

Complementary care to promote mental health

Edited by

Nóra Kerekes, Anja C. Huizink and
Anette Christina Ekström-Bergström

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Complementary care to promote mental health

Topic editors

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Table of contents

- 05 **Imprisoning Yoga: Yoga Practice May Increase the Character Maturity of Male Prison Inmates**
Nóra Kerekes, Sven Brändström and Thomas Nilsson
- 12 **The Experience of Tinnitus and Its Interaction With Unique Life Histories—Life Events, Trauma and Inner Resources Narrated by Patients With Tinnitus**
Soly Inga-Maj Erlandsson, Linda Lundin and Nicolas Dauman
- 24 **The Effect of Mechanical Massage and Mental Training on Heart Rate Variability and Cortisol in Swedish Employees—A Randomized Explorative Pilot Study**
Willeke Van Dijk, Anja C. Huizink, Jasmin Müller, Kerstin Uvnäs-Moberg, Anette Ekström-Bergström and Linda Handlin
- 31 **Effects of Yoga Respiratory Practice (*Bhastrika pranayama*) on Anxiety, Affect, and Brain Functional Connectivity and Activity: A Randomized Controlled Trial**
Morgana M. Novaes, Fernanda Palhano-Fontes, Heloisa Onias, Katia C. Andrade, Bruno Lobão-Soares, Tiago Arruda-Sanchez, Elisa H. Kozasa, Danilo F. Santaella and Draulio Barros de Araujo
- 44 **Effects of the “Inspirational Lecture” in Combination With “Ordinary Antenatal Parental Classes” as Professional Support for Expectant Parents: A Pilot Study as a Randomized Controlled Trial**
Stina Thorstensson, Anette Ekström-Bergström and Caroline Bäckström
- 59 **Midwives’ Experiences of Providing the “Inspirational Lecture” as a Care Intervention for Expectant Parents—A Qualitative Study**
Caroline Bäckström, Tina Söderlund, Stina Thorstensson, Lena B. Mårtensson and Marie Golsäter
- 68 **Efficacy, Treatment Characteristics, and Biopsychological Mechanisms of Music-Listening Interventions in Reducing Pain (MINTREP): Study Protocol of a Three-Armed Pilot Randomized Controlled Trial**
Anja C. Feneberg, Mattes B. Kappert, Rosa M. Maidhof, Bettina K. Doering, Dieter Olbrich and Urs M. Nater
- 86 **Caring for Persons With Intellectual Disabilities and Challenging Behavior: Staff Experiences With a Web-Based Training Program**
Anh Truong, Catrin Alverbratt, Anette Ekström-Bergström and Helena Antonsson
- 98 **Parents’ Experiences of Receiving Professional Support Through Extended Home Visits During Pregnancy and Early Childhood—A Phenomenographic Study**
Caroline Bäckström, Stina Thorstensson, Jessica Pihlblad, Anna-Carin Forsman and Margaretha Larsson

- 111 **To Live, Not Only Survive—An Ongoing Endeavor: Resilience of Adult Swedish Women Abused as Children**
Hrafnhildur Gunnarsdóttir, Jesper Löve, Gunnel Hensing and Åsa Källström
- 122 **Evaluation of a Short-Term Digital Group Intervention to Relieve Mental Distress and Promote Well-Being Among Community-Dwelling Older Individuals During the COVID-19 Outbreak: A Study Protocol**
Stav Shapira, Daphna Yeshua-Katz, Ganit Goren, Limor Aharonson-Daniel, A. Mark Clarfield and Orly Sarid
- 132 **Assessment of Need for Recovery and Its Relationship With Work Characteristics and Health in a Sample of Chinese Doctors: A Cross-Sectional Survey**
Tao Sun, Yu Shi, Dong Yin, Shu'e Zhang and Xiaohe Wang
- 144 **Yoga as Complementary Care for Young People Placed in Juvenile Institutions—A Study Plan**
Nóra Kerekes



Imprisoning Yoga: Yoga Practice May Increase the Character Maturity of Male Prison Inmates

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Background: A specific personality profile, characterized by low character maturity (low scores on the self-directedness and cooperativeness character dimensions) and high scores on the novelty seeking temperament dimension of the temperament and character inventory (TCI), has been associated with aggressive antisocial behavior in male prison inmates. It has also been shown that yoga practiced in Swedish correctional facilities has positive effects on the inmates' well-being and on risk factors associated with criminal recidivism (e.g., antisocial behavior). In this study, we aimed to investigate whether the positive effect of yoga practice on inmates' behaviors could be extended to include eventual changes in their personality profile.

Methods: Male prison inmates ($N = 111$) in Sweden participated in a randomized controlled 10-week long yoga intervention trial. Participants were randomly assigned to either a yoga group (one class a week; $n = 57$) or a control group (free of choice weekly physical activity; $n = 54$). All the inmates completed the TCI questionnaire before and after the intervention period as part of an assessment battery.

Results: After the 10-week-long intervention period male inmates scored significantly lower on the novelty seeking and the harm avoidance and significantly higher on the self-directedness dimensions of the TCI. There was a significant medium strong interaction effect between time and group belonging for the self-directedness dimension of character favoring the yoga group.

Conclusion: A 10-week-long yoga practice intervention among male inmates in Swedish correctional facilities increased the inmates' character maturity, improving such abilities as their capability to take responsibility, feel more purposeful, and being more self-acceptant — features that previously were found to be associated with decreased aggressive antisocial behavior.

Keywords: character maturity, prison, self-directedness, temperament and character inventory, yoga

INTRODUCTION

Personality and Trait Aggression of Prison Inmates

A long-standing question among scientists is whether there is a specific personality profile associated with criminality. Hitherto, no personality profile characterizing all criminals has been identified, although some specific personality constellations may apply to many criminals (1). Generally, extreme temperament constellations in combination with low or very low character maturity have been associated with criminal and aggressive antisocial behaviors (2–4).

According to Cloninger's psychobiological model of personality, the temperament dimensions (comprising the dimensions novelty seeking, harm avoidance, reward dependence, and persistence) of an individual's personality are neurobiologically based, inheritable features (5, 6). These temperament dimensions are defined as habitual responses to stimuli and are considered to be rather stable over the individual's lifetime, although they might interact with and be modified by the character dimensions (comprising the dimensions self-directedness, cooperativeness, and self-transcendence) of an individual's personality (7, 8).

Among the temperament dimensions, high scores on novelty seeking, in particular, have been found to be associated with aggressive and antisocial behaviors in prison inmates (4). This temperament dimension captures exploratory activity in response to novel stimuli, impulsive decision making, and temper outbursts, responses which are highly consistent with aggressive and antisocial acts (5). The second most often recognized increased temperament dimension in prison inmates was found on the harm avoidance dimension. This temperament profile expresses pessimistic, fearful, and doubtful worrying actions, which are highly correlated with self-directed aggression, increased prevalence of self-harm and suicidal behaviors in inmates (4).

The character dimensions, self-directedness, cooperativeness, and self-transcendence, are based on social learning, and are therefore expected to mature over time (5, 8). Low scores on self-directedness and cooperativeness, indicating immaturity, low self-governance, social incompetence or intolerance, uncooperativeness, and revengefulness, have repeatedly been associated with mental ill-health (5, 9–12), also in forensic populations (13), and with aggressive and antisocial behaviors in inmates (4).

Actually, extremes in the temperamental dimensions in combination with low character maturity predict psychiatric ill health and aggressive antisocial behavior. However, a high level of character maturity has been found to be a protective factor (14). Consequently, an extreme temperament is not an unambiguous sign of mental illness or deviant behavior when found in combination with a normal to high level of character maturity. These findings suggest that interventions that increase an individual's character maturity can mitigate the effect of extreme temperaments, decrease aggression, antisocial behavior, and different aspects of psychiatric ill health.

Positive Effects of Yoga on Prison Inmates' Behavior and Mental Health

In recent years, yoga has become popular in many correctional institutions around the world as a complementary rehabilitation

tool offered to inmates. An increasing number of studies show that regular yoga practice is associated with an increased level of impulse control (15), attenuation of anger, aggression (16), and antisocial behaviors (15), and with a significantly decreased level of paranoid ideations (17), each of these phenomena being a key variable related to criminal behavior. Furthermore, improvements on variables that can increase offenders' abilities to participate in treatments have also been observed, for example, that yoga significantly can increase positive and decrease negative emotional states (15, 18); sustain attention (15); decrease depression, anxiety, and obsession (17, 19); and reduce the individual's experienced stress level (15).

Neurobiological changes, including modulation of neurotransmitters (increased serotonin, decreased catecholamines), may explain the above-mentioned phenotypical changes (20, 21), suggesting improvement of cortical controls, and improved social functioning.

Based on this notion of behaviorally induced modification of the neurobiological conditions that regulate decision making, we hypothesize that regular yoga practice can induce neurobiological changes in participants, and that these changes can be phenotypically measured in the form of an improvement in the level of character maturity.

The aim of the present study is therefore to investigate within correctional settings the effect of 10 weeks of yoga practice on male prison inmates' temperament and character profiles.

METHODS

Procedures

For a detailed description of the study procedure and extended information on the participants, please see Ref. (15).

Briefly summarized: data collection was done from November 2013 to July 2015 in seven Swedish high- and medium-security male correctional facilities.

The participants completed a pre-intervention assessment (time 1), which included the Temperament and Character Inventory-Revised 140 (TCI-R140) (see below for a detailed description) and other self-report questionnaires, before being randomly assigned either to yoga classes or to a waiting list (the control group). During the 10-week intervention period, the participants in the yoga group attended a 90 minutes yoga class once a week. The yoga class was led by prison officers trained by the Swedish Prison and Probation Service in a yoga program specifically designed for inmates (Krimiyoga). The participants in the control group were asked to perform some other type of physical activity for 90 minutes each week during the 10-week period, during which they were on a waiting list to participate in yoga classes. Upon completion of the 10-week period, the participants in both groups, i.e., the yoga group and the control group, once again completed the TCI-R140 as part of the post-intervention assessment (time 2), where they also reported the amount of weekly physical activity.

Participants

The study sample included 201 male volunteers. Their age ranged from 18 to 62 years. Sixty-eight (33.8%) individuals of the original

sample left the study for different reasons, such as own request, being transferred to other correctional facilities, misconduct, and so on (Table 1). Of the remaining inmates (133), 67 completed the study within the yoga group and 66 in the control group. Due to the absence of numerous items in their TCIs (more than 5% missing), 22 participants were excluded from the present analyses, leaving 57 participants in the yoga group and 54 in the control group for which TCI data were evaluated.

As depression level could strongly affect different dimensions of the personality profile (such as harm avoidance and self-directedness), it is important to establish whether the study design (randomization) resulted in a somewhat equal variance with regard to depressive symptoms in the two groups. However, it was not possible to merge data files with any clinical data (e.g., inpatient data). Instead, we used the self-reported level of psychological distress (see publication 17) to compare the two groups on the depression primary symptom dimension. There was no significant difference ($p = 0.76$) in self-rated depressive symptoms between the yoga group ($M = 0.99$; $SD = 0.08$) and the control group ($M = 1.04$; $SD = 0.10$).

Measure

TCI-R 140

The TCI is a self-report personality questionnaire based on Cloninger's psychobiological model of temperament and character (5). There are several different versions of the TCI (e.g., TCI-240, TCI-125, and TCI-R), of which we used one of the latest versions, the TCI-R140, which is a short and revised version of the original TCI-240 inventory. The TCI-R140 contains 136 items covering the four temperament dimensions (i.e., novelty seeking, harm avoidance, reward dependence, and persistence) and the three character dimensions (i.e., self-directedness, cooperativeness, and self-transcendence). The remaining four items are built in as control questions. Each dimension contains 20 items, with the exception of self-transcendence, which has only 16 items (22). Each question is rated on a five-point Likert scale ranging from 1 (definitely false) to 5 (definitely true) (23). The Swedish version of the TCI has been validated (8), showing good internal consistency and factor structure and high test-retest reliability. The TCI-R140, the short version of the TCI-R, has also been found to have good reliability coefficients and

factor structures even across cultures (24, 25). Internal reliability of each dimension in the present study was acceptable and varied between Cronbach alphas of .76 (novelty seeking) and .87 (self-directedness).

Statistical Analyses

The data did not violate the assumption of normality. The significance level was set at $p < 0.05$. The scores are presented by mean (M) and standard deviation (SD). Internal reliability of each dimension of TCI was presented with Cronbach alpha. Comparison of attrition rate between the groups was calculated with Fisher's exact test. A two-way repeated-measures ANOVA was used with two factors (time 1 and time 2) and with "group" as between subject's variable. Effect size is calculated as the η^2 , where .01 signals a small, .06 a medium, and .14 a large effect (26).

Ethical Considerations

The study was approved by the regional Ethical Review Board in Linköping (2013/302-31). The prison inmates interested in voluntary participation received both verbal and written information about the study procedure and conditions of participation. Written informed consent was obtained from all participants. Upon study completion, the participants received a phone card valued at 200 Swedish crowns (about 20 euros).

RESULTS

The mean scores of the seven dimensions of the TCI at pre- and post-intervention for the yoga group and for the control group are presented in Table 2 and Figures 1 and 2.

Repeated-measures ANOVA was conducted to assess the impact of the yoga intervention compared to the control group of physical activity on participants' personality traits according to TCI across two periods (pre-intervention and post-intervention). There was a significant interaction between treatment type and time, for the character dimension self-directedness [$F(1,109) = 4.88$, $p = 0.029$, partial $\eta^2 = 0.04$], in favor of the yoga group. There were also univariate within-subjects effects for time for the personality dimensions of

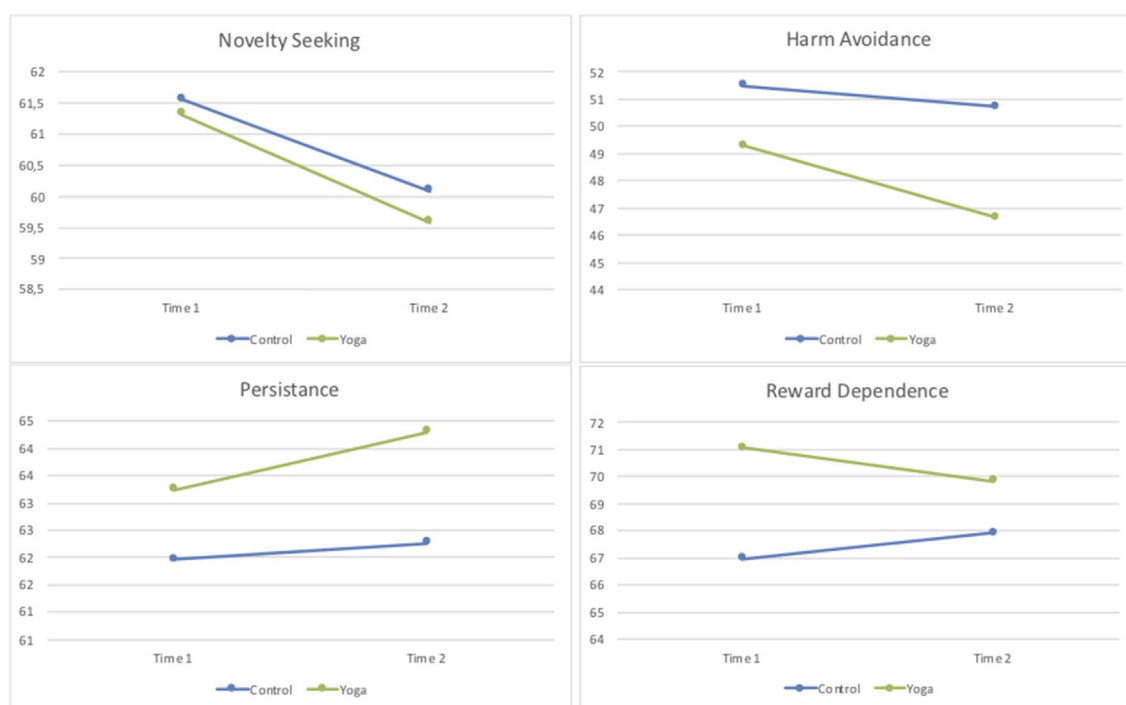
TABLE 1 | Attrition rates and reasons for attrition in the yoga and control groups.

	Number (%)		p
	Yoga group (n = 121)	Control group (n = 80)	
Attrition rate	54 (44.6%)	14 (17.5%)	<0.001
Reason for attrition			
Participant's request	10 (18.5%)	6 (42.9%)	0.08
Transfer	12 (22.2%)	2 (14.3%)	0.72
Misconduct	5 (9.3%)	0 (0%)	0.58
Illness, injury, or mental health problems	7 (13%)	1 (7.1%)	1.00
Did not attend all yoga classes	4 (7.4%)	–	–
Discontinuous yoga classes (personal)	2 (3.7%)	–	–
Yoga class interfered with school or work	4 (7.4%)	–	–
Chose yoga outside the study	–	1 (7.1%)	–
Not collected data	6 (11.1)	3 (21.4%)	0.38
Not specified	4 (7.4%)	1 (7.1%)	1.00

TABLE 2 | Average ratings at pre- and post-intervention assessment (time 1 and time 2) in the yoga and control groups.

TCI dimensions	Yoga group (n = 57), M (SD)		Control group (n = 54), M (SD)	
	Time 1	Time 2	Time 1	Time 2
Temperament dimensions				
Novelty seeking	61.3 (11.4)	59.6 (10.2)	61.6 (10.6)	60.1 (10.1)
Harm avoidance	49.3 (13.9)	46.7 (11.6)	51.5 (11.8)	50.7 (12.8)
Reward dependence	63.2 (12.8)	64.3 (11.8)	62.0 (11.0)	62.3 (10.4)
Persistence	71.1 (12.2)	69.8 (11.5)	67.0 (12.0)	67.9 (12.1)
Character dimensions				
Self-directedness	73.7 (14.4)	78.5 (14.0)	74.7 (13.3)	75.9 (14.3)
Cooperativeness	74.2 (11.3)	76.1 (10.6)	72.4 (9.9)	72.5 (10.6)
Self-transcendence	39.4 (11.6)	37.8 (12.2)	36.9 (11.6)	36.0 (12.1)

TCI, temperament and character inventory.

**FIGURE 1** | Mean scores of the measures in each temperament dimension of temperament and character inventory (TCI) in control and yoga groups at pre- and post-intervention (time 1 and time 2).

novelty seeking [$F(1,109) = 6.09, p = 0.015$, partial $\eta^2 = 0.05$], harm avoidance [$F(1,109) = 4.46, p = 0.037$, partial $\eta^2 = 0.04$], and for the character dimension of self-directedness [$F(1,109) = 13.43, p < 0.001$, partial $\eta^2 = 0.11$]. No significant effects were seen for the remaining personality dimensions of TCI (data upon request).

DISCUSSION

To the best of our knowledge, the present study is the first to investigate the effect of 10 weeks of regular yoga practice on personality traits, operationalized in terms of temperament,

and character profiles, of male prison inmates. According to our results, the male inmates showed significant changes during the 10 weeks of study period in the novelty seeking, harm avoidance, and self-directedness dimensions of their personality profile. Also, we have detected a significant group \times time interaction in the dimension of self-directedness in support of the yoga intervention. The importance of these findings lies in their support of the previously suggested hypothesis that increased character maturity (self-directedness and cooperativeness) may attenuate inmates' deviant behaviors and mental health problems, thereby having a positive effect on the criminogenic factors of the affected individuals and possibly preventing them from criminal reoffending.

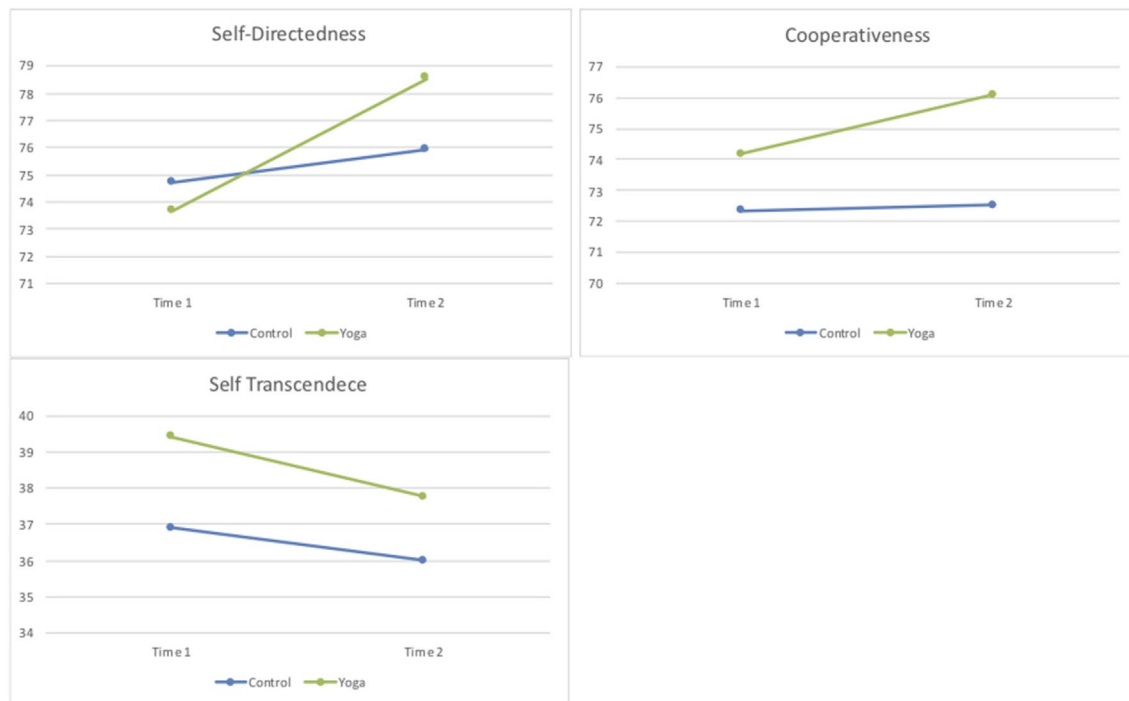


FIGURE 2 | Mean scores of the measures in each character dimension of TCI in the control and yoga groups at pre- and post-intervention (time 1 and time 2).

To measure changes in the personality profiles that are of relevance for antisocial behaviors, it is necessary to use a personality measure that is based on developmental theories covering neurobiological, psychosocial, cognitive, and personality aspects. Cloninger's temperament and character model with its accompanying questionnaire provides a valuable tool for this purpose (27). This psychobiological model of personality states that the character component of an individual's personality changes over time, due to social learning and cognitive maturation. This process is mirrored in the ability to identify the self as an autonomous, purposeful, and in relation to the environment, dynamically integrated individual. These attributes are measured by the self-directedness and cooperativeness dimensions in the TCI (5), which are supposed to encompass the ability to control extreme temperamental variations and to deal with and overcome both external and internal constraints, such as reaction patterns, abilities, and drives. According to the original theory, the character dimensions change and mature due to learning and self-insight processes during adolescence (28), whereas the temperament dimensions are stable and inherited. However, the results of a Japanese research group support the opposite hypothesis, namely that genetic factors play a more important role in the development of character (29, 30). The most recent twin studies offer a "compromise," stating that genetic and shared environmental factors account for a substantial amount of the inter-individual variation in both temperament and character (10). Based on this kind of finding, the present study investigated whether 10 weeks of yoga practice, compared to regular physical activity, can affect the temperament and character dimensions of personality.

Our results clearly indicate that 10 weeks of physical activity (including yoga) had a positive effect on the temperament dimension of novelty seeking in male inmates. That physical activity, and yoga specifically, attenuates inmates' impulsive behavior has previously been shown using a computer-based measure of impulse control (15). These findings, i.e., decreases in impulsive decision making and in loss of temper (high novelty seeking), suggest that there is an improvement of the cortical controls in the brain that are responsible for inhibition of the limbic drives.

In the yoga group a prominent decrease of harm avoidance was detected while the scores in this temperament dimension also decreased in those performing free choice of physical activity. It is in this context important to state that there was no significant difference in the level of depression between participants in the yoga and control groups at preintervention, since depression is a state that strongly could affect ratings on this dimension. Harm avoidance captures worry, fear of uncertainty, and fatigability (27), which can be mirrored in negative deactivated affects (e.g., being scared, bored, tired, ashamed) or in the anxiety, phobic anxiety, and paranoid ideation, which all are primary symptom dimensions of psychological distress. In agreement with our result, showing that yoga specifically decreases the scores on the personality dimension of harm avoidance, it has been shown that yoga-practicing prison inmates also report significantly less negative deactivated affects (15), and that yoga significantly decreases anxiety and phobic anxiety, specifically the distress level expressed as paranoid ideation (17).

Our results also show that the scores on the cooperativeness character dimension increased among the inmates in the yoga

group, however this change did not reach significance. A plausible interpretation of the increase in cooperativeness, at least for prison inmates within the Swedish Prison and Probation Service, can be that organized activities, such as those studied improve inmates' social consciences and possibly also their social acceptance. In other words, yoga practice may, in medium- and high-security prison settings, be a group activity that could improve inmates' compassion, compliance, and social flexibility/tolerance.

The most prominent and interesting result is that there was an interaction effect of time and group, proving that the self-directedness character dimension improved in the inmates who had participated in yoga classes; a significant improvement with an effect that was moderate. In our study, as in other studies on personality profiles in prison samples (4, 31, 32), inmates were generally found to have low character maturity. Any improvement in their character maturity is likely to enhance their ability to control impulses and reactions originating from their extreme temperaments. That is why a significant improvement in the character dimension of self-directedness is so important.

