

Hallgren, M., Herring, M. P., Owen, N., Dunstan, D., Ekblom, O., Helgadottir, B., et al. (2016). Exercise, physical activity, and sedentary behavior in the treatment of depression: broadening the scientific perspectives and clinical opportunities. *Front. Psych.* 7:36. doi: 10.3389/fpsyt.2016.00036

Hansen, N. B., Eriksen, S. B., and Elklit, A. (2014). Effects of an intervention program for female victims of intimate partner violence on psychological symptoms and perceived social support. *Eur. J. Psychotraumatol.* 5:24797. doi: 10.3402/ejpt.v5.24797

Hazlett-Stevens, H., and Fruzzetti, A. E. (2021). "Regulation of physiological arousal and emotion" in *Handbook of cognitive behavioral therapy: Overview and approaches*. ed. A. Wenzel (Washington, DC: American Psychological Association), 349–383.

Herrmann, C. (1997). International experiences with the hospital anxiety and depression scale-a review of validation data and clinical results. *J. Psychosom. Res.* 42, 17–41. doi: 10.1016/S0022-3999(96)00216-4

Hielscher, E., Whitford, T. J., Scott, J. G., and Zopf, R. (2019). When the body is the target—representations of one's own body and bodily sensations in self-harm: a systematic review. *Neurosci. Biobehav. Rev.* 101, 85–112. doi: 10.1016/j.neubiorev.2019.03.007

IBM Corp. (2017). *IBM SPSS statistics for windows, version 24.0*. Armonk, NY: IBM Corp.

Kelly, U. (2010). Intimate partner violence, physical health, posttraumatic stress disorder, depression, and quality of life in Latinas. West. *J. Emerg. Med.* 11:247.

Kirmayer, L. J., and Gómez-Carrillo, A. (2019). Agency, embodiment and enactment in psychosomatic theory and practice. *Med. Humanit.* 45, 169–182. doi: 10.1136/medhum-2018-011618

Klein, L. B., Chesworth, B. R., Howland-Myers, J. R., Rizo, C. F., and Macy, R. J. (2021). Housing interventions for intimate partner violence survivors: a systematic review. *Trauma Violence Abuse* 22, 249–264. doi: 10.1177/15248380198362

Lagdon, S., Armour, C., and Stringer, M. (2014). Adult experience of mental health outcomes as a result of intimate partner violence victimization: a systematic review. *Eur. J. Psychotraumatol.* 5:24794. doi: 10.3402/ejpt.v5.24794

Lebre, P., Dunphy, K., and Juma, S. (2020). Exploring use of the outcomes framework for dance movement therapy to establish a group profile and objectives for psychomotor therapy interventions. *Body Mov. Dance Psychother.* 15, 251–266. doi: 10.1080/17432979.2020.1806926

Levine, P. A.. (2010). *In an unspoken voice: How the body releases trauma and restores goodness*. Berkeley, CA: North Atlantic Books.

Llaurado, C. (2008). Observation of the psychomotrician's intervention: transference attitudes and manifestations. *Rev. Interuniv Form Prof.* 62, 123–154.

Louková, T., Hátlová, B., and Ségard, M. (2015). *Psychomotor therapy and physical self-concept*. Czech Republic: University of JE Purkyně in Ústí nad Labem.

Machorrinho, J., Veiga, G., Santos, G., and Marmeleira, J.. (2021a). *Body ownership of women with and without history of intimate-partner violence [poster]*. Lisbon: Encontro Ciência.

Machorrinho, J., Veiga, G., Santos, G., and Marmeleira, J. (2021b). Embodiment-related risk factors for posttraumatic stress, anxiety and depression in female victims of intimate-partner violence. *J. Trauma Dissociation* 2021, 23, 212–228. doi: 10.1080/15299732.2021.1989109

Machorrinho, J., Veiga, G., Santos, G., and Marmeleira, J. (2022). "Embodiment: features, measures and importance in intimate partner violence" in *Handbook of anger, aggression and violence*. eds. V. Preedy and P. Martin (Switzerland: Springer), 1–21.

MacLaren, H. L.. (2016) *Mutuality in movement: A relational approach to dance/movement therapy with domestic violence survivors*. Unpublished Master's Thesis, Columbia College Chicago, Chicago, IL.

Marcelino, D., and Gonçalves, S. P. (2012). Perturbação pós-stress traumático: Características psicométricas da versão portuguesa da posttraumatic stress disorder checklist–civilian version (PCL-C). *Rev. Port Saude Publica* 30, 71–75. doi: 10.1016/j.rpsp.2012.03.003

Marmeleira, J., Machorrinho, J., Veiga, G., and Santos, G. (2023). "Psychomotor intervention in intimate partner violence: empirical support for preventive and therapeutic approaches" in *Intimate partner violence: Indicators, psychological impact and prevention*. ed. C. Bennett (United States: Nova Science Publishers)

Neves, C. F., Price, C. J., and Carvalheira, A. (2017). The psychometric properties of the scale of body connection (SBC) in a Portuguese sample. *Psychol Commun. Health* 6:2317. doi: 10.23668/psycharchives.2317

Nicholson, A. A., Densmore, M., Frewen, P. A., Théberge, J., Neufeld, R. W., McKinnon, M. C., et al. (2015). The dissociative subtype of posttraumatic stress disorder: unique resting-state functional connectivity of Basolateral and Centromedial amygdala complexes. *Neuropsychopharmacology* 40, 2317–2326. doi: 10.1038/npp.2015.79

O'Shea Brown, G.. (2021). *Dissociation. In healing complex posttraumatic stress disorder: a clinician's guide*. Cham: Springer International Publishing.

Ogbe, E., Harmon, S., Van den Bergh, R., and Degomme, O. (2020). A systematic review of intimate partner violence interventions focused on improving social support and/mental health outcomes of survivors. *PLoS One* 15:e0235177. doi: 10.1371/journal.pone.0235177

Ogden, P., Pain, C., and Fisher, J. (2006). A sensorimotor approach to the treatment of trauma and dissociation. *Psychiatr. Clin. N. Am.* 29, 263–279. doi: 10.1016/j.psc.2005.10.012

Pais-Ribeiro, J., Silva, I., Ferreira, T., Martins, A., Meneses, R., and Baltar, M. (2007). Validation study of a Portuguese version of the hospital anxiety and depression scale. *Psychol. Health Med.* 12, 225–237. doi: 10.1080/13548500500524088

Payne, P., Levine, P. A., and Crane-Godreau, M. A. (2015). Somatic experiencing: using interoception and proprioception as core elements of trauma therapy. *Front. Psychol.* 6:93. doi: 10.3389/fpsyg.2015.00093

Polskaya, N. A., and Melnikova, M. A. (2020). Dissociation, trauma and self-harm. *Couns. Psychol. Psychother.* 28, 25–48. doi: 10.17759/cpp.2020280103

Potel, C. (2019). *Être psychomotricien: Un métier du présent, un métier d'avenir. (Nouvelle édition augmentée)*. Paris: Érès.

Powers, M. B., Asmundson, G. J., and Smits, J. A. (2015). Exercise for mood and anxiety disorders: the state-of-the science. *Cogn. Behav. Ther.* 44, 237–239. doi: 10.1080/16506073.2015.1047286

Price, C. (2007). Dissociation reduction in body therapy during sexual abuse recovery. *Complement. Ther. Clin. Pract.* 13, 116–128. doi: 10.1016/j.ctcp.2006.08.004

Price, C. J., and Thompson, E. A. (2007). Measuring dimensions of body connection: body awareness and bodily dissociation. *J. Altern. Complement. Med.* 13, 945–953. doi: 10.1089/acm.2007.0537

Price, C. J., Thompson, E. A., and Cheng, S. C. (2017). Scale of body connection: a multi-sample construct validation study. *PLoS One* 12:e0184757. doi: 10.1371/journal.pone.0184757

Price, C. J., Wells, E. A., Donovan, D. M., and Rue, T. (2012). Mindful awareness in body-oriented therapy as an adjunct to women's substance use disorder treatment: a pilot feasibility study. *J. Subst. Abus. Treat.* 43, 94–107. doi: 10.1016/j.jsat.2011.09.016

Rekkers, M., Scheffers, M., van Elburg, A. A., and Van Busschbach, J. T. (2021). The protocol for positive body experience (PBE); introducing a psychomotor therapy intervention based on positive body exposure targeting negative body image in eating disorders. *Body Move. Dance Psychother.* 16, 252–266. doi: 10.1080/17432979.2020.1863261

Rosenbaum, S., Sherrington, C., and Tiedemann, A. (2015). Exercise augmentation compared with usual care for post-traumatic stress disorder: a randomized controlled trial. *Acta Psychiatr. Scand.* 131, 350–359. doi: 10.1111/acps.12371

Shepherd, L., and Wild, J. (2014). Emotion regulation, physiological arousal and PTSD symptoms in trauma-exposed individuals. *J. Behav. Ther. Exper. Psychiatr.* 45, 360–367. doi: 10.1016/j.jbtep.2014.03.002

Snaith, R. P. (2003). The hospital anxiety and depression scale. *Health Qual. Life Outcomes* 1:29. doi: 10.1186/1477-7525-1-29

Tavakol, M., and Dennick, R. (2011). Making sense of Cronbach's alpha. *Int. J. Med. Educ.* 2, 53–55. doi: 10.5116/ijme.4dfb.8dfd

Taylor, J., McLean, L., Korner, A., Stratton, E., and Glozier, N. (2020). Mindfulness and yoga for psychological trauma: systematic review and meta-analysis. *J. Trauma Dissoc.* 21, 536–573. doi: 10.1080/15299732.2020.1760167

Tomczak, M., and Tomczak, E. (2014). The need to report effect size estimates revisited. an overview of some recommended measures of effect size. *Trends Sport Sci.* 2, 19–25.

Tschoeke, S., Steinert, T., and Bichescu-Burian, D. (2019). Causal connection between dissociation and ongoing interpersonal violence: a systematic review. *Neurosci. Biobehav. Rev.* 107, 424–437. doi: 10.1016/j.neubiorev.2019.09.030

Van de Kamp, M., and Hoven, M. (2019). "Psychomotor interventions for post-traumatic stress disorder and dissociative disorders" in *Psychomotor interventions for mental health–adults*. eds. J. De Lange, O. Glas, J. Van Busschbach, C. Emck and T. Scheewe (Los Angeles, CA: Boom), 162–179.

Van de Kamp, M., Scheffers, M., Hatzmann, J., Emck, C., Cuijpers, P., and Beek, P. J. (2019). Body- and movement-oriented interventions for posttraumatic stress disorder: a systematic review and meta-analysis. *J. Traumat. Stress* 32, 967–976. doi: 10.1002/jts.22465

Van der Kolk, B.. (2015). *The body keeps the score: Mind, brain and body in the transformation of trauma*. United Kingdom: Penguin.

Van der Kolk, B. (2022). Posttraumatic stress disorder and the nature of trauma. *Dialogues Clin. Neurosci.* 2, 7–22. doi: 10.31887/DCNS.2000.2.1/bvdkolk

Vaz Serra, A., Canavarro, M. C., Simões, M., Pereira, M., Gameiro, S., Quartilho, M. J., et al. (2006). Estudos psicométricos do instrumento de avaliação da qualidade de vida da Organização Mundial de Saúde (WHOQOL-Bref) para Português de Portugal. *Psiquiat Clín.* 27, 41–49. Available at: http://hdl.handle.net/10849/181

Weathers, F. W., Litz, B., Herman, D., Juska, J., and Keane, T. (1994). PTSD checklist–civilian version. *J. Occup. Health Psychol.* 1:2622. doi: 10.1037/t02622-000

Weaver, T. L., and Resnick, H. (2004). Toward developing complex multivariate models for examining the intimate partner violence-physical health relationship. *J. Interper. Viol.* 19, 1342–1349. doi: 10.1177/0886260504269692

World Health Organization. (2021). *Violence against women*. Geneva: World Health Organization. Available at: https://www.who.int/news-room/fact-sheets/detail/violence-against-women. (Accessed October 10, 2022).

Yakubovich, A. R., Bartsch, A., Metheny, N., Gesink, D., and O'Campo, P. (2022). Housing interventions for women experiencing intimate partner violence: a systematic review. *Lancet* 7, e23–e35. doi: 10.1016/S2468-2667(21)00234-6

You, S., Talbot, N. L., He, H., and Conner, K. R. (2012). Emotions and suicidal ideation among depressed women with childhood sexual abuse histories. *Suicide Life Threat. Behav.* 42, 244–254. doi: 10.1111/j.1943-278X.2012.00086.x

Zamir, O., Szepsenwol, O., Englund, M. M., and Simpson, J. A. (2018). The role of dissociation in revictimization across the lifespan: a 32-year prospective study. *Child Abuse Negl.* 79, 144–153. doi: 10.1016/j.chiabu.2018.02.001

Zigmond, A. S., and Snaith, R. P. (1983). The hospital and anxiety and depression scale. *Acta Psychiatr. Scand.* 67, 361–370. doi: 10.1111/j.1600-0447.1983.tb09716.x

frontiers | Frontiers in Psychology

TYPE Original Research
PUBLISHED 19 July 2023
DOI 10.3389/fpsyg.2023.1161575

OPEN ACCESS

EDITED BY
Lara Guedes De Pinho,
University of Evora, Portugal

REVIEWED BY
Tânia Correia,
University of Porto, Portugal
Inga Dennhag,
Umeå University, Sweden

*CORRESPONDENCE
Xingli Zhang
✉ zhangxl@psych.ac.cn

RECEIVED 08 February 2023
ACCEPTED 29 June 2023
PUBLISHED 19 July 2023

CITATION
Zuo ZJ and Zhang XL (2023) A randomized controlled trial of group CBT with positive psychotherapy intervention for university students with maladaptive perfectionism in China.
Front. Psychol. 14:1161575.
doi: 10.3389/fpsyg.2023.1161575

A randomized controlled trial of group CBT with positive psychotherapy intervention for university students with maladaptive perfectionism in China

Zhijuan Zuo[1] and Xingli Zhang[2,3]*

[1]Mental Health Center in Department of Student Affairs, Yunnan University, Kunming, China, [2]Key Laboratory of Behavioral Science, Institute of Psychology, Chinese Academy of Sciences (CAS), Beijing, China, [3]Department of Psychology, University of Chinese Academy of Sciences, Beijing, China

Objective: The primary objective of this randomized controlled trial was to find a more economical and feasible intervention for maladaptive perfectionism, which is a risk and maintenance mechanism for various psychopathologies.

Methods: In total, 64 university students who met the total inclusion criteria were randomly assigned to either group CBT with positive psychotherapy intervention or a 16-week waitlist (WL). The intervention group received 2 h of therapy for eight weekly sessions. Measurements of maladaptive perfectionism and the symptoms of depression and anxiety were conducted at baseline, post-intervention, and follow-up.

Results: There was no statistically significant difference in the scores of the Frost Multidimensional Perfectionism Scale, Self-Rating Depression Scale, and Self-Rating Anxiety Scale between the intervention group and the waitlist group at baseline (all $p > 0.05$). The intervention group had a significant main effect of time and a time × group interaction effect of the maladaptive aspects of perfectionism, Concern over Mistakes and Doubts about Actions, and depression and anxiety scores in comparison with the waitlist group at the post-intervention and 8-week follow-up and had no statistically significant effects on the scores for Personal Standards, Parental Expectation, and Parental Criticism. The analysis showed that group intervention reduced symptoms of depression and anxiety while reducing maladaptive aspects of perfectionism.

Conclusion: This study added to the literature on CBT interventions for maladaptive perfectionism and indicated that group CBT with positive psychotherapy intervention had substantial long-term effects on the maladaptive perfectionism of university students in China. Moreover, the results indicated that the intervention increased participants' self-acceptance.

KEYWORDS

group CBT with positive psychotherapy intervention, maladaptive perfectionism, randomized controlled trial, university students, China

Introduction

Perfectionists can be described as those whose standards are high beyond reach or reason, people who strain compulsively and unremittingly toward impossible goals and who measure their own worth entirely in terms of productivity and accomplishment according to Burns (Lo and Abbott, 2013). The multidimensional construct of perfectionism has been well-established by psychology researchers. Through percentile, median, or clustering methodology, scales of perfectionism divide people into three categories: adaptive perfectionism, maladaptive perfectionism, and nonperfectionism (Yang et al., 2010). Maladaptive perfectionists are conceptualized as experiencing greater levels of distress as they strive to meet unrealistic standards and unattainable goals. They are driven by a fear of failure and criticism and attempt to escape feelings of inferiority (Lo and Abbott, 2013).

Researchers have continued to demonstrate clear associations between perfectionism and personal adjustment problems, including depression disorders, anxiety disorders, and eating disorders, during the past two decades (Lo and Abbott, 2013). Perfectionism is not only elevated across many disorders when compared to healthy controls but is also a transdiagnostic process and is implicated as a risk and maintenance mechanism of various psychopathologies (Galloway et al., 2022). Perfectionism is a complex personality style that encompasses all aspects of one's behavior and is associated with myriad and marked psychological, physical health, relationship, and achievement problems (Hewitt et al., 2017).

Maladaptive perfectionism may positively predict the symptoms of psychiatric disorders and impede the success of treatment for these disorders (Rhéaume et al., 2000). For example, the adverse outcome of standard treatment for depression could be predicted by the level of maladaptive perfectionism before treatment, the reduction in depressive symptoms at the end of treatment and follow-up was negatively correlated with perfectionism, the treatment effect on social anxiety was reduced by perfectionism, and the ability of OCD patients to finish exposure, blocking response, and cognitive reconstruction tasks was interfered with by perfectionism (Steele et al., 2013). Despite the important role maladaptive perfectionism plays in psychopathology and treatment, few interventions have targeted it (Ong et al., 2019). According to some researchers' views, ignoring perfectionism can be a barrier to psychotherapy and undermine effectiveness (Mitchell et al., 2013).

Targeting perfectionism in treatment resulted in better psychological outcomes than targeting each maintenance factor of the psychiatric disorder (Lo and Abbott, 2013). A recent meta-analysis of eight studies found that it was possible to significantly reduce levels of maladaptive perfectionism using short cognitive behavioral interventions (Lloyd et al., 2015). Targeting maladaptive perfectionism may be effective in reducing symptoms across a range of disorders (Lloyd et al., 2015).

Individual CBT (ICBT) was mostly used in past studies, while group interventions were rare. The interventions published in international journals were mostly conducted in English-speaking samples, and only two interventions were conducted in Hispanic samples (Bento et al., 2017; Matos and Steindl, 2020). There is still a lack of a detailed theoretical and psychological understanding of the psychopathological processes in perfectionism associated with psychosis to explain how the changes occurred in treatment for the different cultural backgrounds (Gaudiano, 2005).

The relationship between maladaptive perfectionism and distress has been analyzed by many researchers in China, and interventions have been designed mainly for nonclinical samples. In addition to cognitive behavioral therapy (Zheng, 2014), other therapies included mindfulness (Zhu, 2014), solution-focused brief therapy (Xu, 2019), sandplay therapy (Yu, 2012), and other therapies (Liu, 2015; Zeng, 2018; Wang, 2019). However, these interventions were not normative because they were mostly implemented by graduate students for their dissertation research. The inclusion criteria of participants were not set, and clinical performance of maladaptive perfectionism or related problems such as rumination (Zhu, 2014; Zeng, 2018), procrastination (Zheng, 2014), examination anxiety (Liu, 2015), self-efficacy (Xu, 2019), mental resilience (Wang, 2019), and psychological security perception (Wang, 2019) were mainly aimed at in most interventions. Group tutoring activities were more common, and therapeutic interventions were less common. Effect size data for maladaptive perfectionism, depression, and anxiety were absent in all these interventions. The number of participants was not enough to meet the requirements of a larger effect size (Zheng, 2014; Zhu, 2014; Zeng, 2018). Intervention effects upon follow-up were tracked in only one study (Zeng, 2018). Therefore, it was difficult to prove that the symptom reduction in psychiatric disorders was related to the change in maladaptive perfectionism and how the intervention effect was maintained during the follow-up.

Students may be an at-risk population, as shown by fruitful academic research (Arana et al., 2017). Nearly two-thirds of students can be categorized as perfectionists, with over a quarter considered maladaptive perfectionists (Grzegorek et al., 2004).

The notion of perfectionism is believed to be particularly relevant to the Chinese population (Wang et al., 2007). Despite the fact that interdependence is a cultural value, it still causes increased liability for the maladaptive aspects of perfectionism and augmented the association of perfectionism with depressive symptoms (Dibartolo and Rendón, 2012). Empirical research has found that Asian Americans report high levels of both parental expectations and criticism relative to other ethnic groups. The same tendency exists in Chinese parents (Yin et al., 2022) as Chinese children are nurtured to be very sensitive to mistakes and failures (Fong and Yuen, 2011), and scores in maladaptive perfectionism of university students are higher and more strongly associated with depression in Asian cultures. In the practice of psychological counseling, researchers have found that many university student clients who had not met the diagnostic criteria of a psychiatric disorder had a high perfectionism tendency due to their parents' high expectations or frequent criticism. Positive changes occurred relatively slowly in these individuals with counseling. It is necessary to find a way to reduce the levels of maladaptive perfectionism in Chinese university students.

Unrealistically high standards and excessive focus on mistakes are cognitive biases of perfectionists, and it is not easy to change this cognitive habit consciously. Perfectionism is typically ego-syntonic, and individuals may show resistance to changing what they view as a part of their personality (Ong et al., 2019). The serious resistance problems in the treatment of extreme perfectionists were as follows in this study: fear of failure, rigid adherence to their inflexible

standards, and self-punishment (Zhang et al., 2010). Positive psychotherapy can increase the pleasant experience of participants and replace the habitual negative experience to enhance the motivation for change in perfectionists. However, there are few available studies in which positive psychotherapy was used to target perfectionism treatment.

Therefore, the primary aim of this RCT was to examine whether group CBT with positive psychotherapy intervention was superior to the waitlist condition in reducing maladaptive perfectionism, depression, and anxiety and whether the intervention effects can be maintained during follow-up.

Method

Participants

G*Power 3.1.9.2 was used for sample size calculation, and the effect size criteria were proposed by Cohen (0.8 for large effect, 0.5 for medium effect, and 0.2 for small effect) (Zhao and Wang, 2019). In this study, the effect size was Cohen's $d = 0.8$, one-sided alpha = 0.05, power = 0.90, and a minimal sample size of 56 participants (28 in each group) would be needed.

Volunteers were recruited through advertisements on the public course of Mental Health Education for university students and public accounts of mental health centers on WeChat. The inclusion criteria of participants were as follows: (a) being an undergraduate or postgraduate student; (b) willingness to participate in group intervention; (c) 84 or above total score in the FMPS (an individual with a score above 84 was defined as high perfectionism tendency by Frost); (d) 53 ≤ standard score in the SDS ≤ 72, or 50 ≤ standard score in the SAS ≤ 70; and (e) commitment to participate in group intervention to the end. Exclusion criteria were (a) hallucinations or other acute episodes of psychosis; (b) immediate risk of suicide, self-injury or injury to others; (c) any current psychological treatment for psychiatric problems; and (d) any change in psychotropic medication 3 months prior to entering treatment.

Participants were informed that they should not attend any other form of therapy and if there was a need to do so, they should inform the investigators.

Procedures

Individuals interested in participating scanned the QR code for enrolment. This resulted in 96 students enrolling and following the enrolment measurements with the FMPS, SDS, and SAS. Of these, 80 met the score requirements and 72 took part in a face-to-face interview of 15 min according to appointment. The enrolment criteria were checked during the interview. Three students dropped out because of the change in course time, and five students did not meet the total enrolment criteria. Then, 36 female participants who met all the enrolment criteria were randomized using a random numbers generator in a 1:1 ratio to one of two conditions: intervention (n = 18) or waitlist (n = 18). Similarly, 28 male participants who met all the enrolment criteria were randomized using a random numbers generator in a 1:1 ratio to one of two conditions: intervention ($n = 14$) or waitlist ($n = 14$).

Because there is no Ethics Committee in the university where the research was conducted, the participants were formally invited to take part in the intervention, and formal informed consent documents were given to participants to sign. Participants could choose to quit if they felt that the study was not good for their recovery. They were also informed about the purpose of the study, the risks and benefits of the group intervention, the design of the intervention, and confidentiality principles. The flow of participants through the trial is shown in Figure 1.

Measurement scales were distributed to participants at baseline (T1), post-intervention (immediately after intervention)(T2), and at an 8-week follow-up (T3). Scales were distributed to the intervention group face to face by irrelevant assistants in the Mental Health Center of Yunnan University, while the waitlist group had made an agreement in advance to complete scales on an online database and was reminded by assistants with messages at a fixed time. Data was also collected by these assistants. All data was used for research purposes only. Paper scales and informed consent documents were kept in the archives of the Psychological Center at Yunnan University. Personal information had been deleted from the online original data.

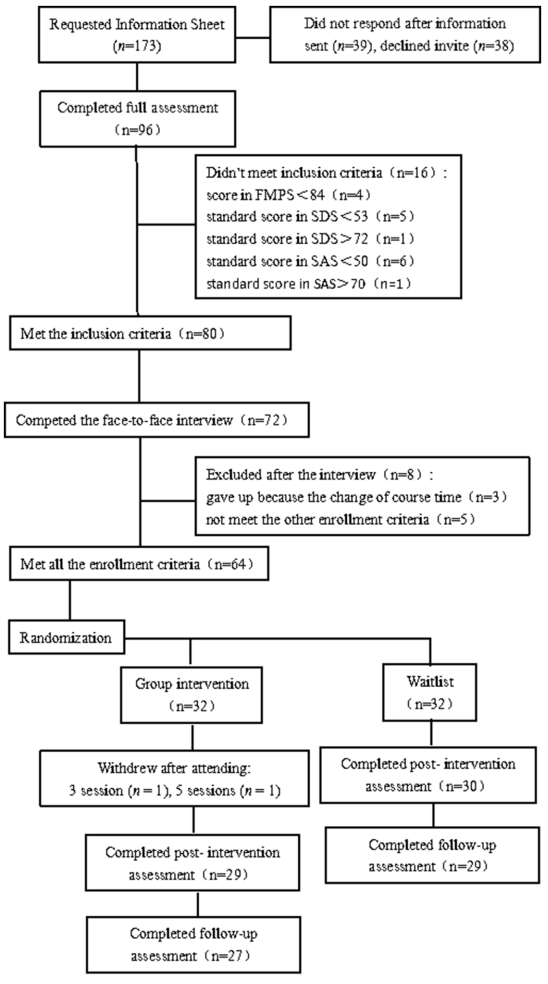


FIGURE 1
Flow of participants through the trial.

Measures

Frost multidimensional perfectionism scale

Perfectionism was measured by the Frost Multidimensional Perfectionism Scale (FMPS). It has been widely used, and demonstrated satisfactory reliability and validity (Limburg et al., 2017). It is a 35-item measure consisting of Concern over Mistakes (CM), Personal Standards (PS), Doubts about Actions (DA), Parental Expectation (PC), Parental Criticism (PE), and Organization (OR) (Frost et al., 1990). Four FMPS subscales (CM, DA, PC, and PE) measure maladaptive aspects of perfectionism (MFMPS) (Slade et al., 2009). In total, 35 items of FMPS are rated on a five-point Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree). The internal consistencies of subscales range from 0.77 to 0.93 (Egan and Hine, 2008).

An FMPS translation translated by Cheng was used in this study, and the translation was slightly modified based on Chinese language habits by Zifei. The Cronbach's alpha values of the subscales range from 0.64–0.83 (Cheng et al., 1999; ZI and ZHOU, 2006). It had good internal consistency (α of subscales range from 0.74–0.91) in this sample.

Self-rating depression scale

The severity of depression was measured by the Self-Rating Depression Scale (SDS). SDS was developed by Zung in 1965. This self-report scale consists of 20 items rated on a four-point Likert scale (no or very little of the time, some of the time, a good part of the time, and most of the time or all the time). Participants rated how much they have experienced symptoms of depression over the past week. Its Cronbach's alpha value was 0.82. According to the Chinese norm, a score below 53 indicates no depression, 53–62 indicates mild depression, 63–72 indicates moderate depression, and 73 or above indicates severe depression (Thi Thuy Ta, 2019). It has good validity and acceptable internal consistency in this study ($\alpha = 0.70$).

Self-rating anxiety scale

The severity of anxiety was measured by Self-Rating Anxiety Scale (SAS). SAS was developed by Zung in 1971. It is a 20-item, 4-point self-rating scale designed to assess the subjective feelings of anxious patients. Studies proved that SAS has a good evaluation effect on adults with anxiety symptoms, and Cronbach's alpha was 0.81. According to the Chinese norm, a score below 50 indicates no anxiety, 50–59 indicates mild anxiety, 60–70 indicates moderate anxiety, and 71 or above indicates severe anxiety (Guo, 2019). The SAS has good reliability in the current study with $\alpha = 0.72$.

Intervention

The intervention was conducted by a licensed counselor of the Clinical and Counselling Psychology Registration System (CCPRS) in China and assisted by 3 graduate students majoring in psychology or social work. The counselor had practiced individual psychological counseling and group intervention for more than 15 years. The group intervention consisted of eight weekly 120-min sessions.

Based on the scientific intervention design of past literature, the structure of the intervention was adapted from the books "Never Good Enough" (Basco, 2000), "The Principles of Cognitive Behavioural" (Beck, 2013), and "Positive Psychotherapy" (Yang, 2010), and from research articles entitled "A comparative study of group positive psychotherapy and group CBT in the treatment of depressive disorders" (Furchtlehner et al., 2020), and "Cognitive-behavioral group therapy in major depressive disorder with focus on self-esteem and optimism" (Moloud et al., 2022). Resistance problems such as "fear of failure," "rigid personal high standards," and "doubt of action" were targeted in the intervention, and the tendency of self-punishment was decreased by changing the participants' self-schema.

In the first part, the problem behaviors related to perfectionism were checked, and a list was made. The second part consisted of recognizing the negative automatic thinking of perfectionism, learning to understand the influence of automatic thinking on their emotions and behaviors (the A-B-C theory), and accepting that their beliefs can be changed. The third part consisted of behavioral experiments and cognitive reconstruction to challenge cognitive distortions and how to change them. The fourth part focused on procrastination, which is a prominent problem behavior in perfectionism, and introduced four ways to change procrastination habits, and developed and implemented plans for immediate action. Positive psychotherapy was added in the following intervention. The fifth part consisted of recognizing the meanings of mistakes and failures from a positive perspective and reconstructing the past mistakes and failures of participants. The sixth part consisted of deliberate practices on learned optimism, including extending the definition of success, hope thinking, and process orientation. During the seventh part, the source of perfectionism (the influence of inheritance and family education) was explored, the barriers to self-esteem caused by cognitive distortions were recognized, and core beliefs were reconstructed (find the strengths that perfectionism can bring to participants). In the eighth part, the strength development plan was developed, and role-play techniques to exercise self-confidence and determination were practiced. In the end, the participants learned to view themselves with a new self-schema.

Data and statistical analyses

Data were collected from participants who were willing to complete baseline, post-treatment, and follow-up assessments. To compare the main effects and interaction effects between the intervention and waitlist groups ANCOVA analyses were conducted using the SPSS 20.0.

Paired t-tests were used to ascertain changes in the measures between baseline, post-intervention, and 8-week follow-up. Independent t-tests were used to assess differences between intervention and waitlist participants at baseline, post-intervention, and 8-week follow-up. Cohen's d statistic served as effect size by using JASP.

Results

Sample descriptive

The participation rate was high in the intervention group, and 30 students (94%) took part in all eight sessions. In total, 27 students (84%) completed all the scales at baseline, immediately following the

intervention, and at the 8-week follow-up, including 11 males and 16 females. In the waitlist group, 29 students (91%) completed all the scales, including 11 males and 18 females. The demographic characteristics of the participants are shown in Table 1.

Data and statistical analyses

Means and standard deviations (SD) of dependent variables at baseline, post-intervention, and 8-week follow-up are presented in Table 2. Baseline assessment indicated that all the participants experienced moderate depression (mean = 60.50, *SD* = 4.80) and moderate severe anxiety (mean = 62.34, *SD* = 5.80) on the SDS and SAS, respectively. Also, the mean score on the FMPS (mean = 109.91, *SD* = 13.41) suggested major difficulties in perfectionism.

As seen in Table 2, results of repeated measure ANOVA design with 3 times (baseline, post, and follow-up) × 2 groups (CBT-P, WL) were presented. There were significant main effects of time and time×group interaction effects for CM, DA, MFMPS, SDS, and SAS. In addition, effect sizes for the interactions were large for these measures.

Independent sample comparisons (*T*-test) were used to evaluate differences between the two groups at T1, T2, and T3. The analysis of simple effects seen in Table 3 indicated that the groups displayed a significant difference between CBT-P and WL in post-intervention for CM, DA, MFMPS, SDS, and SAS ($p < 0.05$). In reducing perfectionism (CM, and DA subscales of the FMPS), depression (SDS), and anxiety (SAS), the CBT-P was significantly more effective than WL.

To examine whether treatment efficacy was maintained at the 8-week follow-up, a paired t-test was conducted for all measures. To identify treatment effectiveness, a paired t-test was conducted first between baseline and post-intervention in the two groups (CBT-P, WL) and then between post-intervention and follow-up, and finally between baseline and follow-up (Table 4). These results show that the intervention group displayed a significant reduction in depression and anxiety symptoms, and perfectionism at post-intervention. In CBT-P, the effect sizes (Cohen's d) were large for CM, MFMPS, SDS, and SAS, and were moderate for DA. The effect was maintained at the 8-week follow-up compared with the effect at baseline, but the long-term effect was not satisfactory compared with the post-intervention effect.

TABLE 1 Sociodemographic characteristics of participants at the pre-treatment assessment.

	Overall (*N* = 56)	intervention group (*n* = 27)	Waitlist (*n* = 29)
Age	M = 21.1 (SD = 2.2)	M = 21.4 (SD = 2.3)	M = 20 (SD =2.1)
Gender			
Males	22 (39.3%)	11 (40.7%)	11 (37.9%)
Females	34 (60.7%)	16 (59.3%)	18 (62.1%)
Highest educational level			
Bachelor's degree	35 (62.5%)	16 (59.3%)	19 (65.5%)
Master's degree	21 (37.5%)	11 (40.7%)	10 (34.5%)
Marital status			
Single	45 (80.4%)	22 (81.5%)	23 (79.3%)
Married/partner	11 (19.6%)	5 (18.5%)	6 (20.7%)
Previous psychological treatment	8 (14.3%)	3 (11.1%)	5 (17.2%)
Previous psychotropic medication	5 (8.19%)	2 (7.4%)	3 (10.3%)

Discussion

Group cognitive behavior therapy with positive psychotherapy intervention was first used to reduce the symptoms of depression or anxiety by targeting maladaptive perfectionism in Chinese students. The results supported the practicability and effects of this group intervention. Through the eight-week group intervention, the main effect of time and the time × group interaction effect were significant for the MFMPS, SDS, and SAS scores.

In addition, the observed effect sizes were comparable to those obtained from CBT treatment trials for perfectionism (Handley et al., 2015; Wade et al., 2019). For example, a previous waitlist-controlled trial for individual ACT reported between-group post-intervention Hedges' gs ranging from 0.42 to 1.05 for FMPS scores (Ong et al., 2019); corresponding effect sizes in the present study ranged from 0.74 to 0.96. This finding supports the conclusion of a meta-analysis that psychological interventions can reduce perfectionism and anxiety and depression symptoms, and the theory that perfectionism interventions can effectively reduce a series of psychiatric disorder symptoms (Lloyd et al., 2015).

The introspection regarding the negative influence of high standards, parents' expectations, and the origin of perfectionism, and the training on how to deal with failure and change procrastination habits were designed in the intervention. There were significant group differences for CM and DA at post-intervention and follow-up but there were no significant group differences for PS, PE, and PC at post-intervention and follow-up. This verified that individuals might show resistance to changing their personal standards, which they view as a dimension of their personality, consistent with the outcomes of previous treatment (Ong et al., 2019). Individuals in the intervention group could still set higher standards but limit them to some areas rather than all areas. In addition, high standards may be adaptive and were associated with positive outcomes in some studies (Bieling et al., 2004; Stoeber and Otto, 2006; Gäde et al., 2017). However, they were not included in maladaptive perfectionism in this study, so individuals may not need to change PS to live a meaningful life. Because perfectionists themselves were mainly involved in the intervention, the source of perfectionism was traced, and participants understood why their parents had high expectations for them, but the parents did not take part in the intervention. We hypothesize that this was why there was no significant change in the scores of PE and PC.

In this study, by targeting transdiagnostic maladaptive perfectionism, the risk and maintenance factors in the treatment of depression and anxiety disorders can be reduced. Compared with previous intervention studies in China, critical scores from the MFMPS, SDS, and SAS were used to select participants, and treatment based on a CBT protocol for depression and anxiety was conducted in the intervention. The subdimensions of perfectionism

TABLE 2 Estimated means, standard deviations, main effect of time, and time*group interaction effect for each outcome measure divided by condition and assessment.

	Group	Baseline	Post-intervention	Follow-up	Main effect of time *F*-value (p, η2)	Time*group interaction *F*-value (p, η2)
CM[a]	CBT-P[i]	21.74 (7.55)	17.00 (4.88)	17.81 (5.97)	15.03 ($p < 0.001$) (biasη2 = 0.36)	16.28 ($p < 0.001$) (biasη2 = 0.38)
	Waitlist	21.10 (5.19)	21.76 (4.99)	21.21 (4.88)		
PS[b]	CBT-P	24.07 (4.85)	23.78 (4.20)	23.56 (4.52)	1.91 ($p = 0.159$) (biasη2 = 0.07)	1.74 ($p = 0.186$) (biasη2 = 0.02)
	Waitlist	23.62 (3.52)	23.03 (4.36)	23.48 (3.72)		
PE[c]	CBT-P	15.52 (4.00)	15.07 (4.13)	15.11 (4.10)	1.04 ($p = 0.362$) (biasη2 = 0.04)	1.74 ($p = 0.185$) (biasη2 = 0.06)
	Waitlist	16.28 (4.36)	16.00 (3.71)	16.34 (3.79)		
PC[d]	CBT-P	9.52 (2.91)	9.19 (3.10)	9.37 (2.86)	0.62 ($p = 0.542$) (biasη2 = 0.02)	1.59 ($p = 0.214$) (biasη2 = 0.06)
	Waitlist	9.24 (2.29)	9.62 (1.72)	9.62 (1.59)		
DA[e]	CBT-P	13.81 (3.76)	11.33 (2.90)	12.00 (2.87)	3.91 ($p = 0.026$) (biasη2 = 0.13)	5.75 ($p = 0.005$) (biasη2 = 0.18)
	Waitlist	13.28 (2.53)	13.52 (2.89)	13.55 (2.43)		
MFMPS[f]	CBT-P	60.59 (12.70)	52.59 (9.68)	54.30 (10.32)	14.11 ($p < 0.001$) (biasη2 = 0.35)	23.78 ($p < 0.001$) (biasη2 = 0.47)
	Waitlist	59.90 (8.90)	60.90 (8.84)	60.72 (8.88)		
SDS[g]	CBT-P	60.03 (6.23)	55.51 (6.34)	56.57 (5.93)	12.98 ($p < 0.001$) (biasη2 = 0.33)	6.99 ($p = 0.002$) (biasη2 = 0.21)
	Waitlist	60.95 (2.96)	59.91 (5.56)	60.56 (3.89)		
SAS[h]	CBT-P	62.69 (5.86)	57.22 (6.36)	58.24 (6.89)	20.20 (p < 0.001) (biasη2 = 0.43)	27.61 ($p < 0.001$) (biasη2 = 0.51)
	Waitlist	62.03 (5.84)	62.41 (7.00)	62.07 (5.60)		

[a]CM, Concern over Mistakes subscale of Frost Multidimensional Perfectionism Scale.
[b]PS, Personal Standards subscale of Frost Multidimensional Perfectionism Scale.
[c]PE, Parental Expectation subscale of Frost Multidimensional Perfectionism Scale.
[d]PC, Parental Criticism subscale of Frost Multidimensional Perfectionism Scale.
[e]DA, Doubts about Actions subscale of Frost Multidimensional Perfectionism Scale.
[f]MFMPS, maladaptive aspects of Frost Multidimensional Perfectionism Scale, consist of four subscales (CM, DA, PC, PE).
[g]SDS, Self-rating Depression Scale.
[h]SAS, Self-rating Anxiety Scale.
[i]CBT-P, CBT with positive psychotherapy.

with a high negative correlation to psychiatric symptoms were targeted. Participants changed for the following reasons at post-intervention and follow-up. They had the opportunity to view unreasonable demands or expectations for each other. The negative influence of perfectionism was clearly defined with a focus on difficulty making a decision, procrastination habits, feelings of frustration, feelings of insecurity, low self-evaluation, fear of failure, etc. By intervening in these aspects, automatic thinking caused negative reactions to be discovered and perceived. Behavior experiments were used to challenge rigid perfect beliefs acting as trustful faith. Intermediate beliefs with maladaptive perfectionism were identified and changed. An alternative adaptive belief was delivered to participants through cognitive restructuring: reacting according to the actual present situation rather than a kind of rigid pattern. Training for procrastination because of avoidance behavior and fear of failure was provided to explore the influence of family members and to increase self-acceptance. Then, their own advantages and strengths could be used to recognize themselves, enhance their confidence and determination, and cultivate positive thinking habits.

When the effect of the intervention was evaluated, we not only compared whether the difference between the intervention group and the waitlist group was significant at baseline, post-intervention, and follow-up but also added effect size indicators, excluding the influence of sample size in this study. Group CBT is an appealing psychological intervention given its potential cost- and time-effectiveness for treating many patients and is viewed as less cost-effective and as more cost-effective than individual CBT (Okumura and Ichikura, 2014).

The deficiencies of this study were as follows. The sample size was just approaching the minimal demand. The change in perfectionism was a gradual process and some participants would have graduated after 8 weeks of intervention, follow-up in this study was at 8 weeks. The effect sizes were maintained with a declining trend and it is necessary to design more long-term and better intervention protocols for maladaptive perfectionism. The participants were selected by the critical scores of the MFMPS, SDS, and SAS scales but were not diagnosed by DSM-V. Those who volunteered to participate might have higher motivation to change. As stated before, perfect thinking and behavior patterns are born in the personality dimensions of maladapted perfectionists, and they are long-term and habitual. Perfectionists may show resistance to change, and the relevant psychiatric symptoms easily relapse. A short-term intervention of 8 weeks may produce a preliminary change in a nonclinical sample, and the validity of the results will not generalize to clinical samples. The intervention will focus on high perfectionist tendencies and clinical samples with diagnoses in the future. If perfectionism is a maintaining mechanism of AXIS I Disorders in DSM-V, then it is more effective to aim at perfectionism, but more research is needed in the future. Finally, despite the intervention being manualized and supervised, treatment adherence measures were not used; thus, it is not known the extent to which therapists adhered to the treatment protocol.

TABLE 3 Between-group effect sizes at baseline (T1), post-intervention (T2), and 8-week follow-up (T3).

	Baseline			Post-intervention			Follow-up		
	t	*p*	Cohen's *d*	*t*	*p*	Cohen's *d*	*t*	*p*	Cohen's *d*
CM									
CBT-P vs. Waitlist	0.37	0.713	0.10	−3.61	< 0.001	−0.96	−2.34	0.023	−0.63
PS									
CBT-P vs. Waitlist	0.40	0.689	0.11	0.65	0.519	0.17	0.07	0.948	0.02
PE									
CBT-P vs. Waitlist	−0.68	0.502	−0.18	−0.88	0.381	−0.24	−1.17	0.247	−0.31
PC									
CBT-P vs. Waitlist	0.40	0.693	0.11	−0.66	0.515	−0.18	−0.41	0.684	−0.11
DA									
CBT-P vs. Waitlist	0.63	0.50	0.17	−2.83	0.007	−0.76	−2.19	0.033	−0.59
MFMPS									
CBT-P vs. Waitlist	0.24	0.812	0.06	−3.35	0.001	−0.90	−2.50	0.015	−0.67
SDS									
CBT-P vs. Waitlist	−0.72	0.477	−0.19	−2.77	0.008	−0.74	−2.99	0.004	−0.80
SAS									
CBT-P vs. Waitlist	0.42	0.675	0.11	−2.90	0.005	−0.78	−2.29	0.026	−0.61

TABLE 4 Within-Groups effect size at baseline (T1), post-intervention (T2) and 8-week follow-up (T3) in the intervention group and waitlist group.

	Baseline to post-intervention			Post-intervention to follow-up			Baseline to follow-up		
	t	*p*	Cohen's *d*	*t*	*p*	Cohen's *d*	*t*	*p*	Cohen's *d*
CM									
CBT-P	5.73	<0.001	1.10	−2.74	0.011	−0.53	5.63	<0.001	1.08
Waitlist	−1.05	0.303	−0.20	1.16	0.255	0.22	−0.50	0.621	−0.09
PS									
CBT-P	1.03	0.311	0.20	0.95	0.352	0.18	2.01	0.055	0.39
Waitlist	1.30	0.204	0.24	−1.28	0.210	−0.24	0.58	0.565	0.11
PE									
CBT-P	1.72	0.097	0.33	−0.21	0.839	−0.04	2.02	0.054	0.39
Waitlist	0.65	0.520	0.12	−1.41	0.169	−0.26	−0.25	0.805	−0.05
PC									
CBT-P	1.73	0.095	0.33	−1.04	0.306	−0.20	1.07	0.294	0.21
Waitlist	−0.99	0.330	−0.18	0.00	1.000	0.00	−1.46	0.155	−0.27
DA									
CBT-P	3.97	<0.001	0.76	−2.73	0.011	−0.53	3.45	0.002	0.66
Waitlist	−0.48	0.638	−0.09	−0.15	0.882	−0.03	−0.74	0.467	−0.14
MFMPS									
CBT-P	6.83	<0.001	1.32	−3.55	0.001	−0.68	6.78	<0.001	1.30
Waitlist	−1.27	0.216	−0.24	0.33	0.741	0.06	−1.68	0.103	−0.31
SDS									
CBT-P	6.02	<0.001	1.16	−2.98	0.006	−0.57	5.03	<0.001	097
Waitlist	1.26	0.217	0.24	−1.12	0.272	−0.21	0.85	0.402	0.16
SAS									
CBT-P	7.63	<0.001	1.47	−3.18	0.004	−0.61	5.68	<0.001	1.09
Waitlist	−1.04	0.307	−0.19	0.79	0.438	0.15	0.10	0.924	−0.02

The strengths of the study are that it is the first RCT with adequate power to check the effectiveness and prognosis of group CBT with positive psychotherapy in targeting core underlying factors such as perfectionism rather than disorder-specific symptoms. The results contribute further evidence of a transdiagnostic effect of group CBT with positive psychotherapy for perfectionism, with significant reductions in depression and anxiety (Shafran et al., 2017).

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Ethics statement

Ethical review and approval was not required for the study on human participants in accordance with the local legislation and institutional requirements. The patients/participants provided their written informed consent to participate in this study.

Author contributions

ZZ conducted the data collection, data analysis, and data curation and wrote the original draft. XZ wrote, reviewed and edited the manuscript. All authors drafted the methodology and conceptualized the aims. All authors approved the submitted version.

Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

All claims expressed in this article are solely those of the authors and do not necessarily represent those of their affiliated organizations, or those of the publisher, the editors and the reviewers. Any product that may be evaluated in this article, or claim that may be made by its manufacturer, is not guaranteed or endorsed by the publisher.

References

Arana, F. G., Miracco, M. C., Galarregui, M. S., and Keegan, E. G. (2017). A brief cognitive Behavioural intervention for maladaptive perfectionism in students: a pilot study. *Behav. Cogn. Psychother.* 45, 537–542. doi: 10.1017/S1352465817000406

Basco, M. R. (2000). *Never good enough: How to use perfectionism to your advantage without letting it ruin your life*. New York: Shanghai Translation Publishing House; Free Press.

Beck, S. J. (2013). *Cognitive behavior therapy: Basics and beyond* (*2nd*). Willawong: China Light Industry Press Ltd.

Bento, C., Pereira, A. T., Roque, C., Tavares Saraiva, J. M., and Ferreira Macedo E Santos, A. J. (2017). Longitudinal effects of an intervention on perfectionism in adolescents. *Psicothema* 29, 317–322. doi: 10.7334/psicothema2016.223

Bieling, P. J., Israeli, A. L., and Antony, M. M. (2004). Is perfectionism good, bad, or both? Examining models of the perfectionism construct. *Pers. Individ. Differ.* 36, 1373–1385. doi: 10.1016/S0191-8869(03)00235-6

Cheng, S. K., Chong, G. H., and Wong, C. W. (1999). Chinese Frost multidimensional perfectionism scale: a validation and prediction of self-esteem and psychological distress. *J. Clin. Psychol.* 55, 1051–1061. doi: 10.1002/(sici)1097-4679(199909)55:9<1051::aid-jclp3>3.0.co;2-1

DiBartolo, P. M., and Rendón, M. J. (2012). A critical examination of the construct of perfectionism and its relationship to mental health in Asian and African Americans using a cross-cultural framework. *Clin. Psychol. Rev.* 32, 139–152. doi: 10.1016/j.cpr.2011.09.007

Egan, S. J., and Hine, P. (2008). Cognitive Behavioural treatment of perfectionism: a single case experimental design series. *Behav. Chang.* 25, 245–258. doi: 10.1375/bech.25.4.245

Fong, R. W., and Yuen, M. (2011). Perfectionism in Chinese elementary school students: validation of the Chinese adaptive/maladaptive perfectionism scale. *Talent Dev. Excell.* 3, 203–213.

Frost, R. O., Marten, P., Lahart, C., and Rosenblate, R. (1990). The dimensions of perfectionism. *Cogn. Ther. Res.* 14, 449–468. doi: 10.1007/BF01172967

Furchtlehner, L. M., Schuster, R., and Laireiter, A.-R. (2020). A comparative study of the efficacy of group positive psychotherapy and group cognitive behavioral therapy in the treatment of depressive disorders: a randomized controlled trial. *J. Posit. Psychol.* 15, 832–845. doi: 10.1080/17439760.2019.1663250

Gäde, J. C., Schermelleh-Engel, K., and Klein, A. G. (2017). Disentangling the common variance of perfectionistic strivings and perfectionistic concerns: a Bifactor model of perfectionism. *Front. Psychol.* 8:160. doi: 10.3389/fpsyg.2017.00160

Galloway, R., Watson, H., Greene, D., Shafran, R., and Egan, S. J. (2022). The efficacy of randomised controlled trials of cognitive behaviour therapy for perfectionism: a systematic review and meta-analysis. *Cogn. Behav. Ther.* 51, 170–184. doi: 10.1080/16506073.2021.1952302

Gaudiano, B. A. (2005). Cognitive behavior therapies for psychotic disorders: current empirical status and future directions. *Clin. Psychol. Sci. Pract.* 12, 33–50. doi: 10.1093/clipsy.bpi004

Grzegorek, J. L., Slaney, R. B., Franze, S., and Rice, K. G. (2004). Self-criticism, dependency, self-esteem, and grade point average satisfaction among clusters of perfectionists and nonperfectionists. *J. Couns. Psychol.* 51, 192–200. doi: 10.1037/0022-0167.51.2.192

Guo, J. (2019). Study on the intervention effect of house-tree-person technique on the anxiety of the newly involved prisoners (Unpublished master's thesis). Zhejiang University.

Handley, A. K., Egan, S. J., Kane, R. T., and Rees, C. S. (2015). A randomized controlled trial of group cognitive behavioural therapy for perfectionism. *Behav. Res. Ther.* 68, 37–47. doi: 10.1016/j.brat.2015.02.006

Hewitt, P.L., Flett, G.L., and Mikail, S.F. (2017). *Perfectionism: conceptualization, assessment, and treatment*. New York, NY: Guilford.

Limburg, K., Watson, H. J., Hagger, M. S., and Egan, S. J. (2017). The relationship between perfectionism and psychopathology: a Meta-analysis. *J. Clin. Psychol.* 73, 1301–1326. doi: 10.1002/jclp.22435

Liu, R. M. (2015). On relationship between junior high school Students' perfectionism and test anxiety and the effect of targeted group counseling interventions experiments (Unpublished master's thesis). Hebei Normal University.

Lloyd, S., Schmidt, U., Khondoker, M., and Tchanturia, K. (2015). Can psychological interventions reduce perfectionism? A systematic review and Meta-analysis. *Behav. Cogn. Psychother.* 43, 705–731. doi: 10.1017/S1352465814000162

Lo, A., and Abbott, M. J. (2013). Review of the theoretical, empirical, and clinical status of adaptive and maladaptive perfectionism. *Behav. Chang.* 30, 96–116. doi: 10.1017/bec.2013.9

Matos, M., and Steindl, S. R. (2020). "You are already all you need to be": a case illustration of compassion-focused therapy for shame and perfectionism. *J. Clin. Psychol.* 76, 2079–2096. doi: 10.1002/jclp.23055

Mitchell, J. H., Newall, C., Broeren, S., and Hudson, J. L. (2013). The role of perfectionism in cognitive behaviour therapy outcomes for clinically anxious children. *Behav. Res. Ther.* 51, 547–554. doi: 10.1016/j.brat.2013.05.015

Moloud, R., Saeed, Y., Mahmonir, H., and Rasool, G. A. (2022). Cognitive-behavioral group therapy in major depressive disorder with focus on self-esteem and op.Timism: an interventional study. *BMC Psychiatry* 22:299. doi: 10.1186/s12888-022-03918-y

Okumura, Y., and Ichikura, K. (2014). Efficacy and acceptability of group cognitive behavioral therapy for depression: a systematic review and meta-analysis. *J. Affect. Disord.* 164, 155–164. doi: 10.1016/j.jad.2014.04.023

Ong, C. W., Lee, E. B., Krafft, J., Terry, C. L., Barrett, T. S., Levin, M. E., et al. (2019). A randomized controlled trial of acceptance and commitment therapy for clinical perfectionism. *J. Obsess. Compul. Relat. Disord.* 22:100444. doi: 10.1016/j.jocrd.2019.100444

Rhéaume, J., Freeston, M. H., Ladouceur, R., Bouchard, C., Gallant, L., Talbot, F., et al. (2000). Functional and dysfunctional perfectionists: are they different on compulsive-like behaviors? *Behav. Res. Ther.* 38, 119–128. doi: 10.1016/s0005-7967(98)00203-4

Shafran, R., Wade, T., Egan, S., Kothari, R., Allcott-Watson, H., Carlbring, P., et al. (2017). Is the devil in the detail? A randomized controlled trial of guided internet based CBT for perfectionism. *Behav. Res. Ther.* 95, 99–106. doi: 10.1016/j.brat.2017.05.014

Slade, P. D., Coppel, D. B., and Townes, B. D. (2009). Neurocognitive correlates of positive and negative perfectionism. *Int. J. Neurosci.* 119, 1741–1754. doi: 10.1080/00207450902915212

Steele, A. L., Waite, S., Egan, S. J., Finnigan, J., Handley, A., and Wade, T. D. (2013). Psycho-education and group cognitive-Behavioural therapy for clinical perfectionism: a case-series evaluation. *Behav. Cogn. Psychother.* 41, 129–143. doi: 10.1017/S1352465812000628

Stoeber, J., and Otto, K. (2006). Positive conceptions of perfectionism: approaches, evidence challenges. *Pers. Soc. Psychol. Rev.* 10, 295–319. doi: 10.1207/s15327957pspr1004_2

Thi Thuy Ta. (2019). The relationship between gratitude and depression: the parallel mediating effect of coping style. (Unpublished master's thesis), Nanjing University.

Wade, T. D., Kay, E., Valle, M. K., Egan, S. J., Andersson, G., Carlbring, P., et al. (2019). Internet-based cognitive behaviour therapy for perfectionism: more is better but no need to be prescriptive. *Clin. Psychol.* 23, 196–205. doi: 10.1111/cp.12193

Wang, Y. (2019). A study on the relationship among perfectionism, rumination, resilience and psychological security of university students and the intervention research. (Unpublished master's thesis). Qufu Normal University.

Wang, K. T., Slaney, R. B., and Rice, K. G. (2007). Perfectionism in Chinese university students from Taiwan: a study of psychological well-being and achievement motivation. *Personal. Individ. Differ.* 42, 1279–1290. doi: 10.1016/j.paid.2006.10.006

Xu, X. F. (2019). A study on the relationship among perfectionism, self-efficacy, procrastination of university students and the intervention research of procrastination (Unpublished master's thesis). Hebei Normal University.

Yang, Z. P. (2010). Operating guide for group activity of positive psychology orientation. *China Machine Press* 157-167, 313–329.

Yang, L., Li, J., Liang, B., and Li, Y. (2010). Researches about the classification of people based on perfectionism. *Stud. Psychol. Behav.* 8, 155–160.

Yin, X., Liu, Y. C., Zhang, H. P., and Tu, W. T. (2022). Parental expectation deviation and educational anxiety. *Youth Stud.* 442:40–48+95.

Yu, C. H. (2012). Study on the Sandplay production characteristics of Collge students of perfectionism and case intervention. (Unpublished master's thesis). Liaoning Normal University.

Zeng, Y. (2018). The relationships and intervention of perfectionism, rumination with anxiety of preschool children's mothers. (Unpublished master's thesis). Zhejiang University.

Zhang, B., Wang, Y. Y., He, D. T., and Cai, T. S. (2010). Perfectionism and cognitive-behavioral therapy. *Med. Philos.* 31, 37–39.

Zhao, L., and Wang, H. (2019). Procedure of power analysis and a multilevel analysis example. *Psychol. Techn. Appl.* 7, 276–283. doi: 10.16842/j.cnki.issn2095-5588.2019.05.002

Zheng, S. (2014). A study on the relationship and intervention between perfectionism, self-esteem and academic procrastination among university students (Unpublished master's thesis). Jiangxi Normal University.

Zhu, T. T. (2014). The research of relationships among rumination, perfectionism and depression and it's intervention in university students (Unpublished master's thesis). Minnan Normal University.

Zi, F., and Zhou, X. (2006). The Chinese Frost multidimensional perfectionism scale: an examination of its reliability and validity. *Chin. J. Clin. Psych.* 14, 560–563.

frontiers | Frontiers in Public Health

TYPE Systematic Review
PUBLISHED 31 August 2023
DOI 10.3389/fpubh.2023.1201552

OPEN ACCESS

EDITED BY
Lara Guedes De Pinho,
University of Evora, Portugal

REVIEWED BY
Naseem Akhtar Qureshi,
Al-Falah University, India
Manuel Lopes,
University of Evora, Portugal

*CORRESPONDENCE
Maija Saijonkari
✉ maija.saijonkari@uef.fi

RECEIVED 06 April 2023
ACCEPTED 14 August 2023
PUBLISHED 31 August 2023

CITATION
Saijonkari M, Paronen E, Lakka T, Tolmunen T, Linnosmaa I, Lammintakanen J, Isotalo J, Rekola H and Mäki-Opas T (2023) Promotive and preventive interventions for mental health and well-being in adult populations: a systematic umbrella review.
Front. Public Health 11:1201552.
doi: 10.3389/fpubh.2023.1201552

Promotive and preventive interventions for mental health and well-being in adult populations: a systematic umbrella review

Maija Saijonkari[1]*, Elsa Paronen[1], Timo Lakka[2,3,4], Tommi Tolmunen[5], Ismo Linnosmaa[1,6], Johanna Lammintakanen[1], Jenni Isotalo[1], Hanna Rekola[7] and Tomi Mäki-Opas[7,8]

[1]Department of Health and Social Management, University of Eastern Finland, Kuopio, Finland, [2]Institute of Biomedicine, School of Medicine, University of Eastern Finland, Kuopio, Finland, [3]Department of Clinical Physiology and Nuclear Medicine, Kuopio University Hospital, Kuopio, Finland, [4]Foundation for Research in Health Exercise and Nutrition, Kuopio Research Institute of Exercise Medicine, Kuopio, Finland, [5]Kuopio University Hospital, Kuopio, Finland, [6]Department of Public Health and Welfare, National Institute for Health and Welfare, Helsinki, Finland, [7]Department of Social Sciences, University of Eastern Finland, Kuopio, Finland, [8]Wellbeing Services Research Center, North Savo Wellbeing Services County, Kuopio, Finland

Introduction: Mental health disorders are increasing worldwide, leading to significant personal, economic, and social consequences. Mental health promotion and prevention have been the subject of many systematic reviews. Thus, decision makers likely face the problem of going through literature to find and utilize the best available evidence. Therefore, this systematic umbrella review aims to evaluate the effectiveness of interventions for promoting mental health and mental well-being, as well as for the primary prevention of mental health disorders.

Methods: Literature searches were performed in APA PsycInfo, Medline, and Proquest Social Science databases from January 2000 to December 2021. The search results were screened for eligibility using pre-defined criteria. The methodological quality of the included reviews was evaluated using the AMSTAR 2 tool. The key findings of the included reviews were narratively synthesized and reported with an emphasis on reviews achieving higher methodological quality.

Results: Out of the 240 articles found, 16 systematic reviews and four systematic umbrella reviews were included. The methodological quality of included reviews was low or critically low.

Discussion: This review suggests that interventions using cognitive-behavioral therapy and those developing resilience, mindfulness, or healthy lifestyles can be effective in the promotion of mental health and well-being in adult populations. Motivational interviewing may reduce alcohol consumption in young adults. Indicated or selective prevention is likely to be cost-effective compared to universal prevention. Parenting interventions and workplace interventions may be cost-effective in terms of promoting mental health. Due to the low methodological quality of the included reviews and substantial heterogeneity among the reported results, the findings from the reviews we summarized should be interpreted with caution. There is a need for further rigorous, high-quality systematic reviews.

10.3389/fpubh.2023.1201552

KEYWORDS

mental health, mental wellbeing, alcohol, promotion, prevention, cognitive behavioral therapy, effectiveness, healthy lifestyle

1. Introduction

Mental health is defined by the World Health Organization (WHO) as "a state of mental well-being that enables people to cope with the stresses of life, realize their abilities, learn well and work well, and contribute to their community" (1). WHO also states that "mental health is an integral component of health and well-being and is more than the absence of mental disorder" (1). Mental health disorders, which also include substance addictions, are increasing worldwide, and have significant human, economic, and social consequences (2). Although mental problems affect every social class, some disadvantaged groups are particularly vulnerable to them (3). These groups, by definition, are lacking basic resources or conditions necessary for an equal position in society (4).

The COVID-19 crisis has affected negatively the already burdening mental health situation (5). In its recent report (5), the Organization for Economic Co-operation and Development (OECD) stressed the urgent need for integrated, mental health support encompassing the whole of society and identified access to evidence-based mental health promotion programs as one priority. Mental health promotion often refers to interventions aimed at improving positive mental health and well-being, that strengthen and protect mental health and may also prevent mental health disorders (6). Prevention of mental disorders, on the other hand, focuses on the causes and risk factors of mental health disorders. It can be defined as primary, secondary, or tertiary prevention depending on whether the strategy aims at (i) preventing the onset of symptoms or disorder, (ii) reducing the prevalence of the disorder or (iii) reducing the severity, course or duration of the disorder and associated disability, respectively (6). Primary prevention activities can be designed as (i) universal (for the general population), (ii) selective (for high-risk groups), or (iii) indicated (for high-risk individuals displaying symptoms of illness but not meeting full diagnostic criteria) (6–9). The promotion of positive mental health and the primary prevention are overlapping and complementary activities that can be present within the same program (6).

When implementing new approaches for mental health and well-being it is important to prioritize the delivery of effective interventions (10). It is also important to understand for whom the intervention works and under what conditions, to be able to embed new interventions in normal activities and practices in a sustainable way (11, 12).

Mental health promotion and prevention have been the subject of many systematic reviews. Thus, decision makers likely face the problem of going through literature to find and utilize the best available evidence. Some scoping reviews have mapped the body of literature concerning mental health promotion and prevention (13, 14), but comprehensive umbrella reviews for this topic are scarce. Hence, a summary of existing research syntheses related to mental health promotion and prevention interventions for the adult population is needed. The aim of this systematic umbrella review was to evaluate the effectiveness of intervention approaches among adult populations aged 18–64 for:

- Promoting mental health and mental well-being, as well as,
- Primary prevention of mental health disorders, including substance abuse problems.

In addition, we aimed to identify the cost-effectiveness of the interventions as well as factors contributing to the effectiveness of the interventions.

2. Methods

This study employed the Joanna Briggs Institute (JBI) umbrella review method (also called review of reviews, overview of reviews), which is an established way of bringing together and summarizing a broad evidence-base utilizing all types of syntheses of research evidence (15). An umbrella review provides a summary of existing research syntheses related to a given topic and does not re-synthesize the results of existing reviews with meta-analysis or meta-synthesis (15). This review was carried out and reported using the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) guideline (16). A completed PRISMA checklist is included in Supplementary Table S1 in the online supplementary materials.

2.1. Search strategy

Literature searches (Table 1) were performed in cooperation with social and health sciences information specialist in three databases, APA PsycInfo, Medline, and ProQuest Social Sciences. The keywords used in the searches were: "mental health," "wellbeing" "well-being," "psych* well-being," "mental illness," "substance abuse," "alcohol," "tobacco," "drug*," "promot*," "prevent*," "intervention," "program." Search limiters that were used (when available) included systematic reviews published between January 2000 to December 2021, and human studies.

In addition, articles identified through relevant reviews were also considered, and the reference lists of the selected articles were checked to identify publications that might not have been found in the search.

2.2. Study selection and quality appraisal

The title and abstract of articles as well as the full text of potentially relevant articles were screened against pre-defined eligibility criteria (Table 2) by two independent reviewers (MS, JI). Consensus on article inclusion was reached via discussion.

Following the criteria of the Database of Abstracts of Reviews of Effects (DARE), used in previous umbrella reviews (17, 18), a review

TABLE 1 Search strategy.

Database	Search strategy	Search result
APA PsycInfo (EBSCOhost)	S1: TI ("mental health" OR "psych* well-being") AND TI promot* AND (program OR intervention) Limiters - Publication Year: 1950–2021, Methodology: meta-analysis or systematic review or literature review.	
	S2: TI ("mental health" OR "psych* well-being") AND TI promot* AND (program OR intervention) AND TI review* Limiters - Publication Year: 1950–2021.	
	S1 OR S2 Limiters – Publication Year: 2000–2021	66
Social Sciences (ProQuest)	S1: ti ("mental health" OR "psych* well-being") AND ti (promot*) AND noft (program OR intervention). Limiters: ("Literature Review" OR "Review" OR "Evidence Based Healthcare") AND PEER(yes)	
	S2: ti("mental health" OR "psych* well-being") AND ti(promot*) AND noft(program OR intervention). Limiters: ("Literature Review" OR "Review" OR "Evidence Based Healthcare") AND PEER(yes)	
	S1 OR S2 Limiters applied: 2000–2021	29
Pubmed (Medline)	("mental health"[Title] OR "psychological well-being"[Title]) AND promot*[Title] AND (program OR intervention) Filters: Meta-Analysis, Review, Systematic Review, Humans, from 2000–2021	103
	("mental illness"[Title] OR "substance abuse"[Title] OR alcohol[Title] OR tobacco[Title] OR drug*[Title]) AND (prevent*[Title]) AND (program[Title] OR intervention[Title]) Filters: Meta-Analysis, Review, Systematic Review, Humans, from 2000–2021	25
		Total 230

TABLE 2 Inclusion and exclusion criteria.

	Inclusion criteria	Exclusion criteria
Population	Non-clinical population	A specific group of patients (e.g., mental health promotion among cancer patients).
	Aged 18–64 years (majority of study participants).	–
Intervention	Promotion of mental health or mental wellbeing or primary prevention of mental health disorder or substance abuse.	Treatment of mental health disorder or substance abuse.
Comparison	Systematic review included mainly studies with controls; any alternative approach to support mental health, or no intervention.	–
Outcome	Any measurable indicator of mental health, mental wellbeing or substance use/ substance use habits.	-
	Success factor or cost data of the intervention.	
Setting	Community (not health care units)	Health services unit
	Western countries (Europe, United States, Canada, Australia, New Zealand)	Non-Western countries
Follow-up	At least one month	Less than one month follow-up
Publication time	2000–2021	–

was deemed systematic if it fulfilled four of the following five criteria with Criteria 1–3 being mandatory: (1) Were inclusion/exclusion criteria reported? (2) Was the search adequate? (3) Were the included studies synthesized? (4) Was the quality of the included studies assessed? (5) Are sufficient details about the individual included studies presented?

An umbrella review was included in this review if it reported the effectiveness of the interventions studied. Otherwise, it was used as a reference source. A review that was already included in one of the umbrella reviews was excluded from this review to avoid giving it too much weight. No separate search was conducted on costs or cost-effectiveness of the interventions and factors contributing to the success of the intervention, but any reported information was collected from studies found in our literature search.

The methodological quality of the included reviews was appraised using the AMSTAR 2 tool (A MeaSurement Tool to Assess systematic Reviews) (19), which has proven its reliability and validity for systematic reviews that include both randomized and observational studies. One reviewer (MS) evaluated the included articles. Another reviewer (JI) independently evaluated five (23%) of the articles for quality control. Discrepancies were resolved by consensus. Inter-rater reliability was calculated with percentage of agreement between reviewers.

2.3. Data extraction and synthesis

The following data were extracted from the included reviews: title, study type, amount, and type of included studies, population,

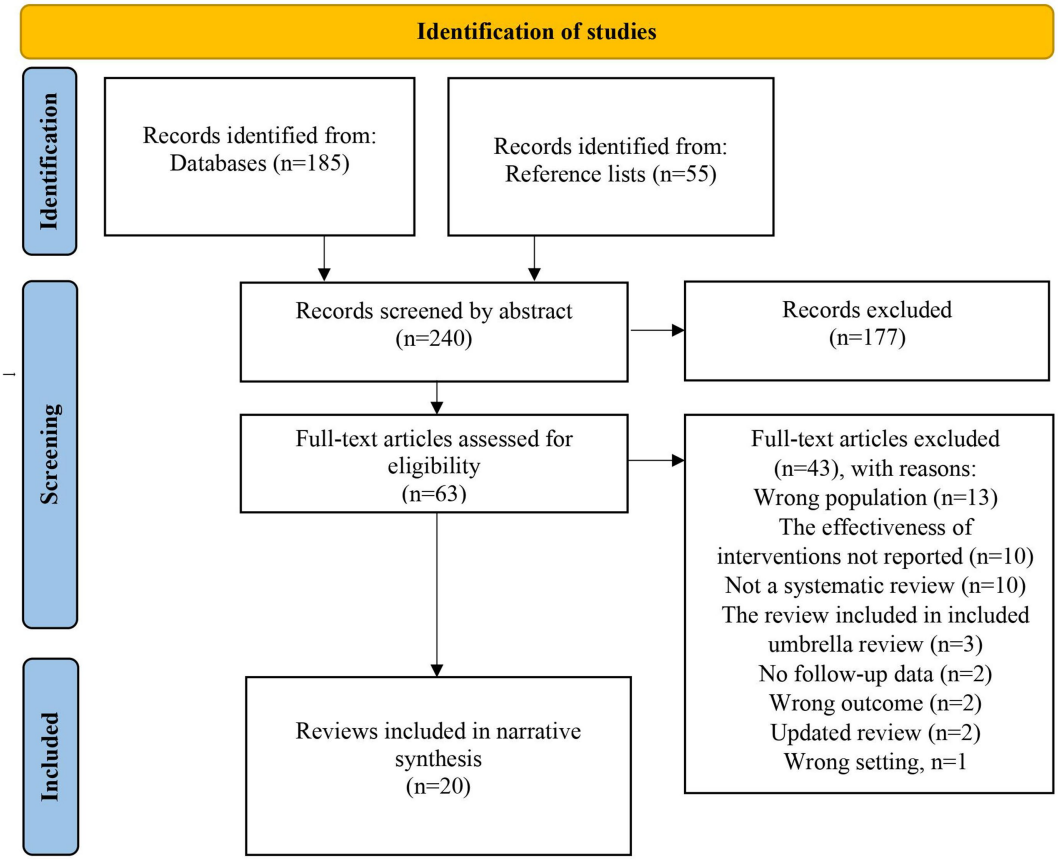


FIGURE 1
Flow chart of the process of identifying and selecting studies (16).

intervention, main findings relevant to this review (data on mental health, mental well-being, substance use/substance use habits of the study participants, or success factors or cost data of the interventions), time of searches, and funding sources. Data was extracted and tabulated by one reviewer (MS) and checked in full by another (JI).

Key findings of included reviews were narratively synthetized by population type with evidence from higher methodological quality reviews reported in greater detail (15).

3. Results

Literature searches yielded 240 papers of which 63 were read in full text. Of these, 43 articles were excluded (Supplementary Table S2 in the online supplementary materials) for reasons outlined in the PRISMA flow chart in Figure 1. Consequently, 20 articles (20–39) were included (see Figure 1 for PRISMA flowchart and details).

3.1. Description of included reviews

The included reviews consisted of four systematic umbrella reviews (29–32) and 16 systematic reviews (20–28, 33–39). Seven of the reviews performed a meta-analysis (20, 21, 25, 33, 35–37). Of these 20 reviews, 18 addressed the effectiveness of mental health promotive and preventive interventions (20–23, 25–38), one the cost-effectiveness of such interventions (24), and one the effectiveness and cost-effectiveness of such interventions (39).

3.2. Quality of included reviews

Critical appraisal using the AMSTAR 2 criteria (Supplementary Table S3) revealed one weakness out of the seven possible critical domains for nine reviews (20, 21, 24, 28, 33, 34, 36, 37, 39) meaning their methodological quality was low. Five reviews had two (22, 23, 27, 29, 30), four had three (25, 26, 31, 38) and two had four (32, 35) weaknesses in critical domains, pointing toward critically low methodological quality. The agreement between reviewers concerning five articles assessed in duplicate was 95%.

Across reviews, there were no or only slight weaknesses regarding the comprehensiveness of the literature search strategy (domain 4) (Supplementary Table S3). Regarding the appropriateness of risk of bias assessment (domain 9), 16 reviews had no weaknesses (20–30, 33, 34, 36, 37, 39). On the contrary, only two reviews had no weaknesses regarding the reporting of excluded studies (domain 7) (20, 28) and eight reviews regarding *a priori* design (domain 2) (20, 21, 24, 28, 33, 34, 36, 37, 39). Critical domains 11 and 15 concerning statistical methods and publication bias, respectively, were not relevant in 13

TABLE 3 Characteristics and main findings of included reviews concerning interventions for young adults.

Publication; Study type; Amount and type of included studies (Search's time span)	Target group	Intervention(s) reviewed	Main findings	Overall methodological quality rating; Weaknesses in critical domains	Funding sources of the review
Dawson, 2020 (36) systematic review and meta-analysis $k = 40$; RCTs (Until March 2017)	University students	Mindfulness-based interventions (MBI)	SMD −0.32; 95% CI −0.50 to −0.13; $p = 0.0007$ for distress and SMD 0.53; 0.33 to 0.73; $p < 0.00001$ for MBI compared to passive controls at three months follow-up. Compared to active control groups (e.g., relaxation or self-awareness strategies), no follow-up data available. The low methodological quality of most of the included trials precludes making firm recommendations for practice, and the variability of the effects means that some students in some contexts may not benefit from MBIs.	12; 1	NR
Lo, 2018 (25) systematic review and meta-analysis $k = 24$; RCTs (Until April 2016)	Health profession students	Group interventions designed to enhance/ maintain mental health	CBT interventions reduced anxiety (SMD −0.26; 95% CI −0.5 to −0.02), depression (SMD −0.29; 95% CI −0.52 to −0.05) and stress (SMD 0.37; 95% CI −0.61 to −0.13). Mindfulness strategies reduced stress (SMD −0.60; 95% CI 0.97 to −0.22) but not anxiety (95% CI −0.21 to 0.18), depression (95% CI −0.36 to 0.03) or burnout (95% CI −0.36 to 0.10). Relaxation strategies reduced anxiety (SMD -0.80; 95% CI −1.03 to −0.58), depression (SMD −0.49; 95% CI −0.88 to −0.11) and stress (SMD −0.34; 95% CI −0.67 to −0.01). Method quality was generally poor.	10; 3	NR
Clarke, 2015 (34) systematic review $k = 28$; RCTs and quasi-experimental studies (Jan. 2000–June 2013)	Youth (majority over 18 years of age)	Online Youth Mental Health Promotion and Prevention Interventions	The evidence regarding mental health promotion gaming interventions is weak, as a result of the absence of a control group and high dropout rates in the two studies reviewed. Online prevention interventions: promising evidence regarding computerized CBT interventions and their impact on emerging adults' anxiety and depression symptoms.	9; 1	Inspire Ireland Foundation and Young and Well Cooperative Research Centre, Australia.
Conley, 2015 (35) systematic review and meta-analysis $k = 90$; RCTs, quasi-experimental (Until Dec. 2012)	Higher Education Students	Universal mental health promotion interventions	Interventions with supervised skills practice: a significant positive effect at follow-up (median 12 weeks) (ES = 0.28, CI = 0.16 to 0.40; $k = 16$), whereas psychoeducational interventions did not (ES = 0.08, CI = −0.04 to 0.21; $k = 10$). The mean ES for the four studies of skills-training interventions without supervised practice was not significant at follow-up (ES = 0.13, CI = −0.14 to 0.39).	4; 4	Loyola University Chicago
Sandler, 2014 (31) review of meta-analytic reviews $k = 4$ relevant reviews (of total of 48 reviews) (2000–2013)	College students up to age of 26	Prevention and promotion programs to prevent alcohol use	Motivational interviewing, blood alcohol content education, normative comparison, and feedback on consumption: small, significant effects on alcohol use and alcohol-related problems at short-term follow-up. Significant effect on frequency of drinking days and alcohol-related problems up to four years after intervention. Heterogeneous effects on alcohol-related problems at short-term follow-up, other effects homogeneous. Face-to-face interventions: small, significant effect on alcohol use at three- and six-month follow-ups. Motivational interviewing and personalized feedback for heavy drinkers: large significant effects on alcohol consumption and alcohol problems one year after participation. The effects for both outcomes were heterogeneous. Meta-analysis of 14 trials of programs that challenged alcohol expectancies: small, significant effects at post-test, but the effects were non-significant at follow-ups greater than a month.	5; 3	NR

CBT, cognitive behavioral therapy; CI, confidential index; *k*, number of studies; NR, not reported; RCT, randomized controlled trial; SMD, standard mean difference.

reviews that did not perform a meta-analysis (22–24, 26–32, 34, 38, 39).

3.3. The effectiveness of interventions

Of the 19 reviews addressing the effectiveness of the interventions, five covered young adults (aged 18–25 years) (25, 31, 34–36), one parents and families (20), five employees at work-places (21, 28–30, 32), two disadvantaged groups (22, 38), and six the general adult population (23, 26, 27, 33, 37, 39). A meta-analysis was performed in seven of these reviews (20, 21, 25, 33, 35–37).

3.3.1. Interventions for young adults

We identified four systematic reviews (25, 34–36) and one umbrella review (31) on the impact of mental health promotion and prevention interventions for young adults aged 18–25 years (Table 3).

Dawson et al. (36) included 40 randomized controlled trials (RCTs) of mindfulness-based interventions for university students and found a small but statistically significant effect on distress and a moderate effect on mindfulness compared to no intervention over

TABLE 4 Characteristics and main findings of included reviews concerning interventions for parents and families.

Publication; Study type; Amount and type of included studies (Search's time span)	Target group	Intervention(s) reviewed	Main findings	Overall methodological quality rating; Weaknesses in critical domains	Funding sources of the review
Barlow, 2014 (20) systematic review and meta-analysis $k = 48$; RCTs (Until 2011)	Parents	Group-based behavioral, cognitive-behavioral or multi-modal parenting program	Statistically significant short-term (2–6 months) improvements in parental depression (standardized mean difference (SMD) -0.17, 95% confidence interval (CI) −0.28 to −0.07), anxiety (SMD −0.22, 95% CI −0.43 to −0.01), stress (SMD −0.29, 95% CI −0.42 to −0.15), anger (SMD −0.60, 95% CI −1.00 to −0.20), guilt (SMD −0.79, 95% CI −1.18 to −0.41), confidence (SMD −0.34, 95% CI −0.51 to −0.17) and satisfaction with the partner relationship (SMD -0.28, 95% CI -0.47 to −0.09). However, only stress and confidence continued to be statistically significant at six-month follow-up, and none were significant at one year. There was no evidence of any effect on self-esteem (SMD −0.01, 95% CI −0.45 to 0.42).	14; 1	UK Cochrane Centre. The University of Warwick, UK. The Institute of Mental Health, Nottingham, UK. NHS Cochrane Programme Grant Scheme, UK.

CI, confidential index; *k*, number of studies; RCT, randomized controlled trial; SMD, standard mean difference; UK, United Kingdom.

3 months. Compared to active control conditions, which typically utilize alternative interventions, no results about follow-up data were available. The authors stressed the low methodological quality of most of the included studies and the variability of the effects. On the other hand, the review by Lo et al. (25) including 24 RCTs found that mindfulness strategies reduced stress but not anxiety, depression, or burnout among health professional students. In addition, cognitive-behavioral interventions showed a significant positive effect on anxiety, depression, and stress, and relaxation-strategy interventions on anxiety, depression, and stress. Again, the quality of included trials was generally poor.

Clarke et al. (34), summarizing 28 RCTs and observational studies, found promising evidence for computerized cognitive behavioral therapy interventions for the prevention of anxiety and depression in emerging adults. The evidence regarding mental health promotion gaming interventions is weak.

Conley et al. (35) included 90 RCTs and quasi-experimental studies on mental health promotion among higher education students. Interventions with supervised skills practice had a significant positive effect on mental health, whereas psychoeducational interventions and skills-training interventions without supervised practice had a nonsignificant effect.

Sandler et al. (31) summarized four meta-analytic reviews of prevention and promotion programs to prevent alcohol use among college students, and found that motivational interviewing, blood alcohol content education, normative comparison, and feedback on consumption have small, statistically significant, but partly heterogeneous effects on alcohol use and alcohol-related problems at short-term follow-up. The effects diminished over time, but the effect on frequency of drinking days and alcohol-related problems remained significant and were homogenous up to 4 years after the intervention. Motivational interviewing and personalized feedback for heavy drinkers had large significant effects of reduced alcohol consumption and alcohol problems 1 year after participation, but the effects on both outcomes were heterogeneous. Programs that challenged alcohol expectancies had no significant effects at follow-ups greater than a month.

Overall, statistically significant beneficial effects were found for mindfulness-based interventions on mindfulness, distress, and stress and for computerized or group-based cognitive behavior techniques, as well as for relaxation strategies on anxiety, depression, and stress among young adults. However, the findings are limited due to the low methodological quality and insufficient number of included primary studies, and the variability of the results. Skills-based mental health promotion interventions with supervision had a significant effect on overall mental health among young adults. Motivational interviewing and personalized feedback were effective in reducing alcohol consumption and alcohol problems.

3.3.2. Interventions for parents and families

We identified one systematic review of mental health promoting interventions for parents and families (20) (Table 4).

Barlow et al. (20) included 48 RCTs and concluded that group-based behavioral, cognitive-behavioral, or multi-modal parenting programs improve parental depression, anxiety, stress, anger, guilt, confidence, and satisfaction with the partner relationship statistically significantly at 2–6 months follow-up. Programs were effective at 6 month follow-up in relieving stress and improving confidence but effects on all outcomes disappeared at 1 year follow-up. No effects on self-esteem were found.

Overall, group-based behavioral, cognitive-behavioral, or multi-modal parenting programs were found to improve parental mental health in the short term.

3.3.3. Workplace interventions

We identified three systematic umbrella reviews (29, 30, 32) and two systematic reviews (21, 28) of studies exploring effects of mental health promoting interventions at the workplace (Table 5).

Bartlett et al. (21) combined the results of 23 RCTs of mindfulness training delivered in the work context and found it beneficial for anxiety, psychological distress, sleep, mindfulness, stress, and well-being compared to active comparators. The authors could not draw conclusions for burnout due to ambivalence in results and for depression due to publication bias.

Otto et al. (28) conducted a systematic review of physical activity, cognitive-behavioral, and organizational interventions among nursing staff in older adult care. Based on three RCTs, the authors found that cognitive-behavioral and multicomponent interventions had positive effects on nurses' mental health. However, they reported that there are not enough high-quality studies to make firm conclusions about the effectiveness of studied interventions in this target group.

TABLE 5 Characteristics and main findings of included reviews concerning interventions at workplace.

Publication; Study type; Amount and type of included studies (Search's time span)	Target group	Intervention(s) reviewed	Main findings	Overall methodological quality rating; Weaknesses in critical domains	Funding sources of the review
Otto, 2021 (28) systematic review $k = 3$ relevant RCTs (of total of 6) (Until Nov. 2020)	Nursing staff in older adult care	1. Physical activity interventions	First positive effects can be demonstrated concerning CBT interventions and multicomponent interventions.	10; 1	No external funding
		2. CBT interventions	There is no strong evidence for any type of intervention affecting physical and mental health. The heterogeneity of the studies regarding all aspects of the interventions and assessed outcome measures makes interpretation more difficult.		
		3. Organizational interventions (resources, working methods, tasks, or the environment)			
Pieper, 2019 (29) review of reviews $k = 38$ relevant reviews (of total of 74) (April 2012 – Oct. 2017)	Male and female employees in different age groups	Workplace interventions (resilience or mindfulness training, CBT, relaxation techniques and organizational-level workplace interventions)	Mindfulness and cognitive-behavioral training as well as peer supervision appeared to help reduce stress. Additionally, organizational interventions including reduction of work impact and flexible worktime seemed to lower stress and burn-out-symptoms. Overall, multi-component programs were more effective than single-component interventions. The authors found cognitive-behavioral programs effective at reducing depression, anxiety, and burnout as well as to improve well-being. One moderate-quality review assessed physical training and yoga-interventions and found them effective in the prevention of stress and anxiety.	7; 2	No external funding
Proper, 2019 (30) review of reviews $k = 6$ relevant reviews (of total of 23) (2009–2018)	Working population	Worksite mental health promotion interventions	Based on high-quality reviews, there is strong evidence that workplace psychological interventions, especially those that use e-health and cognitive behavior techniques, yield positive effects on mental health.	8; 2	European Union, in the framework of the Health Program (2014–2020), grant agreement number 761307.
Bartlett, 2019 (21) systematic review and meta-analysis $k = 23$ RCTs (Until 2016)	Employees in the workplace	Mindfulness training delivered in the work context	Workplace-delivered mindfulness training: beneficial effects for anxiety ($g = 0.62$, $p = 0.001$, $I^2 = 0$), psychological distress ($g = 0.69$, $p = 0.001$, $I^2 = 20$), sleep ($g = 0.26$, $p = 0.003$, $I^2 = 0$), mindfulness ($g = 0.45$, $p = 0.001$, $I^2 = 54$), stress ($g = 0.56$, $p = 0.001$, $I^2 = 79$) and well-being ($g = 0.46$, $p = 0.002$, $I^2 = 66$). Beneficial effects for psychological distress, depression, anxiety, and wellbeing also remained stable at three-month follow-up. No conclusions could be drawn from pooled data for burnout due to ambivalence in results, for depression due to publication bias, or for work performance due to insufficient data. The study that reported null results for mindfulness, wellbeing, and engagement following a six-month mindfulness program saw a continuing absence of effect 12 months from baseline.	14; 1	NR
Bhui, 2012 (32) review of reviews $k = 23$ reviews (1990 – July 2011)	Employees in the workplace	Individual, organizational, and mixed interventions on mental health and absenteeism	CBT was the most effective individual targeted intervention for mental health.	6; 4	Department of Health, UK.
			The only organizational intervention to show convincing effects on absenteeism (the main cause of which are anxiety and depression) was physical activity programs.		

CBT, cognitive behavioral therapy; g, effect size; I^2, heterogeneity; k, number of studies; NR, not reported; RCT, randomized controlled trial; SMD, standard mean difference; UK, United Kingdom.

Proper et al. (30) summarized the results of six reviews of mental health promotion interventions at the workplace. They concluded that there was strong evidence based on high quality reviews indicating that the use of cognitive behavior techniques yields positive effects on employees' mental health. The reports by Pieper et al. (29) including (30) and Bhui et al. (32), including 28 systematic reviews came to the same conclusion. Proper et al. (30) also reported that there was strong evidence regarding e-health interventions. Pieper et al. (29) found physical training and yoga effective in prevention of stress and anxiety. Bhui et al. (32) found that physical activity programs showed convincing positive effects on absenteeism.

Overall, workplace mindfulness training was beneficial in promoting employees' mental health compared to active comparators. Based on three umbrella reviews, cognitive behavior techniques were effective in mental health promotion.

3.3.4. Interventions for disadvantaged groups

We identified two systematic reviews of studies concerning mental health promotion and prevention interventions for disadvantaged groups (Table 6).

Koopman et al. (22) summarized 24 RCTs on the effectiveness of mental health promotion interventions among unemployed people,

TABLE 6 Characteristics and main findings of included reviews concerning interventions for disadvantaged groups.

Publication; Study type; Amount and type of included studies (Search's time span)	Target group	Intervention(s) reviewed	Main findings	Overall methodological quality rating; Weaknesses in critical domains	Funding sources of the review
Koopman, 2017 (22) systematic review $k = 24$, RCTs (NR)	Unemployed people	1. Occupational skills training (OST)	5/8 OST studies reported positive effects and 3/8 no effect on mental health	8; 2	NR
		2. Psychological interventions (PSI)	7/9 PSI studies reported positive effects and 2/9 no effect on mental health		
		3. Combined (OST + PSI)	6/6 Combined studies (including two high-quality studies) reported positive effects on mental health.		
Gottlieb, 2011 (38) systematic review $k = 13$, RCTs and cohort studies (1997–2008)	Unemployed people	Pre-employment training (e.g., employment workshops)	Most community-level preventive interventions for unemployed adults suggested long-term effects of pre-employment training on decreasing depressive symptoms and psychological distress among participants, particularly among those depressed at baseline.	6; 3	NIMH (National Institute of Mental Health) grant #R25MH060288–09.
	Homeless people and people living in public housing	Housing interventions	1/4 studies (the largest study): significant improvement in depressive symptoms.		
	Low-income women, mothers, and victims of domestic violence	Anti-poverty programs, parenting programs, shelter programs	3/4 studies: no improvement in depressive symptoms, but an improvement in other markers of psychological distress, including calmness and peacefulness, self-perception of depressive symptoms, paranoia, hostility, and obsessiveness.		
			3/4 interventions demonstrated improvements in depressive symptoms.		

k, number of studies; NR, not reported; OST, occupational skills training; PSI, psychological interventions; RCT, randomized controlled trial.

while Gottlieb et al. (38) reviewed 11 RCTs and two cohort studies on the impact of contextual interventions on depression. Studies of pre-employment training included in the review of Gottlieb et al. (38) were also included in Koopman et al. (22).

Koopman et al. (22) reported that the evidence was strongest for combined interventions (CI) consisting of psychological interventions that strengthen psychological resilience and vocational skills training aiming at re-employment: all the included CI studies reported positive effects on mental health and two of these studies were of high quality.

Most studies of community-level preventive interventions for unemployed people reviewed by Gottlieb et al. (38) suggested long-term effects of pre-employment training on decreasing depressive symptoms and psychological distress among participants, particularly among those depressed at baseline. Of the four studies focusing on housing interventions for homeless people or people living in public housing, one large study identified a significant improvement in depressive symptoms whereas three studies demonstrated an improvement in other markers of psychological distress. Three of the four other advocacy interventions, including anti-poverty programs and shelter programs, demonstrated improvements in depressive symptoms.

Overall, vocational skills training combined with resilience-building interventions were effective in the promotion of unemployed adults' mental health. Housing interventions for homeless people, anti-poverty programs and shelter programs, had a beneficial effect on some mental health outcomes.

3.3.5. Interventions for the general adult population

We identified six systematic reviews of interventions promoting mental health of the general adult population (23, 26, 27, 33, 37, 39) (Table 7).

Galante et al. (37) included 136 RCTs on the effectiveness of mindfulness-based programs (MBP) in non-clinical settings. Compared to passive control (no intervention or wait list), MBPs on average had a moderate positive effect on psychological distress, depression, and anxiety, as well as on well-being but to a lesser extent. Compared with taking nonspecific action, MBPs had a moderate positive effect on depressive symptoms and the relationship with the self (e.g., self-esteem, self-compassion). There was no statistically significant evidence for improving anxiety or distress and no reliable data on well-being. When compared with specific active control conditions, no significant evidence for MBPs' superiority was found. Given the overall high risk of bias in the included trials and the heterogeneity between studies, there was no certainty that the results represent the true effects and that MBPs work in every setting.

Lampert et al. (23), Hunter et al. (39), and Bowler et al. (33) focused on green space interventions. Lampert summarized eight cross-sectional studies and concluded that community gardeners, when compared with their neighbors who were not engaged in gardening activities, had statistically significantly better health outcomes in terms of life satisfaction, happiness, general health, mental health, and social cohesion. Hunter et al. (39), reviewing 38

TABLE 7 Characteristics and main findings of included reviews concerning interventions for general adult population.

Publication; Study type; Amount and type of included studies (Search's time span)	Target group	Intervention(s) reviewed	Main findings	Overall methodological quality rating; Weaknesses in critical domains	Funding sources of the review
Galante, 2021 (37) systematic review and meta-analysis $k = 136$; RCTs (From inception to Aug. 2020)	Any target group	Mindfulness (MBP)	Compared with no intervention, in most but not all scenarios MBPs improved average anxiety (8 trials; SMD = −0.56; 95% CI −0.80 to −0.33; p-value <0.001; 95% PI −1.19 to 0.06), depression (14 trials; SMD = −0.53; 95% CI −0.72 to −0.34; p-value <0.001; 95% PI −1.14 to 0.07), distress (27 trials; SMD = −0.45; 95% CI −0.58 to −0.31; p-value <0.001; 95% PI −1.04 to 0.14), and well–being (9 trials; SMD = 0.33; 95% CI 0.11 to 0.54; p-value = 0.003; 95% CI −0.29 to 0.94).	14; 1	National Institute for Health Research (NIHR).
			Compared with nonspecific active control conditions, in most but not all scenarios MBPs improved average depression (6 trials; SMD = −0.46; 95% CI −0.81 to −0.10; p-value = 0.012, 95% PI −1.57 to 0.66), with no statistically significant evidence for improving anxiety or distress and no reliable data on well–being. Compared with specific active control conditions, there is no statistically significant evidence of MBPs' superiority.		
Lampert, 2021 (23) systematic review $k = 8$; observational studies (Until Nov. 2020)	Non-clinical population	Community gardening (gardening activities)	Community gardeners had significantly better health outcomes (life satisfaction, happiness, general health, mental health, and social cohesion) than their neighbors not engaged in gardening activities.	7;2	Instituto de Sau'de Ambiental.
Hunter, 2019 (39) systematic review $k = 38$; RCTs or quasi-experimental studies (NR)	Any target group	Urban green space interventions (greenways, trails and park-based interventions)	Strong evidence for park-based (7/7 studies) and greenway/trail (3/3 studies) interventions employing a dual approach (i.e., a physical change to the urban green space and promotion/marketing programs) on health and wellbeing.	9; 1	WHO Regional Office for Europe. National Institute of Health Research (NIHR).
			Strong evidence for greening of vacant lots (4/4 studies) for health and wellbeing (e.g., reduction in stress).		
Macedo, 2014 (26) systematic review $k = 13$; RCTs and CTs (Until Jan. 2013)	Non-clinical samples of adults	Resilience promotion programs	RCTs: 6/7 statistically significant positive change in resilience, hardiness or resilience surrogates (e.g., coping or self-esteem).	4; 3	CNPq* and FAPERJ*
			CTs: 5/5 statistically significant positive change in resilience or hardiness or regarding only some of the resilience surrogates.		
			Open trial: statistically significant positive change in the levels of stress and depression, but not in well-being and distress		
Mammen, 2013 (27) systematic review $k = 30$; prospective, longitudinal studies (Jan.1976–Dec2012)	Nonclinical sample, 11–100 years	Physical activity (PA) in the prevention of depression.	25/30 studies: a significant, inverse relationship between baseline PA and follow-up depression.	5; 2	The Canadian Institute for Health Research (CIHR).
			5/30 studies: no relationship between PA and subsequent depression		
			4/30 studies: women, and not men, who participated in PA were less likely to report depression at follow-up.		
			Among the studies that found a protective role, the majority were considered high ($k = 17$) or modest ($k = 6$) methodologic quality. Among studies that revealed null effects, three were of modest, one of low and one of high quality.		
Bowler, 2010 (33) systematic review and meta-analysis $k = 25$; RCTs and observational studies (NR)	Any target group	Exposure to natural environment	There was evidence of beneficial effects of activity in a natural environment compared to the synthetic environment in terms of reduced negative emotions such as anger (Hedges $g = 0.46$; 95% CI = 0.23, 0.69), fatigue ($g = 0.42$; 0.07, 0.76) and sadness ($g = 0.36$; 0.08, 0.63) and positive effect on attention ($g = 0.32$; 0.06, 0.58). No statistically significant effects for energy scores ($g = 0.28$; −0.01, 0.57), anxiety ($g = 0.12$; −0.34, 0.58) and tranquility ($g = 0.39$; −0.08, 0.86).	13; 1	Natural England Contract FST20-84-037 to ASP*.
			Beneficial changes (before-after) on feelings of energy ES 0.76 (95% CI 0.30 to 1.22); anxiety 0.52 (0.25, 0.79), significant heterogeneity; anger 0.35 (0.07, 0.64); fatigue 0.76 (0.41, 1.11); and sadness 0.66 (0.16, 1.16)		

CBT, cognitive behavioral therapy; CI, confidential index; g, effect size; MBP, mindfulness based program; k, number of studies; NR, not reported; PA, physical activity; PI, predictive interval; RCT, randomized controlled trial; SMD, standard mean difference; WHO, World Health Organization. *Abbreviations not explained in the article.

RCTs or quasi-experimental studies, reported strong evidence to support park-based and greenway/trail interventions employing a dual approach (i.e., a physical change to the urban green space and promotion/marketing programs), as well as interventions related to the greening of vacant lots promoting health and well-being. Based on (30) studies, Bowler et al. (33) found that exposure to the natural environment compared to the synthetic environment reduced negative emotions such as anger, fatigue, and sadness, and had a positive effect on attention. There were no significant effects on energy scores, anxiety, and tranquility.

TABLE 8 Characteristics and main findings of included reviews reporting economic analyses.

Publication; Study type; Amount and type of included studies (Search's time span)	Target group	Intervention(s) reviewed	Main findings	Overall methodological quality rating; Weaknesses in critical domains	Funding sources of the review
Hunter, 2019 (39) systematic review $k = 38$; RCTs or quasi-experimental studies (NR)	Any target group	Urban green space interventions (park-based interventions, greenways, and trails)	Four studies undertook preliminary economic evaluations and found that urban green space interventions were relatively cost-effective. Cost effectiveness of the three park-based interventions was reported to be $0.14 to $2.40 per Metabolic Equivalent of Task (MET) hours/year (cost effectiveness judged on whether the cost was less than between $0.50 and $1.00 per MET-hour)	9; 1	WHO Regional Office for Europe. National Institute of Health Research (NIHR).
Le, 2021 (24) systematic review $k = 35$ relevant economic studies (of total of 65) (2008–2020)	Adults (18–64)	Mental health promotion and prevention interventions	Targeted (indicated or selective) prevention was likely to be cost-effective compared to universal prevention. Parenting interventions had good evidence in mental health promotion. Strong evidence supported screening plus psychological interventions for mental disorder prevention, while workplace interventions targeting employees in general were cost-effective.	10; 1	National Mental Health Commission, Australia.

k, number of studies; MET, metabolic equivalent of task; NR, not reported; RCT, randomized controlled trial; WHO, World Health Organization.

Mammen and Faulkner (27) conducted a systematic review of 30 prospective studies focusing on physical activity in the prevention of depression. Twenty-five of the studies found a statistically significant, inverse relationship between baseline physical activity and follow-up depression. According to the authors, there is sufficient evidence to conclude that physical activity may prevent depression.

Macedo et al. (26) performed a qualitative synthesis of 13 trials, which reported some degree of improvement in resilience-like variables among populations participating in most resilience-promoting programs. Authors concluded there is evidence pointing towards some degree of effectiveness of resilience promotion programs, despite substantial heterogeneity in study designs and measurements.

Overall, evidence suggests effectiveness of mindfulness-based programs in promoting mental health as well as resilience promotion programs in improving resilience-like variables among the average non-clinical adult population. However, due to the overall high risk of bias and great heterogeneity in the included studies, these conclusions should be interpreted with caution. Green space interventions had beneficial effects on some mental health and well-being outcomes studied. Physical activity prevented the onset of depression.

3.4. Cost-effectiveness of the interventions

Two systematic reviews (24, 39) considered cost-effectiveness of mental health promotion and prevention interventions (Table 8).

Le et al. (24) summarized evidence of the cost-effectiveness of mental health promotion and prevention interventions from 2008 onwards. The evidence concerning adults aged 18–64 years is based on 35 economic studies, the majority of which achieved fair to high methodological quality. The review found that indicated or selective prevention was likely to be cost-effective compared to universal prevention. Strong evidence supported cost-effectiveness of screening combined with psychological interventions in preventing mental disorders in adults. In addition, workplace interventions targeting employees in general were also considered to be cost-effective. Parenting interventions showed good evidence of cost-effectiveness in mental health promotion. The included return on investment studies, in turn, provided evidence suggesting that preventive interventions for depression and substance abuse in adults produce considerable returns.

Hunter et al. (39) summarized four preliminary economic evaluations of urban green space interventions. Three of the evaluations found interventions to be cost-effective based on the increased physical activity of park users. Authors of the fourth study found increased walking and cycling attributable to investment in trails for walking and cycling and concluded that the investments may have significant benefit–cost ratios. Overall, Hunter et al. (39) concluded, that urban green space interventions aiming to increase physical activity were relatively cost-effective.

However, the uncertainties relating to the quality of the included health-economic evaluations likely limits the generalizability of conclusions relating to cost-effectiveness which can be drawn from these two qualitative reviews.

3.5. Intervention success factors

Among the key success factors gleaned from this review was the use of supervised practice in universal skills-oriented programs that aimed to promote mental health (35) (Table 9). In the prevention of depression, anxiety, antisocial behavior, and substance abuse, the best results were achieved by programs that used interactive methods to teach the skills needed to bring about the change (31). Methods that engaged participants, such as discussing the materials distributed in the programs and practicing the skills to be taught, also produced better results than simply sharing information (31). Adherence to web-based mental health interventions, which is often poor, could be improved with the provision of face-to-face or online support (34). In studies focusing on alcohol use, largest program effects were achieved for populations with a higher percentage of women; programs delivered face-to-face versus on a computer; and interventions that utilized motivational interviewing, decisional balance exercises, normative feedback, and feedback on expectancies and/or motives for drinking (31).

4. Discussion

In this systematic umbrella review, evidence was found for the effectiveness of cognitive-behavioral, resilience, mindfulness, and physical activity interventions in promoting mental health and

TABLE 9 Characteristics and main findings of included reviews reporting intervention success factors.

Publication; Study type; Amount and type of included studies (Search's time span)	Target group	Intervention(s) reviewed	Main findings	Overall methodological quality rating; Weaknesses in critical domains	Funding sources of the review
Clarke, 2015 (34) systematic review $k = 28$; RCTs and quasi-experimental studies (Jan. 2000–June 2013)	Youth (majority over 18 years of age)	Online Youth Mental Health Promotion and Prevention Interventions	Some evidence that participant face-to-face or web-based support is an important feature of online interventions in terms of participant adherence and program outcomes.	9; 1	Inspire Ireland Foundation and Young and Well Cooperative Research Centre, Australia.
Sandler, 2014 (31) review of meta-analytic reviews $k = 4$ relevant reviews (of total of 48 reviews) (2000–2013)	College students up to age of 26	Prevention and promotion programs to prevent alcohol use	Programs that involved more active strategies, such as discussion of the program material and practice of program skills, had larger effects than those that did not include these strategies. Program effects were larger for samples that contained a higher percentage of women; programs delivered in person versus on a computer; and interventions that included motivational interviewing techniques, normative feedback, and feedback on expectancies and/or motives for drinking or a decisional balance exercise. Face-to-face interventions also had greater effects than computer-based interventions in studies that directly compared them.	5; 3	NR

k, number of studies; NR, not reported; RCT, randomized controlled trial.

well-being of adult populations. However, the clinical significance of the effects could not be assessed thoroughly, as the umbrella review methodology employed in this review does not allow for a re-synthesis of the results. The effect sizes of the impacts of the interventions could be drawn from eight meta-analytical reviews and are presented in Tables 3–5, 7.

More research literature was found on reducing symptoms of depression and anxiety than on promoting resilience and overall mental well-being, which is in line with a scoping review of Enns et al. (13). However, we found three systematic reviews of resilience interventions (21, 22, 26) published later than the literature search of Enns et al. (13) which points toward a stronger evidence base of resilience interventions in the current literature compared to previous.

The results of this review can be applied to mental health promotion programs targeted at the adult working-age population in Western countries. The preliminary results of this review formed the theoretical framework and development of applied interventions for a mental health promotion program in North Savo, Finland, funded by the European Social Fund. In the future, interventions that prove to be effective during the program will be implemented more widely in the region. As the importance of mental health promotion is likely to increase in the coming years, high quality primary studies and systematic reviews are needed to inform the choice of the most effective interventions. Because of the complexity of the phenomenon, a systemic, multilevel approach is needed to support implementation of the interventions, to monitor their effectiveness, and to involve people and communities in the selection, development, and evaluation of the interventions.

4.1. Study strengths and limitations

This systematic umbrella review is relevant to current policymakers and stakeholders, as it evaluated the available evidence of promotive and preventive interventions for mental health and well-being, currently considered a priority in public health. The strengths of this review include the rigorous JBI and PRISMA guidelines, which we followed in carrying out and reporting our work. We included both systematic reviews and umbrella reviews, performed a quality appraisal of included reviews, tabulated the data, and reported the results in as much detail as possible.

The main limitation of this review is the poor methodological quality of the included reviews. The confidence in the results of the included reviews was diminished most often by the lack of a priori design and limited information and justification of the excluded studies. In addition, the methodological quality of the primary studies that were included in the reviews was often poor. Also, when conducting this review, we made some eligibility decisions with undesirably thin data. Thus, some of the included reviews may contain participants in clinical settings or studies with inadequate follow-up time, although we aimed to exclude reviews focusing on participants with a clinical diagnosis as well as studies with less than 1 month of follow-up.

5. Conclusion

This review suggests that interventions using cognitive-behavioral therapy and those developing resilience, mindfulness, or healthy lifestyles can be effective in the promotion of mental health and well-being in adult populations aged 18–64. Skills-based mental health interventions with supervision may promote the mental health of young adults and vocational skills training combined with resilience-building interventions may be effective in promoting the mental health of unemployed adults. Motivational interviewing may reduce alcohol consumption in young adults. Indicated or selective prevention are likely to be cost-effective compared to universal prevention. Strong evidence supports the cost-effectiveness of screening combined with psychological interventions in preventing mental disorders in adults. Parenting interventions and workplace interventions may be cost-effective in mental health promotion. Preventive interventions for depression and substance misuse in

adults may produce considerable returns on investment. Due to the low quality of the included reviews and the great heterogeneity among the reported results, these conclusions should be interpreted with caution. There is a need for further rigorous, high-quality systematic reviews on promotive and preventive interventions for mental health and well-being. Above all, reviews focusing on the enhancing of mental well-being instead of reducing symptoms of mental problems are needed.

Data availability statement

The original contributions presented in the study are included in the article/Supplementary material, further inquiries can be directed to the corresponding author.

Author contributions

MS, EP, TL, TT, IL, JL, and TM-O contributed to conception and design of the study. MS and JI analyzed the data. MS wrote the first draft of the manuscript. TM-O wrote sections of the manuscript. All authors contributed to the article and approved the submitted version.

Funding

This work was part of the Feel Good North Savo program funded by the European Social Fund (#2014/11114/09020101/2020).

Acknowledgments

We thank information specialist Maarit Putous (The University of Eastern Finland) for her advice and help in developing the search strategy and performing the searches. We also thank M.D., Ph.D., M.Sc. Marjukka Mäkelä for valuable comments and suggestions concerning the methodology of the review.

Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

Supplementary material

The Supplementary material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpubh.2023.1201552/full#supplementary-material

References

1. World Health Organization. World mental health report: transforming mental health for all. 16 Jun 2022. License: CC BY-NC-SA 3.0 IGO

2. Mental health. Burden. [Internet]. World Health Organization. Available at: https://www.who.int/health-topics/mental-health#tab=tab_2 (Accessed Jan 11, 2023)

3. Marmot M, Bell R. Fair society, healthy lives. *Public Health London*. (2012) 126:S4–S10. doi: 10.1016/j.puhe.2012.05.014

4. Webster Merriam. Definition of disadvantaged. [Internet]. Available at: https://www.merriam-webster.com/dictionary/disadvantaged (Accessed Jan 15, 2023)

5. OECD. Tackling the mental health impact of the COVID-19 crisis: An integrated, whole-of-society response. OECD Policy Responses to Coronavirus (COVID-19). OECD Publishing, Paris (2021). (2021) doi: 10.1787/0ccafa0b-en

6. World Health Organization. *Prevention and promotion in mental health*. (2002) 1–46. Geneva: World Health Organization

7. Institute of Medicine (US) In: PJ Mrazek and RJ Haggerty, editors. *Committee on prevention of mental disorders. Reducing risks for mental disorders: Frontiers for preventive intervention research*. Washington (DC): National Academies Press (US) (1994)

8. Sharma A, Sharma SD, Sharma M. Mental health promotion: a narrative review of emerging trends. *Curr Opin Psychiatry*. (2017) 30:339–45. doi: 10.1097/YCO.0000000000000347

9. Simpson J, Albani V, Bell Z, Bambra C, Brown H. Effects of social security policy reforms on mental health and inequalities: a systematic review of observational studies in high-income countries. *Soc Sci Med*. (2021) 272:113717. doi: 10.1016/j.socscimed.2021.113717

10. Jané-Llopis E, Katschnig H, McDaid D, Wahlbeck K. Supporting decision-making processes for evidence-based mental health promotion. *Health Promot Int*. (2011) 26:i140–6. doi: 10.1093/heapro/dar076

11. Greve B. Routledge handbook of the welfare state. *2nd Routledge handbook of the welfare state*. Taylor & Francis Group (2017). 46–57

12. RE-AIM. Welcome to RE-AIM and PRISM: Implementation in Context. [Internet]. Available at: https://re-aim.org/ (Accessed Jan 8, 2023)

13. Enns J, Holmqvist M, Wener P, Halas G, Rothney J, Schultz A, et al. Mapping interventions that promote mental health in the general population: a scoping review of reviews. *Prev Med*. (2016) 87:70–80. doi: 10.1016/j.ypmed.2016.02.022

14. Seaton CL, Bottorff JL, Jones-Bricker M, Oliffe JL, DeLeenheer D, Medhurst K. Men's mental health promotion interventions: a scoping review. *Am J Mens Health*. (2017) 11:6. doi: 10.1177/1557988317728353

15. Aromataris E, Fernandez R, Godfrey C, Holly C, Khalil H, Tungpunkom P. Chapter 10: umbrella reviews. E Aromataris and Z Munn (Eds.). *JBI manual for evidence synthesis JBI*. (2020). Available at: https://synthesismanual.jbi.global. (Accessed Jan 11, 2023)

16. Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. *BMJ*. (2021) 372:n71. doi: 10.1136/bmj.n71

17. Bambra C, Gibson M, Sowden A, Wright K, Whitehead M, Petticrew M. Tackling the wider social determinants of health and health inequalities: evidence from systematic reviews. *J Epidemiol Community Health*. (2010) 64:4. doi: 10.1136/jech.2008.082743

18. Thomson K, Hillier-Brown F, Walton N, Bilaj M, Bambra C, Todd A. The effects of community pharmacy-delivered public health interventions on population health and health inequalities: a review of reviews. *Prev Med*. (2019) 124:98–109. doi: 10.1016/j.ypmed.2019.04.003

19. Shea BJ, Reeves BC, Wells G, Thuku M, Hamel C, Moran J, et al. AMSTAR 2: a critical appraisal tool for systematic reviews that include randomised or non-randomised studies of healthcare interventions, or both. *BMJ*. (2017) 358:j4008. doi: 10.1136/bmj.j4008

20. Barlow J, Smailagic N, Huband N, Roloff V, Bennett C. Group-based parent training programmes for improving parental psychosocial health. *Cochrane Database Syst Rev*. (2014):CD002020. doi: 10.1002/14651858.CD002020.pub4

21. Bartlett L, Martin A, Neil AL, Memish K, Otahal P, Kilpatrick M, et al. A systematic review and meta-analysis of workplace mindfulness training randomized controlled trials. *J Occup Health Psychol*. (2019) 24:1. doi: 10.1037/ocp0000146

22. Koopman MY, Pieterse ME, Bohlmeijer ET, Drossaert CHC. Mental health promoting interventions for the unemployed: a systematic review of applied techniques and effectiveness. *Int J Ment Health Promot*. (2017) 19:4. doi: 10.1080/14623730.2017.1328367

23. Lampert T, Costa J, Santos O, Sousa J, Ribeiro T, Freire E. Evidence on the contribution of community gardens to promote physical and mental health and well-being of non-institutionalized individuals: a systematic review. *PLoS One*. (2021) 16:8. doi: 10.1371/journal.pone.0255621

24. Le LKD, Esturas AC, Mihalopoulos C, Chiotelis O, Bucholc J, Lou CM, et al. Cost-effectiveness evidence of mental health prevention and promotion interventions: a systematic review of economic evaluations. *PLoS Med*. (2021) 18:5. doi: 10.1371/journal.pmed.1003606

25. Lo K, Waterland J, Todd P, Gupta T, Bearman M, Hassed C, et al. Group interventions to promote mental health in health professional education: a systematic review and meta-analysis of randomised controlled trials. *Adv Health Sci Educ Theory Pract*. (2018) 23:2. doi: 10.1007/s10459-017-9770-5

26. Macedo T, Wilheim L, Gonçalves R, Coutinho ESF, Vilete L, Figueira I, et al. Building resilience for future adversity: a systematic review of interventions in non-clinical samples of adults. *BMC Psychiatry*. (2014) 14:1. doi: 10.1186/s12888-014-0227-6

27. Mammen G, Faulkner G. Physical activity and the prevention of depression: a systematic review of prospective studies. *Am J Prev Med*. (2013) 45:5. doi: 10.1016/j.amepre.2013.08.001

28. Otto AK, Gutsch C, Bischoff LL, Wollesen B. Interventions to promote physical and mental health of nurses in elderly care: a systematic review. *Prev Med*. (2021) 148:106591. doi: 10.1016/j.ypmed.2021.106591

29. Pieper C, Schröer S, Eilerts AL. Evidence of workplace interventions – a systematic review of systematic reviews. *Int J Environ Res Public Health*. (2019) 16:19. doi: 10.3390/ijerph16193553

30. Proper KI, Van Oostrom SH. The effectiveness of workplace health promotion interventions on physical and mental health outcomes – a systematic review of reviews. *Scand J Work Environ Health*. (2019) 45:6. doi: 10.5271/sjweh.3833

31. Sandler I, Wolchi SA, Cruden G, Mahrer NE, Ahn S, Brincks A, et al. Overview of meta-analyses of the prevention of mental health, substance use, and conduct problems. *Annu Rev Clin Psychol*. (2014) 10:1. doi: 10.1146/annurev-clinpsy-050212-185524

32. Bhui KS, Dinos S, Stansfeld SA, White PD. A synthesis of the evidence for managing stress at work: a review of the reviews reporting on anxiety, depression, and absenteeism. *J Environ Public Health*. (2012) 2012:515874–21. doi: 10.1155/2012/515874

33. Bowler DE, Buyung-Ali LM, Knight TM, Pullin AS. A systematic review of evidence for the added benefits to health of exposure to natural environments. *BMC Public Health*. (2010) 10:1. doi: 10.1186/1471-2458-10-456

34. Clarke AM, Kuosmanen T, Barry MM. A systematic review of online youth mental health promotion and prevention interventions. *J Youth Adolesc*. (2015) 44:90–113. doi: 10.1007/s10964-014-0165-0

35. Conley CS, Durlak JA, Kirsch AC. A meta-analysis of universal mental health prevention programs for higher education students. *Prev Sci*. (2015) 16:487–507. doi: 10.1007/s11121-015-0543-1

36. Dawson AF, Brown WW, Anderson J, Datta B, Donald JN, Hong K, et al. Mindfulness-based interventions for university students: a systematic review and meta-analysis of randomised controlled trials. *Appl Psychol Health Well Being*. (2020) 12:2. doi: 10.1111/aphw.12188

37. Galante J, Friedrich C, Dawson AF, Modrego-Alarcón M, Gebbing P, Delgado-Suárez I, et al. Mindfulness-based programmes for mental health promotion in adults in nonclinical settings: a systematic review and meta-analysis of randomised controlled trials. *PLoS Med*. (2021) 18:1. doi: 10.1371/journal.pmed.1003481

38. Gottlieb L, Waitzkin H, Miranda J. Depressive symptoms and their social contexts: a qualitative systematic literature review of contextual interventions. *Int J Soc Psychiatry*. (2011) 57:402–17. doi: 10.1177/0020764010362863

39. Hunter RF, Cleland C, Cleary A, Droomers M, Wheeler BW, Sinnett D, et al. Environmental, health, wellbeing, social and equity effects of urban green space interventions: a meta-narrative evidence synthesis. *Environ Int*. (2019) 130:104923. doi: 10.1016/j.envint.2019.104923

frontiers | Frontiers in Psychology

TYPE Original Research
PUBLISHED 07 September 2023
DOI 10.3389/fpsyg.2023.1196945

OPEN ACCESS

EDITED BY
Brooke Schneider,
University Medical Center Hamburg-Eppendorf, Germany

REVIEWED BY
Barbara Cludius,
Ludwig Maximilian University of Munich, Germany
Daniel Schöttle,
University Medical Center Hamburg-Eppendorf, Germany

*CORRESPONDENCE
Daniel Wallsten
✉ daniel.wallsten@kau.se

RECEIVED 30 March 2023
ACCEPTED 04 August 2023
PUBLISHED 07 September 2023

CITATION
Wallsten D, Norell A, Anniko M, Eriksson O, Lamourín V, Halldin I, Kindbom T, Hesser H, Watkins E and Tillfors M (2023) Treatment of worry and comorbid symptoms within depression, anxiety, and insomnia with a group-based rumination-focused cognitive-behaviour therapy in a primary health care setting: a randomised controlled trial. *Front. Psychol.* 14:1196945. doi: 10.3389/fpsyg.2023.1196945

Treatment of worry and comorbid symptoms within depression, anxiety, and insomnia with a group-based rumination-focused cognitive-behaviour therapy in a primary health care setting: a randomised controlled trial

Daniel Wallsten[1]*, Annika Norell[2,3], Malin Anniko[3], Oskar Eriksson[4], Varja Lamourín[3], Ida Halldin[3], Tina Kindbom[3], Hugo Hesser[3,5], Edward Watkins[6] and Maria Tillfors[1]

[1]Department of Social and Psychological Studies, Karlstad University, Karlstad, Sweden, [2]Faculty of Health and Science, Kristianstad University, Kristianstad, Sweden, [3]School of Behavioral, Social and Legal Sciences, Örebro University, Örebro, Sweden, [4]Kronoparken Primary Healthcare Center, Karlstad, Sweden, [5]Department of Behavioral Sciences and Learning, Linköping University, Linköping, Sweden, [6]Mood Disorders Centre, School of Psychology, University of Exeter, Exeter, United Kingdom

Introduction: Repetitive negative thinking (RNT) has been described as a maintaining transdiagnostic factor for psychopathology within the areas of depression, anxiety and insomnia. We investigated the effects of rumination-focused cognitive-behaviour therapy (RF-CBT) in a group format at a primary health care centre on symptoms of depression, anxiety, insomnia, RNT, and quality of life. The participants presented clinical symptom levels of worry and at least two disorders among anxiety disorders, major depressive disorder, and insomnia disorder.

Methods: A randomised controlled superiority parallel arm trial was used. 73 participants were included and randomised in pairs to either group-administered RF-CBT or a waiting list condition. The primary outcomes were self-rated worry and transdiagnostic symptoms (depression, anxiety, and insomnia). Intention-to-treat analyses of group differences were conducted using linear mixed models. Adverse side effects and incidents were presented descriptively.

Results: Group RF-CBT significantly reduced self-reported insomnia at post-treatment and self-reported insomnia and depression at the 2 month-follow-up, relative to the wait-list control group. There was no significant difference in change in RNT, anxiety, or quality of life.

Discussion: The current study suggests that group-administered RF-CBT may be effective for insomnia and potentially effective for depression symptomatology. However, the study was underpowered to detect small and moderate effects and the results should therefore be interpreted with caution.

KEYWORDS

anxiety, depression, group therapy, insomnia, repetitive negative thinking, rumination-focused CBT

1. Introduction

Worry and rumination have been conceptualised as transdiagnostic processes and linked to the onset and maintenance of multiple psychiatric disorders, both separately and together as the concept of repetitive negative thinking (RNT). This includes disorders such as Major Depressive Disorder, Social Anxiety Disorder, Generalised Anxiety Disorder, and Insomnia Disorder (Watts et al., 1994; Harvey et al., 2004; Ehring and Watkins, 2008; Nolen-Hoeksema et al., 2008; Watkins and Roberts, 2020). According to Borkovec et al. (1998), worry has been characterised as" a predominance of verbal thought activity, [that] functions as a type of cognitive avoidance, and inhibits emotional processing." Similarly, rumination has been described as "a persistent mental attempt at resolving unattained goals, [that] may be initiated by an intrusive concern over a discrepancy between current state and ideal goals" (Martin and Tesser, 2013; Olatunji et al., 2013). Although rumination involves past events whereas worry involves potential future events, RNT captures three overlapping process characteristics: (1) repetitive, passive and/or (2) relatively uncontrollable (i.e., perceived as difficult to inhibit or withstand from) and (3) focused on negative content. Rumination has been associated with depression, whereas worry have been more broadly associated with anxiety disorders and insomnia (Ehring and Watkins, 2008; Olatunji et al., 2010; Spinhoven et al., 2018). However, these perhaps intuitive associations have also been questioned. For example, Hoyer et al. (2009) found, although in a limited non-clinical sample, that worry was a better predictor for both symptoms of anxiety and emotional symptoms, than rumination. The authors also concluded that the lay term anxiety was strongly associated with *The Penn State Worry Questionnaire* (PSWQ; Meyer et al., 1990) and that the PSWQ therefore can be considered face valid for screening people with high levels of worry and thus suitable for clinical settings. According to Spinhoven et al., RNT have been operationalized with different measures within worry and rumination, which typically are highly correlated, but also through measures that focus directly on the common variance. A meta-analysis from 2018 suggested that rumination-focused cognitive-behaviour therapy (RF-CBT) may be more efficacious than other approaches in addressing RNT (Spinhoven et al., 2018). RF-CBT was originally developed to address depressive rumination (Watkins et al., 2007) and has demonstrated promising results in randomised clinical trials in both individual therapies and group formats (Watkins et al., 2007, 2011; Topper et al., 2017; Hvenegaard et al., 2020). RF-CBT addresses RNT with both common techniques associated with functional analysis, self-compassion, values, and mindfulness, but also specifically through the participants process-style as they get to practise distinguishing concrete or constructive thinking from abstract and unconstructive thinking.

Despite the promising results of RF-CBT and the previously emphasised theoretical link between RNT and psychiatric disorders, there has been limited research on the effects of RF-CBT on disorders other than depression. In an explorative clinical trial in adolescents, the effects of RF-CBT on anxiety, with behavioural activation and global functioning as secondary outcomes, were investigated. Significant results were found regarding decreased anxiety and increased behavioural activation but not for improved global functioning in an adolescent sample (Feldhaus et al., 2020). Another study investigated the prevention of anxiety disorders and depression in a randomised controlled trial by addressing RNT in a sample of adolescents and young adults with elevated worry and rumination (Topper et al., 2017). The authors found that both group-and online RF-CBT significantly reduced the onset of depression and anxiety disorders over the subsequent 12 months. Even though RNT has been linked to sleep problems (Harvey et al., 2004; Ehring and Watkins, 2008), to our knowledge, there have been no studies on the effects of RF-CBT on insomnia disorder. Sleep problems are also assumed to interfere with psychological treatment as for example both concentration and emotions regulation are affected by deprived sleep (Walker and van der Helm, 2009; Lim and Dinges, 2010). This points to the potential benefits of RF-CBT for people with comorbid Insomnia Disorder and therefore also to the need of investigating how RF-CBT may affect comorbid problems including Insomnia Disorder. Further, insomnia have been identified as a maintaining factor of depression, and a risk factor for new depressive episodes (Riemann et al., 2020). Clinical trials in which depression is addressed should therefore investigate to what extent symptoms of insomnia may be affected by the treatment, as this might shed a light on whether a salient risk factor for new episodes has been successfully targeted. To summarize, although being theoretically motivated, there is currently little evidence on how RF-CBT may be effective for problems besides those associated with depression. There are significant gaps concerning the knowledge on efficacy and effectiveness of RF-CBT on disorders within anxiety disorders and insomnia.

Furthermore, to our knowledge, no clinical trials have yet evaluated the effects of RF-CBT on a deliberately recruited transdiagnostic adult sample with clinical symptom levels among the common areas of Major Depressive Disorder, anxiety disorders (Specific Phobia, Social Anxiety Disorder, Panic Disorder, Agoraphobia, Generalized Anxiety Disorder, Separation Anxiety Disorder) and Insomnia Disorder, as defined by the Diagnostic and Statistical Manual of Mental Disorders (American Psychiatric Association, 2013). Also, no identified trials were conducted in a primary health care setting, where about 30% of patients meet the criteria for at least two comorbid psychiatric disorders (Kessler et al., 2005; Roca et al., 2009). Even if evidence-based treatment protocols for individual disorders already exist, a transdiagnostic treatment that addresses a potential maintenance factor seen in multiple disorders could enhance treatment effects among participants with elevated levels of that factor. Thus, even with limited data, the possibility of a transdiagnostic approach addressing persistent negative thinking to treat multiple disorders appears plausible. Finally, few studies on RNT have up and until now focused on worry rather than depressive rumination (Spinhoven et al., 2018).

Therefore, the current study aimed to investigate the effectiveness of group-delivered RF-CBT with a randomised controlled trial in a sample of participants with clinical symptom levels of worry and at least two disorders among anxiety disorders, Major Depressive Disorder, and Insomnia Disorder. We hypothesised that participants randomised to RF-CBT would report greater reductions in anxiety, insomnia, depression, and worry, and greater increases in perceived quality of life from baseline to each of the following time points (post, FU1, FU2) than those randomised to a wait-list control group. We also explored if participation in treatment was associated with any adverse side-effects or events.

2. Method

2.1. Research design

The design was a randomised controlled superiority parallel arm trial with 73 participants who were randomised 1:1 into two conditions: treatment (group RF-CBT; $n = 36$) and wait-list control group (WL; $n = 37$). Measurements were taken before, immediately after, and 2 and 6 months after the end of the treatment. During measurements, participants randomly assigned to the wait-list control group completed the same evaluations as those participating in the treatment group at the same time points, except for the 6-months follow-up since the participants in the waitlist-control group received their treatment after the 2-month follow-up measurements.

2.2. Participants

An ethical approval was obtained from the regional ethics review board in Uppsala, Sweden (Dnr: 2018/197). All participants received written information concerning the study and their participation, and they completed an informed consent form. All data were coded, and the clinical trial was registered at: https://www.anzctr.org.au, Clinical registration number: ACTRN12618001614280.

Participants ($n = 73$) were recruited through advertisements and articles in regional media, regional radio information, social media ads, and information provided in local primary health care centres, between September 2018 and April 2019. The flow of participants through the study is depicted in Figure 1. Applicants were directed to a web page with information about the study and a secure digital platform to collect research data to convey their interest and initial information for the screening procedure.

2.3. Screening and assessment process

In this study, comorbid problems (clinical symptom levels of worry and at least two disorders among anxiety disorders, major depressive disorder, and insomnia disorder) was defined as either reporting clinicals symptom levels of worry and meeting criteria for two disorders among major depressive disorder, insomnia disorder or any anxiety disorder as defined by the diagnostic manual of mental disorders 5 (DSM-5; American Psychiatric Association, 2013) according to the Mini-International Neuropsychiatric Interview (M.I.N.I.; Sheehan et al., 1998) and Insomnia Disorder according to The Duke Structured Interview for Sleeping Disorders (DSISD; Edinger et al., unpublished material; Taylor et al., 2018), OR reporting clinicals symptom levels of worry and meeting criteria for one disorder according to the M.I.N.I. or the DSISD, AND report clinical symptoms levels within at least one of the areas depression, anxiety or insomnia disorder, with an established self-rating scale. Clinical symptom levels of worry were defined in line with the cut-off scores for general anxiety disorder, thus a total score of ≥45[1] on the Penn State Worry Questionnaire (PSWQ; Meyer et al., 1990; Behar et al., 2003), thus the closest to a psychometric operationalization of clinical worry that could be identified.

The screening procedure was conducted in two steps. *First*, participants were deemed potentially eligible for the study if they had conveyed interest in participation, were ≥18 years old, and provided informed consent and health information. They had to report established clinical levels of worry and on two out of three of the following self-rating scales: Major Depressive Disorder [total score of ≥13 on the Montgomery-Åsberg Depression Rating Scale (MADRS-S; Svanborg and Asberg, 1994)], Insomnia Disorder [total score of ≥8 on the Insomnia Severity Index (ISI; Bastien, 2001], Anxiety [total score of ≥8 on the Overall Anxiety Severity and Impairment Scale (OASIS; Norman et al., 2006)]. If any pharmacological treatment for anxiety, depression, or insomnia disorder occurred, the dose had to have been stable over the past 2 months or longer. *Second*, those who met the initial criteria were contacted by the research group for further assessment over the telephone, including the clinical interviews M.I.N.I. (Sheehan et al., 1998) and DSISD (Edinger et al., unpublished material; Taylor et al., 2018). The included participants had to meet the criteria for comorbid problems as defined above.

The following conditions were cause for *exclusion*: Severe depression (total score of ≥30[2] on MADRS-S), ongoing psychosis or mania (M.I.N.I.), suicidal tendencies (total score of ≥4 on MADRS-S item 9), or other concurrent psychological treatments. Those who initially reported severe depression, or an elevated risk of suicide were contacted by licenced psychologists for further advice. The M.I.N.I. and the DSISD were conducted by licensed clinical psychologists and students enrolled in the clinical psychologist master's program under supervision by a licensed clinical psychologist. All interviewers received training in DSISD and a test screening with an actor to ensure interrater reliability. There was full agreement between interviewers concerning diagnoses and recommendations for participation. All interviewers had previous experience from conducting the M.I.N.I., and the master students also needed to consult their assessments with a licenced psychologist within the research group.

Applicants were then contacted by the research group and either offered participation or advice on self-help literature and where to apply for sufficient health care. Each included participant was provided with information about the randomisation procedure, the baseline measurements, and the estimated start date for the treatment group. After the inclusion, each participant received an email with a link to the secure research data collection platform through which the baseline measurements were administered.

2.4. Randomisation

For every two enrolled participants, a 1:1 block randomisation was conducted to ensure equal group sizes.[3] The randomisation

1 In the pre-registration, >45 was mistakenly specified as the clinical threshold.

2 The threshold was later corrected to ≥34 and an updated approval was obtained from regional ethics review board in Uppsala; Dnr: 2019-00987.

3 The ongoing 1:1 randomisation of each enrolled pair before the baseline measurements were collected resulted in 7 participants (3 in the treatment-and 4 in the waitlist condition) who were enrolled but never answered the baseline measurements.

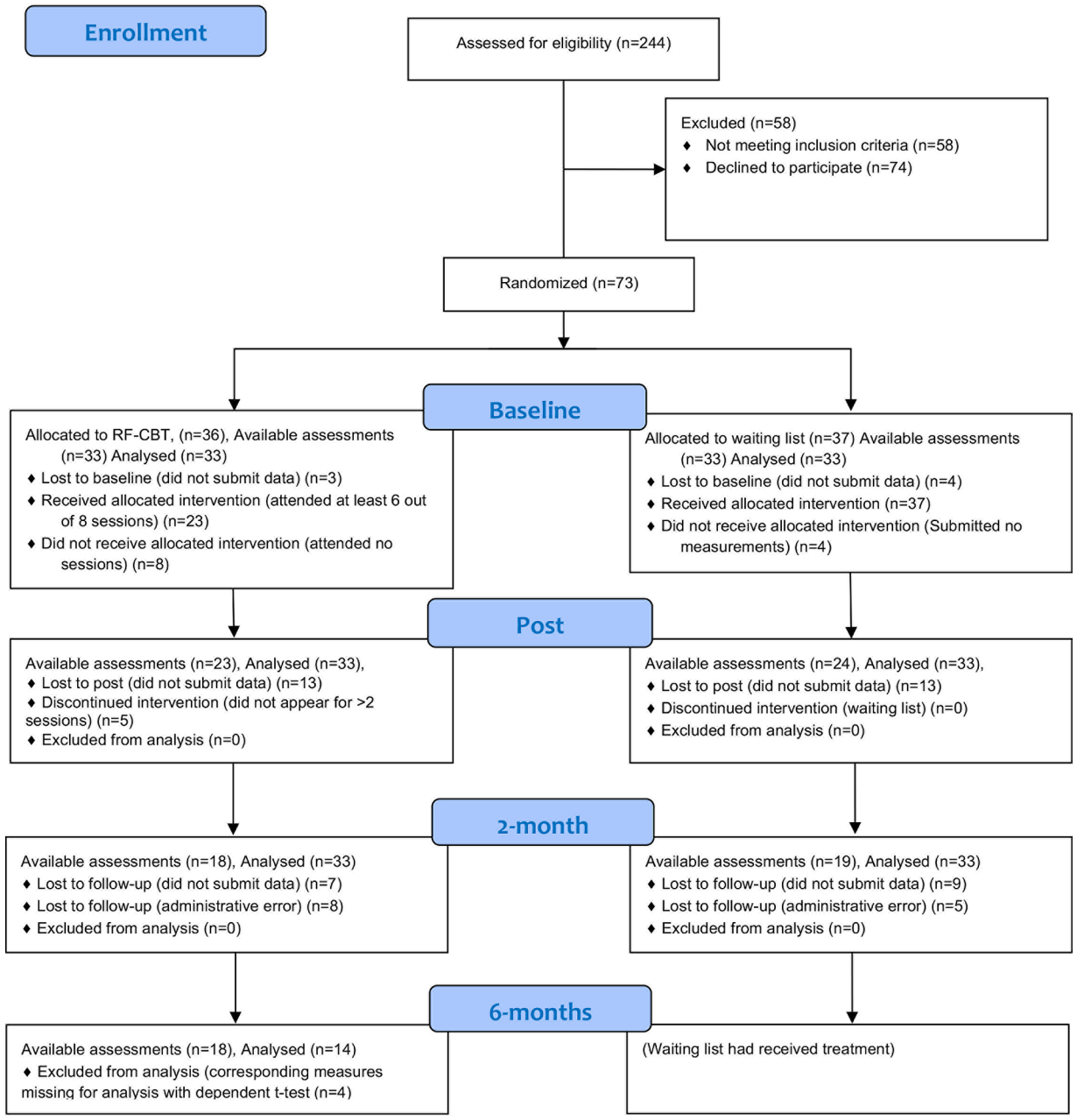


FIGURE 1
Flow diagram of participants (Note that linear mixed models use all available data points and may result in more analyses than available assessments because of how missing data are treated).

was made by an independent researcher at Karlstad University with the Microsoft excel Rand function. When each participant had provided baseline measurement data, they were phoned by a research group member and received practical information about their assignment. The participants who received group-administered RF-CBT visited a local primary healthcare centre

once every week for eight consecutive weeks, 2 h at a time. The time between indication of interest, screening, enrolment, allocation, and the beginning of treatment within the treatment condition varied between the participants depending on the time point of their application but was kept at a minimum duration. At most, about 2 months between application and treatment start, and about 1 month between enrolment and the beginning of treatment.

2.5. Measures

All regular measurements with self-rating scales (at baseline = 0 weeks, post = 10 weeks,[4] follow-up 1 = 2-months and follow-up 2 = 6 months[5]) were sent by email through which participants could access a secure digital system for collecting research data, between November 2018 and December 2019. Three reminders were sent after 2, 4, and 6 days. The baseline measurements were administered up to 2 weeks before the treatment. After the first session, the Credibility and Expectancy Questionnaire (CEQ; Devilly and Borkovec, 2000) was provided to assess perceived credibility and expectancy. After the last session, the Negative Effects Questionnaire (NEQ-20; Rozental et al., 2016) was provided to assess adverse side effects and incidents. All self-report data except the NEQ and the CEQ were collected digitally and ensured that no individual items were missing at any measurements.

2.5.1. Primary outcome measures

2.5.1.1. Worry

The Penn State Worry Questionnaire (PSWQ; Meyer et al., 1990) was used to assess the severity of worry. The PSWQ consists of 16 items, with each item assessing the extent of worry (e.g., "My worries overwhelm me" or "Once I start worrying, I cannot stop") rated on a Likert-scale from 1 (i.e., "not at all typical of me") to 5 (i.e., "very typical of me"), rendering a total score between 16 and 80. A total score of ≥45 was used to indicate clinical levels of worry (Meyer et al., 1990). Cronbach's α in the present study at baseline was 0.86.

2.5.1.2. Transdiagnostic symptoms

The Insomnia Severity Index (ISI; Bastien, 2001) was used to assess symptoms of insomnia disorder. The ISI consists of seven items (e.g., "How difficult is it for you to fall asleep?") rated on a scale from 0 (i.e., "not at all") to 4 (i.e., "much"), rendering a total score between 0 and 28. A total score of ≥8 was used to indicate clinical levels of insomnia symptoms. Cronbach's α in the present study at baseline was 0.85.

The Montgomery-Åsberg Depression Rating Scale (MADRS-S; Svanborg and Asberg, 1994) assessed depressive symptoms. The MADRS-S consists of nine items (e.g., "Here you should assess your interest in your surroundings, in other people, and in activities that normally give you pleasure") rated on a scale between 0 (i.e., description of mild or absent symptoms) to 6 (i.e., description of severe symptoms), rendering a final score between 0 and 45. A total score of ≥13 was used to indicate clinical levels of depression. A score of ≥30 (the threshold was later corrected to ≥34) indicated severe depression. Reported scores of ≥4 on item 9 indicate elevated risks of suicide. Cronbach's α in the present study at baseline was 0.85.

The Overall Anxiety Severity and Impairment Scale (OASIS; Norman et al., 2006) was used to assess anxiety symptoms. The OASIS consists of five items (e.g., "In the past week, how often have you felt anxious?") rated on a scale from 0 (i.e., description of low severity/frequency of symptoms) to 4 (i.e., description of high severity/frequency of symptoms), rendering a final score between 0 and 20. A total score of ≥8 was used to indicate clinical anxiety levels (Campbell-Sills et al., 2009). Cronbach's α in the present study at baseline was 0.87.

2.5.2. Secondary outcome measures

The Perseverative Thinking Questionnaire (PTQ; Ehring et al., 2011) was used to assess the severity of RNT. The PTQ consists of 15 items (e.g., "the same thoughts keep going through my mind again and again) rated on a scale from 0 (i.e., "never") to 4 (i.e., "almost always"), rendering a final score between 0 and 60. No clinical cut-offs are available for PTQ. However, higher scores indicate more severe problems. Cronbach's α in the present study at baseline was 0.93.

Brunnsviken Brief Quality of life scale (BBQ; Lindner et al., 2016) was used to assess quality of life and consists of 12 items (e.g., "I am satisfied with my leisure time: I have the opportunity to do what I want to relax and enjoy myself") rated on a Likert-scale between 0 (i.e., "do not agree at all") and 4 (i.e., "agree"), rendering a final score between 0 and 48. No cut-offs are available for BBQ. However, lower scores indicate lower quality of life. Satisfactory psychometric properties have been reported concerning the validity, internal consistency, and reliability (Lindner et al., 2016). Cronbach's α in the present study was calculated to be 0.79.

The Negative Effects Questionnaire (NEQ-20; Rozental et al., 2016) was used to measure adverse side effects and incidents post-treatment and consisted of 20 questions (e.g., "I started feeling ashamed in front of other people because I was having treatment" and is rated in three steps. The first step indicates whether a phenomenon occurred during treatment or not with yes and no questions. The second step rates the severity of the effect on a five-point scale ranging from "not at all to "extremely." The third step of each question states the cause of the effect; "The treatment I received" or "Other circumstances." Cronbach's α was not calculated in the present study due to large amounts of missing data (see the result sections).

2.5.3. Other measures

The Credibility and Expectancy Questionnaire (CEQ; Devilly and Borkovec, 2000) was used to assess perceived treatment credibility after the first session and consisted of six items (e.g., "at this point, how much sense does the therapy offered to you make?") rated between 1 (i.e., "not at all") and 9 (i.e., "very much"; item 1–3 and 5) or 0 to 100% (item 4 and 6). The first three items have constituted a cognitive factor (credibility), whereas the last three items have constituted an affective factor (expectancy) concerning the treatment. To handle the different scales within CEQ, individual composite scores were calculated by

4 Due to logistics, there could be up to 2weeks between the pre-treatment measurements and first session, thus post-treatment measurements were conducted in close proximity to the treatment ending.

5 Due to a mistake in the pre-registration process, the two-month follow-up measurements were not specified. Also, mid-measurements that were intended for analyses outside of the main article were specified in the pre-registration but not included in the present analyses.

first standardising each item and then summing the items included in each factor case wise (Devilly and Borkovec, 2000). Mean composite scores were presented for items 1–3 and item 4 according to Thompson-Hollands et al. (2014). Cronbach's α in the present study was calculated to be 0.73 for factor 1 and to 0.68 for factor 2.

2.5.4. Structured interviews

The Duke Structured Interview for Sleep Disorders (DSISD; Edinger et al., unpublished material; Taylor et al., 2018) was used to assess DSM-5 criteria for insomnia disorder and sleep apnea during the screening procedure. Satisfactory psychometric properties have been demonstrated concerning discrimination between disorders, inter-rater reliability, and reliability (Carney et al., 2009; Taylor et al., 2018).

The Mini-International Neuropsychiatric Interview (MINI; Sheehan et al., 1998) covered DSM-5 criteria for 17 different psychological disorders and was used to assess comorbid disorders for inclusion and exclusion symptoms present study. Section A, B, C, D, E, F, K, N, and O were used during the screening procedure. Satisfactory psychometric properties have been demonstrated concerning the validity of all diagnostic areas except drug dependence and test–retest-and inter-rater reliability (Sheehan et al., 1998).

2.6. Treatment

The treatment protocol used in the study was based on the published manuals "Rumination-Focused Cognitive-Behavioral Therapy for Depression" (Watkins, 2018) and "Ruminationsfokuseret Kognitiv Adfærdsterapi for Depression" (Møller et al., 2017). All material was translated to Swedish and modified to fit eight 2-h group sessions with nine participants (including 15-min breaks). The treatment modules are presented in Table 1. All sessions included basic therapeutic techniques, such as normalisation and validation, and general principles for cognitive-behavioural therapy, such as presenting an agenda, psychoeducation, within-session practice and home assignments. Functional analysis and "if-then plans" were used throughout the treatment. The "If-then plans" link with the functional analysis of RNT and entails finding the triggers and warning signs for RNT and then making plans for alternative constructive strategies to do instead of RNT to those triggers (e.g., trigger = feeling anxious, prior response = abstract rumination around "What if I'm not good enough? Why is this hard?," alternative strategy = concrete thinking "What steps can I take to prepare?"). For further elaborations and clarifications regarding specific techniques, see Watkins (2018) and Møller et al. (2017). The treatment protocol used in this study may be shared upon on formal request.

2.7. Therapists

There were four RF-CBT groups run for the intervention arm, each delivered by two group leaders, of which at least one was an experienced licensed psychologist with training in CBT. Eight therapists in total delivered the four RF-CBT groups. Four RF-CBT groups were run for the wait-list control group at 8 weeks. The treatment protocol was administered by two group leaders, of which at least one was a licensed psychologist. The therapists were either licensed psychologists, graduates in clinical psychology, or final year undergraduate students in psychology who had received clinical training. All therapists were involved in the formulation of the treatment protocol, conducted extensive self-studies of RF-CBT, and attended discussion seminars with the project group.

2.8. Adherence to treatment and dropout

Data on attendance were collected for all sessions, but no measure for in-session adherence or homework assignments was used. Because of ethical regulations, participants did not have to state the reason for their dropout or missed sessions, and no systematic investigations for dropouts or missed sessions were made.

2.8.1. Therapist adherence

Two sessions from each of the four treatment groups were randomly selected for external review concerning therapist adherence to the protocol (Sessions 2 and 6 in the first group, sessions 3 and 5 in the second group, sessions 5 and 7 in the third group, session 5 and 6 in the fourth group). A licensed psychologist who was previously involved in developing the treatment protocol listened to complete recordings from the randomly selected sessions. Each element (such as review of previous home assignments, exercises on session theme, review of upcoming homework, evaluation of session) of each session was reviewed. The degree of adherence to each element of the session was evaluated on a scale from 1 to 3, where 1 indicates a low degree of adherence, 2 an acceptable degree, and 3 a full degree of adherence to the protocol.

2.9. Power analysis

Power calculations were made for the main statistical analysis Linear mixed models based on mean differences (ES = d = 0.89) in worry (group RF-CBT vs. WL) obtained from Topper et al. (2017). With the desired power of 0.80 alpha level of 0.05, a minimum of 27 participants per arm was required to detect a large standardised mean difference effect size (≥d = 0.80) according to Kazdin and Association, A. P (1992, p.283). In addition, nine participants were added to each arm to handle an expected dropout rate of <20%. During recruitment, an administrative error rendered one extra participant on the waiting list condition, resulting in 73 participants.

2.10. Statistical analyses

SPSS was used to analyse data (IBM Corp, 2017; version 26). Continuous variables collected at the primary assessment points (baseline, post-treatment, and 2-month follow-up) were analysed using linear mixed models (covariance pattern models) fitted with restricted maximum likelihood (Hedeker and Gibbons, 2006). Linear mixed models use all available data, account for the correlations between repeated

10.3389/fpsyg.2023.1196945

TABLE 1 Treatment modules.

Session	Content	Home assignment
1: Emotions, worry and rumination	Practical information, introducing emotions, worry and rumination, functional analysis, worry diary and treatment goal formulation	Complete form for treatment goal formulation and a worry diary
2: Avoidance	Explaining unhelpful avoidance with operant behaviour analysis and if-then plans	Track avoidance with functional analysis and complete forms for If-then plans
3: Relaxation	Functional analysis of worry and rumination (RNT) and introducing relaxation.	Practice relaxation and if-then plans.
4: Changing process style	Introducing abstract thinking versus concrete and specific thinking	Practice concrete thinking and if-then plans
5: Being present in activities	Introducing mindfulness, flow, and visualising	Practice visualising, being mentally present in activities ("flow") and if-then plans
6: Self-compassion	Introducing self-compassion	Practice self-compassion and if-then plans
7: Which are your values? Learning from experience	Introducing values, relapse prevention and maintenance plan	Complete plan for maintenance and relapse prevention
8: Ending and evaluation of treatment goals	Follow-up treatment goals, evaluating treatment	

observations, and provide unbiased estimates under a lenient missing data assumption (Hesser, 2015). All individuals with at least one observation on the dependent variable were included in the models, resulting in an intention-to-treat based analysis.[6] Time was treated as a categorical variable in the model by including two dummy variables representing a change from baseline to post and baseline to follow-up. We analytically determined the best-fitted variance–covariance matrix by comparing various covariance structures to an unstructured form (i.e., full or saturated model for covariance). Estimates of the population's average differential change over time as a function of treatment conditions were evaluated using the model's time by condition interaction effects. Based on parameter estimates from linear mixed models we computed effect sizes in the form of standardised mean difference (Cohen's d) with associated confidence intervals following Feingold's formulas (Feingold, 2009; Feingold et al., 2014).

The total number of participants within each arm moving across the clinical cut-off levels (PSWQ: 45), ISI: 8, OASIS: 8, MADRS: 13) between base-and post, baseline and 2-month follow-up, and baseline and 6-month follow-up were used to assess clinical significance (Appendix; Table 6).

Item scores on CEQ were standardised and summed in two composites: expectancy (item 1–3) and credibility (item 4–6). Pearson correlations were conducted between the credibility/expectancy composites and change scores on outcome variables with significant effects between baseline and post-treatment measurements and between baseline and the 2-month follow-up measurements. These analyses were conducted to investigate if credibility or expectancy were associated with the treatment progress (Devilly and Borkovec, 2000). Because the averages of standardised items scores equal 0, mean scores and standard deviation for each composite are presented according to Thompson-Hollands et al. (2014).

3. Results

3.1. Demographic characteristics

In the study, 73 participants between the ages 21 and 75 (M = 47.41 *SD* = 17.23), 54 women and 19 men were included (Table 2).

3.2. Controlled treatment effects at the post-and 2-month follow up

3.2.1. Primary outcomes

Observed means and standard deviations as a function of the condition, along with model-implied effect sizes, are presented in Table 3, and parameter estimates from linear mixed models are presented in Table 4. Observed changes in RF-CBT were all in the expected direction with improvements from baseline to follow-up assessments, and model-implied within-group effects in RF-CBT between baseline and 2-month follow-up were in the range of $d = 0.65$ to $d = 1.02$ for all primary outcomes.

We observed significant time by group interaction effects regarding insomnia symptoms (ISI) between the baseline and post-measurements, with a model-implied between-group effect size of large strength and between baseline and 2-month follow-up measurements with a model-implied between-group effect size of moderate strength, in favour of RF-CBT. A significant time by group interaction effect with a model-implied between-group medium effect size regarding symptoms of depression (MADRS) was found between the baseline and 2-month follow-up measurements in favour of RG-CBT, but no statistically significant time by group interaction between the baseline and post-measurements was detected. No significant time by group interaction effects were found regarding worry (PSWQ) or anxiety symptoms (OASIS).

6 Since seven participants (three in the treatment- and four in the waitlist condition) were randomised but did not complete the baseline measurements, strict ITT was not maintained.

TABLE 2 Description of the participants.

	RF-CBT		WAITLIST	
	M (SD)	n	M (SD)	n
PSWQ	59.12 (9.81)	33	63.36 (7.98)	33
ISI	15.61 (5.03)	33	15.21 (5.97)	33
OASIS	7.58 (4.1)	33	8.18 (4.05)	33
MADRS-S	18.42 (7.73)	33	20.61 (7.13)	33
BBQ	31.94 (6.75)	33	30.85 (6.94)	33
PTQ	35.03 (10.01)	33	38.09 (8.68)	33
CEQ (credibility)	7.17 (0.94)	28		
CEQ (expectancy)	63.93 (17.07)	28		
Age	51.67 (16.11)	36	43.27 (17.49)	37
Years living in Sweden	50.21 (15.61)	33	43.00 (18.95)	33
Gender		36		37
Female		30		24
Male		6		13
Relationship status				
Married / Living together		18		22
Partner but not living together		1		4
Widow / Widower		3		1
Divorced/separated		5		4
Single		5		2
Other		1		0
Educational level				
Elementary school		0		0
High school/folk high school		10		16
Vocational training		4		2
College / University		19		15
Occupation				
Permanent employment		15		18
Temporary employment		0		1
Unemployed		2		0
Student		0		4
Retired		7		5
Disability pension		0		1
Other		3		2
More than one occupation		6		2
Country of origin				
Sweden		31		30
Other		2		3

PSWQ = Penn state worry questionnaire, ISI = insomnia severity index; OASIS = overall anxiety severity and impairment scale; MADRS-S = Montgomery-Åsberg depression rating scale self-rated; BBQ = Brunnsviken brief quality of life scale; PTQ = perseverative thinking questionnaire; CEQ = credibility/expectancy questionnaire.

3.2.2. Secondary outcomes

Concerning secondary outcomes, no significant time by group interaction effects was found for RNT according to PTQ, or quality of life according to BBQ.

3.3. Attendance at treatment

Participants' adherence to treatment is presented in the (Appendix; Table 8).

TABLE 3 Observed means and SD for the baseline, post-treatment and 2-month follow-up measurements by group and model-implied between-and within-group effect sizes.

		M (*SD*)		Effect size Cohen's *d* (95% CI)			
Instrument and condition	Baseline	Posttreatment	2-month follow-up	Within-group, baseline - post-treatment	Within-group, baseline - 2-month follow-up	Between-group, baseline – posttreatment	Between-group, baseline - 2-m FU
PSWQ						0.39 (0.96, −0.18)	0.41 (1.15, −0.33)
Treatment	59.12 (9.81)	53.58 (11.74)	50.03 (10.37)	0.62	1.02		
Waitlist	63.36 (7.98)	61.29 (9.11)	57.94 (8.69)	0.23	0.61		
ISI						0.84 (1.32, 0.36)	0.56 (1.09, 0.03)
Treatment	15.61 (5.03)	11.25 (5.47)	10.21 (5.33)	0.79	0.98		
Waitlist	15.21 (5.97)	15.5 (5.92)	12.9 (5.99)	−0.05	0.42		
OASIS						0.38 (0.86, −0.10)	0.34 (0.86, −0.19)
Treatment	7.58 (4.10)	5.26 (3.73)	4.71 (3.50)	0.57	0.70		
Waitlist	8.18 (4.05)	7.41 (4.74)	6.68 (4.13)	0.19	0.37		
MADRS						0.39 (0.92, −0.14)	0.54 (0.93, 0.14)
Treatment	18.42 (7.73)	13.87 (7.62)	11.78 (6.38)	0.61	0.89		
Waitlist	20.61 (7.13)	18.96 (8.82)	17.95 (6.48)	0.22	0.36		
BBQ						−0.16 (0.25, −0.56)	−0.3 (0.15, −0.74)
Treatment	31.94 (6.75)	34.17 (7.26)	36.35 (5.11)	0.33	0.64		
Waitlist	30.85 (6.94)	32 (6.23)	33.23 (7.77)	0.17	0.35		
PTQ						0.39 (0.78, −0.11)	0.16 (0.69, −0.53)
Treatment	35.03 (10.01)	28.98 (12.15)	28.9 (11.95)	0.65	0.65		
Waitlist	38.09 (8.68)	35.69 (8.57)	33.45 (7.79)	0.26	0.50		

2-m FU = 2-month follow-up measurements PSWQ = Penn state worry questionnaire, ISI = insomnia severity index; OASIS = overall anxiety severity and impairment scale; MADRS-S = Montgomery-Åsberg depression rating scale self-rated; BBQ = Brunnsviken brief quality of life scale; PTQ = perseverative thinking questionnaire.

3.4. Follow-up attrition

Out of 73 participants randomised, seven did not report any data at the baseline measurements[7] (three (8%) in the treatment condition and four (11%) in the wait-list condition). Data from 26 participants were missing at the post-treatment measurements, 13 (36%) in the treatment condition and 13 (35%) in the wait-list control group condition. Data from 36 participants were missing at the 2-month follow-up, 18 (50%) in the treatment condition and 18 (49%) in the wait-list control group condition. Due to an administrative error, nine participants (25%) in the treatment condition and eight (22%) on the waiting list never received their email prompts for the 2-month follow-up. At the 6-month follow up, data from 18 participants (50%) in the treatment condition were collected. Since the participants in the wait-list condition had received treatment at that time point, no comparative data were collected (see further details in Appendix; Table 9).

7 The ongoing 1:1 block randomization allowed participants to cancel their participation after enrolment but before submitting their baseline measurements.

3.5. Therapist's adherence

The therapist's adherence to the treatment protocol was reported as high, with some notable decline in ratings concerning the element of post-session evaluation (Appendix; Table 7).

3.6. Treatment credibility and expectancy

Twenty-eight out of 36 participants in the RF-CBT condition submitted The Credibility and Expectancy Questionnaire (CEQ) with mean scores of 7.17 ($SD = 0.94$) for credibility and 63.93 ($SD = 17.07$) for expectancy. No significant correlations were found between: credibility and change in ISI scores between the baseline and post measurements, $r(22) = -0.035$, $p = 0.878$ nor between expectancy and change in ISI scores between baseline and post-treatment measurements, $r(22) = 0.026$ $p = 0.908$, nor between credibility and change in ISI scores between baseline and the 2-month follow-up measurements, $r(17) = -0.299$, $p = 0.244$, nor between expectancy and change in ISI scores between the baseline and 2-month follow-up measurements, $r(17) = 0.043$ $p = 0.870$, nor between credibility and change in MADRS-S scores between the baseline and 2-month follow-up measurements, $r(17) = 0.200$, $p = 0.442$, nor between expectancy and change in MADRS-S scores between baseline and the

TABLE 4 Results of the linear mixed-effects regression analyses.

	Linear mixed-effects 95% CI	
Instrument and condition	Beta (*SE*)	*p*
PSWQ		
Time1 (baseline - posttreatment)	−2.08 (1.79)	0.25
Time2 (baseline - 2-month follow-up)	−5.42 (2.35)	0.02
Tx (group)	−4.24 (2.37)	0.08
Time1 * Tx	−3.47 (2.56)	0.18
Time2 * Tx	−3.67 (3.36)	0.28
ISI		
Time1 (baseline-post)	0.29 (0.93)	0.75
Time2 (baseline-2-month follow-up)	−2.31 (1.02)	0.03
Tx (group)	0.39 (1.39)	0.78
Time1 * Tx	−4.65 (1.33)	<0.01
Time2 * Tx	−3.08 (1.46)	0.04
OASIS		
Time1 (baselinepost)	−0.77 (0.69)	0.27
Time2 (baseline-2-month follow-up)	−1.5 (0.76)	0.05
Tx (group)	−0.61 (1.01)	0.55
Time1 * Tx	−1.54 (0.99)	0.12
Time2 * Tx	−1.37 (1.08)	0.21
MADRS		
Time1 (baselinepost)	−1.64 (1.37)	0.24
Time2 (baseline-2-month follow-up)	−2.66 (1.02)	0.01
Tx (group)	−2.18 (1.83)	0.24
Time1 * Tx	−2.91 (1.97)	0.15
Time2 * Tx	−3.98 (1.47)	0.01
BBQ		
Time1 (baselinepost)	1.15 (0.98)	0.24
Time2 (baseline-2-month follow-up)	2.38 (1.07)	0.03
Tx (group)	1.09 (1.68)	0.52
Time1 * Tx	1.08 (1.4)	0.44
Time2 * Tx	2.02 (1.53)	0.19
PTQ		
Time1 (baselinepost)	−2.4 (1.56)	0.13
Time2 (baseline-2-month follow-up)	−4.64 (2.13)	0.03
Tx (group)	−3.06 (2.42)	0.21
Time1 * Tx	−3.64 (2.24)	0.11
Time2 * Tx	−1.49 (3.06)	0.63

Time1 = baseline – posttreatment, time2 = baseline 2-month follow-up, Tx = treatment variable (1 = treatment, 0 = control). PSWQ = Penn state worry questionnaire, ISI = insomnia severity index; OASIS = overall anxiety severity and impairment scale; MADRS-S = Montgomery-Åsberg depression rating scale self-rated; BBQ = Brunnsviken brief quality of life scale; PTQ = Perseverative thinking questionnaire.

2-month follow-up measurements, $r(17) = 0.035$ $p = 0.895$. This suggests that neither treatment credibility nor expectancy seems to be associated with the significant effects of RF-CBT on insomnia symptoms (baseline/post, baseline/2-month follow-up) and depression (baseline/2-month follow-up).

3.7. Uncontrolled treatment effects over the 6-month follow-up

No statistically significant differences were observed between the 2- and 6-month follow-up measurements for those initially

TABLE 5 Within-group-mean-differences in the treatment condition between 2-month and 6-month follow-up measurements.

	2-month follow-up $n = 14$	6-month follow-up $n = 14$	Paired differences	*t*-test			
	M (SD)	M (SD)	M (*SD*)	t	*df*	*p*	Cohen's d
PSWQ	48.57 (10.27)	46 (8.82)	2.57 (6.24)	1.54	13.00	0.15	−0.27
ISI	10.57 (4.99)	10.07 (4.16)	0.5 (5.03)	0.37	13.00	0.72	−0.11
OASIS	4.43 (2.85)	3.79 (3.09)	0.64 (2.34)	1.03	13.00	0.32	−0.22
MADRS-S	10.86 (5.41)	11.64 (7.03)	−0.79 (5.48)	−0.54	13.00	0.60	0.12
BBQ	36.5 (5.14)	35.86 (5.7)	0.64 (6.08)	0.40	13.00	0.70	−0.12
PTQ	27.14 (12.33)	25.57 (11.06)	1.57 (5.96)	0.99	13.00	0.34	−0.13

PSWQ = Penn state worry questionnaire, ISI = insomnia severity index; OASIS = overall anxiety severity and impairment scale; MADRS-S = Montgomery-Åsberg depression rating scale self-rated; BBQ = Brunnsviken brief quality of life scale; PTQ = perseverative thinking questionnaire. Effect sizes according to Cohen (2013) (0.20–0.49 = small effects, 0.50–0.79 medium effects, 0.80 and above large effects.

randomised to treatment. This suggests that observed effects on ISI and MADRS-S were maintained throughout the 6-month follow-up (Table 5).

3.8. Adverse side effects and incidents

A total of 33 participants (including participants from the wait-list control group who were offered treatment after the 2-month follow-up) completed the NEQ-20. A total of 67 instances of adverse side effects were reported by 18 participants, of which 23 were reported as side effects of the treatment rather than other circumstances. A total of 28 instances of reported side effects were missing data on whether the treatment or other circumstances were the probable cause of that side effect.

The following statements and number of instances were reported as "probably caused by the treatment I received": "I had more problems with my sleep" (1) "I felt like I was under more stress" (2), "I experienced more anxiety" (1), "I experienced more hopelessness" (1), "I experienced more unpleasant feelings" (3), "Unpleasant memories resurfaced" (4), "I think that I have developed a dependency on my treatment" (1), and "I did not always understand my treatment" (1).

The extent to which the responder felt affected ranged between 0 ("not at all") and 3 ("very"). Two instances of "very affected" were reported for "I felt like I was under more stress," one instance was reported under "I experienced more anxiety," and one instance was reported under "I experienced more unpleasant feelings." This indicates that RF-CBT provided in a group setting on a comorbid sample may have adverse side effects and incidents.

4. Discussion

The results of this RCT suggest that the RF-CBT group intervention is effective for insomnia (in line with the hypothesis) with large (post) and medium (2-month follow-up) effect sizes and potentially for depression with a medium effect size (2-month follow-up, partly in line/partly at odds with the hypothesis). These improvements remained at the 6-month follow-up. Whilst there were also moderate effect sizes for the effect of the RF-CBT group relative to wait-list control group on anxiety and RNT, there were no statistically significant differences (at odds with the hypothesis). Neither were there any significant differences concerning worry, and quality of life (also at odds with the hypothesis).

It is noteworthy that insomnia severity was significantly lower for those who had received RF-CBT compared to the wait-list control group, even though insomnia was not directly addressed in the treatment protocol (i.e., there were no examples or exercises that specifically addressed sleep) and considering the low statistical power to detect small and moderate effects. This finding, however, is consistent with the hypothesis that elements within RF-CBT designed to reduce RNT and avoidance also improve symptoms of insomnia (Harvey et al., 2004; Ehring and Watkins, 2008). Also, RF-CBT did not significantly reduce RNT relative to the wait-list control group, which is at odds with the general hypothesised mechanism of change. The current results may therefore also add some uncertainty to the theoretical link between RNT and insomnia although the power related issues make such inferences difficult. Thus, if these findings are replicated, it will be important to investigate other processes through which RF-CBT may influence insomnia.

Further, depressive symptoms did not differ significantly between the arms at the post-treatment measurement but during the 2-month follow-up. This is also important to note since previous research has demonstrated clear effects of RF-CBT on depressive symptoms (Watkins et al., 2007, 2011; Topper et al., 2017; Hvenegaard et al., 2020). Moving back to insomnia, considering the well-established role of insomnia as a risk factor for depression (Baglioni et al., 2011), the results could be interpreted as if the risk of depression has been lowered in the treatment condition. Perhaps this is why a lower prevalence of depressive symptoms was found at the follow-up, only after a potential maintaining factor (insomnia) had decreased.

There are several potential alternative explanations to the null-results at odds with the hypotheses. First, it cannot be ruled out that the lack of significant time by group effects for RNT, anxiety, and depressive symptoms (post-treatment) are explained by low statistical power to detect small-to-moderate effects, or on significant attrition at the post-and at the two-month follow-up measurements. In other words, the variability in the data in relation to the sample size and the mean differences between the conditions, may have been too high to detect statistically significant effects. In order not to further increase the risk of type 2-errors, no adjustment for multiple testing was made even though it increases the risk of type 1-errors. Second, only 23 out of the 36 (64%) participants randomised into the treatment condition attended >5 sessions, only nine out of 36 (25%) attended all eight

sessions, and eight (22%) attended no sessions. This may mean that any genuine treatment effect of the RF-CBT groups would be diluted as a significant proportion of patients received little or no exposure to the RF-CBT treatment. However, a meta-analysis found that the average dropout rates in clinical studies with cognitive behavioural therapy in groups were 14,5% (95% CI = 9.7, 21.0%) at baseline and 24,6% (95% CI = 19.9, 30.1%) during treatment (Fernandez et al., 2015). Thus, the drop-out rates in the current study (attended <6 sessions) were close to the upper Cl for both baseline and during treatment. Third. the intervention dose was smaller than in a comparable study (Møller et al., 2017). The current treatment was administered over a shorter period, with eight instead of 12 sessions at 2 h instead of 3 h per session, and an individual session was not offered before the group sessions. However, group-based RF-CBT have been administered over 6 to 10 sessions, and 6 sessions was found effective for participants with clinical problems (Watkins, 2018). Fourth, a transdiagnostic sample with symptoms within two out of three diagnostic areas was included in the study. Thus, it is not necessarily expected that participants with clinical symptom levels within the areas of anxiety and insomnia but not within depression at baseline would report decreased severity of depressive symptoms (i.e., fewer differences on average between the arms and larger in-group variance as compared to samples with consistent symptomology were expected). This should make it harder to detect differences between the arms.

4.1. Limitations

First, the power calculation was based on large effects and significant attrition at the post and follow-up measurements increased the risk of type 2 errors. In order not to further increase the risk of type 2-errors, no adjustment for multiple testing was made even though it increases the risk of type 1-errors.

Second, significant proportions of the participants attended less than six sessions. As previously mentioned, no systematic data on reasons for drop out was collected. However, there are several general potential explanations for the relatively high dropout rate. For example, the clinical contexts will generally suffer from greater attrition (in our case a primary healthcare centre) than more controlled research settings such as a university clinic setting. Also, more health issues (several as opposed to one problem area) might mean greater difficulties tolerating or participating in treatment and a lower willingness to wait for treatment. Since the protocol was addressing RNT rather than problems that are specific to a disorder, it is possible that at least some examples that was used to illustrate problems did not engage the participants enough.

Third, Since PTQ are less evaluated than PSWQ and lacks clinical norms, because of the considerable overlap between the concepts, and since the worry component of RNT was expected to be more prominent than depressive rumination in this heterogenous sample, PSWQ was used to assess clinical levels of worry (thus RNT) during the recruitment in this study. In this context, it is important to note that RF-CBT was originally developed for people with elevated levels of depressive rumination rather than trait worry. According to Spinhoven et al. (2018), most studies on interventions that have addressed RNT in depressive samples have operationalised RNT with the original version of the Ruminative Responses Scale, although PSWQ have also frequently been used. This way of operationalizing RNT may have affected the recruitment in such a way that the sample deviates from other studies with different means for screening for RNT and therefore might make comparisons between treatment effects between trials more difficult.

Future research should aim to address the methodological shortcomings of the current study. It should be highlighted however, that clinical research consists of multiple dilemmas and non-the least concerning maintaining both ecological validity and scientific rigour. But what was lost in one end may allow for gains in another. Fewer participants with more heterogenous symptoms who gets a lower dose of a group-treatment with higher attrition-and drop-out rates better reflect the nature of clinical reality. Although significant attrition indeed may increase the risk for type-1 errors, the risk of type-2 errors would be a lot greater in this study. Considering treatment dose, dropout rates, the sample size (i.e., the standard deviation would be expected to be greater with a smaller sample), the more remarkable it seems that significant improvements of insomnia symptoms were detected. Future research should also consider conducting component analysis of the different elements within RF-CBT (i.e., dismantling).

4.2. Strengths

The following strengths of the study should be emphasised. First, the treatment was administered in a naturalistic setting at a primary health care centre on a heterogenous sample in collaboration with therapists who worked there. This strengthens the ecological and external validity.

Second, it was the first study to look at the effects of RF-CBT on a sample with clinical symptom levels within the common areas of depression, anxiety, and insomnia.

Third, the current study was a randomised controlled trial. This has long been considered the gold standard when evaluating treatment effects. Linear mixed models also deal efficiently with missing data and provide unbiased estimates under acceptable assumptions.

Finally, the participants in the waitlist condition did not start their treatment until after the 2-month follow-up, which strengthens internal validity.

5. Conclusion

RF-CBT provided in a primary care health care setting and delivered in groups for individuals with clinical symptom levels of at least two disorders appeared effective for insomnia and potentially effective for depression symptomatology. Future research should aim to increase knowledge under which circumstances (when, how and for whom) RF-CBT might be considered the first treatment choice and replicate these findings in a larger definitive sample.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Ethics statement

The studies involving human participants were reviewed and approved by The regional ethics review board in Uppsala, Sweden Dnr: 2018/197 and Dnr: 2019-00987. The patients/participants provided their written informed consent to participate in this study.

Author contributions

MA and OE: funding acquisition, investigation, resources, and writing – review and editing. IH, TK, and VL: investigation and writing – review and editing. HH: data curation, formal Analysis, visualisation, and writing – review and editing. AN: funding acquisition, conceptualization, data curation, investigation, methodology, resources, supervision, visualisation, writing – original draft, and writing – review and editing. MT: funding acquisition, conceptualisation, investigation, methodology, project administration, resources, supervision, visualisation, writing – original draft, and writing – review and editing. DW: data curation, formal analysis, investigation, resources, visualisation, writing – original draft, and writing – review and editing. EW: conceptualisation, methodology, and writing – review and editing. All authors contributed to the article and approved the submitted version.