Yoga is a physical exercise that also includes training of the mind. During the different yoga poses participants are encouraged to focus on themselves and their breathing, and to observe their own body (e.g., posture, muscle contraction or relaxation) and the information it provides (e.g., tension, pain, warmth or cold). Yoga practice has been coupled to neurochemical changes, such as decreased production of cortisol and adrenalin and boosted production of serotonin and melatonin (21), which can be associated with improved well-being and enriched self-esteem. These neurochemical changes most probably explain the changes in the personality dimensions found in this study, i.e., the enhanced levels of self-acceptance and resourcefulness found in the inmates who had participated in regular yoga training. This represents a significant improvement of the level of self-determination, coupled with an increased level of responsibility and purposefulness, which are important qualities when it comes to an individual's ability to adapt in a prosocial way. This is exactly the kind of ability that inmates are in need of upon release from correctional facilities and when meeting and managing the challenges related to the process of reintegration into society.

STRENGTHS AND LIMITATIONS

This study has both strengths and limitations. To our knowledge, the study is the biggest randomized controlled trial (RCT) within a correctional setting to have investigated the effects of a 10-week yoga intervention on personality aspects. The randomized controlled design, and its considerable number of participants, gives strength to the study. A further strength is the use of a well-validated psychobiological model of personality and its accompanying questionnaire, which has been shown to measure changes in personality dimensions over time.

One obvious limitation of the study is that we only focused on the male inmates' personality profiles. As personality profiles are strongly gender-specific, we did not attempt to merge data for male and female inmates. Moreover, we were unable to perform separate analyses for female inmates due

to the low number of female participants in the original study (15). Consequently, we lack knowledge about the effects of yoga on females in prison settings. Another limitation of the study is the absence of information about the clinical and demographic characteristics of the participants. However, such eventual bias would most probably have been ruled out by the rigorous study design (RCT), as demonstrated with the example of self-rated depressive symptoms. In addition, the attrition rate was larger in the yoga group fostering some suspicions that individuals not benefiting from this intervention ended their participation. However, when comparing available reasons for termination no significant difference was found between the two groups.

The sole reliance on self-reported data is also a limitation, as is the pre- and post-design without a longer follow-up period reflecting the stability of the gained effects.

CONCLUSION

The present study is the first to provide evidence of the positive effects of regular yoga exercise for male prison inmates in terms of the personality dimension scores measuring the inmates' character maturity. These results show that yoga can strengthen the inmates' self-acceptance, purposefulness, and sense of responsibility, which are qualities that promote a more peaceful and safer environment in the correctional settings, and that also provide a foundation for the development of a prosocial lifestyle upon release. However, despite the promising nature of these results, they must be investigated and confirmed in future studies before we can draw any definitive conclusions.

DATA AVAILABILITY STATEMENT

The datasets generated for this study are available on request to the corresponding author.

ETHICS STATEMENT

The study was approved by the regional Ethical Review Board in Linköping (2013/302-31). The prison inmates interested in voluntary participation received both verbal and written information about the study procedure and conditions of participation. Written informed consent was obtained from all participants. Upon study completion, the participants received a phone card valued at 200 Swedish crowns (about 20 euros).

AUTHOR CONTRIBUTIONS

NK designed and led the yoga study. She performed the data analyses and was responsible for writing the manuscript. SB contributed with coding the TCI raw data, statistic help, and in writing the manuscript. TN contributed to the manuscript with statistical help, critically important intellectual feedback on interpretation of our results as well as on writing the manuscript.

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The Experience of Tinnitus and Its Interaction With Unique Life Histories—Life Events, Trauma and Inner Resources Narrated by Patients With Tinnitus

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Background: The challenges facing people with chronic tinnitus include finding relief and rebuilding quality of life. However, previous traumatic episodes may influence adjustment and prolong suffering. Recovery implies reducing aggravating reactions and improving social roles, relationships and interests. Self-narratives about living with tinnitus have not yet received the attention they deserve in the research literature. Thus, the main goal of the present study was to illustrate how tinnitus suffering interacts with the participants' unique life histories.

Method: Four women and one man (ages 52–58) took part in the study after consulting a special hearing clinic for annoying tinnitus. Criteria for inclusion were that tinnitus was regarded as a problem with negative consequences for quality of life. The participants should be willing to share how the experience of tinnitus suffering interacts with their previous life story. Narrative methodology was employed in order to achieve the goals of the study. We used unstructured interviews with free conversation, which allowed for rich narratives with full contextual meaning.

Results: The findings, based on the narrative analysis, revealed that three out of five participants presented a *regressive* form of narrative indicating ongoing struggles beyond tinnitus itself, which they were unable to bring to closure. For them, valued goals were continuously thwarted by frustrating circumstances in their lives, either past events or current unresolved issues. *Progressive* and *stable* narratives, as identified in the other two participants, demonstrated values that rely on others' attitude and understanding toward their suffering, in sharp contrast to the *regressive* narratives. We suggest that a central issue in tinnitus rehabilitation should be to help suffering patients to overcome unresolved conflicts and thereby extend their ability for a fuller commitment in life.

Conclusion: Considering enduring tinnitus as a chronic condition, whose course is likely to vary depending on the patient's general health status, an alteration of *progressive* and *stable* narratives is likely to occur during the lifespan. A *progressive* narrative shows

similarities to the core construct of the salutogenesis model of health promotion (1). In conclusion, a narrative approach in tinnitus rehabilitation can be health promoting by offering the patient the opportunity to engage in storytelling, which in turn can increase comprehensibility and a sense of coherence.

Keywords: tinnitus, self-narration, psychological needs, trauma, frustration, health promotion, sense of coherence

INTRODUCTION

As hearing human beings, we are surrounded by sounds—and sometimes exposed to them—when sounds that we do not want to listen to demand constant attention. For decades, tinnitus obstinately withstood efforts to identify the underlying mechanisms as an element of identifying a cure, i.e., that the patient becomes totally free from the symptoms. But for the one who suffers, tinnitus is an unwanted experienced buzz or tone, perceived in one or both ears or in the head, and which often cannot be ignored. The prevalence of tinnitus in the adult population ranges between 10.1 and 14.5% and it has been reported that 3–4% of adults consult a family doctor about tinnitus at least once in a lifetime (2). Furthermore, approximately 1.6% of the people with tinnitus are considered to be severely annoyed by it (3). It is well-known that the presence of tinnitus cannot solely be explained by the severity of hearing impairment. Although tinnitus can occur in various types of hearing disorders, it can also exist, for example, in relation to brain damage (4), high blood pressure (5), psychological trauma (6), as well as a side effect of certain types of medication (7). Research using experimental methods to investigate the ways in which information is processed on a subconscious and automatic level has revealed that tinnitus sufferers process words related to tinnitus, such as for example “shriek” and “noise,” in a different way than neutral words (8). One possible explanation for this finding is that words associated with tinnitus are experienced as more emotionally charged than neutral for someone who is annoyed by the symptoms. It means that a heightened vigilance can be present for stimuli associated with tinnitus. Indeed, considering that total suppression of tinnitus is an unattainable goal, it is plausible to advocate that patients must learn to cope with persistent frustration (9) that fuels self-consciousness and rumination (10). Rumination may reinforce the amount of frustration of experiencing a condition for which no cure could be found (despite relentless efforts to reduce tinnitus).

The influence of the somatosensory system on tinnitus has long been acknowledged as an important factor to consider in the rehabilitation of patients with tinnitus who complain about myofascial muscle tension [i.e., temporomandibular joint disorder, see for example, (11–13)]. Very little is known about changes in the individual's experience of tinnitus with time, and to what extent and why tinnitus becomes chronic. Wallhäuser-Franke et al. (14) showed that there is a potential risk for the development of chronic complaints in patients who suffer from tinnitus shortly after its onset. On a methodological level, it may be plausible to focus on intra-individual changes through time (i.e., variability) when attempting to search for what shapes

and drives a personal experience of the symptoms (15). An alternative to the study of intra-individual variability of tinnitus is the longitudinal study design. Erlandsson and Persson (16) performed a 2-year follow-up of patients complaining of tinnitus, revealing their mental health by the use of psychometry, and psychiatric diagnostic interviews. In some patients, self-rated anxiety and depression were improved at the follow-up; in others the experience of mental problems remained or had increased. In the latter case, reason for the increase of experienced mental problems was related to personality disorders.

Difficulties adjusting to a life with tinnitus, such as previous harsh experiences including traumatic episodes, can hamper adjustment and prolong suffering (17).

According to Greenwood (18), a traumatic experience and the feelings associated with this experience might be lost to conscious memory, and thereby cause inhibitions and blockages. Although the memory of the traumatic incident is blocked, the feelings can still be triggered by a similar experience, as for example in the form of a tone, a voice or a place. In a case study from a psychodynamic, narrative perspective, Dauman and Erlandsson (19) illustrated the complex relationship between sensory fragments (i.e., auditory hallucinations and tinnitus) and a non-disclosed trauma, which occurred half a century earlier in the patient's life. Using a chart review, Fagelson (20) investigated the association between tinnitus annoyance and post-traumatic stress disorder (PTSD) in a sample of 300 veterans who were receiving treatment for tinnitus. Around 34% of the study group carried a diagnosis of PTSD. Almost all of those reporting tinnitus and PTSD announced that hearing tinnitus reminded them of traumatic experiences leading to anxiety, which also seemed to increase the perceived tinnitus loudness.

In contrast to traumatic memories, personal narratives necessitate a temporal sequencing and order (21). This observation may lead to a broader perspective on circumstances of life that have the power to disrupt life existence. Difficulties creating a narrative may well-reflect the individual's disorganization as a result of a traumatic encounter. Thus, for the one who suffers from unprocessed and unintegrated trauma, tinnitus can create chaos, agony, demand attention, constant adjustment, and vigilance. Crossley (22) pointed out the extent to which traumatic experiences, such as chronic illness, threaten the individual's orderly sense of existence and coherence. She further argued that post-traumatic narratives can contribute to the restoration of a sense of order in fragmented self-experiences, following the discursive purpose of building orientation and connections between seemingly unrelated events and emotions. Traumatic experiences can impact an individual's sense of identity and outlook on the future (22). Not only is

chronic suffering from the individual's past disruptive, it also outdates previous experiences and orientation in life.

In their review considering trauma etiology and symptoms, Bransford and Blizard (23) stress the likelihood that without knowledge of trauma and its effects, professionals may “misdiagnose individuals and provide treatments that do not address traumatic etiology and that may even exacerbate symptoms” (ibid, p. 87). To recognize signs of a patient's trauma demands the clinician's interest in listening to the person's unheard story. Furthermore, to allow an open dialogue with the patient is the opposite of starting the dialogue from the clinician's own script (24). Here follows an example (unpublished) drawn from psychotherapy with a patient who experienced tinnitus and also suffered from anxiety and depression. Upon beginning psychotherapy, the patient was prescribed with psychotropic medication and had been through treatment of Electroconvulsive therapy (ECT) with no relief. During the course of therapy, clues of an early inhibited trauma became visible mainly through the patient's dreams. The patient's tinnitus and mental problems became unmanageable after retirement and the dreams indicated that leaving work, and particularly work relationships, triggered memories associated with an early trauma. At the age of two, the patient lost his mother to cancer. His father became depressed and unable to care for his children, which led to the patient having to leave his home and live with relatives for some time. At age 14 the patient started to work and stayed at the same company until retirement. Being part of a meaningful social network at work induced a source of secure attachment. After retiring, the patient mourned not only the departure from working life that gave him pleasure and social recognition, but furthermore the patient grieved his dead mother. In Freudian terms, this is an example of “Nachträglichkeit,” i.e., when the patient, 2 years old, is unable to grasp and mourn a severe, traumatic event in the sudden separation from his mother.

The challenges facing people with chronic and severe tinnitus are to retain, or to rebuild, quality of life. With tinnitus, chronic recovery is thus not about eliminating the symptoms; instead it is about reducing the aggravating reactions to the presence of tinnitus, and about recovering social roles, relationships, abilities, possibilities, and interests in daily routines and commitments (9, 25). In personal narratives, individuals can weave together their reconstructed past, perceived present and anticipated future (26, 27). Self-narratives about living with tinnitus have not so far received the attention they deserve in the literature on tinnitus rehabilitation. There are, however, a few studies including patients with tinnitus who have been able to explore self-narratives, for example individual psychotherapy [e.g., Dauman and Erlandsson (19)], group psychotherapy [e.g., Zöger et al., (28)], research interviews [e.g., Dauman et al., (15)] and tinnitus support groups [e.g., Pryce et al., (29)]. They can all be considered attempts aimed at sustaining meaning making as a natural human reaction to the disruption of chronic conditions, thus promoting more progressive narratives among suffering patients (22).

Quantitative research measures provide answers that are detached from context; in the positivistic tradition, the social world is proposed to exist of a concrete and unchangeable

reality, which can be quantified objectively. Qualitative research instead focuses on analyzing subjective meaning; in the interpretative tradition, reality is proposed to be socially constructed by humans. Qualitative research is an umbrella term that covers an array of interpretative techniques. The qualitative approach called narrative method further allows the researcher to go beyond the patient's subjective meaning making by collecting a detailed life story that also addresses social, cultural and psychological issues. An individual's experiences in life, relationships, emotions, goals, opinions and cultural values often impact on decisions, behaviors, challenges, well-being, and health. Narratives are frameworks that compose human histories and identities. The human experience is thus aimed to be recognized holistically, where meaning can never be set apart from context. In many theories, human beings are believed to possess a natural and inherent drive to search for meaning and coherence; these factors have great relevance in health research (1). Human beings thus create meaning from their experiences and this meaning making is health promoting and associated with well-being. One of the ways in which a person can search for meaning and coherence is through language. Through self-narratives and by linking various experiences, feelings and reactions, it is possible to create a coherent story about one's life (26, 27, 30). Meaning and coherence are thus created in the act of telling stories, i.e., the narrative creates order from chaos by forming parts of experiences in life into a coherent whole (31). The self-narrative can thus be perceived as a reflection of the search for meaning and coherence, concepts that belong to the Salutogenic model that Antonovsky introduced in his book “Health, Stress, and Coping” (32).

The Narrative Psychological Approach

Despite the increasingly widespread use of narrative approaches in mainstream psychology, there are very few narrative studies including patients with tinnitus complaints. Narrative research encompasses a *descriptive* and an *explicative* approach (33). In the descriptive approach, narratives are used (from individuals or groups) with the aim to describe and give meanings to conditions of living that should be considered as unique, and therefore beyond comparison with other conditions of living. The individual's subjective experience must be taken into consideration as the condition shapes the whole experience of living and, in turn, how life is narrated. This also means that the narrative disposal—the structure of the interview as well as the interviewer's commitment within it—does contribute to the shape of experience that is individually constructed as a narrative tailored to someone else's understanding. The explicative approach, on the other hand, intends to construct an explanation for *why* a situation/occurrence initiated a human act, i.e., the purpose of the narrative analysis is to reach an understanding of what causes the situation (the final event). In this study, we considered the descriptive approach to be relevant as a first step of analyses, and as a second step we made connections between the narratives and the broader theoretical literature for interpretations of the same (34).

The narrative method is an umbrella for several narrative approaches. One of these methods, i.e., the narrative

psychological approach was developed as a way of understanding the psychology of trauma and how people adhere and respond to traumatizing events (22). Although the meaning-making process is important for mental health and well-being, it can nevertheless be difficult for someone with a history of severe trauma to integrate a narrative about life. Narrative psychology implies that the individual can hold a variety of identities and each identity is connected to different social relationships. As the narrator is an active agent and part of a social context, it is possible to understand both the narrators and their worlds (35). Although no one is capable of becoming a complete author of one's life, we can learn to become the narrator of our own story (36).

AIMS

One of the aims of the present study was to enhance the foundation for making clinical decisions about tinnitus interventions by focusing on the narratives of individuals in need of rehabilitation for tinnitus distress. Based on our clinical understanding, tinnitus is not a phenomenon that simply can be added to the patient's previous experience of life before the symptom begun. This assumption does not consider that tinnitus may also shape the experience of life from top to bottom. To our knowledge, there are few examples in the literature that consider a lay, patient's perspective. The patient's perspective risks being placed in the background. Hence, the study aimed to allow individuals experiencing tinnitus distress to have their voices heard. Following Crossley (22), our intention was to appreciate participants as active social beings formed and influenced by social and cultural norms, who thereby are engaged in a meaning-making process surrounding the onset of tinnitus and its daily consequences. Another part of our main purpose was looking into how the informants attempted to find diverse alternative solutions to their suffering. We were interested in what activities they found helpful, and the kinds of things which possibly made their daily life somewhat more tolerable. Further aspects we intended to explore included the inner resources that the informants could mobilize in order to maintain hopeful about the future.

Research Questions

- What are the challenges that the patients have to face in their daily life, trying to cope with tinnitus?
- How does the experience of tinnitus suffering interact with their previous life story?
- Has tinnitus contributed to altering their image of themselves? Something they learned about themselves; from others; from a previous good/bad event etc.
- In their attempts to find solutions to different stressors in life—What is facilitating? What is hindering?

METHODS

Participants

The sample comprised four women and one man with tinnitus in the ages of 52–58. The informants had previously consulted a special hearing clinic in Sweden in order to get help for

distressing tinnitus and were evaluated for possible hearing impairment (see **Table 1**). Criteria for inclusion were that they experienced tinnitus as a suffering with somewhat negative consequences for quality of life, and that they were willing to share these experiences with the researchers during three interview occasions over a period of 3 to 4 months.

Interview Protocol

The narrative interviews were conversation-like, where a loosely structured interview guide was followed that encouraged participants to generate detailed accounts of experiences. The aim was to conduct fairly unstructured interviews with free conversation that allowed for rich narratives with full contextual meaning. We set out to achieve exploration of personal narratives by asking questions about participants' backgrounds, for example questions about childhood, family situation, working life, social, and cultural context, etc. We also asked questions about tinnitus, for example how they reacted when they first understood that tinnitus was permanent, how they dealt with their emotional reactions, what type of support they had received, etc. Through these questions, we wanted to gain an inside perspective of each participant's life situation, including previous life circumstances in relation to socio-cultural context. With this information, our aim was to more fully understand reactions and feelings linked to the patients living with tinnitus. The loosely structured interview protocol encouraged participants to talk about any part of life, such as hopes, dreams and fears, etc. Examples of questions appear below:

- Tell me about your experiences living with tinnitus?
- Has the presence of tinnitus made you suffer more than ever before?
- Has your perception of life changed since you had tinnitus?
- Is there anything in particular that has had a significant impact on your life up to now?
- Is there anything you can do to make tinnitus more tolerable?

Procedure

Participants were recruited from a Deaf- and Hearing Centre in Sweden. Patients who had been evaluated for possible hearing impairment at a special hearing clinic, and who experienced suffering from tinnitus were informed about the research study in writing via informational fliers. If they were interested in participating in the study, the personnel at the Deaf- and Hearing Centre contacted one of the researchers (SIE) and provided contact information for potential participants. The researchers

TABLE 1 | Participant demographics.

Name & gender	Age	Tinnitus duration	Hearing loss duration
Karin, female	57	2 years	2 years
Ulla, female	55	2 years	2 years
Eva, female	52	10 years	10 years
Frida, female	53	25 years	20 years
Erik, male	58	45 years	13 years

(LL, SIE) phoned those who had expressed interest and booked a time for the first interview, upon agreement to participate in the study. The five participants were interviewed three times and each interview lasted between 40 and 70 min, and took place either at the University, the Deaf- and Hearing Centre, or at the patient's workplace. For one participant who had difficulties traveling to the University, the offer was made to carry out the interviews at the Deaf- and Hearing Centre. All interviews were tape-recorded and transcribed verbatim after each interview session.

Ethical Considerations

The study was carried out in co-operation with personnel at the Deaf- and Hearing Centre, where the patients were recruited. Clinical preparation and administration required was defrayed by the medical service in agreement with the general manager. The researchers followed the principles of the Declaration of Helsinki [1975; revised (37)], a statement of ethical principles to provide guidance in research involving human subjects, and the study was approved by the Regional Ethical Committee in Sweden, see Protocol No. 32013. Written information about the procedure of the study, including examples of interview questions, was provided to those who decided to participate. It was certified that taking part in the study was voluntary and that they could, without explanation, cancel their participation at any time. Prior to participation they were assured that the study would be anonymous, and that any personal information would remain confidential. They were told that in order to enable a rigorous analysis of their story, the interviews had to be recorded, and that the study results would be published in a scientific journal. The participants gave their written informed consent before the start of the interviews.

Analysis

Narrative methodology was employed in order to achieve the goals of the study, i.e., a patient perspective on tinnitus suffering and its consequences for quality of life and demands for future life. A transcription was made after each interview in order for the researchers (LL and SE) to reflect and discuss important issues prior to the following interviews. In total, 15 deep, semi-structured interviews (three per participant) were transcribed verbatim by two of the researchers (LL, SE), and together the transcripts amounted to 167 pages. In order for the third researcher (ND, not Swedish spoken) to be involved in the narrative analysis, a major part of the transcripts was translated into English. The first stage of the analysis involved all three researchers reading through the transcripts in order to familiarize themselves with the content. Notes were taken during this process and the researchers' dialogue and analytical input proceeded until they reached the goal of comprehending the content of the narratives, and how these were socio, culturally and contextually positioned. During the process of close reading, a coding frame that captured the links between sub-plots could be applied to each participant's narrative [see Mishler (38)]. The aim of the coding frame was to find the overall meaning of the narratives, while also observing the specific topic in each of those narratives. In a second step, we applied a broader theoretical

frame of reference to interpret the participants' stories. This means that we went beyond the descriptive phase, toward the interpretative.

In this study, we used the narrative psychological approaches suggested by Gergen and Gergen (39) and Crossley (22) as those best describe people's experience of negative events and suffering. There are several ways in which we can analyze a story by giving it a structure. According to Sarbin (40), a personal narrative has a temporal dimension (a beginning, a middle and an ending) that is held together by a pattern of events named a plot. Gergen and Gergen (39) classify the plot that people use in making sense of negative events, such as suffering from serious illnesses, into three main structurers: *stability*, *progression*, and *regression*. The *progressive* structure is characterized by a movement toward a goal, the *regressive* is defined as mostly a glance backward, and the *stable* as a narrative with little or no change. A classic structure of narrative is Frye's use of the concepts; comedy (i.e., happy ending) romance (somewhat similar to *progressive*), tragedy (to *regressive*) and satire (to *stable*); (41). According to Crossley (22), the tone (i.e., the overall valence of the narrative) should be placed at the center of the narrative. In a *progressive* narrative structure, the tone would be optimistic, while in a *regressive* narrative the tone would be pessimistic. The tone in a *stable* narrative structure would be objective and more like a list of events than a complex story (34).

RESULTS

The three main structurers of the narratives' pattern of events include *progression* (forward looking), *regression* (backward glancing) and *stable* (little change). As shown in **Table 2** below, the narrative structure of Karin, Ulla and Frida was found to be *regressive*, the structure of Eva's narrative is *progressive*, and the structure of Erik's narrative is *stable*. The *tone*, i.e., the overall valence of the narratives, is described as how agency is posited toward events that are narrated and challenging to the participants. The tone of the three participants with *regressive* narratives (Karin, Ulla and Frida) was defined as pessimistic, the tone of Eva's narrative as optimistic, and the tone of Erik's narrative as objective. Recurrent patterns of the participants' intentions are referred to as dominating themes in the narratives (42). Here, the themes, as shown in **Table 2**, are *struggle* (Karin), *competence* (Ulla), *empathy* (Eva), *sadness* (Frida) and *proudness* (Erik). Excerpts from dialogues of each participant can be found under **Supplementary Material**.

TABLE 2 | The manifestation of the narrative in tone, main structure and theme.

	Tone	Main structure	Theme
Karin	Pessimistic	Regressive	struggle
Ulla	Pessimistic	Regressive	competence
Eva	Optimistic	Progressive	empathy
Frida	Pessimistic	Regressive	sadness
Erik	Objective	Stable	proudness

The tone of **Karin's** narrative is **pessimistic**, although she demonstrates an urge to solve her problems that, besides tinnitus and noise intolerance, are mostly economic at the time of the interviews. She started out trying to fulfill the needs of others but found that this way of life made her vulnerable and ended in a mental breakdown. The structure of her narrative is **regressive** and somewhat **tragic** as she experiences a number of obstacles to stabilizing her life. Trying to drive her own business resulted in failure several times. An uncertain work situation seems to influence her emotional reactions to both loud sounds and tinnitus. As a teacher in music, she experiences a worsening of tinnitus after giving several days of music lessons, also making her more concerned about her hearing. Karin stopped playing the guitar for some time, as tinnitus made her play out of tune. When standing in a gathering with people she has difficulties coping with noise or loud voices. Often it forces her to leave the place, because she doesn't know "what to do." When tinnitus is exhausting, it often leads to headaches and vertigo. During one interview, Karin brings up memories of a passed long-term depression, a condition that she worries she could experience again. Tinnitus has an impact on her patience, and it becomes more intense when she feels frustrated, however: "it can be managed in one way or another." The theme in the narrative seems to be a **struggle** to reach what she wishes to obtain for her future life. She maintains her engagement in music activities by playing her own instrument at social events, i.e., birthday parties, weddings, etc. Working in the garden, surrounded by a green environment, Karin has found a way to conquer emotional stress. But she stands by a crossroad where she tries to decide whether to continue working as a teacher. She does not have the legitimate teacher education, and this implies struggling to either maintain a job in an uncertain position or trying to find another position. The latter alternative can be challenging pending on her age.

The tone of **Ulla's** narrative is **pessimistic** because she cannot, with confidence, look forward to a solution to the problem with tinnitus for which she demands help. This situation makes her feel out of control. A traumatic experience of a recent car accident, and the presence of tinnitus, is brought up in a repetitive manner throughout her story. The main structure of the narrative is **regressive** also characterized by **despair**, as she experiences being abandoned and misunderstood by some of the health professionals. Ulla has a university degree—a Master's in Economics, but due to long-term, physical health problems, i.e., scoliosis, she prefers having a flexible work situation and runs a cab business together with her husband. She raises adequate questions regarding the physical consequences of the car accident, but the answers she at times receives from health professionals do not make her calm. One of them has suggested that her tinnitus, which began after the car accident, was stress induced. To think about a life with tinnitus makes Ulla both angry and sad and, in her mind, she dwells about revenge. The general theme in the narrative is **competence** as she sees herself as a skillful person and a qualified cab driver. She used to feel good about her job, which she is able to carry out despite scoliosis. Since the accident, she can no longer join her work mates during lunch hours or at breaks due to sensitivity to sounds, with consequences of her social belonging becoming jeopardized. This

is a source of grief. Ulla notices that she no longer can enjoy listening to music in the church, which used to be a way for her to relax, resulting in another reason for her to feel hurt. She looks back at a time in life when she enjoyed being at her previously owned summer house surrounded by nature and silence.

The structure of **Eva's** narrative is **progressive** and her strength and hopefulness toward the future confirm the underlying **optimistic** tone. There are, however, signs of darkness concerning one of her two children whose prospects in life are most uncertain due to chronic illness. Eva believes in her ability to find help along the way and expresses in a moving way how support from her colleagues gives her courage and hope. The theme that seems most prevalent in Eva's narrative is **empathy**. Throughout her story, there are examples of willingness to be caring together with willingness to hold high moral standards. Her colleagues did not know about her tinnitus until some time ago, which is similar to the mother's way of coping with tinnitus: "it is not even worth mentioning" (Eva's citation). Eva grew up in a country close to Sweden with many siblings and a caring mother whom she is in regular contact with. Her identity has a strong connection to her professional life but also to her roots. Eva is proud of her achievements, although her ambitions at times turned into a heavy workload. At the end of the final interview she expresses her appreciation for being able to give a voice to her struggles with the hearing loss and tinnitus, as well as about life in general. Being able to narrate some part of her history was found to be therapeutic and helpful.

The structure of **Frida's** narrative can be characterized as mostly **regressive**, with a **pessimistic** tone. Regardless of a fragile health condition, physical as well as mental, she still manages to work full time within health care for aging people. In addition to hearing loss and tinnitus, Frida has been diagnosed with benign paroxysmal positional vertigo, migraine, asthma and panic attacks. She worries about her eyesight and that her hearing continually declines as she is aging. Disturbing noise from neighbors and in public places contribute to a restricted lifestyle. An unprocessed trauma early in life still tangles with her. As a child she was brutally raped by her father's friend and the abrupt changes that her family had to make moving to another continent were **dramatic**. Although many years have passed, Frida still blames herself for the reason that they left Sweden. A recurring theme of her narrative is **sadness**, and she remains feeling responsible for this irrevocable change of abode. It is enigmatic that Frida is the only one in the family who moved back to Sweden, while her mother, father and siblings remain living on another continent. Frida, like Erik, has a long history of being in physical pain. She knows what it means to be physically restricted, and what it takes to return to a more "normal" form of life. Memories of a suicidal attempt and circumstances that rescued her from the act are still very vivid and painful. When bringing the hurtful incident up during the interview, Frida falls into tears. She is thankful for being able to tell the researcher about her past and regards the narration as a form of therapy.

The tone of **Erik's** narrative is **objective**. His life, since he left work for a sick pension, did not change much, and characteristic for his narrative, he is an individual living in a day-to-day situation that is rather **stable**. However, Erik must be observant

of his physical health and moderate his emotions alongside the efforts to stay in a stable position. The central theme in his narrative is **proudness**; Erik is proud of himself—he is a survivor from the “social battlefield.” His narrative is imprinted by a form of **satire** influenced by the story told by those who have made a class journey. His image is more or less built up around this version of his narrative, although he claims not being “God’s best child” as a young boy. Erik calls attention to the fact that he is satisfied with his life and what he has accomplished. Other aspects of the narrative are realism and common sense. For Erik, tinnitus is just one health problem among others, of which chronic pain is the most pronounced. For some reason, tinnitus did not become overwhelming as he manages to maintain a tolerant attitude toward its presence. One explanation might be that Erik, from an early age, heard about tinnitus as members of his family were well-acquainted with its presence. Moreover, it was generally seen as a familiar problem for people in a working-class environment.

Summary of Lasting Effects of the Events on the Narrator’s Identity, and How These Events Have Shaped Their Sense of Self When Meeting With Challenges in Life

Having needs of your own has been a sign of selfishness for **Karin**—even in case of illness and emotional hardships. To be a social person with much to offer others has contributed to forming her identity. While not anchored in her own needs, it took time to adjust to the fact that she, like other people, can be fragile and in need of care. This became clear to her in times of suffering as she learned that her self-value cannot depend on fulfilling the needs of others. Caring for herself has been difficult, and therefore the main dimension of Karin’s life story is *regressive*. Her strengths (being a caring person) have not been an asset that she could benefit from during difficult periods in life. Instead, she had to be more “selfish” in order to stay healthy.

Ulla had to realize that life can be unpredictable, as it was when she was hurt in a car accident that also resulted in the start of her tinnitus. She finds herself in the middle of a crises after the unforeseen event, which occupies her day and sometimes night. There is a considerable impact on Ulla’s social life, which used to be part of her enjoyment of working as a cab driver. Ulla’s strength is her ability to find new paths in life, and to adjust to a long-term physical condition that has implied several limitations in her way of living. Due to the negative aftermaths of the car accident she is left ruminating about the loss of agency, making her both angry and sad. She continuously experiences frustration as the loss of agency still lingers with her and makes it difficult to move forward in life. Her story, therefore, leans toward a *regressive* pole.

For **Eva**, to be self-sacrificing and not complaining has been a part of her identity since childhood and a mantra through life. Among her strengths is that she is persistent but nevertheless able to acknowledge her limits. Social support gives Eva courage, together with purpose and meaning when she is supportive to others. She is introspective and can look at her life from different horizons. An important asset for Eva is her identification and close relationships with family members in her birth country. Part of her personal weakness is that she can be self-sacrificing with detrimental consequences for her health. Although life

circumstances can be tough, Eva is able to appreciate her share in life which points to her narrative as *progressive*. Her self-confidence and strength have helped her to find meaning through social belonging, both familywise and at work.

Frida learned that the experience of being secure can be gone in a flash and that your life can change dramatically. She does not convey a sense of belonging in life, instead she conveys loneliness, sadness, guilt, and a sense of alienation. She has carried feelings of shame and guilt about being raped and about feeling responsible for the family’s decision to move abroad. Frida experienced many disappointments both as a child and as an adult individual. For example, she grieves not becoming a mother, as motherhood was something she perceived as a natural way to achieve a sense of belonging in many areas in society. Her personal strength is her rich and eventful life, providing her with experience and opportunities to learn how to deal with challenges. Thereby, there is agency even though she is vulnerable due to previous sad experiences. Frida’s personal fragility from traumatic incidents has colored her, and she carries unprocessed emotions leading to a life story that is primarily *regressive*.

When struggling with tinnitus and his other health issues, **Erik** is using active problem solving—a strategy that enables him to continue living a life filled with interesting activities, adjusted to his abilities. Erik’s story reflects how he, since childhood, has been used to making adjustments in order to overcome disadvantages and hardship, in turn providing him with a strong sense of agency in life. However, he also has to deal with several health problems as he has been physically impaired for a number of years, and his health status may not change for the better. Presumably, his strength has helped him to move forward using mental determination and active strategies for solving problems through life. Those personal traits have contributed to a story line in Erik’s narrative that is stable.

DISCUSSION

The present study belongs to the emerging qualitative research on tinnitus, following earlier works in audiology on hearing impairment (43, 44), Ménière’s disease (45), and otosclerosis (46). Starting a decade ago with tinnitus patients (47), the use of qualitative methods enlightening the lived experience of suffering individuals now encompass grounded theory studies (9, 48, 49), IPA studies [i.e., Interpretative Phenomenological Analysis, (50)], thematic analysis studies (51, 52), and mixed methods studies [i.e., qualitative and quantitative, (53)]. Researchers have contributed to extend original open-ended approaches to the patients suffering [e.g., Tyler and Baker (54) and Sanchez and Stephens (55)], furthering the integration of tinnitus into more parsimonious and patient-centered models (9). In a psychodynamic case study, (19) emphasized that narratives of patients suffering from tinnitus are of special clinical value, for the understanding of prior traumatic experiences entangled with tinnitus [see also Fagelson (20)]. The present study extends the scope of this perspective, with a focus on the forms of the narratives (56) told within a research interview setting.

Living with chronic tinnitus may amplify disruptive and alienating conditions that threaten a patient’s sense of identity, thereby negating previous routines and self-awareness. In these

circumstances, (56) narrative approach is of special relevance to clinicians. Indeed, patients whose narrative testifies for a continuous distancing from any valued goals in life (i.e., *regressive* narratives) should call for the clinicians' attention, in contrast to those showing a possible sense of achievement and agency toward their life goals despite tinnitus hindrance (i.e., *progressive* or *stable* narratives). Three out of five participants in our study were presenting a *regressive* form of narrative (i.e., Frida, Ulla and Karin) indicating ongoing struggles beyond tinnitus itself, which they were unable to bring to closure. For them, valued goals were continuously thwarted by frustrating circumstances in their lives, either past events (Frida) or current, or unresolved issues (Ulla and Karin). A *regressive* form of self-narrative can be related to the perspective of self-determination theory (57), for which a *deprivation* of basic psychological needs leads to the impoverishment and alienation of the self. Conversely, self-determination theory states that the individual's innate tendency toward health, integrity and personal growth is sustained by the fulfillment of such needs throughout the lifespan. Three basic needs—autonomy, competence, and relatedness—have been identified as paving the way for well-being or chronic alienation, depending on whether they are enhanced or thwarted by the social surroundings (57, 58). It is worth noting that the *regressive* narratives in our study give proof of deprivation of these basic psychological needs. The existence of prior trauma (e.g., Frida), ongoing struggle (e.g., Karin), or unattainable goals (e.g., Ulla) shall be taken into account when considering the burden of tinnitus on the life of suffering individuals. An essential aspect of this matter is the amount of resources that are available to the suffering individual *at the onset* of tinnitus.

Stressful events, such as substantial loss, can cause existential questions to come to the fore and pose threats to an individual's conservation of resources (59). In accordance with this perspective, concerns for uncertainty of the future and impoverishment of resources (physical and psychological) are pervasive in patients who are subjected to a chronic condition (60, 61). Thereby, patients who are overwhelmed by facing chronic tinnitus should be considered to be suffering from deprivations and struggles that would have *already* exhausted (and may continue to do so) their inner resources. In addition, it is worth noting that the presence of tinnitus is, in itself, a persistent thwarting of basic psychological needs. Tinnitus can lead to alienation, disablement and isolation (e.g., Ulla) as a result of a repetitive questioning of patients' innate needs for autonomy, competence (i.e., agency), and relatedness to significant others (58). While questionnaires have been the single most used approach in patients with tinnitus, we would like to claim that self-narratives do offer a much deeper understanding of an individual's sense of an orderly existence and available resources to cope with the condition. Thus, approaching the burden of tinnitus as a *regressive* narrative (56) enables clinicians to consider tinnitus biographical disruption (22, 60) and subsequent consequences on personal resources, that would remain otherwise unaddressed through standardized questionnaires.

Our understanding of the challenges encompassed in the tolerance of tinnitus (9) can also be extended by further

considerations on *progressive* and *stable* narratives regarding tinnitus and the personal life story. Two of the five participants (namely Eva and Erik) have elaborated a rather distinct form of narrative on their self-experience with the presence of tinnitus. Considering that persistent tinnitus is a chronic condition, whose course may vary depending on the patient's general health status, it can be argued that an alternation of *progressive* and *stable* narratives is likely to occur during the lifespan. Tinnitus disappearance (i.e., suppression) remains to be an *unattainable* goal for most patients, but a *stable* form of narrative may reflect an individual's long-term relationship to the condition. Indeed, stability in self-experience toward valued goals and life orientation can be considered as accounting for the ability to remain unaffected by the losses and strains the narrator is being subjected to. A precautionary appraisal of personal resources, along with required self-mastery toward disablement, also characterize stability in a self-narrative. Erik's experience is illustrative of a *stable* narrative in the face of a chronic condition such as tinnitus. Interestingly, Erik's narrative also integrates the *fulfillment* of basic psychological needs (58), with regard to his sense of competence (i.e., controlling intrusiveness of symptoms) and autonomy (i.e., being a pensioner, he can organize his day according to his own pace and needs). In addition, the need for relatedness is also satisfied in Erik's narrative, with a supportive spouse and a sense of belonging to the community of manufacture workers, whose lot is to cope with the inevitable physical byproducts of manual work. Therefore, not only does a *stable* narrative seem to be free from deprivation, which is characteristic of *regressive* narratives (see above), but it is also filled with several *resources* (i.e., social "nutriments"), according to Ryan and Deci (57). Thus, a *stable* narrative may reflect a balance that has been found by the sufferer, between strains and personal resources, serving to sustain sound self-confidence on a long-term basis.

In line with the conservation on the resources paradigm of stress (59), a *progressive* narrative can be considered to reflect *enhanced* vitality and orientation in life, as a result of self-enrichment and growth. A feature that may distinguish a *progressive* from a *stable* narrative is the role of self-knowledge that goes along with the strength of orientation in life. The ability to turn potential threats into challenges and to cope entails a capacity for reflection about oneself, and for sustaining engagement in subsequent adjustments to altered circumstances in life. Eva's narrative is illustrative of this form of self-presentation. *Progressive* narratives (56) also show similarities to the core construct of the salutogenesis model of health promotion, i.e., the *sense of coherence* (SOC) in the face of complexity and conflicts in a modern world. SOC has been defined as a global orientation toward life challenges that relies on the ability to find the world comprehensible, manageable, and meaningful (1). According to Antonovsky (62), it is mandatory for an individual to cope with accumulating challenges and factors that include risk of being overwhelmed by life circumstances when events cannot be translated into relevant information. Meaning is considered as a means to restore order from the risk of bewilderment facing the world's complexity and conflict. Thereby, SOC reflects the individual's

ability to pursue attainable goals, to consider manageable means, and sustain self-determination. *Progressive* narratives can be understood as the discursive enactment of SOC, with personal purposes and values in life that must be satisfied. Although referring to distinct concepts, the salutogenesis model (1, 62) and self-determination theory (57) have many features in common. Especially, both emphasize the role of *social* nutriment [e.g., social support, (57)] and *supra-structures* [i.e., health services, (62)] in maintaining order and orientation at an individual level of life experience. The tone of narration provides information over and above how meaning is made, the tone of narration provides information about whether the story is *progressive*, *stable* or *regressive*. They are collective constructs because they integrate forces and resources originating from *social bonds* in the broad sense of the term. Both Eva's (*progressive*) narrative and Erik's (*stable*) narrative have goals and values to pursue, relying on others' attitudes and understanding toward their suffering.

The *regressive* narratives, in sharp contrast with the *progressive* narratives of our study, (Frida's, Ulla's and Karin's) are related to basic psychological deprivation of needs, i.e., the more suffering participants are left alone, lacking appropriate support from supra-structures they addressed (e.g., the lack of recognition Ulla receives from her insurance company regarding her tinnitus as a result of the car accident). Unfortunately, suffering patients with tinnitus often wander through an uncertain health care journey that fuels their distress (50). Here, two forms of supra-structures may be distinguished from one another, i.e., health services (professional perspective) and tinnitus support groups (lay perspective). Pryce et al. (29) recently reported that social connectedness and information sharing were two essential features of valuable resources found by suffering patients in support group settings. Improving patients' sense of coherence (i.e., manageable information) and fulfillment of basic psychological needs (i.e., relatedness) are both the kind of resources consistent with salutogenetic and self-determination perspectives on improved tolerance to tinnitus.

Interestingly, rumination (or ruminative self-focused thoughts) has often been associated with the pursuit of unattained goals (63) and the meeting with unattainable goals (64), as well as the lack of relatedness with others (58). All of these issues can be transposed to the nature of tinnitus, being an intrusive presence that cannot be removed from the individual's perception, which hinders the pursuit of everyday goals. Moreover, it can turn into a barrier to social relationships or occasionally also serve as an obstacle or an excuse for being socially involved (17). Conversely, it has long been recognized that *absorbing* pleasant and meaningful hobbies can bring momentary relief to patients from the intrusiveness of their tinnitus (65). These two directly opposed observations (i.e., rumination and full commitment) are consistent with a dynamic and optimal experience (the "flow" model) as an approach to intrinsic motivation (66, 67). Furthermore, it has been emphasized that full commitment excludes self-consciousness (and rumination) from an ongoing activity (68). As soon as self-consciousness emerges in the individual's perception, the optimal experience of being fully absorbed by an ongoing

activity *ceases*. A sensitive dynamic process like this may have a substantial impact on patients' sense of ability to cope with tinnitus (9).

Limitations and Strengths

The results of the present study should be considered in light of some limitations. One limitation is that the generalizability of the results is limited due to the small sample size and the choice of methodology. However, we would like to refer to the narrative psychological approach in which an important goal is to collect detailed, information-rich data (22), which also means that the number of participants is less crucial for the outcome. The material in the study consists of 15 interviews, of which most interviews are an hour long or sometimes even longer. We believe that it is correct to regard this material as information-rich data. However, our study results cannot be used for generalization purposes, and therefore we advise readers not to make uncritical generalizations from our results. Participants interviewed for the study were from one single health care system, which justifies the findings' lack of transferability across other health care settings. They were also mainly female and homogeneous in age, and therefore we cannot comment on gender or age differences. However, we have brought to the forefront those aspects of living with tinnitus that were perceived as important to the participants, while the aim was not to focus on recruiting a representative sample from which findings could be generalized.

The purpose of our study was to highlight the unique nature of personal experiences of having tinnitus, hoping that the narratives presented would contribute to showing a nuance of the complexity of the problem. Approaching the suffering of tinnitus as a *regressive* narrative enables the clinician to consider subsequent consequences of tinnitus on personal resources. In this approach, the consulting dialogue should focus on the patients' own comprehension of what the condition has implied for them psychologically and for their social belonging. From a rehabilitation perspective, a central issue is to help suffering patients to extend their ability for full commitment in life, while overcoming rumination about past events and unsolved struggles. This perspective can be framed as the passing from a *regressive* to a *progressive* (or even *stable*) narrative about living with tinnitus. When people are faced with challenges in life, such as illness or injury, these challenges interact with a unique individual carrying a history. The humanistic psychological view of what it implies to live with long-term chronic pain, tinnitus or other stress-related disorders with often multifaceted origins, is a complement to medical science with a preference for structured questionnaires and generic instruments. Perhaps though, in the future, narratives of the present study can be used for the construction of questionnaires by which more patients with tinnitus can be reached and this may contribute to new insights.

CONCLUSION

To our knowledge, this is the first study which considers the daily experience of living with tinnitus in a broader perspective

of the narration of individuals' life stories. The literature on tinnitus has remained rather symptom-focused, to the detriment of a more holistic approach to tinnitus (i.e., with concern for biographical backgrounds to the patients' suffering). This appears to be in sharp contrast with research on chronic illness [e.g., Bury (60)], chronic pain [e.g., Smith and Osborn (69)], and trauma studies [e.g., Crossley (22)], that all have emphasized the disruptive feature of chronic conditions with regard to everyday routines. A narrative perspective on tinnitus enlightens its potential impact on the sense of self, life orientation and experienced time, that are seldom addressed in the literature. Illness or injury, such as tinnitus, can have detrimental effects on a person's life and goals, sense of identity and social relationships, as illustrated by the participants' narratives in the present study.

An important goal of rehabilitation is to facilitate and strengthen the possibility of a life that is perceived as meaningful to the particular person by focusing on adaptive coping skills, enhanced resilience, improved functioning and control in areas of life where mastery is still possible and necessary for realizing personal life goals. To meet a suffering patient is challenging because it demands a special interest for the person as a complex, living system. Hall underlines the importance of accuracy in the way clinicians perceive their patients, and she outlines the principles of the concept of *interpersonal sensitivity*. Further, she describes a number of states and traits that clinicians should be aware of in communication with their patients, for example feelings, desires, truthfulness, intentions, needs, physical states, attitudes, beliefs, and values (70). Hall argues that in the area of health communication, only the behavioral aspect (saying or doing, or not saying or doing) is studied, while the perceiving aspect (noticing, interpreting) has been ignored. Finally, we want to acknowledge the clinician's own horizon of experience to be used as a guide to the inner life of our patients (71). The ability to be empathic includes the capacity to interpret non-verbal language, mimics, gestures, and body posture—skills that should be optimal in clinical practice. There is no direct entrance to the patient's inner experience even if we try to understand what it means to feel that one's entire existence is circumscribed by the presence of tinnitus. It is only through our conception or imagination that we can attempt to grasp what the other person is experiencing.

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DATA AVAILABILITY STATEMENT

All datasets generated for this study are included in the article/**Supplementary Material**.

ETHICS STATEMENT

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

AUTHOR CONTRIBUTIONS

SE, LL, and ND planned the study and the design together. SE was responsible for ethical application and the contacts with the Swedish hospital staff for patient involvements in the study. LL and SE made contacts with the participating patients prior to the study. Interviews and transcriptions were undertaken by SE and LL. A major part of the transcripts were translated to ND (Not Swedish spoken) by SE. All three researchers, SE, LL, and ND took part in the narrative analyses and provided expertise, research experience, literature, and references. SE, LL, and ND were also all active in writing and the manuscript took form by the involvement of all researchers.

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SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: <https://www.frontiersin.org/articles/10.3389/fpsy.2020.00136/full#supplementary-material>

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The Effect of Mechanical Massage and Mental Training on Heart Rate Variability and Cortisol in Swedish Employees—A Randomized Explorative Pilot Study

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Work-related stress is relatively common in modern society and is a major cause of sick-leave. Thus, effective stress reducing interventions are needed. This study examined the effects of mental training and mechanical massage, on employee's heart rate variability (HRV) and plasma cortisol at their workplaces. Moreover, it was investigated whether baseline systolic blood pressure (SBP) can explain differences in effectiveness of the intervention. Ninety-three participants from four workplaces were randomly assigned to one of the five programs: (I) Mechanical massage and mental training combined, (II) Mechanical massage, (III) Mental training, (IV) Pause, or (V) Control. HRV and plasma cortisol were measured at baseline and after 4 and 8 weeks. SBP was measured at baseline. On the reduction of cortisol levels, a small effect of the mechanical massage program was found, whereas no effect was found for the other programs. None of the programs showed any effect on HRV. Nonetheless, when the level of systolic blood pressure was taken into account, some small beneficial effects on HRV and cortisol of mental training and the mechanical massage were found. This exploratory pilot-study provides useful information for future studies that aim to reduce stress among employees.

Keywords: stress, mental training, heart rate variability, cortisol, systolic blood pressure, mechanical massage

INTRODUCTION

Work-related stress is one of the most prevalent forms of stress in modern society and it has personal and economic effects as it is a major cause of sick-leave. The high numbers of sick leave days due to stress highlight the need for effective interventions to reduce stress at workplaces (EU-OSHA; 2009). High psychological and emotional demands at work with low control abilities may lead to high levels of physiological and perceived stress which, if people do not take time to recover, can lead to an overactive stress-system (1). Biological indicators that can be used to assess individual's physiological stress level are cortisol and heart rate variability (HRV). Cortisol is a stress hormone that is secreted as a response to stress by the hypothalamic-pituitary-adrenal axis (HPA-axis), and can therefore be used as an index of stress. HRV, defined by the change in time

interval between two consecutive heart beats, provides an indication of adaptability of the autonomic nervous system (2). These indicators can therefore serve as indicators when investigating the effectiveness of stress management interventions. Two stress management methods that have been applied to enable the body and mind to rest and recover are massage and mental training. Manual massage therapy has been shown to be effective in decreasing stress as indicated by a reduction of physiological outcomes, such as blood pressure (3, 4), and cortisol levels (4). This is partly supported in a meta-analysis, in which was reported that single applications of massage resulted in, among other outcomes, reduced blood pressure and heart rate, but not cortisol levels (5). Another method that has been used to reduce stress is mental training, which teaches people techniques to increase mental relaxation. Evidence on the effectiveness of mental training on physiological stress are scarce, however, one study showed a significant decrease in plasma cortisol in people who participated in a mental training intervention when compared to a control group (6). In a randomized controlled pilot study, the effects of massage therapy and mental training, separately or combined, have been examined in Swedish employees (7, 8). In this study a mechanical massage was used instead of the more commonly used manual massage. In contrast to the previously described studies that examined short term effects of massage and mental training programs, Muller et al. (7, 8) performed a randomized controlled study that examined the long term effects of mechanical massage and mental training, used both separately and in combination. In these two papers some positive effects of both the interventions have been described. In Muller et al. (7), positive effects on anxiety, stress susceptibility and detachment were found for both mental training and mechanical massage, separately and in combination. Regarding physiological effects, the mechanical massage significantly reduced heart rate and systolic and diastolic blood pressure, and increased fingertip temperature of the employees. Moreover, they showed that mental training significantly decreased employees' heart rate (8). The current paper further explores outcomes of this study and examines whether the mechanical massage and mental training, either separate or in combination, has an enduring effect on employee's heart rate variability (HRV) and plasma cortisol. It is expected that HRV increases and cortisol levels decrease as a result of the interventions that aim to reduce stress. Furthermore, it will be examined whether participant's baseline stress levels, as indicated by their initial systolic blood pressure (SBP), can have an influence on the effectiveness of the interventions.