Funding

This work was supported by the County Council in Värmland (LIVFOU-763591, 2018–2019).

Acknowledgments

Preliminary data were presented as part of the master's theses by Felicia Dunér and Linnea Modén, Ida Halldin and Tina Kindbom, and Caroline Höglund and Varja Lamourín at Örebro University in 2019. The current manuscript includes more data and different analyses. Lisa Franzen and Hillevi Lignell, Julia Franzén, and Josefin Fridlund also contributed to the data collection, for which the authors are grateful.

Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

Supplementary material

The Supplementary material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpsyg.2023.1196945/full#supplementary-material

References

American Psychiatric Association (2013). *Diagnostic and statistical manual of mental disorders* . (5th ed.). Available from: https://doi.org/10.1176/appi.books.9780890425596

Baglioni, C., Battagliese, G., Feige, B., Spiegelhalder, K., Nissen, C., Voderholzer, U., et al. (2011). Insomnia as a predictor of depression: a meta-analytic evaluation of longitudinal epidemiological studies. *J. Affect. Disord.* 135, 10–19. doi: 10.1016/j.jad.2011.01.011

Bastien, C. (2001). Validation of the insomnia severity index as an outcome measure for insomnia research. *Sleep Med.* 2, 297–307. doi: 10.1016/S1389-9457(00)00065-4

Behar, E., Alcaine, O., Zuellig, A. R., and Borkovec, T. D. (2003). Screening for generalized anxiety disorder using the Penn State worry questionnaire: a receiver operating characteristic analysis. *J. Behav. Ther. Exp. Psychiatry* 34, 25–43. doi: 10.1016/S0005-7916(03)00004-1

Borkovec, T., Ray, W. J., and Stober, J. (1998). Worry: A cognitive phenomenon intimately linked to affective, physiological, and interpersonal behavioral processes. *Cognitive therapy and research* 22, 561–576.

Campbell-Sills, L., Norman, S. B., Craske, M. G., Sullivan, G., Lang, A. J., Chavira, D. A., et al. (2009). Validation of a brief measure of anxiety-related severity and impairment: the overall anxiety severity and impairment scale (OASIS). *J. Affect. Disord.* 112, 92–101. doi: 10.1016/j.jad.2008.03.014

Carney, C. E., Ulmer, C., Edinger, J. D., Krystal, A. D., and Knauss, F. (2009). Assessing depression symptoms in those with insomnia: an examination of the beck depression inventory second edition (BDI-II). *J. Psychiatr. Res.* 43, 576–582. doi: 10.1016/j.jpsychires.2008.09.002

Cohen, J. (2013). *Statistical power analysis for the behavioral sciences*. Academic press.

Devilly, G. J., and Borkovec, T. D. (2000). Psychometric properties of the credibility/expectancy questionnaire. *J. Behav. Ther. Exp. Psychiatry* 31, 73–86. doi: 10.1016/S0005-7916(00)00012-4

Ehring, T., and Watkins, E. R. (2008). Repetitive negative thinking as a Transdiagnostic process. *Int. J. Cogn. Ther.* 1, 192–205. doi: 10.1680/ijct.2008.1.3.192

Ehring, T., Zetsche, U., Weidacker, K., Wahl, K., Schonfeld, S., and Ehlers, A. (2011). The perseverative thinking questionnaire (PTQ): validation of a content-independent measure of repetitive negative thinking. *J. Behav. Ther. Exp. Psychiatry* 42, 225–232. doi: 10.1016/j.jbtep.2010.12.003

Feingold, A. (2009). Effect sizes for growth-modeling analysis for controlled clinical trials in the same metric as for classical analysis. *Psychol. Methods* 14:43. doi: 10.1037/a0014699

Feingold, A., Tiberio, S. S., and Capaldi, D. M. (2014). New approaches for examining associations with latent categorical variables: applications to substance abuse and aggression. *Psychol. Addict. Behav.* 28, 257–267. doi: 10.1037/a0031487

Feldhaus, C. G., Jacobs, R. H., Watkins, E. R., Peters, A. T., Bessette, K., and Langenecker, S. A. (2020). Rumination-focused cognitive behavioral therapy decreases anxiety and increases behavioral activation among remitted adolescents. *J. Child Fam. Stud.* 29, 1982–1991. doi: 10.1007/s10826-020-01711-7

Fernandez, E., Salem, D., Swift, J. K., and Ramtahal, N. (2015). Meta-analysis of dropout from cognitive behavioral therapy: magnitude, timing, and moderators. *J. Consult. Clin. Psychol.* 83, 1108–1122. doi: 10.1037/ccp0000044

Harvey, A. G., Watkins, E., and Mansell, W. (2004). *Cognitive behavioural processes across psychological disorders: A transdiagnostic approach to research and treatment.* Oxford University Press, USA.

Hedeker, D., and Gibbons, R. D. (2006). *Longitudinal data analysis* Wiley-Interscience.

Hesser, H. (2015). Modeling individual differences in randomized experiments using growth models: recommendations for design, statistical analysis and reporting of results of internet interventions. *Internet Interv.* 2, 110–120. doi: 10.1016/j.invent.2015.02.003

Hoyer, J., Gloster, A. T., and Herzberg, P. Y. (2009). Is worry different from rumination? Yes, it is more predictive of psychopathology! *GMS Psycho Soc. Med.* 6:Doc06. doi: 10.3205/psm000062

Hvenegaard, M., Moeller, S. B., Poulsen, S., Gondan, M., Grafton, B., Austin, S. F., et al. (2020). Group rumination-focused cognitive-behavioural therapy (CBT) v. group CBT for depression: phase II trial. *Psychol. Med.* 50, 11–19. doi: 10.1017/S0033291718003835

IBM Corp (2019). *IBM SPSS Statistics for Macintosh, Version 26.0*. Armonk, NY: IBM Corp.

Kazdin, A. E., Association, A. P. (1992). *Methodological issues & strategies in clinical research* JSTOR. doi: 10.1037/10109-000

Kessler, R. C., Berglund, P., Demler, O., Jin, R., Merikangas, K. R., and Walters, E. E. (2005). Lifetime prevalence and age-of-onset distributions of DSM-IV disorders in the National Comorbidity Survey Replication. *Arch. Gen. Psychiatry* 62, 593–602. doi: 10.1001/archpsyc.62.6.593

Lim, J., and Dinges, D. F. (2010). A meta-analysis of the impact of short-term sleep deprivation on cognitive variables. *Psychol. Bull.* 136, 375–389. doi: 10.1037/a0018883

Lindner, P., Frykheden, O., Forsstrom, D., Andersson, E., Ljotsson, B., Hedman, E., et al. (2016). The Brunnsviken brief quality of life scale (BBQ): development and psychometric evaluation. *Cogn. Behav. Ther.* 45, 182–195. doi: 10.1080/16506073.2016.1143526

Martin, L. L., and Tesser, A. (2013). "Some ruminative thoughts" in *Ruminative thoughts*. Ed. W. Roberts (Psychology Press), 1–47.

Meyer, T. J., Miller, M. L., Metzger, R. L., and Borkovec, T. D. (1990). Development and validation of the Penn State worry questionnaire. *Behav. Res. Ther.* 28, 487–495. doi: 10.1016/0005-7967(90)90135-6

Møller, S. B., Hvenegaard, M., and Kistrup, M. (2017). Ruminationsfokuseret kognitiv adfærdsterapi for depression: manual til gruppeterapi. kbh.

Nolen-Hoeksema, S., Wisco, B. E., and Lyubomirsky, S. (2008). Rethinking rumination. *Perspect. Psychol. Sci.* 3, 400–424. doi: 10.1111/j.1745-6924.2008.00088.x

Norman, S. B., Hami Cissell, S., Means-Christensen, A. J., and Stein, M. B. (2006). Development and validation of an overall anxiety severity and impairment scale (OASIS). *Depress. Anxiety* 23, 245–249. doi: 10.1002/da.20182

Olatunji, B. O., Naragon-Gainey, K., and Wolitzky-Taylor, K. B. (2013). Specificity of rumination in anxiety and depression: a multimodal meta-analysis. *Clin. Psychol. Sci. Pract.* 20:225. doi: 10.1037/h0101719

Olatunji, B. O., Wolitzky-Taylor, K. B., Sawchuk, C. N., and Ciesielski, B. G. (2010). Worry and the anxiety disorders: a meta-analytic synthesis of specificity to GAD. *Appl. Prev. Psychol.* 14, 1–24. doi: 10.1016/j.appsy.2011.03.001

Riemann, D., Krone, L. B., Wulff, K., and Nissen, C. (2020). Sleep, insomnia, and depression. *Neuropsychopharmacology* 45, 74–89. doi: 10.1038/s41386-019-0411-y

Roca, M., Gili, M., Garcia-Garcia, M., Salva, J., Vives, M., Garcia Campayo, J., et al. (2009). Prevalence and comorbidity of common mental disorders in primary care. *J. Affect. Disord.* 119, 52–58. doi: 10.1016/j.jad.2009.03.014

Rozental, A., Kottorp, A., Boettcher, J., Andersson, G., and Carlbring, P. (2016). Negative effects of psychological treatments: an exploratory factor analysis of the negative effects questionnaire for monitoring and reporting adverse and unwanted events. *PLoS One* 11:e0157503. doi: 10.1371/journal.pone.0157503

Sheehan, D. V., Lecrubier, Y., Sheehan, K. H., Amorim, P., Janavs, J., Weiller, E., et al. (1998). The Mini-international neuropsychiatric interview (M.I.N.I.): the development and validation of a structured diagnostic psychiatric interview for DSM-IV and ICD-10. *J. Clin. Psychiatry* 59, 22–33.

Spinhoven, P., Klein, N., Kennis, M., Cramer, A. O. J., Siegle, G., Cuijpers, P., et al. (2018). The effects of cognitive-behavior therapy for depression on repetitive negative thinking: a meta-analysis. *Behav. Res. Ther.* 106, 71–85. doi: 10.1016/j.brat.2018.04.002

Svanborg, P., and Asberg, M. (1994). A new self-rating scale for depression and anxiety states based on the comprehensive psychopathological rating scale. *Acta Psychiatr. Scand.* 89, 21–28. doi: 10.1111/j.1600-0447.1994.tb01480.x

Taylor, D. J., Wilkerson, A. K., Pruiksma, K. E., Williams, J. M., Ruggero, C. J., Hale, W., et al. (2018). Reliability of the structured clinical interview for DSM-5 sleep disorders module. *J. Clin. Sleep Med.* 14, 459–464. doi: 10.5664/jcsm.7000

Thompson-Hollands, J., Bentley, K. H., Gallagher, M. W., Boswell, J. F., and Barlow, D. H. (2014). Credibility and outcome expectancy in the unified protocol: relationship to outcomes. *J. Exp. Psychopathol.* 5, 72–82. doi: 10.5127/jep.033712

Topper, M., Emmelkamp, P. M., Watkins, E., and Ehring, T. (2017). Prevention of anxiety disorders and depression by targeting excessive worry and rumination in adolescents and young adults: a randomized controlled trial. *Behav. Res. Ther.* 90, 123–136. doi: 10.1016/j.brat.2016.12.015

Walker, M. P., and van der Helm, E. (2009). Overnight therapy? The role of sleep in emotional brain processing. *Psychol. Bull.* 135, 731–748. doi: 10.1037/a0016570

Watkins, E. R. (2018). *Rumination-focused cognitive-behavioral therapy for depression* Guilford Publications.

Watkins, E. R., Mullan, E., Wingrove, J., Rimes, K., Steiner, H., Bathurst, N., et al. (2011). Rumination-focused cognitive-behavioural therapy for residual depression: phase II randomised controlled trial. *Br. J. Psychiatry* 199, 317–322. doi: 10.1192/bjp.bp.110.090282

Watkins, E. R., and Roberts, H. (2020). Reflecting on rumination: consequences, causes, mechanisms and treatment of rumination. *Behav. Res. Ther.* 127:103573. doi: 10.1016/j.brat.2020.103573

Watkins, E., Scott, J., Wingrove, J., Rimes, K., Bathurst, N., Steiner, H., et al. (2007). Rumination-focused cognitive behaviour therapy for residual depression: a case series. *Behav. Res. Ther.* 45, 2144–2154. doi: 10.1016/j.brat.2006.09.018

Watts, F. N., Coyle, K., and East, M. P. (1994). The contribution of worry to insomnia. *Br. J. Clin. Psychol.* 33, 211–220. doi: 10.1111/j.2044-8260.1994.tb01115.x

frontiers | Frontiers in Psychology

TYPE Original Research
PUBLISHED 14 September 2023
DOI 10.3389/fpsyg.2023.1233901

OPEN ACCESS

EDITED BY
Lara Guedes De Pinho,
University of Evora, Portugal

REVIEWED BY
Tânia Correia,
University of Porto, Portugal
Hong Wang Fung,
Hong Kong Baptist University, Hong Kong SAR, China

*CORRESPONDENCE
Lauren Marlotte
✉ Lmarlotte@mednet.ucla.edu

RECEIVED 02 June 2023
ACCEPTED 11 August 2023
PUBLISHED 14 September 2023

CITATION
Marlotte L, Klomhaus A, Ijadi-Maghsoodi R, Aralis H, Lester P, Griffin Esperon K and Kataoka S (2023) Implementing depression care in under-resourced communities: a school-based family resilience skill-building pilot randomized controlled trial in the United States.
Front. Psychol. 14:1233901.
doi: 10.3389/fpsyg.2023.1233901

Implementing depression care in under-resourced communities: a school-based family resilience skill-building pilot randomized controlled trial in the United States

Lauren Marlotte[1]*, Alexandra Klomhaus[2], Roya Ijadi-Maghsoodi[1,3], Hilary Aralis[1,4], Patricia Lester[1], Kim Griffin Esperon[5] and Sheryl Kataoka[1]

[1]Division of Population Behavioral Health, Jane and Terry Semel Institute for Neuroscience & Human Behavior, University of California, Los Angeles, Los Angeles, CA, United States, [2]Department of Medicine Statistics Core, David Geffen School of Medicine, University of California, Los Angeles, Los Angeles, CA, United States, [3]VA Health Service Research & Development (HSR&D) Center for the Study of Healthcare Innovation, Implementation & Policy (CSHIIP), VA Greater Los Angeles Healthcare System, Los Angeles, CA, United States, [4]Department of Biostatistics, Fielding School of Public Health, University of California, Los Angeles, Los Angeles, CA, United States, [5]Los Angeles Unified School District, Los Angeles, CA, United States

Introduction: Youth in under-resourced communities are more likely to have greater social risk factors for mental health needs yet have less access to needed care. School-based mental health services are effective in treating common disorders such as adolescent depression; however, few have a family-centered approach, which may especially benefit specific populations.

Methods: Utilizing a community-partnered approach, we adapted an established, trauma-informed, resilience skill-building family intervention for adolescents with depression. We conducted a small randomized controlled feasibility pilot of an adapted intervention in a large school district that serves predominately low-income, Latinx students in the Southwest United States between 2014-2017. Youth between the ages of 12-18 years old with a Patient Health Questionnaire (PHQ-8) score of 10 or higher, who spoke English or Spanish, were recruited from 12 school mental health clinics. Twenty-five eligible adolescents with depression and their participating caregivers were enrolled and randomly assigned to receive either the adapted intervention, Families OverComing Under Stress for Families with Adolescent Depression (FOCUS-AD), or usual care, Cognitive Behavioral Therapy (CBT) only. Most of the sample was Latinx and female. We evaluated feasibility, acceptability, and preliminary effectiveness.

Results: Among participants who completed standardized assessments administered at baseline and approximately five months post-randomization (n = 10 FOCUS-AD, n = 11 CBT only), effectiveness was explored by identifying significant changes over time in adolescent mental health within the FOCUS-AD and CBT only groups and comparing the magnitude of these changes between groups. Nonparametric statistical tests were used. We found the FOCUS-AD intervention to be feasible and acceptable; participant retention was high. Adolescent symptoms of depression (measured by the PHQ-8) improved significantly from baseline to follow-up for youth in both FOCUS-AD (median decrease [MD] = 10, p = 0.02) and control (MD = 6, p = 0.01) groups, with no significant difference across the two groups. Results were similar for symptoms of PTSD (measured by the Child PTSD Symptom Scale; FOCUS-AD MD = 12.5, p = 0.01; CBT only MD = 7, p = 0.04; no significant difference between groups).

Conclusion: Family-centered approaches to depression treatment among adolescents living in under-resourced communities may lead to improved mental health, although further research is warranted.

KEYWORDS

adolescent, depression, mental health, family, school-based mental health

1. Introduction

Despite an estimated 17% of adolescents affected by depression nationally during their lifetime, few access mental health care; this is often due to systemic barriers to care, especially for youth living in structurally marginalized and under-resourced communities (Avenevoli et al., 2015; SAMHSA, 2021). Untreated adolescent depression can lead to impaired social, emotional, and cognitive development, serious health risk behaviors, and decreased school performance (Thapar et al., 2012; Vogel, 2012). Youth with depression are also at increased risk for suicide, the second leading cause of death for youth (Curtin and Heron, 2019) and this is particularly true for Latinx youth (Centers for Disease Control and Prevention, 2019). Rates of depression are higher for Latinx youth compared to non-Latinx youth (Gonzales et al., 2012; Kempfer et al., 2017). Latinx youth and youth living in under-resourced communities and in households experiencing greater social stressors are particularly vulnerable to depression (Nurius et al., 2020).

Despite potential social and structural risk factors for depression, youth living in under-resourced communities may have less access to needed mental health care than their peers. Under-resourced youth and families face significant systemic and family-level barriers to obtaining high-quality mental health care, including lack of screening for depression, poor access to local mental health services providers in convenient locations, lack of culturally-sensitive care, lack of affordable care, lack of providers, lack of insurance, cost, transportation barriers, the capability to flexibly take time off of work for appointments, and parental depression (Pumariega et al., 2005; Flores and Tomany-Korman, 2008; Chung et al., 2010; Najman et al., 2010; Keeton et al., 2012). Mufson et al. (2004) emphasize the importance of providing and researching services in school-based clinics and explain that these locations are attractive in terms of barriers presented by transportation, finances, stigma, and familiarity. Providing mental health services in schools can be one way to address some of these barriers to care in a familiar and community-based setting (Lyon et al., 2013), and may be especially important in improving access to comprehensive and coordinated care for BIPOC youth (Keeton et al., 2012). There are few researched treatments for depression with under-resourced youth and their families (Huey and Polo, 2008; Wagstaff and Polo, 2012; Pina et al., 2019), especially school-based interventions (U.S. Public Health Service, 2000), and studies are often not inclusive of BIPOC youth and families.

Stressful life events and traumatic stress can co-occur with depression (Vibhakar et al., 2019). Recent research indicates that stress has a unique relationship to depression. Causes of depression are complex; genetics combined with life and interpersonal stress may predict depression in emerging adults (Vrshek-Schallhorn et al., 2015a,b; Naviya Antony and Sultana, 2021). In cross-cultural samples, interpersonal stress may also be a significant mediator between trauma and depressive symptoms (Fung et al., 2022). Latinx populations report more stress compared to other racial/ethnic groups in the United States (American Psychological Association, 2017) and acculturative stress in Latinx adolescents is associated with greater depression symptoms (Perreira et al., 2019).

Family-centered approaches can support adolescents seeking treatment for depression (Reyes-Portillo et al., 2017), and family support is particularly important in promoting positive mental health outcomes for under-resourced youth (Vega et al., 1991). Positive family environments may decrease depressive symptoms in adolescents (Sela et al., 2020). Family-centered care has five principles: Open information sharing, respect for expertise of the family and honoring cultural differences, partnership and collaboration between families and providers, negotiation and empowerment of families, and being flexible in the care in the context of family and community (Kuo et al., 2012).

Cognitive Behavioral Therapy (CBT) is the most researched treatment for adolescent depression and has been found to be efficacious (e.g., Spirito et al., 2011). In CBT treatment for adolescent depression, families are not commonly included in treatment (Gee et al., 2020), yet family inclusion is considered optimal for depression treatment (Tursi et al., 2013). A recent meta-analysis indicated that family-based CBT, which consisted of only three studies, was superior to treatment as usual and waitlist, however, no differences were found between individual and family CBT in reducing child anxiety symptoms (Sigurvinsdóttir et al., 2020). Large-scale efficacy trials with youth at risk for depression utilizing family-oriented, strength-based, resilience-focused interventions have shown positive effects (Beardslee et al., 2003). Such interventions have promise to simultaneously increase youth engagement in and family support for needed depression services consistent with treatment. Family interventions also address broader family behavioral challenges and contextual issues that affect treatment with a strength-based paradigm and incorporate community-level stressors. Given the promising findings of involving family members in adolescent depression treatment (Reyes-Portillo et al., 2017), the unique role stress appears to play in depression, and the dearth of studies in family-based modalities to address adolescent depression in school-based clinics, we adapted a manualized evidence-based resilience skill-building family intervention called Families OverComing Under Stress (FOCUS; Lester et al., 2012) for delivery to adolescents with depression and their families in a school-based clinic setting. FOCUS is based on the theory of resilience, a positive adaptation to stress and adversity (Luthar, 2006). Lester et al. (2016) developed FOCUS from three evidence-based family-centered preventive interventions evaluated through randomized controlled trials. Components of FOCUS were informed from these interventions; one intervention for youth with parental HIV that showed improved adjustment including school

attendance, an intervention for families with parental depression that showed improved family coping, and an intervention for youth exposed to war that found reduced depression and trauma outcomes (Rotheram-Borus et al., 2004; Beardslee et al., 2007; Layne et al., 2008). Providing psychoeducation and developmental guidance, developing shared family narratives, enhancing family awareness and understanding, improving family empathy and communication, fostering confidence and hope, supporting effective communication, enhancing family resilience skills (emotion regulation, goal setting, problem-solving, communication, and managing stress reminders), supporting coordinated parent leadership are mechanisms of resilience that FOCUS promotes (Saltzman et al., 2011). Skill-building allows the family to learn the skills in a protected environment and includes application in various situations, including after the treatment is completed. FOCUS for Families is a trauma-informed, eight-module, resilience skill-building family preventive intervention. FOCUS is well-studied and has been shown to improve youth and parent mental health outcomes prosocial behavior in youth, and family functioning for families experiencing significant stressors (Lester et al., 2012, 2016). For Latinx youth in particular, social support and perceived stress influence well-being (Lee et al., 2020). FOCUS for Families was selected for adaptation for delivery to adolescents with depression and their families because of the positive outcomes, including reduction of mental health symptoms, improvement in prosocial behaviors, improved family functioning, and gaining of skills that are helpful in overcoming stress and adversity (Lester et al., 2016).

FOCUS integrates SAMHSA's (2014) principles of trauma-informed care. FOCUS promotes an environment that is psychologically and physically safe for participants. FOCUS providers establish rapport with the families with whom they are working, set boundaries and expectations about the skill-building approach, and integrate skills that promote safety (e.g., emotion regulation, trauma reminders, goal setting). FOCUS providers are transparent about the model, the skills, and expectations from the provider and the consumer, work to establish trust with families, and acknowledge that the families are the experts on their experiences. FOCUS providers are also collaborative, offer choice, and empower family members. FOCUS recognizes the impact of historical and cultural trauma, discrimination, racism, and bias. Providers integrate the relevant aspects of cultural, historical, and gender issues for each family and provide psychoeducation, methods to manage trauma reminders and additional skill-building as needed.

The present study aims to (1) describe the adaptation of FOCUS for Families for use with adolescents with depression and their families in a school-based clinic setting, resulting in FOCUS for Families with Adolescent Depression (FOCUS-AD); (2) describe the preliminary feasibility and acceptability of FOCUS-AD among adolescents with depression and their families, and (3) present preliminary results of a pilot randomized controlled trial (RCT) comparing FOCUS-AD to usual care in improving depression symptoms and family functioning. We hypothesized that this intervention would be feasible and acceptable as implemented in a school-based setting. We also hypothesized that our results would preliminarily suggest greater improvements in symptoms and family functioning by participants in FOCUS-AD relative to usual care.

2. Materials and methods

2.1. Community-partnered approach

This study was developed in the context of an academic-community partnership between a large urban school district's mental health unit and clinician researchers, building on a 20-year collaborative relationship. This academic-community partnership is guided by principles of Community-Partnered Participatory Research (CPPR), with co-planning and consensus between the district clinicians and academic researchers at each phase of the research process (Jones and Wells, 2007). For this study, partnered decision-making included co-designing of the protocols, choice of measures, and implementation and workflow within the school-based mental health clinics. This pilot study was delivered in school-based mental health clinics, during the normal course of care as delivered by district-employed Psychiatric Social Workers (PSWs). The school partners provided valuable input regarding the cultural and social context of the students and families being served. For example, PSWs highlighted the stressors related to immigration and fear of deportation common amongst district families and the common misperceptions and stigma of mental health challenges embedded in the beliefs and attitudes of many in the school district's communities. Thus, adapting the skills-based FOCUS intervention (Lester et al., 2012, 2016)—which builds on a family's strengths and has been widely used with culturally diverse families who have experienced trauma—was well-supported by the school partners. In addition to contributing their experience and knowledge working with the communities being served, the school partners played a crucial role in adapting this intervention for implementation within the school-based mental health clinics and in ensuring that the protocol was congruent with their workflow and potentially sustainable. The PSWs considered individual CBT (Chorpita and Weisz, 2009) as their "usual care" for students with depression and suggested that FOCUS-AD be the comparison group.

2.2. Setting

The participating school district is a large, urban district that is comprised of students that identify as 74% Latinx, 10% Caucasian/White, and 9% African American/Black; 81% of students qualify for free or reduced-priced meals. Prior research has demonstrated a high burden of stressors among youth across the district (Ramirez et al., 2012), with 19% of high school students screening positive for PTSD in one pilot study (Ijadi-Maghsoodi et al., 2017). The district employs over 450 PSWs, who provide a range of mental health services from primary prevention, targeted prevention, and intensive mental health services. These intensive services, most relevant to the PSW role for this study, include individual and family outpatient therapy in school-based mental health clinics that is both short- and long-term for a variety of mental health challenges, such as depression, anxiety, and disruptive behaviors for district students in grades K-12. In the district's school-based clinics, for example, PSWs saw 1,515 unique students with over 22,000 encounters in 2016 (personal communication, 2016).

2.3. Participants

Forty students were assessed for eligibility in this study, which included: being 12–18 years old and having a Patient Health Questionnaire (PHQ-8) score of 10 or higher, having at least one parent or caregiver (referred to henceforth as "parent") who consented to participate in the study with the student assenting, speaking English and/or Spanish (for the parent and student), and being a client at one of the district's 12 participating school-based mental health clinics. Exclusion criteria resulted in the exclusion of students who were wards of the court or did not have a parent who wanted to participate, students that the school clinician assessed as not having the cognitive or behavioral ability to participate in or benefit from either intervention, students for whom depression was not the primary presenting problem, and students with psychosis or suicidality requiring a higher level of care. Of the 40 students assessed, 25 students and their parent were included in the study (10 did not meet inclusion criteria and 5 declined to participate), with 11 randomly assigned to FOCUS-AD and 14 to CBT only. Of those who were randomized, 21 completed treatment and follow-up assessments (10 in FOCUS-AD and 11 in CBT); with four lost to follow-up (see Figure 1).

2.4. Procedures

Students were recruited from 10 district school mental health clinics, ranging from 1 to 9 cases per school-based clinic. As new students received intake evaluations at each participating clinic, clinic staff identified potentially eligible students and provided verbal and written information about the study to the parent and student in their preferred language (English or Spanish). Many families had hesitations about receiving on-going mental health treatment and/or participating in research, particularly given the political climate and the high number of Latinx families served at the clinics. Because this was a community-based and partnered study, the number of families were approached but declined to be assessed was not tracked due to the burden on clinic staff. If families were interested, research staff arranged a time to meet with the parent and student to discuss the study in more detail and administer the PHQ-8 to the student.

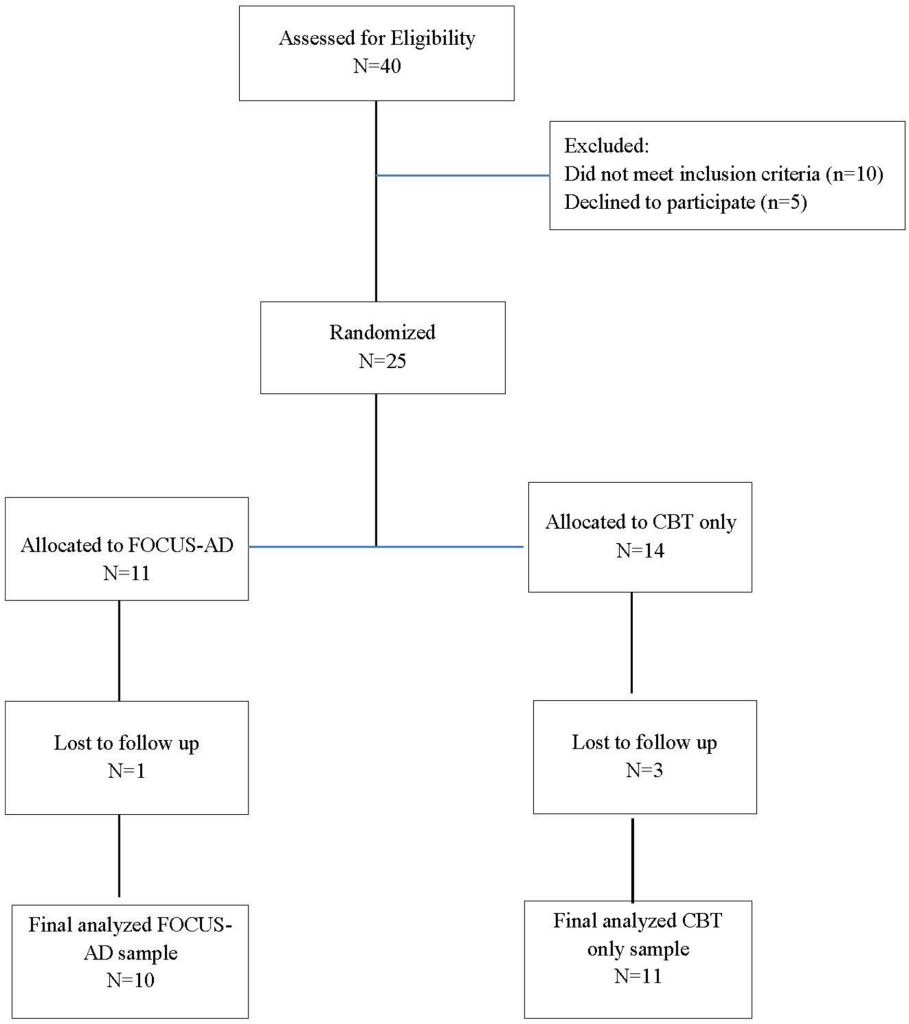


FIGURE 1
CONSORT diagram: FOCUS-AD vs. CBT only.

Students were eligible if they scored a 10 or higher on the PHQ-8, spoke English or Spanish, and both parent and student were interested in participating in the study. Then, the research staff consented parent and assented the student, administered a baseline evaluation, and randomized the family to one of the two interventions (FOCUS-AD or usual care) by referencing a pre-generated randomization list. Follow-up assessments were administered at the end of treatment, approximately 5 months from the initial assessment. The median number of days between baseline and follow-up assessment completion among adolescents was 149 days (IQR = 40.00) and among caregivers was 141 days (IQR = 48.00). Students and parents each received $10 per assessment, for a total of $20 each. This study was approved by the (Institution redacted) IRB and the district's research review committee. A Certificate of Confidentiality was also obtained from the National Center for Advancing Translational Sciences.

3. Interventions

3.1. FOCUS-AD

The FOCUS model has been used with multicultural populations of military and non-military families affected by stress and trauma (Saltzman et al., 2008). Given the promising findings of FOCUS for youth and parents (e.g., Lester et al., 2013, 2016), and given the significant burden of trauma and stressors among youth and families in this particular district (Ramirez et al., 2012; Ijadi-Maghsoodi et al., 2017), FOCUS for Families was chosen by the community-academic partnership team to be adapted to treat adolescent depression in this school setting. The core elements of the FOCUS model were maintained and combined with the best practices in CBT treatment for depression. The core elements of FOCUS are: The Family Check-In, Family Narrative, Family Resilience Skills, and Psychoeducation and Developmental Guidance (Beardslee et al., 2013). FOCUS-AD consists of 14 manualized modules, including the entire eight modules of FOCUS for Families and an additional six modules of CBT skills developed specifically to reduce depressive symptoms, combining a family skills-based preventive intervention with CBT (see Table 1). The CBT sessions included specific techniques to target symptoms of adolescent depression. For example, depression-specific psychoeducation is integrated as well as additional skills such as emotional awareness, relaxation strategies, cognitive coping, understanding the relationship between feelings, thoughts, and behaviors, positive self-talk, additional strength-identifying activities, and planning for utilizing coping skills. These sessions integrated skill-building utilizing known CBT tools to reduce depression. All of the

TABLE 1 Description of FOCUS-AD modules including intended participants and session activities.

Module	Participants	Session activity
1. Introducing parents to FOCUS	Parent(s)/caregiver(s)	1. Overview of FOCUS 2. Depression education 3. Goal-setting
2. Introducing children to FOCUS	Student and siblings	1. Introduce FOCUS 2. Introduce emotional awareness 3. Goal-setting
3. Constructing parents'/caregivers' FOCUS narrative timelines	Parent(s)/caregiver(s)	1. Emotional regulation and communication narrative timeline
4. Emotional awareness	Student	1. Emotional awareness
5. Learning about depression	Student	1. Depression education 2. Emotional awareness
6. Learning to relax	Student and parent(s) /caregiver(s)	1. Calming and grounding activities
7. Cognitive coping	Student	1. Thought distortions 2. Thought swaps
8. Constructing children's FOCUS narrative maps	Student and siblings	1. Emotional regulation and communication narrative timemap/timeline
9. Preparing parents/caregivers for the family sessions	Parent(s) /caregiver(s)	1. Review narrative timeline 2. Parent prep for family session
10. Developing a FOCUS family narrative	Family	1. Family emotional regulation and communication narrative sharing
11. Building family resilience skills	Family	1. Step-wise problem solving method
12. Presenting a positive self	Student	1. Noticing your strengths
13. Plan for coping and goal-setting	Student	1. Plan for coping 2. Goal-setting
14. Preparing for the future	Family	1. Resilience skills 2. Family ritual or activity 3. Develop ongoing family goals and activities

study materials were translated into Spanish, including many of the acronyms used in the FOCUS for Families model were interpreted in a culturally responsive manner in order to reinforce the learning of skills. Additionally, all of the PSWs who implemented either treatment in Spanish were bilingual and bicultural. PSWs were familiar with culturally humble approaches to implementing evidence-based practices and have significant experience working with Latinx families.

Fourteen district PSWs were trained in the Families OverComing Under Stress for Families with Adolescent Depression (FOCUS-AD) adaptation by the lead trainer (initials redacted) with at least one PSW from each participating clinic receiving training (one clinic had three trained PSWs). PSWs were trained in a two-day FOCUS for Families training, then were provided with training on the FOCUS-AD intervention, including modules and information on the research study. The FOCUS-AD manual contains fidelity checklists and providers were trained on how to use them to maintain fidelity to the treatment model.

PSWs trained in FOCUS-AD who were assigned cases, received biweekly FOCUS-AD consultation throughout their cases with a lead trainer and through supervision and/or consultation provided by their school clinic. Consultation served as a time to ensure consistency of the model implementation and discuss challenges and successes. Academic partners also worked with district clinicians in determining how the intervention could be flexibly implemented to best serve the students and families while maintaining fidelity. For example, some of the content across two modules was combined into one meeting time at the end of a school year with a family who had missed several appointments. The fidelity checklists were used to ensure all aspects of the intervention were administered with these adaptations.

3.2. CBT only

The district PSWs utilize individual CBT (Chorpita and Weisz, 2009) as their usual care intervention, which provides optional parent involvement primarily for psychoeducation regarding depression and skills as needed. All participating clinics had PSWs trained in CBT only as part of their usual care and provided training and consultation as needed by the clinic supervisor.

4. Implementation

It was intended that the length of treatment and the number of sessions for both of the interventions was roughly the same (14 sessions), and the interventions were both delivered flexibly to take into account "real-world" implementation issues, such as scheduling challenges.

5. Measures

5.1. Youth and parent report measures

The assessment concluded with eight questions evaluating adolescent and caregiver satisfaction with the program. These questions constitute the 8-item Client Satisfaction Questionnaire (CSQ) designed to measure satisfaction in health and human service systems (Larsen et al., 1979). For each item, Likert response options are translated to numeric values ranging from 1 to 4 and CSQ Score is calculated by taking the average across all 8 items. CSQ Scores of >3.00 are used to suggest high participant satisfaction.

5.2. Youth report measures

The Patient Health Questionnaire-8 (Kroenke and Spitzer, 2002) is an 8-item self-report measure used to diagnose and assess depressive disorders. It is identical to the PHQ-9 (Kroenke et al., 2001, 2009; Razykov et al., 2012), but omits the ninth item that asks about suicidal ideation. Item responses are on a Likert scale and range from 0 = "Not at all" to 3 = "Nearly every day," with higher scores associated with greater depressive symptoms. Numeric responses to the 8 items are summed to yield a PHQ-8 Total Score. Used to identify clinically meaningful symptoms of depression, a total score of 10 or higher has demonstrated sensitivity and specificity for major depressive disorder of 1.00 and 0.95, respectively, and sensitivity and specificity for any depressive disorder of 0.70 and 0.98, respectively (Kroenke et al., 2009). Adolescent PHQ-8 Total Scores at baseline and follow-up were used in this study with higher scores indicating greater symptomatology. Reliable change was defined as a decrease in PHQ-8 Total Score of ≥5 which has been deemed a clinically significant response to depression treatment (Kroenke and Spitzer, 2002). The clinics had a separate protocol for assessing suicide that they completed for every intake and was not included in this study.

The Child PTSD Symptom Scale (CPSS; Foa et al., 2001) is a self-report scale to assess the symptoms of posttraumatic stress disorder (PTSD), using a 17-item measure of PTSD symptomatology, with item responses on a Likert scale that range from 1 = "Not at all" to 4 = "Always (or 5 or more times a week)." These 17 items are summed to yield a CPSS Total Symptom Severity Score. A psychometric properties study suggests that total symptom severity scores of 16 or higher can be used to identify clinically meaningful symptoms of PTSD while establishing an optimal balance between sensitivity and specificity (Nixon et al., 2013). Adolescent CPSS Total Symptom Severity Scores at baseline and follow-up were used in this study with higher scores indicating greater symptomatology. Reliable change was defined as a decrease in CPSS Total Symptom Severity Score of ≥8.98 based on calculation of the reliable change index with assumed test–retest reliability of 0.84 and standard deviation of 8.1 (Foa et al., 2001).

The Strength and Difficulties Questionnaire—Child Report (SDQ; Goodman et al., 1998) is a brief 25-item self-report measure that assesses positive and negative behavioral attributes. The child self-report version can be completed by those aged 11–16 years. The SDQ results in 4 subscales measuring negative behavioral attributes (conduct problems, inattention-hyperactivity, emotional symptoms, and peer problems). Item responses are measured on a Likert scale with range from 0 = "Not True" to 2 = "Certainly True." Used as an overall summary measure, a SDQ Total Difficulties Score can be obtained by summing items across all 4 subscales. A total difficulties score of 16 or higher is used to identify high difficulties (Goodman et al., 2003). Adolescent SDQ Total Difficulties Scores at baseline and follow-up were used in this study with higher scores indicating more difficulties. Reliable change was defined as a decrease in SDQ Total Difficulties Score of ≥8.36 based on prior literature (Wolpert et al., 2014).

Adolescent coping was provided through the Brief COPE (Carver, 1997) a 28-item measure designed to help identify and assess coping and actions, developed as a brief-form of the longer COPE inventory (Carver et al., 1989). It is comprised of 14 subscales, including: self-distraction, active coping, denial, substance use, use of emotional support, use of instrumental support, behavioral disengagement, venting, positive reframing, acceptance, planning, humor, religion, and self-blame, though we did not assess use of instrumental support or self-blame. Item responses are on a Likert scale and range from 0 = "I did not do this at all" to 3 = "I did this a lot." Item responses are on a Likert scale and range from 1 = "I did not do this at all" to 4 = "I did this a lot." Each subscale consists of two items and subscale scores thus range from 2 to 8. Scores of 5 or higher were assumed to indicate use of the coping mechanism.

5.3. Parent-report measures

The McMaster Family Assessment Device (FAD; Epstein et al., 1983) is a 60-item measure that assesses various characteristics of families and family functioning. Item responses are on a Likert scale and range from 1 = "Strongly Agree" to 4 = "Strongly Disagree," with higher scores associated with more problematic functioning. Included within the FAD is a 12-item General Functioning subscale that provides an overall measure of family adjustment (Byles et al., 1988). The FAD General Functioning Score is calculated by summing numeric responses across all 12 items. A score of 2.0 or higher is used to identify unhealthy family functioning and is associated with a sensitivity of 0.67 and specificity of 0.64 (Miller et al., 1985). Parent-reported FAD General Functioning Scores at baseline and follow-up were used in this study with higher scores indicating less healthy family functioning. Reliable change was defined as a decrease in FAD General Functioning Score of ≥0.67 based on calculation of the reliable change index with assumed test–retest reliability of 0.71 and standard deviation of 0.45 (Miller et al., 1985).

5.4. Participant characteristics

In addition to the above measures, participants were asked a series of demographic questions at baseline, including race, ethnicity, age, and gender for both adolescents and caregivers, as well as marital and employment status for caregivers. We evaluated adolescents' use of mental health services through three yes/no questions, asked of the caregiver, to help identify sources of professional help for any emotional or behavioral problems.

Parent participants also provided information about their own mental health symptoms, which were described at baseline for this sample. Parents completed the previously described PHQ-8 and the PTSD Checklist—Civilian Version (PCL-C; Weathers et al., 1993), to measure depression and PTSD symptoms, respectively. The PCL-C is comprised of 17 items designed to assess the primary symptoms of PTSD associated with a traumatic event as outlined by the *DSM-IV*. Item responses are on a Likert scale and range from 1 = "Not at all" to 5 = "Extremely," with higher scores indicating higher stress and PTSD symptomatology. A PCL Total Symptom Severity score is obtained by summing over all 17 items, with scores of 30 or higher indicating clinically meaningful symptoms of PTSD with a sensitivity of 0.78 and specificity of 0.88 (Bliese et al., 2008).

6. Statistical analyses

To describe the sample of participating adolescents and caregivers at baseline, frequencies, percentages, medians and interquartile ranges were calculated among FOCUS-AD and CBT only arms. Statistical analyses were conducted using SAS Version 9.4. To inform acceptability, frequencies and percentages of adolescents and caregivers providing positive responses to each of the CSQ items were calculated within arms and compared across arms using Fisher's Exact Tests. For our purposes, a positive response refers to either of the 2 response options denoting the highest levels of satisfaction. Nonparametric tests referenced previously were used to compare CSQ Scores between arms and to compare percentages of participants with CSQ Scores >3.00.

To compare changes in adolescent mental health and family functioning between adolescents randomized to the FOCUS-AD versus CBT only arm, we calculated mean and median changes from baseline to follow-up on the following measures: Adolescent-reported PHQ-8 Total Score, SDQ Total Difficulties Score, and CPSS Total Symptom Severity Score, and parent-reported FAD General Functioning. Due to the small sample sizes, nonparametric tests relying on fewer distributional assumptions were used. Wilcoxon Signed Rank Tests were used to assess for significant changes from baseline to follow-up within each arm. To evaluate preliminary efficacy, Wilcoxon Rank-Sum Tests were used to assess for significant differences in these changes between arms. Frequencies and percentages of adolescents and parents demonstrating reliable change from baseline to follow-up on each measure were calculated.

7. Results

7.1. Characteristics of youth and caregivers at baseline

Most adolescents participating in the study self-identified as female (81%) and Latinx (86%, see Table 2). Median age among adolescents was 14 years [interquartile range (IQR) = 2.00]. A relatively high percentage reported their emotional/mental health as being fair or poor (86%). From youth-report at baseline, 95% percent of adolescents met the criteria for high difficulties on the SDQ Total Difficulties scale and 100% met the criteria for clinically meaningful PTSD symptoms. In terms of coping strategies, youth most commonly reported using self-distraction (86%) and behavioral disengagement (76%). Based on parent-report of service use, 38% of adolescents had received prior outpatient mental health services from a community mental health clinic, mental health counselor, physician, or day program, and 29% had received services from a hospital, treatment center, group or foster home, juvenile justice facility, or emergency shelter.

The vast majority of parent participants were female (86%) and Latinx (90%). Twenty-nine percent of caregivers met the criteria for clinically meaningful symptoms of depression at baseline and 43% met the criteria for clinically meaningful symptoms of PTSD. In

10.3389/fpsyg.2023.1233901

TABLE 2 Participant characteristics at baseline among families randomized to the FOCUS-AD and CBT only groups.

	FOCUS-AD (*N* = 10)	CBT only (*N* = 11)	Overall (*N* = 21)
Adolescent characteristics		***n* (%)**	
Gender			
Male	2 (20.00)	2 (18.18)	4 (19.05)
Female	8 (80.00)	9 (81.82)	17 (80.95)
Age			
Years, median (IQR)	14.5 (2.00)	13 (3.00)	14 (2.00)
Race/ethnicity			
African American	–	1 (9.09)	1 (4.76)
Caucasian	1 (10.00)	–	1 (4.76)
Latino	9 (90.00)	9 (81.82)	18 (85.71)
Other	–	1 (9.09)	1 (4.76)
Time, baseline to follow-up			
Days, median (IQR)	149 (88.00)	145 (38.00)	149 (40.00)
In general, would you say your emotional/mental health is…			
Excellent/very good/good	2 (20.00)	1 (9.09)	3 (14.29)
Fair/poor	8 (80.00)	10 (90.91)	18 (85.71)
Child received professional mental health services from:[a]			
Hospital, treatment center, group or foster home, juvenile justice facility or emergency shelter?			
Yes	2 (20.00)	4 (36.36)	6 (28.57)
Community mental health clinic, private counselor's office, physician's office, or day program?			
Yes	3 (30.00)	5 (45.45)	8 (38.10)
SDQ: total difficulties			
High difficulties[b]	10 (100.00)	10 (90.91)	20 (95.24)
PTSD			
Clinically meaningful[c]	10 (100.00)	11 (100.00)	21 (100.00)
Brief COPE[d] coping (clinically meaningful)			
Self-distraction	9 (90.00)	9 (81.82)	18 (85.71)
Active coping	5 (50.00)	4 (36.36)	9 (42.86)
Denial	7 (70.00)	2 (18.18)	9 (42.86)
Substance use	2 (20.00)	1 (9.09)	3 (14.29)
Emotional support	5 (50.00)	7 (63.64)	12 (57.14)
Behavioral disengagement	8 (80.00)	8 (72.73)	16 (76.19)
Venting	7 (70.00)	5 (45.45)	12 (57.14)
Positive reframing	6 (60.00)	2 (18.18)	8 (38.10)
Planning	7 (70.00)	4 (36.36)	11 (52.38)
Humor	4 (40.00)	2 (18.18)	6 (28.57)
Acceptance	6 (60.00)	5 (45.45)	11 (52.38)
Religion	3 (30.00)	1 (9.09)	4 (19.05)
Caregiver characteristics		***n* (%)**	
Gender			
Male	1 (10.00)	2 (18.18)	3 (14.29)
Female	9 (90.00)	9 (81.82)	18 (85.71)
Age			

(Continued)

TABLE 2 (Continued)

	FOCUS-AD (*N* = 10)	CBT only (*N* = 11)	Overall (*N* = 21)
Years, median (IQR)	43 (15.00)	40 (13.00)	41 (11.00)
Race/ethnicity			
African American	–	1 (9.09)	1 (4.76)
Caucasian	1 (10.00)	–	1 (4.76)
Latino	9 (90.00)	10 (90.91)	19 (90.48)
Other	–	–	–
Marital status			
Married/cohabitating	5 (50.00)	5 (45.45)	10 (47.62)
Other[e]	5 (50.00)	6 (54.55)	11 (52.38)
Employment			
Full time or part time	4 (40.00)	6 (54.55)	10 (47.62)
Not currently working	6 (60.00)	5 (45.45)	11 (52.38)
Education			
Did not finish high school	6 (60.00)	6 (54.55)	12 (60.00)
High school and above	3 (30.00)	5 (45.45)	8 (40.00)
Depression			
Clinically meaningful[f]	4 (40.00)	2 (18.18)	6 (28.57)
PTSD			
Clinically meaningful[g]	5 (50.00)	4 (36.36)	9 (42.86)
Time, baseline to follow-up			
Days, median (IQR)	151 (80.00)	140 (44.00)	141 (48.00)
Family characteristics		***n* (%)**	
General functioning[a]			
Unhealthy family functioning[h]	7 (70.00)	6 (54.55)	13 (61.90)

[a]Reported by the caregiver.
[b]SDQ total difficulties score ≥ 16.
[c]CPSS score ≥ 16 (17-item version).
[d]For each coping scale, a score ≥ 5 indicated use of the coping mechanism.
[e]Other includes: single, divorced, separated, and widowed.
[f]PHQ-8 total score ≥ 10.
[g]PCL-C score ≥ 30.
[h]FAD general functioning score ≥ 2.0.

reporting on their families at baseline, 62% of parents indicated unhealthy family functioning. All 21 participating adolescents and 29% of parents completed the surveys in English, with the remaining parents participating in Spanish. No significant differences in participant characteristics were found between participants in the FOCUS-AD and the CBT only groups (see Table 2 for details).

7.2. Comparisons between baseline and follow-up in FOCUS-AD and CBT only groups

To evaluate the primary outcome of preliminary feasibility and acceptability of the FOCUS-AD and CBT only interventions among adolescents with depression and their families in a school-based setting, we assessed satisfaction and dropout rates. Mean CSQ scores among adolescents or parents in the FOCUS-AD and CBT only groups did not differ significantly [FOCUS-AD Mean (M) = 3.18, CBT only M = 3.50, $p = 0.15$; FOCUS-AD M = 3.64, CBT only M = 3.53, $p = 0.67$; see Table 3]. The mean scores for both treatments indicate that adolescents and parents in both treatment groups were highly satisfied. Of the 25 families who were randomized, 4 dropped out, 1 from the FOCUS-AD group and 3 from the CBT only group. The average time from baseline to follow-up was 151 days for FOCUS-AD and 140 days for CBT only for caregivers and 149 days for FOCUS-AD and 145 days for CBT only for adolescents.

Adolescent depression symptoms decreased significantly from baseline to follow-up within the two groups [FOCUS-AD median decrease (MD) = 10, $p = 0.02$; CBT only MD = 6, $p = 0.01$; see Table 4]. Similarly, significant decreases within treatment groups from baseline to follow-up were seen for SDQ Total Difficulties (FOCUS-AD MD = 6.5, $p = 0.002$; CBT only MD = 4.5, $p = 0.03$) and PTSD symptoms

TABLE 3 Percentage of participants in the FOCUS-AD and control arms endorsing each of the following items from the Client Satisfaction Questionnaire (CSQ) at follow-up.

	FOCUS-AD		CBT only	
	N (%)		*N* (%)	
	Adolescent (*N* = 10)	Caregiver (*N* = 10)	Adolescent (*N* = 11)	Caregiver (*N* = 11)
How would you rate the quality of service you have received?[a]	10 (100.00)	10 (100.00)	10 (90.91)	11 (100.00)
Did you get the kind of service you wanted?[b]	8 (80.00)	10 (100.00)	11 (100.00)	11 (100.00)
To what extend has our program met your needs?[c]	6 (60.00)	9 (90.00)	9 (81.82)	11 (100.00)
If a friend were in need to similar help, would you recommend our program to him/her?[d]	9 (90.00)	10 (100.00)	11 (100.00)	11 (100.00)
How satisfied are you with the amount of help you have received?[e]	10 (100.00)	10 (100.00)	10 (90.91)	11 (100.00)
Have the services you received helped you to deal more effectively with your problems?[f]	10 (100.00)	10 (100.00)	11 (100.00)	11 (100.00)
In an overall, general sense, how satisfied are you with the service you have received?[e]	8 (80.00)	10 (100.00)	11 (100.00)	11 (100.00)
If you were to seek help again, would you come back to our program?[d]	7 (70.00)	10 (100.00)	11 (100.00)	11 (100.00)
CSQ Score, Mean (SD)	3.18 (0.52)	3.64 (0.36)	3.50 (0.39)	3.53 (0.40)
CSQ Score > 3.00, *N* (%)	5 (50.0)	9 (90.0)	9 (81.8)	9 (81.8)

[a]% responding "Good" or "Excellent."
[b]% responding "Yes, generally" or "Yes, definitely."
[c]% responding "Most of my needs have been met" or "Almost all of my needs have been met."
[d]% responding "Yes, I think so" or "Yes, definitely."
[e]% responding "Mostly satisfied" or "Very satisfied."
[f]% responding "Yes, they helped" or "Yes, they helped a great deal."

(FOCUS-AD MD = 12.5, $p = 0.01$; CBT only MD = 7, $p = 0.04$). However, these symptom decreases did not differ significantly across the two groups. Parent-reported improvements in family functioning were not significant and did not differ between the two groups (FOCUS-AD MD = 0.17; CBT only MD = 0.08).

8. Discussion

The findings from this pilot study suggest that the FOCUS-AD intervention appears to be both feasible and acceptable, as delivered in a school-based clinic setting with this predominantly Latinx adolescent population. Once in treatment, students and their families had a high retention rate in treatment. Those who received FOCUS-AD also generally reported that the intervention was acceptable, with reasonable satisfaction reported by parents and students. Satisfaction was slightly higher for caregivers than students for the FOCUS-AD intervention, which may reflect the developmentally appropriate desire for adolescents to individuate from their caregivers.

Our baseline findings highlight a need for services for those adolescents with depression presenting to school-based mental health clinics. Given that 50% of children and adolescents will have mental health challenges, school-based clinics are one of the ways to provide accessible services (Committee on School Health, 2004; Merikangas et al., 2010; SAMHSA, 2022); and previous studies have shown that Latinx populations are less likely to access mental health services outside of the school (Kataoka et al., 2007). These findings indicate that a family-centered approach could help enhance family involvement in treatment, especially in under-resourced communities where structural barriers to care are high.

In addition, we explored how FOCUS-AD, a combination of a family-based intervention with individual CBT, compared to CBT only, in improving mental health symptoms. This study suggests that both treatments delivered in school-based health clinics, may be helpful. Given the small sample size, we are tentative in our conclusions. However, the findings of this small pilot are helpful in determining that additional research in this area would be supportive to families with adolescents with depression.

As seen in other studies in the literature (Vibhakar et al., 2019), the adolescents in our study not only had clinically significant depressive symptoms at baseline but also universally reported posttraumatic stress symptoms in the clinical range. We found that FOCUS-AD and the CBT only treatments significantly reduced

TABLE 4 Comparisons between baseline to follow-up in adolescent mental health and family functioning in the FOCUS-AD and CBT only groups.

	FOCUS-AD			Wilcoxon signed-rank test	RC	CBT only			Wilcoxon signed-rank test	RC	Wilcoxon rank-sum test
	N	Mean (SD)	Median (IQR)	*p*-value	*n* (%)	*N*	Mean (SD)	Median (IQR)	*p*-value	*n* (%)	*p*-value
Adolescent mental health											
Δ PHQ-8 total score	10	7.8 (6.83)	10.00 (8.00)	0.02	6 (60.0)	11	5.09 (4.74)	6.00 (8.00)	0.01	6 (54.6)	0.27
Δ SDQ total difficulties score	10	6.30 (2.95)	6.50 (4.00)	0.002	2 (20.0)	10	4.10 (4.58)	4.50 (8.00)	0.03	2 (18.2)	0.34
Δ CPSS total symptom severity score	10	12.90 (12.19)	12.50 (17.00)	0.01	6 (60.0)	11	9.27 (12.93)	7.00 (17.00)	0.04	4 (36.4)	0.60
Family functioning[a]											
Δ FAD general functioning score	9	0.11 (0.24)	0.17 (0.25)	0.27	0 (0.0)	10	0.09 (0.25)	0.08 (0.33)	0.33	0 (0.0)	1.00

[a]Reported by the caregiver.
RC, reliable change.

adolescent mental health symptoms, including depression and trauma symptoms, as well as general emotional and behavioral problems. However, no difference between treatment groups was found. Treatment of moderate and severe adolescent depression is challenging and studies often find no or low effect size (Thapar et al., 2012). A larger school-based RCT study of Chilean adolescents with depression did not find a significant reduction of depression symptoms comparing a school-based CBT intervention to a control group receiving no interventions (Gaete et al., 2016). Additionally, a recent meta-analysis of school-based interventions for adolescent depression found that these treatments had a small effect on reducing depression symptoms, which is not dissimilar from adolescent depression treatment in other settings (Gee et al., 2020). Further, research in this area is not vast, with most interventions focusing on the prevention of depression, rather than treatment (Bevan Jones et al., 2018).

Families are seldom included in research studies for adolescent depression, despite family inclusion being considered optimal for depression treatment (Tursi et al., 2013), including in school-based settings (Bevan Jones et al., 2018; Gee et al., 2020). Somewhat surprisingly, in the present study, neither intervention significantly improved family functioning. Family functioning plays an important role in adolescent mental health. For example, research demonstrates that parental closeness and family functioning are associated with lower levels of depression among Latinx youth (Perreira et al., 2019). Others have described the positive role that family cohesion and support can play, in particular, for Latinx youth in preventing depression (Potochnick and Perreira, 2010; Perez et al., 2011). In the FOCUS-AD group, approximately 40% of the sample started with what is considered "healthy" family functioning, which slightly improved although not significantly. Future research should replicate this pilot with a larger sample size and longer follow-up period to determine if family functioning improves with FOCUS-AD.

The parents and families in this study were highly distressed, which was not an inclusion requirement. This is not surprising given that a family history of depression is a risk factor for adolescent depression (Thapar et al., 2012). There are other compelling reasons to include caregivers in interventions. A study found that Latinx teenagers with parents who had greater knowledge about depression were more likely to seek treatment for depression (Chandra et al., 2009). Adolescents who experience greater depression tend to receive less social support from parents/caregivers (Piña-Watson and Castillo, 2015). These findings further emphasize the importance of family involvement in adolescent depression treatment.

Coping skills are some of the few changeable risk factors for depression and often an integral part of depression treatment. Participants in this study reported potentially maladaptive coping strategies such as self distraction and behavioral disengagement on the Brief COPE. Although it was beyond the scope of this pilot to evaluate the mechanism(s) of change in coping approaches as a result of treatment, our preliminary findings suggest that addressing maladaptive coping strategies identified at baseline could be important to target during treatment. Increased behavioral disengagement and distraction could be indicative of a general avoidance of stressors. The understanding of baseline coping strategies could be used to tailor the intervention, build on youths' existing strengths, and reduce maladaptive coping, which may promote well-being and lower stress (García and Wlodarczyk, 2018).

Our findings did not support our secondary hypothesis that FOCUS-AD would be superior to the CBT only treatment in reducing symptoms and improving family functioning; it does provide results indicating that FOCUS-AD is a promising intervention and further study is needed. Although we found promising results, there are several limitations of this pilot study. First, we had a small sample size, which limited our ability to reasonably compare the two interventions adequately and to interpret and generalize statistically significant results. PSWs also reported challenges in referring parents to a family intervention which would necessitate missing work. School settings—in which parents may face barriers to attending school clinics—may not be ideal for this particular family-based intervention, however, given the recent advances in the availability of telehealth during the COVID-19 pandemic (e.g., Kodjebacheva et al., 2023), involving families in remote care that is initiated through schools is an area for

future study. Also of note, this study was completed prior to the COVID-19 pandemic and before telehealth was offered in the school district. Preliminary findings supporting telehealth family interventions, including FOCUS for military-involved families, are promising (Mogil et al., 2022). Future studies would also benefit from a mixed methods approach with both quantitative and qualitative feedback from providers, students, and caregivers, to provide a contextual understanding of implementing the intervention among youth and families.

Given the limitations of conducting the pilot within busy school mental health clinics and the burden on clinical staff, we did not systematically collect information on how many sessions were completed nor on fidelity to the intervention, nor do we know the reasons for refusal of the intervention or drop-out. We do know that relatively few families dropped out of the study once they started. Fidelity checklists are available for each FOCUS-AD module and PSWs were trained on using the fidelity checklists, and fidelity was addressed during consultation calls. The checklists were not systematically collected as a part of the study. It is possible that because families needed to be available during school hours to participate in the study that there was more family involvement in the CBT intervention than typical for this setting. We struggled with recruitment of youth and families. Mufson et al. (2004) outline the multiple challenges in conducting research in school-based clinics such as youth reluctance to include their families in treatment, the burden of completing measures for the research study, challenges with the randomization process, and the time and resources needed to train clinicians to participate in the study. Several of these factors may have played a role in our recruitment as well. García et al. (2017) discuss various reasons why Latinx individuals may be hesitant to participate in research, such as distrust, fear of discrimination, concerns about confidentiality, and a lack of understanding about the research process. To reduce stigma, we did not collect information on documentation status, however, it is likely that at least some of the participants were undocumented or had undocumented family members. Undocumented Latinx individuals report lower access to mental health services than documented US-born Latinx individuals (Ortega et al., 2018) and potential participants who were undocumented immigrants may not have participated because they viewed treatment as futile as mental health services do not address immigration-related stress and/or participants may have a lower perceived need because of the normalization of their stress (Cha et al., 2019).

While our study had a smaller-than-anticipated sample size, a small sample size is justified for a small pilot randomized trial (Whitehead et al., 2016), such as the present study. Some studies even recommend a small sample size at or close to that of the present study (e.g., Kieser and Wassmer, 1996; Julious, 2005). This present study did not aim to obtain an ideal power of 0.8 or above, which would have required approximately 75 families in each of the two arms of the study (based on the observed PHQ outcomes), as this is beyond the scope and resources of this pilot. Additionally, we encountered difficulties in recruitment, which is a valuable lesson learned about challenges with recruitment and retention with this population. The data we gathered does inform potential future effectiveness trials and calculations, a key outcome of pilot studies (Moore et al., 2011).

Further research in this area is warranted as the FOCUS for Families model has been shown to improve mental health symptoms for children and caregivers experiencing stressors in large-scale evaluations (Lester et al., 2016). The best practice in adolescent depression treatment includes families; the FOCUS-AD model decreases barriers for clinicians to be comfortable integrating families and enhances their skills in their work with youth. FOCUS-AD may require more effort on the part of the school clinician to coordinate with parents' schedules and bring in families to the sessions rather than providing individualized CBT with only the adolescent and clinicians must participate in a two-day training in the model. However, we developed the intervention given that our partnered schools wished to offer an intervention that more fully engages parents/caregivers to address the stressors experienced by the family system because of the research outcomes when families are involved in adolescent depression treatment (Tursi et al., 2013; Reyes-Portillo et al., 2017; Bevan Jones et al., 2018; Gee et al., 2020), and because previous studies have shown reduction of mental health symptoms across the family unit (e.g., Lester et al., 2016). Combining this approach with CBT is less burdensome for the providers than having to offer separate CBT and family therapy sessions. The other advantage is that, unlike most individual CBT or family therapy, this one was adapted for delivery in the school setting which improves overall access to care and minimizes some barriers. For schools that wish to take a family-focused approach and that have the desire to engage more with parents, FOCUS-AD is a potentially promising intervention to use.

9. Conclusion

Schools are an important place for providing mental health services, in addition to education. It appears that school-based interventions that focus on prevention and early intervention of depression may be effective (Calear and Christensen, 2010) and there is a need for effective interventions for depression. Given that up to 50% of adolescents have experienced a mental health disorder at some point (Merikangas et al., 2010; SAMHSA, 2022) and previous studies have shown that Latinx populations are less likely to access mental health services outside of the school (Kataoka et al., 2007). Our findings indicate that a family-centered approach could help enhance family involvement in treatment, especially in under-resourced communities where structural barriers to care are high. Given the goals of schools to enhance parent and family engagement, and barriers that we noted in our study, schools may consider offering family-based services that are beyond school hours, held in alternative locations, or through telehealth to increase accessibility, especially for parents, and make efforts to reduce stigma and challenges in accessing services. This study supports the need for further investigation of family involvement in treatment. It adds to the small body of limited research indicating that skills-based interventions are promising for the treatment of adolescent depression among minoritized and under-resourced youth and families. Further studies with a larger sample size are needed to make more conclusive statements about the treatment approach.

This study found that predominately Latinx adolescent participants and their caregivers seeking care at a school mental health clinic experienced significant distress. Both FOCUS-AD and CBT were effective in reducing depression and PTSD symptoms. There were no changes in family functioning for either intervention, although both interventions were satisfactory to the families receiving treatment. A skills-based family intervention which has previously been used with families who are highly stressed and experienced trauma appears to be a promising model for treating adolescent

depression in schools and reaching family members who have also been affected by life stressors (Lester et al., 2016).

Data availability statement

The datasets presented in this article are not readily available because they were accessed with a Data Use Agreement that restricts data sharing outside this project. Requests to access the datasets should be directed to Dr. Marlotte.

Ethics statement

The studies involving humans were approved by University of California Los Angeles. The studies were conducted in accordance with the local legislation and institutional requirements. Written informed consent for participation in this study was provided by the participants' legal guardians/next of kin.

Author contributions

SK, LM, and PL contributed to the conception and design of the study. HA and AK organized the database. AK and HA performed the statistical analysis. LM wrote the first draft of the manuscript. SK, RI-M, KG, AK, and HA wrote sections of the manuscript. All authors contributed to the article and approved the submitted version.

Funding

Research was supported by the UCLA Clinical and Translational Science Institute (NIH NCATS UCLA CTSI Grant number UL1TR000124) and the UCLA Children's Discovery and Innovation Institute (CDI). During the preparation of this manuscript, RI-M received funding from the National Institute on Drug Abuse of the National Institutes of Health under Award Number K12DA000357. SK, RI-M, and HA are funded by National Institute of Mental Health (1U01MH131827-01) and consult to the Los Angeles Unified School District.

Acknowledgments

The content and views expressed in this article are those of the authors and do not necessarily reflect the position or policy of the US Department of Veterans Affairs, the National Institutes of Health, or the United States Government. The authors are grateful to all the clinicians who participated in this pilot and who contributed to this work being informed by their real-world practice in schools.

Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

All claims expressed in this article are solely those of the authors and do not necessarily represent those of their affiliated organizations, or those of the publisher, the editors and the reviewers. Any product that may be evaluated in this article, or claim that may be made by its manufacturer, is not guaranteed or endorsed by the publisher.

References

American Psychological Association. (2017). Stress in America: The state of our nation. Stress in AmericaTM survey. Available at: Available at: https://www.apa.org/news/press/releases/stress/2017/state-nation.pdf (Accessed December 1, 2019)

Avenevoli, S., Swendsen, J., He, J. P., Burstein, M., and Merikangas, K. R. (2015). Major depression in the National Comorbidity Survey–adolescent supplement: prevalence, correlates, and treatment. *J. Am. Acad. Child Adolesc. Psychiatry* 54, 37–44.e2. doi: 10.1016/j.jaac.2014.10.010

Beardslee, W. R., Gladstone, T. R., Wright, E. J., and Cooper, A. B. (2003). A family-based approach to the prevention of depressive symptoms in children at risk: evidence of parental and child change. *Pediatrics* 112, e119–e131. doi: 10.1542/peds.112.2.e119

Beardslee, W., Klosinski, L., Saltzman, W., Mogil, C., Pangelinan, S., Mcknight, C., et al. (2013). Dissemination of family-centered prevention for military and veteran families: adaptations and adoption within community and military systems of care. *Clin. Child. Fam. Psychol. Rev.* 16, 394–409. doi: 10.1007/s10567-013-0154-y

Beardslee, W. R., Wright, E. J., Gladstone, T. R. G., and Forbes, P. (2007). Long-term effects from a randomized trial of two public health preventive interventions for parental depression. *J. Fam. Psychol.* 21, 703–713. doi: 10.1037/0893-3200.21.4.703

Bevan Jones, R., Thapar, A., Stone, Z., Thapar, A., Jones, I., Smith, D., et al. (2018). Psychoeducational interventions in adolescent depression: a systematic review. *Patient Educ. Couns.* 101, 804–816. doi: 10.1016/j.pec.2017.10.015

Bliese, P. D., Wright, K. M., Adler, A. B., Cabrera, O., Castro, C. A., and Hoge, C. W. (2008). Validating the primary care posttraumatic stress disorder screen and the posttraumatic stress disorder checklist with soldiers returning from combat. *J. Consult. Clin. Psychol.* 76, 272–281. doi: 10.1037/0022-006X.76.2.272

Byles, J., Byrne, C., Boyle, M. H., and Offord, D. R. (1988). Ontario child health study: reliability and validity of the general functioning subscale of the McMaster family assessment device. *Fam. Process* 27, 97–104. doi: 10.1111/j.1545-5300.1988.00097.x

Calear, A. L., and Christensen, H. (2010). Systematic review of school-based prevention and early intervention programs for depression. *J. Adolesc.* 33, 429–438. doi: 10.1016/j.adolescence.2009.07.004

Carver, C. S. (1997). You want to measure coping but your protocol too long: consider the brief cope. *Int. J. Behav. Med.* 4, 92–100. doi: 10.1207/s15327558ijbm0401_6

Carver, C. S., Scheier, M. F., and Weintraub, J. K. (1989). Assessing coping strategies: a theoretically based approach. *J. Pers. Soc. Psychol.* 56, 267–283. doi: 10.1037/0022-3514.56.2.267

Centers for Disease Control and Prevention (2019). Youth risk behavior survey: data summary & trends report 2009–2019.

Cha, B. S., Enriquez, L. E., and Ro, A. (2019). Beyond access: psychosocial barriers to undocumented students' use of mental health services. *Soc. Sci. Med.* 233, 193–200. doi: 10.1016/j.socscimed.2019.06.003

Chandra, A., Scott, M. M., Jaycox, L. H., Meredith, L. S., Tanielian, T., and Burnam, A. (2009). Racial/ethnic differences in teen and parent perspectives toward depression treatment. *J. Adolesc. Health* 44, 546–553. doi: 10.1016/j.jadohealth.2008.10.137

Chorpita, B. F., and Weisz, J. R. (2009). *Modular approach to therapy for children with anxiety, depression, trauma, or conduct problems (MATCH-ADTC)*. Satellite Beach, FL: PracticeWise LLC.

Chung, B., Jones, L., Dixon, E. L., Miranda, J., and Wells, K. B.Community Partners in Care Steering Council (2010). Using a community partnered participatory research approach to implement a randomized controlled trial: planning community partners in care. *J. Health Care Poor Underserved* 21, 780–795. doi: 10.1353/hpu.0.0345

Committee on School Health. (2004). School-based mental health services. *Pediatrics* 113, 1839–1845. doi: 10.1542/peds.113.6.1839

Curtin, S. C., and Heron, M. (2019). *Death rates due to suicide and homicide among persons aged 10–24: United States, 2000–2017. NCHS data brief, no 352*. Hyattsville, MD: National Center for Health Statistics.

Epstein, N. B., Baldwin, L. M., and Bishop, D. S. (1983). The McMaster family assessment device. *J. Marital. Fam. Ther.* 9, 171–180. doi: 10.1111/j.1752-0606.1983.tb01497.x

Flores, G., and Tomany-Korman, S. C. (2008). Racial and ethnic disparities in medical and dental health, access to care, and use of services in US children. *Pediatrics* 121, e286–e298. doi: 10.1542/peds.2007-1243

Foa, E. B., Johnson, K. M., Feeny, N. C., and Treadwell, K. R. (2001). The child PTSD symptom scale: a preliminary examination of its psychometric properties. *J. Clin. Child Psychol.* 30, 376–384. doi: 10.1207/S15374424JCCP3003_9

Fung, H. W., Ki Lam, S. K., Chien, W. T., Hung, S. L., Wai-Hang Ling, H., Ping Lee, V. W., et al. (2022). Interpersonal stress mediates the relationship between childhood trauma and depressive symptoms: findings from two culturally different samples. *Aust. N Z J Psychiatry* 57, 1052–1061. doi: 10.1177/00048674221138501

Gaete, J., Martinez, V., Fritsch, R., Rojas, G., Montgomery, A. A., and Araya, R. (2016). Indicated school-based intervention to improve depressive symptoms among at risk Chilean adolescents: a randomized controlled trial. *BMC Psychiatry* 16, 276–210. doi: 10.1186/s12888-016-0985-4

García, F. E., and Wlodarczyk, A. (2018). Communal coping and rumination in the aftermath of Chile earthquake: Multiple mediation analysis of the relationship between subjective severity and posttraumatic growth. *J. Community Appl. Soc. Psychol.* 28, 191–199. doi: 10.1002/casp.2350

García, A. A., Zuñiga, J. A., and Lagon, C. (2017). A personal touch: the most important strategy for recruiting Latino research participants. *J. Transcult. Nurs.* 28, 342–347. doi: 10.1177/1043659616644958

Gee, B., Reynolds, S., Carroll, B., Orchard, F., Clarke, T., Martin, D., et al. (2020). Practitioner review: effectiveness of indicated school-based interventions for adolescent depression and anxiety – a meta-analytic review. *J. Child Psychol. Psychiatry* 61, 739–756. doi: 10.1111/jcpp.13209

Gonzales, N. A., Germán, M., and Fabrett, F. C. (2012). "US Latino youth" in *Handbook of race and development in mental health*. eds. E. C. Chang and C. A. Downey (Berlin: Springer), 259–278.

Goodman, R., Meltzer, H., and Bailey, V. (1998). The strengths and difficulties questionnaire: a pilot study on the validity of the self-report version. *Eur. Child Adolesc. Psychiatry* 7, 125–130. doi: 10.1007/s007870050057

Goodman, R., Meltzer, H., and Bailey, V. (2003). The strengths and difficulties questionnaire: a pilot study on the validity of the self-report version. *Int. Rev. Psychiatry* 15, 173–177. doi: 10.1007/s007870050057

Huey, S. J. Jr., and Polo, A. J. (2008). Evidence-based psychosocial treatments for ethnic minority youth. *J. Clin. Child Adolesc. Psychol.* 37, 262–301. doi: 10.1080/15374410701820174

Ijadi-Maghsoodi, R., Marlotte, L., Garcia, E., Aralis, H., Lester, P., Escudero, P., et al. (2017). Adapting and implementing a school-based resilience-building curriculum among low-income racial and ethnic minority students. *Contemp. Sch. Psychol.* 21, 223–239. doi: 10.1007/s40688-017-0134-1

Jones, L., and Wells, K. (2007). Strategies for academic and clinician engagement in community-participatory partnered research. *J. Am. Med. Assoc.* 297, 407–410. doi: 10.1001/jama.297.4.407

Julious, S. A. (2005). Sample size of 12 per group rule of thumb for a pilot study. *Pharm. Stat.* 4, 287–291. doi: 10.1002/pst.185

Kataoka, S., Stein, B. D., Nadeem, E., and Wong, M. (2007). Who gets care? Mental health service use following a school-based suicide prevention program. *J. Am. Acad. Child Adolesc. Psychiatry* 46, 1341–1348. doi: 10.1097/chi.0b013e31813761fd

Keeton, V., Soleimanpour, S., and Brindis, C. D. (2012). School-based health centers in an era of health care reform: building on history. *Curr. Probl. Pediatr. Adolesc. Health Care* 42, 132–156. doi: 10.1016/S0165-0327(00)00233-0

Kempfer, S. S., Fernandes, G. C. M., Reisdorfer, E., Girondi, J. B. R., Sebold, L. F., Porporatti, A. L., et al. (2017). Epidemiology of depression in low income and low education adolescents: a systematic review and meta-analysis. *Grant Med. J.* 2, 67–77.

Kieser, M., and Wassmer, G. (1996). On the use of the upper confidence limit for the variance from a pilot sample for sample size determination. *Biom. J.* 38, 941–949. doi: 10.1002/bimj.4710380806

Kodjebacheva, G. D., Culinski, T., Kawser, B., and Amin, S. (2023). Satisfaction with pediatric telehealth according to the opinions of children and adolescents during the COVID-19 pandemic: a literature review. *Front. Public Health* 11:1145486. doi: 10.3389/fpubh.2023.1145486

Kroenke, K., and Spitzer, R. L. (2002). The PHQ-9: a new depression diagnostic and severity measure. *Psychiatr. Ann.* 32, 509–515. doi: 10.3928/0048-5713-20020901-06

Kroenke, K., Spitzer, R. L., and Williams, J. B. (2001). The PHQ-9: validity of a brief depression severity measure. *J. Gen. Intern. Med.* 16, 606–613. doi: 10.1046/j.1525-1497.2001.016009606.x

Kroenke, K., Strine, T. W., Spitzer, R. L., Williams, J. B., Berry, J. T., and Mokdad, A. H. (2009). The PHQ-8 as a measure of current depression in the general population. *J. Affect. Disord.* 114, 163–173. doi: 10.1016/j.jad.2008.06.026

Kuo, D. Z., Houtrow, A. J., Arango, P., Kuhlthau, K. A., Simmons, J. M., and Neff, J. M. (2012). Family-centered care: current applications and future directions in pediatric health care. *Matern. Child Health J.* 16, 297–305. doi: 10.1007/s10995-011-0751-7

Larsen, D. L., Attkisson, C. C., Hargreaves, W. A., and Nguyen, T. D. (1979). Assessment of client/patient satisfaction: development of a general scale. *Eval. Program Plann.* 2, 197–207. doi: 10.1016/0149-7189(79)90094-6

Layne, C. M., Saltzman, W. R., Poppleton, L., Burlingame, G. M., Pašalić, A., Duraković, E., et al. (2008). Effectiveness of a school-based group psychotherapy program for war-exposed adolescents: a randomized controlled trial. *J. Am. Acad. Child Adolesc. Psychiatry* 47, 1048–1062. doi: 10.1097/CHI.0b013e31817eecae

Lee, C. Y. S., Goldstein, S. E., Dik, B. J., and Rodas, J. M. (2020). Sources of social support and gender in perceived stress and individual adjustment among Latina/o college-attending emerging adults. *Cult. Divers. Ethn. Minor. Psychol.* 26, 134–147. doi: 10.1037/cdp0000279

Lester, P., Liang, L. J., Milburn, N., Mogil, C., Woodward, K., Nash, W., et al. (2016). Evaluation of a family-centered preventive intervention for military families: parent and child longitudinal outcomes. *J. Am. Acad. Child Adolesc. Psychiatry* 55, 14–24. doi: 10.1016/j.jaac.2015.10.009

Lester, P., Saltzman, W. R., Woodward, K., Glover, D., Leskin, G. A., Bursch, B., et al. (2012). Evaluation of a family-centered prevention intervention for military children and families facing wartime deployments. *Am. J. Public Health* 102, S48–S54. doi: 10.2105/AJPH.2010.300088

Lester, P., Stein, J. A., Saltzman, W., Woodward, K., Mac Dermid, S. W., Milburn, N., et al. (2013). Psychological health of military children: longitudinal evaluation of a family-centered prevention program to enhance family resilience. *Mil. Med.* 178, 838–845. doi: 10.7205/MILMED-D-12-00502

Luthar, S. S. (2006). "Resilience in development: a synthesis of research across five decades" in *Developmental psychopathology: risk, disorder, and adaptation*. eds. D. Cicchetti and D. J. Cohen (New York: Wiley), 740–795.

Lyon, A. R., Ludwig, K. A., Vander Stoep, A., Gudmundsen, G., and McCauley, E. (2013). Patterns and predictors of mental healthcare utilization in schools and other service sectors among adolescents at risk for depression. *Sch. Ment. Heal.* 5, 155–165. doi: 10.1007/s12310-012-9097-6

Merikangas, K. R., He, J. P., Burstein, M., Swanson, S. A., Avenevoli, S., Cui, L., et al. (2010). Lifetime prevalence of mental disorders in U.S. adolescents: results from the National Comorbidity Survey Replication--Adolescent Supplement (NCS-A). *J. Am. Acad. Child Adolesc. Psychiatry* 49, 980–989. doi: 10.1016/j.jaac.2010.05.017

Miller, I. W., Epstein, N. B., Bishop, D. S., and Keitner, G. I. (1985). The McMaster family assessment device: reliability and validity. *J. Marital. Fam. Ther.* 11, 345–356. doi: 10.1111/j.1752-0606.1985.tb00028.x

Mogil, C., Hajal, N., Aralis, H., Paley, B., Milburn, N. G., Barrera, W., et al. (2022). A trauma-informed, family-centered, virtual home visiting program for young children: one-year outcomes. *Child Psychiatry Hum. Dev.* 53, 964–979. doi: 10.1007/s10578-021-01181-y

Moore, C. G., Carter, R. E., Nietert, P. J., and Stewart, P. W. (2011). Recommendations for planning pilot studies in clinical and translational research. *Clin. Transl. Sci.* 4, 332–337. doi: 10.1111/j.1752-8062.2011.00347.x

Mufson, L. H., Dorta, K. P., Olfson, M., Weissman, M. M., and Hoagwood, K. (2004). Effectiveness research: transporting interpersonal psychotherapy for depressed adolescents (IPT-A) from the lab to school-based health clinics. *Clin. Child. Fam. Psychol. Rev.* 7, 251–261. doi: 10.1007/s10567-004-6089-6

Najman, J. M., Hayatbakhsh, M. R., Clavarino, A., Bor, W., O'Callaghan, M. J., and Williams, G. M. (2010). Family poverty over the early life course and recurrent adolescent and young adult anxiety and depression: a longitudinal study. *Am. J. Public Health* 100, 1719–1723. doi: 10.2105/AJPH.2009.180943

Naviya Antony, K., and Sultana, A. S. (2021). Stress, depression and gender differences among adolescents. *Int. J.* 2, 68–76.

Nixon, R. D., Meiser-Stedman, R., Dalgleish, T., Yule, W., Clark, D. M., Perrin, S., et al. (2013). The child PTSD symptom scale: an update and replication of its psychometric properties. *Psychol. Assess.* 25, 1025–1031. doi: 10.1037/a0033324

Nurius, P., LaValley, K., and Kim, M. H. (2020). Victimization, poverty, and resilience resources: stress process considerations for adolescent mental health. *Sch. Ment. Heal.* 12, 124–135. doi: 10.1007/s12310-019-09335-z

Ortega, A. N., McKenna, R. M., Pintor, J. K., Langellier, B. A., Roby, D. H., Pourat, N., et al. (2018). Health care access and physical and behavioral health among undocumented Latinos in California. *Med. Care* 56, 919–926. doi: 10.1097/MLR.0000000000000985

Perez, R. M., Dawson, B. A., and Suárez-Orozco, C. (2011). Understanding acculturation, depressive symptoms, and the protective role of family involvement among Latino (a) immigrant families. *J. Fam. Soc. Work.* 14, 429–445. doi: 10.1080/10522158.2011.617030

Perreira, K. M., Marchante, A. N., Schwartz, S. J., Isasi, C. R., Carnethon, M. R., Corliss, H. L., et al. (2019). Stress and resilience: key correlates of mental health and substance use in the Hispanic community health study of Latino youth. *J. Immigr. Minor. Health* 21, 4–13. doi: 10.1007/s10903-018-0724-7

Piña-Watson, B., and Castillo, L. G. (2015). The role of the perceived parent–child relationship on Latina adolescent depression. *Child Adolesc. Soc. Work J.* 32, 309–315. doi: 10.1007/s10560-014-0374-0

Pina, A. A., Polo, A. J., and Huey, S. J. (2019). Evidence-based psychosocial interventions for ethnic minority youth: the 10-year update. *J. Clin. Child Adolesc. Psychol.* 48, 179–202. doi: 10.1080/15374416.2019.1567350

Potochnick, S. R., and Perreira, K. M. (2010). Depression and anxiety among first-generation immigrant Latino youth: key correlates and implications for future research. *J. Nerv. Ment. Dis.* 198, 470–477. doi: 10.1097/NMD.0b013e3181e4ce24

Pumariega, A. J., Rogers, K., and Rothe, E. (2005). Culturally competent systems of care for children's mental health: advances and challenges. *Community Ment. Health J.* 41, 539–555. doi: 10.1007/s10597-005-6360-4

Ramirez, M., Wu, Y., Kataoka, S., Wong, M., Yang, J., Peek-Asa, C., et al. (2012). Youth violence across multiple dimensions: a study of violence, absenteeism, and suspensions among middle school children. *J. Pediatr.* 161, 542–546.e2. doi: 10.1016/j.jpeds.2012.03.014

Razykov, I., Ziegelstein, R. C., Whooley, M. A., and Thombs, B. D. (2012). The PHQ-9 versus the PHQ-8—is item 9 useful for assessing suicide risk in coronary artery disease patients? Data from the heart and soul study. *J. Psychosom. Res.* 73, 163–168. doi: 10.1016/j.jpsychores.2012.06.001

Reyes-Portillo, J. A., McGlinchey, E. L., Yanes-Lukin, P. K., Turner, J. B., and Mufson, L. (2017). Mediators of interpersonal psychotherapy for depressed adolescents on outcomes in Latinos: the role of peer and family interpersonal functioning. *J. Lat./Psychol.* 5, 248–260. doi: 10.1037/lat0000096

Rotheram-Borus, M. J., Lee, M., Lin, Y., and Lester, P. (2004). Six-year intervention outcomes for adolescent children of parents with the human immunodeficiency virus. *Arch. Pediatr. Adolesc. Med.* 158, 742–748. doi: 10.1001/archpedi.158.8.742

Saltzman, W. R., Babayan, T., Lester, P., Beardslee, W. R., and Pynoos, R. S. (2008). "Family-based treatment for child traumatic stress: a review and report on current innovations" in *Treating traumatized children*. eds. D. Brom, R. Pat-Horenczyk and J. Ford (New York: Routledge), 258–272.