METHOD

Participants

Participants were recruited from four workplaces located in the south-west of Sweden. We randomly allocated 93 participants who signed a written informed consent to one of the five study groups using sealed envelopes: (I) Massage and mental training combined (sitting in the armchair receiving mechanical massage while listening to a mental training program, $n = 19$), (II) Massage (sitting in the armchair receiving mechanical massage,

$n = 19$), (III) Mental training (sitting in the armchair listening to the mental training program, $n = 19$), (IV) Pause (sitting in the armchair but not receiving mechanical massage nor listening to the mental training program, $n = 19$), or (V) Control (not sitting in the armchair at all, $n = 17$). Workplaces and participants were included if they had no prior experience with the armchair and/or mental training. Only healthy employees (self-reported) were included and employees who were pregnant, suffering from influenza, colds, fevers, or who had a skin or kidney disease, were excluded from participation. Participants should work between 75 and 100% within the concerning company. If participants were working <100%, the reason for this should not be stress-related issues.

Procedures

The total study period was 8 weeks and participants in groups I–IV were instructed to attend three times a week to the assigned 15 min program, by preference between 1 and 4 pm. This study follows the Consort recommendations (7, 8) and is registered in Australian New Zealand Clinical Trials Registry <http://www.anzctr.org.au/>; ACTRN12615000020583, Date of registration: 15/01/2015.

Armchair

The armchair (Recovery Chair, Promas MethodTM) is equipped with a mental training (verbal instructions via headphone) and a mechanical massage through which the neck, shoulders, back, and calves can be massaged. Groups I–IV were seated in the armchair while they received different programs. Participants in group V (control group) did not use the armchair.

The participants in the groups that received mechanical massage either listened to music (group II) or listened to the mental training (group I) while they were getting the massage. The mental training included verbal instructions, exercises, and soft background music and covered different topics each week in the following order: 1 "Recovery," 2 "Mindfulness," 3 "The way to a better and deeper sleep," 4 "Reduce the negative stress," 5 "Learn to think positively," 6 "Increase your mental strength," 7 "How to get a greater enjoyment of life" and eight "Recovery."

The pause and control group neither got the massage nor the mental training. The pause group was asked to take a break from their regular work during which they had to sit in the armchair for 15 min doing nothing. The participants in the control group were instructed to continue with their work as usual with no break. More details on the procedures of the different conditions are described elsewhere (7).

Measures

Measurements took place during three sessions; at baseline (before randomization), after 4 weeks, and after 8 weeks (end of study). All data collection was performed at the employees' workplace during working hours by a well-trained and experienced nurse and researcher. Data were collected on days that participants did not use the programs, in order to test long term effects of the programs. The total time of each session was 30 min during which blood collection, HRV, and blood pressure measurements took place. HRV was measured after a

30-min resting period. The participants were in seated position during all measurements. Because of the known circadian variation of cortisol levels, all data collection, including blood sampling, were performed before lunch between 9:00 and 12:00.

Dependent Outcomes

Heart rate variability (HRV) was determined using Biocom Technologies Heart Rhythm Scanner (Biocom 4000, Biocom Technologies, Poulbo, USA) software for 5 min. HRV data were obtained from electrocardiograph (ECG) with electrodes placed on the participant's wrists, and data were manually inspected for errors. The average HRV from the ECG was calculated for each of the occasions. The root mean square of successive differences (RMSSD) between consecutive heart beats, one of the time-domain variables which reflects vagal tone (2), were used as a measure of HRV (RMSSD; European-Society-of-Cardiology, 1996). Cortisol levels were obtained from blood samples collected at each measurement session. First, blood was collected in pre-chilled EDTA tubes and kept on ice until centrifugation. After that, plasma was taken and stored at -20°C until analysis. Plasma samples were processed using the Cortisol ELISA kit (Enzo Life Sciences Inc., Farmingdale, NY).

Independent Outcomes

Blood pressure was measured with an automatic manometer (Omron M6 Comfort, Omron Healthcare, Hoofddorp, the Netherlands). This device was connected to the left arm of the participants and placed in line with the heart.

Ethical Considerations

The study was approved by the Regional Ethics Committee of the University of Gothenburg, Sweden (ref.nr: 980-12) and was carried out in accordance with the Declaration of Helsinki. The participants were allowed to end participation at any time and were informed that the data would only be available for the main researchers and would not be disclosed to employers. Participants assigned to the control group were able to use the armchair after the study period.

Statistical Methods

We performed all statistical analyses with SPSS (version 24.0). To establish normal distributions of HRV and cortisol data, we log-transformed the data. We conducted One-way ANOVA tests and Chi-square tests to compare background characteristics of the groups. To compare baseline group values of HRV and cortisol, we used One-way ANOVA tests. We implemented linear mixed models (LMM) to analyze changes over time for HRV and cortisol separately. The dependent variables were HRV and cortisol measures (logRMSSD, logCortisol), with group (I–V) as independent variable. The measurements at the three time points (baseline, after 4 weeks, after 8 weeks) were the repeated measures. The fixed effects were group, time, and the interaction between group and time to test for differences between the groups over time. We conducted *t*-tests for each group to test for changes of HRV and cortisol between the different time points. Pearson's *r* was computed for HRV and cortisol for each group separately to analyze the relationship between an individual's baseline SBP

and the change (Δ) between start and end of the interventions for the two outcome variables.

RESULTS

The CONSORT flow-chart of participant recruitment can be found in **Figure 1**. **Table 1** presents means and standard deviations of the continuous variables and frequencies of the categorical variables. The total sample of 93 participants consisted of 69 women (74.2%) and 24 men (25.8%) with a mean age of 47.6 years ($SD = 9.84$). The participants of the five study groups did not differ significantly in age ($F_{(4,88)} = 0.54, p = 0.71$).

Effect of the Programs on HRV and Cortisol

We had complete data on HRV from 79 participants. The five groups did not differ significantly in baseline levels of HRV ($F_{(4,85)} = 1.39, p = 0.24$). In our main analysis we found no differences in HRV over time between the five study groups. The results of the LMM analysis suggest that neither time, group, nor the interaction were significant predictors in explaining variance in HRV. We found no significant differences in HRV from baseline to 4 weeks, 4–8 weeks, and baseline to 8 weeks for none of the groups.

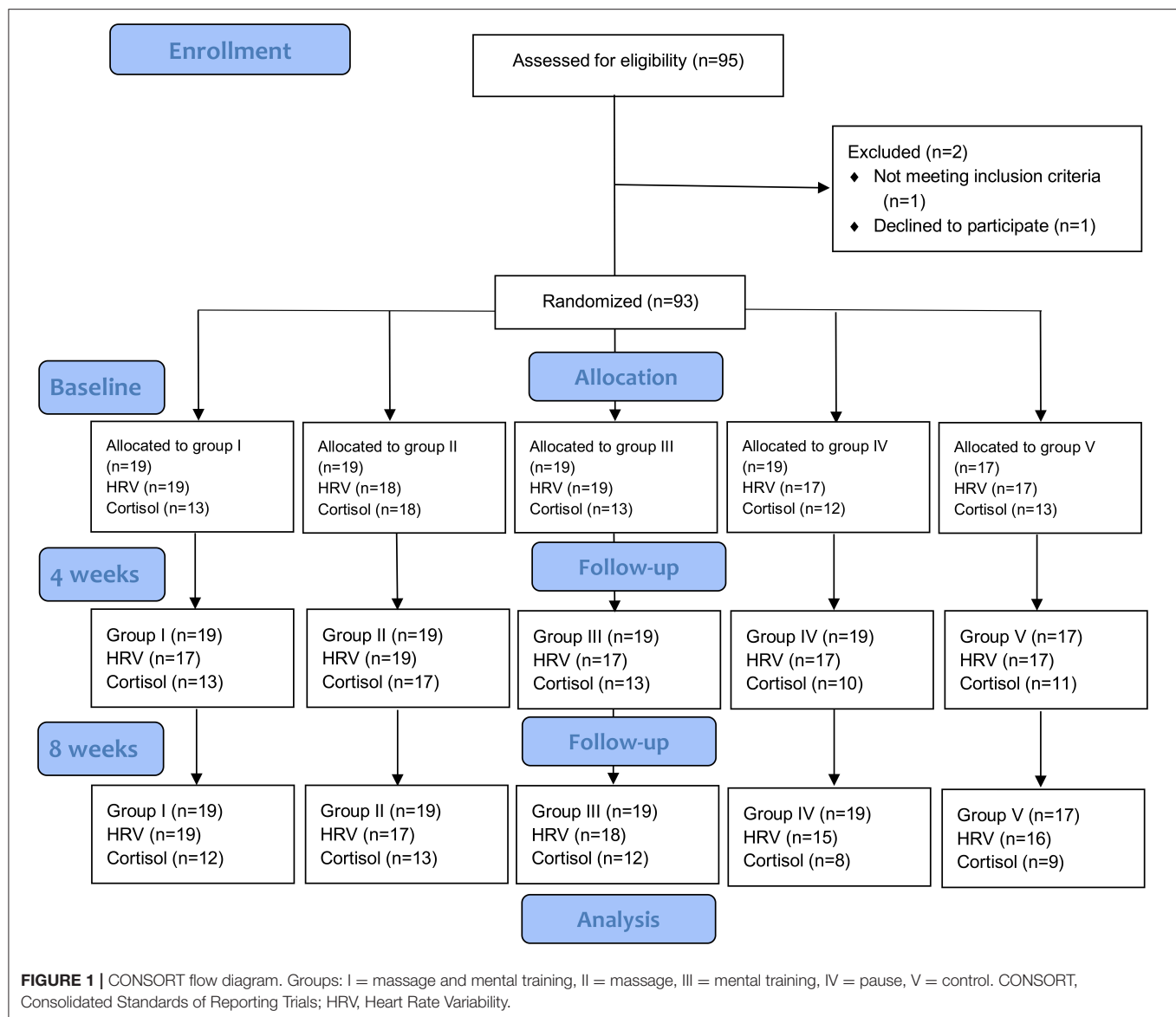
For cortisol, we had complete data of 43 participants. We found no significant differences on baseline cortisol levels ($F_{(4,64)} = 0.23, p = 0.92$). The results of the LMM analysis suggest that neither time, group, nor the interaction were significant predictors in explaining variance in cortisol. We found a significant decrease in cortisol in the massage group only between the fourth ($M = 19.77, SD = 12.59$) and the 8-weeks ($M = 15.96, SD = 7.39$) measurement ($t(12) = 2.19, p < 0.05$). The other measurements of the massage group were not significantly different, nor were the measurements of the other groups.

Correlation Between SBP With HRV and Cortisol

To test if baseline SBP was correlated with the change (from start to the end of the intervention) in HRV and cortisol (**Table 2**), we computed Pearson's *r* for each group. We found no significant differences of baseline SBP between the groups ($F_{(4,85)} = 0.19, p = 0.94$) (**Table 1**). The results for change in HRV show a significant negative correlation with SBP in group II ($r = -0.61, n = 15, p < 0.05$) (**Table 3**), suggesting that only for the group that was offered the mechanical massage as only intervention, lower SBP was correlated with a stronger increase in HRV from baseline to the end of the intervention. In contrast, we found a positive correlation with cortisol and SBP in group III, suggesting that for the group that was offered the mental training as only intervention, lower SBP was correlated with less decrease in cortisol from baseline to the end of the study period (**Table 3**).

DISCUSSION

This small-scaled, randomized controlled pilot study explored whether an 8-weeks lasting mechanical massage and mental training intervention, separate or in combination, could have an effect on employees' HRV and cortisol levels. The main



result of the study shows that there is no difference in change over time between the groups for HRV and cortisol. When baseline stress levels, as indicated by baseline SBP, were taken into account, participants with lower SBP who were offered mechanical massage showed more beneficial effects on HRV and of those with lower SBP who were offered mental training showed more beneficial effects on cortisol when compared with the participants in these groups who had higher SBP.

Effects of the Stress Intervention Programs on HRV and Cortisol

When looking at the effects of the programs within the groups, no change in HRV between the three time points was observed in any of the groups. For cortisol, a significant decrease between the fourth and the 8-weeks measurement was found, only in the group that was offered the mechanical massage. When the

five study groups were compared with each other, there were no differences in HRV and cortisol between the programs, neither at the three different time points, nor in the effects on HRV and cortisol over time. These results are not in line with our expectation that the mechanical massage, mental training, and the combined program, would be more effective in increasing HRV and decreasing cortisol when compared to both the control and pause group.

Some explanations can be provided for these unexpected results. Diego and Field (9), who also examined the effects of massage in healthy participants, distinguished between light and moderate pressure massage. Their findings showed that after light pressure massage an increase in sympathetic activity was found, whereas after moderate massage a shift from a sympathetic to parasympathetic response was shown, indicating higher levels of relaxation in the latter group. The participants in the current

TABLE 1 | Background characteristics of the five study groups ($n = 93$) and baseline measures of systolic blood pressure. Values are presented as means (SD) or proportions.

Characteristic	Groups					Comparisons	
	I ($n = 19$)	II ($n = 19$)	III ($n = 19$)	IV ($n = 19$)	V ($n = 17$)	χ^2/F	p
Age						0.54	0.71
Mean (SD)	50.4 (8.4)	47.5 (12.1)	46.5 (9.1)	47.9 (9.2)	46.7 (19.5)		
Gender						1.99	0.74
Women n (%)	16 (84.2)	15 (78.9)	13 (68.4)	13 (68.4)	12 (70.6)		
Men n (%)	3 (15.8)	4 (21.1)	6 (31.6)	6 (31.6)	5 (29.4)		
Marital status						5.01	0.75
Single n (%)	3 (16)	3 (16)	2 (10)	2 (10)	2 (11)		
Partner/married n (%)	15 (79)	16 (84)	17 (89)	17 (89)	14 (82)		
Living apart/other n (%)	0	0	0	0	1 (6)		
Education						4.67	0.96
Compulsory school n (%)	1 (5)	1 (5)	1 (5)	0	1 (6)		
Senior high school n (%)	5 (26)	3 (16)	2 (10)	4 (21)	2 (11)		
Higher education n (%)	2 (10)	3 (16)	2 (10)	3 (16)	1 (6)		
University n (%)	11 (58)	12 (63)	14 (74)	12 (63)	13 (76)		
SBP						0.19	0.94
Mean (SD)	128.62 (17.36)	125.89 (16.69)	127.74 (20.50)	127.00 (23.56)	123.59 (14.09)		

Groups: I = message and mental training, II = message, III = mental training, IV = pause, V = control; SD, standard deviation; SBP, Systolic blood pressure measured at baseline.

study could adjust the settings of the massage when desired. We assume that people would be able to relax more when they can choose a massage strength where they feel most comfortable with. However, variation in settings amongst the sessions within one participant could have caused different effects of the massage, like Diego and Field (9) found between light and moderate pressure massage. For example, if one would have chosen light massage at 1 day and hard massage at another day, the possible increase in sympathetic activity (due to light massage) and increase in parasympathetic activity (due to hard massage) could have canceled each other out. If this had happened in our study, then the interpretation of effect of the mechanical massage could have been underestimated. We did not assess which strength of the massage chair was used by our participants nor did we measure whether this strength was the same at each occasion they used the chair, which could be interesting for further investigation.

A study that found a positive effect of massage in healthy students, only showed improvement in HRV for individuals with higher stress sensitivity and not for individuals who were less responsive, as determined by the cold pressor stress test Díaz-Rodríguez et al. (10). Thus, when stress responsiveness of the participants was taken into account, massage was differentially

TABLE 2 | Means and standard deviations of the $\Delta\log\text{HRV}$ and $\Delta\log\text{Cortisol}$ for each group separately.

Group	ΔHRV	$\Delta\text{Cortisol}$
	Mean (SD)	Mean (SD)
I ($n = 19$)	-0.24 (0.63)	-6.09 (17.09)
II ($n = 19$)	0.17 (0.44)	3.09 (11.48)
III ($n = 19$)	-0.02 (0.30)	1.02 (9.13)
IV ($n = 19$)	-0.01 (0.54)	2.99 (11.44)
V ($n = 17$)	-0.03 (0.42)	-1.99 (9.28)

Groups: I = message and mental training, II = message, III = mental training, IV = pause, V = control; SD, Standard Deviation.

TABLE 3 | Correlations of change (Δ) in HRV and cortisol, between start (baseline) and end of the intervention (after 8 weeks) with baseline SBP (group I to V) for each group.

Parameter	Group	ΔHRV	$\Delta\text{Cortisol}$
SBP	I	0.01	-0.01
	II	-0.61*	0.07
	III	0.08	0.75*
	IV	-0.004	-0.15
	V	-0.27	0.25

Groups: I = message and mental training, II = message, III = mental training, IV = pause, V = control; $\Delta\text{HRV} = \text{HRV}_{8\text{-weeks}} - \text{HRV}_{\text{baseline}}$; $\Delta\text{Cortisol} = \text{Cortisol}_{\text{baseline}} - \text{Cortisol}_{8\text{-weeks}}$; * $p < 0.05$.

effective among individuals. Individual differences in stress responsivity among participants might explain differences in effect of massage and the other programs of the present study as well, as this was not taken into account in this study. A possible reason why we did not detect differences in cortisol during the intervention period could be that the length of the intervention was just too short to achieve an effect. We found a significant decrease between the fourth and the 8-weeks measurement, but only in the group that was offered the mechanical massage. Johansson and Unestahl (6) showed a positive effect of a 6-months mental training program, as indicated by a decrease in plasma cortisol after the intervention period. Possibly, a longer intervention period than the 2 months of this study is needed to achieve the desired effects of mechanical massage, mental training, and the combined program. It should be mentioned that the current study explored the lasting effects of mechanical massage and mental training program, as assessments were done at days that participants did not perform the program(s). This study did not focus on the acute or short term effects of the interventions, as the previous studies did (6, 9, 10). Positive long lasting effects of both mechanical massage and mental training on psychological as well as physiological outcomes have previously been demonstrated (7, 8). Muller et al. (7) showed positive effects of both mental training and mechanical massage, separately and combined, on anxiety, stress susceptibility and detachment. Muller et al. (8) showed beneficial effects on heart rate, blood pressure, and fingertip temperature after mechanical massage,

and on heart rate only after mental training. When combined with the results of the current study, one could presume that the direct effects of mental training and mechanical massage on cortisol and HRV, if they would have been measured directly after the programs, were less stable over time when compared with other physiological measures, such as heart rate, blood pressure, and fingertip temperature. All in all, whether the effects of massage, either mechanical or manual, and mental training are transient or enduring, needs to be further investigated. To explore a possible temporal change in the effects of such programs, a design that enables testing both immediate and lasting effects is required.

SBP and Effect of Programs on HRV and Cortisol

Furthermore, this study investigated whether individual's baseline SBP, an indicator of people's stress level, can explain differences in effectiveness to the programs between participants as measured by HRV and cortisol. In fact, blood pressure of individuals that is already at a low or healthy level does not need to be further reduced, which is in contrast to people with high blood pressure, who have a higher necessity to lower their blood pressure as hypertension is a risk factor for cardiovascular diseases (11). Therefore, stress interventions might be more relevant for people with high blood pressure. It was hypothesized that for these individuals, a higher positive change in HRV and a higher negative change in cortisol from baseline to the end of the study period would be found as a result of the programs, when compared to participants with lower blood pressure. The results are not fully in line with these expectations since it was only for the mechanical massage group that lower SBP was correlated with a stronger increase in HRV. For cortisol, the results suggest that only for the mental training group, lower SBP was correlated with a stronger decrease in cortisol from baseline to the end of the intervention. A possible explanation for these results could be that individuals with higher SBP are too stressed to relax through the mechanical massage and therefore a stress intervention like mechanical massage is not effective in lowering the stress levels in this specific group. If higher SBP is a true indicator of excessive perceived stress, mechanical massage could be recommended to be used for preventive purposes rather than to help people recover from already too much elevated stress levels.

Strengths and Limitations

One of the strengths of this study is that it is one of the first to examine the effect of mechanical massage, without the need of a masseur, on physiological measurements. The use of a mechanical massage instead of a manual massage excludes the possible bias by therapist-effects and thereby enables to test the true effects of massage. Also, by including a pause group and a control group we were able to examine whether the stress reduction was due to the program(s), or whether a period of rest in between work is sufficient to achieve stress reductions. Moreover, as randomization took place within the participating companies, we reduced the possibility of confounding by differences among workplaces and therefore we provide a less

biased evaluation of the stress intervention programs. The small sample and the associated restricted statistical power are limitations of this study as this may have led to an under- or overestimation of the effect of the interventions. Power calculations prior to the study suggested a sample size of 100 participants in each group [for a 30% reduction of cortisol levels in the experimental groups compared to pause and control ($b = 0.8$ and $\alpha = 0.05$)]. Due to financial and time constraints, we were unable to achieve this required sample size. Due to the small sample size, we were also restricted in using covariates in our main analyses. A second potential short-coming is the lack of control for possible confounding variables such as variation in personality, coping style, as well as lifestyle or early life experiences among participants that may have influenced participants responses to the programs offered. These limitations should be taken into consideration when interpreting the results.

IMPLICATIONS AND CONCLUSION

Work-related stress is a major source of stress related problems in modern society and therefore interventions focusing on the modulation of stress at the workplace are needed. Our current findings suggest that a mechanical massage or mental training seems to be effective for individuals with lower SBP, perhaps implying that people with relatively low levels of stress may benefit from our programs in a preventative manner. In contrast, people with higher SBP at baseline, may need a longer or more intensive program to reduce their levels of stress. Thus, these stress intervention programs can be valuable for clinical practice as, when offered by employers at workplaces, it can help to keep employees healthy and prevent development of stress-related illnesses. Moreover, the programs examined in the current study might be less expensive and easier applicable when compared to other stress interventions such as manual massage. The current study also suggests that there is a small effect of the massage program on the reduction of cortisol. However, as this is a small-scaled exploratory pilot study, further research consisting of a larger sample, including covariates (normative stress, stress susceptibility, coping styles, early life experiences) and follow-up measurements are needed to confirm the possible effects and evaluate the long-term effects of stress interventions. Nonetheless, this exploratory pilot-study provides useful information for future studies that aim to reduce stress among employees.

DATA AVAILABILITY STATEMENT

The datasets analyzed in this article are not publicly available due to risk of compromising individual privacy. The application and the written consent forms approved by the Regional Ethical Review Board in Gothenburg, Sweden, states that the data will only be available to the researchers within the project. Requests to access the datasets should be directed to linda.handlin@his.se.

ETHICS STATEMENT

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

AUTHOR CONTRIBUTIONS

JM, LH, AE-B, and WV were active in the design, data collection, and analysis. WV, LH, and AH were involved in the writing-up of the manuscript. All authors also read and approved the final manuscript.

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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.

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Effects of Yoga Respiratory Practice (*Bhastrika pranayama*) on Anxiety, Affect, and Brain Functional Connectivity and Activity: A Randomized Controlled Trial

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Pranayama refers to a set of yoga breathing exercises. Recent evidence suggests that the practice of *pranayama* has positive effects on measures of clinical stress and anxiety. This study explored the impact of a *Bhastrika pranayama* training program on emotion processing, anxiety, and affect. We used a randomized controlled trial design with thirty healthy young adults assessed at baseline and after 4 weeks of *pranayama* practices. Two functional magnetic resonance imaging (MRI) protocols were used both at baseline and post-intervention: an emotion task as well as a resting-state acquisition. Our results suggest that *pranayama* significantly decreased states of anxiety and negative affect. The practice of *pranayama* also modulated the activity of brain regions involved in emotional processing, particularly the amygdala, anterior cingulate, anterior insula, and prefrontal cortex. Resting-state functional MRI (fMRI) showed significantly reduced functional connectivity involving the anterior insula and lateral portions of the prefrontal cortex. Correlation analysis revealed that changes in connectivity between the ventrolateral prefrontal cortex and the right anterior insula were associated with changes in anxiety. Although it should be noted that these analyses were preliminary and exploratory, it provides the first evidence that 4 weeks of *B. pranayama* significantly reduce the levels of anxiety and negative affect, and that these changes are associated with the modulation of activity and connectivity in brain areas involved in emotion processing, attention, and awareness. The study was registered at [https://www.ensaiosclinicos.gov.br/rg/RBR-2gv5c2/\(RBR-2gv5c2\)](https://www.ensaiosclinicos.gov.br/rg/RBR-2gv5c2/(RBR-2gv5c2)).

Keywords: yoga, pranayama, anxiety, affect, emotion regulation, functional MRI, amygdala, insula

INTRODUCTION

Yoga is a system of practices with ancestral roots in India (1). It is defined as *Chitta Vritti Nirodhah*—the cessation of the whirlwinds of the mind—which is better understood in contemporary language as a tool to calm the mind (2). The Yoga Sutras of Patañjali systematized it a set of eight practices, also called *Ashtanga* Yoga or Yoga of the eight limbs (1, 2): *yamas* (abstentions), *niyamas* (observances), *asanas* (postures), *prāṇāyāma* (control of breath), *pratyāhāra* (withdrawal of senses), *dhāraṇā* (concentration), *dhyāna* (meditation), and *samādhi* (oneness). The breathing practices are called *prāṇāyāma*, which is a Sanskrit word for *prana* (vital energy) and *ayama* (control). It refers to a series of voluntary controlled breathing exercises that manipulate the respiratory frequency, inhalation (*puraka*), retention (*kumbhaka*), exhalation (*rechaka*), and body locks (*bandhas*) (3).

The practice of pranayama influences many physiological variables. Evidence suggests that its practice produces a positive impact on the cardiorespiratory system (4–7), where slow-paced breathing leads to reduced heart rate and decreased systolic and diastolic blood pressure (8), while fast breathing leads to less robust, but consistent increase in heart rate (9–12). In fact, a previous study observed that the practice of the *Bhastrika pranayama* with low respiratory rate decreased significantly both the systolic and diastolic blood pressure, with a modest decrease in heart rate (10). Furthermore, changes in heart rate variability (HRV) also support the notion that the practice of *pranayama* improves respiratory function and cardiac sympathovagal balance, which are important psycho-physiological stress-related variables (13, 14).

A number of studies support significant positive effects of different yoga practices on anxiety and depression (15, 16) but very few have explored the impact of the practice of *pranayama* on neurophysiological, psychological and psychiatric variables, although evidence suggests improved self-regulation, positive mood, reduced stress, and anxiety (4, 5, 17). A study evaluating the effects of fast and slow pranayama on perceived stress and cardiovascular parameters in young students observed a significant and comparable decrease in the perceived stress scores in both types of pranayama practices, while cardiovascular parameters were changed only after the slow-paced pranayama (18). Furthermore, evidence suggests that yoga programs that include pranayama result in reducing anxiety in humans (19, 20), and a recent feasibility study found evidence of the positive impact of pranayama in patients with treatment-resistant generalized anxiety disorder (21).

It has been hypothesized that the psychobiological mechanism through which pranayama exerts its effects are mediated by the vagus nerve, through interconnections between peripheral sensory organs, the solitary nucleus, thalamus, limbic areas, and the prefrontal cortex (17, 22). Furthermore, it has been suggested that the increase of parasympathetic activity (associated with expiration time) reduces the release of hormones associated with stress (22, 23), and enhances GABA inhibition from the prefrontal cortex and insula to the amygdala, reducing its activity, and the psychological and somatic symptoms associated with stress (24, 25).

Recent studies show that yoga practices, such as meditation, are associated with emotional regulation processes (26, 27). It remains unclear, however, whether these changes occur through top-down or bottom-up strategies. The emotional regulation task used in this trial allowed us to investigate both processes. In addition, several brain regions involved in emotion regulation, as the amygdala, insula, and anterior cingulate cortex (ACC) play an important role in anxiety disorders (28), and previous evidence suggests that anxiety-prone individuals have increased activity in the bilateral amygdala and insula when compared to healthy controls (29). Furthermore, the practice of meditation, including focused on breathing, leads to optimized emotion regulation through increased acceptance and enhanced present-moment awareness (30–33) while impaired emotion regulation has been associated with depression and anxiety (34, 35).

However, the neural basis of the effects of pranayama on anxiety, mood, and emotional regulation, has been less explored. This study aimed at exploring the impact of a 30-day training program of *B. pranayama* on a brain network involved in emotion processing and its association with self-reported changes in affect and anxiety. We used functional magnetic resonance imaging (fMRI) to assess changes in activity and connectivity of brain networks involved with anxiety and emotion processing, and questionnaires to access states of anxiety and affect. Our hypotheses were that pranayama training would: i) decrease anxiety levels; ii) decrease negative affect levels; iii) increase positive affect levels; iv) decrease connectivity within emotion processing brain networks; v) decrease activity in the amygdala; vi) increase activity in parts of the prefrontal cortex, anterior cingulate, and insula, all involved in emotion processing and anxiety.

MATERIALS AND METHODS

Participants

Participants were recruited through word-of-mouth and printed advertisements posted at the Federal University of Rio Grande do Norte campus and community. After contacting the experimenter, participants received information about the goal of the study as well as the exclusion criteria. They were informed that they could be allocated in either a group that involves pranayama practices or in a control group, depending on randomization.

Thirty volunteers were selected according to the following inclusion criteria: i) healthy young adults, between 18 and 40 years of age, naïve to the practice of *pranayama*. Exclusion criteria included: i) MRI contraindication, such as metal parts in the body or pregnancy; ii) chronic rhinitis, with partial or complete obstruction of one or both nostrils; iii) frequent use of bronchodilator; iv) regular use of beta-blocker, stimulants or any other substance that interferes with cardiovascular activity; and v) current diagnosis or history of neurological or psychiatric disorders. The Ethics and Research Committee of

the Federal University of Rio Grande do Norte approved the study (protocol #579.226), and all subjects provided written informed consent prior to their participation in the study. This study was registered at [http://www.ensaiosclnicos.gov.br/rg/RBR-2gv5c2/\(RBR-2gv5c2\)](http://www.ensaiosclnicos.gov.br/rg/RBR-2gv5c2/(RBR-2gv5c2)).

Experimental Protocol

This study used a randomized controlled design with two parallel arms, and it was conducted in accordance with the consolidated standards of reporting trials (CONSORT) statement (36). Subjects were allocated in blocks of (4:4) to either a pranayama training group or to a control group, using permuted block randomization (<http://www.randomization.com>). Given the nature of the training, participants and researchers were not blinded. Nevertheless, all the analyses were conducted blindly. In addition, to ensure motivation, those in the control group interested in pranayama were put in a waiting list to receive the training after the study. **Figure 1** shows the experimental protocol used in the study. Participants from both groups (*pranayama* and control) were assessed at baseline and right after a 30-days training program. Both assessments included fMRI and psychometric trait-state measures of affect and anxiety.

The level of anxiety was assessed by the State-Trait Anxiety Inventory (STAI), which has been translated and validated to Brazilian Portuguese (37). We also used the Positive Affect and Negative Affect Scale (PANAS) to assess positive affect (PANAS-P), such as well-being, enthusiasm, inspiration and determination, and negative affect (PANAS-N), aimed at dimensions such as fear, nervousness, and disturbance. We used the adapted and validated PANAS to Brazilian Portuguese (38, 39). Both scales were applied to assess state and trait characteristics. fMRI assessments included an emotional regulation task and a resting state (rs-fMRI) protocol, described below in detail.

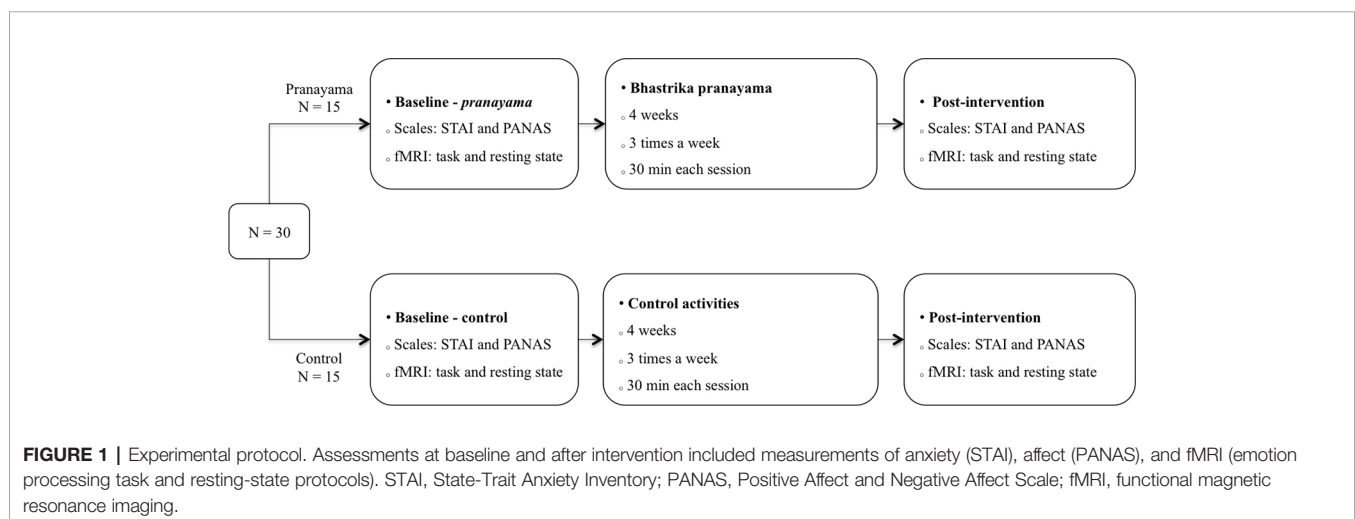
The Training Program

The practice of the *B. pranayama* is not easy for inexperienced Yoga practitioners. Therefore, during the initial 5 days of training, participants were guided for 30 min a day for the correct practice of *B. pranayama*. An instructor was present during these encounters and followed a specific sequence of daily steps designed to guide participants into the correct practice. Each training session had only four participants at a time to allow careful and individualized training.

This initial period was followed by 4 weeks of regular *B. pranayama* practice. In order to assure a volume of practices similar to previous studies from our group (40) and to the ones focused on mindfulness meditation (41), our study was designed with five practices a week, for 4 weeks. For 3 days a week, 30 min per day, participants gathered and practice together with an instructor in supervised training classes. Besides in-person meetings, subjects were instructed to practice at home for at least two more days a week. The control group also gathered with the same frequency and duration but performed ludic cognitive activities such as crosswords, puzzles, domino, checkers, and card games, also in the presence of an instructor. Participants performed one of these activities at each encounter and were asked to alternate between activities to ascertain that each game was practiced at least one to two times during the 12 scheduled meetings. Subjects in the control group were also instructed to practice at home.

Each *B. pranayama* session started with a brief 2-min savasana (relaxation), followed by 5 min of asanas (*pavanamuktasana*, *sukhasana*, *gomukhasana*, *paschimotanasana*, and *vakrasana*) applied solely to prepare the body for the practice of pranayama, as described in Patañjali's Yoga Sutra. Following this short preparation, the *B. pranayama* was performed continuously for 25 min. Sessions ended with another brief savasana (2 min).

The practice of the *B. pranayama* used in this study followed the description of Swami Kunalayananda (13), according to whom, each round of the practice is composed by a set of fast



breathing (*kapalabhati*) followed by a slow inspiration through the right nostril, a comfortable apnea done with the three *bandhas* (*mula*, *jalandhara*, and *uddiyana*) and a slow expiration through the left nostril (*Surya bedhana*). The relation inspiration:apnea:expiration was set according to individual comfort, varying from 1:1:2 to 1:2:2; 1:3:2, or 1:4:2—apnea never exceeded four times the inspiration time, and expiration was set to constantly correspond to twice the inspiration time.

Each *kapalabhati* consists of a series of 30 rapid self-paced expirations generated by contractions of the *rectus abdominis* muscle. Contrary to natural breathing, the *kapalabhati* inspiration is passive while expiration is active. One-cycle of *Surya bedhana* is composed of a slow inspiration through the right nostril, followed by apnea and by a longer, yet comfortable expiration through the left nostril. The suggested ratio between inspiration:apnea:expiration followed the traditional description of 1:4:2. Inspiration, apnea, and expiration times were set individually, according to one's capacity and comfort. Therefore, when the 1:4:2 ratio was felt uncomfortable, volunteers were instructed to decrease apnea duration to one of the following alternative ratios: 1:3:2; 1:2:2, or 1:1:2. During periods of apnea, practitioners were also instructed to execute three *bandhas*, also called locks: *jalandhara bandha*, *uddiyana bandha*, and *mula bandha*. *Jalandhara bandha* is attained by pressing the chin against the jugular notch, with both nostrils closed with the fingers, *uddiyana bandha* by a chest expansion after *jalandhara bandha*, followed by perineum contraction, called *mula bandha*. Participants were instructed to perform 30 cycles of the *B. pranayama* at each encounter.

Magnetic Resonance Imaging Imaging Acquisition

Images were acquired in a 1.5-T MRI scanner (HDxt, General Electric, USA). Functional MRI datasets were acquired with the following EPI sequence parameters: repetition time (TR) = 2000 ms; echo time (TE) = 35 ms; flip angle = 60°; field of view (FOV) = 24 cm; matrix = 64 × 64; slice thickness = 3 mm; gap = 0.3 mm; number of slices = 35; volumes = 165 (emotion processing) and 213 (resting state). High-resolution T1-weighted images were acquired with the following FSPGR BRAVO sequence: TR = 12.7 ms; TE = 5.3 ms; flip angle = 60°; FOV = 24 cm; matrix = 320 × 320; slice thickness = 1.0 mm; number of slices = 128.

Emotion Processing Protocol

All subjects had normal or corrected to normal vision. Immediately before scanning, they received a training session to ensure task compliance, using another set of images for stimuli. During the fMRI emotion processing task, programmed using Psychopy v.1.79 (42), subjects viewed a series of images with different emotion valence (neutral or negative) and were asked to rate the emotional impact of these images using a 5-point Likert scale (very negative, negative, neutral, positive, very positive). Responses were recorded *via* a five-button fiber optic response pad (Current Designs, Philadelphia, USA).

We used pictures from the International Affective Picture System (IAPS) (43) dataset, from which we selected 72 pictures with negative valence and 36 with neutral valence. Images were classified using the valence and arousal scores: negative images had low valence and high arousal scores and neutral images had medium valence and low arousal scores. During negative images presentation, participants were instructed to either observe passively the image or to try to reappraise it, depending on the instruction displayed previous to the image on the screen. In this context, reappraisal describes the attempt to attribute a new meaning to the arousing stimulus in order to reduce its emotional impact (44, 45). A list of possible cognitive reappraisal strategies was presented to the participants beforehand, such as thinking that the pictures were not of a real scene, imagining that the image was from a movie, or imagining a happy ending to the situation depicted on the scene. In addition, we explicitly asked participants to avoid closing their eyes or distracting themselves from the picture. Three conditions served to form 3 fMRI predictors: i) passively looking at neutral pictures (NEU); ii) passively looking at negative pictures (NEG); iii) reappraisal of negative pictures (REAP).

During each fMRI session, subjects were scanned in three separate runs (~5.5 min each), comprising 18 trials, 6 for each condition (NEU, NEG, REAP). Each trial lasted 18 s: 2 s for instructions (LOOK or REAPPRAISE), followed by 6 s of picture presentation, 6 s for the button response, and 4 s of a fixation cross presented at the center of the screen (**Figure S1**).

fMRI Emotion Processing Analysis

The fMRI emotion processing task was analyzed using SPM12 (Statistical Parametric Mapping, UK). The first three volumes were discarded to allow for T1 stabilization. Preprocessing steps included head motion correction, slice timing correction, spatial smoothing [8-mm full width at half maximum (FWHM) Gaussian kernel], and a high-pass filter (128 s). EPI images were coregistered to each subject's anatomical scan, normalized into standardized MNI space and resampled to voxels of 2 mm³. Serial autocorrelations were accounted for by a first-order autoregressive model (AR1). In addition, motion artifact was examined using the Artifact Detection Toolbox (ART) and volumes with a global signal deviation superior to three SD from the mean signal or in which the difference in frame displacement (FD, a composite measure of movement) between two consecutive volumes exceeded 1 mm, were considered as outlier volumes. The entire run was excluded if more than 15% of all volumes behaved as outliers.

A first-level fixed-effects model was used for each subject and each session. Five regressors corresponding to the three conditions (NEU, NEG, REAP), instruction, and rating periods were modeled using a boxcar function convolved with a canonical hemodynamic response function. Periods of fixation cross were defined as the baseline. The model also included six motion parameters and outlier volumes as regressors of no interest. Images contrasts were calculated using t-statistics for: i) NEG, ii) REAP, iii) NEG vs. REAP.

The effect of *pranayama* was inspected in the following region of interest (ROI), previously implicated in emotional processing (46, 47): ACC, amygdala, anterior insula, orbitofrontal cortex (OFC), dorsolateral prefrontal cortex (dlPFC), dorsomedial prefrontal cortex (dmPFC), ventrolateral prefrontal cortex (vlPFC), and ventromedial prefrontal cortex (vmPFC). With the exception of vmPFC (48), and the anterior insula (49) all other ROI were obtained directly from the WFU PickAtlas (50) in SPM12 (Figure S2). Mean β -values for each ROI were extracted from each subject's contrast using MarsBaR (SPM12).

rs-fMRI Data Acquisition and Analysis

The resting-state fMRI acquisition lasted for ~7.1 min, and subjects were instructed to lie down with their eyes closed, avoiding to move or fall asleep. Resting-state data were analyzed using a functional connectivity (fc) toolbox (CONN, <https://www.nitrc.org/projects/conn>). The first three volumes were discarded to allow for T1 equilibrium. Preprocessing steps included head motion correction, slice timing correction, and spatial smoothing (8-mm FWHM Gaussian kernel). Functional and structural images were normalized to the MNI template. Quality control included motion artifacts inspection with ART. Outlier volumes were considered when the global signal deviated more than three standard deviations (SD) from the mean signal or when the difference in FD between two consecutive volumes exceeded 0.5 mm. Denoising step included: CompCor method (to remove physiological and other sources of noise); use of six motion parameters and its derivatives as regressors of no interest; scrubbing and a band-pass filter (0.01–0.1Hz).

We explored the same ROI used in the emotion processing task. A 16 × 16 correlation matrix was generated by computing Pearson's coefficients between the averaged time-series for every pair of ROI.

Statistical Analysis

Demographic variables were compared using the independent Student's t-test when continuous, or chi-square test when categorical. To evaluate the effects of the *B. pranayama* on anxiety and affect, and β -values changes, we used a repeated-measures ANOVA (RM-ANOVA) with two factors: intervention (*pranayama* × control) and time (baseline × post-intervention). In cases where we found significant interactions, within groups *post hoc* analyses were conducted using the dependent Student's t-test. To further investigate the relationship between fMRI changes and the effects of *B. pranayama*, Pearson's correlation analyses were conducted to explore associations between changes in β -values from baseline to post-intervention ($\Delta\beta = \beta_{\text{after}} - \beta_{\text{before}}$) and changes in STAI and PANAS scores from baseline to post-intervention. Also, correlation coefficients were estimated only when significant interaction was found. We set the statistical threshold at $p < 0.05$ and used Cohen's d to estimate effect sizes. Statistical analyses were performed using GraphPad Prism version 7.00 (GraphPad Software, La Jolla CA, USA). Since the trial adheres to the CONSORT statement, between-group baseline differences of primary outcomes should not be reported (51).

RESULTS

The participants recruited for our study were healthy young adults (25.1 ± 4.3 years old; 15 women), mostly university students. There were no significant between-groups differences (control × *pranayama*) with respect to age ($t_{28} = 1.41$; $p = 0.16$), gender ($\chi^2 = 0.13$; $p = 0.71$), years of education ($\chi^2 = 2.91$; $p = 0.23$), and household income ($\chi^2 = 0.57$; $p = 0.90$). Detailed demographic and clinical characteristics are presented in Table 1. Figure S3 shows the CONSORT flow diagram for the trial.

Effects of *B. pranayama* on Anxiety and Affect

One subject from the *pranayama* group did not attend the second evaluation due to health issues. Boxplots were used for outlier identification (values above or below 1.5 times the interquartile range), which resulted in the exclusion of one subject from the *pranayama* group in the STAI and two from the control group in the PANAS-N (Figure S4).

Figure 2 shows changes in the STAI state and trait scores for both groups (*pranayama* and control) from baseline to post-intervention. We observed an interaction effect (intervention × time) in state of anxiety ($F_{1,26} = 4.30$; $p = 0.048$, Cohen's $d = 0.81$), with significant decreased levels in the *pranayama* group after intervention ($t_{12} = 3.01$; $p = 0.01$; Figure 2A). No significant interaction was observed in trait anxiety ($F_{1,27} = 2.13$; $p = 0.16$; Figure 2B).

Figure 3 shows the observed changes in PANAS state and trait scores for both groups before and after intervention. We observed significant interaction effect (intervention × time) in the state of negative affect (state PANAS-N, $F_{1,25} = 8.56$; $p = 0.007$, Cohen's $d = 1.17$; Figure 3A), with a significant decrease within the *pranayama* group ($t_{13} = 3.43$; $p = 0.004$; Figure 3A). States of positive affect were also significantly changed, with a significant interaction (intervention × time) effect (PANAS-P;

TABLE 1 | Socio-demographic and clinical characteristics.

	Pranayama	Control	p-value
Gender (n)			0.71
Male	7	8	
Female	8	7	
Age—years (mean ± SD)	24 ± 4.47	26.2 ± 4.05	0.16
Education—years (n)			0.23
9–11 years	4	5	
12–16 years	10	6	
17 or more years	1	4	
Household income (n)			0.90
<2 minimum wage	6	5	
2–5 min. wage	4	3	
6–10 min. wage	3	4	
11 or more min. wage	2	3	
STAI State (mean ± SD)	37.92 ± 4.09	38 ± 8.32	
STAI Trait (mean ± SD)	42.57 ± 6.47	37.80 ± 8.75	
PANAS-P State (mean ± SD)	31.50 ± 3.44	31.60 ± 6.14	
PANAS-P Trait (mean ± SD)	32.64 ± 5.11	35.40 ± 5.88	
PANAS-N State (mean ± SD)	14.79 ± 3.02	13.15 ± 2.51	
PANAS-N Trait (mean ± SD)	18.07 ± 3.83	16.67 ± 5.73	

STAI, State-Trait Anxiety Inventory; PANAS, Positive Affect and Negative Affect Scale.

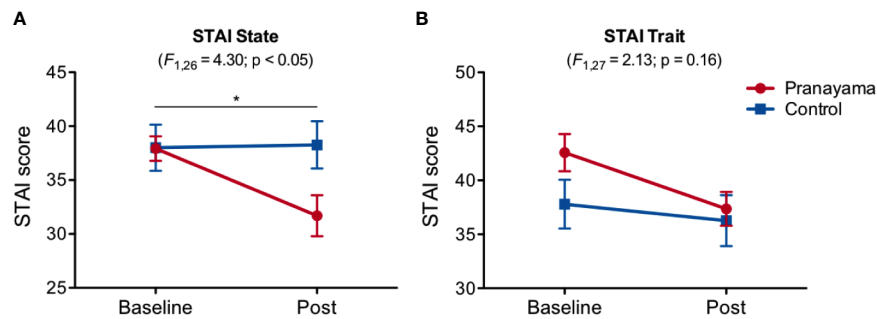


FIGURE 2 | Effects of *Bhastrika pranayama* on anxiety. STAI (state and trait) scores in both groups (*pranayama* and control) at baseline and after the intervention. **(A)** A significant interaction (intervention \times time) was observed in state anxiety ($F_{1,26} = 4.30$; $p = 0.048$) with significantly decreased scores within the *pranayama* group ($t_{12} = 3.01$; $p = 0.01$). **(B)** No significant interaction was observed in trait anxiety. Graphs depict mean values and standard error of the mean. * $p < 0.05$.

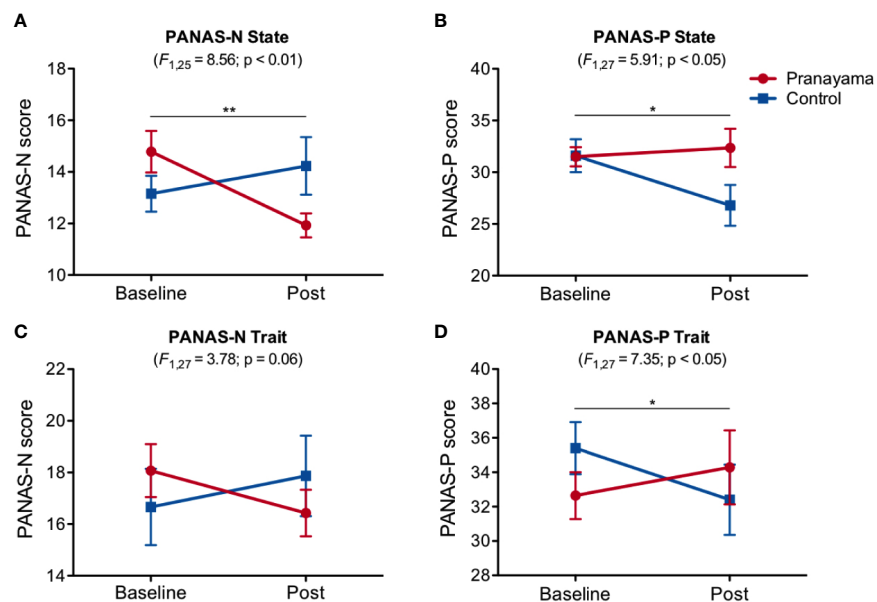


FIGURE 3 | Effects of *Bhastrika pranayama* on affect. PANAS (state and trait), positive (PANAS-P), and negative (PANAS-N) scores for both groups (*pranayama* and control) at baseline and after the intervention. Significant interactions (intervention \times time) were observed in state affect, both negative **(A)** $F_{1,25} = 8.56$; $p = 0.007$, Cohen's $d = 1.17$ and positive **(B)** $F_{1,27} = 5.91$; $p = 0.02$, Cohen's $d = 0.93$, with a significant decrease in negative affect within the *pranayama* group ($t_{13} = 3.43$; $p = 0.004$). For trait PANAS, a trend for PANAS-N **(C)** $F_{1,27} = 3.78$; $p = 0.06$; Cohen's $d = 0.78$; was found. A significant interaction effect in PANAS-P **(D)** $F_{1,27} = 7.35$; $p = 0.012$, Cohen's $d = 1.04$; Graphs depict mean values and standard error of the mean. ** $p < 0.01$, * $p < 0.05$.

$F_{1,27} = 5.91$; $p = 0.02$, Cohen's $d = 0.93$; **Figure 3B**). For trait PANAS, we found a significant interaction (intervention \times time) effect in PANAS-P ($F_{1,27} = 7.35$; $p = 0.012$, Cohen's $d = 1.04$; **Figure 3D**), and a trend for PANAS-N ($F_{1,27} = 3.78$; $p = 0.06$; Cohen's $d = 0.78$; **Figure 3C**).

Effects of *B. pranayama* on fMRI

fMRI analysis was conducted in 13 subjects from each group. One subject from the *pranayama* group did not attend the second fMRI session due to health issues and three subjects were excluded due

to excessive head motion artifact, two from the control group (C8 and C12) and one from *pranayama* group (P8).