Saltzman, W. R., Lester, P., Beardslee, W. R., Layne, C. M., Woodward, K., and Nash, W. P. (2011). Mechanisms of risk and resilience in military families: theoretical and empirical basis of a family-focused resilience enhancement program. *Clin. Child. Fam. Psychol. Rev.* 14, 213–230. doi: 10.1007/s10567-011-0096-1

SAMHSA. (2014). *SAMHSA's concept of trauma and guidance for a trauma-informed approach (HHS publication no. SMA 14–4884)*. Rockville, MD: Substance Abuse and Mental Health Services Administration.

SAMHSA. (2021). *Key substance use and mental health indicators in the United States: results from the 2020 National Survey on Drug Use and Health (HHS publication no. PEP21-07-01-003, NSDUH series H-56)*. Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Available at: https://www.samhsa.gov/data/

SAMHSA. (2022). *Key substance use and mental health indicators in the United States: results from the 2021 National Survey on Drug Use and Health (HHS publication no. PEP22-07-01-005, NSDUH series H-57)*. Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Available at: https://www.samhsa.gov/data/report/2021-nsduh-annual-national-report

Sela, Y., Zach, M., Amichay-Hamburger, Y., Mishali, M., and Omer, H. (2020). Family environment and problematic internet use among adolescents: The mediating roles of depression and Fear of Missing Out. *Comput. Hum. Behav.* 106:106226. doi: 10.1016/j.chb.2019.106226

Sigurvinsdóttir, A. L., Jensínudóttir, K. B., Baldvinsdóttir, K. D., Smárason, O., and Skarphedinsson, G. (2020). Effectiveness of cognitive behavioral therapy (CBT) for child and adolescent anxiety disorders across different CBT modalities and comparisons: a systematic review and meta-analysis. *Nord. J. Psychiatry* 74, 168–180. doi: 10.1080/08039488.2019.1686653

Spirito, A., Esposito-Smythers, C., Wolff, J., and Uhl, K. (2011). Cognitive-behavioral therapy for adolescent depression and suicidality. *Child Adolesc. Psychiatr. Clin. N Am.* 20, 191–204. doi: 10.1016/j.chc.2011.01.012

Thapar, A., Collishaw, S., Pine, D. S., and Thapar, A. K. (2012). Depression in adolescence. *Lancet* 379, 1056–1067. doi: 10.1016/S0140-6736(11)60871-4

Tursi, S., Baes, W., Camacho, B., Tofoli, C., and Juruena, M. F. (2013). Effectiveness of psychoeducation for depression: a systematic review. *Aust. N Z J. Psychiatry* 47, 1019–1031. doi: 10.1177/0004867413491154

U.S. Public Health Service. (2000). *Publications and reports of the surgeon general report of the surgeon General's conference on Children's mental health: a national action agenda*. Washington (DC): US Department of Health and Human Services.

Vega, W. A., Kolody, B., Valle, R., and Weir, J. (1991). Social networks, social support, and their relationship to depression among immigrant Mexican women. *Hum. Organ.* 50, 154–162. doi: 10.17730/humo.50.2.p340266397214724

Vibhakar, V., Allen, L. R., Gee, B., and Meiser-Stedman, R. (2019). A systematic review and meta-analysis on the prevalence of depression in children and adolescents after exposure to trauma. *J. Affect. Disord.* 255, 77–89. doi: 10.1016/j.jad.2019.05.005

Vogel, W. (2012). Depression in children and adolescents. *CME: Your SA J. CPD* 105, 149–155. doi: 10.3238/arztebl.2008.0149

Vrshek-Schallhorn, S., Stroud, C. B., Mineka, S., Hammen, C., Zinbarg, R. E., Wolitzky-Taylor, K., et al. (2015a). Chronic and episodic interpersonal stress as statistically unique predictors of depression in two samples of emerging adults. *J. Abnorm. Psychol.* 124, 918–932. doi: 10.1037/abn0000088

Vrshek-Schallhorn, S., Stroud, C. B., Mineka, S., Zinbarg, R. E., Adam, E. K., Redei, E. E., et al. (2015b). Additive genetic risk from five serotonin system polymorphisms interacts with interpersonal stress to predict depression. *J. Abnorm. Psychol.* 124, 776–790. doi: 10.1037/abn0000098

Wagstaff, A. E., and Polo, A. J. (2012). Ethnicity and adolescent depression: prevalence, access to services, and promising interventions. *Prev. Res.* 19, 8–11. Available at: https://web.p.ebscohost.com/ehost/pdfviewer/pdfviewer?vid=0&sid=e7313157-5084-4d1e-a947-b4ed599606d6%40redis

Weathers, F. W., Litz, B. T., Herman, D. S., Huska, J. A., and Keane, T. M. (1993). The PTSD checklist (PCL): reliability, validity, and diagnostic utility. In Annual Convention of the International Society for Traumatic Stress Studies, San Antonio, TX (Vol. 462).

Whitehead, A. L., Julious, S. A., Cooper, C. L., and Campbell, M. JJ. (2016). Estimating the sample size for a pilot randomised trial to minimise the overall trial sample size for the external pilot and main trial for a continuous outcome variable. *Stat. Methods Med. Res.* 25, 1057–1073. doi: 10.1177/0962280215588241

Wolpert, M., Goerzig, A., Deighton, J., Fugard, A., Newman, R., and Ford, T. (2014). Comparison of indices of clinically meaningful change in child and adolescent mental health services: difference scores, reliable change, crossing clinical thresholds and 'added value' – an exploration using parent rated scores on the SDQ. *Child Adolesc. Mental Health* 20, 94–101. doi: 10.1111/camh.12080

frontiers | Frontiers in Psychology

TYPE Original Research
PUBLISHED 31 October 2023
DOI 10.3389/fpsyg.2023.1253179

OPEN ACCESS

EDITED BY
Brooke Schneider,
University Medical Center Hamburg-Eppendorf, Germany

REVIEWED BY
Massimo Tusconi,
University of Cagliari, Italy
Paolo Meneguzzo,
University of Padua, Italy

*CORRESPONDENCE
Rebeca Robles
✉ reberobles@imp.edu.mx;
✉ reberobles@hotmail.com

RECEIVED 05 July 2023
ACCEPTED 12 October 2023
PUBLISHED 31 October 2023

CITATION
Robles R, Infante S, Feria M, Arango I, Tirado E, Rodríguez-Delgado A, Miranda E, Fresán A, Becerra C, Escamilla R and Madrigal de León EA (2023) Remote crisis intervention and suicide risk management in COVID-19 frontline healthcare workers.
Front. Psychol. 14:1253179.
doi: 10.3389/fpsyg.2023.1253179

Remote crisis intervention and suicide risk management in COVID-19 frontline healthcare workers

Rebeca Robles[1]*, Sara Infante[2], Miriam Feria[2], Iván Arango[2], Elsa Tirado[2], Andrés Rodríguez-Delgado[2], Edgar Miranda[2], Ana Fresán[3], Claudia Becerra[2], Raul Escamilla[2] and Eduardo Angel Madrigal de León[4]

[1]Global Mental Health Research Center, Ramón de la Fuente Muñiz National Institute of Psychiatry, Mexico City, Mexico, [2]Directorate of Clinical Services, Ramón de la Fuente Muñiz National Institute of Psychiatry, Mexico City, Mexico, [3]Laboratory of Clinical Epidemiology, Subdirectorate of Clinical Research, Ramón de la Fuente Muñiz National Institute of Psychiatry, Mexico City, Mexico, [4]General Directorate Ramón de la Fuente Muñiz National Institute of Psychiatry, Mexico City, Mexico

Introduction: Despite the propagation of virtual mental health services for vulnerable groups during COVID-19 pandemic, the implementation and evaluation of remote evidence-based practices (EBP) to manage them in low- and middle-income countries remains scarce. In the current study, we describe and evaluate the implementation process and clinical impact of brief, remote, manualized EBP for crisis intervention and suicide risk management among healthcare workers attending patients with COVID-19 (COVID-19-HCWs) in Mexico.

Methods: The implementation process comprised community engagement of volunteer mental health specialists, creation of new clinical teams with different disciplines and skills, intervention systematization through manuals and education through 4-h remote training as main strategies. Mexican COVID-19-HCWs who had used a free 24-h helpline rated their pre- and post-intervention emotional distress. Therapists recorded patients' pre-intervention diagnosis, severity, and suicide risk, the techniques used in each case, and their post-treatment perception of COVID-19-HCWs' improvement at the end of the intervention.

Results: All techniques included in the intervention manual were employed at least in one case ($n = 51$). At the beginning of the intervention, 65.9% of the COVID-19-HCWs were considered moderately ill or worse according to Clinical Global Impression-Severity (CGI-S) scores, whereas at the end, 79.4% of them were perceived as much or very much improved according to CGI-Improvement scores (CGI-I), and their emotional distress had been significantly reduced ($p < 0.001$).

Discussion: This prospective study provides evidence that implementation of remote EBP is feasible and useful to reduce emotional distress and suicide risk among COVID-19-HCWs from a middle-income country. However, this study was limited by lack of a control group, improvement ratings provided by therapists and non-anonymous satisfaction ratings.

KEYWORDS

crisis intervention, suicide, healthcare workers, COVID-19, e-mental health, implementation science

Introduction

Healthcare workers attending patients with COVID-19 (COVID-19-HCWs) constituted one of the known vulnerable groups in terms of mental health problems (MHP) and suicide risk (Adhanom, 2020). Thus, in parallel with universal suicide prevention strategies designed for the entire population (Mann and Currier, 2011), selective interventions for this (and other vulnerable groups) had to be provided, including mental disorders and suicide risk assessment (Gunnell et al., 2020) as well as indicated evidence-based practices (EBP) targeting those experiencing emotional crises and suicidal risk.

Main examples of EPB for these purposes include psychological first aid (American Psychiatric Association, 1954; Vernberg et al., 2008; Corey et al., 2021), pharmacotherapy for mental disorders (Brent, 2016), brief cognitive-behavioral therapy (CBT) (DeCou et al., 2019), and safety planning (Stanley and Brown, 2012). which had to be adapted to ensure their safe implementation in the context of such highly contagious virus by increasing the development and use of helplines, telemedicine and other digital methods (Gunnell et al., 2020).

The propagation of remote mental health services during COVID-19 might expand access to mental health care during and beyond the pandemic (Wind et al., 2020; Zhou et al., 2020), which is unfortunately low among healthcare students and professionals, even among those with substantial risk factors for suicide (Givens and Tjia, 2002). Barriers to using face-to-face mental health services, which are often offered in institutions where healthcare students and professionals work, include lack of time and fear of documentation in academic or professional records. Such barriers might be solved through remote interventions (e.g., hotlines) not associated with these institutions.

Scientific evidence demonstrates that EBP have effectively been applied remotely to reduce distress and suicide risk in general population and in HCWs (Berrouiguet et al., 2018; Pospos et al., 2018; Reinhardt et al., 2019). According to a systematic review of studies carried out prior to the pandemic, Pospos et al. (2018), showed that web-based tools and mobile applications that incorporate techniques usually employed as part of psychological first aid and suicide prevention (e.g., deep breathing, cognitive-behavioral techniques to cope with unpleasant thoughts and emotions, development of a customized safety plan and grounding exercises), are useful to improve healthcare student's and professional's coping, thus mitigating psychological distress and suicide risk.

However, it is still necessary to increase research efforts on which methods are useful for achieving their effective implementation (adoption by clinicians) in the contexts in which they are applied (Wasserman et al., 2020) when significant changes in clinicians' routine delivery methods (remote vs. face-to-face), and patients (HCW-COVID-19) are in place.

In line with this, according to the emerging field of implementation science of EBP—as opposed to the sciences for their development through clinical trials—, research in this field should be oriented toward understanding the methods for promoting their incorporation into clinical practice (Berrouiguet et al., 2018). Therefore, implementation studies typically focus on the impact of specific strategies on the rates and quality of use of EBP, the proportion of patients who attend a minimum number of treatment sessions, and the adaptations required to improve the implementation process.

The present study sets forth the results of the evaluation of the implementation process and clinical impact of remote EBP designed to address emotional crises and suicide risk in Mexican COVID-19-HCWs, as part of a country-level strategy coordinated by the Mexican Ministry of Health (through its National Institute of Psychiatry), in collaboration with the National Autonomous University of Mexico (UNAM) since the beginning of the COVID-19 pandemic in the country.

Specific objectives include describing: (1) COVID-19-HCWs' help-seeking process (including their sociodemographic and professional profile, sources of referral and reasons for consultation), (2) COVID-19-HCWs' MHP and suicide risk according to service providers, (3) the EBP most frequently used by providers (and the reasons for adopting them), (4) the clinical utility of the intervention according to providers (by comparing their perception of the severity of COVID-19-HCWs' MHP at the start of the intervention with COVID-19-HCWs' improvement at the end of it), and (5) the acceptability and clinical utility of the intervention according to users (by comparing COVID-19-HCWs' pre-post perception of emotional distress).

Materials and methods

Participants: clinicians, and patients

A total of 18 clinicians voluntarily participated; 5 were psychiatrists attending cases with suicide risk and/or in need for pharmacotherapy in addition to psychological techniques; and 13 were psychologists with at least a master's degree. The sample of patients comprised 51 Mexican COVID-19-HCWs over 18 years old who voluntarily agreed to participate in the study, be assessed by a mental health specialist before and after the intervention, and attended at least one intervention session, from April 17 to December 15, 2020, the period encompassing the clusters of cases scenario (when a country experiences cases clusters in time, geographic location, or common exposure; World Health Organization, 2020) and the community transmission scenario (when a country experiences larger outbreaks of local transmission; World Health Organization, 2020), including the first COVID-19 peak in Mexico.

Variables and measures

Sociodemographic, professional, and COVID-19-related variables were evaluated using self-report questions on subjects' sex, age, marital status, education, profession, personal COVID-19 status, and the COVID-19 status of friends and relatives.

Contact, reason for consultation, and emotional distress

Each subject was asked how they had found out about the free 24-h helpline and the reason for their call. The answers to these open-ended questions were recorded in a previously designed format for patients seeking psychological crisis intervention and suicide risk management. They were subsequently coded for analysis. Emotional distress was assessed at the beginning and end of the intervention through the following sentence: *"Which number best describes how much emotional distress you are experiencing right now, on a scale of 0 to 10?"* (Almanza-Muñoz et al., 2008).

Diagnostic impression and overall clinical impression

Each mental health professional recorded their diagnostic impression and assessed the severity of the symptoms reported during the psychological crisis using the Clinical Global Impression (CGI)-Severity Scale (CGI-S), rated on a 7-point Likert scale ranging from 1 (normal) to 7 (among the most severely ill patients). At the end of the intervention, the CGI-Improvement Scale (CGI-I) was assessed. CGI-I scores range from 1 (very much improved) to 7 (very much worse) (Guy, 1976).

Suicide risk assessment

The level of suicide risk (mild, moderate, high) was assessed in keeping with the risk of suicide module of the Mini-International Neuropsychiatric Interview (MINI) (Sheehan et al., 1997; Ferrando et al., 1998), comprising six items with a yes/no answer. In addition, the type of intervention required was determined by the total number of the ten risk factors included in the SAD Persons scale (0–4 = ambulatory treatment, 5–19 = hospitalization) (Patterson et al., 1983; Comité de Consenso de Catalunya en Terapéutica de los Trastornos Mentales, 2005; Gobierno de Canarias, 2008).

Clinicians' adoption of EBP

To determine the level of adoption of the manual and the need to incorporate new techniques, clinicians were asked to record the techniques used and the reasons for their use in every session and case in an *ad hoc* form designed for the study.

Acceptability of the Intervention was evaluated using three questions; two regarding the level of patients´ satisfaction with the contents and intervention modality (remote), and the degree of complexity of the intervention, to be answered on a 5-point Likert scale, where 0 = not at all satisfied/complex, 1 = not very satisfied/complex, 2 = moderately satisfied/complex, 3 = very satisfied/complex, and 4 = fully satisfied/complex. At the end, a dichotomous question (yes/no) was included on whether subjects would recommend the intervention to other health workers coping with COVID-19.

Procedures

Main implementation strategies and outcomes

Implementation strategies included *community engagement* (Pinto et al., 2021) of volunteer mental health specialists willing to attend COVID-19-HCWs (psychiatrists and psychologists from de National Institute of Psychiatry with extensive experience treating emotional crises and/or psychiatric urgencies), in order to warrantee the availability of sufficient professional resources and the *creation of new clinical teams* with different disciplines and skills (Powell et al., 2015); *intervention systematization* through manuals and *education* through 4-h. online training session (Powell et al., 2015) in order to strength their skills to implement remote EBP to address emotional crises and suicide risk; and allow better assessment of implementation and clinical outcomes (Pinto, 2013).

Training session's topics, teaching strategies and time employed to each topic were: 1) Use of the intervention manuals (described below) through conference and group discussion on the application of each strategy to case vignettes (of HCWs in emotional crises and/or with suicide risk during the pandemic) during two hours, 2) Process for referring patients to a psychiatrist, different virtual clinics and services if needed, though conference and exemplification during 30 min, and 3) Administration of the instruments and recording the data for the study (including the additional techniques they considered necessary for each case), through conference, groups exercises applying instruments to case vignettes and recording data in corresponding Excel formats, during 90 min. At the end of the online training session on intervention and evaluation methods, a case vignette was presented to determine interrater reliability between clinicians in the assessment of the patients´ initial severity, suicide risk and improvement after intervention. The Fleiss' kappa coefficient was determined with values over 0.80 obtained in all cases, reflecting an adequate level of agreement between clinicians.

The main expected implementation outcome was a high level of adoption of EBPs by clinicians. Secondly, we expected high patient satisfaction and significant clinical utility of the intervention. Thus, to be part of the study's sample, the record of the techniques employed during intervention sessions must be totally complete, and the evaluations of patients´ clinical improvement and treatment satisfaction were not mandatory.

Remote recruitment, evaluation, and intervention

Mexican COVID-19-HCWs were invited to use the free 24-h helpline to cope with emotional crises and/or suicidal thoughts through several sources, including a brief online evaluation and referral to treatment tool (at the national COVID-19 website: coronavirus.gob.mx), which automatically delivered personal feedback after completion of valid, reliable scales, including specific contact information on virtual clinics and other specialized services, if required, (2) the coordinators or therapists of other national virtual clinics for COVID-19-HCWs, (3) the National Institute of Psychiatry's website and social networks, (4) press conferences and remote meetings with COVID-19-HCWs and COVID-19 health care center authorities (mainly at congresses and academic sessions), and (5) posters at the entrance to the COVID-19 zones of COVID-19 health care centers.

The free 24-h helpline for managing emotional crises and/or suicidal thoughts was answered by one of the participating clinicians. All of them were equipped with a mobile phone to answer the helpline according to a scheduled agenda of days and hours to be covered by each one to cover the service 24 h. Then, clinicians and patients decided together the best way to communicate remotely, whether it was the phone or a session using a virtual platform (for example, Zoom).

Sociodemographic, professional, COVID-19-related variables, source of referral, reasons for consultation and emotional distress were registered at the beginning of the intervention, prioritizing the attention of the patients. At the end of first session, clinicians registered their diagnostic and overall clinical impression, as well as patients´ suicide risk.

Crisis intervention was delivered according to the operational manual for remote psychosocial care during the COVID-19 pandemic in Mexico (Álvarez et al., 2020), which include a detailed description of a psychological intervention in emergencies based on Crisis Intervention Model and Cognitive Behavioral Therapy. Table 1 includes a description of the content and adaptations for COVID-19 pandemic in each manual. Suicide risk was handled using Dialectic Behavioral Therapy techniques (such as TIPP and mindfulness skills), according Linehan's (2014) DBT Skills training manual.

However, therapists could use the techniques of their choice for each case, regardless of whether they were included in the intervention

TABLE 1 Manual for crisis intervention (Álvarez et al., 2020): content and adaptations for COVID-19 pandemic.

Themes and subthemes	Adaptations for COVID-19 pandemic
Emergencies and crisis	
Definition and types of emergencies and crisis. Psychological reactions: Acute stress reaction, posttraumatic stress disorder, depression, and generalized anxiety disorder.	Inclusion of health emergencies, highlighting specific stressors of COVID-19 pandemic (such as quarantine, physical/social distance, fear of contagion)
Psychological first Aid	
General principles and objectives. Therapeutic alliance, active listening and containment, encouraging emotional expression and validating emotions, problem solving and positive reinforcement, identification and management of suicide risk (including reference to psychiatric evaluation if needed)	Emphasis on online implementation and teamwork (as part of the health emergency personnel). Use of the brief online evaluation and referral to treatment tool for COVID-19 HCWs (described in methods section) and other helplines. Inclusion of the importance of psychoeducation on dealing with grief during COVID-19.
Crisis Intervention	
Definition and guidelines to stablish a safety and crisis plan including personal, social and institutional resources. Deactivation techniques: deep breathing, relaxation (imagery and muscular), meditation and mindfulness. Physiological activation: body self-massage, body movement. Thought modification: ABC model, weighing the evidence and generating alternative interpretations, reattribution, semantic method, terms definition, survey method, and cost–benefit analysis.	Consideration of need for pharmacological and/or other specialized treatments and use of the brief online evaluation and referral to treatment tool for COVID-19 HCWs (described in methods section). Inclusion of specific examples expressing cognitive distortions during COVID-19 pandemic. Inclusion of case vignettes (e,g, a women with extreme worries about COVID-19 contagion due to one simple symptom, and the recommended intervention.
Healthcare workers self-care Self-care measures (nutrition, rest, exercise, social contact, avoiding maladaptive strategies (e.g., use of alcohol in the face of negative emotions)	Inclusion of recommendations for health care professionals during COVID-19

manuals, including pharmacotherapy for MHP, and hospitalization for severe cases. At the end of each session, clinicians recorded the techniques used and the reasons for their use, as well as new important information for case management if they considered it necessary (e.g., antecedents of mental health problems and psychological/pharmacological treatments, comorbidity, etc.). At the end of the intervention, clinicians registered patients´ global improvement and patients´ acceptability of the intervention.

Data analyses

All analyses were performed using SPSS-X v.21.0. All descriptive information was determined by frequencies and percentages for categorical variables and means and standard deviation for continuous variables.

Demographics, professional, COVID-19-related variables, reason for consultation (including suicide risk), diagnostic impression and CGI scores among HCWs were described as well as the frequency and percentage of sessions and the use of the techniques included in the intervention manual and the additional ones. We also recorded subjects' degree of satisfaction with the contents and modality of the intervention, and perception of its complexity.

Emotional distress before and after the intervention (in those who finished the intervention and completed both evaluations) was compared using repeated-measures Student's t-tests with a prefixed alpha value of $p < 0.05$. Cohen's d for t-tests were obtained to determine the effect sizes of the comparisons.

Finally, a content analysis was conducted by categorizing the meanings (Kvale, 1996) of the reasons for the use of additional techniques, to reveal the reason for their use by the therapist.

Results

A total of 234 HCWs was attended in the virtual clinic for crisis intervention and suicide risk management during the period of the study. 183 HCWs were excluded from the study's sample given the reports of their evaluations were not delivered by the treating psychotherapist given they did not have time to complete the records

10.3389/fpsyg.2023.1253179

TABLE 2 Demographic, professional and COVID-19-related variables ($n = 51$).

Variables	Categories	Descriptives
Sex, *n (%)*	Men	17 (33.3)
	Women	34 (66.7)
Age, *mean (S.D; range)*		36.4 (8.5; 21–60)
Marital status, *n (%)*	Partnered	22 (43.1)
	Unpartnered	29 (56.9)
Educational attainment, *n (%)*	Undergraduate	7 (13.7)
	Bachelor's degree	27 (52.9)
	Specialty degree	9 (17.6)
	Master's or PhD degree	8 (15.7)
Professional profile, *n (%)*	Medicine [a]	20 (39.2)
	Psychology	9 (17.6)
	Nursing	8 (15.7)
	Social work	3 (5.9)
	Other	11 (21.6)
Primary institution, *n (%)*	Federal Ministry of Health (SSA)	21 (41.2)
	Public State Health Services	9 (17.6)
	Private practice	8 (15.7)
	Other	13 (25.5)
COVID-19 status, *n (%)*	No symptom	30 (58.8)
	Acute respiratory disease	8 (13.7)
	Confirmed COVID-19 diagnosis	13 (25.5)

[a]Includes undergraduate physicians, general practitioners, interns, medical specialty residents, and specialist physicians.

(in 150 cases) or patients did not accept to complete the evaluations for the study (n = 33). Reports of the remaining 51 HCWs were provided for the present study: 66.7% ($n = 34$) was women and the remaining 33.3% (n = 17) men, with a mean age of 36.4 (S.D. = 8.5, range 21–60) years. All of them began treatment but three (5.9%) dropped out (two after the first session and one after the fourth session), meaning that 48 (94.1%) completed the intervention. Of the latter, 51.0% ($n = 25$) failed to complete the questionnaire on the acceptability of the intervention arguing they did not have time to do so. Table 2 shows the main demographic, professional and COVID-19-related variables of the sample. None of the participants was receiving other types of mental health care during the study.

As can be seen in Table 3, the most frequent source of referral to the helpline was another HCW. The main reasons for consultation included having tested positive for COVID-19 ($n = 10$, 21.3%) or the suspicion or fear of having COVID-19 (n = 9, 19.1%), as well as experiencing the death of close friends or loved ones from COVID-19 (n = 10, 21.3%). According to the mental health professionals answering the helpline, more than 60 % of the sample presented some form of depression (with or without anxiety symptoms), while nearly 30 % were at risk of suicide.

Intervention techniques

The number of sessions and techniques used for the subjects was reported, including those who dropped out of treatment. The average number of intervention sessions was 3.5 (S.D. = 2.5, range = 1–12); initial sessions were longer than follow up sessions (60 to 90 min vs. 40 to 60 min). Table 4 presents the frequency of use of the intervention techniques, comprising those contained in the manual, as well as those not included in it yet considered necessary for the cases under treatment by the therapist. Table 4 also shows the reasons for the use of these additional techniques, which are classified into three main categories: 1) Psychopharmacology, 2) Self-disclosure and 3) Use of metaphors.

Clinical utility of the intervention

The CGI assessment at the beginning and end of the intervention and the comparison of the emotional distress experienced are included in Table 5. As can be seen, at the beginning of the intervention, more than half of the HCWs were classified as moderately ill, whereas by the end of the intervention, 79.4% were considered "very much" or "much" improved by the treating mental health professional. Seven women (23.3% of the total female participants) were classified as moderately to severely ill, while all men were assessed with lower illness severity (borderline moderately ill, to moderately ill), which is in line with women's initial report of higher distress than men. However, at the end of the intervention, no differences in the distress experienced by sex were founded. Congruently, both women and men reported a significant reduction in emotional distress after the intervention, with "large" effect sizes according to Cohen's d

TABLE 3 Source of referral to helpline, reason for consultation, diagnostic impression, and suicide risk.

Variables	Categories	*n* (%)
Source of referral to helpline ($n = 47$[a])	Another HCW	16 (34.0)
	Official media	9 (19.1)
	National Autonomous University	8 (17.0)
	Social media	4 (8.5)
	Physical propaganda	2 (4.3)
	Coordinator of another clinic	1 (2.0)
	Other	7 (14.9)
HCWs' reason for consultation ($n = 47$[b])	COVID-19 positive test	10 (21.3)
	Death from COVID-19 (family, colleagues, patients)	10 (21.3)
	Fear of COVID-19 contagion	9 (19.1)
	Mental health problems (depression, anxiety, etc.)	6 (12.8)
	Having COVID-19 symptoms/waiting for test results	4 (8.6)
	Helping others with their mental health problems due to COVID-19	3 (6.3)
	Colleagues infected with COVID-19	2 (4.3)
	Relationship problems (friends/family)	1 (2.1)
	Fear of failing to complete studies due to the pandemic	1 (2.1)
	Death of family members from non-COVID-19 causes	1 (2.1)
Therapist's diagnostic impression ($n = 51$)	Depression with anxiety symptoms	29 (56.9)
	Anxiety disorder	12 (23.5)
	Depression	5 (9.8)
	Alcohol dependence/abuse	2 (3.9)
	Panic disorder	1 (2.0)
	Health anxiety disorder	1 (2.0)
	Grief due to death of family member from COVID-19	1 (2.0)
Suicide risk ($n = 51$)	None	22 (43.1)
	Minimal risk, ambulatory treatment	7 (13.7)
	Moderate risk, ambulatory treatment	6 (11.8)
	High risk, hospitalization	2 (3.9)
	Therapist considered it unnecessary to assess subject	14 (27.5)

[a]7.8% ($n = 4$) HCW failed to provide information on how they found out about the hotline.
[b]7.8% ($n = 4$) HCW did not give their personal reasons for attending the service.

coefficients (Cohen, 1992). Interestingly, higher proportion of men reported being significantly improved (according to CGI-I scale) at the end of the intervention.

Acceptability of the intervention

Of the 48 HCWs who completed the intervention, a subsample of 26 reported their level of satisfaction with and perception of the complexity of the intervention. All of them (100%) stated that they were "totally satisfied" with the contents of the intervention. Moreover, the majority (n = 17, 65.4% of the subsample) answered that the intervention was "not complex" (followed by 19.2% (n = 5) who considered it "not very complex" and only 7.7% (n = 2) reported that it was "very complex." All the subjects reported that they would recommend it to their colleagues. Almost all the HCWs were "totally satisfied" (n = 24, 92.3% of the subsample) or "very satisfied (n = 2, 7.7%) with the remote modality of the intervention.

Discussion

Present implementation study carried out a preliminary or basic evaluation of the utility of *community engagement* (Pinto et al., 2021), *creation of new clinical teams*, *intervention systematization* and *education* (Powell et al., 2015) as the implementation strategies to achieve clinicians´ adoption of remote EBP to address emotional crises and suicide risk, and therefore some indicators of significant clinical improvements and high levels of satisfaction with the

TABLE 4 Type, frequency of intervention techniques throughout sessions, reasons for use of additional techniques ($n = 51$), CGI and emotional distress assessment.

Manual techniques		Additional techniques		
	n (%)	*n* (%)		Reasons (examples)
Listen & containment	46 (90.2)			
Emotion validation	23 (45.1)			
Breathing & relaxation	16 (31.4)			
Thought modification	11 (21.6)			
Safety plan	6 (11.8)	Psychopharmacology	20 (39.2)	*"Antecedents of depression four to five years ago. Current persistent demotivation and lack of energy; anxiety related to returning to work and being re-infected. Suggest patient should continue with self-prescribed anxiolytic treatment and being taking an antidepressant."*
Crisis plan	4 (7.8)			
Meditation and mindfulness	4 (7.8)			
TIPP skills	3 (5.9)			
Problem solving: use of COVID-19 protective measures	3 (5.9)			
Positive reinforcement	3 (5.9)			
Self-care measures	3 (5.9)			
Reasons for living	2 (3.9)	Self-disclosure	8 (15.7)	*"To be empathetic by showing that I understand the fear of contagion as part of the vulnerability of being medical personnel and then suggest focusing on the here and now to modify catastrophic thoughts that increase anxiety."*
Psychoeducation and data on dealing with grief	2 (3.9)			
Problem solving: family issues	2 (3.9)			
Chain analysis of problem	1 (2.0)			
beahaviour (alcohol use)	1 (2.0)			
Problem solving: Assertiveness in the face of work pressure	1 (2.0)			
Problem solving: Establishing limits to over-involvement in work	1 (2.0)			
Assessment of support network	1 (2.0)	Use of metaphors	2 (3.9)	*"The metaphor about catastrophic thoughts as if they were a runaway horse was used. Thought stopping techniques or other anxiety control tools are the reins that hold them back. The patient was asked to repeat to herself that these catastrophic thoughts are thoughts, not realities."*
Emotional expression (catharsis)	1 (2.0)			
Psychoeducation for depression	1 (2.0)			
Referral to addiction intervention	1 (2.0)			

Percentages by column do not sum 100 given different techniques were employed in each case (for example: in any case "listen and contain" was the only strategy employed).

TABLE 5 Severity of mental health condition at the start of the intervention, improvement at the end of the intervention and HCWs' pre-post perception of emotional distress: data from the total sample and by sex.

CGI severity (n = 47)		Men ($n = 17$)	Women ($n = 30$)	Improvement ($n = 34$)		Men *n* (%)	Women *n* (%)	Distress	Men media (SD)	Women media (SD)
2 = borderline ill	3 (6.4)	3 (17.6)	-	1 = very much	22 (64.7)	9 (90.0)	13 (54.2)	Initial (n = 45): 7.3 (2.1)	6.1 (1.7)	8.0 (2.1)
3 = mildly ill	11(23.4)	3 (17.6)	8 (26.7)	2 = much	5 (14.7)	1 (10.0)	4 (16.7)	Final (n = 44): 2.4 (2.4)	1.6 (1.4)	2.8 (2.8)
4 = moderately ill	26 (51.0)	11 (64.7)	15 (50.0)	3 = minimally	5 (14.7)	-	5 (20.8)	$t = 12.1$, $p < 0.001$	$t = 8.1$, $p < 0.001$	$t = 12.1$, $p < 0.001$
5 = markedly ill	4 (8.5)	-	4 (13.3)	4 = no change	2 (5.9)	-	2 (8.3)	Cohen's $d = 2.3$	Cohen's $d = 2.8$	Cohen's $d = 2.1$
6 = severely ill	3 (6.4)	-	3 (10.0)							

Due to the empty cells on the CGI Severity and Improvement scales, no statistical comparisons between men and women were performed.

intervention among a sample of COVID-19-HCWs in a middle income country (Mexico).

According to our results, these implementation strategies were useful to attain high rates of use of EBP, referred in implementation science as adoption level (Proctor et al., 2011). All techniques included in the intervention manual were employed at least in one of the 51 cases included in the study, particularly listening and providing containment (as a psychological first aid employed to help COVID-19-HCWs feel calm), which were adopted by clinicians to treat 90% of COVID-19-HCWs. This figure is in line with Buselli et al. (2020) previous report on the high perception (around 70%) of CBT techniques´ appropriates for the psychological care of Italian COVID-19-HCWs.

Moreover, the evaluation of the EBP´ level of adoption allows the exploration of specific techniques that are considered necessary to add by participating therapists (Proctor et al., 2011), which was expected given the need for psychological techniques to address patients in extraordinary stressful circumstances (Chen et al., 2020). In general terms, the manualized intervention might be improved by the addition of EBP considered relevant for this specific population and context (COVID-19-HCWs) by the mental health specialists providing treatment, including: a) pharmacological prescription and follow-up, which was recorded as a procedure in approximately 40 % of the sessions for treating moderate to severe MHP; and b) two psychological techniques that seems to be essential tools to treat

people suffering significant stressors outside their control (e.g., regular direct contact with COVID-19 patients that increases their risk of contagion):

1) Therapist's "self-disclosure" of personal worries and feelings of vulnerability to COVID-19 as a health professional. By cautiously modeling openness and sharing intense feelings, therapists can use self-disclosure to enhance patients' perception of their warmth and connection with them, and elicit more self-disclosure and positive responses on the part of the patient (Henretty and Levitt (2010), dispelling the widespread myth about the inherent difficulty of establishing a therapeutic alliance in non-face-to-face interventions (Berger, 2017).
2) The "use of metaphors," specially to encourage patients to employe the techniques to manage maladaptive thoughts and emotions (see an example of a therapist-generated metaphor that can be part of a stock of metaphors for this in Table 4). The use of metaphors has demonstrated to be an effective conceptual and clinical strategy to facilitate therapeutic communication (Stine, 2005), information processing (Otto, 2000) and constructive change (Lenrow, 1966), and has been referred to as one of the most important therapeutic tools (Törneke, 2017) available to psychotherapists from different therapeutic orientations, including CBT.

Besides, a significant clinical improvement (as a measure of intervention's effectiveness) was registered in all COVID-19-HCWs, and nearly 80% managed to improve after the intervention (even though more than 65% were moderately to severely ill at the beginning of the intervention). Additionally, a subset of patients who provided reports on acceptance were "totally satisfied" with the contents of the intervention and would recommend it to their colleagues (referred in implementation science as acceptability level) (Proctor et al., 2011).

In sum, our results indicate that the brief, remote, evidence-based intervention was a feasible and acceptable manner to attend emotional distress in Mexican COVID-19-HCWs, and 79.4% of participants demonstrated a significant improvement. These findings are congruent with previous reports on the effectivity of remote crisis intervention (Berrouiguet et al., 2018; Reinhardt et al., 2019) and the utility of helplines providing psychological first aid to first respondents during emergencies (Pekevski, 2013).

Other interesting results regards to COVID-19-HCWs' help-seeking process during emotional crises and suicide risk, which might help to understand the type of vulnerable HCWs that could be attending helplines in future emergencies, as well as the efforts needed to increase the use of mental health services among other vulnerable subgroups of HCWs. First, most of those seeking help were women and COVID-19-HCWs associated with the medical profession. Gender differences may be due to the well-known greater tendency to seek and receive mental health care in women than men (Oliver et al., 2005) and the higher prevalence of anxious, depressive and stress-related MHP in women than men (Seedat et al., 2009); and differences between the type of HCWs could be explained given in Mexico (Robles et al., 2021a), as in other countries (Vizheh et al., 2020), those with a medical profession had higher frequencies of all MHP than psychologists, nurses and social workers.

Second, the main source of referral to the helpline was another HCW, which adds to evidence on the increased receipt of mental health care among healthcare professionals when it is suggested by someone in their social network (Dew et al., 1991), and the utility of informing key people—such as human resource colleagues and managers—about the signs of MHP and suicide risk and the services available to individuals requiring them) (World Health Organization, 2014). An example of an effective method to do so in general population that might be useful for this purpose in the future is the Mental Health First Aid (MHFA) Training and Research Program (for a description see: Kitchener and Jorm, 2008).

Third, the most important reason for COVID-19-HCWs to seek help and attend the intervention was testing positive for COVID-19, which has been reported as one of the main predictive factors of MHP among Mexican COVID-19-HCWs (Robles et al., 2021b). Along these same lines, one of the most frequently reported measures required to cope with COVID-19 by COVID-19-HCWs was biosafety equipment (Chen et al., 2020).

Fourth, according to the participating clinicians, a high proportion of COVID-19-HCWs seeking help presented some form of depression (with or without anxiety symptoms) and nearly a third part were at risk of suicide. This is in congruence with previous reports on mental health problems in COVID-19-HCWs. In Mexico, for example, according to Robles et al. (2021a,b) depression was one of the main common mental disorders among COVID-19-HCWs since the cluster of cases to the commentary transmission scenarios of the pandemic. Moreover, those with depression and alcohol abuse or dependence were at moderate suicide risk (vs. minimal or none), which highlight the need for monitoring of HCWs with this comorbidity.

This study has several and significant limitations. First, its hybrid effectiveness-implementation design (Curran et al., 2012) without a control group provides only preliminary evidence regarding the utility of the EBP implementation strategies and of the interventions themselves, which must be confirmed through controlled randomized clinical trials for better comparison and interpretation of their effects. Additionally, the absence of a follow-up evaluation prevents determining result's maintenance in the long-term, and therefore is highly recommended in future studies on the field.

Another limitation is that, given the recruitment and sample selection method (of volunteer COVID-19-HCWs who engage in remote crisis intervention and/or suicide management), the results regarding MHP and suicide risk among COVID-19-HCWs should not be taken as estimates of prevalence or other epidemiological parameters. Moreover, an examination of whether the patterns of COVID-19-HCWs' help-seeking during emotional crises and periods of suicide risk noted in this study apply across cultures and languages is warranted to make generalized conclusions in this regard.

Additionally, use of techniques and CGI ratings was reported by therapists rather that unbiased observers/raters, self-reported patients´ stress was based only on one item, and ratings of patients´ satisfaction with the intervention were asked directly by therapists, which might increase patients´ social desirability. Further assessments solving these limitations would improve the clarity of the effects of the intervention.

Conclusion

The present study add evidence regarding the utility and acceptability of brief and remote crisis intervention and suicide risk management. Importantly, this evidence is produced among one highly vulnerable group in the context of a sanitarian emergency (COVID-19) and among inhabitants from middle-income countries, where scare information about the feasibility and effectivity of psychological interventions has been a constant (even more in the case of remote treatments). More women (than men), medicine undergraduate and graduate professionals (than other HCWs), moderately or more depressed seek this type of interventions, which substantially improve their mental health in nearly 80 % of the cases.

Data availability statement

The datasets presented in this study can be found in online repositories. The names of the repository/repositories and accession number(s) can be found at: https://1drv.ms/f/s!AmLeJVltqurSgQJjOeerQliEDMHB?e=KOBYfk.

Ethics statement

The study involved humans and was approved by Ramón de la Fuente Muñiz National Institute of Psychiatry Research Ethics Committee. The study was conducted in accordance with the local legislation and institutional requirements. The participants provided their written informed consent to participate in this study.

Author contributions

RR: conceptualization, methodology, formal analysis, supervision, and writing – original draft. IS and FM: project administration, investigation, data curation, and writing – review & editing. AI, TE, R-DA, and MiE: investigation and writing – review & editing. FA: formal analysis, validation, and writing – review & editing. BC and ER: investigation, validation, and writing – review & editing. MAe: investigation, resources, and software. All authors contributed to the article and approved the submitted version.

Funding

The author(s) declare that no financial support was received for the research, authorship, and/or publication of this article.

Acknowledgments

We would like to thank Silvia Morales-Chainé, Juan-Manuel Quijada, Diana Tejadilla, Lorena Rodríguez Bores, Evalinda Barrón, Fátima Moneta and José Javier Mendoza for supporting the development of this Project nationwide.

Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

References

Adhanom, G. T. (2020). Addressing mental health needs: an integral part of COVID-19 response. *World Psychiatry* 19, 129–130. doi: 10.1002/wps.20768

Almanza-Muñoz, J. J., Juárez, I. R., and Pérez, S. (2008). Traducción, adaptación y validación del Termómetro de Distrés en una muestra de pacientes mexicanos con cáncer. [Translation, adaptation and validation of the Distress Thermometer in a sample of Mexican cancer patients]. *Revista Sanidad Militar.* 62, 209–217.

Álvarez, J., Andrade, C., Vieyra, V., Esquivias, H., Merlín, I., Neria, R., et al. (2020). "Manual operativo del Curso Emergente para la Brigada de Atención Psicoemocional y Psicosocial a distancia durante la pandemia de la COVID- 19 en México" in *Operational manual of the emerging course for the remote psycho-emotional and psychosocial care brigade during the COVID-19 pandemic in Mexico* (Mexico City: Instituto Nacional de Psiquiatría Ramón de la Fuente Muñiz)

American Psychiatric Association. (1954). *Psychological first aid in community disasters*. Washington D.C.: American Psychiatric Association.

Berger, T. (2017). The therapeutic alliance in internet interventions: a narrative review and suggestions for future research. *Psychother. Res.* 27, 511–524. doi: 10.1080/10503307.2015.1119908

Berrouiguet, S., Larsen, M. E., Mesmeur, C., Gravey, M., Billot, R., Walter, M., et al. (2018). Toward mhealth brief contact interventions in suicide prevention: case series from the suicide intervention assisted by messages (SIAM) randomized controlled trial. *JMIR Mhealth Uhealth* 6:e8. doi: 10.2196/mhealth.7780

Brent, D. A. (2016). Antidepressants and suicidality. *Psychiatr. Clin. N. Am.* 39, 503–512. doi: 10.1016/j.psc.2016.04.002

Buselli, R., Baldanzi, S., Corsi, M., Chiumiento, M., Del Lupo, E., Carmassi, C., et al. (2020). Psychological care of health workers during the COVID-19 outbreak in Italy: preliminary report of an occupational health department (AOUP) responsible for monitoring hospital staff condition. *Sustainability.* 12:5039. doi: 10.3390/su12125039

Chen, Q., Liang, M., Li, Y., Guo, J., Fei, D., Wang, L., et al. (2020). Mental health care for medical staff in China during the COVID-19 outbreak. *Lancet Psychiatry* 7, e15–e16. doi: 10.1016/S2215-0366(20)30078-X

Cohen, J. (1992). A power primer. *Psychol. Bull.* 112, 155–159. doi: 10.1037/003-2909.112.1.155

Comité de Consenso de Catalunya en Terapéutica de los Trastornos Mentales. (2005). *Recomendaciones terapéuticas en los trastornos mentales: Conducta suicida. [Therapeutic recommendations in mental disorders: Suicidal behavior]*. Mexico City: Ars Medica.

Corey, J., Vallières, F., Frawley, T., De Brún, A., Davidson, S., and Gilmore, B. (2021). A rapid realist review of group psychological first aid for humanitarian workers and volunteers. *Int. J. Environ. Res. Public Health* 18:1452. doi: 10.3390/ijerph18041452

Curran, G. M., Bauer, M., Mittman, B., Pyne, J. M., and Stetler, C. (2012). Effectiveness-implementation hybrid designs: combining elements of clinical effectiveness and implementation research to enhance public health impact. *Med. Care* 50, 217–226. doi: 10.1097/MLR.0b013e3182408812

DeCou, C. R., Comtois, K. A., and Landes, S. J. (2019). Dialectical behavior therapy is effective for the treatment of suicidal behavior: a meta-analysis. *Behav. Ther.* 50, 60–72. doi: 10.1016/j.beth.2018.03.009

Dew, M. A., Bromet, E. J., Schulberg, H. C., Parkinson, D., and Curtis, E. C. (1991). Factors affecting service utilization for depression in a white-collar population. *Soc. Psychiatry Psychiatr. Epidemiol.* 26, 230–237. doi: 10.1007/BF00788971

Ferrando, L., Bobes, J., Gilbert, J., Soto, M., and Soto, O. (1998). *M.I.N.I. Mini international neuropsychiatric interview. Versión en español 5.0.0. DSM-IV*. Madrid: Instituto IAP.

Givens, J. L., and Tjia, J. (2002). Depressed medical Students' use of mental health services and barriers to use. *Acad. Med.* 77, 918–921. doi: 10.1097/00001888-200209000-00024

Gobierno de Canarias (2008). "Consejería de Sanidad. Salud Mental en Atención Primaria" in *Recomendaciones Para el abordaje de los trastornos más prevalentes: Conducta suicida. [recommendations for the approach of the most prevalent disorders: Suicidal behavior]* (Canarias: Gobierno de Canarias)

Gunnell, D., Appleby, L., Arensman, E., Hawton, K., John, A., Kapur, N., et al. (2020). Suicide risk and prevention during the COVID-19 pandemic. *Lancet Psychiatry* 7, 468–471. doi: 10.1016/S2215-0366(20)30171-1

Guy, W. (1976). *ECDEU assessment manual for psychopharmacology*. Rockville: National Institute of Mental Health.

Henretty, J. R., and Levitt, H. M. (2010). The role of therapist self-disclosure in psychotherapy: a qualitative review. *Clin. Psychol. Rev.* 30, 63–77. doi: 10.1016/j.cpr.2009.09.004

Kitchener, B. A., and Jorm, A. F. (2008). Mental health first aid: an international programme for early intervention. *Early Interv. Psychiatry* 2, 55–61. doi: 10.1111/j.1751-7893.2007.00056.x

Kvale, S. (1996). *Interviews. An introduction to qualitative research interviewing*. Michigan: Sage Publications.

Lenrow, P. B. (1966). Use of metaphor in facilitating constructive behavior change. *Psychol. Psychother. Theory Res. Pract.* 3, 145–148. doi: 10.1037/h0087921

Linehan, M. (2014). *DBT Skills training manual*. New York: Guilford Press.

Mann, J. J., and Currier, D. (2011). "Evidence-based suicide prevention strategies" in *Evidence-based practice in suicidology: A source book*. eds. M. Pompili and T. Tatarelli (Cambridge, MA: Hogrefe Publishing), 67–87.

Oliver, M. I., Pearson, N., Coe, N., and Gunnell, D. (2005). Help-seeking behavior in men and women with common mental health problems: cross-sectional study. *BJPsych.* 186, 297–301. doi: 10.1192/bjp.186.4.297

Otto, M. W. (2000). Stories and metaphors in cognitive-behavior therapy. *Cogn. Behav. Pract.* 7, 166–172. doi: 10.1016/S1077-7229(00)80027-9

Patterson, W. M., Dohn, H. H., Bird, J., and Patterson, G. A. (1983). Evaluation of suicidal patients: the SAD PERSONS scale. *Psychosomatics* 24, 343–349. doi: 10.1016/S0033-3182(83)73213-5

Pekevski, J. (2013). First responders and psychological first aid. *J Emerg Manag.* 11, 39–48. doi: 10.5055/jem.2013.0126

Pinto, R. M. (2013). What makes or breaks provider–researcher collaborations in HIV research? A mixed method analysis of providers' willingness to partner. *Health Educ. Behav.* 40, 223–230. doi: 10.1177/1090198112447616

Pinto, R. M., Park, S. E., Miles, R., and Ni Ong, P. (2021). Community engagement in dissemination and implementation models: a narrative review. *Implement Res Pract.* 2, 263348952098530–263348952098518. doi: 10.1177/2633489520985305

Pospos, S., Young, I. T., Downs, N., Iglewicz, A., Depp, C., Chen, J. Y., et al. (2018). Web-based tools and mobile applications to mitigate burnout, depression, and suicidality among healthcare students and professionals: a systematic review. *Acad. Psychiatry* 42, 109–120. doi: 10.1007/s40596-017-0868-0

Powell, B. J., Waltz, T. J., Chinman, M. J., Damschroeder, L. J., Smith, J. L., Matthieu, M. M., et al. (2015). A refined compilation of implementation strategies: result from the expert recommendations for implementing change (ERIC) project. *Implement. Sci.* 10:21. doi: 10.1186/s13012-015-0209-1

Proctor, E., Silmere, H., Raghavan, R., Hovmand, P., Aarons, G., Bunger, A., et al. (2011). Outcomes for implementation research: conceptual distinctions, measurement challenges, and research agenda. *Admin. Pol. Ment. Health* 38, 65–76. doi: 10.1007/s10488-010-0319-7

Reinhardt, I., Gouzoulis-Mayfrank, E., and Zielasek, J. (2019). Use of telepsychiatry in emergency and crisis intervention: current evidence. *Curr. Psychiatry Rep.* 21:63. doi: 10.1007/s11920-019-1054-8

Robles, R., Morales-Chainé, S., Bosch, A., Astudillo-García, C., Feria, M., Infante, S., et al. (2021a). Mental health problems among Covid-19 frontline healthcare workers and the other country-level epidemics: the case of Mexico. *Int. J. Environ. Res. Public Health* 19:421. doi: 10.3390/ijerph19010421

Robles, R., Rodríguez, E., Vega-Ramírez, H., Álvarez-Icaza, D., Madrigal, E., Durand, S., et al. (2021b). Mental health problems among healthcare workers involved with the COVID-19 outbreak. *Braz J Psychiatry.* 43, 494–503. doi: 10.1590/1516-4446-2020-1346

Seedat, S., Scott, K. M., and Angermeyer, M. C. (2009). Cross-national associations between gender and mental disorders in the World Health Organization world mental health surveys. *Arc Gen Psychiatr.* 66, 785–795. doi: 10.1001/archgenpsychiatry.2009.36

Sheehan, D. V., Lecrubier, Y., Harnett-Sheehan, K., Janavs, J., Weiller, E., Keskiner, A., et al. (1997). The validity of the Mini international neuropsychiatric interview (MINI) according to the SCID-P and its re-liability. *Eur. Psychiatry* 12, 232–241. doi: 10.1016/S0924-9338(97)83297-X

Stanley, B., and Brown, G. K. (2012). Safety planning intervention: a brief intervention to mitigate suicide risk. *Cogn. Behav. Pract.* 19, 256–264. doi: 10.1016/j.cbpra.2011.01.001

Stine, J. J. (2005). The use of metaphors in the Service of the Therapeutic Alliance and Therapeutic Communication. *J. Am. Acad. Psychoanal. Dyn. Psychiatry* 33, 531–545. doi: 10.1521/jaap.200 5.33.3.531

Törneke, N. (2017). *Metaphor in practice: A Professional's guide to using the science of language in psychotherapy*. Oakland, California: New Harbinger Publications.

Vernberg, E. M., Steinberg, A. M., Jacobs, A. K., Brymer, M., Watson, P. J., Layne, C. M., et al. (2008). Innovations in disaster mental health: psychological first aid. *Prof Psychol Res Pr.* 39, 381–388. doi: 10.1037/a0012663

Vizheh, M., Qorbani, M., Arzaghi, S. M., Muhidin, S., Javanmard, Z., and Esmaeli, M. (2020). The mental health of healthcare workers in the COVID-19 pandemic: a systematic review. *J. Diabetes Metab. Disord.* 19, 1967–1978. doi: 10.1007/s40200-020-00643-9

Wasserman, D., Iosue, M., Wuestefeld, A., and Carli, V. (2020). Adaptation of evidence-based suicide prevention strategies during and after the COVID-19 pandemic. *World Psychiatry* 19, 294–306. doi: 10.1002/wps.20801

Wind, T. R., Rijkeboer, M., Andersson, G., and Riper, H. (2020). The COVID-19 pandemic: the 'black swan' for mental health care and a turning point for e-health. *Internet Interv.* 20:100317. doi: 10.1016/j.invent.2020.100317

World Health Organization. (2014). *Preventing suicide: a global imperative*. Geneva: World Health Organization.

World Health Organization. (2020). *Critical preparedness, readiness and response actions for COVID-19. Interim guidance*. World Health Organization. Geneva

Zhou, X., Snoswell, C. L., Harding, L. E., Bambling, M., Edirippulige, S., Bai, X., et al. (2020). The role of telehealth in reducing the mental health burden from COVID-19. *Telemed e-Health.* 26, 377–379. doi: 10.1089/tmj.2020.0068

frontiers | Frontiers in Psychology

TYPE Study Protocol
PUBLISHED 31 October 2023
DOI 10.3389/fpsyg.2023.1167860

OPEN ACCESS

EDITED BY
María Roncero,
University of Valencia, Spain

REVIEWED BY
Vittorio Di Michele,
National Health Trust ASL Pescara, Italy
Riitta Kuokkanen,
Niuvanniemi Hospital, Finland
Safiye Özgüç,
Gaziantep University, Türkiye

*CORRESPONDENCE
Lara Guedes de Pinho
✉ lmgp@uevora.pt

†These authors have contributed equally to this work and share first authorship

RECEIVED 16 February 2023
ACCEPTED 18 September 2023
PUBLISHED 31 October 2023

CITATION
Pinho LG, Silva C, Fonseca C, Morgado B, Lopes M, Moritz S, Jelinek L and Schneider BC (2023) A randomized controlled trial to evaluate the efficacy of metacognitive training for older adults with depression (MCT-Silver) in Portugal: study protocol. *Front. Psychol.* 14:1167860. doi: 10.3389/fpsyg.2023.1167860

A randomized controlled trial to evaluate the efficacy of metacognitive training for older adults with depression (MCT-Silver) in Portugal: study protocol

Lara Guedes de Pinho[1,2*†], Celso Silva[2,3†], César Fonseca[1,2], Bruno Morgado[4,5], Manuel Lopes[1,2], Steffen Moritz[6], Lena Jelinek[6] and Brooke C. Schneider[6]

[1]Department of Nursing, University of Évora, Évora, Portugal, [2]Comprehensive Health Research Centre (CHRC), Évora, Portugal, [3]Higher School of Health, Polytechnic Institute of Beja, Beja, Portugal, [4]Universitat Rovira i Virgili, Tarragona, Spain, [5]Hospital Garcia de Orta, Almada, Portugal, [6]University Medical Center Hamburg-Eppendorf, Hamburg, Germany

Introduction: Depression is one of the most common psychological disorders in later life. Although psychological interventions are recommended by treatment guidelines, most older adults with depression remain untreated. The aim of this study is to evaluate the efficacy of the Portuguese version of Metacognitive Training for Depression in later life (MCT-Silver).

Methods: This is a study protocol of an observer-blind, parallel-group, randomized controlled trial to compare the efficacy of MCT-Silver with a treatment as usual (TAU) control group among older adults (age 65 years and older) with depressive symptoms according to the Montgomery-Asberg Depression Scale. Participants will be tested at three assessment time points (baseline, immediately following the intervention [8 weeks], and 3 months after the intervention). The primary outcome is change in self-rated depression symptoms assessed by the Beck Depression Inventory (BDI-II). Secondary outcomes include clinician-rated depression, self-esteem, dysfunctional beliefs, metacognitive beliefs, ruminations, attitudes toward aging and quality of life. A self-designed subjective appraisal rating scale consisting of 21-items will be used to assess participant acceptance of MCT-Silver.

Discussion: MCT-Silver is an innovative intervention, which aims to reduce dysfunctional thoughts as well as depression-related behaviors and coping strategies through the metacognitive perspective. Until now, the training has only been tested in Germany. It is expected that after 8 weeks of treatment and 3 months later, the experimental group will demonstrate significant reductions in depressive symptoms, metacognitive beliefs, dysfunctional attitudes and ruminative responses compared to the TAU group. Moreover, quality of life, self-esteem, and attitudes towards aging will be significantly improved in MCT-Silver compared to the TAU group.

Clinical trial registration: ClinicalTrials.gov, NCT05640492.

KEYWORDS

depression, depressive symptoms, older adults, metacognitive training, intervention, cognitive behavioral therapy, randomized controlled trial, geriatric depression

1. Introduction

According to the World Health Organization, depression is a common mental disorder, with around 280 million people diagnosed with the condition worldwide (World Health Organization, 2021). In 2019, depression was estimated to affect around 10.4% of adults, reaching about 5.7% in people over 60 years old (World Health Organization, 2021). In addition, depression is one of the main causes of years lived with disability (James et al., 2018; Santomauro et al., 2021) and it has been identified as a cause of dementia in older adults (Wu et al., 2020).

Depression is a mental disorder that can be manifested by persistent sadness, hopelessness, pessimism, loss of pleasure or interest in activities, and depressed mood (e.g., sad, irritable, empty). This symptomatology is present during most of the day, almost every day, for at least 2 weeks and most episodes can last considerably longer (American Psychiatric Association, 2014). Over time, depression can lead to cognitive and social dysfunction. It is therefore important to intervene as early as possible in order to minimize or eliminate disabilities and improve quality of life (Pinho et al., 2021).

The treatment of depression with antidepressant monotherapy is still a reality due to limited resources for treatment in community health centers or psychosocial rehabilitation facilities, but is limiteddue to side effects of medications, polypharmacy and poor adherence (e.g., due to memory impairment or organizational deficits). Given that rate of relapse after discontinuation of antidepressant medication reaches 56% (Kishi et al., 2023), implementation of psychotherapeutic strategies in the development of care management plans for depression is necessary. Moreover, the pharmaceutical treatment of depression is insufficient for the full rehabilitation of patients (Carvalho Pereira de Melo and Pereira de Melo, 2021; Mommaerts, 2022).

Metacognitive training for older adults with depression (MCT-Silver; Schneider et al., 2018; Bücker, 2019), is a cognitive-behavioral (CBT)-based group intervention, specifically designed for adults ages 60 years and older (all materials are available for free[1]). MCT-Silver aims to reduce the treatment gap by improving access to mental health care for the estimated 73% of older adults with depression who go untreated (Horackova et al., 2019). MCT-Silver is based on metacognitive training for psychosis (MCT; Moritz and Woodward, 2007) and metacognitive training for depression (D-MCT; Jelinek et al., 2015). Randomized controlled trials on D-MCT provide evidence for its efficacy on depressive symptoms (Jelinek et al., 2016), as well as metacognitive and negative cognitive beliefs (Hauschildt et al., 2022; Özgüç and Tanriverdi, 2022) at short- and intermediate follow-up intervals. Long-term efficacy of D-MCT remains equivocal (Jelinek et al., 2019). A pilot study examined the feasibility, acceptance, and effects of D-MCT as an add-on intervention in a group of older adults with depression who were completing an intensive inpatient treatment program (55+ years; $N = 116$). Per protocol analyses ($n = 55$) yielded a significant decrease in depressive symptoms ($d = 1.06$) and cognitive biases ($d = 0.33$). These results support the feasibility and acceptance of D-MCT among older adults with depression. A recently completed RCT in Germany, which compared MCT-Silver to an active control group (cognitive remediation; (Schneider et al., 2018)) yielded large and significant reductions on the primary outcome (Hamilton Depression Rating Scale) from baseline to post and 3-month follow-up ($d_{MCT\text{-}Silver} = 1.25 - 1.42$; $d_{CR} = 1.05 - 1.12$). Group differences; however, did not reach significance ($\eta_p^2 = 0.001 - 0.002$). MCT-Silver yielded significant moderate to large effects compared to CR immediately following the intervention and after 3 months for self-reported depression (BDI-II: $\eta_p^2 = 0.075 - 0.135$) and rumination (RRS: $\eta_p^2 = 0.087 - 0.127$). A significant moderate effect was found for positive metacognitive beliefs (MCQ-PB) at post-assessment ($\eta_p^2 = 0.067$), but group differences did not reach significance at follow-up ($\eta_p^2 = 0.027$). Small reductions in negative cognitive beliefs (Dysfunctional Attitudes Scale-18B) at post- and at 3-month follow-up ($d_{MCT\text{-}Silver} = 0.24 - 0.30$) were found for the MCT-Silver group, whereas negative cognitive beliefs were unchanged in the CR group ($d_{CR} = -0.06 - 0.06$).

Like D-MCT, the main goal of MCT-Silver is to strengthen patients' ability to reflect upon their thinking, and to recognize and correct their dysfunctional thought patterns and behavior (Moritz et al., 2018; Schneider et al., 2018) in order to ultimately reduce depressive symptoms. Additionally, MCT-Silver aims to increase awareness of depression-related information processing strategies, such as attentional preferences for negative information and mood-congruent memory (Blaney, 1986; Wittekind et al., 2014; McConnell and Troop-Gordon, 2021). Individual modules also address dysfunctional coping strategies (e.g., thought suppression, rumination) and metacognitive beliefs (e.g., rumination helps to solve problems). As a "modern" CBT-intervention, MCT-Silver includes third-wave elements drawn from acceptance and commitment therapy (Hayes et al., 2006) and imagery rescripting (Holmes et al., 2016). The training also addresses age-specific challenges and risk factors for depression in older adults (e.g., loneliness, functional limitations, loss of relationships).

MCT-Silver has not yet been validated for the Portuguese population and studies are needed to prove its efficacy in this population. Therefore, after the completion of a pilot study, a randomized controlled trial will be conducted to evaluate the efficacy of the intervention in older adults with depression. The research question of this study is as follows: "Does MCT-Silver in older adults with depression lead to a greater reduction in depressive symptoms and dysfunctional beliefs as well as improved metacognitive beliefs, quality of life, ruminative responses, self-esteem and attitudes towards aging compared to treatment as usual?." The pilot study is in preparation. After completion of the pilot study and application of results as necessary (e.g., adjustment of MCT-Silver for the Portuguese population), we will continue with the intervention in order to finalise the RCT.

2. Materials and methods

2.1. Aim

The aim of this study is to evaluate the efficacy of MCT-Silver and its effects on depressive symptoms, dysfunctional beliefs, metacognitive beliefs, quality of life, ruminative responses, self-esteem and attitudes towards aging. The hypotheses that we want toexamine in this trial are the following:

1 www.uke.de/mct-silver

1. Primary outcome: There will be a greater reduction in self-reported depression (as measured by the Beck Depression Inventory-II) for MCT-Silver vs. TAU (pre-post; pre-follow-up).
2. Secondary outcomes: There will be a greater reduction in clinician-rated depression (MADRS), metacognitive beliefs (Metacognitions Questionnaire-30), self-reported depression (PHQ-9), dysfunctional beliefs (DAS-18B), ruminative responses (RRS), self-esteem (Self-Esteem Questionnaire), quality of life (WHO QOL-Bref??), and attitudes to aging (Attitudes to Aging Questionnaire) for MCT-Silver vs. TAU (pre-post; pre-follow-up).
3. Tertiary outcome: Participants will rate the intervention positively on a satisfaction questionnaire administered after the 8-week intervention period.

2.2. Design/methodology

2.2.1. Study design

This study represents an observer-blind, parallel-groups randomized controlled trial.

All procedures follow CONSORT (Consolidated Standards of Reporting Trials) guidelines and follow four phases: enrollment, intervention allocation, follow-up, and data analysis. The follow-up will occur 3 months after completion of the intervention. The trial has been registered at ClinicalTrials.gov (NCT05640492).

2.2.2. Participants

The sample will be selected by a probabilistic method and participants will be randomly assigned to one of two groups (MCT-Silver vs. TAU) based on a randomized plan.

2.2.2.1. Inclusion criteria

(1) Age 60 years and over; (2) score greater than 8 on the Montgomery and Åsberg Depression Rating Scale (MADRS) (which corresponds to mild depression, optimal cut-off) (Zimmerman et al., 2004); (3) ability to give informed consent; (4) sufficient command of the Portuguese language; and (5) willingness to participate in the intervention over the period of the study. The diagnosis of depression will be identified by a trained professional, using the DSM-5 as a reference (American Psychiatric Association, 2014).

2.2.2.2. Exclusion criteria

(1) Lifetime psychotic symptoms (i.e., delusions, hallucinations); (2) current or a history of mania; (3) acute suicidality; and (4) dementia or other neurological disorder which could be related to the onset of depressive symptoms (e.g., Parkinson's disease, stroke, multiple sclerosis); (5) current substance dependence (substance abuse will be tolerated); (6) not having attended a similar training in the last 3 months; (7) patients with the MMSE score below 24 points will not be included.

Participants will be informed about the study and conditions of participation individually and written informed consent will be obtained from each participant. Participants will be asked if they have a guardian for medical decision-making. In this case, if the potential participant generally meets the criteria for inclusion, a permission to participate will be obtained from the guardian.

2.2.3. Randomization and blinding

Eligible participants will be recruited at each institution (the mental health service of each hospital that agreed to take part in the study in Portugal) through telephone contact by the researchers in collaboration with the multidisciplinary team. The study will also be publicized in the media so that older adults can contact the researchers if they are interested in participating. A baseline assessment will be carried out and all instruments will be applied after informed consent from participants. All participants who agree to participate in the study will be assigned a code and will be randomly assigned to either MCT-Silver (experimental group where the intervention will be applied) or the control group (no stratification factors). This randomization will be performed using a computer program. The control group will not be administered the intervention (MCT-Silver). In both groups, treatment will be maintained as usual (Treatment As Usual – TAU) and participation in other interventions as well as use of medications will be carefully monitored. Study participants will be informed that they should not reveal which group they are in and will be reminded of this at each testing session. All participants will be re-assessed at the end of the intervention and 3 months after completion, with the application of all planned instruments. Assessments will be performed by the same rater before and after the intervention and at follow-up. Assessors will be trained in the administration of all instruments prior to the start of the study. A third researcher will inform patients of group assignment so that raters will remain blinded throughout the study. The Side Effects of Intervention questionnaire and patient satisfaction with MCT-Silver will be applied to the experimental group post-intervention (Table 1; Figure 1).

2.2.4. Sample size calculation

In RCTs to calculate the sample size, four factors are required: significance level, power analysis, difference between groups, and standard deviation (SD; Charles et al., 2009). As there is only one RCT in Germany that applied the MCT-Silver, we chose to conduct a pilot study, and the sample size calculation for the RCT is calculated *a posteriori*. For the pilot study, we will include 32 participants, as 15–20 participants are needed to ensure the scientific validity of the results of a pilot study (Hertzog, 2008). The results of the pilot study will provide information on the above four factors as they are necessary for the calculation of the sample size.

2.2.5. Study intervention

2.2.5.1. Treatment as usual

All participants (experimental and control group) will continue to receive treatment as usual (TAU) at their institution. TAU may consist of psychiatric and psychosocial treatment by a multidisciplinary team, which includes mental health psychiatric nurses, psychiatrists, psychologists, social workers, occupational therapists and other mental health professionals. TAU may also include treatment in community settings, day hospital and inpatient settings, as well as antidepressant medication, psychosocial rehabilitation, socialisation groups and psychoeducational and therapeutic groups. The care of participants in TAU will not be limited or influenced in any way. To

10.3389/fpsyg.2023.1167860

TABLE 1 Study schedule.

	Study period				
	Enrolment	Randomization	Intervention (8 weekly sessions)	Post (8 weeks)	Follow-up (3 months)
TIMEPOINT	T-1	T0		T1	T2
Enrolment:					
Eligibility screen	X				
Informed consent		X			
Randomization		X			
Interventions:					
Treatment As Usual (TAU)	X	X	X	X	X
MCT-Silver			X		
Assessments: *Baseline*		X			
Post-intevention				X	
Follow up					X

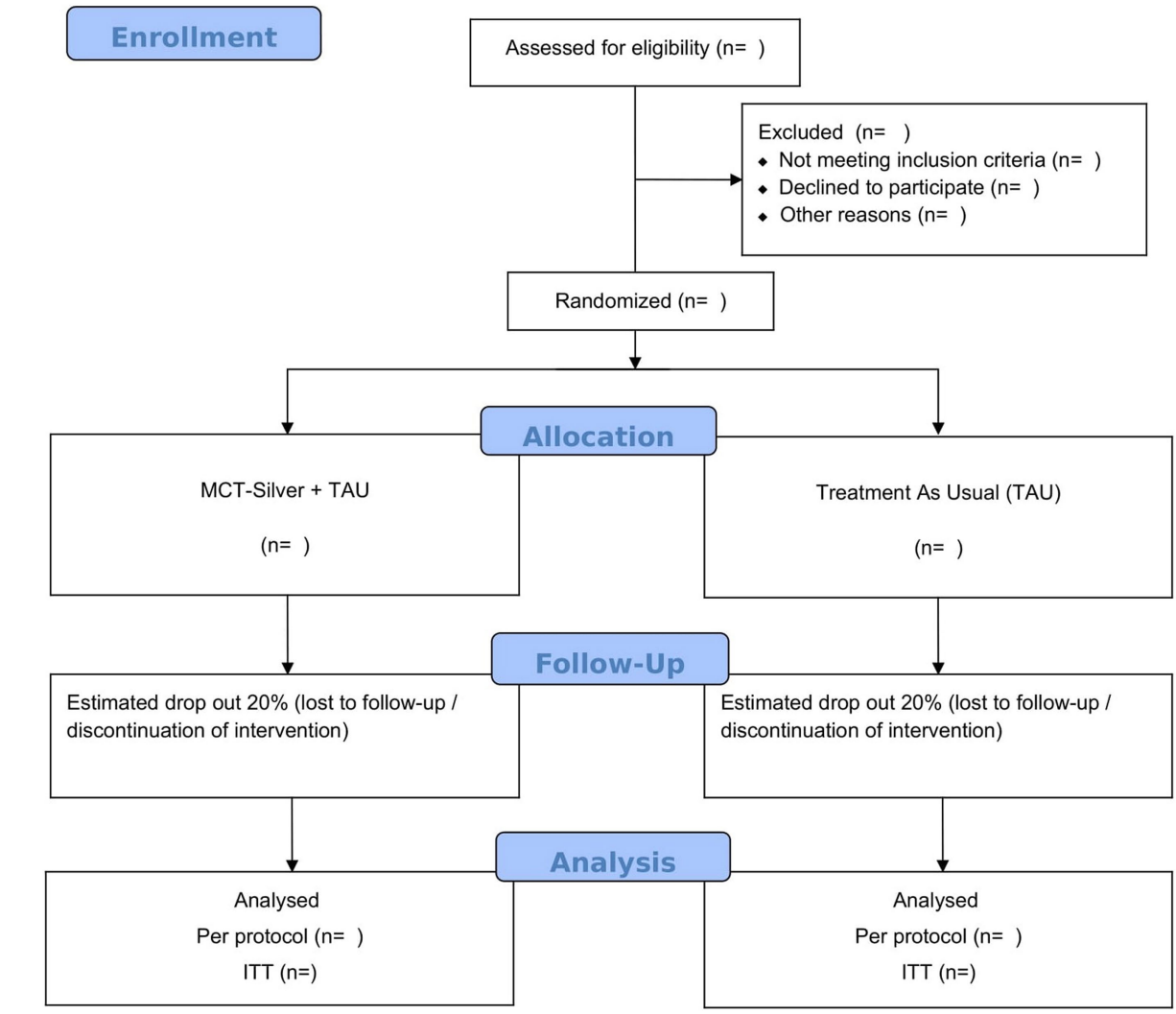


FIGURE 1
CONSORT flow diagram.

control for TAU, we will carefully record participation in concurrent treatment. The control group will not participate in the MCT-Silver programme.

2.2.5.2. Metacognitive training for depression (MCT-Silver)

Metacognitive training (MCT) has its origins in 2003 with the development of "metacognitive training for psychosis" (Moritz et al., 2013, 2017). MCT has since been developed for other psychiatric disorders, e.g., depression (D-MCT; Moritz et al., 2013; Jelinek et al., 2015), and an adaptation of the D-MCT, called MCT-Silver (pilot study), has been developed for older adults with depression (Schneider et al., 2018). Although certain terms have been adapted for the Portuguese translation, case examples, exercises and general content were maintained to ensure consistency across countries. However, the intervention and examples can be tailored by the trainers to meet specific group needs of the group concerned (e.g., to reduce the length of sessions or tailor content to specific issues of group members). All information about this programme is available[2] in English, German and Portuguese.

MCT-Silver is a manualized treatment program comprised of eight modules addressing common cognitive distortions and biases in information processing in depression as well as depression-related behaviors and metacognitive beliefs. Differing from D-MCT, MCT-Silver also includes components drawn from acceptance and commitment therapy as well as imagery rescripting. All content is supported by significant empirical work linking these processes to depression. The topics of MCT-Silver include the following: Modul 1: Mental filter; Module 2: Mood-congruent memory / false memories (Mathews and Macleod, 2005; Moritz et al., 2008); Module 3: "Should" statements (Egan et al., 2011; Mcgrath et al., 2012) and disqualifying the positive (Cane and Gotlib, 1985; Elliott et al., 1997) as well as acceptance of negative feelings (Hayes et al., 1996; Butler and Ciarrochi, 2007); Module 4: Values (Isaacowitz and Seligman, 2002; Hayes et al., 2006; Wrosch et al., 2013); Module 5: Exaggeration/ Minimization (Garber and Hollon, 1980; Hoehn-Hyde et al., 1982; Cane and Gotlib, 1985; Wenzlaffand and Grozier, 1988) as well as Attribution Style (Carver and Ganellen, 1983; Wenzlaffand and Grozier, 1988); Module 6: Rumination and Withdrawal (Rood et al., 2009; Seidel et al., 2010; Wells, 2011); Module 7: Jumping to Conclusions (Strunk et al., 2006; Miranda et al., 2008), and Module 8: Self-Worth in Later Life (Davey et al., 2004; Orth et al., 2009; Holmes et al., 2016; Table 2).

Figure 2 shows an example of Module 7: Jumping to Conclusions.

Through interactive exercises and a structured multimedia presentation, MCT-Silver aims to convey knowledge about cognitive distortions, helps participants to reflect critically about and change the content of their thoughts, and acquire new strategies to solve problems. Each session lasts 45–60 min (Jelinek et al., 2022).

In the current study, MCT-Silver will be applied to the experimental group by mental health and psychiatry professionals with experience in the care of individuals with depression. A training course on the application of the MCT-Silver programme will be completed by these professionals prior to the start of the study. Administration of the training will also be monitored and supervised by the study PI (LGP). For adherence monitoring of the MCT-Silver application the sessions will be recorded, and no images of the participants will be taken to safeguard ethical issues.

MCT-Silver sessions will be applied once a week for a total of eight sessions. The intervention will be applied face-to-face in groups in a quiet room of the institution to which the group belongs.

2.2.6. Data collection and outcome measures

The instruments will be administered to all study participants through an interview at three planned assessments (Table 3). To characterize the sample, sociodemographic, and clinical data will be collected [age, sex, marital status, cohabitation, educational level, professional/employment status, duration of depression diagnosis (if applicable), number of psychiatric hospitalizations, medication, type of treatment, and substance use; Table 4]. These data will be collected before the start of the MCT-Silver intervention for all participants.

2.2.6.1. Mini Mental State Examination (MMSE)

The MMSE will be applied to screen for cognitive deficits. Participants with cognitive impairments according to the cut-offs for the MMSE will be excluded from the study. This instrument evaluates cognitive function and was developed by Folstein et al. (1975). It is composed of six groups of questions that assess orientation to time and place, attention / concentration, short-term memory (recall), language skills, visuospatial abilities and ability to understand and follow instructions. Higher scores indicate better cognitive ability. The MMSE was adapted for the Portuguese population (Guerreiro et al., 1994). The cut-off for establishing cognitive impairment adjusted for years of education and, thus, also exclusion from the study is as follows: 0 years education ≤15 points; 1-11 years of education ≤22 points; 11+ years of education ≤24 (Folstein et al., 1975).

2.2.7. Primary outcome measure

2.2.7.1. Beck's Depression Inventory (BDI-II)

The scale developed by Beck et al. (1961) was adapted and validated in Portuguese by Martins et al. (Martins et al., 2000; Coelho et al., 2002) aims to differentiate between depressed and non-depressed individuals, as well as to measure the severity of depressive symptomatology. It includes 21 items grouped into three factors: Cognitive Factor ($n = 8$ items); Affective Factor ($n = 6$ items); and Somatic Factor ($n = 7$ items). Symptom severity over the past 2 weeks is ranked on a four-point Likert scale, (e.g., sadness, 0 – I do not feel sad; 3 – I am so sad or unhappy that I cannot take it anymore) (Araújo, 2011). The BDI-II has adequate internal consistency, considered by some authors as "excellent" (Coelho et al., 2002). Scores ≤13 indicate minimal depressive symptomatology; scores between 14 and 19 indicate mild depression; scores between 20 and 28 indicate moderate depression; and scores >28 indicate severe depression (Beck et al., 1966).

2.2.8. Secondary outcome measures

2.2.8.1. Montgomery-Asberg Depression Rating Scale (MADRS)

This instrument is a 10-item rating scale developed by Montgomery and Åsberg (1979). The severity of each symptom is

2 http://www.uke.de/mct-silver

10.3389/fpsyg.2023.1167860

TABLE 2 Descriptions of the content of MCT-Silver modules.

Module	Name	Cognitive bias/Behavior	Aims	Training example
1	Thinking and reasoning I	Mental filter, overgeneralization	• Identify and modify selective perception (i.e., mental filter) and exaggerated generalizations of negative experiences.	*Modification of overgeneralization of negative experiences*: Situational examples are presented along with possible (depressive) interpretations. More helpful interpretations of these situations are identified.
2	Memory	Mood-congruent memory, false memories	• Normalize and explain concentration and memory issue. • Increase awareness of memory biases.	*False memory effect*: Participants are asked to remember objects presented in a picture. They are then provided with a list of words and are asked to identify the incorrect objects, which were not presented.
3	Thinking and reasoning II	"Should" statements, "all or nothing" thinking, acceptance of negative feelings related to life changes.	• Encourage participants to question rigid and perfectionistic behavior • Present the concept of acceptance for negative feelings.	*Examining perfectionistic standards*: • The pros and cons of holding oneself to certain (high) standards (e.g., to always have a perfectly clean home) are discussed. *Acceptance*: • Identification of areas in life in which participants would like to practice more acceptance.
4	Values	Identifying values and strategies for living a value-based life	• Identify personal values.	Values: • Communication regarding the importance of improving insight into personal values. • Processing of strategies that can support a value-oriented life.
5	Thinking and reasoning III	Magnification and minimization, depressive attributional style	• Identify and modify biases in judging the extent and consequences of perceived successes and failures.	*One-sided attributions*: Examples of one-sided attributions are presented, and participants are encouraged to identify multiple causes for an outcome.
6	Behaviors and strategies	Dysfunctional coping strategies: withdrawal, rumination, thought suppression	• Reduce dysfunctional behaviors associated with depression. • Develope new helpful coping behaviors.	*Helpful coping strategies*: • Mindfulness exercise to practice gaining inner (psychological) distance.
7	Thinking and reasoning IV	Jumping to conclusions, mind reading, fortune telling (catastrophizing)	• Identify instances of jumping to conclusions. • Encourage consideration of multiple sources of information before reaching a conclusion.	*Considering alternative information*: • Paintings are presented and participants are asked to guess the correct title from a list of choices.
8	Self-esteem	Self-esteem, changing negative self-perceptions through imagery	• Communicate strategies to improve self-esteem • Reduce and modify unfair comparisons (e.g., with the younger self).	• Imagination exercise: Transformation of negative images into strong, positive images (e.g., transformation of a weak, nervous chick into a proud eagle).

rated from 0 to 6, with higher scores indicating more severe symptoms. Snaith et al. (1986) proposed the following total score interpretations: 0 –6 indicate no symptoms; 7 – 19 indicate mild depression; 20 – 34 indicate moderate depression and 35 and greater indicates severe depression. The reliability of the MADRS ranges from $\alpha = 0.64 - 0.89$ (Huijbrechts et al., 1999). A methodological study to adapt this instrument to the Portuguese population will be conducted within this study.

2.2.8.2. Patient Health Questionnaire (PHQ-9)

The PHQ-9 was developed by Kroenke et al. (2001) and has been adapted and validated for the Portuguese population (Monteiro et al., 2013). The Portuguese version of the PHQ-9 has satisfactory internal consistency (Cronbach's alpha = 0.86) and showed strong convergent validity with the BDI ($r = 0.85$; $p < 0.01$) (Monteiro et al., 2013). The PHQ-9 consists of nine items that assess the severity of depression-related symptomatology on a 4-point Likert scale (from 0 "Never" to

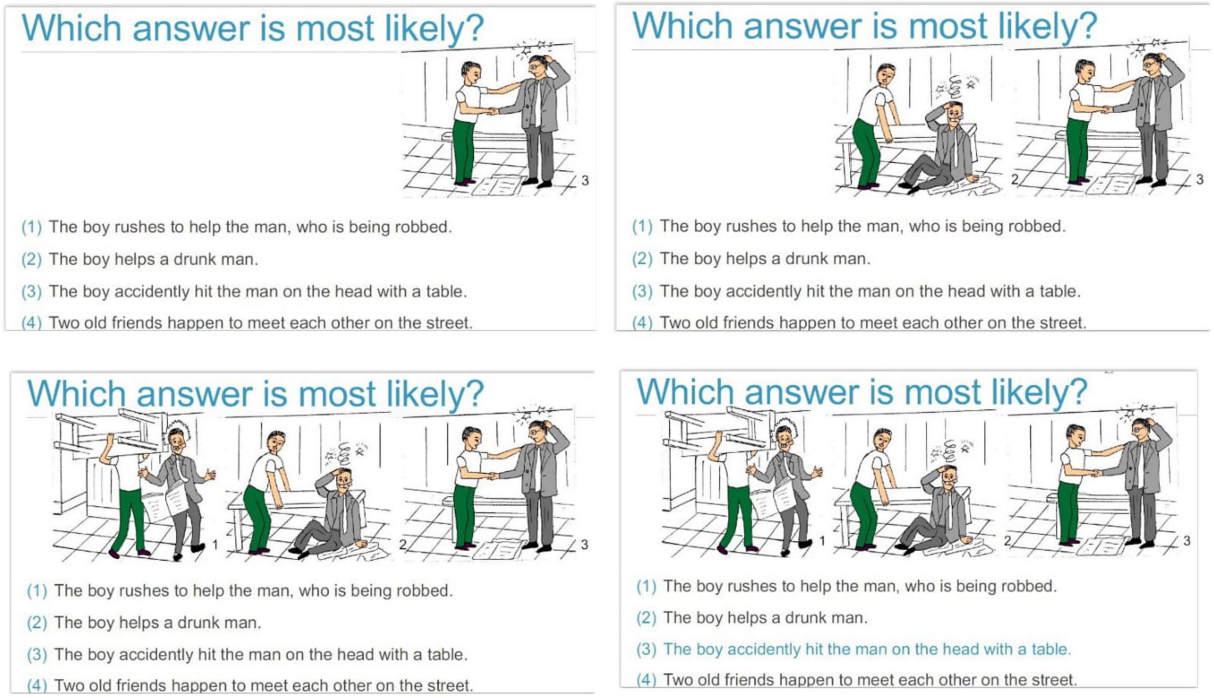


FIGURE 2
Example of Module 7: Jumping to Conclusions.

3 "Nearly every day"). Summed scores range from 0 to 27. Higher scores indicate more severe depression: scores between 0 and 4 indicate minimal depression, scores between 5 and 9 indicate mild depression, scores between 10 and 14 indicate moderate depression, scores between 15 and 19 indicate moderately severe depression, and scores between 20 and 27 indicate severe depression (Kroenke et al., 2001).