Emotion Processing Task—Behavioral Results

Scores attributed to the emotional impact of each image were analyzed using an ANOVA with two within-subjects factors: condition (NEU, NEG, REAP) and time (baseline and post-intervention), and one-factor between-subjects: intervention (*pranayama* and control). We observed a main effect for condition ($F_{2,24} = 96.72$; $p < 0.0001$) and *post hoc* comparisons,

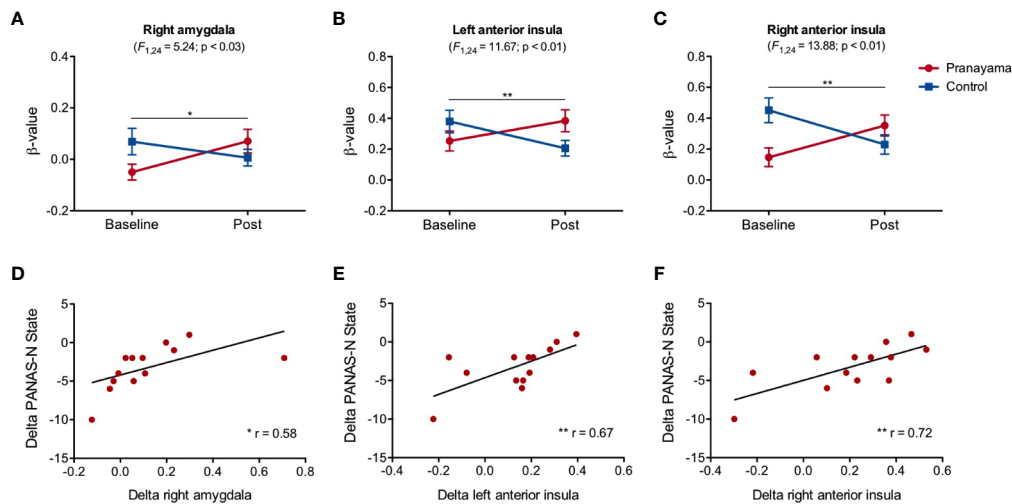


FIGURE 4 | Effects of the intervention in the NEG condition. **(A)** Significant interaction effect(intervention \times time) in the right amygdala ($F_{1,24} = 5.24$; $p = 0.03$; Cohen's $d = 0.93$); **(B)** left anterior insula ($F_{1,24} = 11.67$, $p = 0.002$; Cohen's $d = 1.39$); **(C)** right anterior insula ($F_{1,24} = 13.88$; $p = 0.001$; Cohen's $d = 1.52$). Beta values and standard error of the mean for each group (*pranayama* and control) before and after intervention. Correlation between changes in β -values and PANAS scores. Significant Pearson's correlation analysis between change in state negative affect (PANAS-N) and changes in the activity of **(D)** the right amygdala ($r = 0.59$, $p = 0.034$); **(E)** left anterior insula ($r = 0.67$, $p = 0.012$); **(F)** right anterior insula ($r = 0.72$, $p = 0.005$), in the *pranayama* group. Correlation values are represented as changes in individual β -values (after-before) and changes in individual scale scores (after-before). * $p < 0.05$, ** $p < 0.01$.

corrected by the Sidak test, showed significant differences between conditions NEG \times NEU ($p < 0.0001$) and NEG \times REAP ($p < 0.0001$). There were no significant differences in REAP \times NEU condition ($p = 0.73$). No effects of time, intervention or interactions between them were found.

Emotion Processing Task: fMRI Results

Effects of the *B. pranayama* were analyzed with an RM-ANOVA with a time factor (baseline and post-intervention) and an intervention factor (control and *pranayama*) in each condition (NEG, REAP, and NEG $>$ REAP).

Figure 4 shows the results in the NEG condition (**Figure S5** shows the main effect for this condition). We observed a significant interaction in the right amygdala ($F_{1,24} = 5.24$; $p = 0.03$, Cohen's $d =$

0.93; **Figure 4A**), the left anterior insula ($F_{1,24} = 11.67$, $p = 0.002$, Cohen's $d = 1.39$; **Figure 4B**), and in the right anterior insula ($F_{1,24} = 13.88$; $p = 0.001$, Cohen's $d = 1.52$; **Figure 4C**). Within-group analysis in the *pranayama* group showed significant increased activity after intervention in bilateral anterior insula (right: $t_{12} = 3.01$; $p = 0.011$; left: $t_{12} = 2.62$; $p = 0.023$).

Correlation analysis revealed a significant association between state of negative affect and changes in the activity of the right amygdala ($r = 0.59$, $p = 0.034$; **Figure 4D**), left anterior insula ($r = 0.67$; $p = 0.012$; **Figure 4E**), and right anterior insula ($r = 0.72$; $p = 0.005$; **Figure 4F**). These associations revealed that subjects in the *pranayama* group with increased activity in these areas had the least decreased state of negative affect. We found no significant correlation between BOLD signal changes and behavior on the emotional regulation task.

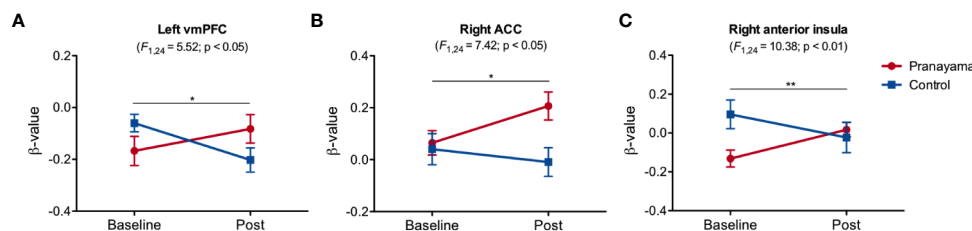


FIGURE 5 | Effects of the intervention in the reappraisal condition. Significant interaction was found in **(A)** the left vmPFC ($F_{1,24} = 5.52$, $p = 0.027$, Cohen's $d = 0.95$); **(B)** right ACC ($F_{1,24} = 7.42$, $p = 0.012$, Cohen's $d = 1.11$), with significant increased activity in the *pranayama* group ($t_{12} = 2.37$; $p = 0.035$); **(C)** right anterior insula ($F_{1,24} = 10.38$; $p = 0.003$, Cohen's $d = 1.31$). Figures show mean beta values and standard error of the mean for each group (*pranayama* and control) before and after the intervention. Effects of the intervention in the NEG-REAP condition. * $p < 0.05$, ** $p < 0.01$.

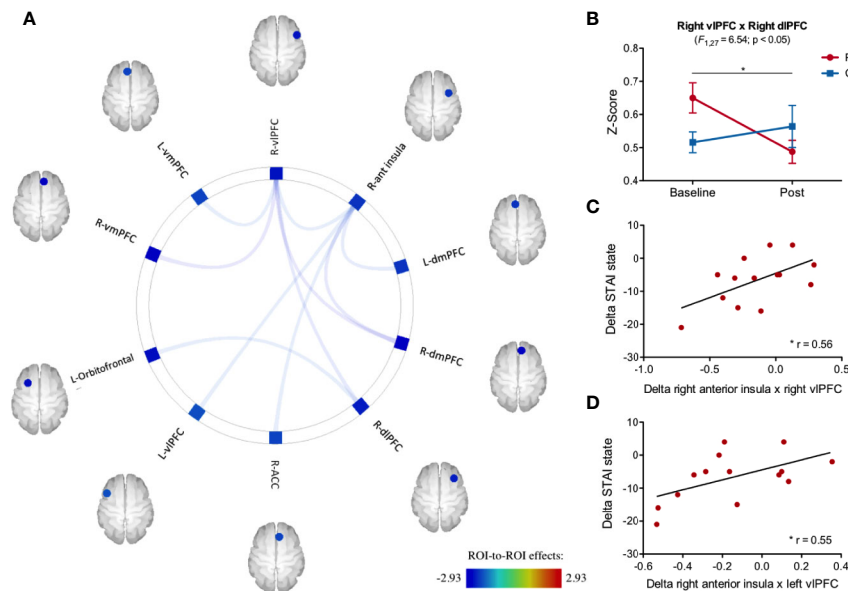


FIGURE 6 | Impact of intervention on functional connectivity and correlation with STAI-s scores. **(A)** Significant interaction effect in the 16 ROI analyzed that are related to emotional processing. **(B)** Significant connectivity interaction effect (intervention \times time) between the right vIPFC and the right dIPFC ($F_{1,27} = 6.54$; $p = 0.01$) with a significant decrease within the *pranayama* group ($t_{13} = 3.97$; $p = 0.001$). **(C)** Pearson's correlation between changes in STAI-s and fc changes between the right anterior insula and right vIPFC ($r = 0.56$, $p = 0.03$); and **(D)** Pearson's correlation of changes between the right anterior insula and left vIPFC ($r = 0.55$, $p = 0.03$). * $p < 0.05$.

Figure 5 presents the results for the REAP condition (**Figure S6** shows the main effect for this condition). We observed significant interaction in the left vmPFC ($F_{1,24} = 5.52$; $p = 0.027$; Cohen's $d = 0.95$; **Figure 5A**) and right ACC ($F_{1,24} = 7.42$, $p = 0.012$; Cohen's $d = 1.11$; **Figure 5B**), with significant increase within the *pranayama* group ($t_{12} = 2.37$; $p = 0.035$). **Figure 5C** shows significant interaction in the right anterior insula ($F_{1,24} = 10.38$; $p = 0.004$, Cohen's $d = 1.31$) with respect to the NEG-REAP condition.

Resting-State fMRI

Figure 6A shows the effects of the intervention on fc. The right anterior insula and the right vIPFC were the two regions with the most consistent fc changes both with other ROIs and also with each other. The anterior insula showed significant fc changes with the following areas: right vIPFC ($F_{1,27} = 4.72$; $p = 0.03$; Cohen's $d = 0.83$), left vIPFC ($F_{1,27} = 4.73$; $p = 0.03$; Cohen's $d = 0.83$), right dmPFC ($F_{1,27} = 7.07$; $p = 0.01$; Cohen's $d = 1.02$), left dmPFC ($F_{1,27} = 5.17$; $p = 0.03$, Cohen's $d = 0.87$), and right ACC ($F_{1,27} = 4.47$; $p = 0.04$, Cohen's $d = 0.86$). We observed significant interaction (intervention \times time) fc between the vIPFC and the following areas: right vmPFC ($F_{1,27} = 8.00$; $p = 0.008$; Cohen's $d = 1.08$), left vmPFC ($F_{1,27} = 4.82$; $p = 0.003$; Cohen's $d = 0.84$), right dIPFC ($F_{1,27} = 6.54$; $p = 0.01$; Cohen's $d = 0.98$), and right dmPFC ($F_{1,27} = 8.57$; $p = 0.006$; Cohen's $d = 1.12$).

RM-ANOVA analysis showed a significant interaction effect (intervention \times time) between the right vIPFC and the right dIPFC ($F_{1,27} = 6.54$; $p = 0.01$; Cohen's $d = 1.04$; **Figure 6B**). *Post hoc* analysis within the *pranayama* group showed significant

decreased connectivity between right vIPFC and right dIPFC ($t_{13} = 3.97$; $p = 0.001$; **Figure 6B**).

Correlation analysis suggests an association within the *pranayama* group between changes in the state anxiety and changes in connectivity between the right anterior insula and bilateral vIPFC (right: $r = 0.56$; $p = 0.03$; left: $r = 0.55$; $p = 0.03$), where volunteers with the greater reduction in connectivity had the best outcomes with respect to reduced state of anxiety (STAI-state) (**Figures 6C, D**).

DISCUSSION

One month of *B. pranayama* training led to significant changes in affect and anxiety, which were associated with changes in activity and connectivity of a few brain areas involved in emotion processing. This exploratory study yielded the following main results: changes in PANAS and STAI scores suggest significantly decreased levels of state of negative affect and anxiety, increased positive affect and fMRI changes suggesting the involvement of the amygdala, anterior insula, ACC, vmPFC, vIPFC, and dIPFC. Although not pathological, our subjects presented measurable levels of anxiety, corresponding to a representative sample of our society, particularly of university students (52). Our results suggest that anxiety levels were significantly reduced, which might encourage the future exploration of the anxiolytic effects of pranayama in a clinical population (21).

Reduced anxiety and changes in affect as an effect of *pranayama* have been observed previously (4, 5, 17, 53), even after a single

session of alternate yoga breathing (7). Previous studies report that 3 months of the practice of the *Anuloma-Viloma* (alternating nostril breathing) *pranayama* reduced levels of anxiety (5), as well as after 6 weeks of *Sudarshan Kriya* (4) or 6 months of slow breathing training (17). It has been hypothesized that reduced levels of anxiety are related to change in sympathovagal balance. In fact, stress reduction observed after a yoga breathing training (22, 23) was associated with the predominance of parasympathetic activity found after the practice (13, 54).

In our study, fMRI changes while passive looking at negative images suggest a significant interaction effect in the right amygdala and bilateral insula. Furthermore, individuals with greater increased activity in the amygdala and insula presented less prominent reduced negative affect. Our results are supported by previous evidence suggesting that anxiety-prone individuals have significantly increased activity in the bilateral amygdala and insula when compared to a control population (55).

The amygdala has been the most cited brain region in studies related to emotion processing (56). This structure is part of the limbic system and has been particularly associated with negative emotions (56). fMRI studies in humans have linked increased amygdala responses to emotion-laden stimuli, particularly of fear (57), and bilateral lesions to the amygdala lead to the deterioration of fear recognition and expression (58). There is evidence suggesting functional differences between the right and left amygdala. For instance, electrical stimulation to the right amygdala was related to arousal of negative emotions, while positive and negative emotions were induced when stimulation was applied to the left amygdala (59). We observed changes in the right amygdala, and damage to this area has also been linked to impaired overall autonomic response, such as skin conductance during highly arousal emotional stimulation (60). We found that changes in the amygdala activity were correlated with changes in negative affect. Likewise, it has been observed that positive affect influences amygdala activity (61), and that amygdala activity correlates positively with increased negative affect (62).

The awareness and the emotional impact of a stimulus may be modulated by top-down control mechanisms, such as by reappraisal. In such, cognitive strategies are deliberately used to lessen the impact and emotional response to a given stimulus (63). Evidence suggests that these processes are associated with changes in the activity in prefrontal regions, as well as in the insula and ACC (61, 64, 65). In fact, our results are supportive of the involvement of the ACC during the reappraisal task.

Different models of emotion reappraisal stand to the idea that the attenuation of the impact from negative stimuli would be in part due to a down-regulation of amygdala activity by regions in the prefrontal cortex (66, 67). Emotion reappraisal tasks appear to recruit a network of brain areas involving the prefrontal cortex, particularly of its medial portion but also including vLPFC and dLPFC (46, 68). During reappraisal, we found significant interaction in the prefrontal cortex (vmPFC), which has been implicated in fear processing and a critical brain structure involved in the regulation of amygdala activity (69).

Studies suggest that emotion regulation is also influenced by attention and awareness (70, 71), and the emotional impact of a given stimulus is driven by changes in the activity of the insula, ACC and amygdala (61, 65). In line with this hypothesis, it has been suggested that the practice of meditation is associated with decreased activity in the amygdala in response to emotional stimuli (26, 72–74), besides suggesting the influence of meditation particularly in the insula, ACC, and thalamus (75). Therefore, bottom-up models of emotion regulation seem to better fit the observed brain changes related to contemplative practices, such as meditation and pranayama (76–79).

Functional neuroimaging studies give support to the notion that the insula is an important connection between emotional experiences and the autonomic nervous system (80–82) as anterior insula activity has been predictive of levels of anxiety and trait of interoception (80), besides response to noxious stimuli (83). Together, the insula and ACC form the salience network, with extensive connections to various parts of the brain including the limbic system (84, 85). The salience network has been associated with the awareness of stimuli, and in fact, the anterior insula has been implicated in emotion recognition (86). Therefore, changes observed in the ACC and anterior insula may not necessarily reflect the regulatory process *per se*, but signal differences in the perceived stimuli salience, or awareness (85). Furthermore, there is recent evidence that interoceptive ability can be enhanced by different meditation practices (87, 88) and that such effect is accompanied by structural and functional brain changes. For example, experienced meditators have increased the cortical thickness of the right anterior insula when compared to non-meditators (89), and 8 weeks of mindfulness meditation practice has been related to increased recruitment of areas related to visceral representation, including the right insula, right ACC, vmPFC, and vLPFC (90).

Adding to this hypothesis are the significant changes we observed in the ACC during the emotion regulation portion of the fMRI task. Besides being part of the salience network, the ACC has been implicated in a number of processes of emotion and reasoning, including the reassessment of emotional stimuli (66, 91). The dorsal portion connects primarily to the prefrontal cortex and has been related to executive functions, such as conflict resolution and decision making (84), while subgenual ACC is strongly connected to the limbic system, and its relation to emotion processing goes back to the first models of emotion (92).

During the resting-state condition, we observed significantly reduced functional connectivity between the vLPFC and dLPFC after training, and between bilateral vLPFC and the right anterior insula which was correlated with the observed reduced anxiety. Lateral portions of the PFC have been involved with the regulation of affect and emotion, and cognitive reappraisal tasks consistently recruit PFC regions including the dLPFC and vLPFC, which was found to be inversely correlated with the arousal of the negative emotion (62, 93). While lesions to the vLPFC have been related to heightened negative emotion in monkeys (94), recent human studies suggest the role of the amygdala and vLPFC activity as a predictor of anxiety in young adults (95), and that greater functional coupling between

vIPFC and the amygdala is associated with emotion regulation success (96).

Previous studies suggest that the vIPFC is also involved in a number of different tasks that demand cognitive control. Neuroimaging studies support that the vIPFC is particularly important for selective attention either toward goal-relevant information or inhibiting irrelevant information (97). As such, increased activity in the vIPFC is found in response inhibition task (98), semantic processing (99), and during classification tasks (100), just to name a few. It is therefore not clear whether the functional role of the vIPFC is specific to emotion processing, or if it plays a more general role of executive control (99). It should be noted that the changes observed in lateral PFC were observed during the rest condition and not during the performance of a task. It is curious therefore to observe changes in coupling between areas in the brain associated with emotion processing in particular, and selective attention in general, even in the absence of an actual emotion regulation task.

It is also important to point out the major limitations and caveats of the study. First, the lack of adequate assessment of the autonomic nervous system hampers the direct association between changes in anxiety and affect with potential autonomic markers, such as heart rate or interoceptive attention assessment. Individuals were instructed to practice at home, however, we did not control these practices. Therefore, particular variations are expected due to differences related to home practices. The study was designed to assess changes after a single short 30 days intervention against an active control condition. It does not allow the conclusion of how specific the intervention with pranayama really is with respect to other contemplative practices. Therefore, we cannot be absolutely sure that the observed effects were due to pranayama alone, since asanas and savasana also were performed during the sessions, although briefly. The study was conducted in a small number of volunteers, composed mostly of young healthy well-educated individuals, and therefore does not allow the extension of the results to individuals with anxiety disorders or other groups of individuals. It should be noted that these analyses were preliminary and exploratory. Due to sample size limitations and the exploratory nature of this study, for these analyses, we chose not to correct for multiple comparisons, thus the results should be taken with caution and further investigation is recommended.

This study provides the first preliminary evidence that 4 weeks of *B. pranayama* reduced anxiety and increase positive affect, and that these changes are associated with the activity and connectivity of a brain network involved in emotion processing, particularly the amygdala, anterior cingulate, anterior insula, and the prefrontal cortex. Resting-state fMRI revealed significantly reduced functional connectivity particularly involving the

anterior insula and lateral portions of the prefrontal cortex which participate in awareness and attention.

DATA AVAILABILITY STATEMENT

The datasets generated for this study are available on request to the corresponding author.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by Ethics and Research Committee of the Federal University of Rio Grande do Norte (#579.226). The patients/participants provided their written informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

MN, BL-S, FP-F, HO, KA, DS, and DA designed the experiments. MN, FP-F, HO, KA, and DA implemented the protocol. MN and FP-F collected experimental data. MN, BL-S, FP-F, HO, and KA carried out statistical analysis. MN, FP-F, HO, and DA prepared the figures. MN, FP-F, DA, TA-S, EK, BL-S, and DS interpreted and discussed the results. MN, FP-F, and DA prepared the manuscript. MN, FP-F, DA, HO, TA-S, EK, BL-S, and DS revised the manuscript.

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SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: <https://www.frontiersin.org/articles/10.3389/fpsy.2020.00467/full#supplementary-material>

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Effects of the “Inspirational Lecture” in Combination With “Ordinary Antenatal Parental Classes” as Professional Support for Expectant Parents: A Pilot Study as a Randomized Controlled Trial

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Background: Both expectant mothers and their partners describe weaknesses in ordinary parental preparatory professional support provided internationally and nationally within Sweden. Therefore, it is necessary to develop the parental preparatory professional support provided by midwives for expectant parents within Sweden. This study will evaluate the effects on expectant parents of receiving a combination of an “inspirational lecture” and “ordinary antenatal parental classes” compared with only “ordinary antenatal parental classes.”

Methods/Design: This block randomized controlled trial included an intervention as a pilot study, in which expectant parents were randomized for (1) the inspirational lecture and ordinary antenatal parental classes (intervention group [IG]) ($n = 66$) or (2) ordinary antenatal parental classes (control group [CG]) ($n = 60$). Data collection with repeated questionnaires was conducted in the first week and 6 months after birth. Statistical analyses were conducted for participant characteristics, differences between parents within IG and CG, effects of the intervention, intention to treat, and internal consistency of the included measurements.

Results: The intervention showed a tendency to be gainful for one out of four outcomes related to birth experience, and parents’ perceived quality of parental couple relationship consensus and sexuality and manageability. These results were more prominent for the partners. Parents within both the intervention and control groups reported decreased social support in the first 6 months after birth.

Conclusion and Clinical Implications: Overall, the concept of the inspirational lecture in combination with ordinary antenatal parental classes as parental preparatory professional support seems to be a valuable care intervention. However, this study was a pilot study and the results should therefore be interpreted with caution. More research is needed since childbirth and transition to parenthood are complex processes in need of comprehension.

Keywords: transition, pregnancy, childbirth experience, parenthood, sense of coherence, couple relationship, QDR36

INTRODUCTION

Becoming parents for the first time is a major change of life event (1), a transition that involves the physical endeavors of pregnancy, birth, and breastfeeding (2) but also changes in social roles and roles for the parental couple (1, 3, 4). Parents-to-be can be unaware of the challenges posed by pregnancy, childbirth, and parenthood (5). Negative experiences from childbirth are, for example, associated with deterioration of maternal health (6), development of postpartum depression (7), and problematic bonding between mother and infant (8). The challenges of transitioning to parenthood may result in decreased quality within the parental couple's relationship (3, 9–12), with increased risk of separation (13). Positive experiences from birth are, on the other hand, associated with women feeling empowered and encouraged in their motherhood (14). Such positive experiences have previously been described as related to the mothers' personal strength and sense of control and coherence (15). Individuals' ability to manage their own health and to cope with everyday problems plays a key role in sense of coherence (SOC) (16), which also seems to be affected by parents' transition to parenthood (9, 17, 18).

To handle the challenge of transition to parenthood, both first-time mothers and partners need parental preparatory support, particularly socially and professionally (19–21). However, partners to first-time mothers describe that professional support in counseling during pregnancy mainly focuses on the woman and the physiological changes, and partners felt left out and ignored (22). Also, professional support in antenatal parental classes is mainly focused on physiological changes, while parents want more focus on parenthood and partner relationships (23). Internationally, antenatal parental classes are given various names, such as expectant parent classes, antenatal parenthood education, antenatal education, childbirth classes, and antenatal classes. For this study, the term “ordinary antenatal parental classes” is used.

To prepare for parenthood, first-time mothers describe the importance of different kinds of professional support (19). Professionals should support parents' couple relationship during the transition to parenthood (24), and such support could have a positive effect on communication between the couple (19, 20). Professionals, such as midwives, who provide professional support for parents need to have knowledge about parents' supportive needs. They also need competence to be attentive to parents' individual needs (25, 26), since the parents may not be able to express their needs themselves. Both professional and social support has been described as interactive processes that affect well-being and health (27, 28). However, social support is offered within the individual's social network and needs to be based on working relationships and trust. Professional support, on the other hand, is directly available but limited

by professional domain and knowledge. Professional support could be considered as a care intervention and should focus on strengthening the individual's access to social support (27).

Internationally, professional support offered during pregnancy varies, depending on the country. For example, some countries offer antenatal parental classes, while others do not. International studies have also found that professional support during pregnancy leads to increased knowledge and better preparation for labor and birth (29) and improved infant care (30). In Sweden, first-time mothers and partners are offered professional support together during antenatal care and in-group sessions (ordinary antenatal parental classes), mostly provided by midwives (31). Research shows weaknesses in the professional preparatory support offered to parents; therefore, it is important to increase knowledge about such support. Since autumn 2012, midwives who work in a hospital labor ward in central Sweden have provided an inspirational lecture as a large-group parental class for expectant parents. The purpose of the lecture is to give the parents a more satisfactory preparation for birth and safer experience during birth as well. Previous research on parents' perceptions of the lecture is that their ability to absorb adequate information is increased by the pedagogically mediated information provided through role-play by the midwives (19, 20). Also, the humor used by the midwives who provide the lecture makes the parents laugh at something they, in fact, are nervous about (giving birth to a child). The laughter helps the parents to relax and understand the information provided. Besides this, parents perceive that the lecture facilitates their understanding of how to prepare for birth and parenthood together with their partner. This understanding facilitates the parental couple's ability to communicate with each other, which contribute to their feelings of togetherness (19, 20). However, there is no previous research on the effect of the inspirational lecture on parents. Further research is therefore needed to gain deeper knowledge about the effects of professional support for expectant parents.

The present study tested the inspirational lecture as an intervention to be provided in combination with ordinary antenatal parental classes as parental preparatory support. The aim of the present study was to evaluate the effects of expectant parents receiving a combination of the inspirational lecture and ordinary antenatal parental classes compared with expectant parents receiving only ordinary antenatal parental classes. The study was guided by hypotheses that the inspirational lecture in combination with ordinary antenatal parental classes would have an effect on first-time mothers' and partners' (1) birth experience (primary outcome), (2) breastfeeding and skin-to-skin contact, (3) perceived professional support, (4) perceived quality of the parental couple's relationship, (5) perceived social support, (6) sense of coherence, and (7) parent-to-infant relations and feelings (secondary outcomes).

METHODS

Trial Design and Participants

This is a randomized control trial that was performed as a pilot study with a follow-up design (32). Participants were

Abbreviations: MoPPS scale, Mother Perceived Professionals Support Scale; QDR36, Perceived Quality of Parental Couple Relationship Scale; MSPSS scale, The Multidimensional Scale of Perceived Social Support; SOC-13, Sense of Coherence, 13-Item Scale; MIRF scale, Mother to Infant Relations and Feelings scale.

randomly assigned in blocks (i.e., through block randomization) to one of two groups and received professional support through (1) the inspirational lecture provided by midwives as a large-group parental class in combination with ordinary antenatal parental classes provided by midwives (intervention group) or (2) ordinary antenatal parental classes provided by midwives (control group).

Participants gave their consent before randomization. To select trial participants, the following inclusion criteria were used: (1) first-time mother with her partner, (2) singleton pregnancy between gestational weeks 24 and 35, (3) intention to give birth at the county hospital, and (4) ability to understand and speak the Swedish language. The sampling plan was predisposed by a time aspect, which was to recruit participants between May 1 and June 1, 2015. Therefore, a consecutive sampling was performed to recruit all of the parents who met the inclusion criteria over the specific time interval (32). Based on calculations, we intended to include 200 expectant parents (expectant first-time mothers $n = 100$; partners $n = 100$) within this study. In total, we targeted 100 parents for the intervention group and another 100 parents for the control group, which corresponds to an allocation ratio of 1:1. Furthermore, we targeted an equal randomization regarding gender since the two parents within the same parental couple were randomized to the same group (intervention or control group).

Settings

This study was conducted in a county in southwestern Sweden, consisting of urban, suburban, and rural districts. The county hospital labor-ward sees an average of around 3,500 births per year. Within this county, as well as nationally in Sweden, pregnant women are offered professional support free of charge through the Swedish public primary healthcare system (31). Within the setting for the present study, professional support is offered within midwifery care in terms of prenatal assessments at antenatal units and ordinary antenatal parental classes.

Stratification, Randomization, and Participant Recruitment

Eligible parents who met the inclusion criteria were provided information about the study from midwives who worked at the three antenatal units. The information was provided both orally and in writing to the parents during a routine control (prenatal assessment) with the midwife. Among those parents who agreed to participate in the study, block randomization was performed to allocate the participants into groups that resulted in equal sample sizes. We used an intention-to-treat approach since we aimed to keep participants who were randomized in the groups to which they were assigned. To achieve this, a box was presented that included sequentially numbered sealed envelopes with either (1) a ticket for both the inspirational lecture and a ticket for ordinary antenatal parental classes (IG) or (2) a ticket to ordinary antenatal parental classes (CG). The midwives who handled the sealed envelopes did not know which envelopes contained a ticket to the inspirational lecture and which envelopes did not. To participate in the inspirational lecture, a ticket was needed, which made it possible to control that only those parents included in the IG

received the intervention. The randomization was carried out directly after the parents had agreed to participate. The midwives were instructed beforehand to provide the parents with envelopes in numbered order, starting with the lowest number. This was to ensure that the randomization was correctly performed without impact by the midwives. The midwives noted the number of the specific envelope on the specific parent's completed consent form. This was to control for whether the parent was randomized to an IG or CG. A flow diagram of how parents were allocated to the IG and CG is shown in **Figure 1**.

Intervention

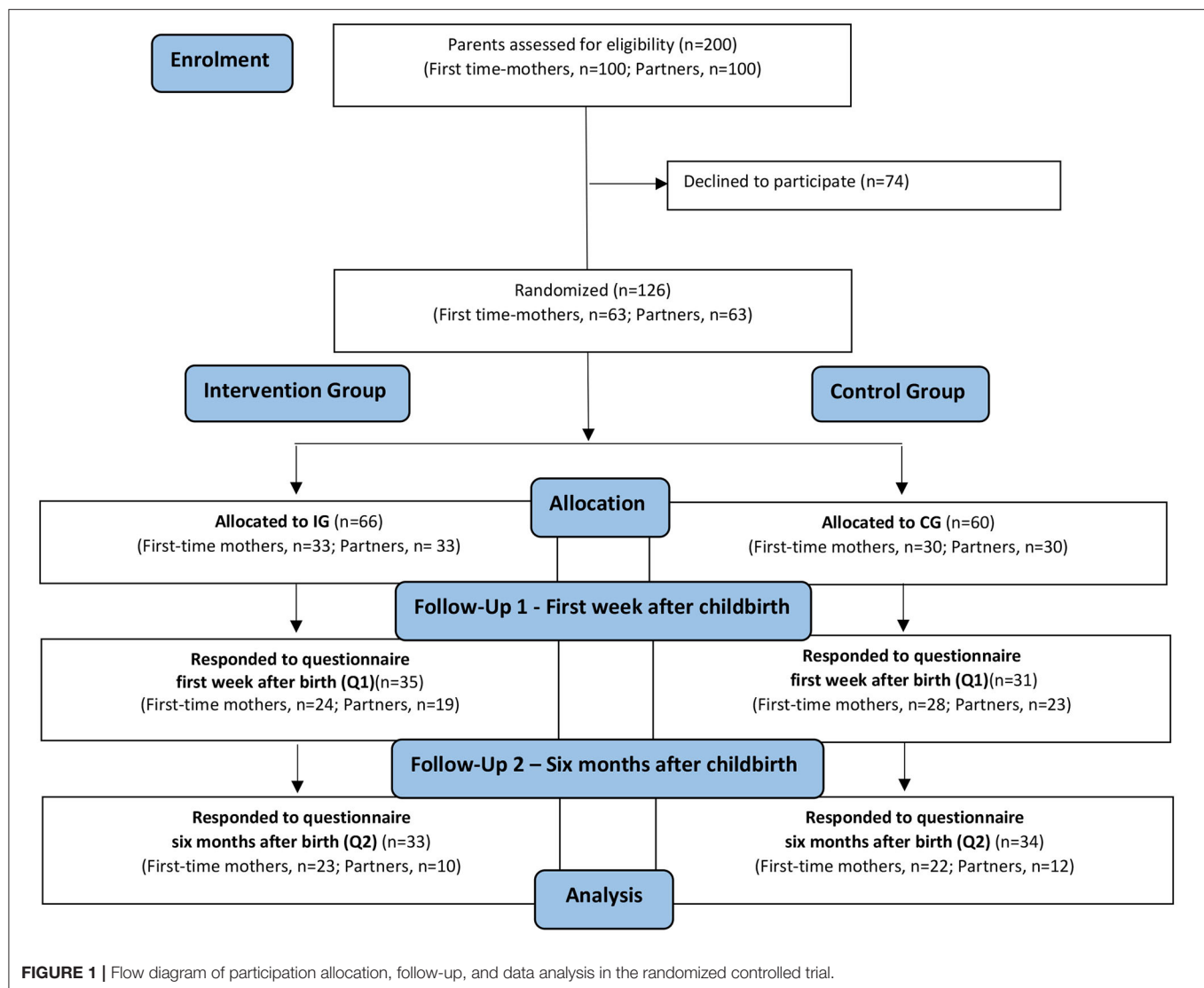
The intervention consisted of the inspirational lecture as a parental class for expectant parents provided as a complement to the ordinary antenatal parental classes. The **intervention group (IG)** consisted of parents who received a combination of the following: (1) the inspirational lecture as a large-group parental class provided by midwives and (2) ordinary antenatal parental classes provided by midwives at antenatal units. The CG consisted of parents who received only ordinary antenatal parental classes provided by midwives at antenatal units. The intervention will be explained in detail below.

The Inspirational Lecture

For the intervention, the hospital introduced the inspirational lecture as a large-group parental class for expectant parents. The lecture was originally developed and provided at another hospital that was not included in this study. At the time of this study, the inspirational lecture was not provided elsewhere within Sweden (except at the hospital that developed the lecture). In total, four midwives were trained as providers of the inspirational lecture at the hospital. Those four midwives were taught to provide the lecture in pairs, which gave two pairs in total. The inspirational lecture is a professional support provided by midwives for expectant parents as a large-group lecture. During the inspirational lecture, midwives who work within antenatal and/or labor care explain how parents can prepare for birth. The information is focused on normal birth and how parents can strengthen their individual as well as mutual skills as a parental couple to be able to handle the challenges that come with childbirth (labor). For example, midwives strive to present childbirth (labor) as a normal life event that the parents themselves can prepare to cope with. The midwives use a pedagogical approach that includes role-playing to increase the parents' understanding. By role-playing, the midwives who provide the inspirational lecture illustrate the pregnant woman's and the partner's perspective. This is to make both perspectives visible and to emphasize the value of each as well. The inspirational lecture lasts for 2 h. Within the present study, the inspirational lecture was provided on two specific dates for the parents who were randomized for the IG. Only expectant parents who were in the IG received the inspirational lecture.

Ordinary Antenatal Parental Classes

According to routines already established within the setting, ordinary antenatal parental classes were offered to expectant parents. These classes were given in accordance with the national



Swedish guidelines (31). For the intervention within the present study, these classes were included, without any changes from how they already were provided for expectant parents. Midwives at antenatal units provided these parental classes four to five times during pregnancy, in groups of six to eight parental couples and one midwife. During these classes, parents were provided with information about pregnancy, labor, breastfeeding, parenthood, and relationships between parents.

Measurements and Data Collection

The primary and secondary outcomes were measured at (1) first week (Q1) and (2) 6 months after birth (Q2). Q1 was provided to the parents by the midwives at the postnatal ward of the hospital. The parents answered Q1 in paper format. The parents filled out Q2 using the web-based computer system titled Education Survey Automation Suite (EvaSys). Q2 was sent to the parents via email 6 months after the birth. For those participants who did not answer Q1 or Q2, one reminder was sent at each of the time points. The primary outcomes were the

parents' birth experience measured by questions selected from the short version of the intrapartal-specific QPP questionnaire (QPP-I) (33) at Q1 and Q2. To assess parents' perceived birth experience, four questions (items) were included: "I had a positive birth experience"; "I had a normal birth"; "I perceived that I had control during birth"; and "I perceived myself being safe during birth." Each item was a four-point response scale ranging from 1 ("I do not agree at all") to 4 ("I completely agree"). Two questions that concerned the subjective importance of the parents' birth experience were also included from the QPP questionnaire: "This is how important it was to me to have a positive birth experience" and "This is how important it was to me to have a normal birth." Each item was a four-point response scale ranging from 1 ("of little or no importance") to 4 ("of the very highest importance"). In total, six items were included within Q1 and Q2. All the items included also a "not applicable" response alternative. Each item was calculated separately within this study; the higher the score, the more positive the experience (Table 1).

TABLE 1 | Measurements and time of measurements.

Measurements	First week after childbirth (Q1)	Six months after childbirth (Q2)
Socio-demographic characteristics	X	
Birth experience	X	X
Breastfeeding	X	X
Skin-to-skin contact	X	
Mother Perceived Professionals Support scale (MoPPS scale)	X	
Sense of Coherence (SOC-13)	X	X
Quality of Dyadic Relationship (QDR36)	X	X
The Multidimensional Scale of Perceived Social Support (MSPSS)	X	X
Mother to Infant Relations and Feelings scale (MIRF-scale): <i>First section: Parent's perceived relation to the child</i>	X	X
<i>Second section: Parent's perceived feelings for the child</i>		

Socio-demographic characteristics: age; gender; employment; perceived economy.

Birth experience: 6 items calculated separately. Each item score range 1–4, the higher the score, the more positive birth experience.

Breastfeeding: 3 items concerning whether or not the mothers were breastfeeding, as well as exclusive and partly breastfeeding.

Skin-to-skin contact: 1 item concerning the parent's skin-to-skin contact with the child during the child's first period of alertness after birth (first 2 h after birth).

Mother Perceived Professionals Support scale (MoPPS scale): 8 items. Index is the sum of all items. Index score range 8–56, the higher the score, the stronger the perceived professional support.

Sense of Coherence (SOC-13): 13 items, divided into three dimensions: Comprehensibility (5 items); Manageability (4 items); Meaningfulness (4 items). Index is the sum of all items. Index score range 13–91, the higher the score, the higher Sense of Coherence.

Quality of Dyadic Relationship (QDR36): 36 items, divided into five dimensions (score range 1–6): Dyadic Consensus (11 items); Dyadic Cohesion (4 items); Dyadic Satisfaction (11 items); Dyadic Sensuality (5 items); Dyadic Sexuality (5 items). Index is the sum of mean values from all dimensions. Index score range 5–30, the higher the score, the higher perceived quality of dyadic relationship.

The Multidimensional Scale of Perceived Social Support (MSPSS): 12 items, divided into three dimensions (score range 1–7): Family (4 items); Friends (4 items); Significant others (4 items). Index is the sum of all items. Index score range 12–84, the higher the score, the higher perceived social support.

Mother to Infant Relations and Feelings scale (MIRF-scale): *First section (Parent's perceived relation to the child): 7 items. For first-time mothers index is the sum of all items, index score range 7–49. For partners index is the sum of 6 items (question about breastfeeding excluded from index), index score range 6–42. The higher the score, the stronger perceived relation to the child. Second section (Parent's perceived feelings for the child): 7 items. Index is the sum of all items. Index score range 7–49, the higher the score, the stronger perceived parent's feelings for the child.*

The secondary outcomes were data of obstetric and neonatal outcomes collected from electronic medical records and psychometric scales measuring psychosocial variables. Data for birth (obstetric and neonatal) outcomes were collected through the first-time mothers' hospital medical records. Data of obstetric outcome included duration of labor (hours between onset of contractions/labor start and birth); dilation of the cervix (centimeters) when arriving at labor ward; type of birth (spontaneous vaginal birth, vacuum extraction, forceps, or cesarean section); and gestational week at birth. Data on neonatal outcomes consisted of the Apgar score. Questions concerning

breastfeeding were included within the questionnaires. The first-time mothers responded to questions whether they were breastfeeding (1) *during the child's first period of alertness (first two hours after birth)*; (2) *at one week and six months after birth*; and (3) *exclusively (child was given only breastmilk) or partly (child was given both breastmilk and formula)*. Included within Q1 was also a question about skin-to-skin contact between the parent and child during the child's first period of alertness (first 2 h after birth): *"Did you have skin-to-skin contact with your child during his/hers first period of alertness after birth?"* Response alternatives were "yes," "no," or "I do not remember" (Table 1).

All psychometric instruments included within the questionnaires were available in Swedish, and most of them have been validated previously with good internal consistency. The *MoPPS scale* (Mother Perceived Professionals Support scale) is a seven-graded Likert scale, ranging from 1 to 7, developed to assess mothers' perceived experiences with professional support (34). The scale is validated through interviews with parents (22, 35–38). The scale consists of one question about how professional support from healthcare professionals, such as midwives, is perceived. This question is followed by eight statements, such as *"sensitive/not at all sensitive," "understanding/not at all understanding,"* and *"were calmed/were stressed."* The index was a calculated summary of the total score of the eight items. The higher the score, the more positive the perceived experience with professional support. Within the current study, the MoPPS scale was used to measure parents' perceived experiences with professional support from both (1) healthcare professionals at the labor ward and (2) healthcare professionals at the postnatal ward (Table 1).

To assess the parents' perceived quality of parental couple relationship, the validated Quality of Dyadic Relationship (QDR36) scale was used (3, 39). QDR36 consists of 36 items scored with Likert scales from 1 to 6. The scale covers five dimensions: *Dyadic Consensus, Dyadic Cohesion, Dyadic Satisfaction, Dyadic Sensuality,* and *Dyadic Sexuality*. The index score is the total sum of the mean values from the separate dimensions; the higher the score index, the stronger the person's estimated perceived quality of couple's relationship (Table 1).

To assess parents' perceived social support, the Swedish version (40) of the Multidimensional Scale of Perceived Social Support (MSPSS) (41, 42) was used. The scale used within this study was previously validated among women with hirsutism and nursing students (40). In total, the scale consists of 12 items (seven-point Likert scales ranging from 1 to 7) that cover three dimensions: *family, friends,* and *significant others*. The index is calculated by summarizing the total score for all items; the higher the score, the stronger the perceived social support (Table 1).

To assess the parents' sense of coherence, the validated Swedish version of the SOC-13 was used (43). The SOC-13 consists of 13 items scored with Likert scales ranging from 1 to 7 (16, 44). The scale covers three dimensions: *comprehensibility, manageability,* and *meaningfulness*. The index score is the total sum of all items; the higher the score, the higher the person's estimated sense of coherence (Table 1).

The seven-graded Likert MIRF scale (Mother to Infant Relations and Feelings scale) (ranging from 1 to 7) was used

to assess the parents' relation toward and feelings for their child (34, 45–47). The scale is validated through interviews with parents (34). The MIRF scale consists of two different sections that assess (1) the parent's perceived relation to his/her child and (2) the parent's perceived feelings for his/her child. Within the first section, the parent's perceived relationship to the child is assessed through seven different statements, such as: “*I talk a lot with my baby/I do not talk at all with my baby*” and “*I enjoy resting when my baby is with me/I enjoy resting when my baby is with someone else*” and so on. The index is calculated by summarizing the seven items; the higher the score, the stronger the perceived relation to the child between the parents. The first section of the MIRF scale includes a question about breastfeeding: “*I enjoy breastfeeding/I do not enjoy breastfeeding*.” For the first-time mothers, this question is included within the index score, plus it is calculated and analyzed separately. For the partners, the question regarding breastfeeding was not included in the calculation of the score index for the partner's perceived relation to his/her child. For analysis, the variable that describes the first section of the MIRF scale is named “*Parent's perceived relation to the child*.” Within the second section of the MIRF scale, the parent's feelings for his/her child are assessed with a question concerning the parent's perceived contact with the child. Seven different items (seven-graded response rate, ranging 1 to 7) constructed of opposing word pairs follow the question: “*warm/cold*,” “*secure/insecure*,” “*close/distant*,” “*confident/unconfident*,” “*stable/unstable*,” “*easy/difficult*,” and “*pleasant/unpleasant*.” The index is calculated by summarizing the seven items. The higher the grade, the stronger the parent's perceived feelings for the child. The variable that describes the index score of the second part of the MIRF-scale is named “*Parent's perceived feelings for the child*” within the current study (Table 1).

Socio-demographic characteristics were self-reported within Q1 (Table 1). Before the current study, two pilot studies were conducted to test parents' experiences from responding to questionnaires in paper and web-based form. The results of the pilot studies showed that the information included in the questionnaires and the composition of the same was generally understandable and manageable.

Data Analysis

Statistical analyses were conducted using the Statistical Package for the Social Sciences (SPSS) version 22 (IBM, Corp, Armonk, NY, USA). Descriptive statistics were conducted to describe the socio-demographic characteristics of the participants. The index and dimensions for the measurements were presented as a mean (M) and dispersion by standard deviation (SD) (Table 2). To analyze the questionnaires and the effects of the intervention on first-time mothers and partners, the Mann–Whitney U-test was performed. To analyze differences between parents within IG and CG, the Mann–Whitney test was used for ordinal variables, and the chi-squared test was performed for discrete variables. Cohen's guidelines were used to interpret clinical change when a significant result was achieved from Mann–Whitney; the effect was defined as small ($\eta^2 > 0.01$), medium ($\eta^2 > 0.06$), or large ($\eta^2 > 0.14$) (48). Analyses were carried out for first-time

mothers and partners separately, as well as mutually as a group of parents within the IG or CG. Intention-to-treat analysis was performed for comparison of changes over time within groups using the non-parametric Friedman's test for the continuous variables: birth experience, QDR36, MSPSS, and SOC-13. The Wilcoxon signed-rank test for *post hoc* testing was performed after a statistically significant Friedman's test. To evaluate the internal consistency for the index of the scales, MoPPS, QDR36, MSPSS, SOC-13, *parent's perceived relation to the child*, and *parent's perceived feelings for the child*, Cronbach's alpha was calculated. $P \leq 0.05$ were considered significant, and $p \leq 0.1$ were interpreted as tendencies.

Ethical Considerations

The Regional Ethical Review Board in Gothenburg, Sweden, approved this study (Dnr: 275–15). All participants were provided with information about the study and their right to withdraw their participation at any time. The participants gave written consent. Before data analysis, each questionnaire was stripped of identifiers and coded. Also, the results are reported on a group level, which makes it impossible for the reader of this article to identify the answers of a specific participant.

RESULTS

Eligible for analysis were first-time mothers and partners who responded to questionnaires at Q1 (IG first-time mothers $n = 24$, partners $n = 19$; CG first-time mothers $n = 28$, partners $n = 23$) and Q2 (IG first-time mothers $n = 23$, partners $n = 10$; CG first-time mothers $n = 22$, partners $n = 12$), as presented in Figure 1.

The socio-demographic characteristics of the participants are described in Table 2. A significant difference was observed between first-time mothers' age in IG and CG. No further significant differences were observed between the two study groups (results are not presented in tables). The index and dimensions were calculated for the different measurements included within this study; the results are presented in Table 3.

Effects of the Intervention for First-Time Mothers and Partners

In relation to the primary outcome, the results showed a tendency to a *positive* effect from the intervention on the first-time mothers' feelings of having control during birth at Q1 ($U = 90.0$, $p = 0.096$) with a large clinical effect size (Table 4).

In relation to the secondary outcomes, the results revealed that parents within the CG reported significantly *stronger* perceived support than parents within the IG ($U = 224.5$, $p = 0.011$) with a large effect size. Furthermore, the results revealed that the intervention had a significant *positive* effect on parents' (IG) perceived dyadic sexuality (dimension within QDR36) at Q2 ($U = 366.5$, $p = 0.033$) with a large effect size. Parents within the IG reported a *stronger* manageability (dimension within SOC-13) at Q1 ($U = 389.5$, $p = 0.048$) with a large effect size. Also, there was a tendency for a *positive* effect of the intervention on parents' (IG) SOC-13 index at Q1 ($U = 405.0$, $p = 0.077$), with a large effect size (Table 4).

TABLE 2 | Overview of characteristics for first-time mothers and partners within the intervention (IG) and control group (CG) at different times (Q) throughout the study.

	IG		CG	
	First-time mothers	Partners	First-time mothers	Partners
	(<i>n</i> = 24) <i>n</i> (%)	(<i>n</i> = 19) <i>n</i> (%)	(<i>n</i> = 28) <i>n</i> (%)	(<i>n</i> = 23) <i>n</i> (%)
Age				
≤25 years	9 (37.5)	1 (5.3)	2 (7.1)	1 (4.3)
26–34	12 (50.0)	6 (31.6)	15 (53.6)	4 (17.4)
≥35	2 (8.3)	2 (10.5)	4 (14.3)	7 (30.5)
Missing	1 (4.2)	10 (52.6)	7 (25.0)	11 (47.8)
Marital status				
Cohabiting	16 (66.7)	16 (84.2)	16 (57.1)	15 (65.2)
Not cohabiting	2 (8.3)	1 (5.3)	0 (0)	0 (0)
Missing	6 (25.0)	2 (10.5)	12 (42.9)	8 (34.8)
Perceived economy, at Q1				
Very good	3 (12.5)	4 (21.1)	0 (0)	1 (4.3)
Good	10 (41.7)	9 (47.4)	14 (50.0)	11 (47.8)
Sufficient	5 (20.8)	4 (21.1)	2 (7.1)	3 (13.0)
Strained	0 (0)	0 (0)	0 (0)	0 (0)
Missing	6 (25.0)	2 (10.4)	12 (42.9)	8 (34.9)
Perceived economy, at Q2				
Very good	2 (8.3)	3 (15.8)	1 (3.6)	1 (4.3)
Good	8 (33.3)	3 (15.8)	15 (53.6)	6 (26.2)
Sufficient	11 (45.9)	4 (21.1)	6 (21.4)	4 (17.4)
Strained	2 (8.3)	0 (0)	0 (0)	1 (4.3)
Missing	1 (4.2)	9 (47.3)	6 (21.4)	11 (47.8)
Employment, at Q2				
On parental leave	22 (91.7)	0 (0)	20 (71.4)	2 (8.7)
Other	1 (4.2)	10 (52.6)	2 (7.1)	10 (43.5)
Missing	1 (4.2)	9 (47.4)	6 (21.4)	11 (47.8)

Questionnaires: Q1 First week after birth; Q2 Six months after birth.

Values: *n* = Number of participants; *M*, Mean; *SD*, Standard deviation.

When comparing differences between first-time mothers and partners separately, the results showed a *positive* effect in the IG intervention on partners' manageability (dimension within SOC-13) at Q1 ($U = 71.5$, $p = 0.033$) with a large effect size and consensus (dimension within QDR36) at Q2 ($U = 26.5$, $p = 0.050$) with a medium effect size (Table 4). For the inspiration lecture, no effectiveness was found with regard to obstetric and neonatal outcomes (Table 5), breastfeeding (Table 6), skin-to-skin contact after birth (Table 4), or the parents' perceived relation and feelings for the child (Table 4).

Change Over Time in the Birth Experience, Perceived Quality of Parental Couple Relationship, Social Support, and SOC

The change in scores between the first week (Q1) and 6 months (Q2) after birth was calculated and analyzed. In relation to the primary outcome and the longitudinal effect of the intervention, the following significant results were revealed: (1) both parents within the IG and CG reported *lower* scores related to the meaningfulness of a perceived normal birth at Q2 in comparison

with Q1 and (2) the parents' reported feelings of being safe during birth was *higher* at Q2 in comparison with Q1. In relation to the secondary outcomes, a significant difference was found in that the QDR36 index *decreased* between Q1 and Q2 among all parents within the CG ($p = 0.019$), as well as among partners separately within the CG ($p = 0.028$). The MSPSS index *decreased* between Q1 and Q2 among all parents within the IG ($p = 0.001$) and CG ($p = 0.024$), as well as among first-time mothers separately within the IG ($p = 0.013$). For change in the SOC-13 index between Q1 and Q2, there were no significant results. The results are presented in Table 7.