2.2.8.3. Metacognitions Questionnaire (MCQ-30)

The MCQ-30 was developed by Wells and Cartwright-Hatton (2004) and is available in Portugese (Dinis and Gouveia, 2011). The questionnaire assesses metacognitive beliefs on five subscales: cognitive confidence, positive beliefs about worry, cognitive self-consciousness, negative beliefs about the uncontrollability of thoughts and danger, and beliefs about the need to control thoughts. The Portuguese version of the MCQ-30 has good internal consistency (Cronbach's alpha = 0.91; Dinis and Gouveia, 2011). In our study we will apply three subscales of MCQ-30: (1) Positive Beliefs about worry (6 items); (2) Negative Beliefs about thoughts concerning uncontrollability and danger (6 items), and (3) beliefs about the need to control thoughts (6 items). We will only use these three subscales because they are most closely related to depression (Ruiz and Odriozola-González, 2015) and because the remaining two subscales of the MCQ-30, "cognitive confidence" and "cognitive self-awareness," do not correspond to the concepts of MCT (Jelinek et al., 2013, 2017).

2.2.8.4. Dysfunctional Attitudes Scale (DAS-18B)

The DAS-18B is a self-report questionnaire designed to assess dysfunctional attitudes, thoughts, and schemas associated with depression. It consists of 18 items answered on a seven-point Likert scale (1 = total agreement to 7 = total disagreement). Higher scores indicate more dysfunctional attitudes (Rojas et al., 2015). A methodological study to adapt this instrument to the Portuguese population in an 18-item version will be carried out within the scope of this study.

2.2.8.5. WHOQOL-BREF item 1

The global item ("How would you rate your quality of life?") of the WHOQOL-Bref (World Health Organization Quality of Life Instruments - Bref) will be used for this study. The WHOQOL-Bref was developed by the WHO in 1998 (The Whoqol Group, 1998) and adapted for the Portuguese population by Vaz Serra et al. (2006).

2.2.8.6. Ruminative Response Scale (ERR-10-A)

This scale is the reduced version (10 items; Treynor et al., 2003) of the Response Styles Questionnaire (RSQ: Response Styles Questionnaire; Nolen-Hoeksema and Morrow, 1991), which was adapted and validated for the Portuguese population (Dinis et al., 2011). This instrument assesses ruminative responses. The ERR-10-A includes 10 items with two factors. The "reflection" factor refers to attempts to understand the reasons for depressed mood (Cronbach's alpha = 0.75). The "brooding" factor refers to perseverative thinking focused on negative consequences of depressed mood and obstacles to problem-solving (Cronbach's alpha = 0.76). Respondents are provided with a series of statements referring to "what they usually do when they feel sad depressed or down" and provide answers on a four-point Likert scale, ranging from 1 ('hardly ever') to 4 ("almost always"; Dinis et al., 2011).

2.2.8.7. Rosenberg Self-Esteem Scale (RSE)

The Rosenberg Self-Esteem Scale (Rosenberg, 1965) is available in Portuguese (Cronbach's alpha = 0.86; Santos and

TABLE 3 List of study measures and questionnaires.

Instruments	Baseline	8 weeks (post)	3 months (follow-up)
Mini Mental State Examination	X		
Beck's Depression Inventory (BDI-II)	X	X	X
Patient Health Questionnaire (PHQ-9)	X	X	X
Montgomery-Asberg Depression Rating Scale (MADRS)	X	X	X
Metacognitions Questionnaire (MCQ-30)	X	X	X
Dysfunctional Attitudes Scale (DAS-18B)	X	X	X
WHOQOL-BREF Item 1	X	X	X
Ruminative Response Scale (ERR-10-A)	X	X	X
Rosenberg Self-Esteem Scale	X	X	X
The Attitudes to Ageing Questionnaire (AAQ-12)	X	X	X
Intervention questionnaire and patient satisfaction		X	X

Maia, 2003) and is comprised of 10 items concerning self-confidence and self-depreciation. A high score indicates positive feelings that the individual has about himself, leading to self-respect and the awareness that he is capable, without the feeling of superiority. A low score expresses low self-esteem, which implies self-rejection, dissatisfaction, and contempt for oneself (Santos and Maia, 2003).

2.2.8.8. The Attitudes to Ageing Questionnaire – Short form (AAQ-SF)

This instrument was originally created in its 24-item form by Laidlaw et al. (2007) and a short-form (AAQ-SF) was later developed (Laidlaw et al., 2018). The AAQ-SF is a 12-item rating scale and utilizes a 5-point Likert scale. Items query participants' attitudes regarding aging on three factors (psychosocial loss, psychological growth, physical change). The 12-item AAQ-SF showed adequate internal consistency and confirmatory factor analysis confirmed that the structure of the AAQ-SF reflects that of the original 24-item AAQ (Laidlaw et al., 2018).

2.2.8.9. Intervention questionnaire and patient satisfaction

Assessment of satisfaction with care/treatment should be evaluated in patient-centered approaches (Pinho et al., 2021). The Side Effects of Intervention questionnaire and patient satisfaction with MCT-Silver will be applied to the experimental group post-intervention. To assess the participants' acceptance of the interventions, a self-designed subjective evaluation scale will be used, consisting of 21 items. This includes 18 items (e.g., "I found the Metacognitive Training programme useful and important"; "I able to cope better with my illness after completing the training"; "The training programme helped me to gain a better understanding of my illness.") in which participants are asked to respond to the items on a 5-point Likert scale (1 = totally agree; 2 = agree; 3 = neutral; 4 = disagree; 5 = totally disagree). For the interpretation of the evaluation ratings, both positive ratings (i.e., totally agree and agree) are combined for the positively worded items and vice versa for the reversed items. There are also three open-ended items (e.g., "I particularly liked:…"). This information will be useful to understand patient acceptance of and satisfaction with the participants in the study.

2.2.9. Data analysis

The data will be analysed using Statistical Package for Social Sciences software (SPSS®) version 24.0 for Windows. Descriptive analysis will be used to characterize the sample. Within-group differences (t0 to t1 and t0 to t2) will be examined using paired sample *t*-tests. To evaluate change in primary and secondary outcomes between the two groups, we will perform ANCOVAs with treatment as the between-subject factor (MCT-Silver + TAU vs. TAU), the difference score of the outcomes (t1 – t0 and t2 – t0, respectively) as the dependent variable, and the baseline score of the respective outcome as the covariate. We chose ANCOVAs with difference scores instead of a repeated measures ANOVA to avoid regression to the mean and to control for potential baseline differences.

Intention-to-treat (ITT) analyses (including all participants who provided baseline data) using multiple imputation (MI) will be conducted. Analyses utilizing a complete cases sample (CC; including only complete data—i.e., baseline, post, and follow-up) will also be conducted. We will use analogous models to assess changes (t0-t1; t0-t2) for the secondary outcomes (WHOQOL-BREF item 1, DAS-18B, ERR-10-A, AAQ12, MCQ-30, MADRS, PHQ-9, RSE). We will also conduct planned moderation analyses for the primary outcome at post-assessment (BDI-II). Demographic characteristics (age, sex, education) and clinical characteristics (previous or current treatment, comorbid anxiety disorder, number of sessions attended) as well as baseline scores on secondary outcomes (WHOQOL-BREF item 1, DAS-18B, ERR-10-A, AAQ12, MCQ-30, MADRS, BDI, RSE) will be examined separately using moderation models as defined as defined by the PROCESS SPSS macro (model 1) [59]. Self-rated depression difference scores (t0–t1 and t0–t2) will be entered as the dependent variable (Y) and depression severity at t0 as the covariate.

2.3. Ethical considerations and dissemination

Approval will be obtained from the ethics committees of all institutions where the study will be carried out. All participants will be informed of the study's objectives, methodology, benefits, and possible risks. All participants will sign a written informed consent expressing their agreement to participate in this study. Participants' confidentiality

TABLE 4 Summary of the clinical and demographic characteristics of the sample.

Questions	Answers						
Age							
Gender	Female	Male					
Marital status	Single	Married/ marital partnership	Widowed	Divorced/ separated			
Level of education	Cannot read or write	Can read and write, but has not attended school	Attended school, but not higher education	Number of years of schooling	Higher education		
Who you live with	Institution	Alone	Spouse/partner	Child	Brother/sister	Other relative	Other non-family member
Labour status	Employed	Unemployed	Retired	Retired on invalidity	On sick leave	Current or past occupation	
Do you take any medication? If yes, which one?	No	Yes	If so, which one?				
Have you ever been admitted to a psychiatric ward?	No	Yes	How many times?				
Have you ever been to a psychiatric day hospital?	No	Yes	How many times?				
Are you followed up in follow-up appointments/ programmes?	No	Yes	Which ones?				
What is your current substance consumption?	None	Tobacco	Alcohol (more than 3 drinks a day)	Other drugs, which ones?			
Do you have any diagnosed illness(es)?	No	Yes	If so, which one or ones?				

will be ensured during all study procedures. Participants will be informed that they may withdraw their participation at any time without penalty or other consequence. Only research team members and healthcare professionals who care for participants have access to participant data. This data will be destroyed 5 years at the end of the study. If there is a need to change planned procedures, and that may have an impact on the execution of the study (e.g., changes in the study design, in the study objectives and in the study procedures), they will be reviewed by independent investigators and communicated to the ethics committees of all institutions where the study was carried out. The results of the study will be disseminated through oral communications and posters at conferences, and publications in scientific journals.

2.4. Validity and reliability/rigour

Variables such as educational level, duration of mental disorder, and type of treatment may influence the results of this study. The proposal to use the stratified random sampling method in this study aims to minimize confounding bias. All procedures, including the implementation of the intervention will be carried out after trainers have completed MCT-Silver training to minimize the risk of bias. Participants will be randomly allocated to either the experimental group [MCT-Silver + Treatment As Usual (TAU)] or the control group (TAU only). A computer-generated stratified random sampling method will be applied taking into consideration an equitable distribution by sex and age to promote sex and age equality and inclusiveness. Finally, all raters will be blinded to participant group assignment.

3. Discussion

MCT-Silver is a low intensity, CBT-based group intervention, which appears to have great potential in reducing depressive symptoms but further studies are needed to better validate its efficacy as the pilot study was limited due to lack of a control group (Schneider et al., 2018) as well as the lack of follow-up assessments. Only one RCT on MCT-Silver has been conducted (in Germany) (Schneider et al., under review).[3] The efficacy of MCT-Silver for older adults with depression has not yet been studied in the Portuguese population and, therefore, the development of the present trial is essential.

Portugal is one of the countries of the Organization for Economic Co-operation and Development (OECD) with the highest consumption of antidepressants (OECD, 2019) and, despite international guidelines recommending complementary treatment

3 Schneider, Brooke C., Veckenstedt, Rute, Karamatskos, Evangelos, Ahlf-Schumacher, Jana, et al. (under review) "Efficacy and moderators of metacognitive training for depression in later life (MCT-silver): a randomized controlled trial."

with non-pharmacological interventions (American Psychological Association, 2019), in Portugal this practice is not common. Most people with depression are only treated with medications.

It is expected that the results of this trial will provide support for the efficacy of the Portuguese version of MCT-Silver on the reduction of depressive symptoms. Moreover, it is anticipated that participants in the MCT-Silver group will demonstrate greater reductions in metacognitive beliefs, dysfunctional attitudes, ruminative responses and (negative) attitudes towards aging, as well as greater improvements in quality of life and self-esteem compared to a TAU group. The results of this trial are expected to allow future implementation of MCT-Silver by mental health and psychiatry professionals in various contexts. The MCT-Silver programme aims to contribute to the psychosocial rehabilitation of older adults with depression. The trial illustrated in this protocol intends to assess the efficacy of MCT-Silver in the Portuguese population.

Since people with depression often have cognitive deficits (Muhammad and Meher, 2021), patients with significantly impaired cognitive abilities may have difficulty understanding MCT-Silver exercises. To overcome this limitation, we will apply the MMSE to screen for cognitive deficits. Other limitations may be transportation difficulties getting to sessions regularly, as well as health problems, which may limit participation in the study or the changes in medication during the course of the study.

Minimal negative side effects of D-MCT have been previously reported (Dietrichkeit et al., 2021). We anticipate similar findings, such as disappointment that the training did not result in (greater) symptom improvement and being more burdened by symptoms because patients may think about them more during the training. Attendance (i.e., coming to appointments) may also be perceived as stressful. It is also possible that patients could experience a clinically significance worsening of symptoms. In this case, participation in the study would be discontinued and, if necessary, participants would be offered assistance in identifying needed treatment.

This study includes many measurement instruments and were chosen to improve comparability with previous trails on MCT-Silver and D-MCT (see Jelinek et al., 2015) (Schneider et al., under review, see footnote 3). Nonetheless, completion of study measures can be burdensome and time-intensive for participants. Given that this is the first MCT-Silver trial in Portugal and participants are receiving a psychological intervention, we believe that the potential knowledge to be obtained from the study justifies participants' time and potential burden related to participation in the study. Additionally, participants are allowed to discontinue testing and will not be penalized for this. Use of self-report measures is common in RCTs of psychological interventions and provide indications regarding patients' perceptions of symptoms and suffering from these symptoms. Nonetheless, responses are impacted by many factors, including social desirability and insight, as well as reading competence and motivation, which may limit the validity of our findings. For this reason, we have also included a clinician-rated measure of depression (MADRS). The results of the RCT will be implemented to improve the training, provide information regarding efficacy among Portuguese patients (vs. TAU) and, in the case of efficacy, to support dissemination and uptake in Portugal, which would lead to a reduced treatment gap among older adults with depression.

Author contributions

LP and BS initiated the study design. LJ, CF, ML, and SM reviewed the study design. CS, LP, BM, and BS wrote the first draft of the manuscript. LP, BS, LJ, and SM provided theoretical, practical, and research expertise on metacognitive training. CF, ML, LJ, and SM revised the manuscript. All authors contributed to the refinement of the study protocol and approved the final manuscript.

Funding

This research was funded by the Federal Ministery of Education and Research (Bundesministerium für Bildung und Forschung; #57610786), Foundation for Science and Technology (FCT: Fundação para a Ciência e Tecnologia). Programme for Cooperation in Science between Portugal and German. This work is funded by national funds through the Foundation for Science and Technology, under the project UIDP/04923/2020.

Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

References

American Psychiatric Association. (2014). *DSM-5 Manual de Diagnóstico e Estatística Das Perturbações Mentais. 5a*. Lisboa: Climepsi Editores.

American Psychological Association. (2019). "*APA clinical practice guideline for the treatment of depression across three age cohorts* Washington, DC American Psychological Association

Araújo, M. (2011). *A Doença Oncológica Na Criança: Adaptação e Bem-Estar Psicológico Das Mães Dos Seus Filhos e a Relação Entre Ambos*. Lisboa: Coisas de Ler.

Beck, A. T., Steer, R., and Steer, G. (1966). *Beck depression inventory-II manual*. New York: The Psychological Corporation.

Beck, A. T., Ward, C. H., Mendelson, M., Mock, J., and Erbaugh, J. (1961). An inventory for measuring depression. *Arch. Gen. Psychiatry* 4:561. doi: 10.1001/archpsyc.1961.01710120031004

Blaney, P. H. (1986). Affect and memory: a review. *Psychol. Bull.* 99, 229–246. doi: 10.1037/0033-2909.99.2.229

Bücker, L. (2019). Negative Gedanken Auflösen – Metakognitives Training Bei Depression Im Alter. *Ergopraxis* 12, 22–27. doi: 10.1055/a-0839-2153

Butler, J., and Ciarrochi, J. (2007). Psychological acceptance and quality of life in the elderly. *Qual. Life Res.* 16, 607–615. doi: 10.1007/s11136-006-9149-1

Cane, D. B., and Gotlib, I. H. (1985). Depression and the effects of positive and negative feedback on expectations, evaluations, and performance. *Cogn. Ther. Res.* 9, 145–160. doi: 10.1007/BF01204846

Carvalho Pereira de Melo, R. C., and Pereira de Melo, A. S. (2021). Da Inatividade Ao Sentimiento de Utilidade Da Pessoa Idosa: Efeito Na Redução Dos Sintomas de Ansiedade e Depressão. *Revista INFAD de Psicología. Int. J. Dev. Educ. Psychol* 2, 75–82. doi: 10.17060/ijodaep.2021.n1.v2.2120

Carver, C. S., and Ganellen, R. J. (1983). Depression and components of self-punitiveness: high standards, self-criticism, and overgeneralization. *J. Abnorm. Psychol.* 92, 330–337. doi: 10.1037/0021-843X.92.3.330

Charles, P., Giraudeau, B., Dechartres, A., Baron, G., and Ravaud, P. (2009). Reporting of sample size calculation in randomised controlled trials: review. *BMJ* 338:b1732. doi: 10.1136/bmj.b1732

Coelho, R., Martins, A., and Barros, H. (2002). Clinical profiles relating gender and depressive symptoms among adolescents ascertained by the beck depression inventory II. *Eur. Psychiatry* 17, 222–226. doi: 10.1016/S0924-9338(02)00663-6

Davey, A., Halverson, C. F., Zonderman, A. B., and Costa, P. T. (2004). Change in depressive symptoms in the baltimore longitudinal study of aging. *J. Gerontol. B Psychol. Sci. Soc. Sci.* 59, 270–277. doi: 10.1093/geronb/59.6.P270

Dietrichkeit, M., Hagemann-Goebel, M., Nestoriuc, Y., Moritz, S., and Jelinek, L. (2021). Side effects of the metacognitive training for depression compared to a cognitive remediation training in patients with depression. *Scientific Reports.* 11:7861. doi: 10.1038/s41598-021-87198-8

Dinis, A., and Gouveia, J. P. (2011). Estudo Das Características Psicométricas Da Versão Portuguesa Do Questionário de Metacognições – Versão Reduzida e Do Questionário de Meta-Preocupação. *Psychologica* 54, 281–307. doi: 10.14195/1647-8606_54_11

Dinis, A., Gouveia, J. P., Duarte, C., and Castro, T. (2011). Estudo de Validação Da Versão Portuguesa Da Escala de Respostas Ruminativas – Versão Reduzida. *Psychologica* 54, 175–202. doi: 10.14195/1647-8606_54_7

Egan, S. J., Wade, T. D., and Shafran, R. (2011). Perfectionism as a transdiagnostic process: a clinical review. *Clin. Psychol. Rev.* 31, 203–212. doi: 10.1016/j.cpr.2010.04.009

Elliott, R., Sahakian, B. J., Herrod, J. J., Robbins, T. W., and Paykel, E. S. (1997). Abnormal response to negative feedback in unipolar depression: evidence for a diagnosis specific impairment. *J. Neurol. Neurosurg. Psychiatry* 63, 74–82. doi: 10.1136/jnnp.63.1.74

Folstein, M. F., Folstein, S. E., and McHugh, P. R. (1975). 'Mini-mental state': a practical method for grading the cognitive state of patients for the clinician. *J. Psychiatr. Res.* 12, 189–198. doi: 10.1016/0022-3956(75)90026-6

Garber, J., and Hollon, S. D. (1980). Universal versus personal helplessness in depression: belief in uncontrollability or incompetence? *J. Abnorm. Psychol.* 89, 56–66. doi: 10.1037/0021-843X.89.1.56

Guerreiro, M. P. S. A., Silva, A. P., Botelho, M. A., Leitão, O., Castro-Caldas, A., and Garcia, C. (1994). Adaptação à População Portuguesa Da Tradução Do Mini Mental State Examination (MMSE). *Revista Portuguesa de Neurologia* 1, 9–10.

Hauschildt, M., Arlt, S., Moritz, S., Yassari, A. H., and Jelinek, L. (2022). Efficacy of metacognitive training for depression as add-on intervention for patients with depression in acute intensive psychiatric inpatient care: a randomized controlled trial. *Clin. Psychol. Psychother.* 29, 1542–1555. doi: 10.1002/cpp.2733

Hayes, S. C., Luoma, J. B., Bond, F. W., Masuda, A., and Lillis, J. (2006). Acceptance and commitment therapy: model, processes and outcomes. *Behav. Res. Ther.* 44, 1–25. doi: 10.1016/J.BRAT.2005.06.006

Hayes, S. C., Wilson, K. G., Gifford, E. V., Follette, V. M., and Strosahl, K. D. (1996). Experiential avoidance and behavioral disorders: a functional dimensional approach to diagnosis and treatment comparing syndromal and functional classification. *J. Consult. Clin. Psychol.* 64, 1152–1168. doi: 10.1037/0022-006X.64.6.1152

Hertzog, M. A. (2008). Considerations in determining sample size for pilot studies. *Res. Nurs. Health* 31, 180–191. doi: 10.1002/nur.20247

Hoehn-Hyde, D., Schlottmann, R. S., and John Rush, A. (1982). Perception of social interactions in depressed psychiatric patients. *J. Consult. Clin. Psychol.* 50, 209–212. doi: 10.1037/0022-006X.50.2.209

Holmes, E. A., Blackwell, S. E., Heyes, S. B., Renner, F., and Raes, F. (2016). Mental imagery in depression: phenomenology, potential mechanisms, and treatment implications. *Annu. Rev. Clin. Psychol.* 12, 249–280. doi: 10.1146/annurev-clinpsy-021815-092925

Horackova, K., Kopecek, M., Machů, V., Kagstrom, A., Aarsland, D., Motlova, L. B., et al. (2019). Prevalence of late-life depression and gap in mental health service use across European regions. *Eur. Psychiatry* 57, 19–25. doi: 10.1016/j.eurpsy.2018.12.002

Huijbrechts, I. P. A. M., Haffmans, P. M. J., Jonker, K., van Dijke, A., and Hoencamp, E. (1999). A comparison of the 'Hamilton rating scale for depression' and the 'Montgomery-Asberg depression rating scale'. *Acta Neuropsychiatrica* 11, 34–37. doi: 10.1017/S0924270800036358

Isaacowitz, D. M., and Seligman, M. E. (2002). Cognitive style predictors of affect change in older adults. *Int. J. Aging Hum. Dev.* 54, 233–253. doi: 10.2190/J6E5-NP5K-2UC4-2F8B

James, S. L., Abate, D., Abate, K. H., Abay, S. M., Abbafati, C., Abbasi, N., et al. (2018). Global, regional, and National Incidence, prevalence, and years lived with disability for 354 diseases and injuries for 195 countries and territories, 1990–2017: a systematic analysis for the global burden of disease study 2017. *Lancet* 392, 1789–1858. doi: 10.1016/S0140-6736(18)32279-7

Jelinek, L., Faissner, M., Moritz, S., and Kriston, L. (2019). Long-term efficacy of metacognitive training for depression (D-MCT): a randomized controlled trial. *Br. J. Clin. Psychol.* 58, 245–259. doi: 10.1111/bjc.12213

Jelinek, L., Hauschildt, M., and Moritz, S. (2015). "Metakognitives training Bei depression (D-MKT)" in *Metacognitive training for depression (D-MCT)*. ed. H. Starvemann (Weinheim: Beltz)

Jelinek, L., Hauschildt, M., Wittekind, C. E., Schneider, B. C., Kriston, L., and Moritz, S. (2016). Efficacy of metacognitive training for depression: a randomized controlled trial. *Psychother. Psychosom.* 85, 231–234. doi: 10.1159/000443699

Jelinek, L., Otte, C., Arlt, S., and Hauschildt, M. (2013). Denkverzerrungen Erkennen Und Korrigieren: Eine Machbarkeitsstudie Zum Metakognitiven Training Bei Depression (D-MKT). *Zeitschrift Fur Psychiatrie, Psychologie Und Psychotherapie* 61, 247–254. doi: 10.1024/1661-4747/a000167

Jelinek, Lena, Schneider, Brooke C, Hauschildt, Marit, and Moritz, Steffen. (2022). Metacognitive training for depression (D-MCT): A short manual for its original version and its adaption for older adults (MCT-silver). Version: 13.01.22. Available at: https://clinical-neuropsychology.de/metacognitive-training-for-depression-mct-silver/

Jelinek, L., Van Quaquebeke, N., and Moritz, S. (2017). Cognitive and metacognitive mechanisms of change in metacognitive training for depression. *Sci. Rep.* 7, 1–8. doi: 10.1038/s41598-017-03626-8

Kishi, T., Sakuma, K., Hatano, M., Okuya, M., Matsuda, Y., Kato, M., et al. (2023). Relapse and its modifiers in major depressive disorder after antidepressant discontinuation: meta-analysis and meta-regression. *Mol. Psychiatry* 8, 974–976. doi: 10.1038/s41380-022-01920-0

Kroenke, K., Spitzer, R. L., and Williams, J. B. W. (2001). The PHQ-9. *J. Gen. Intern. Med.* 16, 606–613. doi: 10.1046/j.1525-1497.2001.016009606.x

Laidlaw, K., Kishita, N., Shenkin, S. D., and Power, M. J. (2018). Development of a short form of the attitudes to ageing questionnaire (AAQ). *Int. J. Geriatr. Psychiatry* 33, 113–121. doi: 10.1002/gps.4687

Laidlaw, K., Power, M. J., and Schmidt, S. (2007). The attitudes to ageing questionnaire (AAQ): development and psychometric properties. *Int. J. Geriatr. Psychiatry* 22, 367–379. doi: 10.1002/gps.1683

Martins, A., Coelho, R., Ramos, E., and Barros, H. (2000). Administração Do BDI-II a Adolescentes Portugueses: Resultados Preliminares. *Revista Portuguesa de Psicossomática* 2, 123–132.

Mathews, A., and Macleod, C. (2005). Cognitive vulnerability to emotional disorders. *Annu. Rev. Clin. Psychol.* 1, 167–195. doi: 10.1146/annurev.clinpsy.1.102803.143916

McConnell, L., and Troop-Gordon, W. (2021). Attentional biases to bullies and bystanders and youth's coping with peer victimization. *J. Early Adolesc.* 41, 97–127. doi: 10.1177/0272431620931206

Mcgrath, D. S., Sherry, S. B., Stewart, S. H., Mushquash, A. R., Allen, S. L., Nealis, L. J., et al. (2012). Reciprocal relations between self-critical perfectionism and depressive symptoms: evidence from a short-term, four-wave longitudinal study 44, 169–181. doi: 10.1037/a0027764,

Miranda, R., Fontes, M., and Marroquín, B. (2008). Cognitive content-specificity in future expectancies: role of hopelessness and intolerance of uncertainty in depression and GAD symptoms. *Behav. Res. Ther.* 46, 1151–1159. doi: 10.1016/j.brat.2008.05.009

Mommaerts, J.-L. (2022). Lack of blinding in a cloud of unknowing: what remains of antidepressants' effectiveness? *Psychiatry Res.* 313:114609. doi: 10.1016/j.psychres.2022.114609

Monteiro, S., Torres, A., Pereira, A., Albuquerque, E., and Morgadinho, R. (2013). Preliminary validation study of a Portuguese version of the patient health questionnaire (PHQ-9). *Eur. Psychiatry* 28:1. doi: 10.1016/S0924-9338(13)76982-7

Montgomery, S. A., and Åsberg, M. (1979). A new depression scale designed to be sensitive to change. *Br. J. Psychiatry* 134, 382–389. doi: 10.1192/bjp.134.4.382

Moritz, Steffen, De Boer, Klaas, Bohn, Francesca, Veckenstedt, Ruth, Randjbar, Sarah, and Ferwerda, Janneke. (2008). "Metacognitieve training bij schizofrenie: van fundamenteel onderzoek tot interventie."*Handboek psychose* Amsterdam:Boom, GaagM. van der, S. Tonnie and L. Valsmaggia

Moritz, S., Krieger, E., Bohn, F., and Veckenstedt, R. (2017). "Individualisiertes Metakognitives Therapieprogramm (MKT+)" in *MKT+* (Berlin, Heidelberg: Springer Berlin Heidelberg), 55–65.

Moritz, S., Lysaker, P. H., Hofmann, S. G., and Hautzinger, M. (2018). Going meta on metacognitive interventions. *Expert Rev. Neurother* 18, 739–741. doi: 10.1080/14737175.2018.1520636

Moritz, S., Veckenstedt, R., Bohn, F., Hottenrott, B., Scheu, F., Randjbar, S., et al. (2013). Complementary group metacognitive training (MCT) reduces delusional ideation in schizophrenia. *Schizophr. Res.* 151, 61–69. doi: 10.1016/j.schres.2013.10.007

Moritz, S., and Woodward, T. S. (2007). Metacognitive training for schizophrenia patients (MCT): a pilot study on feasibility, treatment adherence, and subjective efficacy. *Ger. J. Psychiatry* 10, 69–78.

Muhammad, T., and Meher, T. (2021). Association of Late-Life Depression with cognitive impairment: evidence from a cross-sectional study among older adults in India. *BMC Geriatr.* 21:364. doi: 10.1186/s12877-021-02314-7

Nolen-Hoeksema, S., and Morrow, J. (1991). A prospective study of depression and posttraumatic stress symptoms after a natural disaster: the 1989 Loma Prieta earthquake. *J. Pers. Soc. Psychol.* 61, 115–121. doi: 10.1037/0022-3514.61.1.115

OECD (2019). "Health at a glance 2019: OECD indicators" in *Health at a Glance* (Paris: OECD)

Orth, U., Robins, R. W., Trzesniewski, K. H., Maes, J., and Schmitt, M. (2009). Low self-esteem is a risk factor for depressive symptoms from young adulthood to old age. *J. Abnorm. Psychol.* 118, 472–478. doi: 10.1037/a0015922

Özgüç, S., and Tanriverdi, D. (2022). Effects of metacognitive training (D-MCT) on metacognition and ruminative thought levels of major depression patients. *Int. J. Ment. Heal. Addict.* 21, 2017–2028. doi: 10.1007/s11469-022-00869-z

Pinho, L. G., Lopes, M. J., Correia, T., Sampaio, F., Arco, H. R. d., Mendes, A., et al. (2021). Patient-centered Care for Patients with depression or anxiety disorder: an integrative review. *J. Pers. Med.* 11:776. doi: 10.3390/jpm11080776

Rojas, R., Geissner, E., and Hautzinger, M. (2015). DAS-18 form a und form B. *Diagnostica* 61, 173–183. doi: 10.1026/0012-1924/a000123

Rood, L., Roelofs, J., Bögels, S. M., Nolen-Hoeksema, S., and Schouten, E. (2009). The influence of emotion-focused rumination and distraction on depressive symptoms in non-clinical youth: a meta-analytic review. *Clin. Psychol. Rev.* 29, 607–616. doi: 10.1016/j.cpr.2009.07.001

Rosenberg, M. (1965). Rosenberg self-esteem scale. *J. Relig. Health*

Ruiz, F. J., and Odriozola-González, P. (2015). Comparing cognitive, metacognitive, and acceptance and commitment therapy models of depression: a longitudinal study survey. *Span. J. Psychol.* 18:E39. doi: 10.1017/sjp.2015.31

Santomauro, D. F., Mantilla, A. M., Herrera, J. S., Zheng, P., Ashbaugh, C., Pigott, D. M., et al. (2021). Global prevalence and burden of depressive and anxiety disorders in 204 countries and territories in 2020 due to the COVID-19 pandemic. *Lancet* 398, 1700–1712. doi: 10.1016/S0140-6736(21)02143-7

Santos, P., and Maia, J. (2003). "Análise Factorial Confrmatória e Validação Preliminar de Uma Versão Portuguesa Da Escala de Avaliação de Auto-Estima de Rosenberg" in *Psicologia: Teoria, Investigação e Prática*, vol. 2, 253–268.

Schneider, B. C., Bücker, L., Riker, S., Karamatskos, E., and Jelinek, L. (2018). A pilot study of metacognitive training (D-MCT) for older adults with depression. *Z. Neuropsychol.* 29, 7–19. doi: 10.1024/1016-264x/a000210

Seidel, E. M., Habel, U., Finkelmeyer, A., Schneider, F., Gur, R. C., and Derntl, B. (2010). Implicit and explicit behavioral tendencies in male and female depression. *Psychiatry Res.* 177, 124–130. doi: 10.1016/j.psychres.2010.02.001

Snaith, R. P., Harrop, F. M., Newby, D. A., and Teale, C. (1986). Grade scores of the montgomery—åsberg depression and the clinical anxiety scales. *Br. J. Psychiatry* 148, 599–601. doi: 10.1192/bjp.148.5.599

Strunk, D. R., Lopez, H., and DeRubeis, R. J. (2006). Depressive symptoms are associated with unrealistic negative predictions of future life events. *Behav. Res. Ther.* 44, 861–882. doi: 10.1016/j.brat.2005.07.001

The Whoqol Group (1998). The World Health Organization Quality of Life Assessment (WHOQOL): development and general psychometric properties. *Soc. Sci. Med.* 46, 1569–1585. doi: 10.1016/S0277-9536(98)00009-4

Treynor, W., Gonzalez, R., and Nolen-Hoeksema, S. (2003). Rumination reconsidered: a psychometric analysis. *Cogn. Ther. Res.* 27, 247–259. doi: 10.1023/A:1023910315561

Vaz Serra, A., Canavarro, M. C., Simões, M., Pereira, M., Gameiro, S., Quartilho, M. J., et al. (2006). Estudos Psicométricos Do Instrumento de Avaliação Da Qualidade de Vida Da Organização Mundial de Saúde (WHOQOL-Bref) Para Português de Portugal. *Psiquiat. Clín.* 27, 41–49.

Wells, A. (2011). *Metacognitive therapy for anxiety and depression*. New York: The Guilford Press.

Wells, A., and Cartwright-Hatton, S. (2004). A short form of the metacognitions questionnaire: properties of the MCQ-30. *Behav. Res. Ther.* 42, 385–396. doi: 10.1016/S0005-7967(03)00147-5

Wenzlaffand, R. M., and Grozier, S. A. (1988). Depression and the magnification of failure 97, 90–93. doi: 10.1037//0021-843x.97.1.90,

Wittekind, C. E., Terfehr, K., Otte, C., Jelinek, L., Hinkelmann, K., and Moritz, S. (2014). Mood-congruent memory in depression - the influence of personal relevance and emotional context. *Psychiatry Res.* 215, 606–613. doi: 10.1016/j.psychres.2013.11.027

World Health Organization. (2021). "*Depression*." Available at: https://www.who.int/News-Room/Fact-Sheets/Detail/Depression

Wrosch, C., Scheier, M. F., and Miller, G. E. (2013). Goal adjustment capacities, subjective well-being, and physical health. *Soc. Personal. Psychol. Compass* 7, 847–860. doi: 10.1111/spc3.12074

Wu, J.-J., Hui-Xin Wang, W., Yao, Z. Y., and Pei, J.-J. (2020). Late-life depression and the risk of dementia in 14 countries: a 10-year follow-up study from the survey of health, ageing and retirement in Europe. *J. Affect. Disord.* 274, 671–677. doi: 10.1016/j.jad.2020.05.059

Zimmerman, M., Chelminski, I., and Posternak, M. (2004). A review of studies of the Montgomery Asberg depression rating scale in controls: implications for the definition of remission in treatment studies of depression. *Int. Clin. Psychopharmacol.* 19, 1–7. doi: 10.1097/00004850-200401000-00001

frontiers | Frontiers in Psychology

TYPE Clinical Trial
PUBLISHED 29 November 2023
DOI 10.3389/fpsyg.2023.1247725

OPEN ACCESS

EDITED BY
Lara Guedes De Pinho,
University of Evora, Portugal

REVIEWED BY
Celso Silva,
Instituto Politécnico de Beja, Portugal
Mareike Samaan,
Evangelische Krankenhaus Königin Elisabeth Herzberge (KEH), Germany
Tânia Correia,
University of Porto, Portugal

*CORRESPONDENCE
Rabea Fischer
✉ r.fischer@uke.de

RECEIVED 26 June 2023
ACCEPTED 20 October 2023
PUBLISHED 29 November 2023

CITATION
Fischer R, Nagel M, Schöttle D, Lüdecke D, Lassay F, Moritz S and Scheunemann J (2023) Metacognitive training in the acute psychiatric care setting: feasibility, acceptability, and safety. *Front. Psychol.* 14:1247725. doi: 10.3389/fpsyg.2023.1247725

Metacognitive training in the acute psychiatric care setting: feasibility, acceptability, and safety

Rabea Fischer[1,2]*, Matthias Nagel[2,3], Daniel Schöttle[1,4], Daniel Lüdecke[1], Franziska Lassay[1], Steffen Moritz[1] and Jakob Scheunemann[1]

[1]Department of Psychiatry and Psychotherapy, University Medical Center Hamburg-Eppendorf, Hamburg, Germany, [2]Department of Psychiatry and Psychotherapy, Asklepios Clinic North Wandsbek, Hamburg, Germany, [3]Department of Psychiatry and Psychotherapy, University Hospital Schleswig-Holstein, Luebeck, Germany, [4]Department of Psychiatry and Psychotherapy, Asklepios Clinic Harburg, Hamburg, Germany

Patients on acute psychiatric wards desire more psychosocial treatment than they receive, according to recent studies, but evidence-based interventions tailored to this setting are currently lacking. Metacognitive Training for psychosis (MCT) is a flexible, easy-to-administer group therapy that has been adapted to meet this demand (MCT-Acute). Thirty-seven patients with severe mental illness took part in MCT-Acute twice a week during their stay on a locked acute ward and were interviewed before, during, and after the intervention period regarding subjective utility, subjective adverse events, and symptom severity; attendance rates and reasons for absence were recorded. In addition, staff rated adverse events, symptom severity, and functioning (German Clinical Trial Register ID: DRKS00020551). Overall, most patients evaluated MCT-Acute positively and reported symptom stabilization. Staff also reported improvement in functioning. No clinician-rated adverse events related to participation in MCT-Acute were reported. Conducting MCT-Acute is feasible and safe and may contribute to meeting patients', practitioners', and researchers' demands for more evidence-based psychotherapeutic interventions for the acute psychiatric care setting.

Clinical Trial Registration: ID: DRKS00020551, https://drks.de/search/de/trial/DRKS00020551

KEYWORDS

locked ward, psychosis, psychiatry, psychological intervention, group therapy, severe mental illness, metacognitive training

1 Introduction

Risk of harm to oneself or others represent key aspects of patient safety in inpatient psychiatry (Marcus et al., 2021) and constitute legal grounds for acute involuntary psychiatric inpatient treatment in many parts of the world (Rains et al., 2019; Saya et al., 2019). While 9.1% of all Europeans experience suicidal ideation in their lifetime (Castillejos et al., 2020), this number rises to 34.5% for people diagnosed with schizophrenia (Bai et al., 2021) and individuals with a diagnosis of bipolar disorder show suicide attempt rates at least 20 times higher than the adult general population (Tondo et al., 2021). Patients with schizophrenia or bipolar disorder are also at higher risk of committing crimes (Senior et al., 2020; Yee et al., 2020), although they are overall responsible for only a small fraction of all crimes committed, a much larger number

of people experiencing psychosis are victims rather than perpetrators of violent crimes (Thornicroft, 2020). People with psychosis also show victimization rates several times higher than the general population (de Vries et al., 2019). Thus, one essential purpose of acute psychiatric services has been to assess and, where possible, avoid harm, at times placing little emphasis on fostering positive aims through therapeutic means (Bowers et al., 2014; Tracy and Phillips, 2022).

Acute psychiatric care has moved from custodial models of treatment, often meaning indefinite confinement and equating mental illness with criminality, to curative goals, shared decision-making, and increasing attempts to integrate care into the community today (Saya et al., 2019; Johnson et al., 2022). Yet, in many countries, acute psychiatric care still ordinarily takes place in inpatient settings, often on locked wards staffed by a multidisciplinary team of psychiatrists, nurses, and specialized therapists. Even in places where a variety of psychiatric emergency services exist outside of hospitals, such as in the United Kingdom (e.g., Odejimi et al., 2020), psychiatric emergency wards for patients in acute crisis still exist. In many cases, patients are mandated to enter inpatient care, and in some countries they may experience involuntary treatment lasting up to several months (Zhang et al., 2015; Sashidharan et al., 2019). At this stage of treatment, psychological interventions offer a range of benefits such as identifying problems and strategies to reduce them, reducing stress, fostering a recovery-oriented outlook and hope through the therapeutic relationship, improving social functioning and treatment compliance and reducing risk of rehospitalization (Donaghay-Spire et al., 2016; Barnicot et al., 2020).

Psychological care is often lacking during the acute stage, even though many patients endorse more therapeutic interactions with ward staff and several national treatment guidelines for severe mental illnesses explicitly call for psychosocial treatment options across the various stages of the illness, including during the acute phase (National Institute for Health and Care Excellence (NICE), 2014; Wood and Alsawy, 2016; American Psychiatric Association (APA), 2020; Berry et al., 2022). In recent years, several psychological interventions have been developed for the acute care setting. For instance, Jacobsen et al. (2020) examined a mindfulness-based crisis intervention for patients with psychosis. No drop-outs were observed during the intervention, and it was associated with a decreased risk of readmission and relapse rates at 12 months' follow-up. Paterson et al. (2019) examined a cross-diagnostic psychologically informed acute inpatient therapy service that provided both individual and group sessions, and found that their intervention was feasible to conduct with acute inpatients and that it might lead to reduced psychological distress and increased mental health-related self-efficacy compared to treatment as usual. However, evidence-based interventions specifically designed or adapted to fit this particular setting are scarce and are rarely implemented in the clinical context. Studies evaluating their efficacy are lacking (Paterson et al., 2019; Berry et al., 2022).

Several factors unique to the acute ward setting make the evaluation of such interventions particularly challenging. One of these is the high symptom load, especially neurocognitive impairments, which make it difficult for participants to answer even short and/or simple questionnaires, along with the high distress that participants often experience as a result (Wood et al., 2021; Berry et al., 2022). Accordingly, comprehension is often low and informed consent cannot always be properly obtained. Another characteristic of the acute setting that makes research particularly challenging is that in many countries there is no continuity of treatment from the acute inpatient to subsequent (open) settings (Wood et al., 2022), although care continuity, particularly the ability to build a therapeutic relationship, is associated with a variety of positive outcomes (Ruud and Friis, 2022). As stays on acute wards are often brief, ranging from a few days to around four weeks, and interventions that are limited to the ward itself cannot continue seamlessly once the patient leaves care, interventions must be very brief as well (Bullock et al., 2021). Due to the high turnover of patients, group interventions in particular should not be sequential so that patients can join the intervention at any time point and can resume participation without having missed essential information if they miss sessions due to worsening of symptoms or other reasons (Fife et al., 2019). In addition, it is often difficult to contact participants for follow-up assessments after they have been discharged from the ward (Paterson et al., 2019; Raphael et al., 2021a).

There are also several barriers to the implementation of psychological therapies itself, including the busy ward setting with frequent emergencies and departures from routine treatment, lack of training of ward staff, lack of support from leadership, acute exacerbation of symptoms precluding, for example, the ability to concentrate for several minutes, as well as lack of specific adaptation of interventions to the acute care setting (Evlat et al., 2021; Raphael et al., 2021b).

In order to address the aforementioned challenges and to contribute to narrowing the current treatment gap for patients with acute symptoms, particularly on closed wards, we developed the Metacognitive Training for the acute psychiatric setting (MCT-Acute). The MCT-Acute is an adaption of Metacognitive Training for psychosis (MCT; Moritz and Woodward, 2007a). MCT is a psychological group intervention based on more than 30 years of research suggesting that individuals who experience psychosis are prone to certain cognitive biases that underlie the foundation and maintenance of psychotic symptoms, particularly delusions (e.g., Moritz et al., 2017; Ward and Garety, 2019). One of the most researched biases that constitutes a key mechanism in the development of delusions is the jumping to conclusions bias (Dudley et al., 2016; McLean et al., 2017), in which participants make hasty decisions based on very little information (Garety et al., 1991). Research has also shown that patients with psychosis demonstrate a bias against disconfirmatory evidence (e.g., Woodward et al., 2006; Veckenstedt et al., 2011) and do not revise their decision, even when they are confronted with evidence that goes against their decision. This bias also constitutes a central mechanism in the development and maintenance of delusions (Eisenacher and Zink, 2017). Another cognitive bias contributing to the development of delusions, particularly persecutory delusions (Murphy et al., 2018), is the self-serving attributional style first described by Kaney and Bentall (1989), Bentall et al. (1991, 1994). MCT is a multimedia-based group intervention that uses engaging exercises to provoke, for example, hasty decision making within a group session and thus produce so-called aha moments, allowing patients to recognize their biased thinking directly through the exercise instead of through theoretical explanations. This realization is followed by exercises that help patients develop alternative ways of thinking. According to recent meta-analyses, MCT is effective for a range of symptoms, particularly delusions and positive symptoms overall (Eichner and Berna, 2016; Liu et al., 2018; Sauvé et al., 2020; Penney et al., 2022). However, it is too challenging and difficult for

many patients with high symptom severity (van Oosterhout et al., 2014). In addition to MCT for psychosis, versions of Metacognitive Training have been developed for other disorders in recent years, including MCT for depression (Jelinek et al., 2013) and suicidality (Jelinek et al., 2021), depression in later life (Schneider et al., 2018), obsessive-compulsive disorder (Miegel et al., 2022), gambling disorder (Gehlenborg et al., 2021), and borderline personality disorder (Schilling et al., 2018). A case report describes the adaptation process of MCT-Acute in detail and outlines its potential as an add-on treatment in the acute-care setting (Fischer et al., 2022). MCT-Acute was designed to be suitable for patients with psychosis but also for patients with (comorbid) depression. Most topics that are addressed by MCT for psychosis are also relevant to individuals with depression, although the emphasis may differ between psychosis and depression (e.g., self-serving attributional style in psychosis vs. depressive attributional style in depression). In addition, several modules in MCT for psychosis already address depression-specific topics, such as mood and self-esteem. Furthermore, one module was adapted from the MCT for depression; thus, MCT-Acute also targets depression-specific cognitive biases that may be relevant to patients on acute wards with a variety of primary diagnoses who suffer from (comorbid) depression.

The aim of the present feasibility trial was to assess the acceptability and safety of the adapted version of a well-researched, easy-to-implement, evidence-based intervention. In particular, we aimed to assess whether patients on acute psychiatric wards who are being treated for different forms of severe mental illness (mainly psychosis but also depression, borderline personality disorder, and substance use disorder) would attend the offered sessions (and why they would not), whether they would view the treatment as useful, and whether they would experience any adverse events or symptom worsening related to their participation. Regarding safety, we not only assessed adverse events rated by clinical staff but also included subjective adverse events as side effects occur not only with pharmacological treatment but also with psychotherapy (Linden and Schermuly-Haupt, 2014). Thus, the pilot trial addressed the following hypotheses. We hypothesized that patients in an acute psychiatric inpatient setting would be willing to attend MCT-Acute sessions, that they would rate MCT-Acute as subjectively useful, and that there would be no severe subjective adverse events or unwanted events associated with participation in MCT-Acute. In addition, we hypothesized that patients' clinician-rated and self-rated overall symptom severity would decrease significantly and that patients' overall functioning would increase significantly over the course of the intervention period.

2 Materials and methods

2.1 Design

The trial was planned as an uncontrolled, observational pilot trial that included patients with severe mental disorders in an acute locked psychiatric setting. We decided against a controlled trial because a wait-list control design would not be feasible in this setting and there was no suitable control group program for this setting available. In addition, the trial's primary aim was to prove the feasibility and safety of the intervention. Patients could attend MCT-Acute sessions over a period of 3.5 weeks in addition to a standardized acute inpatient treatment program (including, e.g., psychopharmacotherapy and occupational therapy). Before the first group session (t0; baseline assessment), after two weeks of intervention (t1; interim assessment) and after four weeks of intervention (t2; post assessment), participants completed clinical interviews comprising self- and other-rated symptom assessments as well as questionnaires regarding the subjective utility and subjective adverse events of the intervention. Prior to their participation, all patients gave written informed consent. The University Medical Center Hamburg-Eppendorf's Ethics Committee for Psychological Studies approved the study (LPEK-0108); we preregistered the study in the German Clinical Trial Register (DRKS-ID: DRKS00020551). The preregistration included further measures that will be reported elsewhere as they do not immediately relate to the feasibility and safety of the intervention.

2.2 Setting

The trial was conducted at two sites: the Department of Psychiatry and Psychotherapy of the University Medical Center Hamburg-Eppendorf and the Department of Psychiatry and Psychotherapy of the Asklepios Clinic Hamburg North (both in Germany). The University Medical Center Hamburg-Eppendorf includes two locked inpatient units (crisis intervention wards) with 13 and 19 beds, respectively. The Department of Psychiatry and Psychotherapy of the Asklepios Clinic North also includes two locked inpatient units, each with 21 beds. The hospitals' catchment areas are urban areas with approximately 450,000 and 320,000 residents, respectively. All four locked acute inpatient psychiatric wards provide care for people with any psychiatric diagnosis that require intensive care to prevent harm, including suicidality or risk of aggression against others.

2.3 Sample

Patients were eligible for participation if they had a primary diagnosis of a severe mental disorder (diagnoses classified in the DSM-V or the ICD-10 F-codes), were expected to stay on the ward for at least two weeks, and were at least 18 years old. Exclusion criteria were insufficient command of the German language, intellectual disability, dementia, or inability to confirm consent with a legal guardian where applicable. Patients who were acutely intoxicated were not approached for participation until their intoxication had subsided. Patients admitted to one of the locked wards were screened soon after admission to determine whether they met the inclusion criteria, and eligible patients were approached by study staff regarding trial participation.

All patients received acute psychiatric standard treatment, including primarily psychopharmacotherapy (all participants were taking psychotropic medication; all but one [2.7%] were taking antipsychotic medication), as well as occupational and physical therapy, doctor's visits three times per week, one-on-one meetings with a psychologist up to twice a week for some patients, and, at one

of the hospitals, psychologist-led group interventions. Additionally, patients were offered the opportunity to take part in MCT-Acute up to two times per week (regardless of their participation in the study). We screened 1017 patients for participation and approached 138, 63 of whom declined participation and 75 of whom were assessed at baseline (see Figure 1). Of those assessed at baseline, seven patients did not participate in any MCT-Acute session. Of the remaining participants, 51 (75.0%) completed the assessment at two weeks and 38 (55.9%) also completed the assessment at four weeks. Whenever participants were unable to complete questionnaires themselves (e.g., due to difficulties concentrating or writing or due to circumstances such as lacking appropriate eyeglasses), they received support from the assessors (e.g., reading questions aloud, writing down participants' answers). Some participants were unable to complete all questionnaires, due, for example, to high symptom load or poor neurocognitive abilities.

2.4 Procedure

2.4.1 Intervention (MCT-Acute)

Two trainers delivered MCT-Acute on the locked acute wards of the two hospitals. Most trainers in this study were psychologists who had completed a master's degree and were currently undergoing postgraduate training in cognitive behavioral therapy; the other trainers were occupational therapists who worked on the respective

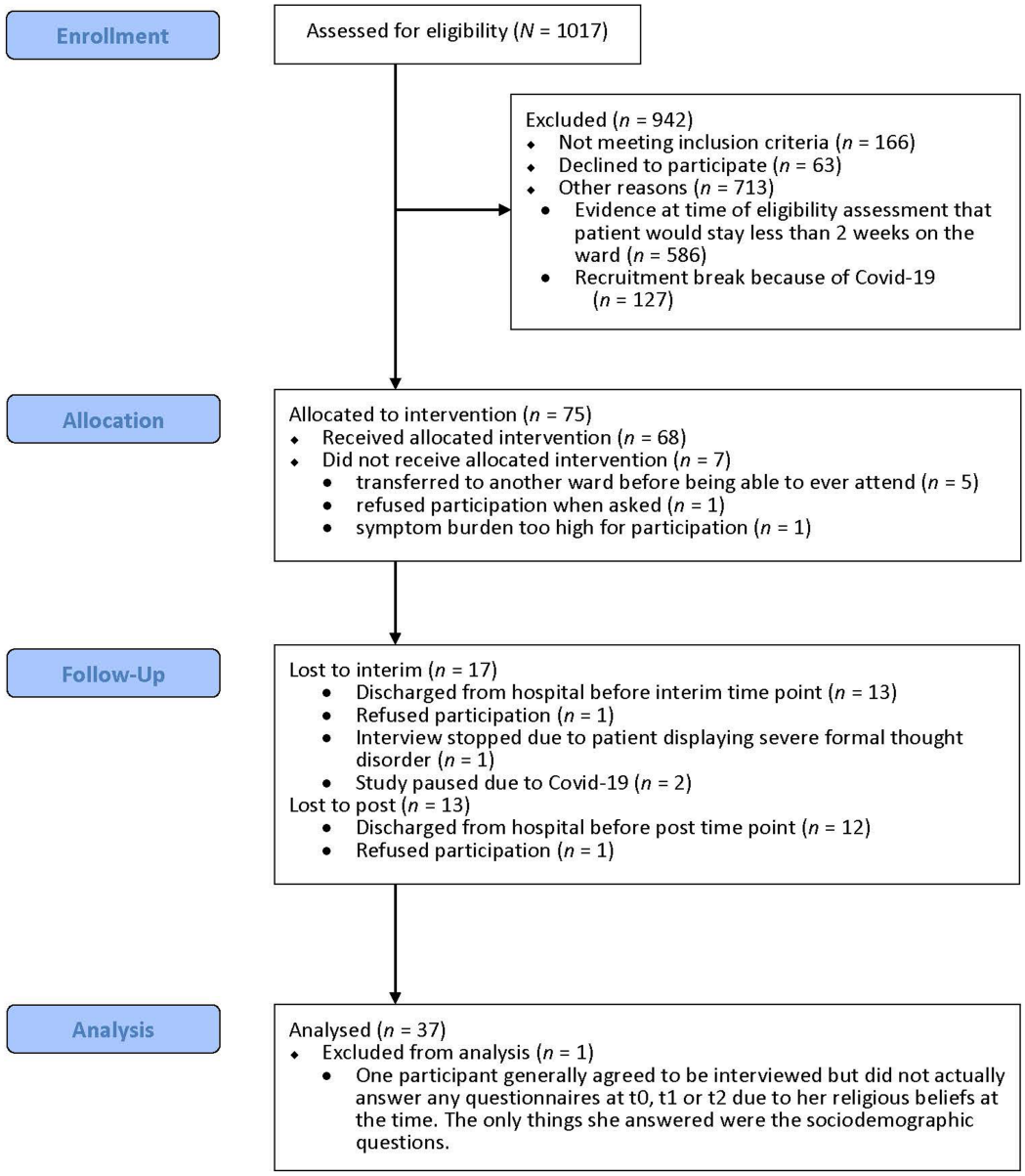


FIGURE 1
Flow diagram of participant inclusion.

wards. At least one psychologist was present during all sessions. Either RF or JS, the developers of MCT-Acute, was present at the majority of the training sessions ($n = 236$, 90.0% of all sessions). RF and JS both received training on MCT's delivery by its developer SM and have several years of experience delivering MCT for psychosis. All other therapists involved underwent the online training for MCT for psychosis offered by MCT's developers (see www.uke.de/e-mct) and received intensive one-on-one training by RF or JS. The training took place twice a week. Group size varied between two and nine patients. One cycle through all seven modules of MCT-Acute took 3.5 weeks to complete, although participants could continue participating after they had completed one cycle. The seven MCT-Acute modules address the following topics: *empathy, mood, attributional style, stigma, jumping to conclusions, coping strategies,* and *self-esteem*. We describe the adaptation process from the regular MCT for psychosis (Moritz and Woodward, 2007b) to MCT-Acute in detail in Fischer et al. (2022). All training material can be downloaded free of charge from www.uke.de/mct-acute.

2.4.2 Recruitment

Participants were consecutively recruited shortly after their admission to a locked inpatient ward. In addition to acute psychiatric standard treatment, they were invited to take part in MCT-Acute up to two times per week.

Patients provided written informed consent to participate in the study and then completed the baseline assessment (t0), the interim assessment two weeks later (t1), and the post assessment another two weeks later (t2). In addition, subjective utility, motivation to continue participation, and potentially negative events occurring during the sessions were assessed at the end of each session via a short, non-mandatory questionnaire (Post-Session Questionnaire).

2.5 Instruments

2.5.1 Acceptability of the intervention

We determined acceptance and feasibility of the intervention based on the number of attended sessions, reasons for missing sessions, and several feedback questionnaires regarding the intervention.

2.5.1.1 MCT-Acute feedback questionnaire

The MCT-Acute Feedback Questionnaire is based on a questionnaire previously used to evaluate MCT (Moritz and Woodward, 2007a,b). It is designed to capture general feelings, evaluations, and understanding of the participants regarding the MCT-Acute (e.g., *"The MCT-Acute was useful and sensible"*). The present version of the questionnaire comprises 12 quantitative items rated on a four-point Likert scale ranging from 0 ("I do not agree at all") to 3 ("I agree completely") and three open-ended items (see Appendix A1). It was administered at t1 and at t2.

2.5.1.2 Session-specific feedback

In addition to administering the feedback questionnaire at t1 and t2, we collected feedback at the end of each session using a brief 10-item questionnaire that included items such as "*MCT-Acute was fun*" and "*MCT-Acute confuses me*." The first seven items were answered on a three-point scale (from "rather agree" to "rather disagree"), while the last three items were open-ended (see Appendix A2). This questionnaire was handed out not only to study participants but also to other patients who attended the MCT-Acute group and agreed to give anonymous feedback.

2.5.2 Safety

2.5.2.1 Adapted questionnaire about side effects psychosis and internet

The Adapted-QueSPI (based on Rüegg et al., 2018) was adapted to assess potential subjective adverse events of the MCT-Acute at t1 and t2. After removal of items that were inappropriate for the current trial (e.g., "*I experienced technical difficulties that bothered me*"), the questionnaire comprised 13 quantitative items rated on a four-point Likert scale ranging from 0 ("I do not agree at all") to 3 ("I agree completely") as well as three open-ended items (see Appendix A3).

2.5.2.2 Unwanted events

Based on the Unwanted Events-Adverse Treatment Reactions Checklist (UE-ATR Checklist; Linden, 2013), we monitored the following unwanted events throughout the intervention period: prolongation of treatment, emergence of new symptoms, deterioration of symptoms, and strains in the patient-therapist relationship. We also monitored suicidal ideation and suicide attempts. We used the UE-ATR Checklist's relation to treatment rating scheme (1 = "unrelated to therapy," 5 = "extremely likely due to therapy"), but omitted the context of development and the severity ratings. We based ratings on the ward staff's clinical documentation of the patients' behavior on the ward.

2.5.3 Symptoms

We assessed patients' baseline psychopathology levels and monitored their symptom development throughout the intervention period to detect changes in symptoms across patients.

2.5.3.1 Brief psychiatric rating scale (4.0) expanded version

To assess baseline symptom levels, we administered the BPRS-E (Lukoff et al., 1986; Ventura et al., 1993) at t0, which is comprised of 24 items assessing the presence and severity of a variety of psychiatric symptoms. Its scale points range from 1 ("not present") to 7 ("extremely severe"), yielding sum scores between 24 and 168 with higher scores indicating more severe psychopathology.

2.5.3.2 Clinical global impressions scale

The CGI (Guy, 1976) is a clinician-rated scale that consists of a Severity (CGI-S) and an Improvement (CGI-I) scale. In the present study, the patient's treating psychiatrist or the head psychiatrist on the locked ward rated the CGI. The CGI-S reflects the clinician's assessment of the patient's present illness status in comparison with other patients from the same clinical population. The CGI-I assesses the improvement or worsening of the patient's condition since the previous rating. The CGI-S ranges in scores from 1 ("normal, not at all ill") to 7 ("among the most extremely ill patients"); the CGI-I ranges from 1 ("very much improved") to 7 ("very much worse").

2.5.3.3 Brief symptom inventory-18

The BSI-18 (German version: Spitzer et al., 2011) is a short form scale of the Symptom Checklist-90-Revised that measures psychological

stress symptoms during the past seven days. The inventory consists of 18 items that assess the three symptom subscales Somatization, Depression, and Anxiety. Each item is rated on a five-point Likert scale (0 = "not at all"; 4 = "extremely") based on patient reports.

2.5.3.4 Global assessment of functioning scale

The DSM-IV Axis V (GAF; American Psychiatric Association, 2000) assesses overall functioning on a scale from 100 ("superior functioning, no symptoms") to 1 ("extreme impairment").

2.6 Data analysis

As specified in the preregistration, only participants who had completed assessments at all three time points and who had participated in the intervention at least once ('completers') were considered for the final analysis ($N = 37$).

Measurement point t1 mainly served to ensure the presence of at least preliminary data in case too many included patients transferred out of the ward before the post-intervention measurement point t2. Thus, as subjective utility and subjective adverse events at t2 are based on more attended sessions than at t1 for many participants, we report here only the subjective utility ratings and subjective adverse events for t2. Ratings at t1 can be found in Appendices A4 and A5. For subjective utility and subjective adverse events, we focus here on the quantitative data (readers interested in the analysis of the qualitative data may contact the first author).

Clinician-rated symptoms and functioning were assessed by the acute ward's head physician or the patient's primary treating physician on the acute ward. Thus, whenever patients transferred to another ward or were discharged from the hospital entirely before t1 or t2, there were no CGI and GAF ratings available for t1 and/or t2. The GAF analysis was run twice; once using only the available data and once using the last observation carried forward method for data imputation.

To assess the acceptability and safety of the intervention, the number of attended sessions, subjective utility, session specific feedback and unwanted events were analyzed descriptively. Symptom improvement was analyzed both descriptively (CGI) and using repeated measures ANOVAs to assess significant changes in patient-rated symptoms (BSI-18) and clinician-rated overall functioning (GAF) over the course of study participation.

3 Results

As shown in Table 1, there was no statistically significant difference between completers vs. non-completers (patients who were assessed at t0 but did not complete all three assessments and/or did not participate in the intervention at least once) on any sociodemographic variable (all $p > 0.1$).

3.1 Acceptability of the intervention

3.1.1 Number of attended sessions and reasons for missing sessions

During their intervention period, participants could attend a maximum of seven sessions of MCT-Acute. On average, patients attended 3.6 sessions ($SD = 1.85$, range 1–7). Of the 259 total sessions, 133 were missed (51.4%). The reasons for missing sessions included participants being discharged from the ward ($X = 57$, 42.9%), declining participation in the session ($X = 40$, 30.1%), currently undergoing seclusion or restraint measures ($X = 12$, 9.0%), being asleep ($X = 11$, 8.3%), other appointments during a given session ($X = 9$, 6.8%), and being judged ineligible by staff for a given session due to acutely high symptomatology (e.g., severe agitation, disorganization; $X = 4$, 3.0%).

3.1.2 Subjective utility

Figure 2 shows participants' ratings of subjective utility at t2. Overall, participants reported mostly positive experiences with MCT-Acute; a majority fully endorsed that they would recommend MCT-Acute to others (64.9%; $n = 24$) and that they would have liked to have similar interventions to MCT-Acute on the ward (64.9%; $n = 24$). The majority of participants also disagreed with the statement "*My thinking is more confused*" (70.3%; $n = 26$). Subjective utility showed a large negative correlation with subjective adverse events related to the intervention ($r = -0.67$, $p < 0.001$, 95% CI [−0.83, −0.41]).

3.1.3 Session-specific feedback

Of those who attended a given module, 13.6% ($n = 3$; module 7) to 36.4% ($n = 12$; module 4) filled in a questionnaire at the end of the session. Across modules, most participants evaluated the sessions positively, largely rejecting the statement "*MCT-Acute confuses me*" ($X = 51$, 73.9%) and endorsing statements such as "*MCT-Acute was fun*" ($X = 61$, 89.7%; see Table 2). Specifically, only three individual participants endorsed the statement "*MCT-Acute confuses me*" (eight times in total across all modules). Internal consistency of the questionnaire using Cronbach's alpha was $\alpha = 0.55$.

3.2 Safety

3.2.1 Subjective adverse events during MCT-Acute (adapted-QueSPI; self-rating)

Mean endorsements of subjective adverse events did not significantly differ between t1 and t2. The number of subjective adverse events reported at t2 was available for 31 participants and ranged from zero ($n = 5$, 13.5%) to 12 ($n = 1$, 2.7%); on average, participants endorsed 3.1 subjective adverse events ($SD = 3.03$; median = 2). Table 3 shows how many participants endorsed each event. To varying degrees, participants most frequently critically appraised MCT-Acute for not sufficiently considering their personal needs or preferences (54.1%; $n = 20$), and because, after participation in MCT-Acute, they believed that taking medication was less important than they had previously thought (40.5%; $n = 15$). Internal consistency was good ($\alpha = 0.82$).

3.2.2 Unwanted events (clinician rating)

Overall, we recorded unwanted events for 17 participants (45.9%), 15 of whom experienced more than one unwanted event. We recorded extension of treatment for 15 patients, worsening of symptoms for nine, emergence of new symptoms for three, and suicidal ideation for one. All of these events (100%) were classified as

TABLE 1 Comparison between patients who were included in the final analysis (completers) and those who were not (non-completers).

	Completers ($n = 37$)	Non-completers ($n = 38$)	
	M (SD)	*M (SD)*	Statistics
Age	39.5 (14.0)	38.5 (11.8)	$t(73) = 0.34$, $p = 0.735$, $d = 0.079$
Primary education in years	11.1 (1.6)	10.7 (2.5)	$t(72) = 0.86$, $p = 0.394$, $d = 0.200$
BPRS baseline score	59.6 (19.9)	57.9 (13.5)	$t(56.456) = 0.40$, $p = 0.692$, $d = 0.099$
GAF baseline score	37.5 (9.1)	41.1 (10.9)	$t(55) = 1.39$, $p = 0.170$, $d = 0.259$
BSI-18 baseline score	19.6 (15.0)	15.2 (13.0)	$t(63) = 1.27$, $p = 0.208$, $d = 0.315$
	n (%)	*n* (%)	
Gender (female)	17 (45.9)	19 (50)	$\chi^2(1, N = 75) = 0.12$, $p = 0.725$, $V = 0.041$
Primary diagnosis			
Mental disorders due to a general medical condition	0	2 (5.3)	-
Substance-Related and Addictive Disorders	2 (5.4)	2 (5.3)	-
Schizophrenia Spectrum and other Psychotic Disorders	26 (70.3)	25 (65.8)	-
Bipolar and Related Disorders	6 (16.2)	8 (21.0)	-
Depressive Disorders	0	1 (2.6)	-
Trauma- and Stressor-Related Disorders	1 (2.7)	0	-
Personality Disorders	2 (5.4)	0	-
Number of previous admissions	$n = 35$	$n = 36$	-
0	3 (8.6)	6 (16.7)	$\chi^2(2, N = 71) = 3.31$, $p = 0.191$, $V = 0.216$
1 to 5	22 (62.9)	15 (41.7)	
6 or more	10 (28.6)	15 (41.7)	
Legal status of stay			
Voluntary	8 (21.6)	6 (15.8)	$\chi^2(2, N = 75) = 0.52$, $p = 0.773$, $V = 0.083$
Emergency mandatory admission	17 (45.9)	20 (52.6)	
Mandatory admission by legal guardian	12 (32.4)	12 (31.6)	

either unrelated (66.0%) or probably unrelated to the intervention (33.0%).

3.3 Symptoms

3.3.1 CGI (clinician rating)

CGI-Severity scores at t0 ranged from moderately ill ($n = 5$; 13.5%), to markedly ill ($n = 5$; 13.5%), to severely ill ($n = 18$; 48.6%), and finally to among the most extremely ill patients ($n = 6$, 16.2%). For three participants (8.1%), there was no CGI-S rating available.

CGI-Improvement ratings at t1 ranged from much improved ($n = 6$; 16.2%), to minimally improved ($n = 9$; 24.3%), to no change ($n = 14$; 37.8%), and finally to minimally worse ($n = 1$; 2.7%). For seven participants (18.9%), there was no CGI-I rating available at t1.

At t2, CGI-I ratings ranged from much improved ($n = 1$; 2.7%) to minimally improved ($n = 11$; 29.7%), to no change ($n = 9$; 24.3%), to minimally worse ($n = 1$; 2.7%), and finally to much worse ($n = 1$; 2.7%). For 14 participants (37.8%), there was no CGI-I rating available at t2.

Two of the participants got worse during their intervention period according to the clinician ratings. The participant whose

condition was minimally worse at t1 was also the participant whose condition was much worse at t2. His initial CGI-Severity rating was among the most extremely ill patients. The participant whose condition was minimally worse at t2 had also received an initial CGI-Severity rating of being among the most extremely ill patients. Neither patient's treating physician attributed their patient's worsening to their participation in MCT-Acute.

3.3.2 BSI-18 (self-rating)

Numerically, patients improved on the BSI-18 scale from t0 to t2. A repeated measures ANOVA using the Greenhouse–Geisser correction revealed a small sized difference in BSI-18 scores between time points that failed to reach significance ($F(1.371, 37.013) = 0.49$, $p = 0.546$, $\eta_p^2 = 0.018$). Internal consistency was excellent at all three time points ($\alpha_{t0} = 0.91$; $\alpha_{t1} = 0.91$; $\alpha_{t2} = 0.94$).

3.3.3 GAF (clinician rating)

GAF scores for all three time points were available for 21 of the participants. For these, a repeated measures ANOVA using the Greenhouse–Geisser correction determined that there was a large difference in GAF scores between time points, with scores increasing over time ($F(1.416, 28.311) = 17.79$, $p < 0.001$, $\eta_p^2 = 0.471$). Using the last observation carried forward method of data imputation, the repeated measures ANOVA using the

TABLE 2 End-of-session feedback summarized over all modules.

	Rather agree (%)	Neither agree nor disagree (%)	Rather disagree (%)	*n*
MCT-Acute was fun.	61 (89.7)	4 (5.9)	3 (4.4)	68
I am motivated to continue participating in MCT-Acute.	60 (87.0)	7 (10.1)	2 (2.9)	69
MCT-Acute helps me.	55 (83.3)	9 (13.6)	2 (3.0)	66
I learned something new during MCT-Acute.	51 (76.1)	10 (14.9)	6 (9.0)	67
MCT-Acute gives me hope for the future.	46 (69.7)	17 (25.8)	3 (4.5)	66
MCT-Acute reduces my health complaints.	35 (54.7)	22 (34.4)	7 (10.9)	64
MCT-Acute confuses me.	8 (11.6)	10 (14.5)	51 (73.9)	69

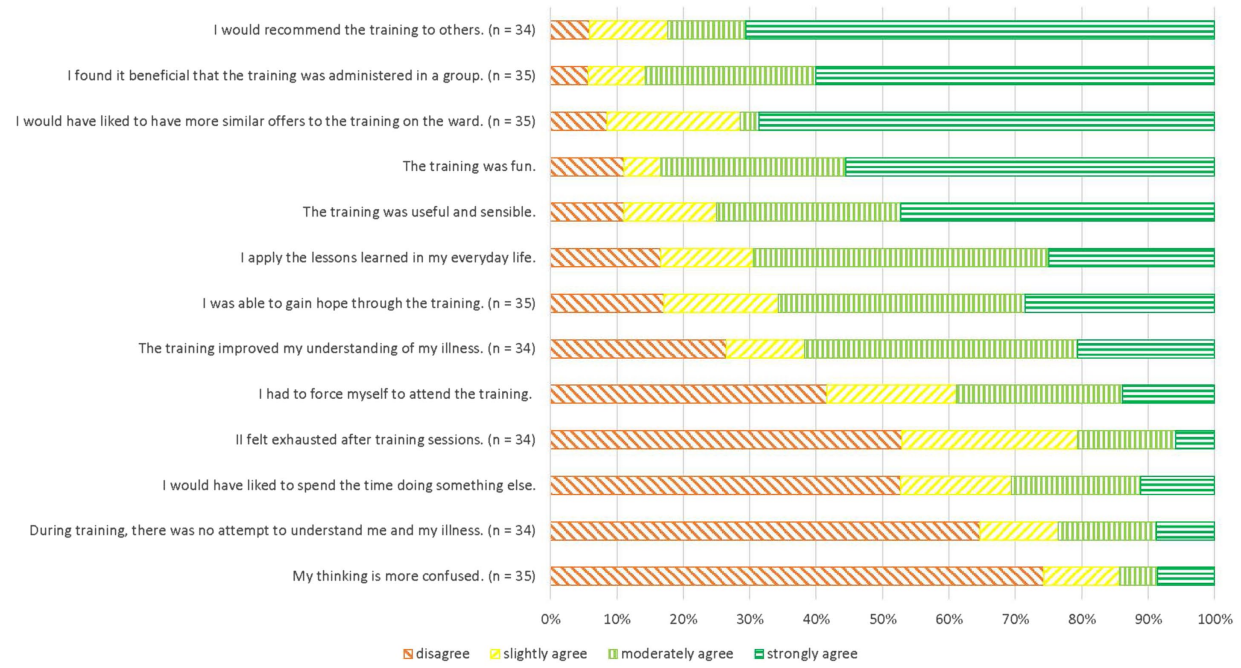


FIGURE 2
Acceptability of MCT-Acute at t2 in descending order of agreement.

TABLE 3 Self-rated side effects at post intervention (t2).

Item	*M* (*SD*)	I do not agree at all (%)	I slightly agree (%)	I moderately agree (%)	I completely agree (%)
MCT-Acute did not sufficiently address my personal needs. ($n = 35$)	1.2 (1.3)	15 (42.9)	7 (20)	3 (8.6)	10 (28.6)
Because of participating in MCT-Acute, I believe that taking medication is less important than I thought before participation. ($n = 33$)	0.9 (1.1)	18 (54.5)	6 (18.2)	4 (12.1)	5 (15.2)
MCT-Acute makes me feel like I am responsible for my problems. ($n = 35$)	0.5 (0.9)	23 (65.7)	6 (17.1)	5 (14.3)	1 (2.9)
My hope of improvement due to MCT-Acute was disappointed. ($n = 35$)	0.6 (1.1)	25 (71.4)	4 (11.4)	1 (2.9)	5 (14.3)
I often did not understand what MCT-Acute tried to tell me. ($n = 34$)	0.5 (1.0)	25 (73.5)	4 (11.8)	2 (5.9)	3 (8.8)
MCT-Acute makes me feel abnormal. ($n = 33$)	0.4 (0.7)	25 (75.8)	5 (15.2)	2 (6.1)	1 (3)
Participation in MCT-Acute reduced my interest to participate in a psychotherapy with personal contact. ($n = 34$)	0.5 (0.9)	26 (76.5)	2 (5.9)	4 (11.8)	2 (5.9)
MCT-Acute overwhelmed me with its abundance of information. ($n = 35$)	0.4 (0.9)	27 (77.1)	3 (8.6)	3 (8.6)	2 (5.7)
I feared that MCT-Acute could increase my symptoms. ($n = 34$)	0.3 (0.8)	28 (82.4)	3 (8.8)	1 (2.9)	2 (5.9)
MCT-Acute has triggered me to lose faith in psychotherapy in general. ($n = 34$)	0.3 (0.7)	28 (82.4)	4 (11.8)	1 (2.9)	1 (2.9)
The participation in MCT-Acute caused me to have more conflicts with others.($n = 34$)	0.2 (0.6)	28 (82.4)	4 (11.8)	2 (5.9)	0 (0)
The participation in MCT-Acute has put pressure on me. ($n = 34$)	0.2 (0.7)	29 (85.3)	3 (8.8)	1 (2.9)	1 (2.9)

Greenhouse–Geisser correction still found a large increase in GAF scores over time ($F(1.332, 47.943) = 20.44$, $p < 0.001$, $\eta_p^2 = 0.362$).

3.4 Correlations between outcomes

There were no other significant correlations between outcomes (see Appendix A6).

4 Discussion

We assessed the feasibility, acceptability and safety of the Metacognitive Training version adapted for the acute inpatient care setting (MCT-Acute). A sample of 37 patients on closed wards, the majority of whom were classified as at least severely ill, were assessed at baseline and then two weeks and four weeks later. Participants evaluated MCT-Acute positively, the majority stating that they would recommend the training to others and that they would have liked more therapeutic interventions similar to it offered on the ward. Negative subjective evaluations mostly concerned MCT-Acute not addressing participants' individual needs sufficiently. As symptoms decreased across the sample throughout the intervention period, we deem the intervention safe for application in the acute ward setting.

Overall, patients took part in about half of the sessions they could have attended during their intervention period, resulting in an average of three attended sessions per participant, similar to Paterson et al. (2019). The majority of missed sessions in the present study were missed not because of the patients' direct choice but, for example, because they were released from the ward early (42.9%). Fife et al. (2019) also found discharge from the ward to be the most common reason for not attending their group (45%). In only 15.4% of all sessions, patients directly declined participation in MCT-Acute. Reasons for this included participants not feeling well on a given day, conflicts with other patients who might be attending the group, other appointments (e.g., with a social worker), or visits from family and were similar to those described in other interventions in the acute setting (e.g., Heriot-Maitland et al., 2014; Fife et al., 2019).

The subjective utility of MCT-Acute was high and comparable to that of Metacognitive Training for patients with psychosis (Moritz and Woodward, 2007b) and of MCT for other disorders such as depression (Jelinek et al., 2017) or OCD (Jelinek et al., 2018). What is new about MCT-Acute is that it specifically targets patients who are in a highly acute crisis and/or are experiencing severe symptoms. With this, MCT-Acute aims to fulfill both, patients' need for more therapeutic interactions (Wood and Alsawy, 2016) as well as researchers' calls for documenting adaptations of psychological therapies to acute inpatient care (Jacobsen et al., 2020). In particular, the high endorsement of the

statement "I would have liked more similar offers to this one on the ward" (64.9%) shows that patients are open to participating in psychological therapies during the acute stage of illness. Patients' ability to judge an intervention's usefulness and their ability to participate in it constitutes an important determinant of patient engagement with psycho social interventions (Raphael et al., 2021b). This is an encouraging result for the continued adaptation of evidence-based psychological therapies to the acute setting.

In recent years, several other psychological/non-pharmacological interventions have been developed for the acute setting and examined in clinical trials. These interventions target a variety of therapeutic aims, including reducing specific symptoms such as self-harm or psychotic symptoms as well as targeting dysfunctional processing and high levels of arousal more generally. The interventions also vary regarding their target populations (e.g., patients with psychosis vs. transdiagnostic) and their mode of delivery (individual, group, or combined approaches). For instance, Fife et al. (2019) examined a DBT-based group intervention focused on self-harm and crisis management strategies regarding feasibility. The authors used content analysis to show that their participants viewed the strategies they were taught in the program to be helpful (Fife et al., 2019). Both Paterson et al. (2019) and Bullock et al. (2021) examined therapeutic approaches based on the comprehend, cope and connect approach (CCC; Clarke and Nicholls, 2018), which grants participants the opportunity to express their emotions, understand the context of their current crisis better, and strengthen self-efficacy. Paterson et al. (2019) reported descriptive statistics showing small readmission rate differences between the intervention and a TAU control group and small to moderate differences regarding certain psychological distress and self-efficacy measures post-intervention. Bullock et al. (2021) found significantly increased mood ratings post- vs. pre-intervention as well as a high mean post-intervention helpfulness rating as indicators of acceptability. Trials examining psychosis-specific non-pharmacological interventions in the acute care setting include Jacobsen et al. (2020) who compared a mindfulness-based crisis intervention (MBCI) with an active control condition (social activity therapy). Their main outcome, readmission rate, was similar across groups at 6 months' follow-up and lower in the intervention group at 12 months' follow-up. Thus, despite the various challenges to conducting research on non-pharmacological interventions in the acute inpatient psychiatric setting, the body of literature is increasing, particularly within the last few years, and the present trial contributes to building a more solid scientific basis for such interventions.

Concerns that psychosocial interventions may not be sufficiently understood by patients or that they may be too distressing constitute barriers to the implementation of such interventions (Raphael et al., 2021b), so at the end of each session we assessed whether patients were confused by MCT-Acute. Only three participants endorsed feeling confused after one or more sessions of the intervention, with the majority reporting they were able to follow the training. At the same time, in 89.7% of the questionnaires that were completed, participants indicated that the intervention was fun, which is similar to results from other MCT interventions (e.g., Jelinek et al., 2017).

Although the number of subjective adverse events reported ranged from zero to 12, the majority of participants reported 3 or fewer events. The most frequently voiced critique, that MCT-Acute did not sufficiently address a participant's personal needs or preferences, is a commonly voiced argument against group therapy (Shechtman and Kiezel, 2016). However, some patients also mention that they prefer group therapy because it allows them to share experiences with other group members (Osma et al., 2019). Practitioners agree that establishing a sense of sharing and belonging to a collective, as well as learning from other participants, are among the key advantages of the group setting which may outweigh drawbacks such as the inevitable lack of individualization (Kealy and Kongerslev, 2022) and lack of privacy as well as participants' fear of criticism from others (Osma et al., 2019; Raphael et al., 2021b).

The definition of unwanted events and whether they involve statements about causality vary considerably across clinical trials, particularly those assessing psychotherapy (Klatte et al., 2022). In trials in the acute setting, adverse events, including events related to investigating psychological therapies and/or the acute setting specifically, are common but mostly occur independent of participation in the investigated intervention (e.g., Paterson et al., 2019; Jacobsen et al., 2020). Thus, the reported adverse events recorded in this trial (e.g., extension of stay, worsening of symptoms) were expected. Importantly, based on the ward staff's ratings, none of the reported unwanted events were directly associated with participation in MCT-Acute. Similarly, based on the judgment of the ward's head psychiatrist or the patients' treating psychiatrist (CGI) only two participants' conditions became significantly worse during the intervention period; neither of these cases were related to the intervention, in the psychiatrists' opinion. Similarly, self-rated symptoms and clinician-rated psychosocial functioning improved across patients throughout the intervention period. These results are encouraging as they support the perspective that psychological interventions in the acute setting are not harmful to patients but may, in fact, aid with problem formulation, stress reduction, and fostering hope. (Donaghay-Spire et al., 2016).

4.1 Limitations

The present study has several limitations, such as a comparatively small sample size and the high number of patients who dropped out of the study and were therefore not analyzed further. High patient fluctuation and challenges in recruiting acutely ill patients suffering from severe mental illness for studies in acute psychiatric settings are common. For the present study, assessments could still be conducted when patients were transferred to another ward and were even offered online for patients to complete at home after they had been discharged from the hospital. Still, the present sample was most likely skewed toward the more severely ill patients as by far the most frequent reason for dropout was discharge from the hospital due to sufficient stabilization. As many studies have shown the feasibility of Metacognitive Training programs for moderately acutely ill patients, the likely bias within the present sample does not take away from the finding that MCT-Acute is feasible and safe for severely acutely ill patients. Average attendance rates were low for multiple reasons (e.g., being discharged from the ward early) but were comparable to other studies (Paterson et al., 2019). Another limitation is that we did not include a control group, and we assessed transdiagnostic (global) symptom severity rather than disorder-specific symptoms. In addition, based on the study design, we cannot discern the impact that MCT-Acute had on patients' symptom development as opposed

to the impact of the various other therapies that constitute the treatment as usual on acute wards. As assessment of safety rather than symptom improvement was the aim of this study, we can conclude that stabilization and improvement, regardless of underlying causes, constitute a positive outcome. Since the majority of participants had a diagnosis of schizophrenia spectrum disorder or bipolar disorder, the generalizability of our results to other disorders that patients frequently present with on an acute ward, such as depression and borderline personality disorder, is limited. However, there was no indication that MCT-Acute might be less feasible or safe to conduct with patients who suffer from these disorders. This trial demonstrates that MCT-Acute is feasible and safe as well as valued by patients, countering the broad skepticism regarding conducting any type of psychological individual or group therapy with severely acutely ill patients (Evlat et al., 2021; Raphael et al., 2021b).

4.2 Clinical implications

MCT-Acute is a highly standardized and easy-to-implement intervention. Our results add to the growing body of literature on psychologically informed interventions for the acute setting that demonstrates the feasibility of specifically tailored, flexibly administered programs that take into account patients' particular needs during the acute phase. MCT-Acute enables practitioners to deliver an intervention based on well-researched cognitive mechanisms that is well accepted by patients, even during the acute stage of illness.

4.3 Future research

Researchers should conduct a larger MCT-Acute trial, including a control group, to examine positive symptoms as well as cognitive bias measures pre and post intervention in order to replicate MCT's mechanism of action. In order to increase the sample size and to address the number of drop-outs due to discharge from the hospital, future studies should increase efforts to reach patients at the later assessment time points, e.g., by using monetary incentives and by emphasizing the possibility of conducting assessments via phone from home. To recruit more patients with non-psychosis diagnoses, researchers might consider offering participation in MCT-Acute even after patients have left the locked acute ward. This would also attenuate the inherent selection bias toward more severely impaired patients who are likely to stay longer on acute wards.

5 Conclusion

Patients experiencing acute exacerbations of mental illness value the opportunity to participate in interventions such as MCT-Acute on their acute psychiatric ward, mirroring prior reports that patients with severe mental illness are open to psychotherapeutic treatment. The lack of evidence-based interventions tailored specifically for this setting, together with our finding that MCT-Acute is acceptable and feasible, demonstrates that more research and efforts should be devoted to the development of psychosocial treatment options during acute mental health crises. As an easy-to-implement, freely available intervention program, MCT-Acute can represent one component of a biopsychosocial treatment plan for patients on acute psychiatric wards.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Ethics statement

The studies involving humans were approved by the University Medical Center Hamburg-Eppendorf's Ethics Committee for Psychological Studies. The studies were conducted in accordance with the local legislation and institutional requirements. The participants provided their written informed consent to participate in this study.

Author contributions

RF, JS, SM, and MN conceived and planned the project. RF, JS, and FL carried out the study. SM and MN supervised the project. DS and DL helped supervise the project. RF wrote the manuscript with support from JS, SM, MN, DS, DL, and FL. All authors contributed to the article and approved the submitted version.

Funding

This study was funded in part by Asklepios proresearch (grant number: 3902). The funding organization did not interfere with the design or execution of the study nor with the collection, management, analysis, or interpretation of the data. No other funds were received. We acknowledge financial support from the Open Access Publication Fund of UKE - Universitätsklinikum Hamburg-Eppendorf and DFG – German Research Foundation.

Acknowledgments

The authors would like to thank Rebecca Westphal and Charlotte Osthues for their help in study organization and recruitment, as well as Patric Duletzki, Simon Kirchhof, Patricia Rietzler, Josephine Kresnik, Jenny Hoeck, Isabel Murach, Lina Jallalvand and Ida Schultze-Kalthoff for their support in delivering the intervention. The authors would further like to thank Roland Garbella and Frank Oelkers for conducting psychopathological assessments. Finally, we would like to thank all the participants for the trust that they put in us, the time they spent with us and the valuable insights and information they provided us with.

Conflict of interest

MCT-Acute was developed by RF, SM and JS. JS and RF teach paid workshops on Metacognitive Training.

The remaining authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Any product that may be evaluated in this article, or claim that may be made by its manufacturer, is not guaranteed or endorsed by the publisher.

Publisher's note

All claims expressed in this article are solely those of the authors and do not necessarily represent those of their affiliated organizations, or those of the publisher, the editors and the reviewers.

Supplementary material

The Supplementary material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpsyg.2023.1247725/full#supplementary-material

References

American Psychiatric Association (2000) *Diagnostic and statistical manual of mental disorders* Virginia: American Psychiatric Association.

American Psychiatric Association (APA) (2020) *The American Psychiatric Association practice guideline for the treatment of patients with schizophrenia*, Virginia: American Psychiatric Association.

Bai, W., Liu, Z. H., Jiang, Y. Y., Zhang, Q. E., Rao, W. W., Cheung, T., et al. (2021). Worldwide prevalence of suicidal ideation and suicide plan among people with schizophrenia: a meta-analysis and systematic review of epidemiological surveys. *Trans. Psych.* 11:552. doi: 10.1038/s41398-021-01671-6

Barnicot, K., Michael, C., Trione, E., Lang, S., Saunders, T., Sharp, M., et al. (2020). Psychological interventions for acute psychiatric inpatients with schizophrenia-spectrum disorders: a systematic review and meta-analysis. *Clin. Psychol. Rev.* 82:101929. doi: 10.1016/J.CPR.2020.101929

Bentall, R. P., Kaney, S., and Dewey, M. E. (1991). Paranoia and social reasoning: an attribution theory analysis. *Br. J. Clin. Psychol.* 30, 13–23. doi: 10.1111/J.2044-8260.1991.TB00915.X

Bentall, R. P., Kinderman, P., and Kaney, S. (1994). The self, attributional processes and abnormal beliefs: towards a model of persecutory delusions. *Behav. Res. Ther.* 32, 331–341. doi: 10.1016/0005-7967(94)90131-7

Berry, K., Raphael, J., Wilson, H., Bucci, S., Drake, R. J., Edge, D., et al. (2022). A cluster randomised controlled trial of a ward-based intervention to improve access to psychologically-informed care and psychological therapy for mental health in-patients. *BMC Psychiatry* 22:82. doi: 10.1186/s12888-022-03696-7

Bowers, L., Alexander, J., Bilgin, H., Botha, M., Dack, C., James, K., et al. (2014). Safewards: the empirical basis of the model and a critical appraisal. *J. Psychiatr. Ment. Health Nurs.* 21, 354–364. doi: 10.1111/jpm.12085

Bullock, J., Whiteley, C., Moakes, K., Clarke, I., and Riches, S. (2021). Single-session comprehend, cope, and connect intervention in acute and crisis psychology: a feasibility and acceptability study. *Clin. Psychol. Psychother.* 28, 219–225. doi: 10.1002/cpp.2505

Castillejos, M. C., Huertas, P., Martín, P., and Moreno Küstner, B. (2020). Prevalence of suicidality in the European general population: a systematic review and Meta-analysis. *Arch. Suicide Res.* 25, 810–828. doi: 10.1080/13811118.2020.1765928

Clarke, I., and Nicholls, H. (2018) *Third wave CBT integration for individuals and teams: Comprehend, cope and connect*. London: Routledge.

de Vries, B., van Busschbach, J. T., van der Stouwe, E. C., Aleman, A., van Dijk, J. J., Lysaker, P. H., et al. (2019). Prevalence rate and risk factors of victimization in adult patients with a psychotic disorder: a systematic review and meta-analysis. *Schizophrenia bulletin*, 45, 114–126. doi: 10.1093/schbul/sby020

Donaghay-Spire, E. G., McGowan, J., Griffiths, K., and Barazzone, N. (2016). Exploring narratives of psychological input in the acute inpatient setting. *Psychol. Psychother. Theory Res. Pract.* 89, 464–482. doi: 10.1111/papt.12081

Dudley, R., Taylor, P., Wickham, S., and Hutton, P. (2016). Psychosis, delusions and the "jumping to conclusions" reasoning bias: a systematic review and meta-analysis. *Schizophr. Bull.* 42, 652–665. doi: 10.1093/SCHBUL/SBV150

Eichner, C., and Berna, F. (2016). Acceptance and efficacy of metacognitive training (MCT) on positive symptoms and delusions in patients with schizophrenia: a Meta-analysis taking into account important moderators. *Schizophr. Bull.* 42, 952–962. doi: 10.1093/schbul/sbv225

Eisenacher, S., and Zink, M. (2017). Holding on to false beliefs: the bias against disconfirmatory evidence over the course of psychosis. *J. Behav. Ther. Exp. Psychiatry* 56, 79–89. doi: 10.1016/J.JBTEP.2016.08.015

Evlat, G., Wood, L., and Glover, N. (2021). A systematic review of the implementation of psychological therapies in acute mental health inpatient settings. *Clin. Psychol. Psychother.* 28, 1574–1586. doi: 10.1002/cpp.2600

Fife, S., Blumenfeld, F., Williams, C., and Wood, L. (2019). A feasibility study highlighting challenges in evaluating a structured, psychological treatment for self-harm in adult psychiatric inpatient settings. *Psychiatry Res.* 282:112609. doi: 10.1016/j.psychres.2019.112609

Fischer, R., Scheunemann, J., Bohlender, A., Duletzki, P., Nagel, M., and Moritz, S. (2022). "You are trying to teach us to think more slowly!": adapting metacognitive training for the acute care setting—a case report. *Clin. Psychol. Psychother.* 29, 1877–1885. doi: 10.1002/CPP.2755

Garety, P. A., Hemsley, D. R., and Wessely, S. (1991). Reasoning in deluded schizophrenic and paranoid patients. Biases in performance on a probabilistic inference task. *J. Nerv. Ment. Dis.* 179, 194–201. doi: 10.1097/00005053-199104000-00003

Gehlenborg, J., Bücker, L., Berthold, M., Miegel, F., and Moritz, S. (2021). Feasibility, acceptance, and safety of metacognitive training for problem and pathological gamblers (gambling-MCT): a pilot study. *J. Gambl. Stud.* 37, 663–687. doi: 10.1007/S10899-020-09975-W

Guy, W. (1976) Clinical Global Impressions, Assessment manual for Psychopharmacology, *ECDEU assessment manual for psychopharmacology*. In: ed W Guy. Rockville: National Institute of Mental Health. 218–22.

Heriot-Maitland, C., Vidal, J. B., Ball, S., and Irons, C. (2014). A compassionate-focused therapy group approach for acute inpatients: feasibility, initial pilot outcome data, and recommendations. *Br. J. Clin. Psychol.* 53, 78–94. doi: 10.1111/BJC.12040

Jacobsen, P., Peters, E., Robinson, E. J., and Chadwick, P. (2020). Mindfulness-based crisis interventions (MBCI) for psychosis within acute inpatient psychiatric settings; a feasibility randomised controlled trial. *BMC Psych.* 20:193. doi: 10.1186/s12888-020-02608-x

Jelinek, L., Moritz, S., and Hauschildt, M. (2017). Patients' perspectives on treatment with metacognitive training for depression (D-MCT): results on acceptability. *J. Affect. Disord.* 221, 17–24. doi: 10.1016/j.jad.2017.06.003

Jelinek, L., Otte, C., Arlt, S., and Hauschildt, M. (2013). Denkverzerrungen erkennen und korrigieren: Eine Machbarkeitsstudie zum Metakognitiven Training bei Depression (D-MKT). *Zeitschrift fur Psychiatrie, Psychologie und Psychotherapie* 61, 247–254. doi: 10.1024/1661-4747/A000167

Jelinek, L., Peth, J., Runde, A., Arlt, S., Scheunemann, J., and Gallinat, J. (2021). Metacognitive training for depression: feasibility, safety and acceptability of two new treatment modules to reduce suicidality. *Clin. Psychol. Psychother.* 28, 669–681. doi: 10.1002/CPP.2529

Jelinek, L., Zielke, L., Hottenrott, B., Miegel, F., Cludius, B., Sure, A., et al. (2018). Patients' perspectives on treatment with metacognitive training for OCD. *Zeitschrift für Neuropsychologie* 29, 20–28. doi: 10.1024/1016-264X/a000xxx

Johnson, S., Dalton-Locke, C., Baker, J., Hanlon, C., Salisbury, T. T., Fossey, M., et al. (2022). Acute psychiatric care: approaches to increasing the range of services and improving access and quality of care 21, 220–236. doi: 10.1002/wps.20962

Kaney, S., and Bentall, R. P. (1989). Persecutory delusions and attributional style. *Br. J. Med. Psychol.* 62, 191–198. doi: 10.1111/J.2044-8341.1989.TB02826.X

Kealy, D., and Kongerslev, M. T. (2022). Structured group psychotherapies: advantages, challenges, and possibilities. *J. Clin. Psychol.* 78, 1559–1566. doi: 10.1002/jclp.23377

Klatte, R., Strauss, B., Flückiger, C., Färber, F., and Rosendahl, J. (2022). Defining and assessing adverse events and harmful effects in psychotherapy study protocols: a systematic review. *Psychotherapy* 60, 130–148. doi: 10.1037/pst0000359

Linden, M. (2013). How to define, find and classify side effects in psychotherapy: from unwanted events to adverse treatment reactions. *Clin. Psychol. Psychother.* 20, 286–296. doi: 10.1002/CPP.1765

Linden, M., and Schermuly-Haupt, M. L. (2014). Definition, assessment and rate of psychotherapy side effects. *World Psychiatry* 13, 306–309. doi: 10.1002/wps.20153

Liu, Y. C., Tang, C. C., Hung, T. T., Tsai, P. C., and Lin, M. F. (2018). The efficacy of metacognitive training for delusions in patients with schizophrenia: a Meta-analysis of randomized controlled trials informs evidence-based practice. *Worldviews Evid.-Based Nurs.* 15, 130–139. doi: 10.1111/WVN.12282

Lukoff, D., Nuechterlein, K. H., and Ventura, J. (1986). Manual for the expanded brief psychiatric rating scale. *Schizophr. Bull.* 12, 594–602.

Marcus, S. C., Hermann, R. C., and Cullen, S. W. (2021). Defining patient safety events in inpatient psychiatry. *J. Patient Saf.* 17, E1452–E1457. doi: 10.1097/PTS.0000000000000520

McLean, B. F., Mattiske, J. K., and Balzan, R. P. (2017). Association of the Jumping to conclusions and evidence integration biases with delusions in psychosis: a detailed Meta-analysis. *Schizophr. Bull.* 43, sbw056–sbw354. doi: 10.1093/SCHBUL/SBW056

Miegel, F., Demiralay, C., Sure, A., Moritz, S., Hottenrott, B., Cludius, B., et al. (2022). The metacognitive training for obsessive-compulsive disorder: a pilot study. *Curr. Psychol.* 41, 7114–7124. doi: 10.1007/S12144-020-01158-5

Moritz, S., Pfuhl, G., Lüdtke, T., Menon, M., Balzan, R. P., and Andreou, C. (2017). A two-stage cognitive theory of the positive symptoms of psychosis. Highlighting the role of lowered decision thresholds. *J. Behav. Ther. Exp. Psychiatry* 56, 12–20. doi: 10.1016/j.jbtep.2016.07.004

Moritz, S., and Woodward, T. S. (2007a). Metacognitive training for schizophrenia patients (MCT): a pilot study on feasibility, treatment adherence, and subjective efficacy. *Germ. J. Psych.* 10, 69–78.

Moritz, S., and Woodward, T. S. (2007b). Metacognitive training in schizophrenia: from basic research to knowledge translation and intervention. *Curr. Opin. Psychiatry* 20, 619–625. doi: 10.1097/YCO.0B013E3282F0B8ED

Murphy, P., Bentall, R. P., Freeman, D., O'Rourke, S., and Hutton, P. (2018). The paranoia as defence model of persecutory delusions: a systematic review and meta-analysis. *Lancet Psychiatry* 5, 913–929. doi: 10.1016/S2215-0366(18)30339-0

National Institute for Health and Care Excellence (NICE) (2014) 'Psychosis and schizophrenia in adults: prevention and management Clinical guideline'. Available at: www.nice.org.uk/guidance/cg178 (accessed: May 28, 2023).

Odejimi, O., Bagchi, D., and Tadros, G. (2020). Typology of psychiatric emergency services in the United Kingdom: a narrative literature review. *BMC Psychiatry* 20:587. doi: 10.1186/s12888-020-02983-5

Osma, J., Suso-Ribera, C., Peris-Baquero, Ó., Gil-Lacruz, M., Pérez-Ayerra, L., Ferreres-Galan, V., et al. (2019). What format of treatment do patients with emotional disorders prefer and why? Implications for public mental health settings and policies. *PLoS One* 14:e0218117. doi: 10.1371/JOURNAL.PONE.0218117

Paterson, C., Karatzias, T., Harper, S., Dougall, N., Dickson, A., and Hutton, P. (2019). A feasibility study of a cross-diagnostic, CBT-based psychological intervention for acute mental health inpatients: results, challenges, and methodological implications. *Br. J. Clin. Psychol.* 58, 211–230. doi: 10.1111/bjc.12209

Penney, D., Sauvé, G., Mendelson, D., Thibaudeau, É., Moritz, S., and Lepage, M. (2022). Immediate and sustained outcomes and moderators associated with metacognitive training for psychosis: a systematic review and Meta-analysis. *JAMA Psych.* 79, 417–429. doi: 10.1001/JAMAPSYCHIATRY.2022.0277

Rains, L. S., Zenina, T., Dias, M. C., Jones, R., Jeffreys, S., Branthonne-Foster, S., et al. (2019). Variations in patterns of involuntary hospitalisation and in legal frameworks: an international comparative study. *The Lancet Psychiatry*, 6, 403–417. doi: 10.1016/S2215-0366(19)30090-2

Raphael, J., Hutchinson, T., Haddock, G., Emsley, R., Bucci, S., Lovell, K., et al. (2021a). A study on the feasibility of delivering a psychologically informed ward-based intervention on an acute mental health ward. *Clin. Psychol. Psychother.* 28, 1587–1597. doi: 10.1002/cpp.2597

Raphael, J., Price, O., Hartley, S., Haddock, G., Bucci, S., and Berry, K. (2021b). Overcoming barriers to implementing ward-based psychosocial interventions in acute inpatient mental health settings: a meta-synthesis. *Int. J. Nurs. Stud.* 115:103870. doi: 10.1016/j.ijnurstu.2021.103870

Rüegg, N., et al. (2018). An internet-based intervention for people with psychosis (EviBaS): study protocol for a randomized controlled trial. *BMC Psych.* 18, 1–12. doi: 10.1186/S12888-018-1644-8/TABLES/2

Ruud, T., and Friis, S., (2022). Continuity of care and therapeutic relationships as critical elements in acute psychiatric care. *World Psychiatry*, 21, 241. doi: 10.1002/wps.20966

Sashidharan, S. P., Mezzina, R., and Puras, D. (2019). Reducing coercion in mental healthcare. *Epidemiol. Psych. Sci.* 28, 605–612. doi: 10.1017/S2045796019000350

Sauvé, G., Lavigne, K. M., Pochiet, G., Brodeur, M. B., and Lepage, M. (2020). Efficacy of psychological interventions targeting cognitive biases in schizophrenia: a systematic review and meta-analysis. *Clin. Psychol. Rev.* 78:101854. doi: 10.1016/J.CPR.2020.101854

Saya, A., Brugnoli, C., Piazzi, G., Liberato, D., di Ciaccia, G., Niolu, C., et al. (2019). Criteria, procedures, and future prospects of involuntary treatment in psychiatry around the world: a narrative review. *Front. Psych.* 10:e00271. doi: 10.3389/fpsyt.2019.00271

Schilling, L., Moritz, S., Kriston, L., Krieger, M., and Nagel, M. (2018). Efficacy of metacognitive training for patients with borderline personality disorder: preliminary results. *Psychiatry Res.* 262, 459–464. doi: 10.1016/J.PSYCHRES.2017.09.024

Schneider, B., Bücker, L., Riker, S., Karamatskos, E., and Jelinek, L. (2018). Eine machbarkeitsstudie zum metakognitiven training bei depression (D-MKT) im alter. *Neuropsychologie* 29, 7–19. doi: 10.1024/1016-264X/A000210

Senior, M., Fazel, S., and Tsiachristas, A. (2020) 'Articles the economic impact of violence perpetration in severe mental illness: a retrospective, prevalence-based analysis in England and Wales'. Available at: www.thelancet.com/ (accessed: May 28, 2023).

Shechtman, Z., and Kiezel, A. (2016). Why do people prefer individual therapy over Group therapy? *Int. J. Group Psychother.* 66, 571–591. doi: 10.1080/00207284.2016.1180042

Spitzer, C., Hammer, S., Löwe, B., Grabe, H., Barnow, S., Rose, M., et al. (2011). Die Kurzform des Brief Symptom Inventory (BSI-18): erste Befunde zu den psychometrischen Kennwerten der deutschen Version. *Fortschritte der Neurologie Psychiatrie* 79, 517–523. doi: 10.1055/S-0031-1281602/BIB

Thornicroft, G. (2020). People with severe mental illness as the perpetrators and victims of violence: time for a new public health approach. *Lancet Public Health* 5, e72–e73. doi: 10.1016/S2468-2667(20)30002-5

Tondo, L., Vázquez, G. H., and Baldessarini, R. J. (2021). Prevention of suicidal behavior in bipolar disorder. *Bipolar disorders*. 23, 14–23. doi: 10.1111/bdi.13017

Tracy, D. K., and Phillips, D. M. (2022). What is good acute psychiatric care (and how would you know)?. *World Psychiatry*, 21, 166. doi: 10.1002/wps.20958

van Oosterhout, B., Krabbendam, L., de Boer, K., Ferwerda, J., van der Helm, M., Stant, A. D., et al. (2014). Metacognitive group training for schizophrenia spectrum patients with delusions: a randomized controlled trial. *Psychol. Med.* 44, 3025–3035. doi: 10.1017/S0033291714000555

Veckenstedt, R., Randjbar, S., Vitzthum, F., Hottenrott, B., Woodward, T. S., and Moritz, S. (2011). Incorrigibility, jumping to conclusions, and decision threshold in schizophrenia. *MoritzCognitive neuropsychiatry* 16, 174–192. doi: 10.1080/13546805.2010.536084

Ventura, J., et al. (1993). Manual for the expanded brief psychiatric rating scale. *Int. J. Methods Psychiatr. Res.* 3, 227–244.

Ward, T., and Garety, P. A. (2019). Fast and slow thinking in distressing delusions: a review of the literature and implications for targeted therapy. *Schizophr. Res.* 203, 80–87. doi: 10.1016/j.schres.2017.08.045

Wood, L., Alonso, C., Morera, T., and Williams, C. (2021). The evaluation of a highly specialist inpatient psychologist working with patients with high risk presentations in an acute mental health inpatient setting. *J. Psych. Intens. Care* 17, 29–40. doi: 10.20299/JPI.2020.019

Wood, L., and Alsawy, S. (2016). Patient experiences of psychiatric inpatient care: a systematic review of qualitative evidence. *J. Psych. Intens. Care* 12, 35–43. doi: 10.20299/JPI.2016.001

Wood, L., Jacobsen, P., Ovin, F., and Morrison, A. P. (2022). Key components for the delivery of cognitive behavioral therapies for psychosis in acute psychiatric inpatient settings: a Delphi study of therapists' views. *Schizophrenia Bulletin Open* 3;sgac005. doi: 10.1093/schizbullopen/sgac005

Woodward, T. S., Moritz, S., Cuttler, C., and Whitman, J. C. (2006). The contribution of a cognitive bias against disconfirmatory evidence (BADE) to delusions in schizophrenia. *J. Clin. Exp. Neuropsychol.* 28, 605–617. doi: 10.1080/13803390590949511

Yee, N., Matheson, S., Korobanova, D., Large, M., Nielssen, O., Carr, V., et al. (2020). A meta-analysis of the relationship between psychosis and any type of criminal offending, in both men and women. *Schizophrenia Research*, 220, 16–24. doi: 10.1016/j.schres.2020.04.009

Zhang, S., Mellsop, G., Brink, J., and Wang, X. (2015). Involuntary admission and treatment of patients with mental disorder. *Neurosci. Bull.* 31, 99–112. doi: 10.1007/S12264-014-1493-5/METRICS

frontiers | Frontiers in Psychology

TYPE Brief Research Report
PUBLISHED 13 December 2023
DOI 10.3389/fpsyg.2023.1292439

OPEN ACCESS

EDITED BY
Lara Guedes De Pinho,
University of Evora, Portugal

REVIEWED BY
Nenad Predrag Glumbić,
University of Belgrade, Serbia
Catherine Caldwell-Harris,
Boston University, United States
Sarah Rotschafer,
Mercer University, United States

*CORRESPONDENCE
Jennifer B. Grandits
✉ jbgrand@clemson.edu

RECEIVED 11 September 2023
ACCEPTED 27 November 2023
PUBLISHED 13 December 2023

CITATION
Grandits JB, Kent HW, Sanborn SM and Pilcher JJ (2023) The effect of compression on repetitive behaviors and task participation in children with autism spectrum disorder. *Front. Psychol.* 14:1292439. doi: 10.3389/fpsyg.2023.1292439

The effect of compression on repetitive behaviors and task participation in children with autism spectrum disorder

Jennifer B. Grandits*, Hanna W. Kent, Sarah M. Sanborn and June J. Pilcher

Department of Psychology, Clemson University, Clemson, SC, United States

Compression clothes are marketed to relieve anxiety and decrease hyperactivity in children with autism. However, few studies have examined the impact of compression for individuals with autism spectrum disorder (ASD). In this study, nine children with autism were observed during Applied Behavioral Analysis therapy sessions while wearing compression clothing. The participants were randomly assigned to wear compression clothing for either their first five sessions or their last five sessions. Videos of the therapy sessions were reviewed and each child's "off task" behavior was identified in the following domains: motor, verbal, and visual. In addition, frequency of the child's repetitive behaviors and external visual stimuli were recorded. The compression clothes failed to increase task participation or reduce the participants' repetitive behavior suggesting that the clothing may not contribute to professional practice of ABA therapy.

KEYWORDS

autism, compression, deep pressure therapy, repetitive behavior, applied behavior analysis

Introduction

Autism spectrum disorder (ASD) is a neurodevelopmental disorder that is associated with challenges involving social communication and restricted or repetitive behaviors (American Psychiatric Association, 2013). The Centers for Disease Control and Prevention estimates that 1 in 36 children are diagnosed with ASD and boys are four times more likely to be diagnosed than girls (Maenner et al., 2020). Within the ASD population, there is significant heterogeneity in symptoms (Hassan and Mokhtar, 2019).

One of the criteria for diagnosing ASD in the fifth edition of the Diagnostic and Statistical Manual (American Psychiatric Association, 2013) is the presence of restricted and repetitive behaviors (sometimes referred to as stereotypical behaviors). Repetitive behaviors are repetitive movements or sounds such as body rocking, spinning, hand flapping, head-nodding, echolalia (i.e., repeating sounds) and object tapping, among others (Rosenthal-Malek and Mitchell, 1997). ASD is diagnosed in the DSM 5 along with severity level. Determination of ASD severity is based on the degree of support required as a result of social communication impairments and restricted, repetitive patterns of behavior. When determining the degree of impairments related to restricted and repetitive patterns of behavior, clinicians are encouraged to evaluate hyper- or hyporeactivity to sensory input or unusual interest in sensory aspects of the environment (e.g., indifference to pain, adverse response to specific sounds or textures, excessive smelling or

touching of objects, visual fascination with lights or movement; American Psychiatric Association, 2013).

These repetitive behaviors vary among individuals and can change over time (Militerni et al., 2002). They are also shown to interfere with learning in children with ASD (Koegel and Covert, 1972). The cause for these mannerisms has yet to be determined, perhaps due to the large focus on the social deficits of ASD (Lewis and Bodfish, 1998).

One mechanism used to explain the presence of repetitive behaviors observed in ASD is that these behaviors are the product of operant conditioning (Lovaas et al., 1987). This explanation posits that the learned behaviors elicit some type of reinforcement, as a direct result of the behaviors themselves or due to the behaviors involvement in a particular setting (e.g., disengaging with an unpleasant stimulus).

Another suggested mechanism is that repetitive behaviors are used to regulate homeostasis. The homeostatic equilibrium theory suggests that all organisms tend to regulate their internal conditions. Some researchers have suggested that individuals with autism use repetitive (i.e., stereotypical) behaviors as a mode of regulating over or under arousal (Hodgetts et al., 2011). In this theory, children's behaviors are seen as serving the function of either activating or deactivating their endogenous system.

Other proposed mechanisms for repetitive behaviors in individuals with autism includes the presence of anxiety-related processes (Lovaas et al., 1971; Rodgers et al., 2012; Lidstone et al., 2014). For example, parents of children with autism report that higher levels of child anxiety correlate with higher levels of repetitive behaviors (Sukhodolsky et al., 2008). Similarly, in a study with adults on the spectrum, participants self-reported the primary function for their repetitive behavior was managing emotions such as stress, distress, and excitement (Lovaas et al., 1971; Manor-Binyamini and Schreiber-Divon, 2019).

It is important to note that recent literature and information from autistic self-advocates that these repetitive behaviors are important for autistic individuals to calm themselves or communicate feelings and this study is not intending to limit or "reduce" the presence of these movements (Kapp et al., 2019) rather to determine if compression garments may benefit the potential underlying causes (i.e., anxiety) in autistic individuals.

Therapies for children with ASD

One of the most common therapies recommended for individuals with autism is Applied Behavior Analysis (ABA) therapy. ABA therapy utilizes positive reinforcement to teach social skills, reduce maladaptive behaviors, and advance independent living skills. During ABA therapy sessions, therapists assess the child's needs and create an individualized plan, utilizing various techniques such as discrete trial training, natural environment training, and functional communication, to address specific behaviors. One survey of participants primarily from the United States suggested that over 50% of individuals with autism received some form of ABA therapy (Green et al., 2006). When introduced early, this therapy is an effective intervention for individuals with autism that addresses language and emotional skills, cognition, and maladaptive behavior (Smith et al., 1997; Orinstein et al., 2014; Vietze and Lax, 2020). Depending on the severity and type of symptoms, children with autism can be recommended various amounts of ABA support, ranging from 5 to 40 h of ABA therapy a week. To benefit the most from ABA therapy, individuals with ASD need to remain engaged with the content.

Individuals with autism often have difficulties staying on task and attending to information in educational and therapy settings (Patten and Watson, 2011). Compared to their typically developing peers, children with autism engage in less task participation (Hilton et al., 2008). However, little research has been conducted to identify strategies for better managing behaviors and task participation in education and therapy settings for individuals diagnosed with ASD. Most previous research has focused on problems with student motivation, teaching strategies, and ineffective consequences for academic behavior (Meindl et al., 2020). Few studies have examined the role that sensory sensitivities (or treatment of sensory sensitivities) play in therapy engagement.

Another common therapy used for individuals with ASD is sensory integration therapy (SIT). SIT is often offered in occupational therapy settings and includes exercises or activities that affect the sensory experience of the individual (Ayres, 2005). Common SIT therapies include deep pressure, joint compression, and weighted vests (Devlin et al., 2011). A recent review of evidence-based practices for individuals with ASD shows that the impact of SIT has been examined in the following domains: cognitive, communication, motor, social, academic performance, self-help, and challenging behaviors (Hume et al., 2021). However, there is on-going debate in the literature on the effectiveness of SIT in treating ASD (Schreck and Miller, 2010; Lang et al., 2012). Despite the debate in the scientific community, many parents with a child diagnosed with ASD have tried some type of SIT for their child. For example, in a large survey study examining common therapies for ASD, SIT was second only to ABA as the most commonly used treatment for ASD (Bowker et al., 2011).

A common form of SIT is deep pressure therapy (DPT). Deep pressure therapy includes massage, weighted vests, blankets, and compression clothing. There is some evidence that deep pressure therapy including hugging and massage leads to reduced anxiety and increased engagement in individuals with ASD (Edelson et al., 1999; Bestbier and Williams, 2017). DPT devices, like weighted vests, are thought to activate arousal by providing input in a similar manner to homeostatic function thus providing the increase or decrease in stimulation needed (Hodgetts et al., 2011). As children with autism often have difficulties with on-task participation and repetitive behaviors, DPT may affect arousal levels and therefore enhance attention and performance of children with autism (Turner, 1999).

Although weighted vests are currently used by many children on the spectrum, studies that examine the effectiveness of these instruments yield inconclusive results. One study with six children studied the effect that weighted vests had on heart rate and stereotypical behaviors (Hodgetts et al., 2011). Both heart rate and stereotypical behaviors were unchanged when wearing weighted vests. Similarly, weighted vests do not appear to decrease self-injury behaviors (Doughty and Doughty, 2008). Conversely, other studies found a positive impact of using weighted vests. Fertel-Daly et al. (2001) found that weighted vests led to an increase in attention and decrease in self-stimulatory behaviors in five children with pervasive developmental disorders. Additionally, they found that the weighted vest contributed to a decrease in distractibility.

Compression clothing is also marketed as a tool that provides a calming effect that helps individuals cope with sensory overstimulation. Yet, little research has been done to determine if

compression garments produce any effects on children with autism. To our knowledge, there are only two studies that have examined the effect of compression clothing. In a longitudinal study with 14 participants with ASD (7 children/adolescents with ASD and 7 adults with ASD), the researchers found that wearing compression clothing resulted in a significant decrease in challenging behaviors. Postural control and motor performance were also significantly improved (Guinchat et al., 2020). The second study examined the impact of compression vests in three children with ASD (Losinski et al., 2017). This study used an alternative treatment design with three experimental conditions, including a compression vest, a weighted blanket, and antecedent exercise, to determine their effects on stereotypical behavior and attention to task. The weighted blanket and compression vest did not have a significant effect on stereotypical behavior or attention (Losinski et al., 2017). Due to the limited number of studies and the small sample sizes that are often taken due to the demanding nature of the research, it is imperative that more research be conducted on the effectiveness of compression garments and to examine potential interaction effects between ABA therapy and deep pressure therapy.

The aim of the current study was to examine the clinical effectiveness of compression garments on task participation and repetitive behaviors in children with ASD during their regularly scheduled ABA therapy sessions. Based on the homeostatic equilibrium theory, we predicted that the compression clothing would reduce repetitive behaviors and decrease off-task behaviors. Additional exploratory analyses were conducted to examine whether compression clothing affected how external visual stimuli (e.g., non-therapist such as parents, siblings, etc.) impact repetitive behaviors and task participation.

Method

Participants

Nine children (six boys and three girls), between the ages of 4 and 12 ($M = 6.3$ yrs.; $SD = 2.5$), took part in the study. All participants were recruited through ABA service providers. Each child was diagnosed with autism spectrum disorder, as confirmed by their ABA service providers and parents.

Procedure

Before the study took place, a research assistant met with the family to answer questions, obtain informed consent from the parent and informed assent from the child, fit the child with the compression garments, and instruct the parents on how to dress their child for the therapy sessions. All children were provided with a long-sleeve compression shirt and a pair of long compression pants, from the brand Kozie Clothes, to wear during the study. The compression clothing consisted of 90% nylon and 10% spandex material with 4-way stretch. Both the shirt and pants were available to the participants in five sizes: XS, S, M, L, and XL. The largest shirt that clung firmly to the torso was considered an appropriate "fit" for the child's top. Pants were considered the appropriate size when fabric puckering was eliminated. Parents were asked to dress their child in the compression garments under their typical clothes for half of the therapy sessions. After receiving family consent, approval was obtained from the directors of the ABA clinics to video record the participants' therapy sessions. Their regular ABA therapists reported a list of repetitive behaviors that each child normally presented, and the researchers confirmed these behaviors when reviewing the videos (see Table 1). Participants did not receive compensation for taking part in the study.

A within-subject study design was used to observe the effects of compression clothing on attention and repetitive behaviors during 10 ABA therapy sessions. During half of the sessions, each participant wore compression shirts and pants. There were two groups in the study, group 1 ($n = 6$) wore compression clothes for their first five ABA therapy sessions and wore their typical clothing for the last five therapy sessions.[1] Group 2 ($n = 3$) wore

1 Due to variability in symptom severity, there was variability in the length of time that passed between therapy sessions among participants.

TABLE 1 Common repetitive behaviors and external stimuli for each participant.

Participant number	Common repetitive behaviors	Common external stimuli
Participant 1	Hand waving, rubbing face with hands, knocking on the table, and pursing lips together and blowing	Additional therapist
Participant 2	Rubbing various body parts with hands and feet.	Siblings and an additional therapist
Participant 3	Hand flapping, rubbing hands together, and bouncing legs.	No common external stimuli observed
Participant 4	Rocking, hand and feet flapping, pacing, spinning, and moving objects	Sibling
Participant 5	Hand flapping, leg bouncing, toe walking, humming, and moving head	Additional therapist
Participant 6	Rocking, bouncing in chairs, hand flapping, sucking air between her teeth, and screaming	No common external stimuli observed
Participant 7	Bringing objects close to eyes, hand flapping, rocking, rubbing hands on different objects (e.g., body parts, clothing) and waving hands	Family members and a cat
Participant 8	No reported repetitive behaviors*	Family members and an additional therapist
Participant 9	No reported repetitive behaviors*	Family members and an additional therapist

*Although there were no repetitive behaviors reported by ABA therapists that were consistent in nature across therapy sessions for participant 8 and 9, there were behaviors that met the current authors' definition of repetitive behaviors (i.e., repeated in 15 s, apparently purposeless, and not better explained by other movement disorders; Meindl et al., 2020). As with all participants, these behaviors (along with common or stereotyped behaviors) were included in the coding of repetitive behaviors.

their typical clothing for the first five ABA therapy sessions and the compression clothes for the last five sessions. Each participant was randomly assigned to either group 1 or group 2 using an online random number generator.[2] During each therapy session, the therapists were instructed to set up a video camera and tripod to record the first five minutes of the child's therapy session, 5 min in the middle of the child's therapy session, and 5 min at the end of the therapy session. Therapists were also instructed not to alter the child's therapy routine while filming. Sessions took place either at the participants' home or in an ABA clinic. Eight of the 9 participants engaged in their ABA therapy sessions in their homes and one participant's therapy took place in the clinic. This is consistent with previous research that documents most ABA therapy takes place in the home setting (Love et al., 2009). During the sessions, the children were filmed performing various tasks assigned by the therapist such as reading, practicing handwriting, answering questions, bouncing a ball, and numerous other activities.

Coding

In order to look at "off task" behavior, only therapy sessions where the child was given a task to complete by the therapist were coded (in order to ensure consistency across participants). All 5-min, video sessions were uploaded and coded through the software, Elan. For each video, visual off-task behaviors, motor off-task behaviors, and verbal off-task behaviors were coded in 15-s intervals; repetitive behaviors and visual external stimuli were coded as present in 5-s intervals.

Task participation

Task participation was coded based on visual, motor, and verbal behavior. When off-task behavior occurred for most of the 15-s segment (i.e., 7.5 s or longer), it was applied to the entire interval. Intervals were not coded in instances where the child was not captured on video for more than half of the 15-s interval (i.e., absent from the video for more than 7.5 s) or in instances where the child did not have a specific task to focus on (for at least 7.5 s) or they had been given a break (e.g., given a reinforcer or verbally told by therapist that they were on a break). The identification of "off task" behaviors differed between behaviors and is described below and was not mutually exclusive or exhaustive.

Visual off-task behavior

Off-task visual behavior was coded when the child's eye movement focused on something unrelated to the task, such as looking away, making eye contact with other people or objects, or closing their eyes. To determine the degree of interrater reliability for all off-task behavior, a second rater coded all 5-min video segments for two participants. Interrater reliability for visual off-task behavior was high with a raw score agreement of 0.835.

Motor off-task behavior

Off-task motor behaviors were coded as behaviors that include any physical movements, unrelated to the assigned task, such as standing up, hand flapping, talking, or fidgeting. Interrater reliability was high with a raw score agreement of 0.830.

Verbal off-task behavior

Off-task verbal behavior was coded when vocalizations, not required during the task, were made such as screaming, crying, humming, or inappropriate/out of context utterances. Interrater reliability was high with a raw score agreement of 0.830.

Scoring participation

To allow for comparison across participants, the off-task behaviors described above were converted into percentages. For each five-minute video, the total number of intervals that included off task behavior was divided by the total number of 15-s intervals that were codable (i.e., all 15-s intervals, excluding intervals coded as no task or null). This yielded three percentages for each 5-min video clip: *Percentage Visual Off Task, Percentage Motor Off-task,* and *Percentage Verbal Off-task*. For each participant, all of the percentages were averaged for the 5-min video clips when the child was wearing the compression garments yielding three additional variables: *Percentage Visual Off-task for Compression, Percentage Motor Off-task for Compression,* and *Percentage Verbal Off-task for Compression*. For comparison, all of the percentages were averaged for the 5-min video clips when the child had on their typical clothes (i.e., without compression) yielding three additional variables: *Percentage Visual Off-task for Control, Percentage Motor Off-task for Control,* and *Percentage Verbal Off-task for Control*.

Repetitive behaviors

Using Elan, the 5-min video clips were also coded for the frequency and type of repetitive behavior for each participant. The behavior was documented if the movement or vocalization was (1) repetitive in nature, (2) could repeat in 15 s (even though the videos were coded in 5-s intervals), (3) were apparently purposeless, and (4) not better explained by other movement disorders (such as tics, chorea, or dystonia) or paroxysmal event (epileptic or non-epileptic) (Meindl et al., 2020). This yielded the total number of repetitive behaviors for each child in each session and the percentage of the session that included repetitive behaviors for each child. See Table 1 for a list of common repetitive behaviors for each child. Interrater reliability (i.e., kappa) was high with a raw score agreement of 0.821.

External visual stimuli

The length of external stimuli present during each therapy session was also observed. External stimuli were defined as any person or animal, other than the therapist, participant, and any other individual that was directly involved in the task and visible to the coder for the majority of the five-second interval (see Table 1). Interrater reliability was high with raw score agreement of 0.941.

2 No order effects (due to group assignment) were observed for the dependent variables (i.e., visual off-task behavior, motor off-task behavior, verbal off-task behavior, and repetitive behavior) so order was not included in the analyses.

Results

Task participation

Three paired-samples t-tests were conducted to explore differences in off-task behavior (i.e., visual behavior, motor behavior, and verbal behavior) between the treatment and control condition. There was no significant difference between the treatment and control conditions for visual off-task behavior, motor off-task behavior, or verbal off-task behavior (see Table 2).

Repetitive Behaviors

Another paired-samples t-test was conducted to examine differences in repetitive behaviors between the treatment and control conditions. There was no significant difference between the treatment and control conditions for repetitive behaviors (see Table 2).

External visual stimuli

Pearson correlations were used to explore the relationship between visual distractors and behavior (i.e., off-task behavior and repetitive behavior) in both the treatment and control conditions. There were no significant relationships between external visual stimuli and behaviors for the treatment or control condition (see Table 3).

Discussion

This study assessed the effect of compression clothing on task participation and repetitive behaviors in children with autism. As deep pressure therapy has shown to reduce anxiety and increase engagement and responsiveness, we hypothesized that this specific form of deep pressure therapy (compression garments) would increase task participation and decrease repetitive behaviors (Edelson et al., 1999; Bestbier and Williams, 2017). However, off-task behaviors (visual, motor, verbal) and repetitive behaviors did not differ between conditions (compression clothing and no compression clothing) in the current study. The findings of this study suggest that compression garments do not have a positive or a negative effect on task participation or repetitive behaviors among children on the autism spectrum.

Additionally, we explored whether compression affects the impact that external visual stimuli have on repetitive behaviors and task participation in children with ASD. Again, the garments did not alter the influence that external visual stimuli had on repetitive behaviors and task participation. These findings could be related to the garments not having a direct effect on participation and therefore not specifically contributing to the external visual stimuli.

The results of this study are consistent with previous studies investigating compression garments. The current results using nine participants during ABA sessions supplements the findings from the Losinski et al. study which included three participants and took place in a school setting. The current study included a larger and more diverse sample size of which the results still replicated the previous findings (Losinski et al., 2017). These outcomes suggest that further research is needed to determine the effectiveness of compression garments in treating individuals with ASD.

Limitations and future directions

Although this study contributed to the limited research surrounding supportive devices for individuals with autism, several limitations should be noted. First, although our sample size was three times larger than previous studies of compression garments, the sample size was still small. Therefore, the power to detect effects in this sample was limited. It is important to note, however, that though the sample size was small, the observed off-task behaviors occurred on average more when compression was used than when compression was not used. In other words, the means do not suggest that

TABLE 2 Results of paired samples *t* test between control and treatment.

Behaviors	Without compression		With compression		*t*	*df*	*p*	Cohen's *d*
	M	*SD*	*M*	*SD*				
Visual off-task behavior	0.34	0.32	0.45	0.37	0.99	6	0.360	0.37
Motor off-task behavior	0.42	0.23	0.50	0.25	1.19	6	0.280	0.45
Verbal off-task behavior	0.20	0.21	0.22	0.11	0.24	6	0.819	0.09
Repetitive behaviors	0.32	0.23	0.31	0.17	−0.19	7	0.855	−0.07

TABLE 3 Correlation group results of off-task behaviors, repetitive behaviors, and external stimuli.

	1.	2.	3.	4.	5.
1. External visual stimuli	–	−0.004	0.170	0.263	0.355
2. Visual off-task behavior	−0.452	–	0.290	0.015	0.413
3. Motor off-task behavior	−0.134	0.864*	–	0.275	0.601
4. Verbal off-task behavior	−0.354	0.795	0.386	–	0.473
5. Repetitive behavior	−0.065	0.756*	0.567	0.823*	–

Correlations for the treatment condition are above the diagonal (in gray) and correlations for the control condition are below the diagonal. ***$p < 0.001$; ** $p < 0.01$; * $p < 0.05$.

compression decreases off-task behavior or repetitive behaviors even if the sample size was increased.

Similarly, it is possible that the compression garments were effective for some of the participants. The researchers were unable to account for the impact of individual differences (e.g., gender, ability, sensory sensitivities) on the effectiveness of the compression clothing. Therefore, this study could serve as a preliminary investigation to be replicated with a larger sample which would allow individual and gender differences to be analyzed.

Additionally, our study consisted of a relatively diverse sample with varied age and levels of autism severity. Therefore, participants did not engage in exactly the same activity across timepoints. Future studies could hold the environment and the task consistent to help identify more nuanced differences in behavioral outcomes. Moreover, as these garments did not hinder the task participation of the participants or increase the frequency of repetitive behaviors, it is important to determine if they have an additional effect on other behaviors such as mood or anxiety levels. Future research is needed to explore various other effects of these garments and their effects on other behavioral measures and in other populations.

There were also limitations in the sizing of the compression clothes used in the current study. The compression garments were fitted at the torso, but there was variability in how the clothes clung to the arms and legs. Since the individual measurements of the children were not taken, additional research is needed with garments that are specifically designed to each child's specifications.

Additionally, as the treatment condition only took place for five therapy sessions, it is important to consider that more time wearing the garments could have been needed to see the potential impact of the garments. As such, a future longitudinal study could be used to identify change over time, indicating whether there is an optimal application of the compression garments.

Finally, in this study, no qualitative information was solicited from the participants. In the future, the children should be asked about their experience with the compression garments. It is possible that the compression helped the children in meaningful ways that were not examined (or in contexts that were not explored).

Implications for therapy practice

As compression garments are a type of sensory integration tool and may be used with individuals with autism, there are several implications that should be noted. First, occupational and ABA therapists may consider other interventions to address repetitive behaviors and task participation in children with autism until more research supports the use of these clothing. However, if children with autism prefer to wear these garments, therapists may choose to allow individuals to wear them as they do not interfere with task participation.

Conclusion

The current study found that compression garments had no significant effect on task participation and repetitive behaviors in children with autism. As such, if these garments are preferred by individuals, they can be used since they do not seem to negatively impede task participation or increase repetitive behaviors. To date, this is the first study which examined how compression garments affected repetitive behaviors and task participation during ABA therapies. The current findings support the only other study investigating compression clothing (Losinski et al., 2017), suggesting that compression clothing do not have a positive therapeutic effect. Although more research is needed, the research to date suggests that therapists and parents should consider the potential usefulness of compression clothing prior to making a monetary investment.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Ethics statement

The studies involving humans were approved by Clemson University's Institutional Review Board. The studies were conducted in accordance with the local legislation and institutional requirements. Written informed consent for participation in this study was provided by the participants' legal guardians/next of kin.

Author contributions

JG: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Supervision, Writing – original draft, Writing – review & editing. HK: Conceptualization, Data curation, Investigation, Software, Writing – original draft. SS: Supervision, Writing – review & editing. JP: Supervision, Writing – original draft.

Funding

The author(s) declare financial support was received for the research, authorship, and/or publication of this article. This research was sponsored by Clemson University's Creative Inquiry initiative.

Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

References

American Psychiatric Association (2013). Diagnostic and statistical manual of mental disorders (DSM-5®). *Am. Psych. Pub.* United Kingdom: Hindawi Limited.

Ayres, A. J. (2005). *Sensory integration and the child: Understanding hidden sensory challenges*. Los Angeles: Western Psychological Services.

Bestbier, L., and Williams, T. I. (2017). The immediate effects of deep pressure on young people with autism and severe intellectual difficulties: Demonstrating individual differences. *Occup. Ther. Inter.* United Kingdom: Hindawi Limited, 2017.

Bowker, A., Apos Angelo, N. M., Hicks, R., and Wells, K. (2011). Treatments for autism: parental choices and perceptions of change [article]. *J. Autism Dev. Disord.* 41, 1373–1382. doi: 10.1007/s10803-010-1164-y

Devlin, S., Healy, O., Leader, G., and Hughes, B. M. (2011). Comparison of behavioral intervention and sensory-integration therapy in the treatment of challenging behavior. *J. Autism Dev. Disord.* 41, 1303–1320. doi: 10.1007/s10803-010-1149-x

Doughty, S. S., and Doughty, A. H. (2008). Evaluation of body-pressure intervention for self injury in autism. *Behavioral Development Bulletin* 14, 23–29. doi: 10.1037/h0100504 (Searching for Evidence on Controversial Behavioral Interventions for Individuals with Autism Spectrum Disorders)

Edelson, S. M., Edelson, M. G., Kerr, D. C. R., and Grandin, T. (1999). Behavioral and physiological effects of deep pressure on children with autism: a pilot study evaluating the efficacy of Grandin's hug machine. *Am. J. Occup. Ther.* 53, 145–152. doi: 10.5014/ajot.53.2.145

Fertel-Daly, D., Bedell, G., and Hinojosa, J. (2001). Effects of a weighted vest on attention to task and self-stimulatory behaviors in preschoolers with pervasive developmental disorders. *Am. J. Occup. Ther.* 55, 629–640. doi: 10.5014/ajot.55.6.629

Green, V. A., Pituch, K. A., Itchon, J., Choi, A., O'Reilly, M., and Sigafoos, J. (2006). Internet survey of treatments used by parents of children with autism. *Res. Dev. Disabil.* 27, 70–84. doi: 10.1016/j.ridd.2004.12.002

Guinchat, V., Vlamynck, E., Diaz, L., Chambon, C., Pouzenc, J., Cravero, C., et al. (2020). Compressive garments in individuals with autism and severe proprioceptive dysfunction: a retrospective exploratory case series. *Children (Basel, Switzerland)* 7:77. doi: 10.3390/children7070077

Hassan, M., and Mokhtar, H. (2019). Investigating autism etiology and heterogeneity by decision tree algorithm. *Informatics in Medicine Unlocked* 16:100215. doi: 10.1016/j.imu.2019.100215

Hilton, C. L., Crouch, M. C., and Israel, H. (2008). Out-of-school participation patterns in children with high-functioning autism spectrum disorders. *Am. J. Occup. Ther.* 62, 554–563. doi: 10.5014/ajot.62.5.554

Hodgetts, S., Magill-Evans, J., and Misiaszek, J. E. (2011). Weighted vests, stereotyped behaviors and arousal in children with autism. *J. Autism Dev. Disord.* 41, 805–814. doi: 10.1007/s10803-010-1104-x

Hume, K., Steinbrenner, J. R., Odom, S. L., Morin, K. L., Nowell, S. W., Tomaszewski, B., et al. (2021). Evidence-based practices for children, youth, and young adults with autism: third generation review. *J. Autism Dev. Disord.* 51, 4013–4032. doi: 10.1007/s10803-020-04844-2

Kapp, S., Steward, R., Crane, L., Elliott, D., Elphick, C., Pellicano, E., et al. (2019). 'People should be allowed to do what they like': autistic adults' views and experiences of stimming. *Autism* 23, 1782–1792. doi: 10.1177/1362361319829628

Koegel, R. L., and Covert, A. (1972). The relationship of self-stimulation to learning in autistic children. *J. Appl. Behav. Anal.* 5, 381–387. doi: 10.1901/jaba.1972.5-381

Lang, R., O'Reilly, M., Healy, O., Rispoli, M., Lydon, H., Streusand, W., et al. (2012). Sensory integration therapy for autism spectrum disorders: a systematic review. *Res. Autism Spectr. Disord.* 6, 1004–1018. doi: 10.1016/j.rasd.2012.01.006

Lewis, M. H., and Bodfish, J. W. (1998). Repetitive behavior disorders in autism. *Ment. Retard. Dev. Disabil. Res. Rev.* 4, 80–89. doi: 10.1002/(SICI)1098-2779(1998)4:2<80::AID-MRDD4>3.0.CO;2-0 (Autism)

Lidstone, J., Uljarević, M., Sullivan, J., Rodgers, J., McConachie, H., Freeston, M., et al. (2014). Relations among restricted and repetitive behaviors, anxiety and sensory features in children with autism spectrum disorders. *Res. Autism Spectr. Disord.* 8, 82–92. doi: 10.1016/j.rasd.2013.10.001

Losinski, M., Cook, K., Hirsch, S., and Sanders, S. (2017). The effects of deep pressure therapies and antecedent exercise on stereotypical behaviors of students with autism spectrum disorders. *Behav. Disord.* 42, 196–208. doi: 10.1177/0198742917715873

Lovaas, O. I., Litrownik, A., and Mann, R. (1971). Response latencies to auditory stimuli in autistic children engaged in self-stimulatory behavior. *Behav. Res. Ther.* 9, 39–49. doi: 10.1016/0005-7967(71)90035-0

Lovaas, I., Newsom, C., and Hickman, C. (1987). Self-stimulatory behavior and perceptual reinforcement. *J. Appl. Behav. Anal.* 20, 45–68. doi: 10.1901/jaba.1987.20-45

Love, J. R., Carr, J. E., Almason, S. M., and Petursdottir, A. I. (2009). Early and intensive behavioral intervention for autism: a survey of clinical practices. *Res. Autism Spectr. Disord.* 3, 421–428. doi: 10.1016/j.rasd.2008.08.008

Maenner, M. J., Shaw, K. A., Baio, J., Washington, A., Patrick, M., D'iRienzo, M., et al. (2020). Prevalence of autism Spectrum disorder among children aged 8 years - autism and developmental disabilities monitoring network, 11 sites. *MMWR Surveill. Summ.* 69, 1–12. doi: 10.15585/mmwr.ss6904a1

Manor-Binyamini, I., and Schreiber-Divon, M. (2019). Repetitive behaviors: listening to the voice of people with high-functioning autism spectrum disorder. *Res. Autism Spectr. Disord.* 64, 23–30. doi: 10.1016/j.rasd.2019.04.001

Meindl, J. N., Delgado, D., and Casey, L. B. (2020). Increasing engagement in students with autism in inclusion classrooms. *Child Youth Serv. Rev.* 111:104854. doi: 10.1016/j.childyouth.2020.104854

Militerni, R., Bravaccio, C., Falco, C., Fico, C., and Palermo, M. T. (2002). Repetitive behaviors in autistic disorder. *Eur. Child Adolesc. Psychiatry* 11, 210–218. doi: 10.1007/s00787-002-0279-x

Orinstein, A. J., Helt, M., Troyb, E., Tyson, K. E., Barton, M. L., Eigsti, I.-M., et al. (2014). Intervention for optimal outcome in children and adolescents with a history of autism. *J. Dev. Behav. Pediatr.* 35, 247–256. doi: 10.1097/DBP.0000000000000037

Patten, E., and Watson, L. R. (2011). Interventions targeting attention in young children with autism [article]. *Am. J. Speech Lang. Pathol.* 20, 60–69. doi: 10.1044/1058-0360(2010/09-0081)

Rodgers, J., Glod, M., Connolly, B., and McConachie, H. (2012). The relationship between anxiety and repetitive behaviours in autism spectrum disorder. *J. Autism Dev. Disord.* 42, 2404–2409. doi: 10.1007/s10803-012-1531-y

Rosenthal-Malek, A., and Mitchell, S. (1997). Brief report: the effects of exercise on the self-stimulatory behaviors and positive responding of adolescents with autism. *J. Autism Dev. Disord.* 27, 193–202. doi: 10.1023/A:1025848009248

Schreck, K. A., and Miller, V. A. (2010). How to behave ethically in a world of fads. *Behav. Interv.* 25, 307–324. doi: 10.1002/bin.305

Smith, T., Eikeseth, S., Klevstrand, M., and Lovaas, O. I. (1997). Intensive behavioral treatment for preschoolers with severe mental retardations and pervasive developmental disorder. *Am. J. Ment. Retard.* 102, 238–249. doi: 10.1352/0895-8017(1997)102<0238:IBTFPW>2.0.CO;2

Sukhodolsky, D. G., Scahill, L., Gadow, K. D., Arnold, L. E., Aman, M. G., McDougle, C. J., et al. (2008). Parent-rated anxiety symptoms in children with pervasive developmental disorders: frequency and association with core autism symptoms and cognitive functioning. *J. Abnorm. Child Psychol.* 36, 117–128. doi: 10.1007/s10802-007-9165-9

Turner, M. (1999). Repetitive behaviour in autism: a review of psychological research. *J. Child Psychol. Psychiatry* 40, 839–849. doi: 10.1111/1469-7610.00502

Vietze, P., and Lax, L. E. (2020). Early intervention ABA for toddlers with ASD: effect of age and amount. *Current Psychology: A Journal for Diverse Perspectives on Diverse Psychological Issues* 39, 1234–1244. doi: 10.1007/s12144-018-9812-z

frontiers | Frontiers in Psychology

TYPE Original Research
PUBLISHED 18 December 2023
DOI 10.3389/fpsyg.2023.1285575

OPEN ACCESS

EDITED BY
Lara Guedes De Pinho,
University of Evora, Portugal

REVIEWED BY
Celso Silva,
Instituto Politécnico de Beja, Portugal
Christian Huber,
University Psychiatric Clinic Basel, Switzerland

*CORRESPONDENCE
Anja Christine Rohenkohl
a.rohenkohl@uke.de

RECEIVED 30 August 2023
ACCEPTED 23 November 2023
PUBLISHED 18 December 2023

CITATION
Rohenkohl AC, Sowada P, Lambert M, Gallinat J, Karow A, Lüdecke D, Rühl F and Schöttle D (2023) Service users' perceptions of relevant and helpful components of an integrated care concept (ACCESS) for psychosis.
Front. Psychol. 14:1285575.
doi: 10.3389/fpsyg.2023.1285575

Service users' perceptions of relevant and helpful components of an integrated care concept (ACCESS) for psychosis

Anja Christine Rohenkohl*, Pia Sowada, Martin Lambert, Jürgen Gallinat, Anne Karow, Daniel Lüdecke, Friederike Rühl and Daniel Schöttle

Department of Psychiatry and Psychotherapy, University Medical Center Hamburg-Eppendorf (UKE), Hamburg, Germany

Introduction: Psychotic disorders have a significant impact on patients' lives and their families, and long-term treatment with individually tailored multimodal combinations of therapies is often required. Integrated care (IC) concepts such as the "Hamburg Model (ACCESS)" with a focus on psychotic disorders, includes different (therapeutic) components with pharmaco- and psychotherapy, family involvement, home treatment and the option of using a 24/7 crisis hotline. All components are offered by a therapeutically-oriented assertive community treatment (TACT) team in a need-adapted manner. So far, however, little is known about which specific components are regarded as especially relevant and helpful by the users of IC.

Methods: Patients currently participating in IC completed a questionnaire as part of the continuous quality assurance study (ACCESS II) in which they were asked to rate the different components of treatment according to their relevance and helpfulness, considering the individual's unique experiences with IC and needs in mental health care. Furthermore, they were asked to make suggestions regarding additional helpful components of treatment.

Results: Fifty patients participated in this survey (23% of the patients currently participating in the IC concept). For participants, the most helpful and important factors were having the same therapist in the long-term and the 24/7 crisis telephone. Additional components suggested by patients included more addiction-specific therapies and increased focus on vocational rehabilitation and integration.

Conclusion: From the perspective of the users of IC, long-term care from a trusted therapist with whom there is a therapeutic relationship and the possibility to reach someone they already know from the TACT team 24/7 serves as the best basis for effective care, fostering trust, understanding, and open communication. In contrast, home treatment remains a relevant aspect of evidence-based care for people with severe mental illness, but perhaps surprisingly, is not viewed as the most important issue.

KEYWORDS

assertive community treatment, integrated care, psychosis, schizophrenia, bipolar disorder, severe mental illness, patient-reported outcome

1 Introduction

Individuals with schizophrenia, bipolar disorder, and major depression with psychotic symptoms often suffer from poor quality of life (Ruggeri et al., 2000) and lack of community integration (Lambert et al., 2010). To provide comprehensive support for individuals with severe mental illness, it is imperative to address their unique needs and offer treatment in a coordinated and integrated care (IC) system (Schöttle et al., 2013).

Patients with severe and persistent mental illness (SPMI) frequently experience a chronic course of illness, underscoring the importance of timely identification, accurate diagnosis and consequent subsequent treatment (Schöttle et al., 2013; Correll et al., 2017). Collaboration among mental health professionals, primary care physicians, and family members is essential to coordinate therapies and to identify, assess and act upon early signs and symptoms of a psychotic relapse (De Hert et al., 2011). To manage symptoms effectively, treatment plans should take a holistic approach by linking psychotherapy, pharmacological treatment, and psychosocial interventions (Correll et al., 2018; Hansen et al., 2023).

Several IC models have been developed for treating people with severe mental illness (SMI), employing diverse approaches such as Assertive Community Treatments (ACT; Sytema et al., 2007; Lambert et al., 2010; Schöttle et al., 2018), Community Mental Health Teams (CMHTs; Malone et al., 2009), and Intensive Case Management (ICM; Schöttle et al., 2013; Dieterich et al., 2017).

In the early 1970s, the Assertive Community Treatment (ACT) approach played an important role in transforming interventions for people with severe mental illness (Stein and Santos, 1998). ACT comprises an evidence-based, team-centered approach with continuous, open-end treatment. To ensure comprehensive care and support for the patient, a multidisciplinary team including, for example, psychiatrists, social workers, psychologists, nurses, etc., is available (Olfson, 1990; Marshall and Lockwood, 2011). ACT also focuses on community and family integration, fostering inclusion in the community (e.g., housing, recreational activities) and involving family members in treatment as needed (Dixon et al., 1998; Stein and Santos, 1998; Philips et al., 2001), as families can foster a supportive and understanding environment for patients (Waller et al., 2019). Additionally, case management aids patients in coordinating and organizing their services and regular home visits are offered to ensure comprehensive care tailored to individual needs (Bertelsen et al., 2008). Home visits represent an important aspect: they enable continuous treatment utilization, the minimization of barriers, and the recording of living conditions by the treatment team. Severe psychotic disorders can occasionally lead to crises and relapses. Through the development of crisis intervention plans and the establishment of counseling centers, an immediate contact person is available by telephone 24 h a day (Philips et al., 2001).

Studies on the effectiveness of IC models for patients with severe mental illness have observed an overall positive impact, e.g., on symptomatology, functioning, and quality of life (Bond et al., 2001). IC models also enhance adherence, improve the perceived quality of treatment, and facilitate access to psychiatric services (Schöttle et al., 2013; Baxter et al., 2018). In previous studies (Bond et al., 2001; Lambert et al., 2010, 2015; Schöttle et al., 2018, 2019; Rohenkohl et al., 2022; Schröter et al., 2023), ACT treatment (also as a possible component of an IC concept) has been linked to various effects. Patients, who received ACT, showed improvements in quality of life, illness severity, global functioning, performance satisfaction, and treatment adherence. The efficacy of ACT has also been confirmed in reducing relapse rates (Chien et al., 2013), involuntary admissions and treatment (Schöttle et al., 2019). Due to the variety of intervention strategies offered, the question arises: which treatments are perceived as particularly helpful and effective from the patients' perspective. For example, research has shown that CMHTs care approach results in higher patient treatment satisfaction and contributes to decreased hospitalizations compared to standard care (Malone et al., 2009).

Over the past decades, most intervention approaches have been based primarily on experiences from experts and studies not involving the users of these systems so that it remains unclear which treatment components or combination of components are regarded as especially useful and helpful by patients. Ignoring the patient's perspective in therapy can have adverse effects on intervention effectiveness (Glynn et al., 2006). This can lead to consequences, including low motivation, higher rates of treatment discontinuation, and medication non-adherence. Previous studies have shown that patient satisfaction with the quality of care plays a critical role in treatment outcomes (Small et al., 1965; Ware and Davies, 1983). Furthermore, to achieve improved therapy adherence, cultivating a positive therapeutic relationship between the patient and the multidisciplinary team is important. Maintaining a strong therapeutic relationship over an extended period positively affects the patient's outcomes (Holzinger et al., 2002). Thus, considering the patient's perspective represents a crucial factor in psychiatric care. In addition to providing valuable insights into the needs, preferences, and experiences of those who need mental health care, involving patients in the assessment process can also help in continuously enhancing the quality of mental health care. By tailoring treatment plans to individual needs, mental and psychosocial health status, best possible satisfaction with treatment as well as long-term effectiveness can be achieved.

This study focuses on the patient perspective regarding which components of care users of the "Hamburg Model of Integrated Care (ACCESS)" with an adapted ACT concept perceive as being most effective and helpful. The effectiveness and efficiency of the ACCESS model was assessed in three studies: the ACCESS I study (Lambert et al., 2010) assessed the implementation of the model; the ongoing ACCESS II study (Schöttle et al., 2018; Ruppelt et al., 2020) assesses all patients entering the model; the ACCESS III study (Lambert et al., 2018) evaluated the effectiveness of the expansion of the model to adolescents (from the age of 12 years) and young adult patients in the early stage of the illness. In this current patient-based evaluation, data from the ongoing ACCESS II-study were used.

2 Materials and methods

In order to examine the most important elements of care from a user perspective, in the first step, a questionnaire including all care modules of IC provided by the "Hamburg Model of Integrated Care (ACCESS)" was developed. In a second step, this questionnaire was presented to all practitioners of the two ACT teams with the request to complete it and comment on it. Drawing from Delphi survey methodology, the questionnaire was adapted and, through an iterative process, the expertise of the multi-professional teams was used to improve and finalize the questionnaire to reflect all areas of care (see

Methods for content of the questionnaire). In the present study, the questionnaire was then presented to ACCESS users (e.g., patients) with the request to rate the items according to helpfulness and relevance of intervention components. Moreover, participants were also asked to note if intervention components were missing from the questionnaire.

2.1 Study design and sample

The "Hamburg Model of Integrated Care" (ACCESS II study) is a prospective, long-term study of an IC model for people with severe psychotic disorders (non-affective and affective). The model includes Therapeutic Assertive Community Treatment (TACT) within a cross-sectoral and interdisciplinary network of inpatient and outpatient services from the adult psychiatry clinic of the University Medical Center Hamburg-Eppendorf as described in detail in previous articles (Lambert et al., 2010; Karow et al., 2012; Schöttle et al., 2014, 2018; Rohenkohl et al., 2022).

From May 2007 to November 2021, 433 patients had been treated in the continuing *"Hamburg Model of Integrated Care (ACCESS)."* As part of the ACCESS study, which represents an ongoing evaluation of the Hamburg model, trained raters evaluate the effects of treatment on symptom burden, functional level and severity of the disease at fixed intervals at the beginning of treatment and every 6 months thereafter. In addition, quality of life and satisfaction with treatment are assessed from the patients' perspective. Because every patient in IC is approached for the ongoing evaluation within 6 months, a time interval of 6 months was selected for this survey. Patients who participated in the IC model between November 2021 and April 2022 were potentially eligible to participate in this voluntary and additional survey on patient-oriented components of care. The ACCESS trial was approved by the local ethics committee (number: PV4059) and is registered at ClinicalTrials.gov (identifier: NCT01888627). The additional survey was approved by the Local Psychological Ethics Committee at the Center for Psychosocial Medicine of the University Medical Center Hamburg – Eppendorf (number: LPEK-0379) and EmPeeRie (Empower Peers to Research) as a user-oriented science advisory service.

2.2 Inclusion and exclusion criteria

The eligibility criteria for participation in the ACCESS II study are as follows: Individuals (a) aged 12 years or above, (b) diagnosed with a severe psychotic disorder [Diagnostic and Statistical Manual of Mental Disorders (DSM-IV-TR): schizophrenia, schizophreniform disorder, schizoaffective disorder, delusional disorder, psychotic disorder not otherwise specified, bipolar disorder with recent severe psychotic symptoms, and major depression with severe psychotic symptoms], (c) with a symptom load indicated by a BPRS score of ≥40. (d) providing written informed consent (for participants aged 18 years or older) or written informed assent from a parent or legal guardian (for patients aged 12–17 years). Exclusion criteria included diagnoses like alcohol- or substance-induced psychosis, except when accompanied by comorbid alcohol or substance abuse or dependence, psychotic disorder resulting from a medical condition, and mental disability.

2.3 Assessments and measures

The questionnaire on relevant treatment impact factors recorded from the perspective of the participating patients included six scales (The questionnaire can be obtained in German from the corresponding author on request.): (1) Concept, treatment philosophy and attitude (15 items, e.g., "There are fixed reference therapists who are approachable and responsible for me."); (2) Multi-professional teams (5 items, e.g., "Due to the availability of doctors in the team, it is easier to take or try out a medication because I can consult them at short notice."); (3) On-call telephone – 24/7 availability of the team (2 items, e.g., "In case of a crisis, I can always reach someone by phone, even outside office hours and at weekends."); (4) Home treatment/mobility (3 items, e.g., "The reference therapist/TACT Team will come to my home if needed/in crisis."); (5) Crisis & inpatient stay (7 items, e.g., "My reference therapist/IV team is also there for me in case of forced/compulsory admission."; "Through Integrated Care, placement (and coercion) can be avoided."); and (6) Network [4 items, "The reference therapist/IC team exchanges information with all persons/institutions involved in the treatment (exchange/networking)."]. In total, the 36 items are answered on a graded Likert scale with the overarching question of how helpful and important patients perceive the content of the item to be for their psychiatric health care in the context of IC. Specifically, the question is: "How helpful and important is/would this item be for you": (1) very helpful & important (2) somewhat helpful & important (3) neither helpful nor important (4) not helpful & important (5) not at all helpful & important (6) The statement is not applicable. At the end, participants were also asked for comments and additions (Open text field: "Comments, additions - is something still missing?") and "What are the most helpful and important treatment offers in IC for you personally?"

In addition, socio-demographic variables [age, gender, first or multiple episode(s) of psychosis, diagnosis (affective versus non-affective psychosis)] were collected at the time of admission to the IC concept. Clinical outcome variables, such as level of functioning [Global Assessment of Functioning Scale (GAF); American Psychiatric Association, 2000], symptom burden [Brief Psychiatric Rating Scale (BPRS); Overall and Gorham, 1962], and severity of illness [Clinical Global Impressions Scale-Schizophrenia (CGI-S); Haro et al., 2003] were also recorded through the simultaneous regular evaluation.

2.4 Statistical analyses

A descriptive statistical analysis of the collected data on the impact factors from the perspective of participating patients was carried out. This includes mean (*M*) and standard deviation (*SD*). All analyses were carried out using SPSS, Version 27.0 (IBM Corp, 2020).

3 Results

3.1 Sample characteristics

Patients who participated in the IC model between November 2021 and April 2022 ($N = 218$) were potentially eligible to participate in this voluntary and additional survey on patient-oriented components of care. Fifty patients (23%) agreed to complete the

TABLE 1 Clinical and sociodemographic characteristics.

Sociodemographic characteristics		*N*	Mean	*SD*
Age (years)		50	39.58	12.61
Duration in IC (months)		50	70.38	49.94
Gender	female	25		
	male	25		
Clinical characteristics				
Type of psychosis	affective	23 (46%)		
	non-affective	27 (54%)		
No. of Episodes	first	13 (26%)		
	multiple	37 (74%)		
CGI		49	5.33	0.85
GAF		49	40.39	19.96
BPRS		48	74	15.61

IC, Integrated CARE; BPRS, Brief Psychiatric Rating Scale; CGI, Clinical Global Impression Scale; GAF, Global Assessment of Functioning Scale (0–100) (Ruggeri et al., 2000; Lambert et al., 2010; De Hert et al., 2011; Schöttle et al., 2013; Correll et al., 2017, 2018; Hansen et al., 2023); informations (Exception: Duration in IC) were assessed at the time of admission to the IC concept.

additional and voluntary survey on the evaluation of treatment components and filled out the questionnaire completely. Sociodemographic and clinical characteristics of the final sample are displayed in Table 1. The gender ratio was balanced, also the ratio between affective and non-affective psychotic illness was similar distributed. According to clinical variables obtained at the time of the survey administration, most participants (74%) had already had several psychotic episodes, all patients had moderate to high scores for psychopathology [BPRS: *M* (*SD*) = 43.10 (15.67)] and severity of illness [CGI-S: *M* (*SD*) = 3.96 (0.90)], and a lower level of functioning [GAF: *M* (*SD*) = 59.86 (12.19)]. On average, participants had been in IC for 70.38 months (range 1 to 170 months).

3.2 Results of the service users' perceptions of relevant and helpful components of IC

With regard to the most helpful and important treatment components, assessed from the perspective of the participants, the components are listed in Table 2.

The answers that were rated most strongly in terms of relevance in care by the user's perspective were, "There are fixed reference therapists who are approachable & responsible for me.," "In case of a crisis, I can always reach someone by phone; even outside office hours and at weekends.," "I have a trusting relationship with my reference therapist." (See Table 2). Home treatment as a core component of the *Hamburg Model of IC* was rated as a helpful and important component, but is not counted among the most relevant components ($M = 1.73$; $SD = 1.30$). Treatment elements related to network management were rated as least helpful and important by patients [e.g." The reference therapist/the IV team is linked to/in exchange with the ward." ($M = 2.52$; $SD = 2.18$); "The reference therapist/the IV team has the opportunity to accompany me to network meetings." ($M = 3.02$; $SD = 1.77$)].

In response to the open question, "What is most important to you as a service user in IC?," no new topics or treatment modules were mentioned that were not already included in the questionnaire (e.g., "therapeutic relationship," "one-on-one talks," "24/7 accessibility"). For the question on what is missing in the existing IC concept, more focus on the treatment of addiction as well as more support for vocational therapies were mentioned. Additional components in the IC concept that were not recorded in the questionnaire were not listed.

4 Discussion

Patients with non-affective and affective disorders treated in the ACCESS model of IC are offered a wide range of therapies focusing on psychopharmacological, psychotherapeutic and psychosocial treatment delivered by the TACT teams. To our knowledge, there is no study asking the users of an IC system which components of treatment they experience as most helpful and important.

The answers to the relevant treatment components from the perspective of patients as service users clearly focus on the continuous long-term relationship with their assigned therapist and the TACT team. In our teams in IC, the same therapist coordinates and conducts therapy regardless of which intensity of treatment the patient needs (e.g., inpatient, day clinic or outpatient). Within the team, the primary assigned therapist has a co-therapist who the patient knows well and who acts as a substitute for the assigned therapist in case of holidays or sickness. Developing and maintaining a trustful and stable alliance is of utmost importance, particularly when long-term treatment is necessary. Working with the same therapist over the long-term can help foster this alliance, which is particular important when working with patients with severe mental illnesses (Davis and Lysaker, 2007; Priebe et al., 2011; Goldsmith et al., 2015; Shattock et al., 2018; Browne et al., 2019; Hasson-Ohayon et al., 2019) as a strong working alliance has been shown to promote insight and improve recovery functional status and medication adherence. In our ACCESS model of IC, we had low service disengagement rates (Schöttle et al., 2013; Lambert et al., 2015, 2017; Schöttle et al., 2018, 2019). Therefore, we speculate (Lambert et al., 2017) that the clinically meaningful effects were mainly a result of the highly intensive and need-adapted IC interventions primary conducted by the same interdisciplinary TACT-Team with a focus on high quality psychopharmacological and psychotherapeutic treatment. Although we can only make assumptions as we also did not measure the therapeutic alliance itself and only asked how important it is for the service users, results of this study corroborate our hypotheses that the positive impact of our ACCESS model could at least partly be associated with the intensive and strong therapeutic alliance developed during the intensive treatment in IC.

Earlier research has demonstrated a favorable connection between therapeutic alliance and medication adherence (McCabe et al., 2012; Misdrahi et al., 2012; Shattock et al., 2018; Browne et al., 2019; Hsieh et al., 2022). Patients who demonstrated poor adherence over a period of 3 months were inclined to assign lower ratings to their perceived therapeutic alliance, unlike patients who adhered more consistently to their prescribed medication regimen (Lincoln et al., 2016). This suggests that a strong therapeutic alliance could significantly contribute to improving medication adherence. The 24/7 accessibility of a therapist they know in a crisis is also an important treatment component that is mentioned. This component can also be seen as a

TABLE 2 Relevant and helpful components of integrated care.

	M (*SD*)	Scale Content	Item*
1	1.02 (0.14)	Concept, treatment philosophy and attitude	There are **fixed reference therapists** who are **approachable & responsible** for me.
2	1.02 (0.14)	On-call telephone – 24/7 availability of the team	In case of a crisis, I can **always reach someone by phone**, even outside office hours and on weekends.
3	1.04 (0.20)	Concept, treatment philosophy and attitude	I have a **trusting relationship** with my reference therapist.
4	1.06 (0.24)	Concept, treatment philosophy and attitude	**Appointments** are made **promptly**, at **short notice** and **flexibly**.
5	1.06 (0.32)	Multi-professional teams	In integrated care, **psychotherapeutic talks** are **regularly offered**.
6	1.08 (0.27)	Crisis & inpatient stay	In the event of an inpatient admission, **UKE** is the **responsible hospital**.
7	1.10 (0.36)	Crisis & inpatient stay	**Relapse** can **be prevented** through integrated care.
8	1.12 (0.48)	Concept, treatment philosophy and attitude	The **frequency** and **duration of the appointments** can be adjusted **according to need**.
9	1.14 (0.40)	Concept, treatment philosophy and attitude	My **reference therapist** can be **easily reached**.
10	1.18 (0.44)	Concept, treatment philosophy and attitude	I feel comfortable to **talk about critical issues** (e.g., suicidal thoughts).
11	1.18 (0.77)	Crisis & inpatient stay	Integrated care can **shorten a crisis**.
12	1.18 (0.44)	On-call telephone – 24/7 availability of the team	I can also **contact the IV team at any time** when the practitioner is on holiday.
13	1.20 (0.40)	Concept, treatment philosophy and attitude	The **treatment** takes place at **eye level**.
14	1.22 (0.79)	Crisis & inpatient stay	Integrated care **can avoid/reduce inpatient admission**.
15	1.24 (0.77)	Concept, treatment philosophy and attitude	There is **no fixed end to treatment** in IV.
16	1.27 (0.45)	Multi-professional teams	The **teams are multi-professional**, i.e., doctors, psychologists, recovery counselors and social workers are available.
17	1.41 (1.10)	Multi-professional teams	The **availability of doctors** in the team makes it **easier to take or try out a medication** because I can also consult them at short notice.
18	1.51 (1.21)	Network	The reference therapist/the IV team **exchanges information with all persons/institutions** involved in the treatment (exchange/networking).
19	1.53 (1.40)	Concept, treatment philosophy and attitude	I feel **confident** enough to **openly discuss** things like a lower dose or stopping the medication on my own.
20	1.61 (1.53)	Crisis & inpatient stay	Integrated care **can avoid hospitalization** (and pressure).
21	1.69 (1.27)	Crisis & inpatient stay	For me, it is important that there is a **crisis plan**.
22	1.70 (1.27)	Network	The reference therapist/the IV team **coordinates important appointments** during treatment.
23	1.73 (1.30)	Home treatment/mobility	The reference therapist/the IV team **comes to my home** if necessary/in the crisis.
24	1.78 (4.57)	Concept, treatment philosophy and attitude	The reference therapist/the IV team **knows me over a longer period of time/the crisis**.
25	1.80 (1.17)	Multi-professional teams	I have the **option of contacting a social worker**.
26	1.82 (1.62)	Crisis & inpatient stay	My **reference therapist**/the IV team is also **there for me** in the case of placement/forced hospitalization.
27	1.86 (1.43)	Home treatment/mobility	The reference therapist/the IV team also has the **option of arranging meetings** with me **outside the UKE**.
28	1.87 (1.65)	Concept, treatment philosophy and attitude	**Addiction/consumption** and failure to keep appointments **do not lead to exclusion from IV**.
29	1.92 (1.59)	Network	**Examination** and **diagnosis of somatic** (physical) **diseases** is **coordinated** by the IV.
30	2.22 (1.93)	Concept, treatment philosophy and attitude	I feel **confident** enough to **talk openly about my consumption** (e.g., alcohol, drugs).
31	2.52 (2.18)	Network	The reference therapist/the IV team **is linked to/in exchange with the ward**.
32	2.53 (1.68)	Multi-professional teams	There is the opportunity to **exchange ideas with recovery counselors**.
33	2.62 (6.50)	Concept, treatment philosophy and attitude	The **reference therapist**/the IV team is **responsible for me** on the ward, as a day patient and as an outpatient.
34	2.98 (4.73)	Concept, treatment philosophy and attitude	There is the **possibility of couple/family therapy**.
35	3.02 (1.77)	Home treatment/mobility	The reference therapist/the IV team has the **opportunity to accompany me to network meetings**.
36	3.70 (6.41)	Concept, treatment philosophy and attitude	There is **low-threshold access to other services** in the building.

*items were rated on a Likert scale: (1) very helpful & important (2) somewhat helpful & important (3) neither helpful nor important (4) not helpful & important (5) not at all helpful & important (6) The statement is not applicable; Items were freely translated into English; the original questionnaire is available in German on request from the corresponding author.

continuation of the therapeutic relationship. Treatment elements related to network management in IC were rated as least helpful and important because it is likely to have the last direct impact and effect for patients.

The results of this study show that obtaining the patient perspective can provide unique information on quality of care. While there is good evidence for ACT treatment in severe mental illness in terms of clinical outcomes (Bond et al., 2001; Lambert et al., 2010, 2015; Chien et al., 2013; Schöttle et al., 2018, 2019; Rohenkohl et al., 2022), it is not mentioned by participating patients as one of the most relevant components of the "Hamburg Model" care concept.

Long-term treatment in psychiatry often involves establishing a therapeutic relationship between the patient and the mental health professional. This relationship serves as a foundation for effective care, fostering trust, understanding, and open communication. Through ongoing sessions and interventions, the therapeutic relationship allows for the exploration of deeply rooted issues, the development of coping strategies, and the gradual progress toward mental well-being. The continuity of this relationship over an extended period enables the patient to work through challenges, gain insights into their condition, and achieve lasting positive changes in their emotional and psychological state (Adair et al., 2005; Catty et al., 2013; Puntis et al., 2015; de Cruppé et al., 2023).

In summary, this preliminary study gives an indication that the effectiveness and efficiency of psychiatric and psychotherapeutic care for people with psychosis is not solely a question of guidelines and economics. A triad consisting of patient perspective, guidelines (evidence level) and economic perspective (cost-effectiveness) can thus best answer the question of the best possible care for people with severe mental illness.

5 Limitations and outline

During the COVID-19 pandemic, much of the treatment was also shifted to the telephone or meetings outside the clinic. This is one possible reason why only about 25% of eligible participants participated in this survey. Some of the interviews of the regular quality assurance survey were also conducted by telephone but this additional survey was not due to the length of the questionnaire, which means that some patients were likely not asked to participate at all.

According to this user survey, the existing IC concept should be slightly adapted to include additional addiction-specific interventions, as well as more counseling in the direction of supported employment and education. To address this topic, there is an ongoing study investigating whether targeted job coaching during the early stages of psychosis (first 5 years of illness) has an impact on participation in the primary job market (Jäckel et al., 2023). Results might aid to implement the field of supported employment as an additional component in the care of individuals with severe psychotic disorders, e.g., within the IC concept. To address comorbid substance use disorders more effectively, it is essential to further enhance the connectivity with outpatient resources, such as addiction counseling centers. This expansion can encourage the regular utilization of services offered from these centers and lower the barrier for individuals to seek assistance from them.

To further focus on this topic and continue involving patients, it should be investigated on a larger sample whether there are, e.g., differences in needs per diagnostic group (affective versus non-affective psychosis) or age group. In additional analyses with all participating patients, it should be considered which treatment components have an influence on clinical outcomes, quality of life and satisfaction with care.

5.1 Clinical implications

The findings speak to the need for the implementation and promotion of long-term approaches in the care of people with severe mental illness (psychosis). Additionally constant accessibility serves as relevant component of care to avoid crises and optimize care.

Thus, a patient-centered approach to mental health care provision should be fostered, aiming to enhance quality of life and empowering patients to take a more active role in their course of treatment. Furthermore, a patient-centered assessment allows for greater consideration of patient's individual needs within a care framework, thereby addressing gaps in provision. Additionally, patient concerns consistently serve as compelling incentives to tailor and enhance mental health services.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Ethics statement

The studies involving humans were approved by the local ethic committee approved the ACCESS study (registration number: PV4059). The study was registered at ClinicalTrials.gov (identifier: NCT01888627). This survey was approved by the Local Psychological Ethics Committee at the Center for Psychosocial Medicine of the University Medical Center Hamburg – Eppendorf (number: LPEK-0379) and EmPeeRie (Empower Peers to Research) as a user-oriented science advisory service. The studies were conducted in accordance with the local legislation and institutional requirements. The participants provided their written informed consent to participate in this study.

Author contributions

AR: Conceptualization, Formal analysis, Methodology, Project administration, Writing – original draft, Writing – review & editing. PS: Writing – original draft, Writing – review & editing. ML: Conceptualization, Investigation, Supervision, Writing – review & editing. JG: Writing – review & editing. AK: Writing – review & editing. DL: Writing – review & editing. FR: Writing – review & editing. DS: Conceptualization, Methodology, Supervision, Writing – original draft, Writing – review & editing.

Funding

The author(s) declare financial support was received for the research, authorship, and/or publication of this article. We acknowledge financial support from the Open Access Publication Fund of UKE - Universitätsklinikum Hamburg-Eppendorf and DFG – German Research Foundation.

Acknowledgments

The authors express their gratitude to all participating patients, private psychiatrists and outpatient services who were involved in the Hamburg model of Integrated Care.

Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

All claims expressed in this article are solely those of the authors and do not necessarily represent those of their affiliated organizations, or those of the publisher, the editors and the reviewers. Any product that may be evaluated in this article, or claim that may be made by its manufacturer, is not guaranteed or endorsed by the publisher.

References

Adair, C. E., McDougall, G. M., Mitton, C. R., Joyce, A. S., Wild, T. C., Gordon, A., et al. (2005). Continuity of care and health outcomes among persons with severe mental illness. *Psychiatr. Serv.* 56, 1061–1069. doi: 10.1176/appi.ps.56.9.1061

American Psychiatric Association. *Diagnostic and statistical manual of mental disorders fourth edition text revision (DSM-IV-TR)*. Washington DC: American Psychiatric Association. (2000).

Baxter, S., Johnson, M., Chambers, D., Sutton, A., Goyder, E., and Booth, A. (2018). The effects of integrated care: a systematic review of UK and international evidence. *BMC Health Serv. Res.* 18:350. doi: 10.1186/s12913-018-3161-3

Bertelsen, M., Jeppesen, P., Petersen, L., Thorup, A., Øhlenschlæger, J., le Quach, P., et al. (2008). Five-year follow-up of a randomized multicenter trial of intensive early intervention vs standard treatment for patients with a first episode of psychotic illness: the OPUS trial. *Arch. Gen. Psychiatry* 65, 762–771. doi: 10.1001/archpsyc.65.7.762

Bond, G. R., Drake, R. E., Mueser, K. T., and Latimer, E. (2001). Assertive community treatment for people with severe mental illness: critical ingredients and impact on clients. *Dis. Manag. Health Out.* 9, 141–159. doi: 10.2165/00115677-200109030-00003

Browne, J., Nagendra, A., Kurtz, M., Berry, K., and Penna, D. L. (2019). The relationship between the therapeutic alliance and client variables in individual treatment for schizophrenia spectrum disorders and early psychosis: narrative review. *Clin. Psychol. Rev.* 71, 51–62. doi: 10.1016/j.cpr.2019.05.002

Catty, J., White, S., Clement, S., Cowan, N., Geyer, C., Harvey, K., et al. (2013). Continuity of care for people with psychotic illness: its relationship to clinical and social functioning. *Int. J. Soc. Psychiatry* 59, 5–17. doi: 10.1177/0020764011421440

Chien, W. T., Leung, S. F., Yeung, F. K., and Wong, W. K. (2013). Current approaches to treatments for schizophrenia spectrum disorders, part II: psychosocial interventions and patient-focused perspectives in psychiatric care. *Neuropsychiatr. Dis. Treat.* 9, 1463–1481. doi: 10.2147/NDT.S49263

Correll, C. U., Galling, B., Pawar, A., Krivko, A., Bonetto, C., Ruggeri, M., et al. (2018). Comparison of early intervention services vs treatment as usual for early-phase psychosis: a systematic review, Meta-analysis, and Meta-regression. *JAMA Psychiatry* 75, 555–565. doi: 10.1001/jamapsychiatry.2018.0623

Correll, C. U., Solmi, M., Veronese, N., Bortolato, B., Rosson, S., Santonastaso, P., et al. (2017). Prevalence, incidence and mortality from cardiovascular disease in patients with pooled and specific severe mental illness: a large-scale meta-analysis of 3,211,768 patients and 113,383,368 controls. *World Psychiatry* 16, 163–180. doi: 10.1002/wps.20420

Davis, L. W., and Lysaker, P. H. (2007). Therapeutic alliance and improvements in work performance over time in patients with schizophrenia. *J. Nerv. Ment. Dis.* 195, 353–357. doi: 10.1097/01.nmd.0000261954.36030.a1

de Cruppé, W., Assheuer, M., Geraedts, M., and Beine, K. (2023). Association between continuity of care and treatment outcomes in psychiatric patients in Germany: a prospective cohort study. *BMC Psychiatry* 23:52. doi: 10.1186/s12888-023-04545-x

De Hert, M., Cohen, D., Bobes, J., Cetkovich-Bakmas, M., Leucht, S., Ndetei, D. M., et al. (2011). Physical illness in patients with severe mental disorders. II. Barriers to care, monitoring and treatment guidelines, plus recommendations at the system and individual level. *World Psychiatry* 10, 138–151. doi: 10.1002/j.2051-5545.2011.tb00036.x

Dieterich, M., Irving, C. B., Bergman, H., Khokhar, M. A., Park, B., and Marshall, M. (2017). Intensive case management for severe mental illness. *Cochrane Database Syst. Rev.* 2017:CD007906. doi: 10.1002/14651858.cd007906.pub3

Dixon, L., Stewart, B., Krauss, N., Robbins, J., Hackman, A., and Lehman, A. (1998). The participation of families of homeless Personswith Severe mental illness in an OutreachIntervention. *Community Ment. Health J.* 34, 251–259. doi: 10.1023/a:1018713707283

Glynn, S. M., Cohen, A. N., Dixon, L. B., and Niv, N. (2006). The potential impact of the recovery movement on family interventions for schizophrenia: opportunities and obstacles. *Schizophr. Bull.* 32, 451–463. doi: 10.1093/schbul/sbj066

Goldsmith, L. P., Lewis, S. W., Dunn, G., and Bentall, R. P. (2015). Psychological treatments for early psychosis can be beneficial or harmful, depending on the therapeutic alliance: an instrumental variable analysis. *Psychol. Med.* 45, 2365–2373. doi: 10.1017/S003329171500032X

Hansen, H. G., Starzer, M., Nilsson, S. F., Hjorthøj, C., Albert, N., and Nordentoft, M. (2023). Clinical recovery and long-term Association of Specialized Early Intervention Services vs treatment as usual among individuals with first-episode schizophrenia Spectrum disorder 20-year follow-up of the OPUS trial. *JAMA Psychiatry* 80, 371–379. doi: 10.1001/jamapsychiatry.2022.5164

Haro, J. M., Kamath, S. A., Ochoa, S., Novick, D., Rele, K., Fargaset, A., et al. (2003). The clinical global impression-schizophrenia scale: a simple instrument to measure the diversity of symptoms present in schizophrenia. *Acta Psychiatr. Scand.* 107, 16–23. doi: 10.1034/j.1600-0447.107.s416.5.x

Hasson-Ohayon, I., Mashiach-Eizenberg, M., Lavi-Rotenberg, A., and Roe, D. (2019). Randomized controlled trial of adjunctive social cognition and interaction training, adjunctive therapeutic Alliance focused therapy, and treatment as usual among persons with serious mental illness. *Front. Psychol.* 10:364. doi: 10.3389/fpsyt.2019.00364

Holzinger, A., Loffler, W., Muller, P., Priebe, S., and Angermeyer, M. C. (2002). Subjective illness theory and antipsychotic medication compliance by patients with schizophrenia. *J. Nerv. Ment. Dis.* 190, 597–603. doi: 10.1097/01.NMD.0000030524.45210.FD

Hsieh, W. L., Yeh, S. T., Liu, W. I., Li, I. H., Lee, S. K., and Chien, W. T. (2022). Improving medication adherence in community-dwelling patients with schizophrenia through therapeutic Alliance and medication attitude: a serial multiple mediation model. *Patient Prefer. Adherence* 16, 1017–1026. doi: 10.2147/PPA.S351848

IBM Corp. *IBM SPSS statistics for windows, version 27.0*. Armonk, NY: IBM Corp; (2020).

Jäckel, D., Willert, A., Brose, A., Leopold, K., Nischk, D., Senner, S., et al. (2023). Enhancing educational and vocational recovery in adolescents and young adults with early psychosis through supported employment and education (SEEearly): study protocol for a multicenter randomized controlled trial. *Trials* 24:440. doi: 10.1186/s13063-023-07462-2

Karow, A., Reimer, J., König, H. H., Heider, D., Bock, T., Huber, C., et al. (2012). Cost-effectiveness of 12-month therapeutic assertive community treatment as part of integrated care versus standard care in patients with schizophrenia treated with quetiapine immediate release (ACCESS trial). *J. Clin. Psychiatry* 73, e402–e408. doi: 10.4088/JCP.11m06875

Lambert, M., Bock, T., Schottle, D., Golks, D., Meister, K., Rietschel, L., et al. (2010). Assertive community treatment as part of integrated care versus standard care: a 12-month trial in patients with first- and multiple-episode schizophrenia spectrum disorders treated with quetiapine immediate release (ACCESS trial). *J. Clin. Psychiatry* 71, 1313–1323. doi: 10.4088/JCP.09m05113yel

Lambert, M., Ruppelt, F., Siem, A. K., Rohenkohl, A., Niehaus, V., Lüdecke, D., et al. (2018). Comorbidity of chronic somatic diseases in patients with psychotic disorders and their influence on 4-year outcomes of integrated care treatment (ACCESS II study). *Schizophr. Res.* 193, 377–383. doi: 10.1016/j.schres.2017.07.036

Lambert, M., Schöttle, D., Ruppelt, F., Rohenkohl, A., Sengutta, M., Luedecke, D., et al. (2017). Early detection and integrated care for adolescents and young adults with psychotic disorders: the ACCESS III study. *Acta Psychiatr. Scand.* 136, 188–200. doi: 10.1111/acps.12762

Lambert, M., Schöttle, D., Ruppert, F., Lüdecke, D., Sarikaya, G., Schulte-Markwortet, M., et al. (2015). Integrated care for patients with first and multiple episodes of severe psychotic illnesses: 3-year results of the Hamburg model. *Bundesgesundheitsbl. Gesundheitsforsch. Gesundheitsschutz* 58, 408–419. doi: 10.1007/s00103-015-2123-8

Lincoln, T. M., Jung, E., Wiesjahn, M., Wendt, H., Bock, T., and Schlier, B. (2016). The impact of negative treatment experiences on persistent refusal of antipsychotics. *Compr. Psychiatry* 70, 165–173. doi: 10.1016/j.comppsych.2016.07.009

Malone, D., Marriott, S., Newton-Howes, G., Simmonds, S., and Tyrer, P. (2009). Community mental health teams for people with Severe mental illnesses and disordered personality. *Schizophr. Bull.* 35, 13–14. doi: 10.1093/schbul/sbn164

Marshall, M., and Lockwood, A. (2011). Assertive community treatment for people with severe mental disorders. *Cochrane Database Syst. Rev.* 3. doi: 10.1002/14651858.cd001089.p

McCabe, R., Bullenkamp, J., Hansson, L., Lauber, C., Martinez-Leal, R., Rössler, W., et al. (2012). The therapeutic relationship and adherence to antipsychotic medication in schizophrenia. *PLoS One* 7:e36080. doi: 10.1371/journal.pone.0036080

Misdrahi, D., Petit, M., Blanc, O., Bayle, F., and Llorca, P.-M. (2012). The influence of therapeutic alliance and insight on medication adherence in schizophrenia. *Nord. J. Psychiatry* 66, 49–54. doi: 10.3109/08039488.2011.598556

Olfson, M. (1990). Assertive community treatment: an evaluation of the experimental evidence. *Psychiatr. Serv.* 41, 634–641. doi: 10.1176/ps.41.6.634

Overall, J. E., and Gorham, D. R. (1962). The brief psychiatric rating scale. *Psychol. Rep.* 10, 799–812. doi: 10.2466/pr0.1962.10.3.799

Philips, S. D., Burns, B. J., Edgar, E. R., Mueser, K. T., Linkins, K. W., Rosenheck, R. A., et al. (2001). Moving assertive community treatment into standard practice. *Psychiatr. Serv.* 52, 771–779. doi: 10.1176/appi.ps.52.6.771

Priebe, S., Richardson, M., Cooney, M., Adedeji, O., and McCabe, R. (2011). Does the therapeutic relationship predict outcomes of psychiatric treatment in patients with psychosis? *Systematic Rev. Psychotherapy and Psychosomatics* 80, 70–77. doi: 10.1159/000320976

Puntis, S., Rugkåsa, J., Forrest, A., Mitchell, A., and Burns, T. (2015). Associations between continuity of care and patient outcomes in mental health care: a systematic review. *Psychiatr. Serv.* 66, 354–363. doi: 10.1176/appi.ps.201400178

Rohenkohl, A. C., Daubmann, A., Gallinat, J., Karow, A., Kraft, V., Rühl, F., et al. (2022). Health-related quality of life in severe psychotic disorders during integrated care: 5-year course, prediction and treatment implications (ACCESS II). *Health Qual. Life Outcomes* 20:133. doi: 10.1186/s12955-022-02039-0

Ruggeri, M., Leese, M., Thornicroft, G., Bisoffi, G., and Tansella, M. (2000). Definition and prevalence of severe and persistent mental illness. *Br. J. Psychiatry* 177, 149–155. doi: 10.1192/bjp.177.2.149

Ruppelt, F., Rohenkohl, A., Kraft, V., Schöttle, S., Schröter, R., Gaianigo, J., et al. (2020). Course, remission and recovery in patients with severe psychotic disorders with or without comorbid substance use disorders: long-term outcome in evidence-based integrated care (ACCESS II study). *Schizophr. Res.* 222, 437–443. doi: 10.1016/j.schres.2020.03.058

Schöttle, D., Karow, A., Schimmelmann, B. G., and Lambert, M. (2013). Integrated care in patients with schizophrenia: results of trials published between 2011 and 2013 focusing on effectiveness and efficiency. *Curr. Opin. Psychiatry* 26, 384–408. doi: 10.1097/YCO.0b013e328361ec3b

Schöttle, D., Ruppelt, F., Schimmelmann, B. G., Karow, A., Bussopulos, A., Gallinat, J., et al. (2019). Reduction of involuntary admissions in patients with severe psychotic disorders treated in the access integrated care model including therapeutic assertive community treatment. *Front. Psychol.* 10:736. doi: 10.3389/fpsyt.2019.00736

Schöttle, D., Schimmelmann, B. G., Karow, A., Ruppelt, F., Sauerbier, A. L., and Bussopulos, A. (2014). Effectiveness of integrated care including therapeutic assertive community treatment in severe schizophrenia spectrum and bipolar I disorders: the 24-month follow-up ACCESS II study. *J. Clin. Psychiatry* 75, 1371–1379. doi: 10.4088/JCP.13m08817

Schöttle, D., Schimmelmann, B. G., Ruppelt, F., Bussopulos, A., Frieling, M., Nika, E., et al. (2018). Effectiveness of integrated care including therapeutic assertive community treatment in severe schizophrenia-spectrum and bipolar I disorders: four-year follow-up of the ACCESS II study. *PLoS One* 13:e0192929. doi: 10.1371/journal.pone.0192929

Schröter, R., Lambert, M., Rohenkohl, A., Kraft, V., Rühl, F., Luedecke, D., et al. (2023). Mediators of quality of life change in people with severe psychotic disorders treated in integrated care: ACCESS II study. *Eur. Psychiatry* 66:e1. doi: 10.1192/j.eurpsy.2022.2332

Shattock, L., Berry, K., Degnan, A., and Edge, D. (2018). Therapeutic alliance in psychological therapy for people with schizophrenia and related psychoses: a systematic review. *Clin. Psychol. Psychother.* 25, e60–e85. doi: 10.1002/cpp.2135

Small, J. G., Small, F., and Hayden, M. P. (1965). Prognosis and changes in attitude. *J Mental Dis.* 140, 215–217. doi: 10.1097/00005053-196503000-00006

Stein, L. I., and Santos, A. B. (1998). *Assertive community treatment of persons with severe mental illness*. New York: W. W. Norton & Company.

Sytema, S., Wunderink, L., Bloemers, W., Roorda, L., and Wiersma, D. (2007). Assertive community treatment in the Netherlands: a randomized controlled trial. *Acta Psychiatr. Scand.* 116, 105–112. doi: 10.1111/j.1600-0447.2007.01021.x

Waller, S., Reupert, A., Ward, B., McCormick, F., and Kidd, S. (2019). Family-focused recovery: perspectives from individuals with a mental illness. *Int. J. Ment. Health Nurs.* 28, 247–255. doi: 10.1111/inm.12528

Ware, J. E., and Davies, A. R. (1983). Behavioural consequences of consumer dissatisfaction with medical care. *Evaluation Program Planning* 6, 291–297. doi: 10.1016/0149-7189(83)90009-5

frontiers | Frontiers in Psychology

TYPE Systematic Review
PUBLISHED 19 December 2023
DOI 10.3389/fpsyg.2023.1196177

OPEN ACCESS

EDITED BY
Hui Zheng,
Chengdu University of Traditional Chinese Medicine, China

REVIEWED BY
Im Quah-Smith,
Royal Hospital for Women, Australia
Takefumi Suzuki,
University of Yamanashi, Japan

*CORRESPONDENCE
Kyeong Han Kim
✉ solip922@hanmail.net
Seong-Gyu Ko
✉ epiko@khu.ac.kr

†These authors have contributed equally to this work

RECEIVED 29 March 2023
ACCEPTED 27 November 2023
PUBLISHED 19 December 2023

CITATION
Hong Wk, Kim YJ, Lee Yr, Jeong HI, Kim KH and Ko S-G (2023) Effectiveness of electroacupuncture on anxiety: a systematic review and meta-analysis of randomized controlled trials.
Front. Psychol. 14:1196177.
doi: 10.3389/fpsyg.2023.1196177

Effectiveness of electroacupuncture on anxiety: a systematic review and meta-analysis of randomized controlled trials

Wan ki Hong[1†], Yeon Ji Kim[1†], Ye rim Lee[1†], Hye In Jeong[2], Kyeong Han Kim[3*†] and Seong-Gyu Ko[2*]

[1]College of Korean Medicine, Woosuk University, Jeonju, Republic of Korea, [2]Department of Preventive Medicine, College of Korean Medicine, Kyung Hee University, Seoul, Republic of Korea, [3]Department of Preventive Medicine, College of Korean Medicine, Woosuk University, Jeonju, Republic of Korea

This systematic review and meta-analysis aimed to comprehensively evaluate the effectiveness of electroacupuncture (EA) for patients with anxiety. Randomized controlled trials (RCTs) on the treatment of anxiety by EA up to November 2022 were searched and collected from nine databases. Hamilton Anxiety Rating Scale (HAMA), self-rating anxiety scale (SAS), and adverse reactions were used as outcome indicators. The quality of relevant articles was evaluated using the Cochrane Collaboration's risk of bias tool. The quality of evidence for each outcome was classified as "low risk," "unclear risk," or "high risk." RevMan 5.0 was used for data analysis. A total of 633 articles were identified from nine electronic databases; 37 RCTs were included, which measured anxiety changes by using EA alone compared to the control group. For the main outcome, EA significantly reduced the HAMA score [Mean difference (MD):−1.13 (95% CI:−2.55−0.29), I^2:80%], and the quality of evidence was moderate. EA significantly reduced the SAS score (MD:−3.47 (95% CI,−6.57−−0.36), I^2:88%), and the quality of evidence was moderate. Our meta-analysis shows that EA reduces HAMA and SAS. This study suggests that EA can relieve anxiety. For various uses, additional research is needed on its effect when combined with other treatments.

Systematic review registration: https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=345658, identifier (CRD42022345658).

KEYWORDS

electroacupuncture, anxiety, systematic review, meta-analysis, randomized controlled trials

1 Introduction

Anxiety ranks among the top five conditions individuals treat with medical marijuana in Canada and the United States (Reinarman et al., 2011). Anxiety is a detrimental mental disturbance that includes persistent feelings of apprehension, tension, despair, and distress. These disturbances induce physical symptoms such as tachycardia, nervousness, and inability to relax. It is also frequently associated with complications and disability. Anxiety is different from anxiety disorder. Anxiety disorders are one of the most common mental health conditions (Remes et al., 2016; Amorim et al., 2018). The terminology "Anxiety disorders" comprises several conditions, such as panic disorder, social anxiety disorders, anxiety associated with a medical condition, anxiety induced by substance use, and generalized

anxiety disorder. They differ from developmentally normative or stress-induced transient anxiety in persistence and impairment of daily functioning (Craske and Stein, 2016). We targeted anxiety, which is a broader category than anxiety disorders, in order to include more studies.

Anxiety is an emotional response to stimuli that humans perceive as threatening. Anxiety implies responses that affect the psychological and emotional sphere and have physiological and functional consequences (Stamenkovic et al., 2018). Pharmacotherapy and psychotherapy are the conventional treatments for anxiety. Regarding pharmacotherapy, anxiolytics, antidepressants, or monoamine oxidase inhibitors are used, with benzo-diazepines being the most used pharmacological resource as anxiolytics (Remes et al., 2016). However, these pharmacological resources can lead to habituation and cause side effects like chronicity, the need for long-term treatment, and high relapse rates. Due to the seriousness of these effects and the drawbacks of pharmacotherapy, finding an effective treatment with fewer undesirable side effects is a crucial task for modern medicine.

Electroacupuncture (EA), based on traditional Chinese medicine acupuncture, uses an electrical device connected to a needle to send electrical currents to the acupoint, thereby stimulating it (Han et al., 2021). The effect of EA is mediated by beta-endorphin (Ulett et al., 1998). High levels of plasma beta-endorphin may be associated with anxiety (Darko et al., 1992). EA, an improvement of traditional acupuncture, is commonly used to treat chronic pain (Vickers and Linde, 2014; Xiang et al., 2019) because of its safety, efficacy, and fewer side effects. Moreover, EA can also relieve anxiety (Pilkington, 2010), though this evidence is from animal experiments. Numerous studies have shown that EA is well tolerated by patients and is as effective as routine care. EA has displayed anxiety-relief effects in many clinical studies (Han et al., 2021).

The purpose of this study is to describe and critically evaluate the effectiveness of EA in treating anxiety. We provide a review of meta-analyses of research concerning the effectiveness of EA in treating anxiety to complement our study of the randomized clinical trials (RCTs) that have been conducted targeting participants with elevated anxiety levels. Although the previous study (Amorim et al., 2018) provided significant evidence regarding the treatment of anxiety by EA, we searched for RCTs concerning such a treatment to reinforce the research conducted in 2018 (Gao et al., 2020). Additionally, we expanded the scope of the target to anxiety and reinforced the databases or search strategy to collect and analyze more RCTs.

2 Materials and methods

2.1 Criteria for inclusion and exclusion

2.1.1 Study types

RCTs were included. We excluded crossover studies to reduce the risk of potential bias. There were no limitations regarding the publication language of the study.

2.1.2 Participant types

Participants in all groups included people with disease, menopause, addiction, and the healthy. There were no limitations regarding the sex, race, and nationality of the participants. Additionally, we included anxiety but excluded anxiety disorders.

2.1.3 Intervention types and controls

For treatment interventions, studies using EA therapies were included. However, studies that combined EA with other treatments or did not clearly specify anxiety measures were excluded. Control interventions included no treatment or sham acupuncture or other therapies, such as psychosocial interventions, pharmacological interventions, and other conventional interventions.

2.1.4 Outcomes measures

All studies had to use an established rating scale or other effective measures to access the degree of anxiety. The primary outcomes are SAS (Dunstan and Scott, 2020), HAMA (Thompson, 2015). The SAS is a 20-item self-report assessment device built to measure anxiety levels. The total raw scores range from 20 to 80 (20–44: Normal Range, 45–59: Mild to Moderate Anxiety Levels, 60–74: Marked to Severe Anxiety Levels, 75 and above: Extreme Anxiety Levels). HAMA is a psychological questionnaire used by clinicians to rate the se-verity of a patient's anxiety. The secondary outcomes are (1) state–trait anxiety inventory (STAI), (2)Beck Anxiety Inventories (BAI), (3) Symptom Checklist-90-Revised (SCL-90), (4) Hospital Anxiety and Depression Scale (HADS), (5) Generalized Anxiety Disorder questionnaire of 7 items (GAD-7), (6) VAS (anxiety scores), (7) HRSD (Hamilton Rating Scale for Depression), (8) CAS, (9) PAC-QOL (Patient assessment of constipation quality of life).

2.2 Literature searches

We comprehensively searched the following English, Korean and Chinese electronic databases from their inception date to 11 July 2022: Medline (via PubMed), EMBASE (via Elsevier), Cochrane Central Register of Controlled Trials, Science ON, Korean Studies Information Service System, Research Information Sharing Service, Oriental Medicine Advanced Searching Integrated System, China National Knowledge Infrastructure and American Psychological Association PsycArticles. We additionally reviewed the reference lists of the relevant studies to include any potentially relevant studies. We included both the broad term "anxiety [all fields]" AND "Electroacupuncture [all fields]" AND "Randomized Controlled Trials" [all fields]. The detailed search strategies for each database and search results are presented in Supplementary Table. Results were limited to "human" studies. Searches were performed without restriction by year.

2.3 Data selection

After removing duplicates, the titles and abstracts of the articles were reviewed for first inclusion. For the studies included after the initial screening, the full texts were retrieved and reviewed for final inclusion.

2.4 Data extraction

For the studies finally included, we extracted the following information using a standardized, pilot-tested Excel form: first author's name, publication year, sample size, details of participants,

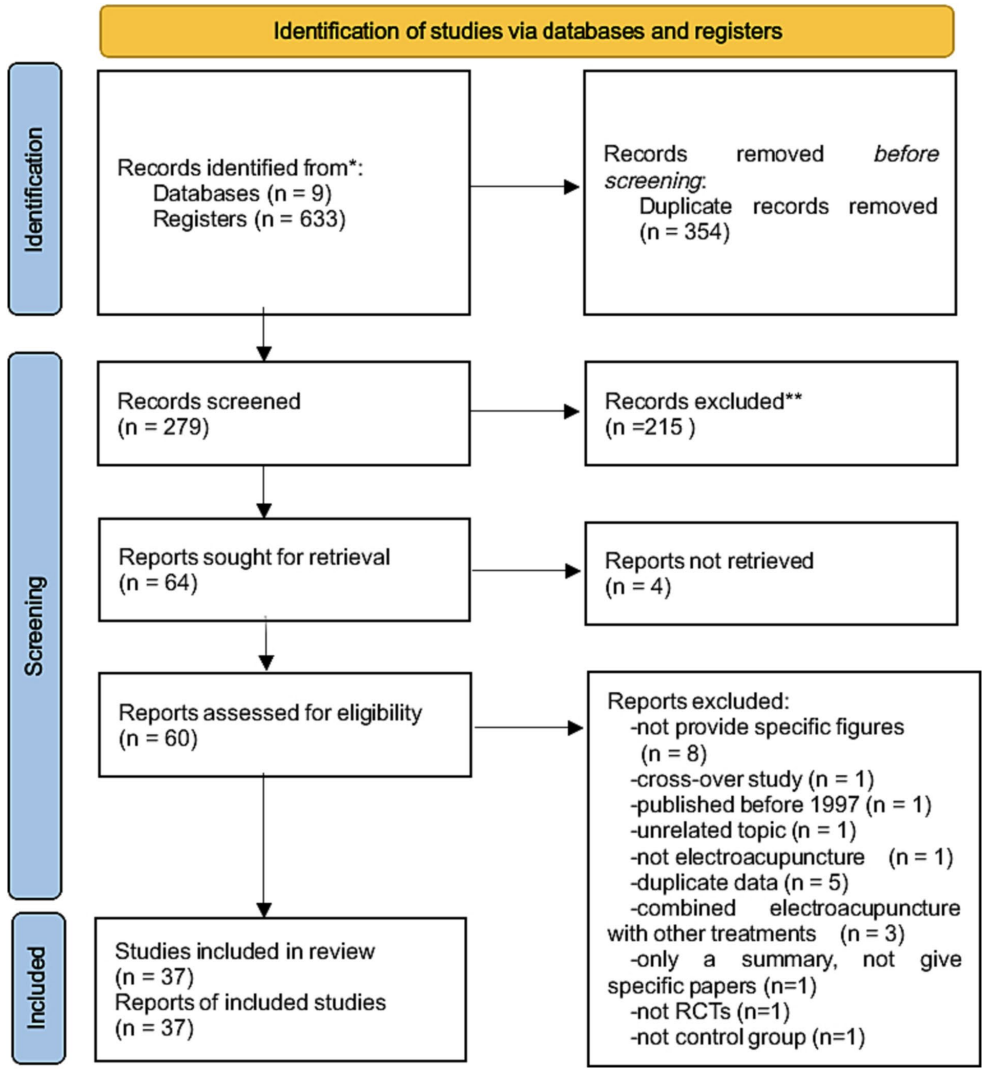


FIGURE 1
Flow chart showing the number of studies included and excluded from the systematic review.

intervention (acupoints, frequency, duration), control, outcomes, results.

Study selection and data extraction were independently conducted by three researchers (WK, YJ, and YR), and any disagreement was resolved by discussions with the other researchers (HI). If the data were ambiguous or insufficient, we contacted the authors of the included studies via e-mail if possible.

2.5 Quality/risk of bias assessment of included studies

We evaluated the methodological quality of the included studies using the Cochrane Collaboration's risk of bias tool including items of random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessors, completeness of outcome data, selective reporting, other potential threats to validity. Three researchers (WK, YJ, and YR) independently conducted the risk of bias assessment, and a consensus was reached through discussions with other researcher (HI) if there were disagreements. We classified each item as "low risk," "unclear risk," or "high risk."

2.6 Data analysis

If sufficient studies were selected, a meta-analysis was conducted using the mean difference (MD) for continuous variables as effect estimates. The data was analyzed using the Cochrane Review Manager software (RevMan 5.0). Statistical heterogeneity of the RCTs was evaluated using I^2 statistics and its 95% CI, where $I^2 > 50\%$ or $p < 0.05$ indicated significant heterogeneity. Subgroup analyses were performed for anxiety symptoms to explore potential factors that contributed to the heterogeneity.

3 Results

A total of 633 articles were initially identified from 9 electronic databases. After removing 354 duplicate records, we screened 279

TABLE 1 Summary of the studies included in the review.

Study	Participants	Sample size (EA/CT)	Intervention				Control	Outcomes	Outcome (pre → pro, $\chi \pm s$)		Result (O/△)
			Acupoint(s)	Frequency (Hz)	Type	Duration (min, times/week, total)			Intervention	Control	
Tong et al. (2022) ①	Conservative breast surgery	36/34	HT7,PC6, EX-HN3, DU20	2	L	pre-op, 30 min, 3 t/w, 8 weeks	NA	SAS	47.92 ± 4.05 → 41.14 ± 4.77	46.06 ± 5.08 → 49.91 ± 5.27	O
Tong et al. (2022) ②		36/34				pre-op and intra-op, 30 min, 3 t/w, 8 weeks			47.78 ± 4.92 → 41.97 ± 4.10		O
Yin et al. (2022)	Insomnia	83/83	GV20, GV29	2	L	30 min, 3 t/w, 8 weeks	SA	SAS	2.9*	0.14*	O
Xu et al. (2022) ①	Functional dyspepsia	24/19	ST25, BL25	2	L	30 min, 3–5 t/w, 4 weeks	Medication (loperamide hydrochloride capsule 2 mg)	SAS	31.63 → 25.41	32.47 → 32.87	O
Xu et al. (2022) ②		25/19	ST25, BL25	50	M	30 min, 3–5 t/w, 4 weeks			31.85 → 28.9	32.47 → 32.87	O
Bakacak et al. (2020)	HSG	36/37	H7, Du20, Liv-3, P-6, HT7, PC6, LI4, LI10, SP6, LR3, ST36, GB26, CP15, ST28 and Ren-4 points	1–20	L-M	before HSG 20 min	NA	STAI-S	43 → 32	44 → 41	O
Xing et al. (2020)	Insomnia	30/30	DU20, EX-HN1, EX-HN22, SP6, HT7, PC6, BL62, KI6	2, 100	L-H	30 min, 3 t/w, 4 weeks	CBT	HAMA	11.42 ± 4.23 → 9.52 ± 4.02	11.81 ± 5.10 → 9.41 ± 4.73	△
Liu et al. (2020)	PSAD	35/32	GV20, GV16. BL15, HT7	20	M	20 min, e.o.d, 3 t/w, 4 weeks	Medication (Paroxetine, 10–20 mg)	HAMA	22.20 ± 4.50 → 10.77 ± 3.45	21.91 ± 3.83 → 11.94 ± 2.85	O
Wang et al. (2019)	PCOS	23/20	CV3, CV6, ST29, SP6, SP9, LI4, GV20. The second points: ST25, ST29, CV3, CV6, LR3, PC6, GV20	2	L	30 min, 2 t/w, 16 weeks	SA	SAS	38 → 35	42 → 43	O
Yinjie et al. (2018)	Spinal cord injury	25/25	GV points, back-shu points	5	L	20 min, 1 t/day, 2 month	Conventional needling	HAMA	19.16 ± 6.55 → 13.98 ± 5.64	20.52 ± 7.86 → 16.65 ± 8.70	O

(Continued)

10.3389/fpsyg.2023.1196177

TABLE 1 (Continued)

Study	Participants	Sample size (EA/CT)	Intervention				Control	Outcomes	Outcome (pre → pro, χ ± s)		Result (O/△)
			Acupoint(s)	Frequency (Hz)	Type	Duration (min, times/week, total)			Intervention	Control	
Zeng et al. (2018)	MA addiction	31/33	T5, L2, PC6, HT7, ST36, SP6	2	L	3 t/w, 4 weeks	SA	HAMA	23.32 ± 5.06 → 5.77 ± 2.53	24.61 ± 5.17 → 8.79 ± 4.46	O
Teoh et al. (2018)	Diagnostic EUS	64/64	LI4, PC6, ST36	2	L	45 min, before op, during op	SA	VAS	4.4 → 1.7	4.3 → 5.1	O
Hui et al. (2017)	IAD	39/36	GV20 EX-HN1, LI4, PC6, LR3, SP6	10–100	L-H	30 min, e.o.d for 10 turns, 2 course	PI	SCL-90	1.5 ± 0.8 → 1.1 ± 0.9	1.5 ± 0.9 → 1.1 ± 0.8	O
Jin et al. (2016)	PCOS	35/33	BL18, CV17, LR14, CV4, ST25, CV4, EX-CA1, SP6, ST36, LR3	20	M	30 min, 10 weeks, total 30 ~ 40 times	Medication (dyne-35,1 tablet)	SCL-90	1.52 ± 0.44 → 1.62 ± 0.46	1.31 ± 0.29 → 1.56 ± 0.42	△
Zhao et al. (2015)	D-IBS	32/30	ST25, ST37	2	L	30 min, qd, 6 t/w, 4 weeks	Moxibustion	HAMA	-***		△
Dalamagka et al. (2015) ①	Inguinal hernia	18/18	SP6, ST36, LI4, PC6, BL60, KI3, auricular points Thalamus 26a, Shen-Men55, Lung101	1–2	L	Pre-op 40 min, during surgery, post-op 60 min	SA	STAI	-***		O
Dalamagka et al. (2015) ②						Pre-op 40 min, post-op 60 min			-**		O
Xiong et al. (2014) ①	Functional constipation	33/34	LI11, ST37	2	L	30 min, 16 times, 4 weeks	Medication (mosapride citrate, 5 mg)	SAS	39.78 ± 8.10 → 37.90 ± 8.22	39.83 ± 10.35 → 40.17 ± 13.01	O
Xiong et al. (2014)②		37/34	LI11, ST37	50	M				40.02 ± 8.01 → 34.49 ± 7.36		O
Dias et al. (2014)	Medical students	30/34	ST36, PC6, GB14, GV20, EX-HN1	2	L	20 min, 6–8 weeks	NA	BAI	15.6 ± 12.7 → 7.9 ± 6.9	12.3 ± 9.1 → 10.8 ± 9.3	O

(Continued)

10.3389/fpsyg.2023.1196177

TABLE 1 (Continued)

Study	Participants	Sample size (EA/CT)	Intervention				Control	Outcomes	Outcome (pre → pro, χ ± s)		Result (O/△)
			Acupoint(s)	Frequency (Hz)	Type	Duration (min, times/week, total)			Intervention	Control	
Mao et al. (2014)	WBC	19/19	at least 4 local points around the joint, at least 4 distant points	2	L	30 min, 10 times, 8 weeks	SA	HADS	−3.5 → −0.7	−1.0 → 0.5	O
Chen and Fan (2013)	GAD	32/31	GV20,EX-HN1,PC6,HT5,KI6,ST36,SP6,LR3	2–15	L-M	30 min, qd, 5 t/w, 6 weeks	Medication (Celite, 10 ~ 20 mg)	HAMA	21.81 ± 3.93 → 11.28 ± 5.72	21.45 ± 4.06 → 10.58 ± 4.84	△
Wang et al. (2012)	E-PTSD	63/64	Ex-HN1, GV20, GV24, GB20	100	H	30 min, e.o.d, 12 weeks	Medication (paroxetine, 20 mg)	HAMA	11.6 ± 5.11 → 2.95 ± 2.85	11.7 ± 5.85 → 3.86 ± 3.15	O
Dias et al. (2012)	Medical students	12/13	ST36, PC6, GB14, GV20, EX-HN1	2	L	20 min, 1 t/w, 8 weeks	NA	BAI	10.2 ± 8.7 → 5.7 ± 2.9	13.3 ± 11.4 → 14.0 ± 13.6	O
Chung et al. (2012)	postpartum depression	5/9	DU20, EX-HN3, EX-HN1, GB15, EX-HN1, GB15, GB8, EX-HN5, ST8, SP6, LR3, HE7, PC6	2	L	30 min, 2 sessions weekly, 4 weeks	SA	HADS	11.0 ± 2.3 → 8.6 ± 3.7	10.3 ± 2.9 → 8.7 ± 4.2	O
Zhu et al. (2011)	IAD	39/36	GV20, EX-HN1, LI4, PC6, LR3, SP6	10–100	L-H	e.o.d, total 20 times	the cognition and behavior therapy	SAS	54.1 ± 10.93 → 44.18 ± 8.85	55.83 ± 9.02 → 47.31 ± 11.56	O
Ping and Songhai (2008)	PSAN	34/33	GV20, GV24, EX-HN3, GV26, LI4, LR3, HT7, PC6	a frequency of 80-100/min	·	30 min, 15 times, OD, 2 courses	Medication (Alprazolam, 0.4–0.8 mg)	HAMA	22.31 ± 3.14 → 15.38 ± 3.20	22.27 ± 3.22 → 14.15 ± 3.46	△
								SAS	62.42 ± 7.28 → 51.66 ± 6.57	63.75 ± 6.07 → 48.83 ± 7.13	△
Peng et al. (2008)	Functional dyspepsia	20/20	PC6, ST36	40	M	30 min, qd, 2 weeks	Medication (Cisapride, 10 mg)	SAS	-***		O
Gejervall et al. (2005)	IVF	78/80	KI11, ST29, LI10, LI4, ST36, GV20	2–80	L-H	From surgery to recovery	Medication (flunitrazepam 0.5 mg, rectal paracetamol 1 g, alfentanil 0.5 mg)	VAS	28.6 ± 19.8 → 6.5 ± 8.7	30.4 ± 21.2 → 7.2 ± 11.1	△
								STAI	34.8 ± 8.4 → 26.8 ± 5.6	34.3 ± 8.5 → 28.6 ± 7.8	△

(Continued)

10.3389/fpsyg.2023.1196177

TABLE 1 (Continued)

Study	Participants	Sample size (EA/CT)	Intervention				Control	Outcomes	Outcome (pre → pro, $\chi \pm s$)		Result (O/△)
			Acupoint(s)	Frequency (Hz)	Type	Duration (min, times/week, total)			Intervention	Control	
Luo et al. (1998)	Depressive	133/108	GV20, EX-HN3	2	L	45 min, 6 t/w, 6 weeks	Medication (amitriptyline, 161 mg)	HRSD	1.35 ± 0.05 → 0.17 ± 0.03	1.24 ± 0.06 → 0.32 ± 0.05	O
Rampes et al. (1997)	AD or -abuse	23/16	HT7	100	H	30 min, weekly, 6 weeks	Counseling	CAS	11 → 4.6	9.2 → 12.0	O
Lee et al. (2020)	Insomnia	49/49	HT7, PC6, BL63, KI4	4	M	30 min, 2–3 t/w, for 4 weeks	SA	HADS	4.59 → 2.63	4.85 → 3.28	O
Yin et al. (2020)	Depressive	27/24	GV20, GV24, GV29, bilateral EX-HN22, HT7, SP6, PC6.	30	M	30 min, e.o.d, 3 t/w, 8 weeks	SA	HAMA	22.33 ± 8.76 → 10.53 ± 7.53	24.87 ± 8.42 → 20.90 ± 8.17	O
Zhao et al. (2018)	C-IBS + healthy (7)	30/30	ST25, ST37 bilaterally	2	L	30 min, OD, 6 t/w, 4 weeks	Moxibustion	HAMA	-***		O
Xu et al. (2020)	Functional constipation	30/30	LI11, ST37 bilaterally	2/50	L-H	30 min, 3–5 t/w, 4 weeks	Medication (mosapride citrate, 5 mg)	SAS	-**		O
Li et al. (2020)	PMI	42/42	GV20, GV24, GV29, CV6, CV4, bilateral EX-HN22, SP6, HT7, GV4, BL23, KI3, KI7	2.5	L	30 min, 1–3 t/w, 8 weeks	SA	SAS	46.43 ± 4.45 → 44.98 ± 3.85	47.43 ± 6.66 → 48.10 ± 6.04	O
Caiyuzhu et al. (2017)	Manopasual	25/25	CV4, EX-CA1, ST25, SP6	10, 50	M-H	30 min, e.o.d, 3 t/w, 8 weeks	SA	SAS	38.72 ± 5.37 → 32.67 ± 4.46	39.50 ± 6.45 → 31.89 ± 5.05	△
Zhang et al. (2018)	Depressive	30/30	GV20, GV24, PC6, HT7, SP6, LR3	10, 50	M-H	QD, 30 min, 5 days/week, 8 weeks	Music	HAMA	18.07 ± 2.74 → 10.60 ± 1.94	18.03 ± 3.20 → 9.67 ± 3.33	△
Ma et al. (2021)	knee osteoarthritis	38/39	LI10,LI11,TE14,LI14,LU5,TE9	2	L	QD post OP, 20 min, 5 days	Medication (fentanyl, 0.25 μg)	HADS	10.23 ± 3.37 → 9.00	10.58 ± 2.98 → 7.00	△

(Continued)

10.3389/fpsyg.2023.1196177

TABLE 1 (Continued)

Study	Participants	Sample size (EA/CT)	Intervention				Control	Outcomes	Outcome (pre → pro, $\chi \pm s$)		Result (O/△)
			Acupoint(s)	Frequency (Hz)	Type	Duration (min, times/week, total)			Intervention	Control	
Kim et al. (2021)	MDD	14/16	GV20, EX-HN3	10	M	20 min, 20 sessions, 8 weeks	SA	STAI (state)	−2.58*	−1.25*	O
								STAI (trait)	−5.42*	−3*	O
Yeung et al. (2019)	Long-term b users	72/72	EX-HN1, EX-HN22, GB8, ST8, EX-HN5, GB15, PC6, HT7, SP6, LV 3, EX-HN3, GV24, GV20	4	L	30 min	SA	HADS	3.5 → 3.9	3.8 → 4.3	O

EA: electro acupuncture; STAI:state–trait anxiety inventory; PI: psychological intervention; SCL-90: Symptom Checklist-90-Revised;SAS: Self-rating anxiety scale; BAI: the Beck Anxiety Inventories; HADS: Hospital Anxiety and Depression Scale; qd: quaque die (daily);SA: Sham acupuncture; LIS, HIS: Low, High intensity stimulation; Tid: tid ter in die (3 times a day); NI: no intervention; qn: quaque nocte; e.o.d: every other day; ESAS: Edmonton Symptom Assessment System; OD: once a day;SAS: self-rating anxiety scale; BAI: Beck Anxiety Inventory; GAD-7: Generalized Anxiety Disorder questionnaire of 7 items; OASIS: Overall Anxiety Severity and Impairment Scale; CBT: cognitive behavioral therapy; SSRIs: selective serotonin reuptake inhibitors; PCA: patient-controlled sedation and analgesia; VAS: visual analogue scale; OPU: ovum pick up; qd: quaque die (daily) L: Low (2-5 Hz); M: Mid (6-49 Hz); H: High (50-100 Hz); L-H: The range overlaps L and H; *change value; **Graph only, no specific figure; ***no graph and specific figure; O: The EA group reduced anxiety values more than the control group; △: The Control group reduced anxiety values more than the EA group.

records based on the titles and abstracts, and examined 64 eligible reports further for retrieval. Among these, full-texts were not available for 4 of them. A full-text review was conducted for the remaining 60 articles. After excluding 20 articles for the following reasons: 8 studies did not provide specific figures, 1 study did not use EA, 1 study was a cross-over study, 1 study was not an RCT, 1 study did not include a control group which was inconsistent with our intentions, 1 study only provided a summary but not specific papers, 1 study was unrelated to the topic, 5 studies contained duplicate data, and 4 studies combined EA with other treatments. Finally, a total of 37 studies were included in our analysis (Figure 1).

3.1 Study characteristics

The articles included in the review were published in English, Korean, and Chinese between the start date and 11 July 2022, with a variety of patient conditions represented. The most frequently studied conditions were insomnia (4 studies) and depression (3 studies), followed by functional dyspepsia, polycystic ovary syndrome, irritable bowel syndrome, functional constipation, and healthy participants (2 studies each). Other conditions were studied only once. The EA group utilized a total of 68 acupuncture points, with PC6 used most frequently (19 times), followed by GV20 (18 times) and SP6 (15 times). HT7 was used 12 times, while ST36 and LR3 were used 10 and 9 times, respectively. The electricity frequency categories in the EA group were Low (2-5 Hz) in 19 studies, L-H (the range overlapping L and H) and L-M in 6 studies each. The control group was most commonly treated with SA (sham acupuncture) or drugs, with 12 studies each. Psychological interventions were used in 3 studies, while moxibustion and NA were used in 2 studies each. The most commonly used outcome measures were HAMA and SAS (11 studies each), followed by HADS (5 studies), while other measures were used only once or twice (Table 1).

3.2 Quality/risk of bias of included studies

All 27 studies included in the analysis reported their methods for random sequence generation, which included the use of computer programs and random number generators, and were assessed as having a low risk of bias. Among the allocation concealment methods used, 15 studies used sealed envelopes and were assessed as having a low risk of bias, while 21 studies had an uncertain risk due to lack of specific description about blinding of participants and investigators. Thirty-five studies were evaluated as high risk, one was unclear, and only one study was evaluated as having a low risk of blindness. Sixteen RCTs reported detailed outcome assessment of blindness and were rated as having a low risk of bias. Regarding data integrity, all 29 studies provided detailed descriptions, indicating a low risk of bias. All expected outcomes, including adverse events, were reported in the 15 studies, which were assessed as having a low risk of bias. However, the remaining studies either did not document the protocol or did not mention adverse events, leading to high or uncertain risks. There were 11 studies with high-risk sources of bias, 11 with low-risk, and others were unclear. The risk of bias in each trial is presented in Figures 2, 3.

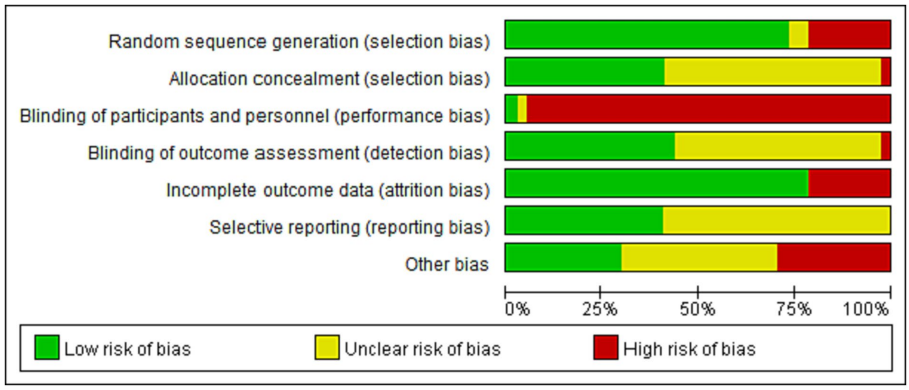


FIGURE 2
Risk of bias (ROB).

3.3 Intervention effects

The studies included in the analysis used EA as the intervention for anxiety in patients with various diseases. The patient populations across the studies were diverse, with three studies focusing on patients with depression and insomnia, and two studies each on patients with constipation, functional indigestion, Internet addiction, polycystic ovary syndrome, and general medical students experiencing anxiety. The remaining studies examined the use of EA for anxiety symptoms independent of any particular disease. Acupuncture points, frequency, and outcome scales varied across the studies. HAMA and SAS were the most frequently used outcome measures, with 11 trials using them. HADS was used in five trials. A meta-analysis was performed on studies using HAMA and SAS as outcome measures, while other studies used different outcome measures.

3.3.1 HAMA

A total of 11 RCTs investigated the effect of EA on HAMA scores in our meta-analysis. Meta-analysis of 9 RCTs involving 9 trials with 609 participants were not statistically significant (MD: −1.13 (95% CI −2.55 to 0.29), I^2:80%, Figure 4).

3.3.2 SAS

A total of 11 RCTs investigated the effect of EA on SAS scores in our meta. Meta-analysis of 6 RCTs involving 8 trials with 554 participants revealed significant differences in HAMA score reduction (MD: −3.47 (95% CI −6.57 to −0.36), I^2:88%, Figure 5) and no significant publication bias.

3.4 Subgroup analysis

Since anxiety is a common symptom in many diseases, the primary symptoms of the patients in the studies were not anxiety, but rather other diseases. Therefore, we conducted a meta-analysis using participant status to explore potential differences that may be attributed to variations in patients' diseases. Among the 37 studies, there were 28 unique participant statuses, indicating little overlap and considerable diversity. The most frequent participant status was insomnia and depression, followed by constipation, diarrhea, Internet addiction, polycystic ovarian syndrome, and two studies involving general patients. We categorized the studies into psychiatric disorders and digestive disorders for the meta-analysis.

3.4.1 Mental symptoms

A total of 13 RCTs investigated the effects of EA on participants with psychiatric conditions in the meta-analysis. Insomnia, depression, stress disorder, and methamphetamine addiction were included, but Internet addiction was not included (Grant and Chamberlain, 2016). A meta-analysis of 8 RCTs using HAMA outcome measure found results that can infer the tendency that anxiety is effective compared to previous graph results, but were not statistically significant (Figures 4, 5; MD: −1.01 (95% CI −2.47 to 0.45), I^2:82%, Figure 6).

4 Discussion

Anxiety ranks in the top 10 causes of disability worldwide (Remes et al., 2016). Pharmacotherapy and psychotherapy are the conventional treatments for anxiety. However, these pharmacological resources can lead to habituation and cause side effects. Due to its chronicity, high relapse rates, and need for long-term maintenance treatment, there is an urgent need for effective treatment of anxiety with fewer undesirable side effects. Several studies have shown the positive effects of acupuncture on state anxiety (Yang et al., 2021).

This study aimed to update the treatment effect of EA on anxiety by collecting data from RCTs. In this review, we searched several databases to identify comprehensive data sources. The purpose of this review was to provide an overview of previous studies and investigate the effectiveness of EA. Forty-one trials from 37 studies were included in this review, and 20 studies were suitable for meta-analysis. They were mainly conducted in Korea, the United States, and China. The conditions of the patients almost varied without overlapping.

The frequently used acupoint (PC6) was among patients with poststroke onset insomnia and was reported to be effective due to

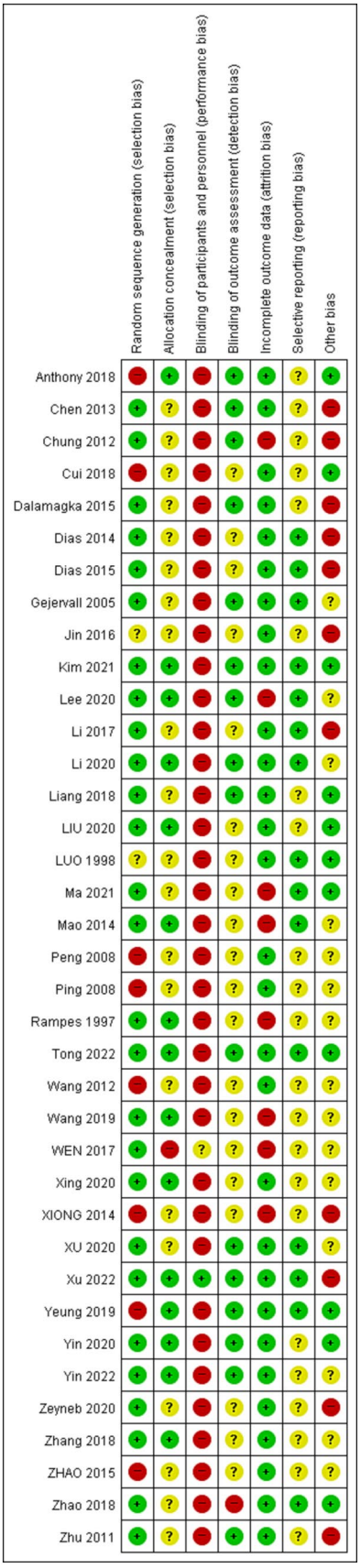


FIGURE 3
Risk of bias. (graph).

the reduction in sympathetic hyperactivities after acupuncture (Lee et al., 2009). Reduction of sympathetic hypersensitivity was shown to relieve anxiety in this study. The second most used acupoint was GV20. Acupuncture at this point calms the mind and invigorates the brain (Er-Jun et al., 2020). The third and fourth most frequently used acupoints were SP6 and HT7. EA at SP6 and HT7 reduced serum dopamine levels in patients with anxiety, suggesting that EA at SP6 and HT7 could improve the threshold of awakening and regulate abnormal emotions (Li et al., 2022). For the 13 RCTs in the previous paper (Amorim et al., 2018) related to anxiety and acupuncture, PC6 was used seven times, HT7 five times, GV20 three times, and SP6 two times. All four acupuncture points frequently used in our paper were also frequently used in previous papers. Therefore, the four acupoints are often used to relieve anxiety.

For the electric frequency, 19 out of 37 experiments used a low frequency of 2–5 Hz. Two experiments used 100 Hz high frequency alone. In general, in the case of low frequency, beta-endorphin in the brain and enkephalin and dynorphin in the spinal cord are secreted, and it is known that serotonin is involved in high frequency. Anxiety is associated with beta-endorphin, so lower frequencies were used more frequently (Han and Sun, 1990).

The degree of risk of bias (ROB) in other parts is compliant, but the ROB of performance bias is high. This is because the acupuncturist's blindfold is difficult to implement.

The outcome measures frequently used in this study are divided into two types: using HAMA and SAS to score the acuteness of anxiety level of patients. The results were generally effective, but the heterogeneity was high, so the interpretation should be careful. In previous studies, various outcome indicators were used to measure anxiety. Although a study reported that STAI was the most popular inventory for determining the degree of anxiety during an RCT (Amorim et al., 2018), our analysis confirmed that HAMA and SAS were more frequently used as measures of anxiety to determine the effect of EA.

Previous studies have investigated the relationship between anxiety disorders and acupuncture. We expanded the range of anxiety disorders and checked whether EA was effective on more transient anxiety states. Unlike the existing papers on the relationship be-tween acupuncture and anxiety, we selected studies that only compared the results of the EA and control groups and excluded studies on other treatments. Therefore, the effect of EA on anxiety was observed more clearly.

This review had several limitations. First, the diversity of data could not be secured because it was impossible to research other databases, such as the Japanese database. To overcome this shortcoming, multi-regional studies are required to supply solid clinical outcomes and diverse mechanistic techniques (Guo et al., 2020). Second, the EA parameters, including acupoints and times and frequency of EA, were selected without a consolidated standard in the included studies, which could be a potential source of clinical heterogeneity (Gao et al., 2021). Third, this study regarded EA as the only intervention and did not explore the combined use of other treatment methods for better efficacy. Only the efficacy of EA alone was reviewed; hence, the effect of EA combined with other treatments is unknown. Further research is needed in this area (Zhou et al., 2022). Fourth, studies with a high methodological quality were relatively limited, based on the

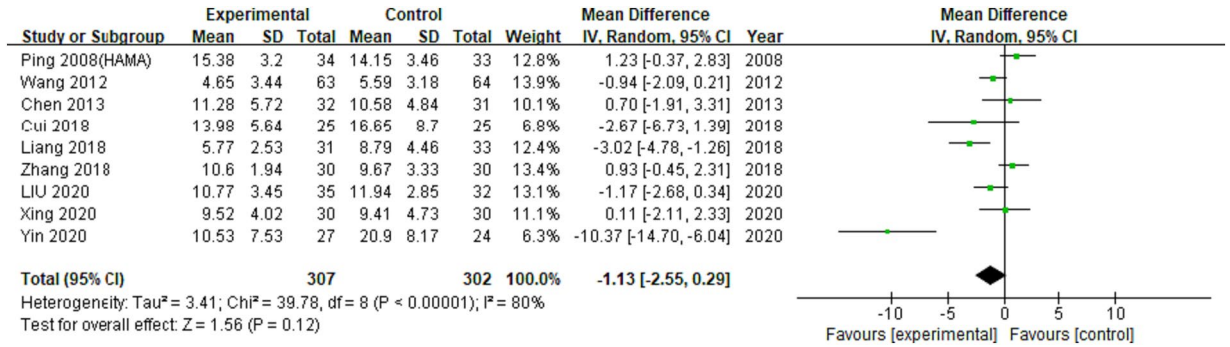


FIGURE 4
Meta-analysis (HAMA).

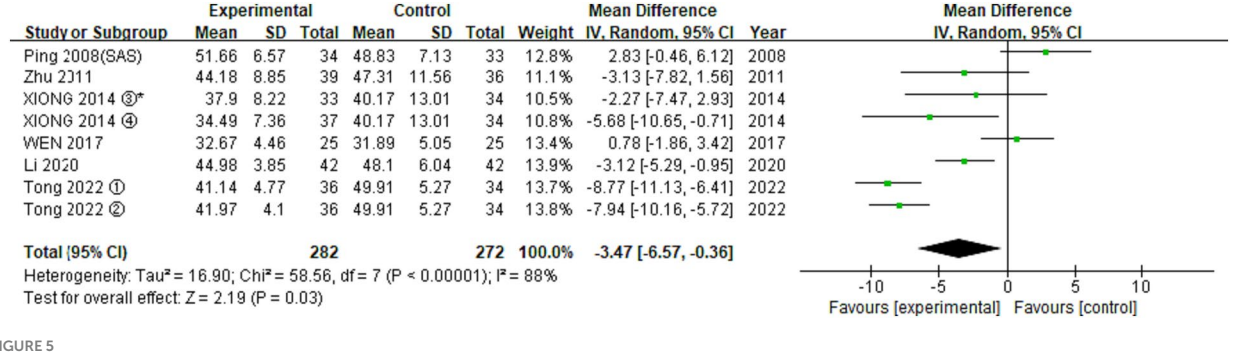


FIGURE 5
Meta-analysis (SAS).

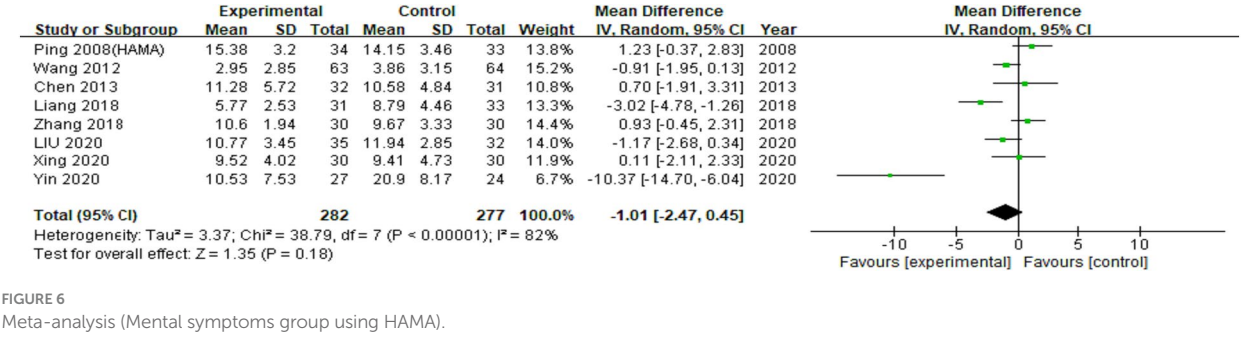


FIGURE 6
Meta-analysis (Mental symptoms group using HAMA).

Cochrane Collaboration's assessment tool. Critical information related to allocation concealment, blinding methods of participants, and personnel and outcome assessment was missing in most of the included trials (Guo et al., 2020). Due to the active manipulation of EA, most clinical studies could not be completely blinded.

However, unlike previous studies, the scope of the subjects was not limited to anxiety disorders with long-term symptoms; it included many studies by broadening the scope of subject RCTs to include transient anxiety emotions. As EA is effective for anxiety, it is expected to be used as an adjunct therapy in surgery and as a direct anxiety treatment. Since we only targeted RCTs in which electroacupuncture was treated as a single treatment, the relationship between electroacupuncture and anxiety could be identified.

5 Conclusion

The information gathered in this systematic review leads to observation and conclusion that is that different methodologies (different acupoints, frequency type, duration) lead to similar results which are decreased levels of anxiety. Our meta-analysis shows that

EA reduces HAMA and SAS. The evidences from this study suggest that EA can help in relieving anxiety.

Data availability statement

The original contributions presented in the study are included in the article/Supplementary material, further inquiries can be directed to the corresponding author.

Author contributions

WH, YK, and YL: conceptualization, methodology, formal analysis, investigation, data curation, writing—original draft preparation, and visualization. WH: software. HJ: writing—review and editing. HJ, KK, and SK: supervision, project administration. S-G.K: Writing – review & editing, Supervision, Project administration, and Funding acquisition. All authors contributed to the article and approved the submitted version.

Funding

The author(s) declare financial support was received for the research, authorship, and/or publication of this article. This work was supported by the National Research Foundation of Korea (NRF) grant funded by the Korea government (MSIT) (No. 2020R1A5A2019413).

Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

Supplementary material

The Supplementary material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpsyg.2023.1196177/full#supplementary-material

References

Amorim, D., Amado, J., Brito, I., Fiuza, S. M., Amorim, N., Costeira, C., et al. (2018). Acupuncture and electroacupuncture for anxiety disorders: a systematic review of the clinical research. *Complement. Ther. Clin. Pract.* 31, 31–37. doi: 10.1016/j.ctcp.2018.01.008

Bakacak, Z., Demirel, A., Bakacak, M., Urfalıoğlu, A., Yaylalı, A., Boran, Ö. F., et al. (2020). A randomized pilot study of electro-acupuncture treatment for hysterosalpingography pain relief and related anxiety. *J. Turkish Soc. Obst. Gynecol.* 17, 253–258. doi: 10.4274/tjod.galenos.2020.66592

Caiyuzhu, W., Yafei, L., Xiaoli, P., Zhen, M., Li, Z., and Hongxing, Z. (2017). Manual acupuncture versus electroacupuncture for menopausal syndrome: a randomized controlled trial. *Zhongguo Zhen Jiu* 37, 491–495. doi: 10.13703/j.0255-2930.2017.05.011

Chen, Y., and Fan, Z. (2013). Randomized control study on combination of ear acupoint bloodletting and electroacupuncture for treating mild to moderate generalized anxiety disorder. *J. Mod. Med. Health* 13, 1928–1930. doi: 10.3969/j.issn.1009-5519.2013.13.004

Chung, K.-F., Yeung, W.-F., Zhang, Z.-J., Yung, K.-P., Man, S.-C., Lee, C.-P., et al. (2012). Randomized non-invasive sham-controlled pilot trial of electroacupuncture for postpartum depression. *J. Affect. Disord.* 142, 115–121. doi: 10.1016/j.jad.2012.04.008

Craske, M. G., and Stein, M. B. (2016). Anxiety. *Lancet* 388, 3048–3059. doi: 10.1016/S0140-6736(16)30381-6

Dalamagka, M., Mavrommatis, C., Grosomanidis, V., Karakoulas, K., Vasilakos, D., Samara, M., et al. (2015). Postoperative analgesia after low-frequency electroacupuncture as adjunctive treatment in inguinal hernia surgery with abdominal wall mesh reconstruction. *Acupunct. Med.* 33, 360–367. doi: 10.1136/acupmed-2014-010689

Darko, D. F., Risch, S. C., Gillin, J. C., and Golshan, S. (1992). Association of beta-endorphin with specific clinical symptoms of depression. *Am. J. Psychiatr.* 149, 1162–1167. doi: 10.1176/ajp.149.9.1162

Dias, M., Pagnin, D., de Queiroz Pagnin, V., Reis, R. L. R., and Olej, B. (2012). Effects of electroacupuncture on stress-related symptoms in medical students: a randomised controlled pilot study. *Acupunct. Med.* 30, 89–95. doi: 10.1136/acupmed-2011-010082

Dias, M., Vellarde, G. C., Olej, B., Teófilo Salgado, A. E., and de Barros Rezende, I. (2014). Effects of electroacupuncture on stress-related symptoms in medical students: a randomised placebo-controlled study. *Acupunct. Med.* 32, 4–11. doi: 10.1136/acupmed-2013-010408

Dunstan, D. A., and Scott, N. (2020). Norms for Zung's self-rating anxiety scale. *BMC Psychiatry* 20:90. doi: 10.1186/s12888-019-2427-6

Er-Jun, L., Wei-Ling, Z., Jian-Bing, W., Fu-Gang, Z., and Ya-Ping, B. (2020). Acupuncture combined with cranial electrotherapy stimulation on generalized anxiety disorder: a randomized controlled trial. *Zhongguo Zhen Jiu* 40, 1187–1190. doi: 10.13703/j.0255-2930.20190917-k0004

Gao, Y., Wang, Y., Zhou, J., Hu, Z., and Shi, Y. (2020). Effectiveness of electroacupuncture for simple obesity: a systematic review and Meta-analysis of randomized controlled trials. *Evid. Based Complement. Alternat. Med.* 2020, 1–14. doi: 10.1155/2020/2367610

Gao, X., Zhang, Y., Zhang, Y., Ku, Y., and Guo, Y. (2021). Electroacupuncture for gastrointestinal function recovery after gynecological surgery: a systematic review and Meta-analysis. *Evid. Based Complement. Alternat. Med.* 2021, 1–16. doi: 10.1155/2021/8329366

Gejervall, A.-L., Stener-Victorin, E., Möller, A., Janson, P. O., Werner, C., and Bergh, C. (2005). Electro-acupuncture versus conventional analgesia: a comparison of pain levels during oocyte aspiration and patients' experiences of well-being after surgery. *Hum. Reprod.* 20, 728–735. doi: 10.1093/humrep/deh665

Grant, J. E., and Chamberlain, S. R. (2016). Expanding the definition of addiction: DSM-5 vs. ICD-11. *CNS Spectr.* 21, 300–303. doi: 10.1017/S1092852916000183

Guo, Y., Wei, W., and Chen, J. D. (2020). Effects and mechanisms of acupuncture and electroacupuncture for functional dyspepsia: a systematic review. *World J. Gastroenterol.* 26, 2440–2457. doi: 10.3748/wjg.v26.i19.2440

Han, X., Gao, Y., Yin, X., Zhang, Z., Lao, L., Chen, Q., et al. (2021). The mechanism of electroacupuncture for depression on basic research: a systematic review. *Chin. Med.* 16:10. doi: 10.1186/s13020-020-00421-y

Han, J. S., and Sun, S. L. (1990). Differential release of enkephalin and dynorphin by low and high frequency electroacupuncture in the central nervous system. *Acupunct. Sci. Int. J.* 1, 19–27.

Hui, L., Rongjiang, J., Kezhu, Y., Bo, Z., Zhong, Z., Ying, L., et al. (2017). Effect of electro-acupuncture combined with psychological intervention on mental symptoms and P50 of auditory evoked potential in patients with internet addiction disorder. *J. Tradit. Chin. Med.* 37, 43–48. doi: 10.1016/S0254-6272(17)30025-0

Jin, C., Pang, R., Huang, J., Jing, X., Wu, Z., and Zhao, J. (2016). Impacts on physical and mental health of patients with polycystic ovary syndrome treated with electroacupuncture:a randomized controlled trial. *Zhongguo Zhen Jiu* 36, 591–595. doi: 10.13703/j.0255-2930.2016.06.009

Kim, M., Choi, E.-J., Kwon, O.-J., Park, H.-J., Kim, A.-R., Seo, B.-N., et al. (2021). Electroacupuncture plus moxibustion for major depressive disorder: a randomized, sham-controlled, pilot clinical trial. *Integr. Med. Res.* 10:100727. doi: 10.1016/j.imr.2021.100727

Lee, S. Y., Baek, Y. H., Park, S. U., Moon, S. K., Park, J. M., Kim, Y. S., et al. (2009). Intradermal acupuncture on Shen-Men and Nei-Kuan acupoints improves insomnia in stroke patients by reducing the sympathetic nervous activity: a randomized clinical trial. *Am. J. Chin. Med.* 37, 1013–1021. doi: 10.1142/S0192415X09007624

Lee, B., Kim, B.-K., Kim, H.-J., Jung, I. C., Kim, A.-R., Park, H.-J., et al. (2020). Efficacy and safety of electroacupuncture for insomnia disorder: a multicenter, randomized, assessor-blinded, controlled trial. *Nat. Sci. Sleep* 12, 1145–1159. doi: 10.2147/NSS.S281231

Li, S., Wang, Z., Wu, H., Yue, H., Yin, P., Zhang, W., et al. (2020). Electroacupuncture versus sham acupuncture for perimenopausal insomnia: a randomized controlled clinical trial. *Nat. Sci. Sleep* 12, 1201–1213. doi: 10.2147/NSS.S282315

Li, D., Xiao-Jun, S., Zhong-Wen, L., Ling-Xin, L., and Yi-Hui, Z. (2022). Combined use of Shenmen (HT 7) and Sanyinjiao (SP 6) to improve the anxiety and depression in patients with insomnia: a randomized controlled trial. *Zhongguo Zhen Jiu* 42, 13–17. doi: 10.13703/j.0255-2930.20210113-k0002

Liu, R., Chen, S., and Wang, J. (2020). electroacupuncture for post-stroke anxiety disorder on the base of the heart-brain theory: a randomized controlled trial从心脑论治电针中风后焦虑障碍:随机对照试验. *World J. Acupunc.* 30, 23–28. doi: 10.1016/j.wjam.2020.02.008

Luo, H., Meng, F., Jia, Y., and Zhao, X. (1998). Clinical research on the therapeutic effect of the electro-acupuncture treatment in patients with depression. *Psychiatry Clin. Neurosci.* 52, S338–S340. doi: 10.1111/j.1440-1819.1998.tb03262.x

Ma, C., Huang, H., Lu, R., Qin, Z., Wang, H., Nie, Z., et al. (2021). Effect of crossing acupoints of the same name of hands and feet on pain after total knee arthroplasty. *Chin. J. Tissue Eng. Res.* 25, 5798–5803. doi: 10.12307/2021.345

Mao, J. J., Farrar, J. T., Bruner, D., Zee, J., Bowman, M., Seluzicki, C., et al. (2014). Electroacupuncture for fatigue, sleep, and psychological distress in breast cancer patients with aromatase inhibitor-related arthralgia: a randomized trial. *Cancer* 120, 3744–3751. doi: 10.1002/cncr.28917

Peng, S.-F., Yang, J.-Y., and Shi, Z.-H. (2008). Electroacupuncture improves gastric motility, autonomic nerve activity and psychological state in patients with functional dyspepsia. *World Chin. J. Digestol.* 16:4105. doi: 10.11569/wcjd.v16.i36.4105

Pilkington, K. (2010). Anxiety, depression and acupuncture: a review of the clinical research. *Auton. Neurosci.* 157, 91–95. doi: 10.1016/j.autneu.2010.04.002

Ping, W., and Songhai, L. (2008). Clinical observation on post-stroke anxiety neurosis treated by acupuncture. *J. Tradit. Chin. Med.* 28, 186–188. doi: 10.1016/S0254-6272(08)60043-6

Rampes, H., Pereira, S., Mortimer, A., Manoharan, S., and Knowles, M. (1997). Does electroacupuncture reduce craving for alcohol? A randomized controlled study. *Complement. Ther. Med.* 5, 19–26. doi: 10.1016/S0965-2299(97)80085-4

Reinarman, C., Nunberg, H., Lanthier, F., and Heddleston, T. (2011). Who are medical marijuana patients? Population characteristics from nine California assessment clinics. *J. Psychoactive Drugs* 43, 128–135. doi: 10.1080/02791072.2011.587700

Remes, O., Brayne, C., van der Linde, R., and Lafortune, L. (2016). A systematic review of reviews on the prevalence of anxiety disorders in adult populations. *Brain Behav.* 6:e00497. doi: 10.1002/brb3.497

Stamenkovic, D. M., Rancic, N. K., Latas, M. B., Neskovic, V., Rondovic, G. M., Wu, J. D., et al. (2018). Preoperative anxiety and implications on postoperative recovery: what can we do to change our history. *Minerva Anestesiol.* 84, 1307–1317. doi: 10.23736/S0375-9393.18.12520-X

Teoh, A. Y. B., Chong, C. C. N., Leung, W. W., Chan, S. K. C., Tse, Y. K., Ng, E. K. W., et al. (2018). Electroacupuncture-reduced sedative and analgesic requirements for diagnostic EUS: a prospective, randomized, double-blinded, sham-controlled study. *Gastrointest. Endosc.* 87, 476–485. doi: 10.1016/j.gie.2017.07.029

Thompson, E. (2015). Hamilton rating scale for anxiety (HAM-A). *Occup. Med.* 65:601. doi: 10.1093/occmed/kqv054

Tong, Q., Liu, R., Gao, Y., Zhang, K., Ma, W., and Shen, W. (2022). Effect of electroacupuncture based on ERAS for preoperative anxiety in breast cancer surgery: a single-center, randomized, controlled trial. *Clin. Breast Cancer* 22, 724–736. doi: 10.1016/j.clbc.2022.04.010

Ulett, G. A., Han, S., and Han, J. (1998). Electroacupuncture: mechanisms and clinical application. *Biol. Psychiatry* 44, 129–138. doi: 10.1016/S0006-3223(97)00394-6

Vickers, A. J., and Linde, K. (2014). Acupuncture for chronic pain. *JAMA* 311, 955–956. doi: 10.1001/jama.2013.285478

Wang, Z., Dong, H., Wang, Q., Zhang, L., Wu, X., Zhou, Z., et al. (2019). Effects of electroacupuncture on anxiety and depression in unmarried patients with polycystic ovarian syndrome: secondary analysis of a pilot randomised controlled trial. *Acupunct. Med.* 37, 40–46. doi: 10.1136/acupmed-2017-011615

Wang, Y., Hu, Y., Wang, W., Pang, R., and Zhang, A. (2012). Clinical studies on treatment of earthquake-caused posttraumatic stress disorder using electroacupuncture. *Evid. Based Complement. Alternat. Med.* 2012, 1–7. doi: 10.1155/2012/431279

Xiang, X., Wang, S., Shao, F., Fang, J., Xu, Y., Wang, W., et al. (2019). Electroacupuncture stimulation alleviates CFA-induced inflammatory pain via suppressing P2X3 expression. *Int. J. Mol. Sci.* 20:3248. doi: 10.3390/ijms20133248

Xing, J., Wu, X., Liu, H., Wang, J., Jiang, S., Lozada, A., et al. (2020). Effects of electroacupuncture therapy and cognitive behavioral therapy in chronic insomnia: a randomized controlled study. *Evid. Based Complement. Alternat. Med.* 2020, 1–12. doi: 10.1155/2020/5630130

Xiong, F., Wang, Y., Li, S., Tian, M., Zheng, C., and Huang, G. (2014). Clinical study of electro-acupuncture treatment with different intensities for functional constipation patients. *J. Huazhong Univ. Sci. Technolog. Med. Sci.* 34, 775–781. doi: 10.1007/s11596-014-1351-8

Xu, X., Zhang, M., Wu, X., Xu, S., Wang, W., Zheng, C., et al. (2020). Efficacy of electro-acupuncture in treatment of functional constipation: a randomized controlled trial. *Curr. Med. Sci.* 40, 363–371. doi: 10.1007/s11596-020-2188-y

Xu, X., Zhang, M., Wu, X., Zheng, C., and Huang, G. (2022). The effect of electroacupuncture treatment with different intensities for functional diarrhea: a randomized controlled trial. *Evid. Based Complement. Alternat. Med.* 2022, 1–8. doi: 10.1155/2022/2564979

Yang, X., Yang, N., Huang, F., Ren, S., and Li, Z. (2021). Effectiveness of acupuncture on anxiety disorder: a systematic review and meta-analysis of randomised controlled trials. *Ann. General Psychiatry* 20:9. doi: 10.1186/s12991-021-00327-5

Yeung, W.-F., Chung, K.-F., Zhang, Z.-J., Zhang, S.-P., Chan, W.-C., Ng, R. M.-K., et al. (2019). Electroacupuncture for tapering off long-term benzodiazepine use: a randomized controlled trial. *J. Psychiatr. Res.* 109, 59–67. doi: 10.1016/j.jpsychires.2018.11.015

Yin, X., Li, W., Liang, T., Lu, B., Yue, H., Li, S., et al. (2022). Effect of electroacupuncture on insomnia in patients with depression. *JAMA Netw. Open* 5:e2220563. doi: 10.1001/jamanetworkopen.2022.20563

Yin, X., Li, W., Wu, H., Dong, B., Ma, J., Li, S., et al. (2020). Efficacy of electroacupuncture on treating depression-related insomnia: a randomized controlled trial. *Nat. Sci. Sleep* 12, 497–508. doi: 10.2147/NSS.S253320

Yinjie, C., Xiaojuan, S., Qian, W., Wenchun, W., and Anren, Z. (2018). The effect of "paraplegic triple needling" combined with rehabilitation training on psychological and daily living ability of patients with spinal cord injury. *Zhongguo Zhen Jiu* 38, 4833–4839. doi: 10.13703/j.0255-2930.2018.05.009

Zeng, L., Tao, Y., Hou, W., Zong, L., and Yu, L. (2018). Electro-acupuncture improves psychiatric symptoms, anxiety and depression in methamphetamine addicts during abstinence. *Medicine* 97:e11905. doi: 10.1097/MD.0000000000011905

Zhang, H., Xu, N., Li, Z., Zhang, W., and Yi, W. (2018). Effects on female depression treated with the combined therapy of acupuncture and the five-element music therapy. *Zhongguo Zhen Jiu* 38, 1293–1297. doi: 10.13703/j.0255-2930.2018.12.011

Zhao, J., Lu, J., Yin, X., Chen, X., Chen, Y., Tang, W., et al. (2015). Comparison of electroacupuncture and moxibustion on brain-gut function in patients with diarrhea-predominant irritable bowel syndrome: a randomized controlled trial. *Chin. J. Integr. Med.* 21, 855–865. doi: 10.1007/s11655-015-2049-x

Zhao, J., Lu, J., Yin, X., Wu, L., Bao, C., Chen, X., et al. (2018). Comparison of electroacupuncture and mild-warm moxibustion on brain-gut function in patients with constipation-predominant irritable bowel syndrome: a randomized controlled trial. *Chin. J. Integr. Med.* 24, 328–335. doi: 10.1007/s11655-018-2838-0

Zhou, Z., Xu, G., Huang, L., Tian, H., Huang, F., Liu, Y., et al. (2022). Effectiveness and safety of Electroacupuncture for depression: a systematic review and meta-analysis. *Evid. Based Complement. Alternat. Med.* 2022, 1–15. doi: 10.1155/2022/4414113

Zhu, T., Li, H., Du, Y., Zheng, Z., and Jin, R. (2011). Intervention on network craving and encephalofluctuogram in patients with internet addiction disorder:a randomized controlled trial. *Chin. Acupunc. Moxibustion* 31, 395–399. doi: 10.13703/j.0255-2930.2011.05.006

frontiers | Frontiers in Psychology

TYPE Original Research
PUBLISHED 12 January 2024
DOI 10.3389/fpsyg.2023.1280397

OPEN ACCESS

EDITED BY
Lara Guedes De Pinho,
University of Evora, Portugal

REVIEWED BY
Golnaz Baghdadi,
Amirkabir University of Technology, Iran
Paloma González-Castro,
University of Oviedo, Spain

*CORRESPONDENCE
Niclas Braun
✉ Niclas.Braun@ukbonn.de

RECEIVED 20 August 2023
ACCEPTED 23 November 2023
PUBLISHED 12 January 2024

CITATION
Kannen K, Rasbach J, Fantazi A, Wiebe A, Selaskowski B, Asché L, Aslan B, Lux S, Herrmann CS, Philipsen A and Braun N (2024) Alpha modulation via transcranial alternating current stimulation in adults with attention-deficit hyperactivity disorder.
Front. Psychol. 14:1280397.
doi: 10.3389/fpsyg.2023.1280397

Alpha modulation via transcranial alternating current stimulation in adults with attention-deficit hyperactivity disorder

Kyra Kannen[1], Johanna Rasbach[1], Amin Fantazi[1], Annika Wiebe[1], Benjamin Selaskowski[1], Laura Asché[1], Behrem Aslan[1], Silke Lux[1], Christoph S. Herrmann[2], Alexandra Philipsen[1] and Niclas Braun[1]*

[1]Department of Psychiatry and Psychotherapy, University Hospital Bonn, Bonn, Germany, [2]Experimental Psychology Lab, Department of Psychology, University of Oldenburg, Oldenburg, Germany

Background: One potential therapy treating attention-deficit/hyperactivity disorder (ADHD) is to modulate dysfunctional brain activations using brain stimulation techniques. While the number of studies investigating the effect of transcranial direct current stimulation on ADHD symptoms continues to increase, transcranial alternating current stimulation (tACS) is poorly examined. Previous studies reported impaired alpha brain oscillation (8–12 Hz) that may be associated with increased attention deficits in ADHD. Our aim was to enhance alpha power in adult ADHD patients via tACS, using different methods to explore potential therapeutic effects.

Methods: Undergoing a crossover design, adults with ADHD received active and sham stimulation on distinct days. Before and after each intervention, mean alpha power, attention performance, subjective symptom ratings, as well as head and gaze movement were examined.

Results: Frequency analyses revealed a significant power increase in the alpha band after both interventions. Despite a trend toward an interaction effect, this alpha power increase was, however, not significantly higher after active stimulation compared to sham stimulation. For the other measures, some additional pre-post effects were found, which were not intervention-related.

Conclusion: Our study cannot provide clear evidence for a tACS-induced increase in alpha power in adult ADHD patients, and thus no stimulation related improvement of attention parameters. We provide further recommendations for the future investigation of tACS as a potential ADHD treatment.

KEYWORDS

attention, ADHD, alpha, virtual reality, brain stimulation, tACS

1 Introduction

To alleviate their inattention, hyperactivity and impulsivity, adults with attention-deficit/hyperactivity disorder (ADHD) often receive long-lasting psychopharmacological treatment. While this form of treatment is still yielding the greatest success for adult ADHD, it can be accompanied by undesirable side effects, such as weight loss and sleep

disturbances (Graham et al., 2011; Wynchank et al., 2017; Kis et al., 2020). In addition, psychostimulants appear to be less effective in adult ADHD patients than in children and adolescents with ADHD (Wilens et al., 2011; Cortese et al., 2018). Although ADHD medication has shown high short-term efficacy in many studies (Mészáros et al., 2009; Cunill et al., 2016), their longer-term efficacy awaits further investigation (Cortese et al., 2018; Swanson, 2019) given that several patients seem to develop tolerance to psychostimulants (Handelman and Sumiya, 2022).

In view of these drawbacks of psychopharmacological ADHD treatment, in the last decade various potential alternatives to non-pharmacological treatment have been investigated that enable ADHD treatment without or with fewer side effects. Besides psychotherapeutic approaches, for instance, physical activity training (Barudin-Carreiro et al., 2022; Montalva-Valenzuela et al., 2022; Seiffer et al., 2022), herbal treatments (Sarris et al., 2011), and digital health interventions (Lakes et al., 2022), including virtual reality (VR) interventions (for review, see Bashiri et al., 2017; Romero-Ayuso et al., 2021) and app-based psychoeducation (Selaskowski et al., 2022, 2023b) have been investigated. The probably most famous and controversially discussed alternative ADHD treatment approach, however, is still neurofeedback. This therapy intervention aims to improve the self-regulation of brain activity and has been under investigation for almost 50 years (Arns et al., 2014). While some researchers conclude positive effects of neurofeedback on ADHD symptoms (see, e.g., systematic review by Moreno-García et al., 2022) others have been more sceptical (for a systematic review and meta-analysis, see Louthrenoo et al., 2022; Rahmani et al., 2022). Therefore, its efficacy remains unclear. Accordingly, there is still a substantial need for developing more effective ADHD treatment approaches with less side effects.

Another treatment approach, though still in its infancy, is the idea of using brain stimulation techniques in place of, or as an adjunct to, traditional treatments. So far, the most established non-invasive brain stimulation techniques are transcranial magnetic stimulation (TMS) and transcranial electrical stimulation (TES). While TMS is delivered by a pulsing electromagnetic coil that is held next to the skull, in TES, multiple electrodes are placed onto the scalp to apply an electrical current to decrease or increase neural activity (Vosskuhl et al., 2018). Prominent TES subtypes are transcranial direct current stimulation (tDCS) and transcranial alternating current stimulation (tACS). While under tDCS a constant current is applied, under tACS the current alternates at a specified frequency (Herrmann et al., 2013). Accordingly, the respective mechanism of action on brain activity is different: Whereas tDCS seeks to increase or decrease the general neuronal excitability in a stimulated brain area of interest depending on the type of stimulation used, tACS seeks to amplify a specific brain oscillation by stimulating the brain with the dominant frequency of the oscillation of interest. Notably, both methods are thereby considered safe and with few side effects (Vosskuhl et al., 2018; Westwood et al., 2021).

Although various studies have already investigated TMS and tDCS as possible treatment approaches for ADHD (for systematic reviews, see Salehinejad et al., 2020; Westwood et al., 2021; Chen et al., 2023), only few clinical investigations addressed the efficacy and tolerability of tACS for ADHD treatment. In fact, to our knowledge, only three studies have so far explored tACS as treatment for adult ADHD (Dallmer-Zerbe et al., 2020; Farokhzadi et al., 2020; Kannen et al., 2022). While one of the studies compared tACS to methylphenidate (Farokhzadi et al., 2020) and reported tACS as an effective treatment, the other two studies investigated tACS as an alternative treatment for ADHD by trying to increase the P300 amplitude (Dallmer-Zerbe et al., 2020; Kannen et al., 2022), which is considered to be diminished in ADHD patients (Hasler et al., 2016; Marquardt et al., 2018; Kaiser et al., 2020). Dallmer-Zerbe et al. (2020) observed an increase in the P300 amplitude accompanied by a decrease in omission errors among adult ADHD patients, whereas Kannen et al. (2022) did not confirm these results. Therefore, the extent to which tACS might be beneficial in treating ADHD remains unclear.

Besides the diminished P300, another possible neuronal target for the application of tACS could be the brain's alpha rhythm (8–12 Hz), which is known to be modulated during attention and considered as a potential biomarker for ADHD (Kiiski et al., 2020). In healthy individuals, alpha oscillations are dominant in posterior brain regions during relaxed wakefulness, and progressively relocate towards central and frontal cortical regions with increasing drowsiness (see, e.g., Goldman et al., 2002). The hypothesis thereby is that alpha oscillations enable basal cognitive functions and attentional processes (Klimesch, 2012). Moreover, of particular interest in the present context, alpha oscillations are reported to be reduced in ADHD patients in both power and frequency (Loo et al., 2009; Woltering et al., 2012; Poil et al., 2014; Liu et al., 2016; Deiber et al., 2020), although this finding could not be corroborated in other studies (for discussion, see Adamou et al., 2020). In addition, in line with this assumed alpha alleviation, some studies showed that increasing alpha power using neurofeedback resulted in clinical improvement of ADHD symptoms as well as in an increase of attentional performance (Bazanova et al., 2018; Deiber et al., 2020). Considering these findings, the question arises whether a tACS-induced increase of the participant's individual alpha activity might improve the attentional performance of ADHD patients.

To prove a tACS-induced improvement of impairments in attentional functions, however, the difficulty arises that such ADHD symptoms often cannot be reliably detected with standard neuropsychological tests. One potential factor for this limited diagnostic utility might be the low ecological validity, which might fail to mimic everyday life challenges of ADHD patients (Wasserman and Wasserman, 2012; Varao-Sousa et al., 2018). A possible solution for creating more reality-close test situations might be offered by VR technology. By creating three-dimensional, immersive, and interactive virtual environments which allow to mimic everyday life demands, ecological validity can be increased while maintaining a high level of standardization (Parsons, 2015).

The aim of the present study was to increase the individual alpha power in patients with adult ADHD and to investigate possible behavioral and neurophysiological changes resulting therefrom. To this end, a crossover trial was carried out, in which all patients underwent both an individual tACS-based alpha stimulation (active stimulation) and a placebo stimulation (sham stimulation). To simulate an everyday situation, a developed virtual seminar room (VSR) was used that allowed for a multimodal and standardized, but symptom-valid measurement of inattention,

hyperactivity and impulsivity (Wiebe et al., 2022, 2023; Selaskowski et al., 2023a).

2 Materials and methods

2.1 Participants

Twenty-seven ADHD patients volunteered in this study, out of which 24 (7 female; $M_{age} = 32.25$, $SD_{age} = 10.46$, aged between 19 and 53) completed the experiment. The recruitment of the sample was conducted via the specialized outpatient clinic for adult ADHD of the Department of Psychiatry and Psychotherapy at the University Hospital Bonn. Participants were either personally invited to the study during medical consultations or via a study applicant pool in which they had registered before. The study was approved by the medical ethics committee of the University of Bonn (protocol number: 195/20), conducted in accordance with the Declaration of Helsinki, and pre-registered at the German Clinical Trials Register (https://www.drks.de/, Trial-ID: DRKS00022927). Written informed consent was obtained from all participants and they all received a monetary compensation of 25 € for their participation.

2.2 Study design and general procedure

The trial was carried out as a crossover study with two interventions on three measurement days: "active stimulation" (the true tACS intervention) and "sham stimulation" (the placebo intervention). On Day 1, a comprehensive clinical examination was performed during which the ADHD diagnosis was validated, and comorbidities were evaluated. On Days 2 and 3, the stimulation experiment took place, with one of the two interventions being applied on each measurement day. The order of interventions (sham stimulation or active stimulation) was counterbalanced.

2.3 Eligibility assessment and clinical characterization

For confirmation of the ADHD diagnoses and further characterization of the individual ADHD symptom profiles, all participants were administered the structured clinical "Interview of Integrated Diagnosis of ADHD in Adulthood" (IDA-R; Retz et al., 2014). In addition, to check for exclusion criteria and to assess potential comorbidities, the German version of the "Diagnostic Short Interview for Mental Disorders" (Mini-Dips-OA; Margraf et al., 2017) was carried out. Both clinical interviews were conducted via video call using the online-platform RED medical.[1] Moreover, participants completed a battery of online-surveys, including, for instance, a demographic questionnaire, a questionnaire concerning quality of life (WHO-QOL; Harper et al., 1998) and the ADHD Self-Report-Scale (ADHS-SB; Rösler et al., 2004).

To be eligible for the study, participants needed to be right-handed (according to the Edinburgh Handedness Inventory; Oldfield, 1971), to be between 18 and 60 years old, and to have corrected-to-normal or normal vision. In addition, any of the following exclusion criteria had to be absent: current severe major depression or current substance dependence, psychosis, presence of a serious neurological disorder (especially epilepsy), presence of a dermatological disorder of the head, pregnancy, or no command of the German language. Intake of ADHD medication (reported by 12 participants of the final cohort) was discontinued 24 h prior to each of the laboratory sessions. Participants were instructed to abstain from caffeine and alcohol for at least 24 h before each laboratory session.

2.4 Experimental procedure

The experiment took place in the VR laboratory of the Department of Psychiatry and Psychotherapy at the University Hospital in Bonn and was scheduled at two separate appointments. On one appointment the active stimulation was applied, while on the other appointment only a sham stimulation was applied. Each appointment started with the preparation of tACS- and EEG-electrodes. Afterwards, participants took their seat in front of a 1 × 1 m table within a 3.70 m x 2.65 m VR play area. The active experiment started by measuring 2 min of resting state baseline EEG, followed by the determination of the individual alpha frequency (IAF). Once the IAF was determined, participants became equipped with the head mounted display *HTC Vive Pro Eye* (HTC Corporation, Taoyuan City, Taiwan) and entered the VSR. Immersed into the VSR, participants were familiarized with this new virtual environment as well as with the continuous performance task (CPT) that next would take place within the VSR (*cf.* section 2.5). In total, three CPT blocks were presented, whereby each CPT block lasted 18 min and was suspended by a two-minute resting state EEG measurement and a one-minute-long break. Moreover, after each block, the participants' subjective ADHD symptoms (one question regarding inattention, impulsivity, hyperactivity, respectively, answered on a 7-point Likert-scale) was prompted by a gesture-controlled user interface inside VR (for further details, see Wiebe et al., 2022). Finally, after the last CPT block ended, participants completed the Virtual Reality Sickness Questionnaire (VSRQ; Kim et al., 2018) and a questionnaire about tACS side effects (Brunoni et al., 2011). Also, to investigate if participants were blinded to the experimental condition, they were asked whether they thought they received the active stimulation or sham stimulation.

2.5 Virtual seminar room and continuous performance task

The VSR and the implemented CPT are depicted in Figure 1 and have been described in detail previously (Wiebe et al., 2022). In brief, based on existing assets (i.a. the "School Classroom" from 3D everything available in the Unity Asset Store), the VSR was developed under Unity 3D version 2019.1.10f1 (Unity technologies, San Francisco, CA, United Staes) and contained the typical furniture found in a seminar room, including chairs and tables as well as a canvas at the front of the VSR. Moreover, the VSR comprised virtual classmates that performed unobtrusive idle movements during

1 https://www.redmedical.de

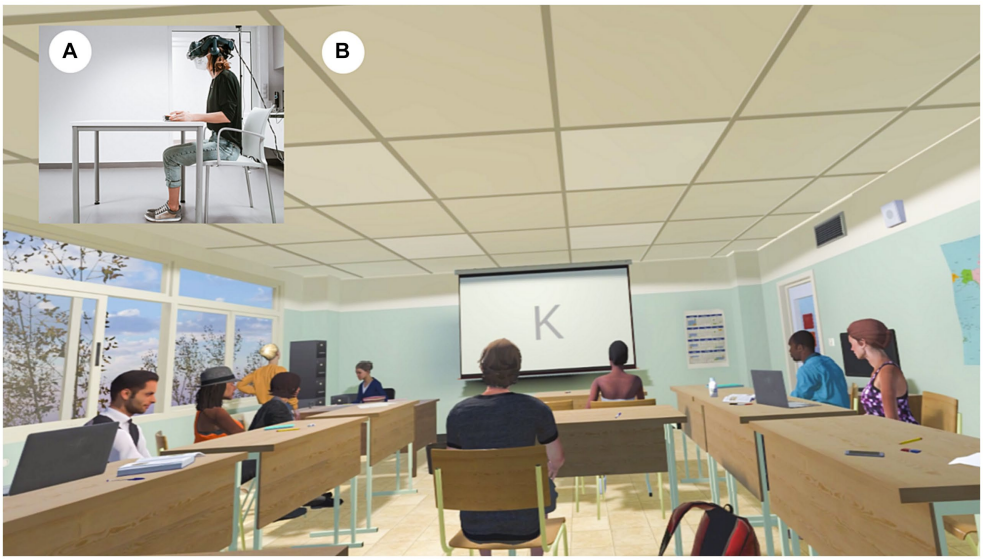


FIGURE 1
The virtual seminar room (VSR). **(A)** Real-world third-person perspective and **(B)** virtual-environment first person perspective. Adults with ADHD were immersed into the VSR, in which the continuous performance task (CPT) was presented at the canvas. **(A)** is an exemplary depiction and thus without attached tACS. For programming the virtual seminar room we only used non-restricted assets. "School Classroom" (Reprinted from 3D Everything via Unity Asset Store, licensed under Standard Unity Asset Store EULA).

non-distractor phases (NDP) and more complex actions during distractor phases (DP; details below). The virtual table where the participants found themselves seated, was thereby located in the back of the VSR, so that participants had a good overview of the entire VSR.

The CPT itself was presented on the canvas and consisted of a pseudorandomly-presented series of letters ranging from "A" to "Z", each presented with a 1.1 s inter-stimulus-interval and 100 ms duration. The task was to press the space bar as soon as the letter "A" was followed by the letter "K", while in all other cases, a response had to be withhold (Neguț et al., 2017; Mühlberger et al., 2020). After a practice run of 20 trials, the actual CPT began, which was split into three consecutive blocks: A pre-intervention block that occurred before active or sham stimulation was applied; a during-intervention block in which the active or sham stimulation was applied; and a post-intervention block that occurred after the active or sham stimulation.

Each of the CPT-blocks thereby lasted approximately 18 min and included 450 letter pairs, partitioned into 135 target sequences (~30%) and 315 non-target sequences (~70%). To elevate task difficulty, non-target sequences included 158 pseudo target sequences ("K" not preceded by "A"). Furthermore, each CPT block consisted of three DP and three NDP, each lasting three min. While during NDP no distractors were played, during DP, 54 different distracting events were played in total, of which 18 were exclusively visual (e.g., a paper airplane), another 18 solely auditory (e.g., a bell noise) and the remaining 18 audiovisual (e.g., passing fire trucks). Across participants, the order of distractors was thereby randomized, and the order of phases counterbalanced.

For analyzing CPT-performances, three main parameters of interest were defined: Omission error rate (i.e., the percentage of missed responses to target stimuli), commission error rate (i.e., the percentage of invalid responses to non-target stimuli) and reaction time variability (RTV, i.e., the standard deviation of reaction times towards correct hit trials divided by the mean reaction time). While omission error rates are regarded to reflect inattention, commission error rates are considered to reflect impulsive behavior (Nichols and Waschbusch, 2004), and RTV is considered a measure of vigilance (Llevy et al., 2018).

2.6 Electrical brain stimulation and electrode montage

The tACS was delivered by a battery-operated stimulator system (DC Stimulator Plus, Neuroconn, Illmenau, Germany). With the help of an electrically conductive paste (ten20 conductive paste, Weaver and Co., Aurora, CO, United States), two rubber electrodes were attached to the participants' scalp. Since former studies reported significant differences in the alpha band power of posterior brain regions between ADHD patients and healthy controls (see scalp plots, e.g., Woltering et al., 2012; Deiber et al., 2020), one electrode was placed above Cz (5 × 7 cm) and another above Oz (4 × 4 cm). Modeling studies have shown that this montage achieves the highest current densities in posterior brain regions (Neuling et al., 2012) and elicits aftereffects in alpha band power (Neuling et al., 2013; Kasten et al., 2016). Impedances were kept below 15 kΩ ($M = 4.55$, $SD = 2.92$). Participants were stimulated at their IAF (9.63 Hz ± 0.69 Hz active stimulation, 9.67 Hz ± 0.98 Hz sham stimulation) with an intensity of 1.5 mA. Baseline resting-EEG measurements (2 min, eyes open) for determining the IAF were performed before the actual experiment and outside VR (for analysis steps *cf.* section 2.4.1). After the first CPT block, participants received either 18 min of tACS (active stimulation) or 10 s of tACS (sham stimulation) with 10 s fade-in and fade-out (30 s in total to evoke a light tingling sensation in both conditions, implemented for blinding purposes). This sham stimulation procedure

is one of the commonly used placebo stimulation techniques (Davis et al., 2013).

2.7 EEG recording and analysis

To acquire electroencephalography (EEG) data, we used a wireless EEG system (Smarting®, mBrainTrain®, Belgrade, Serbia) with 22 Ag/AgCl sintered ring electrodes (Fp1, Fp2, AFz, F3, Fz, F4, T7, C3, Cz, C4, T8, CPz, P7, P3, Pz, P4, P8, POz, O1, O2, M1, M2) of the international 10/20 system that were mounted to an elastic EEG cap (Easycap, Herrsching, Germany). While electrode FPz served as ground, FCz served as reference electrode. The amplifier was connected via Bluetooth with the recording computer. Data was sampled at 500 Hz frequency via Lab Streaming Layer (LSL)[2] and all impedances were kept below 15 kΩ. EEG data were processed with Matlab 2021b (MathWorks Inc., Natick, MA, United States), using EEGLAB 2021.0 (Delorme and Makeig, 2004) and in-house scripts.

2.7.1 On-site analysis of IAF

For the evaluation of the individual stimulation frequency, resting EEG at channel Pz was filtered between 0.1 and 40 Hz and epoched into 2 s long segments. Afterwards, non-stereotyped artifacts were removed using built-in EEGLAB functions (joint probability test, ±1.7-SD single-channel and global-channel thresholds) before an independent-component-analysis (ICA) ("fastica" version) was conducted. After visual inspection of the generated ICA components, artifacts like vertical and horizontal eye movements were identified and removed in the continuous EEG data set. Clean continuous EEG data from channel Pz was epoched into 2 s long segments and the frequency power spectrum was extracted by Matlab's *pspectrum()* function between 0 and 40 Hz. The resulting frequency resolution was 0.05 Hz, while the resulting time resolution amounted to 0.25 s. Next, the power spectra were logarithmized and averaged across trials. Finally, the maximum alpha frequency between 7 and 13 Hz was used for the calculation of stimulation parameters.

2.7.2 Stereotyped artifact removal for offline wavelet analysis

Before wavelet analyses were performed, the EEG datasets were cleaned from stereotypic artifacts by the following steps: First, the EEG data was resampled to 250 Hz, filtered between 1 and 40 Hz, and detrended. Second, due to tACS artifacts during stimulation, the second CPT block was removed. Third, noisy EEG channels were detected (6 datasets, $M = 1.67$, $SD = 0.82$) and replaced via spherical interpolation. Fourth, for computing an independent component analysis (ICA), the continuous EEG data was segmented into 2 s time windows and non-stereotypic artifacts were removed using built-in EEGLAB functions (joint probability test, ± 2-SD single-channel and global-channel thresholds). Fifth, the ICA ("extended" version) was computed on the epoched data and components reflecting horizontal or vertical eye movements, heartbeat, muscle activity, or electrode artifacts were visually identified, backprojected to the continuous EEG data, and then rejected. All components that included a 10 Hz peak were retained.

2.7.3 Offline wavelet analysis of alpha activity during CPT blocks

One wavelet analysis focused on potential differences in alpha activity between blocks (pre-intervention vs. post-intervention block) and interventions (active stimulation vs. sham stimulation) during CPT performance. To this end, the ICA-corrected continuous EEG datasets were split into four segmented subsets, such that each subset represented one of the four compared conditions and entailed as many non-overlapping 2 s EEG segments as available within the CPT block of the respecting condition. Next, the following identical pre-processing and analysis steps were performed on each subset: First, the same non-stereotypic artifact removal was conducted that had already been conducted for the ICA calculation. Second, additional non-stereotypic artifact removal was conducted with the help of an eeglab plugin (Ben-Shachar, 2020), in that within each epoch, channels that exceeded 150 μV were marked for rejection. If the channels being marked for rejection were noisy in more than 15% of all epochs, the channels were excluded. In addition, epochs with more than 10 identified bad channels were rejected, while epochs with less than 10 bad channels were included, whereby bad-channel data was replaced by spherical interpolation. Third, a continuous wavelet transformation (CWT) was calculated on each retained epoch of the respective dataset (intervention) for channels Pz, POz, CPz, P3, P4. The frequency range obtained thereby reached from 0.27 Hz to 30.00 Hz in 69 steps on a log scale and the time resolution amounted to 0.004 s. After that, the derived power spectra were logarithmized and a mean power spectrum was derived by averaging across all derived power spectra. Finally, for statistical analyses, the mean alpha power (7–13 Hz) across all five channels for both blocks (pre intervention/post intervention) and both interventions (active stimulation/sham stimulation) was derived by taking the average power across all frequency bins falling into the respecting frequency range and time range between 0.2 and 1.8 s. To check for outliers, the pre-to-post-difference for alpha power was calculated and it was examined whether any datasets differed ±2 standard deviations from the mean alpha power change.

2.7.4 Offline wavelet analysis of alpha activity during resting states

Another wavelet analysis focused on potential differences in alpha activity between blocks and interventions during the 2 min resting state phases. Here, the preprocessing steps were identical to the just described wavelet analysis on the CPT blocks, with the only exception that the segmentation into the four individual subsets was not based on the CPT blocks themselves, but on the 2 min resting state phases. The obtained frequency range and time range was the same as reported above (*cf.* section 2.4.3).

2.7.5 Eye tracking recording and analyses

Eye tracking analyses focused on differences in gaze behavior between blocks (pre-intervention vs. post-intervention) and interventions (active stimulation vs. sham stimulation). To acquire eye tracking data, eye movements were recorded with a sampling rate of ~50 Hz and an accuracy of approximately 0.5°-1.1° via the infrared-based Tobii eye tracker built into the head-mounted display

2 https://github.com/sccn/labstreaminglayer

(HMD). While the software developmental kit (SDK) SRanipal version 1.3.1.1 (HTC Corporation, Taoyuan, Taiwan) procured access to the eye tracking raw data within Unity, the Tobii XR SDK version 1.16.36.0 (Tobii Technology, Stockholm, Sweden) allowed to track the participant's momentary gaze on specified virtual objects within the VSR. Specifically, it was tracked when and for how long the participants looked at the canvas as well as on 3D objects that were implemented as distracting events (during DP). Offline analyses were run in Matlab 2021b (MathWorks Inc., Natick, MA, United States). To statistically compare gaze locations for each block and intervention, three parameters were extracted (Selaskowski et al., 2023a): Time looking at canvas (as a measure of task focus), time looking at distractors (as a measure of focus on specific distractors) and time of gaze wandering (i.e., that time amount the participants neither looked at a distractor nor at the canvas). Moreover, based on these three derived parameters, a composite distractibility score was calculated by dividing the sum of the time of looking at distractors (in %) and time of gaze-wandering (in %) by the time of looking at canvas (in %), with higher values indicating a higher level of distraction.

2.7.6 Actigraphy recording and analyses

Actigraphy analyses focused on differences in head position shifts and head rotations between blocks (pre-intervention vs. post-intervention) and interventions (sham stimulation vs. active stimulation). The two actigraphy parameters were inferred from the built-in positional tracking of the Vive system by means of which the HMDs momentary positions and rotations during the experiment were each recorded with a ~ 90 Hz sampling rate in three-dimensional Euclidean space coordinates. For offline analyses, actigraphy data was first down-sampled to 10 Hz. Next, the Euclidean distance between each sample point (three-dimensional position or rotation vector) and its preceding sample point was specifically calculated for the HMD position and HMD rotation data. Finally, to statistically compare the amount of head position shifts and rotations between conditions, the mean Euclidean distance in respect to head position shifts and head rotations was derived for each block and intervention.

2.8 Data exclusion

Twelve participants had to be excluded from the overall analyses: three because they refrained from the study after the diagnostic appointment or first measurement date; four because of technical difficulties (on at least one experimental day, EEG measurements were aborted or key presses were not recorded), four because the CPT in these subjects accidentally had a different number of pseudo-targets, and one because there were large outliers in CPT performance. Hence, 15 participants (4 female, $M_{age} = 32.53$, $SD = 11.07$) remained for analyses. Two datasets did not contain eye tracking data, hence only 13 datasets remained for these analyses. Considering a power analysis for a within-between interaction, a sample size of $n = 16$ would be required to establish reliable results with an effect size of $\eta^2 = 0.14$ and a power of 0.80. The effect sizes of our study exceeded these with $\eta^2 = 0.23$ for the EEG alpha power interaction effect, thereby determining the *post-hoc* power to 97.5% for this model (see section 3.4). Therefore, the obtained sample should be sufficient to detect potential tACS effects.

2.9 Statistical analyses

For statistical analyses with Matlab 2021b (MathWorks Inc., Natick, MA, United States), the following outcome variables were included: omission error rate, commission error rate, and RTV for the CPT analysis; hyperactivity, inattention, and impulsivity ratings for the subjective ADHD symptom evaluation; mean alpha power for the wavelet analysis; composite distractibility score, gaze time on canvas, gaze time on distractors and gaze-wandering time for eye tracking analysis; and head movement and rotation for actigraphy analyses. For each main dependent variable, a two-way repeated measures ANOVA with the two within-factors "Block" (pre-intervention vs. post-intervention) and "Intervention" (active stimulation vs. sham stimulation) was conducted, with an α-level of 0.05. In case of a significant interaction, we followed up this interaction via *post-hoc* *t*-tests (sham pre vs. sham post; active pre vs. active post; sham pre vs. active pre; sham post vs. active post). In order to correct for multiple comparison by Bonferroni correction, only those $p < 0.0125$ (α-level of 0.05/4 *post-hoc* tests) were considered as statistically significant.

3 Results

3.1 Sample characteristics

Results of the eligibility assessment and clinical characterization are reported in Table 1. Out of the 15 participants analyzed (4 female, $M_{age} = 32.53$, $SD = 11.07$), 14 participants (93.3%) were found to have a combined ADHD presentation and one participant (6.7%) had a predominantly inattentive presentation. None of our participants were assigned to the impulsive–hyperactive subtype. An ADHD diagnosis had been evident since childhood in 12 participants (80%). Six patients received ADHD-medication. Moreover, five patients took selective serotonin reuptake inhibitors or selective serotonin-noradrenalin-reuptake-inhibitors for the treatment of depression or anxiety. Most participants had a higher education entrance qualification (73.3%). The most common current comorbidities found were anxiety disorders (53.3%) and affective disorders (46.7%). According to the depression-anxiety-scales (DASS-21; Nilges and Essau, 2015), participants revealed, on average, only low scores for symptoms of depression ($M = 12.73$; $SD = 2.91$), anxiety ($M = 12.13$; $SD = 3.11$) and stress ($M = 15.00$; $SD = 3.70$).

Most frequently reported tACS side effects, according to the questionnaire about tACS side effects (Brunoni et al., 2011), were fatigue ($n = 12$ per condition, 80%), whereby only two participants (13.4%) in the active stimulation condition associated fatigue symptoms with tACS, but rather linking it to the experiment duration. In addition, difficulties in concentration and headaches were reported (for detailed results, see Supplementary material 2). This implies that during the experiment, participants experienced some discomfort, but no one aborted the experiment and no serious adverse events occurred. Checking for blinding, analyses revealed that for active stimulation 9 participants (60%) detected the condition correctly.

3.2 Behavioral performance

Results of the CPT analyses are shown in Figure 2. Regarding omission error rate (Figure 2A), the ANOVA revealed neither a

TABLE 1 Demographic and clinical characteristics of the sample.

Total sample (*n*)	15
Female [*n* (%)]	4 (26.67)
Age [*M* (*SD*)]	32.53 (11.07)

Interview data		
IDA-R		**Maximum scores**
ADHD presentations [n (%)]		
Combined type	14 (93.33)	
Predominantly hyperactive–impulsive type	0	
Predominantly inattentive type	1 (6.67)	
ADHD scores [M (SD)]		
Total	35.60 (6.20)	54
Inattention	19.80 (3.41)	27
Hyperactivity	9.13 (2.88)	15
Impulsivity	6.67 (3.09)	12

Mini-DIPS*		
	Current diagnosis (*n*)	**Previous diagnosis (*n*)**
Affective disorder	6	2
Anxiety disorder	5	0
Somatoform disorder	1	0
Sleep disorder	2	1

Questionnaire data:		
ADHS-SB	***M* (*SD*)**	**Maximum scores**
Total	45.67 (9.54)	54
Inattention	24.67 (4.59)	27
Hyperactivity	11.87 (3.42)	15
Impulsivity	9.13 (2.90)	12
WHOQOL		**Maximum scores**
Total	61.08 (13.44)	100
Physical health	59.66 (18.12)	100
Psychological health	49.72 (19.70)	100
Social relationships	62.22 (16.33)	100
Environment	72.71 (14.87)	100
DASS-21		**Maximum scores**
Total	13.29 (2.26)	21
Depression	12.73 (2.91)	21
Anxiety	12.13 (3.11)	21
Stress	15.00 (3.70)	21

Results of the eligibility assessment and clinical characterization of the sample. *Only comorbidities with > 0 occurrences are reported. Maximum scores for IDA-R and ADHD-SB depict sum scores, while for WHQOL and DASS mean scores.

significant main effect of "Block" (F (1, 14) = 0.96, p = 0.347, η_p^2 = 0.06), nor a main effect of "Intervention" (F (1, 14) = 1.48, p = 0.244, η_p^2 = 0.10) and no interaction effect (F (1, 14) = 0.22, p = 0.647, η_p^2 = 0.02). Also, for commission error rate (Figure 2B), the ANOVA revealed neither a significant effect of "Block" (F (1, 14) = 3.27, p = 0.092, η_p^2 = 0.19), nor a significant effect of "Intervention" (F (1, 14) = 0.36, p = 0.557, η_p^2 = 0.03), and no interaction effect (F (1, 14) = 0.04, p = 0.848, η_p^2 = 0.00) was found. And finally, the ANOVA for reaction time variability (Figure 2C) yielded neither a significant main effect of "Block" (F (1, 14) = 0.33, p = 0.577, η_p^2 = 0.02) or "Intervention" (F (1, 14) = 0.14, p = 0.712, η_p^2 = 0.01), nor an interaction effect (F (1, 14) = 1.12, p = 0.307, η_p^2 = 0.07).

3.3 Subjective ADHD symptom evaluation

Results of the subjective evaluations are shown in Figure 3. For reported hyperactivity (Figure 3A), the ANOVA revealed a significant effect of "Block" (F (1, 14) = 5.38, p = 0.036, η_p^2 = 0.28), but no significant effect of "Intervention" (F (1, 14) = 2.34, p = 0.148, η_p^2 = 0.14) and no interaction effect (F (1, 14) = 2.13, p = 0.167, η_p^2 = 0.13). The significant "Block" effect consisted of higher hyperactivity scores during the pre-intervention (M = 1.19; SD = 0.45) than post-intervention (M = 1.03; SD = 0.45) block.

For reported inattention (Figure 3B), in turn, the ANOVA revealed neither a significant effect of "Block" (F (1, 14) = 0.03, p = 0.862, η_p^2 = 0.00) nor an effect of "Intervention" (F (1, 14) = 0.01, p = 0.939, η_p^2 = 0.00), and no interaction effect (F (1, 14) = 3.81, p = 0.071, η_p^2 = 0.21). Finally, regarding reported impulsivity (Figure 3C), the ANOVA revealed no significant main effect of "Block" (F (1, 14) = 0.44, p = 0.648, η_p^2 = 0.03), or "Intervention" (F (1, 14) = 1.91, p = 0.188, η_p^2 = 0.12), but a significant interaction effect (F (1, 14) = 3.40, p = 0.048, η_p^2 = 0.20). Following up this interaction effect, Bonferroni corrected paired t-tests neither revealed a significant difference between pre- to post- intervention for active stimulation (t (14) = 0.33, p = 0.746) nor sham stimulation (t (14) = −1.99, p = 0.067). All other follow-up t-test were non-significant.

3.4 Wavelet analysis

Before starting the actual experiment, the mean alpha frequency outside VR amounted to M = 9.63 (SD = 0.69) in the stimulation group and M = 9.67 (SD = 0.98) in the sham group. Results of the wavelet analysis during CPT are shown in Figure 4, while the individual mean alpha power during CPT before and after both interventions are depicted in Figure 5. The ANOVA on the mean alpha power revealed no significant main effect for "Intervention" (F (1, 14) = 0.97, p = 0.342, η_p^2 = 0.06), but a significant main effect of "Block" (F (1, 14) = 23.11, p < 0.001, η_p^2 = 0.62), and a trend for an interaction effect (F (1, 14) = 4.19, p = 0.060, η_p^2 = 0.23). The block effect resulted from higher amplitude values during the post-intervention block (M = 3.61, SD = 1.25) compared to the pre-intervention block (M = 3.13, SD = 0.10). Following up the trend for an interaction exploratively, we see a significant increase from pre- to post-measurements during sham stimulation (t (14) = −3.14, p = 0.007) and active stimulation (t (14) = −5.64, p = <0.001), even after Bonferroni correction. All other follow-up t-test were non-significant.

Results of the wavelet analyses during the two-minutes resting phases, are, in turn, depicted in the Supplementary material 1. Here, the ANOVA revealed a significant main effect of "Block" (F (1, 14) = 9.87, p = 0.007, η_p^2 = 0.41), but no significant effect for

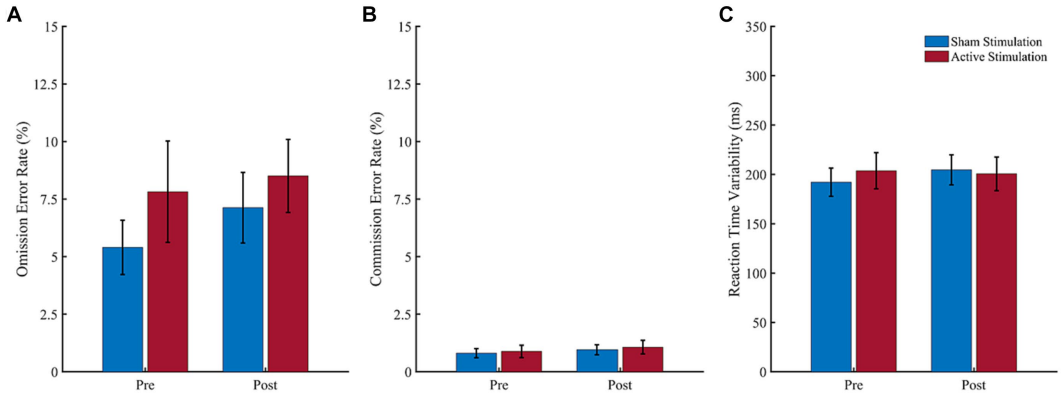


FIGURE 2
Results of the CPT. Values depict means for the **(A)** omission error rate, **(B)** commission error rate and **(C)** reaction time variability before (pre) and after (post) sham stimulation (blue bars) and active stimulation (red bars). Error bars represent the standard error of the mean.

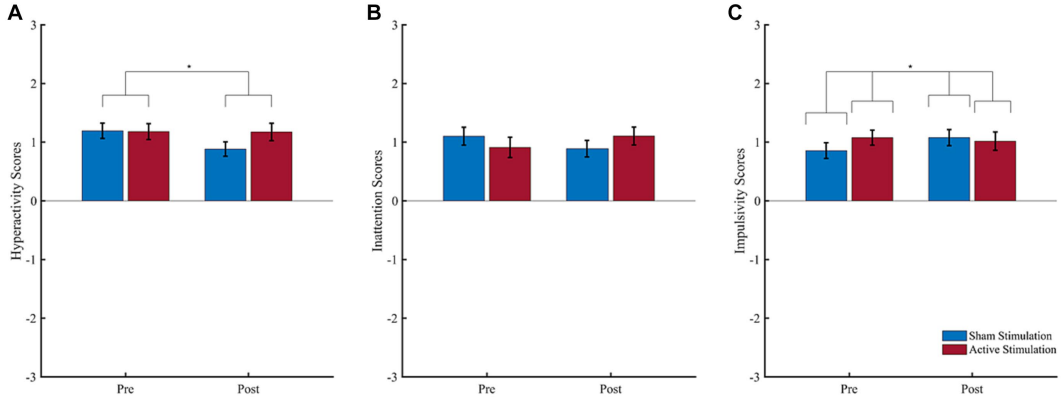


FIGURE 3
Subjective ratings of core ADHD symptoms. Patient-rated symptoms of **(A)** hyperactivity, **(B)** inattention, and **(C)** impulsivity before (pre) and after (post) intervention. Scores ranged from −3 (strongly disagree) to 3 (strongly agree). Error bars represent the standard error of the mean. *$p < 0.05$.

"Intervention" (F (1, 14) = 3.60, p = 0.079, η_p^2 = 0.20), and only a trend for an interaction effect (F (1, 14) = 4.09, p = 0.063, η_p^2 = 0.23). Following up on the trend for an interaction exploratively, after applying the Bonferroni correction, none of the paired t-tests yielded statistically significant differences in any of the tests conducted.

3.5 Eye tracking

Results of the eye tracking analyses are depicted in Figure 6. The ANOVA for gaze time on canvas revealed no significant main effect of "Block" (F (1, 12) = 2.23, p = 0.161, η_p^2 = 0.16), or "Intervention" (F (1, 12) = 0.01, p = 0.914, η_p^2 = 0.00), and no significant interaction (F (1, 12) = 0.01, p = 0.942, η_p^2 = 0.00). For the gaze time looking on distractors, in turn, there was a trend for "Block" (F (1, 12) = 4.47, p = 0.056, η_p^2 = 0.27), but no effect for "Intervention" (F (1, 12) = 0.32, p = 0.580, η_p^2 = 0.03) or the interaction (F (1, 12) = 3.21, p = 0.098, η_p^2 = 0.21). The trend effect indicated potentially higher gaze time on distractors during the post-intervention block (M = 4.75, SD = 3.71) compared to the pre-intervention block (M = 3.60, SD = 2.61). The ANOVA for gaze wandering revealed no significant main effect of "Block" (F (1, 12) = 0.77, p = 0.396, η_p^2 = 0.06), or "Intervention" (F (1, 12) = 0.05, p = 0.824, η_p^2 = 0.00), and no significant interaction (F (1, 12) = 0.16, p = 0.700, η_p^2 = 0.01).

3.6 Actigraphy

Results of the actigraphy analyses are depicted in Figure 7. For head position, there was a significant effect for "Block" (F (1, 14) = 18.83, p < 0.001, η_p^2 = 0.57) but neither for "Intervention" (F (1, 14) = 0.70, p = 0.418, η_p^2 = 0.05) nor for the interaction (F (1, 14) = 0.08, p = 0.776, η_p^2 = 0.01). The block effect resulted from higher head position scores in the post-intervention block (M = 4.01, SD = 2.26) compared to the pre-intervention block (M = 3.00, SD = 2.10). For head rotation, there was no significant effect for "Block" (F (1, 14) = 0.02, p = 0.897, η_p^2 = 0.00) or "Intervention" (F (1, 14) = 0.01, p = 911, η_p^2 = 0.00), and no significant interaction (F (1, 14) = 3.61, p = 0.078, η_p^2 = 0.21).

4 Discussion

Given the evidence for a decreased EEG alpha power in adult ADHD (Loo et al., 2009; Woltering et al., 2012; Poil et al., 2014; Liu

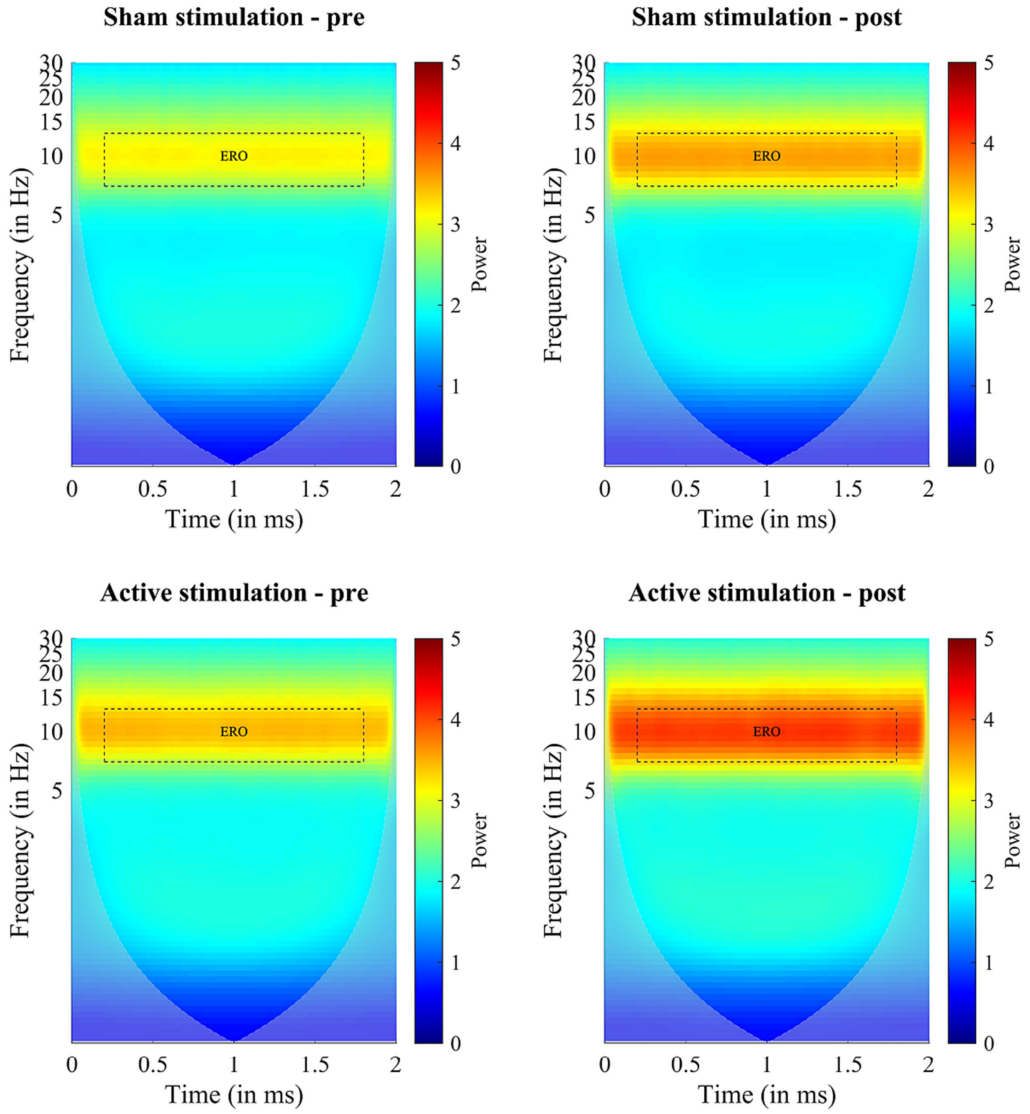


FIGURE 4
Results of the Wavelet analyses during CPT performance before (pre) and after (post) intervention (sham stimulation vs. active stimulation). Data analyses based on $n = 15$ datasets. ERO = event related potential.

et al., 2016; Deiber et al., 2020), the objective of the current study was to increase the alpha power of adult ADHD patients and to explore possible resulting neurophysiological and/or behavioral changes. Therefore, we carried out a crossover trial, in which a final sample of $n = 15$ adult patients with ADHD underwent both an individual tACS-based alpha stimulation (active stimulation) and a placebo stimulation (sham stimulation) while performing a CPT in a VSR scenario. We examined the mean alpha power at rest (2 min each) and during CPT conductance (18 min each), CPT performances, subjective ADHD symptoms, head movement and rotation, and gaze behavior before and after both interventions.

While alpha power significantly increased from pre- to post-interventions, we were not able to find a significantly stronger increase in alpha power due to active stimulation compared to sham stimulation, neither at rest nor during CPT execution. Although both statistical analyses each yielded a trend for a significant interaction, exploratively assessed trend interactions indicated time differences rather than intervention effects. While the block effect can be attributed to a natural alpha rise in both groups, which is a well-known phenomenon during a prolonged cognitive task as a function of time on task and mental fatigue (Fan et al., 2015; Gharagozlou et al., 2015; Trejo et al., 2015; Benwell et al., 2019), it is not clear why we do not find a significant difference in the participants' alpha power comparing the application of active and sham stimulation. Nevertheless, since we only expect a small effect of tACS anyway and, in addition, the effect of tACS is quite variable, the small sample size is a constraint in our study. It seems that a larger sample size could have resulted in a significant effect.

In addition, patients with different ADHD presentations seem to show varying levels of alpha power. Most studies suggest a decreased alpha power in patients with ADHD (Loo et al., 2009; Woltering et al., 2012; Poil et al., 2014; Liu et al., 2016; Deiber et al., 2020), but some studies also report an increased alpha power (Koehler et al., 2009; Poil et al., 2014; Deiber et al., 2020), especially for those suffering from

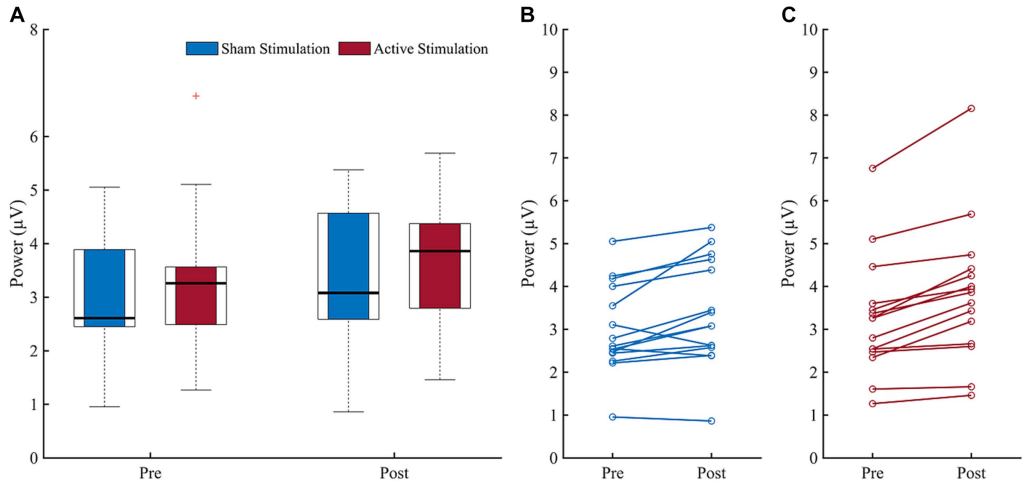


FIGURE 5
Block comparison (pre vs. post) of individual mean alpha power. **(A)** Boxplots depict mean alpha power before (pre) and after (post) for sham stimulation (blue) and active stimulation (red). **(B)** Pre to post change of individual mean alpha power for sham stimulation and **(C)** for active stimulation. Data analyses based on $n = 15$ datasets. Error bars represent the standard error of the mean.

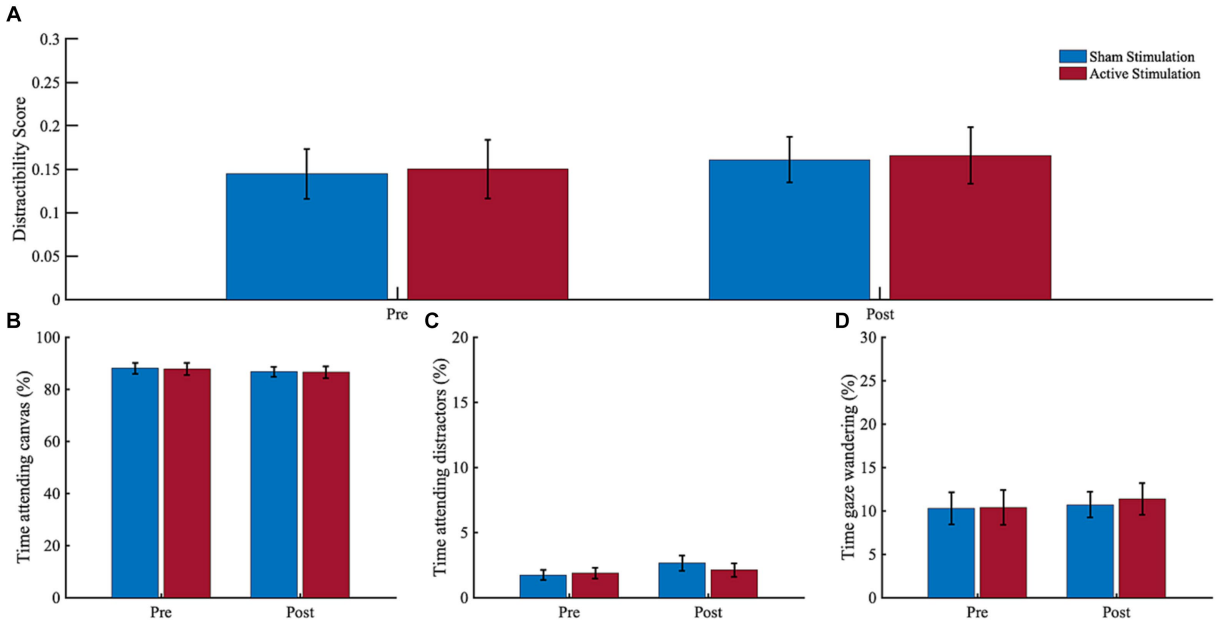


FIGURE 6
Eye tracking results. **(A)** Distractibility score, **(B)** Time attending canvas, **(C)** Time attending distractors, and **(D)** Time gaze wandering. Dwell time percentages before (pre) and after (post) sham stimulation (blue bars) and active stimulation (red bars). Data analyses based on $n = 13$ datasets. Error bars represent the standard error of the mean.

hyperactivity/impulsivity (Deiber et al., 2020). Of note, our ADHD sample almost exclusively consisted of patients with the combined ADHD presentation. Hence, almost all our patients also exhibited a level of hyperactivity, which might be associated with a higher and therefore not strongly further increasable alpha power. This indicates that a subgroup of ADHD patients (e.g., a predominantly inattentive sample) associated with a diminished alpha power, might have benefited more from the tACS application. However, since our data seem to show a high variability in the alpha power pre-to-post change (*cf.* Figures 5B,C), further basic research is needed to clarify whether abnormal alpha power is a neuromarker for a specific ADHD subtype, and to what extent subtype-specific neural activity patterns need to be taken more into account in the application of tACS.

Finally, the success of brain stimulation might have been influenced by inter- and intraindividual variability, e.g., by an unfavorable brain state during the application of tACS or by using a non-individualized

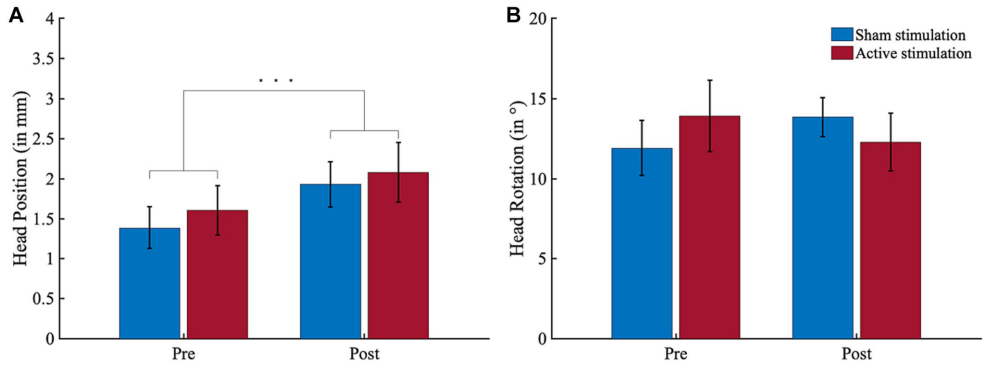


FIGURE 7
Actigraphy results. **(A)** Head position (in mm per 100 ms) and **(B)** head ration (in ° per 100 ms) shifts in block 1 (pre-intervention) and block 3 (post-intervention). All participants conducted greater head position shifts during block 3 than block 1. Error bars represent the standard error of the mean. ***$p < 0.001$.

electrode montage that failed to target the correct source (Bergmann, 2018; von Conta et al., 2021; Kasten and Herrmann, 2022). This could have affected the subsequent aftereffects (the so called "offline effects" that we have investigated) of induced synaptic changes by non-invasive brain stimulation (for details, see, e.g., Vossen et al., 2015). One possible innovative approach to overcome the individual variability would be to use a closed loop system that tracks brain activity during tACS application and adjusts the stimulation accordingly (Zrenner et al., 2016). Since there are only few studies investigating online adaptation of stimulation parameters depending on current brain activity so far, the efficiency and practicability of such closed loop systems needs to be further evaluated (Bergmann et al., 2016; Karabanov et al., 2016; Thut et al., 2017; Stecher et al., 2021).

Regarding behavioral measures, we found no indication for a tACS-induced cognitive improvement for any of our CPT performance, eye tracking, actigraphy or subjective measures. In sum, our tACS application does not appear to have induced any clinically meaningful effect in terms of behavioral changes.

4.1 Task related time-on-task effects

Regarding pre-post effects, one interesting finding is that there was a higher gaze time spent on distractors as well as a higher amount of head position movements in the post-intervention block as compared to the pre-intervention block. The latter result is consistent with the results of a virtual classroom study in ADHD children by Mühlberger et al. (2020) as well as with our own VSR study in healthy controls (Wiebe et al., 2022), which both yielded very similar time-on-task head movement effects. Regarding gaze duration on distractors, the outcome agrees with Wiebe et al. (2023), who found that unmedicated ADHD patients spent significantly more time gazing at distracting stimuli while being immersed into the VSR, compared to healthy controls. Interpreting both results, it could be assumed that our participants became increasingly inattentive and/or restless over the duration of the experiment. This, in turn, may suggest that our VSR setup was able to induce the neuropsychologically-desired boredom and monotony in our participants that may provoke inattention, hyperactivity, and impulsivity in adults with ADHD. If this is true, this induction of monotony was, however, insufficiently small, as no pre-post effect was found for any of the CPT performance measures.

Another finding is that in contrast to the pre-post increase of head movements, participants reported to be less hyperactive in the post-intervention block as compared to the pre-intervention block. In other words, while the participants perceived that their motor activity decreased over the course of the experiment, their motor activity increased. One possible explanation for this mismatch between active and experienced movement behavior might be a "positive illusory bias" (i.e., an overestimation of one's own competence that does not correspond to one's active performance) that has already been repeatedly reported for ADHD children (Owens et al., 2007; Prevatt et al., 2012; Volz-Sidiropoulou et al., 2016) and recently also for ADHD adults (Butzbach et al., 2021). Another alternative explanation might be habituation. That is, our participants got used to the experimental procedure and virtual surrounding and thereby became less excited over time, what resulted in diminished feeling of restlessness. Likewise, it is also conceivable that head movements might not be a reliable marker of hyperactivity in patients with ADHD. Nevertheless, these diverging outcomes underline the importance of a multimodal assessment when testing the efficacy of tACS or other therapeutic interventions in ADHD, as our data suggests that one cannot rely on subjective data alone.

4.2 Limitations and future directions

A limitation of this study is the small final sample size ($n = 15$). Reasons for this included our technically challenging multimodal VR paradigm, which caused some technical difficulties during data acquisition, as well as an impeded ADHD patient access due to the Corona pandemic. Our data suggest that a stimulation effect might have been found with a larger sample. Moreover, a larger sample could indicate the extent to which the specific ADHD presentation might be associated with a significant stimulation effect.

Another aspect to be considered is that, in addition to the studies cited for decreased alpha power (Loo et al., 2009; Woltering et al., 2012; Poil et al., 2014; Liu et al., 2016; Deiber et al., 2020), there is also some evidence for equal (van Dongen-Boomsma et al., 2010) or even increased alpha power (Bresnahan and Barry, 2002; Koehler et al.,

2009) in adult ADHD patients compared to healthy individuals. Assuming that the alpha power is increased, the mechanism of action proposed in this study to achieve attentional improvement through alpha amplification might be ineffective, since an already elevated endogenous alpha power cannot be further increased by tACS (Neuling et al., 2013). To account for heterogeneity, future studies might evaluate the alpha power of adult ADHD patients beforehand and allocate them accordingly into groups of low and high alpha power before applying tACS to test its therapeutic effect. Additionally, further work is needed to explore the potential differential effects of tACS on the different ADHD subtypes, thereby contributing to a more detailed understanding of its potential therapeutic applicability. Unfortunately, in the present study it was not possible to conduct such an analysis, as the majority of our participants was diagnosed with the combined ADHD type and only one participant with the predominantly inattentive subtype, thereby precluding a subgroup analysis.

It is also conceivable that other potential ADHD neuromarkers could be considered for tACS. One possibility might be the theta-beta-ratio (TBR), which seems encouraging since TBR differences between children with ADHD and healthy controls appear to exist (Monastra et al., 2001; Snyder and Hall, 2006; Zhang et al., 2017). The prospect of using tACS to correct this ratio would offer a non-invasive therapeutic approach aimed at improving attention and cognitive deficits in the ADHD population. Another promising option would be to enhance the P300 (Prox et al., 2007; Itagaki et al., 2011; Marquardt et al., 2018) by the application of tACS. Some studies already aimed for this goal (Dallmer-Zerbe et al., 2020; Kannen et al., 2022). A recent study by Boetzel et al. (2023) accomplished to increase the P300 amplitude in healthy controls but revealed no dependent effect on behavioral performance parameters yet.

Finally, to our knowledge, this study is one of the first attempting to increase the alpha power of adult ADHD patients using tACS. In addition, we combined the application of tACS with a multimodal VR assessment, creating a functional setup in which various measurement techniques (EEG, eye tracking, actigraphy, behavioral performance, subjective measures) are used to investigate a potential stimulation effect in psychophysiological, behavioral, and subjective domains. In fact, there are many different possibilities to apply tACS by changing stimulation parameters (e.g., stimulation intensity), electrode positions, electrode size, or stimulation frequency, which is why further studies will need to be undertaken.

5 Conclusion

In conclusion, our study provides no evidence that tACS can increase the alpha power in adult ADHD patients. With a larger sample, however, there might have been a significant difference, since the analyses revealed large effect sizes. Since alpha power in adult ADHD has not yet been investigated in depth and since there are still many conceivable parameter settings for the application of tACS, more research is needed to clarify whether alpha power enhancement via tACS could be advantageous as a possible therapeutic intervention for ADHD. Overall, we have succeeded in creating a multimodal experimental design including multiple measures (subjective, behavioral, electrophysiological, actigraphy, and eyetracking) to test the potential effects of tACS on adult ADHD and our research has raised numerous questions that require further investigation.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Ethics statement

The studies involving humans were approved by Medical ethics committee of the University of Bonn. The studies were conducted in accordance with the local legislation and institutional requirements. Written informed consent for participation in this study was provided by the participants. Written informed consent was obtained from the individual(s) for the publication of any potentially identifiable images or data included in this article.

Author contributions

KK: Conceptualization, Formal analysis, Investigation, Methodology, Project administration, Visualization, Writing – original draft, Writing – review & editing. JR: Investigation, Writing – review & editing. AF: Investigation, Writing – review & editing. AW: Formal analysis, Writing – review & editing. BS: Formal analysis, Writing – review & editing. LA: Writing – review & editing. BA: Writing – review & editing. SL: Writing – review & editing. CSH: Conceptualization, Methodology, Supervision, Writing – review & editing. AP: Conceptualization, Funding acquisition, Supervision, Writing – review & editing, Methodology. NB: Conceptualization, Formal analysis, Methodology, Supervision, Visualization, Writing – original draft, Writing – review & editing.

Funding

The author(s) declare financial support was received for the research, authorship, and/or publication of this article. The work was supported by a grant of the Federal Ministry of Education and Research (BMBF, 13GW0273E, given to AP). This publication was supported by the Open Access Publication Fund of the University of Bonn. NB received funding from BONFOR, by which NB and BS were partly funded. AP received funding from the German Federal Ministry of Education, by which BS's and KK's PhD positions were partly funded. AP and NB received funding from Medice, by which AW's PhD position was funded. AP receives funding from the State of North Rhine-Westphalia by which LA's PhD position is funded.

Conflict of interest

Over the past 3 years, AP received funding by the German Federal Ministry of Education and Research, Horizon 2020, Medice and DFG; she reports serving on advisory boards for Takeda, Medice and Boehringer; delivering lectures sponsored by Medice and Takeda; and being the author of books and articles on ADHD. CSH holds a patent on brain stimulation.

The remaining authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

CSH, NB, and SL declared that they were an editorial board member of Frontiers, at the time of submission. This had no impact on the peer review process and the final decision.

Publisher's note

All claims expressed in this article are solely those of the authors and do not necessarily represent those of their affiliated organizations, or those of the publisher, the editors and the reviewers. Any product that may be evaluated in this article, or claim that may be made by its manufacturer, is not guaranteed or endorsed by the publisher.

Supplementary material

The Supplementary material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpsyg.2023.1280397/full#supplementary-material

References

Adamou, M., Fullen, T., and Jones, S. L. (2020). EEG for diagnosis of adult ADHD: a systematic review with narrative analysis. *Front. Psych.* 11:871. doi: 10.3389/fpsyt.2020.00871

Arns, M., Heinrich, H., and Strehl, U. (2014). Evaluation of neurofeedback in ADHD: the long and winding road. *Biol. Psychol.* 95, 108–115. doi: 10.1016/J.BIOPSYCHO.2013.11.013

Barudin-Carreiro, A. M., Camhi, S. M., Lindsay, A. C., and Wright, J. A. (2022). Physical activity and executive function in children with ADHD: a systematic review. *Transl J Am Coll Sports Med* 7:e000183. doi: 10.1249/TJX.0000000000000183

Bashiri, A., Ghazisaeedi, M., and Shahmorasdi, L. (2017). The opportunities of virtual reality in the rehabilitation of children with attention deficit hyperactivity disorder: a literature review. *Korean J. Pediatr.* 60, 337–343. doi: 10.3345/KJP.2017.60.11.337

Bazanova, O. M., Auer, T., and Sapina, E. A. (2018). On the efficiency of individualized Theta/Beta ratio neurofeedback combined with forehead EMG training in ADHD children. *Front. Hum. Neurosci.* 12:3. doi: 10.3389/FNHUM.2018.00003

Ben-Shachar, M. S. (2020). TBT: Reject and interpolate channels on a epoch by epoch basis (2.6.1). *Zenodo.* doi: 10.5281/zenodo.3784278

Benwell, C. S. Y., London, R. E., Tagliabue, C. F., Veniero, D., Gross, J., Keitel, C., et al. (2019). Frequency and power of human alpha oscillations drift systematically with time-on-task. *NeuroImage* 192, 101–114. doi: 10.1016/J.NEUROIMAGE.2019.02.067

Bergmann, T. O. (2018). Brain state-dependent brain stimulation. *Front. Psychol.* 9:2108. doi: 10.3389/FPSYG.2018.02108

Bergmann, T. O., Karabanov, A., Hartwigsen, G., Thielscher, A., and Siebner, H. R. (2016). Combining non-invasive transcranial brain stimulation with neuroimaging and electrophysiology: current approaches and future perspectives. *NeuroImage* 140, 4–19. doi: 10.1016/J.NEUROIMAGE.2016.02.012

Boetzel, C., Stecher, H. I., and Herrmann, C. S. (2023). ERP-aligned delta transcranial alternating current stimulation modulates the P3 amplitude. *Int. J. Psychophysiol.* 193:112247. doi: 10.1016/j.ijpsycho.2023.112247

Bresnahan, S. M., and Barry, R. J. (2002). Specificity of quantitative EEG analysis in adults with attention deficit hyperactivity disorder. *Psychiatry Res.* 112, 133–144. doi: 10.1016/S0165-1781(02)00190-7

Brunoni, A. R., Amadera, J., Berbel, B., Volz, M. S., Rizzerio, B. G., and Fregni, F. (2011). A systematic review on reporting and assessment of adverse effects associated with transcranial direct current stimulation. *Int. J. Neuropsychopharmacol.* 14, 1133–1145. doi: 10.1017/S1461145710001690

Butzbach, M., Fuermaier, A. B. M., Aschenbrenner, S., Weisbrod, M., Tucha, L., and Tucha, O. (2021). Metacognition in adult ADHD: subjective and objective perspectives on self-awareness of cognitive functioning. *J. Neural Transm.* 128, 939–955. doi: 10.1007/s00702-020-02293-w

Chen, Y. H., Liang, S. C., Sun, C. K., Cheng, Y. S., Tzang, R. F., Chiu, H. J., et al. (2023). A meta-analysis on the therapeutic efficacy of repetitive transcranial magnetic stimulation for cognitive functions in attention-deficit/hyperactivity disorders. *BMC Psychiatry* 23:756. doi: 10.1186/s12888-023-05261-2

Cortese, S., Adamo, N., Del Giovane, C., Mohr-Jensen, C., Hayes, A. J., Carucci, S., et al. (2018). Comparative efficacy and tolerability of medications for attention-deficit hyperactivity disorder in children, adolescents, and adults: a systematic review and network meta-analysis. *Lancet Psychiatry* 5, 727–738. doi: 10.1016/S2215-0366(18)30269-4

Cunill, R., Castells, X., Tobias, A., and Capellà, D. (2016). Efficacy, safety and variability in pharmacotherapy for adults with attention deficit hyperactivity disorder: a meta-analysis and meta-regression in over 9000 patients. *Psychopharmacology* 233, 187–197. doi: 10.1007/s00213-015-4099-3

Dallmer-Zerbe, I., Popp, F., Lam, A. P., Philipsen, A., and Herrmann, C. S. (2020). Transcranial alternating current stimulation (tACS) as a tool to modulate P300 amplitude in attention deficit hyperactivity disorder (ADHD): preliminary findings. *Brain Topogr.* 33, 191–207. doi: 10.1007/s10548-020-00752-x

Davis, N. J., Gold, E., Pascual-Leone, A., and Bracewell, R. M. (2013). Challenges of proper placebo control for non-invasive brain stimulation in clinical and experimental applications. *Eur. J. Neurosci.* 38, 2973–2977. doi: 10.1111/ejn.12307

Deiber, M. P., Hasler, R., Colin, J., Dayer, A., Aubry, J. M., Baggio, S., et al. (2020). Linking alpha oscillations, attention and inhibitory control in adult ADHD with EEG neurofeedback. *Neuroimage Clin* 25:102145. doi: 10.1016/j.nicl.2019.102145

Delorme, A., and Makeig, S. (2004). EEGLAB: an open-source toolbox for analysis of single-trial EEG dynamics including independent component analysis. *J. Neurosci. Methods* 134, 9–21. doi: 10.1016/J.JNEUMETH.2003.10.009

Fan, X., Zhou, Q., Liu, Z., and Xie, F. (2015). Electroencephalogram assessment of mental fatigue in visual search. *Biomed. Mater. Eng.* 26, S1455–S1463. doi: 10.3233/BME-151444

Farokhzadi, F., Mohamadi, M. R., Khajevand Khosli, A., Akbarfahimi, M., Ali Beigi, N., and Torabi, P. (2020). Comparing the effectiveness of the transcranial alternating current stimulation (TACS) and Ritalin on symptoms of attention deficit hyperactivity disorder in 7-14-year-old children. *Acta Med. Iran.* 58, 637–648. doi: 10.18502/ACTA.V58I12.5156

Gharagozlou, F., Nasl Saraji, G., Mazloumi, A., Nahvi, A., Motie Nasrabadi, A., Rahimi Foroushani, A., et al. (2015). Detecting driver mental fatigue based on EEG alpha Power changes during simulated driving. *Iran J Public Health* 44, 1693–1700.

Goldman, R. I., Stern, J. M., Engel, J. J., Cohen, M. S. (2002). Simultaneous EEG and fMRI of the alpha rhythm. *NeuroReport* 13, 2487–2492. doi: 10.1097/01.wnr.0000047685.08940.d0

Graham, J., Banaschewski, T., Buitelaar, J., Coghill, D., Danckaerts, M., Dittmann, R. W., et al. (2011). European guidelines on managing adverse effects of medication for ADHD. *Eur. Child Adolesc. Psychiatry* 20, 17–37. doi: 10.1007/s00787-010-0140-6

Handelman, K., and Sumiya, F. (2022). Tolerance to stimulant medication for attention deficit hyperactivity disorder: literature review and case report. *Brain Sci.* 12:959. doi: 10.3390/brainsci12080959

Harper, A., Power, M., Orley, J., Herrman, H., Schofield, H., Murphy, B., et al. (1998). Development of the World Health Organization WHOQOL-BREF quality of life assessment. The WHOQOL Group. *Psychol Med* 28, 551–558. doi: 10.1017/S0033291798006667

Hasler, R., Perroud, N., Meziane, H. B., Herrmann, F., Prada, P., Giannakopoulos, P., et al. (2016). Attention-related EEG markers in adult ADHD. *Neuropsychologia* 87, 120–133. doi: 10.1016/j.neuropsychologia.2016.05.008

Herrmann, C. S., Rach, S., Neuling, T., and Strüber, D. (2013). Transcranial alternating current stimulation: a review of the underlying mechanisms and modulation of cognitive processes. *Front. Hum. Neurosci.* 7:279. doi: 10.3389/fnhum.2013.00279

Itagaki, S., Yabe, H., Mori, Y., Ishikawa, H., Takanashi, Y., and Niwa, S. (2011). Event-related potentials in patients with adult attention-deficit/hyperactivity disorder versus schizophrenia. *Psychiatry Res.* 189, 288–291. doi: 10.1016/j.psychres.2011.03.005

Kaiser, A., Aggensteiner, P. M., Baumeister, S., Holz, N. E., Banaschewski, T., and Brandeis, D. (2020). Earlier versus later cognitive event-related potentials (ERPs) in attention-deficit/hyperactivity disorder (ADHD): a meta-analysis. *Neurosci. Biobehav. Rev.* 112, 117–134. doi: 10.1016/J.NEUBIOREV.2020.01.019

Kannen, K., Aslan, B., Boetzel, C., Herrmann, C. S., Lux, S., Rosen, H., et al. (2022). P300 modulation via transcranial alternating current stimulation in adult attention-deficit/hyperactivity disorder: a crossover study. *Front. Psych.* 13:1469. doi: 10.3389/fpsyt.2022.928145

Karabanov, A., Thielscher, A., and Siebner, H. R. (2016). Transcranial brain stimulation: closing the loop between brain and stimulation. *Curr. Opin. Neurol.* 29, 397–404. doi: 10.1097/WCO.0000000000000342

Kasten, F. H., Dowsett, J., and Herrmann, C. S. (2016). Sustained aftereffect of α-tACS lasts up to 70 min after stimulation. *Front. Hum. Neurosci.* 10:245. doi: 10.3389/fnhum.2016.00245

Kasten, F. H., and Herrmann, C. S. (2022). The hidden brain-state dynamics of tACS aftereffects. *NeuroImage* 264:119713. doi: 10.1016/J.NEUROIMAGE.2022.119713

Kiiski, H., Bennett, M., Rueda-Delgado, L. M., Farina, F. R., Knight, R., Boyle, R., et al. (2020). EEG spectral power, but not theta/beta ratio, is a neuromarker for adult ADHD. *Eur. J. Neurosci.* 51, 2095–2109. doi: 10.1111/ejn.14645

Kim, H. K., Park, J., Choi, Y., and Choe, M. (2018). Virtual reality sickness questionnaire (VRSQ): motion sickness measurement index in a virtual reality environment. *Appl. Ergon.* 69, 66–73. doi: 10.1016/j.apergo.2017.12.016

Kis, B., Lücke, C., Abdel-Hamid, M., Heßmann, P., Graf, E., Berger, M., et al. (2020). Safety profile of methylphenidate under long-term treatment in adult ADHD patients - results of the COMPAS study. *Pharmacopsychiatry* 53, 263–271. doi: 10.1055/A-1207-9851

Klimesch, W. (2012). Alpha-band oscillations, attention, and controlled access to stored information. *Trends Cogn. Sci.* 16, 606–617. doi: 10.1016/j.tics.2012.10.007

Koehler, S., Lauer, P., Schreppel, T., Jacob, C., Heine, M., Boreatti-Hümmer, A., et al. (2009). Increased EEG power density in alpha and theta bands in adult ADHD patients. *J. Neural Transm.* 116, 97–104. doi: 10.1007/S00702-008-0157-X

Lakes, K. D., Cibrian, F. L., Schuck, S. E. B., Nelson, M., and Hayes, G. R. (2022). Digital health interventions for youth with ADHD: a mapping review. *Comput. Hum. Behav. Rep.* 6:100174. doi: 10.1016/J.CHBR.2022.100174

Liu, Z. X., Glizer, D., Tannock, R., and Woltering, S. (2016). EEG alpha power during maintenance of information in working memory in adults with ADHD and its plasticity due to working memory training: a randomized controlled trial. *Clin. Neurophysiol.* 127, 1307–1320. doi: 10.1016/J.CLINPH.2015.10.032

Llevy, F., Pipingas, A., Harris, E. V., Farrow, M., and Silberstein, R. B. (2018). Continuous performance task in ADHD: is reaction time variability a key measure? *Neuropsychiatr. Dis. Treat.* 14, 781–786. doi: 10.2147/NDT.S158308

Loo, S. K., Hale, T. S., Macion, J., Hanada, G., McGough, J. J., McCracken, J. T., et al. (2009). Cortical activity patterns in ADHD during arousal, activation and sustained attention. *Neuropsychologia* 47, 2114–2119. doi: 10.1016/j.neuropsychologia.2009.04.013

Louthrenoo, O., Boonchooduang, N., Likhitweerawong, N., Charoenkwan, K., and Srisurapanont, M. (2022). The effects of neurofeedback on executive functioning in children with ADHD: a meta-analysis. *J. Atten. Disord.* 26, 976–984. doi: 10.1177/10870547211045738

Margraf, J., Cwik, J. C., Pflug, V., and Schneider, S. (2017). Strukturierte klinische Interviews zur Erfassung psychischer Störungen über die Lebensspanne. *Z. Klin. Psychol. Psychother.* 46, 176–186. doi: 10.1026/1616-3443/a000430

Marquardt, L., Eichele, H., Lundervold, A. J., Haavik, J., and Eichele, T. (2018). Event-related-potential (ERP) correlates of performance monitoring in adults with attention-deficit hyperactivity disorder (ADHD). *Front. Psychol.* 9:485. doi: 10.3389/fpsyg.2018.00485

Mészáros, Á., Czobor, P., Bálint, S., Komlósi, S., Simon, V., and Bitter, I. (2009). Pharmacotherapy of adult attention deficit hyperactivity disorder (ADHD): a meta-analysis. *Int. J. Neuropsychopharmacol.* 12, 1137–1147. doi: 10.1017/S1461145709990198

Monastra, V. J., Lubar, J. F., and Linden, M. (2001). The development of a quantitative electroencephalographic scanning process for attention deficit–hyperactivity disorder: reliability and validity studies. *Neuropsychology* 15, 136–144. doi: 10.1037/0894-4105.15.1.136

Montalva-Valenzuela, F., Andrades-Ramírez, O., and Castillo-Paredes, A. (2022). Effects of physical activity, exercise and sport on executive function in young people with attention deficit hyperactivity disorder: a systematic review. *Eur J Investig Health Psychol Educ* 12, 61–76. doi: 10.3390/EJIHPE12010006

Moreno-García, I., Cano-Crespo, A., and Rivera, F. (2022). Results of neurofeedback in treatment of children with ADHD: a systematic review of randomized controlled trials. *Appl. Psychophysiol. Biofeedback* 47, 145–181. doi: 10.1007/s10484-022-09547-1

Mühlberger, A., Jekel, K., Probst, T., Schecklmann, M., Conzelmann, A., Andreatta, M., et al. (2020). The influence of methylphenidate on hyperactivity and attention deficits in children with ADHD: a virtual classroom test. *J. Atten. Disord.* 24, 277–289. doi: 10.1177/1087054716647480

Neguț, A., Jurma, A. M., and David, D. (2017). Virtual-reality-based attention assessment of ADHD: ClinicaVR: classroom-CPT versus a traditional continuous performance test. *Child Neuropsychol.* 23, 692–712. doi: 10.1080/09297049.2016.1186617

Neuling, T., Rach, S., and Herrmann, C. S. (2013). Orchestrating neuronal networks: sustained after-effects of transcranial alternating current stimulation depend upon brain states. *Front. Hum. Neurosci.* 7:161. doi: 10.3389/fnhum.2013.00161

Neuling, T., Wagner, S., Wolters, C. H., Zaehle, T., and Herrmann, C. S. (2012). Finite-element model predicts current density distribution for clinical applications of tDCS and tACS. *Front. Psych.* 3:83. doi: 10.3389/FPSYT.2012.00083/BIBTEX

Nichols, S. L., and Waschbusch, D. A. (2004). A review of the validity of laboratory cognitive tasks used to assess symptoms of ADHD. *Child Psychiatry Hum. Dev.* 34, 297–315. doi: 10.1023/B:CHUD.0000020681.06865.97

Nilges, P., and Essau, C. (2015). Die Depressions-Angst-Stress-Skalen: Der DASS–ein Screeningverfahren nicht nur für Schmerzpatienten. *Schmerz* 29, 649–657. doi: 10.1007/s00482-015-0019-z

Oldfield, R. C. (1971). The assessment and analysis of handedness: the Edinburgh inventory. *Neuropsychologia* 9, 97–113. doi: 10.1016/0028-3932(71)90067-4

Owens, J. S., Goldfine, M. E., Evangelista, N. M., Hoza, B., and Kaiser, N. M. (2007). A critical review of self-perceptions and the positive illusory Bias in children with ADHD. *Clin. Child. Fam. Psychol. Rev.* 10, 335–351. doi: 10.1007/s10567-007-0027-3

Parsons, T. D. (2015). Virtual reality for enhanced ecological validity and experimental control in the clinical, affective and social neurosciences. *Front. Hum. Neurosci.* 9:660. doi: 10.3389/fnhum.2015.00660

Poil, S.-S., Bollmann, S., Ghisleni, C., O'Gorman, R. L., Klaver, P., Ball, J., et al. (2014). Age dependent electroencephalographic changes in attention-deficit/hyperactivity disorder (ADHD). *Clin. Neurophysiol.* 125, 1626–1638. doi: 10.1016/j.clinph.2013.12.118

Prevatt, F., Proctor, B., Best, L., Baker, L., van Walker, J., and Taylor, N. W. (2012). The positive illusory bias: does it explain self-evaluations in college students with ADHD? *J. Atten. Disord.* 16, 235–243. doi: 10.1177/1087054710392538

Prox, V., Dietrich, D. E., Zhang, Y., Emrich, H. M., and Ohlmeier, M. D. (2007). Attentional processing in adults with ADHD as reflected by event-related potentials. *Neurosci. Lett.* 419, 236–241. doi: 10.1016/j.neulet.2007.04.011

Rahmani, E., Mahvelati, A., Alizadeh, A., Mokhayeri, Y., Rahmani, M., Zarabi, H., et al. (2022). Is neurofeedback effective in children with ADHD? A systematic review and meta-analysis. *Neurocase* 28, 84–95. doi: 10.1080/13554794.2022.2027456

Retz, W., Retz-Junginger, P., and Rösler, M. (2014). *Integrierte Diagnose der ADHS im Erwachsenenalter-Revidierte Version (IDA-R)*. Iserlohn: MEDICE.

Romero-Ayuso, D., Toledano-González, A., Rodríguez-Martínez, M., Arroyo-Castillo, P., Triviño-Juárez, J. M., González, P., et al. (2021). Effectiveness of virtual reality-based interventions for children and adolescents with ADHD: a systematic review and meta-analysis. *Children* 8:70. doi: 10.3390/children8020070

Rösler, M., Retz, W., Retz-Junginger, P., Thome, J., Supprian, T., Nissen, T., et al. (2004). Instrumente zur Diagnostik der Aufmerksamkeitsdefizit-/Hyperaktivitätsstörung (ADHS) im Erwachsenenalter. *Nervenarzt* 75, 888–895. doi: 10.1007/s00115-003-1622-2

Salehinejad, M. A., Nejati, V., Mosayebi-Samani, M., Mohammadi, A., Wischnewski, M., Kuo, M. F., et al. (2020). Transcranial direct current stimulation in ADHD: a systematic review of efficacy, safety, and protocol-induced electrical field modeling results. *Neurosci. Bull.* 36, 1191–1212. doi: 10.1007/S12264-020-00501-X

Sarris, J., Kean, J., Schweitzer, I., and Lake, J. (2011). Complementary medicines (herbal and nutritional products) in the treatment of attention deficit hyperactivity disorder (ADHD): a systematic review of the evidence. *Complement. Ther. Med.* 19, 216–227. doi: 10.1016/J.CTIM.2011.06.007

Seiffer, B., Hautzinger, M., Ulrich, R., and Wolf, S. (2022). The efficacy of physical activity for children with attention deficit hyperactivity disorder: a meta-analysis of randomized controlled trials. *J. Atten. Disord.* 26, 656–673. doi: 10.1177/10870547211017982

Selaskowski, B., Asché, L. M., Wiebe, A., Kannen, K., Aslan, B., Gerding, T. M., et al. (2023a). Gaze-based attention refocusing training in virtual reality for adult attention-deficit/hyperactivity disorder. *BMC Psychiatry* 23:74. doi: 10.1186/s12888-023-04551-z

Selaskowski, B., Reiland, M., Schulze, M., Aslan, B., Kannen, K., Wiebe, A., et al. (2023b). Chatbot-supported psychoeducation in adult attention-deficit hyperactivity disorder: Randomised controlled trial. *BJPsych Open* 9:E192. doi: 10.1192/bjo.2023.573

Selaskowski, B., Steffens, M., Schulze, M., Lingen, M., Aslan, B., Rosen, H., et al. (2022). Smartphone-assisted psychoeducation in adult attention-deficit/hyperactivity disorder: a randomized controlled trial. *Psychiatry Res.* 317:114802. doi: 10.1016/j.psychres.2022.114802

Snyder, S. M., and Hall, J. R. (2006). A meta-analysis of quantitative EEG Power associated with attention-deficit hyperactivity disorder. *J. Clin. Neurophysiol.* 23, 441–456. doi: 10.1097/01.wnp.0000221363.12503.78

Stecher, H. I., Notbohm, A., Kasten, F. H., and Herrmann, C. S. (2021). A comparison of closed loop vs. fixed frequency tACS on modulating brain oscillations and visual detection. *Front. Hum. Neurosci.* 15:272. doi: 10.3389/FNHUM.2021.661432/BIBTEX

Swanson, J. M. (2019). Debate: are stimulant medications for attention-deficit/hyperactivity disorder effective in the long term? (against). *J. Am. Acad. Child Adolesc. Psychiatry* 58, 936–938. doi: 10.1016/j.jaac.2019.07.001

Thut, G., Bergmann, T. O., Fröhlich, F., Soekadar, S. R., Brittain, J. S., Valero-Cabré, A., et al. (2017). Guiding transcranial brain stimulation by EEG/MEG to interact with ongoing brain activity and associated functions: a position paper. *Clin. Neurophysiol.* 128, 843–857. doi: 10.1016/J.CLINPH.2017.01.003

Trejo, L. J., Kubitz, K., Rosipal, R., Kochavi, R. L., and Montgomery, L. D. (2015). EEG-based estimation and classification of mental fatigue. *Psychology* 6, 572–589. doi: 10.4236/PSYCH.2015.65055

van Dongen-Boomsma, M., Lansbergen, M. M., Bekker, E. M., Sandra Kooij, J. J., van der Molen, M., Kenemans, J. L., et al. (2010). Relation between resting EEG to cognitive performance and clinical symptoms in adults with attention-deficit/hyperactivity disorder. *Neurosci. Lett.* 469, 102–106. doi: 10.1016/J.NEULET.2009.11.053

Varao-Sousa, T. L., Smilek, D., and Kingstone, A. (2018). In the lab and in the wild: how distraction and mind wandering affect attention and memory. *Cogn Res Princ Implic* 3:42. doi: 10.1186/s41235-018-0137-0

Volz-Sidiropoulou, E., Boecker, M., and Gauggel, S. (2016). The positive illusory Bias in children and adolescents with ADHD: further evidence. *J. Atten. Disord.* 20, 178–186. doi: 10.1177/1087054713489849

von Conta, J., Kasten, F. H., Ćurčić-Blake, B., Aleman, A., Thielscher, A., and Herrmann, C. S. (2021). Interindividual variability of electric fields during transcranial temporal interference stimulation (tTIS). *Sci. Rep.* 11:20357. doi: 10.1038/s41598-021-99749-0

Vossen, A., Gross, J., and Thut, G. (2015). Alpha Power increase after transcranial alternating current stimulation at alpha frequency (α-tACS) reflects plastic changes rather than entrainment. *Brain Stimul.* 8, 499–508. doi: 10.1016/J.BRS.2014.12.004

Vosskuhl, J., Strüber, D., and Herrmann, C. S. (2018). Non-invasive brain stimulation: a paradigm shift in understanding brain oscillations. *Front. Hum. Neurosci.* 12:211. doi: 10.3389/fnhum.2018.00211

Wasserman, T., and Wasserman, L. D. (2012). The sensitivity and specificity of neuropsychological tests in the diagnosis of attention deficit hyperactivity disorder. *Appl. Neuropsychol. Child* 1, 90–99. doi: 10.1080/21622965.2012.702025

Westwood, S. J., Radua, J., and Rubia, K. (2021). Noninvasive brain stimulation in children and adults with attention-deficit/hyperactivity disorder: a systematic review and meta-analysis. *J. Psychiatry Neurosci.* 46, E14–E33. doi: 10.1503/JPN.190179

Wiebe, A., Aslan, B., Brockmann, C., Lepartz, A., Dudek, D., Kannen, K., et al. (2023). Multimodal assessment of adult attention-deficit hyperactivity disorder: a controlled virtual seminar room study. *Clin. Psychol. Psychother.* 30, 1111–1129. doi: 10.1002/cpp.2863

Wiebe, A., Kannen, K., Li, M., Aslan, B., Anders, D., Selaskowski, B., et al. (2022). Multimodal virtual reality-based assessment of adult ADHD: a feasibility study in healthy subjects. *Assessment* 30, 1435–1453. doi: 10.1177/10731911221089193

Wilens, T. E., Morrison, N. R., and Prince, J. (2011). An update on the pharmacotherapy of attention-deficit/hyperactivity disorder in adults. *Expert. Rev. Neurother.* 11, 1443–1465. doi: 10.1586/ern.11.137

Woltering, S., Jung, J., Liu, Z., and Tannock, R. (2012). Resting state EEG oscillatory power differences in ADHD college students and their peers. *Behav. Brain Funct.* 8:60. doi: 10.1186/1744-9081-8-60

Wynchank, D., Bijlenga, D., Beekman, A. T., Kooij, J. J. S., and Penninx, B. W. (2017). Adult attention-deficit/hyperactivity disorder (ADHD) and insomnia: an update of the literature. *Curr. Psychiatry Rep.* 19:98. doi: 10.1007/S11920-017-0860-0

Zhang, D.-W., Roodenrys, S., Li, H., Barry, R. J., Clarke, A. R., Wu, Z., et al. (2017). Atypical interference control in children with AD/HD with elevated theta/beta ratio. *Biol. Psychol.* 128, 82–88. doi: 10.1016/j.biopsycho.2017.07.009

Zrenner, C., Belardinelli, P., Müller-Dahlhaus, F., and Ziemann, U. (2016). Closed-loop neuroscience and non-invasive brain stimulation: a tale of two loops. *Front. Cell. Neurosci.* 10:92. doi: 10.3389/fncel.2016.00092

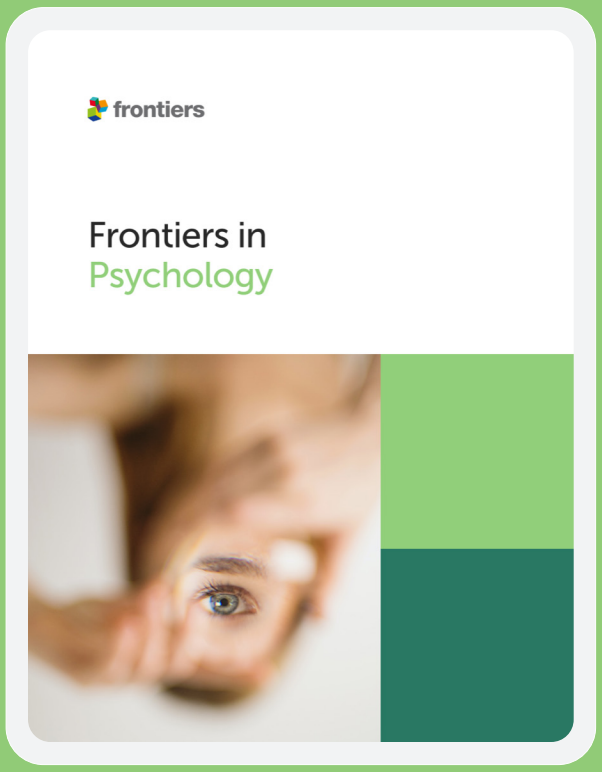
Frontiers in Psychology

Paving the way for a greater understanding of human behavior

The most cited journal in its field, exploring psychological sciences - from clinical research to cognitive science, from imaging studies to human factors, and from animal cognition to social psychology.

Discover the latest Research Topics

See more →



Frontiers

Avenue du Tribunal-Fédéral 34
1005 Lausanne, Switzerland
frontiersin.org

Contact us

+41 (0)21 510 17 00
frontiersin.org/about/contact