Internal Consistency of the Measurements

Cronbach's alpha was calculated to evaluate the internal consistency for different measurements included in the study. The results showed high values for several of the included measures (MoPPS index labor ward; QDR36 index; MSPSS index; SOC-13 index; and parents' perceived feelings for the child index) and lower values for the MoPPS index postnatal ward, the parents' perceived relation to and feelings for the child index (Table 3).

TABLE 3 | Overview of index, dimensions and outcome measures at different times throughout the study.

	1 week after childbirth (Q1)						6 months after childbirth (Q2)					
	IG			CG			IG			CG		
	All participants (n = 43)	First-time mothers (n = 24)	Partners (n = 19)	All participants (n = 51)	First-time mothers (n = 28)	Partners (n = 23)	All participants (n = 43)	First-time mothers (n = 24)	Partners (n = 19)	All participants (n = 51)	First-time mothers (n = 28)	Partners (n = 23)
	Mean (SD) α	Mean (SD)	Mean (SD)	Mean (SD) α	Mean (SD)	Mean (SD)	Mean (SD) α	Mean (SD)	Mean (SD)	Mean (SD) α	Mean (SD)	Mean (SD)
Positive birth experience	3.3 (1.0)	3.3 (1.0)	3.2 (1.0)	3.5 (0.8)	3.3 (0.8)	3.6 (0.8)	3.5 (0.9)	3.5 (1.0)	3.7 (0.5)	3.3 (0.9)	3.2 (1.0)	3.5 (0.8)
Meaningfulness of a perceived positive birth experience	3.3 (0.9)	3.5 (0.8)	3.0 (1.0)	3.4 (0.7)	3.7 (0.8)	3.1 (0.8)	3.3 (0.8)	3.3 (0.8)	3.4 (0.7)	3.2 (1.0)	3.5 (0.7)	2.7 (1.2)
Perception of a normal birth	3.0 (1.2)	3.1 (1.3)	3.0 (1.1)	3.2 (1.0)	3.3 (0.9)	3.2 (1.1)	3.2 (1.1)	3.1 (1.1)	3.3 (0.7)	3.2 (1.1)	3.2 (1.1)	3.3 (1.1)
Meaningfulness of a perceived normal birth	3.2 (1.0)	3.4 (0.8)	3.0 (1.2)	3.5 (0.7)	3.6 (0.5)	3.3 (0.8)	1.9 (0.9)	1.9 (0.9)	1.8 (0.8)	1.8 (1.0)	1.6 (1.0)	2.1 (1.1)
Feelings of being safe during birth	3.5 (1.1)	3.2 (0.9)	3.8 (1.2)	3.4 (0.7)	3.5 (0.5)	3.3 (0.9)	5.2 (1.0)	5.3 (1.0)	5.0 (0.9)	5.3 (1.0)	5.2 (1.2)	5.4 (0.5)
Feelings of having control during birth	3.6 (1.7)	3.6 (1.6)	3.7 (1.9)	3.1 (1.7)	2.5 (1.4)	3.6 (1.9)	4.3 (1.3)	4.5 (1.4)	4.0 (0.9)	3.9 (1.4)	4.2 (1.3)	3.5 (1.4)
Skin-to-skin contact after birth ^a	65.1% (n = 28)	62.5% (n = 15)	68.4% (n = 13)	47.1% (n = 24)	42.9% (n = 12)	52.2% (n = 12)						
MoPPS index labor ward	45.4 (8.7) 0.88	45.5 (8.2)	45.2 (9.6)	48.8 (5.1) 0.76	47.9 (5.2)	49.8 (5.1)						
MoPPS index postnatal ward	47.4 (8.2) 0.54	47.7 (7.4)	46.8 (9.5)	52.0 (5.6) 0.51	51.2 (6.2)	53.5 (3.9) 8						
QDR36 index	25.3 (2.1) 0.89	25.4 (2.3)	25.2 (1.9)	25.1 (2.9) 0.94	25.0 (3.3)	25.1 (2.7)	24.3 (2.6) 0.92	24.3 (2.9)	24.5 (1.6)	24.1 (2.5) 0.91	24.6 (2.5)	23.2 (2.1)
Dimensions												
Consensus	5.4 (0.4)	5.4 (0.3)	5.3 (0.4)	5.2 (0.5)	5.3 (0.6)	5.2 (0.5)	5.2 (0.5)	5.2 (0.5)	5.4 (0.4)	5.2 (0.4)	5.3 (0.4)	5.0 (0.4)
Cohesion	5.3 (0.6)	5.3 (0.6)	5.3 (0.6)	5.3 (0.7)	5.4 (0.8)	5.2 (0.7)	4.9 (0.8)	4.8 (0.8)	5.1 (0.8)	5.0 (0.7)	5.2 (0.7)	4.8 (0.7)
Satisfaction	5.3 (0.4)	5.3 (0.4)	5.3 (0.5)	5.3 (0.5)	5.3 (0.5)	5.3 (0.4)	5.1 (0.4)	5.1 (0.5)	5.1 (0.3)	5.1 (0.4)	5.1 (0.5)	5.1 (0.3)
Sensuality	5.2 (0.7)	5.3 (0.8)	5.1 (0.7)	5.2 (0.8)	5.3 (0.8)	5.1 (0.8)	5.1 (0.9)	5.1 (0.9)	5.2 (0.7)	5.1 (0.8)	5.1 (0.9)	4.9 (0.7)
Sexuality	4.1 (0.7)	4.2 (0.5)	4.1 (0.8)	4.0 (1.0)	4.0 (1.0)	4.0 (1.0)	4.1 (0.8)	4.1 (0.8)	4.0 (0.6)	3.6 (0.9)	3.7 (0.9)	3.4 (0.8)
MSPSS index	79.7 (5.8) 0.92	80.7 (5.1)	78.6 (6.4)	80.0 (5.5) 0.89	80.6 (5.8)	79.4 (5.3)	76.6 (7.6) 0.90	76.7 (8.0)	76.1 (6.9)	73.6 (11.3) 0.94	77.6 (6.8)	66.8 (14.2)
Dimensions												
Family	26.4 (2.4)	27.0 (1.8)	25.8 (2.8)	27.0 (1.7)	27.1 (1.9)	26.9 (1.6)	25.4 (4.0)	25.7 (3.9)	24.5 (4.1)	24.5 (3.9)	25.8 (2.4)	22.1 (4.9)
Friends	25.6 (3.1)	25.9 (3.3)	25.2 (3.1)	25.4 (3.5)	25.7 (3.7)	25.0 (3.3)	24.1 (3.5)	24.0 (3.5)	24.5 (3.6)	23.4 (5.5)	24.5 (5.2)	21.6 (5.8)
Significant others	27.7 (1.0)	27.8 (0.6)	27.6 (1.3)	27.7 (0.8)	27.8 (0.8)	27.5 (0.9)	27.0 (2.1)	27.0 (2.3)	27.0 (1.6)	25.7 (3.8)	27.1 (1.5)	23.2 (5.3)

(Continued)

TABLE 3 | Continued

	1 week after childbirth (Q1)						6 months after childbirth (Q2)					
	IG			CG			IG			CG		
	All participants (n = 43)	First-time mothers (n = 24)	Partners (n = 19)	All participants (n = 51)	First-time mothers (n = 28)	Partners (n = 23)	All participants (n = 43)	First-time mothers (n = 24)	Partners (n = 19)	All participants (n = 51)	First-time mothers (n = 28)	Partners (n = 23)
	Mean (SD) α	Mean (SD)	Mean (SD)	Mean (SD) α	Mean (SD)	Mean (SD)	Mean (SD) α	Mean (SD)	Mean (SD)	Mean (SD) α	Mean (SD)	Mean (SD)
SOC-13 index	73.8 (10.0) 0.87	74.7 (9.2)	72.9 (10.9)	70.5 (8.1) 0.78	72.9 (7.0)	68.0 (8.7)	70.9 (9.4) 0.81	69.6 (9.5)	73.9 (8.9)	70.8 (9.6) 0.83	72.6 (9.3)	67.8 (9.8)
Dimensions												
Comprehensibility	27.5 (4.3)	27.4 (3.9)	27.7 (4.9)	26.2 (3.8)	27.3 (3.1)	25.1 (4.1)	26.4 (4.3)	25.8 (4.3)	27.8 (4.2)	25.9 (5.1)	26.4 (5.4)	25.0 (4.8)
Manageability	22.7 (3.0)	22.7 (2.8)	22.8 (3.2)	21.4 (2.7)	22.1 (2.6)	20.7 (2.8)	21.7 (3.3)	21.1 (3.4)	23.0 (3.0)	21.5 (3.3)	21.9 (3.2)	21.0 (3.5)
Meaningfulness	23.5 (3.7)	24.6 (3.4)	22.4 (3.7)	22.9 (2.8)	23.4 (2.3)	22.3 (3.2)	23.0 (3.1)	23.0 (3.1)	23.1 (3.1)	23.4 (3.4)	24.3 (2.8)	22.0 (4.0)
Parent's perceived relation to the child index		41.9 (3.9) 0.65	36.1 (3.5) 0.57		43.4 (3.8) 0.50	35.7 (25) 0.60		44.9 (2.4) 0.30	36.4 (3.5) 0.67		44.6 (3.1) 0.39	35.3 (3.8) 0.60
Parent's perceived feelings for the child index	44.9 (4.6) 0.87	44.8 (4.0)	45.1 (5.2)	46.4 (2.9) 0.56	46.5 (3.3)	46.3 (2.5)	47.3 (2.7) 0.87	47.6 (2.5)	46.5 (3.0)	47.4 (2.7) 0.78	48.0 (2.0)	46.4 (3.4)

Results from Cronbach's alpha test included for index.

Response mean values:

Positive birth experience: theoretical range 1–4.

Meaningfulness of a perceived positive birth experience: theoretical range 1–4.

Perception of a normal birth: theoretical range 1–4.

Meaningfulness of a perceived normal birth: theoretical range 1–4.

Feelings of safety during birth: theoretical range 1–6.

Feelings of having control during birth: theoretical range 1–6.

^aSkin-to-skin contact after birth: a variable with two categories: (1) skin-to-skin contact during the first 2 h after birth and (2) no skin-to-skin contact during the first 2 h after birth.

MoPPS index: theoretical range 8–56.

QDR36 index: theoretical range 5–30, dimensions: range 1–6.

MSPSS index: theoretical range 12–84, dimensions: range 4–28.

SOC-13 index: theoretical range 13–91, dimensions: range Comprehensibility (5 items) range 5–35; Manageability (4 items) range 4–28; Meaningfulness (4 items) range 4–28.

Parent's perceived relation to the child index: For first-time mothers (7 items, 'Enjoy to breastfeed' included in index): theoretical range 7–49; For partners (6 items, "Enjoy to breastfeed" excluded from index): theoretical range 6–42.

Parent's perceived feelings for the child index: theoretical range 7–49.

Values: n, number of participants; M, mean; SD, standard deviation; α , Cronbach's alpha.

TABLE 4 | Results from the Mann-Whitney test for comparison between IG and CG among first-time mothers and partners first week (Q1) and 6 months after birth (Q2).

	1 week after childbirth (Q1)			6 months after childbirth (Q2)			Change between Q1 and Q2		
	Total (IG/CG) U (p-value) η^2	First-time mothers (IG/CG) U (p-value) η^2	Partners (IG/CG) U (p-value) η^2	Total (IG/CG) U (p-value) η^2	First-time mothers (IG/CG) U (p-value) η^2	Partners (IG/CG) U (p-value) η^2	Total (IG/CG) U (p-value) η^2	First-time mothers (IG/CG) U (p-value) η^2	Partners (IG/CG) U (p-value) η^2
Positive birth experience	500.0 (0.536)	132.5 (0.658)	97.5 (0.190)	450.5 (0.159)	188.0 (0.149)	55.0 (0.688)			
Meaningfulness of a perceived positive birth experience	519.5 (0.745)	133.5 (0.660)	125.5 (0.936)	538.0 (0.928)	197.0 (0.245)	38.0 (0.122)			
Perception of a normal birth	508.5 (0.635)	140.0 (0.880)	115.0 (0.611)	513.5 (0.654)	227.5 (0.714)	57.5 (0.848)			
Meaningfulness of a perceived normal birth	507.5 (0.618)	133.0 (0.659)	119.5 (0.745)	485.5 (0.416)	185.0 (0.149)	53.0 (0.623)			
Feelings of being safe during birth	500.5 (0.889)	105.0 (0.229)	89.0 (0.189)	535.5 (0.899)	226.5 (0.695)	46.0 (0.299)			
Feelings of having control during birth	433.0 (0.218)	90.0 (0.096#) >0.14	122.0 (0.833)	446.5 (0.197)	200.0 (0.315)	47.0 (0.376)			
Skin-to-skin contact after birth	0.00 (0.999)	130.5 (0.808)	123.0 (0.812)						
MoPPS index labor ward	365.5 (0.162)	116.0 (0.491)	72.0 (0.238)						
MoPPS index postnatal ward	224.5 (0.011*) >0.14	96.0 (0.094#) >0.14	27.0 (0.062#) >0.14						
QDR36index	492.5 (0.840)	133.0 (0.942)	115.5 (0.889)	417.0 (0.489)	215.0 (0.900)	26.0 (0.137)	168.0 (0.415)	86.0 (0.921)	10.0 (0.116)
Dimensions									
Consensus	462.0 (0.299)	131.0 (0.652)	104.0 (0.373)	474.0 (0.477)	221.0 (0.628)	26.5 (0.050*) >0.06			
Cohesion	502.0 (0.759)	123.0 (0.458)	114.0 (0.841)	508.0 (0.637)	189.0 (0.215)	43.0 (0.256)			
Satisfaction	538.0 (0.954)	135.0 (0.755)	124.5 (0.909)	464.0 (0.399)	198.0 (0.435)	56.5 (0.816)			
Sensuality	521.5 (0.785)	136.5 (0.793)	125.5 (0.939)	456.0 (0.449)	230.0 (0.980)	37.0 (0.201)			
Sexuality	504.0 (0.781)	126.5 (0.757)	126.0 (0.955)	366.5 (0.033*) >0.14	180.5 (0.150)	31.0 (0.100)			
MSPSS index	504.0 (0.774)	143.5 (0.985)	110.5 (0.731)	452.0 (0.419)	220.5 (0.816)	31.0 (0.100)	169.0 (0.353)	83.0 (0.920)	12.5 (0.124)
Dimensions									
Family	454.5 (0.294)	135.5 (0.716)	92.5 (0.262)	425.5 (0.115)	196.5 (0.262)	43.0 (0.257)			
Friends	523.0 (0.978)	141.0 (0.911)	114.5 (0.855)	526.5 (0.984)	181.0 (0.228)	39.5 (0.170)			
Significant others	500.0 (0.584)	138.0 (0.674)	101.5 (0.314)	434.5 (0.151)	227.0 (0.672)	30.5 (0.070#) >0.06			
SOC-13 index	405.0 (0.077#) >0.14	116.5 (0.342)	89.5 (0.151)	525.5 (0.974)	185.5 (0.268)	38.0 (0.146)	189.0 (0.339)	57.5 (0.132)	26.0 (0.527)
Dimensions									
Comprehensibility	437.0 (0.174)	139.5 (0.976)	85.5 (0.112)	494.0 (0.655)	211.5 (0.635)	39.5 (0.175)			
Manageability	389.5 (0.048*) >0.14	123.0 (0.466)	71.5 (0.033*) >0.14	525.5 (0.806)	215.5 (0.539)	41.0 (0.207)			
Meaningfulness	435.0 (0.165)	100.5 (0.131)	117.0 (0.689)	485.5 (0.446)	178.5 (0.136)	52.0 (0.594)			
^a Parent's perceived relation to the child index		84.5 (0.274)			197.0 (0.935)	51.0 (0.551)			
Parent's perceived feelings for the child index		98.0 (0.174)			229.0 (0.953)	58.5 (0.917)			

Measurements:

^aParent's perceived relation to the child index: For first-time mothers, the question regarding breastfeeding was included, score index 7–49; For partners, the question regarding breastfeeding was excluded, score index 6–42.

p-values: *p < 0.05 two tailed. Tendencies: #p ≤ 0.1.

 η^2 interpretation sensu Cohen (48): Calculated for significant results from the Mann-Whitney test. >0.01 small effect, >0.06 medium effect; >0.14 large effect.

TABLE 5 | Data for birth outcome collected through the first-time mothers' hospital medical records and results from the Mann-Whitney test.

	First-time mothers IG (<i>n</i> = 24) Mean (SD)	First-time mothers CG (<i>n</i> = 28) Mean (SD)	First-time mothers (IG/CG) U (<i>p</i> -value)
Length of birth (h) ^a	12.3 (6.3)	15.4 (10.6)	112.5 (0.559)
Dilation of cervix when arriving to labor ward (cm)	5.9 (3.0)	5.0 (3.0)	69.0 (0.436)
Vaginal/Instrumental birth ^b , <i>n</i> (%)	14 (78.0)/4 (22.0)	12 (75.0)/4 (25.0)	140.0 (0.851)
Time between arrival at labor ward and birth (h)	10.3 (14.5)	11.7 (11.0)	126.0 (0.534)
Gestational week at birth	39.8 (1.2)	39.9 (1.9)	121.5 (0.424)
Apgar Score at 5 min	9.5 (1.2)	9.6 (0.8)	129.0 (0.486)

^aLength of birth: time from start of contractions (first stage of labor/latent phase) to birth, in hours.

^bVaginal/Instrumental birth: a variable with two categories: (1) vaginal spontaneous birth and (2) vacuum extraction, forceps or section.

TABLE 6 | Breastfeeding descriptives and results from Mann-Whitney.

	1 week after childbirth (Q1)			6 months after childbirth (Q2)		
	First-time mothers IG (<i>n</i> = 24) <i>n</i> (%)	First-time mothers CG (<i>n</i> = 28) <i>n</i> (%)	<i>p</i> -value	First-time mothers IG (<i>n</i> = 24) <i>n</i> (%)	First-time mothers CG (<i>n</i> = 28) <i>n</i> (%)	<i>p</i> -value
Breastfeeding during first 2 h after birth ^a						
Yes	12 (50.0)	9 (32.1)	109.5 (0.418)			
Tried	4 (16.7)	3 (10.7)				
No	1 (4.2)	4 (10.7)				
Any breastfeeding ^b						
Yes	16 (66.7)	14 (50.0)	126.5 (0.928)	14 (58.3)	13 (46.4)	239.0 (0.944)
No	1 (4.2)	1 (3.6)		9 (37.5)	8 (28.6)	
Breastfeeding						
Exclusive	12 (50.0)	10 (35.7)		9 (37.5)	6 (21.4)	
Partly	3 (12.5)	3 (10.7)		6 (25.0)	7 (25.0)	
Enjoy to breastfeed, mean (SD) <i>n</i>	5.8 (1.4) 16	6.0 (1.3) 12	98.5 (0.593)	2.4 (1.8) 20	2.5 (1.5) 20	188.0 (0.735)

^aBreastfeeding during the first 2 h after birth: (1) No, I did not breastfeed the first 2 h after birth; (1) I tried to breastfeed but did not succeed to; (3) Yes, I breastfed the first 2 h after birth.

^bBreastfeeding: Any breastfeeding, both exclusively and partially breastfeeding included.

Enjoy to breastfeed: theoretical range 1–7.

DISCUSSION

In this trial of the inspirational lecture provided as a professional support for expectant parents in combination with ordinary antenatal parental classes, we observed a tendency for an effect on first-time mothers' feelings of having control during birth. However, the effects of the intervention seemed to be more prominent for partners. The results suggest positive effects on the IG parents' couple relationship, such as sexuality for both mothers and partners, as well as the couple's consensus for partners. The dimension of consensus within QDR36 relates to the couple's ability to respond to common stimulation in the exchange of ideas, laughter, or discussions, and so on (3). Therefore, these findings are in line with earlier studies that the inspirational lecture can facilitate partners' engagement in preparation for childbirth and parenthood (19, 20), and first-time mothers perceive higher quality within the couple's relationship

when partners show positive feelings for parenthood (9). These findings contribute valuable knowledge since the transition to parenthood is a period of vulnerability (49, 50), and parents need both professional and social support (19, 20). It is known that the quality of a parental couple's relationship generally decreases after birth (3, 4, 9, 11, 12), which could be due to the challenge of the transition to parenthood (3, 10, 24). If the inspirational lecture in combination with ordinary antenatal parental classes could have effects that strengthen the relationship of the parental couple, it could be a valuable intervention to introduce on a wide scale in society. However, the longitudinal effects of the combination between the inspirational lecture and ordinary antenatal parental classes on parents' strengthened couple relationship beyond 6 months after birth need further exploration.

Intervention in this pilot study had a positive effect on the SOC dimension of IG parents' and IG partners' manageability. This is a valuable result since a high SOC previously has been

TABLE 7 | Change over time in index and dimensions throughout the study between participants in IG and CG.

	Change between Q1 and Q2 IG			Change between Q1 and Q2 CG		
	All participants <i>p</i> -value	First-time mothers <i>p</i> -value	Partners <i>p</i> -value	All participants <i>p</i> -value	First-time mothers <i>p</i> -value	Partners <i>p</i> -value
Positive birth experience	ns	ns	ns	ns	ns	ns
Meaningfulness of a perceived positive birth experience	ns	ns	ns	ns	ns	ns
Perception of a normal birth	ns	ns	ns	ns	ns	ns
Meaningfulness of a perceived normal birth	0.001***	0.005**	ns	0.002**	0.004**	0.136
Feelings of being safe during birth	0.000***	0.000***	0.067	0.000***	0.003**	0.008**
Feelings of having control during birth	0.101	0.195	ns	ns	0.023	ns
QDR36 index	ns	ns	ns	0.019*	ns	0.028*
MSPSS index	0.001***	0.013*	ns	0.024*	0.085	ns
SOC-13 index	ns	ns	ns	ns	ns	ns

Results from non-parametric test (Wilcoxon Signed Rank test).

p-values: **p* ≤ 0.05, ***p* ≤ 0.01, ****p* ≤ 0.001, ns, non-significant Friedman's test. Tendencies: #*p* ≤ 0.1.

described as important for how parents perceive and cope with the challenges that come with childbirth and parenthood (15, 51). The fact that the combination of the inspirational lecture and ordinary antenatal parental classes led to the parents' higher manageability highlights the importance of a combination of different types of professional support for expectant parents. This is because manageability deals with the parents' overall sense that life is filled with meaning and purpose (16, 52), which is valuable during the transition to parenthood. Previously, parents' SOC has been described as increasing after birth (9, 53–55). However, the results of the present study showed no significant change in the parents' SOC between the first week and 6 months after birth. This result could be due to the small number of parents included in the present study. Therefore, it is suggested that both changes in SOC during the transition to parenthood and effects of the intervention on SOC beyond 6 months after birth be further explored.

The result that both IG and CG parents reported a decrease in perceived social support is in line with the results from a previous longitudinal cohort study, which also reveals that social support is associated with a higher quality of parental couples' relationships 6 months after birth (9). This stresses the value of group dialogue during parents-to-be meetings in antenatal parental classes. During such classes, expectant parents can relate the challenge of parental transition to others' experiences, which is described positively (19, 20). The intervention included in this study, the inspirational lecture, is a large-group lecture, and parents are not encouraged to interact with each other during the lecture. During the ordinary parental antenatal classes included in this study, the parents were, on the other hand, encouraged to discuss different issues regarding childbirth and parenthood in smaller groups of parents. According to other studies, first-time fathers experience exclusion by midwives who should offer both parents the opportunity to pose questions. It is also important to expectant fathers that time for discussion is included in antenatal parental classes (22), and first-time fathers require child health nurses' support to adapt to their role of

fatherhood (38). As mentioned, the inspirational lecture does not promote interaction between attending couples, which could be an area for development of the concept. Further, the results revealed that parents in the CG perceived stronger professional support from professionals in the postnatal ward than parents in the IG. This is not in line with earlier research that shows that extended professional support during pregnancy will improve perceived professional support after birth (35). One explanation for this result could be that the parents within the IG had higher manageability and therefore were less in need of professional support in the postnatal ward. However, childbirth is complex and more research is needed to fully understand the effects of the inspirational lecture as a complement to ordinary antenatal parental classes.

The intervention tended to produce positive effects on IG mothers' feelings of having control during birth. These results point to an important finding since a woman's birth experiences will influence her throughout her life (56). A positive birth experience has a good impact for both the woman and the baby's well-being but also for the couple's relationship (57). One reason for IG mothers' feelings of having control during birth could be that the inspirational lecture also had positive effects on partners' SOC and parental couple's relationships. This could lead to a partner being more able to support integrative power during birth. Integrative power means to support the woman's ability to surrender herself to the power of physiological birth (58) and thereby have a feeling of control yet surrendering to the process (56). A trusting relationship with her partner during birth is important for a woman (59, 60) and contributes to each woman feeling safe (34), plus her relationship with her partner may be strengthened (61). Feeling safe during birth has positive effects on mothers' breastfeeding (62). The results of this study showed no significant results for the analysis concerning breastfeeding. This could, however, be due to the relatively small data available. In addition, birth is complex, and more research is needed to fully understand how different processes interact. In this pilot study, we evaluated the effects of

expectant parents receiving a combination of the inspirational lecture and ordinary antenatal parental classes compared with expectant parents receiving only ordinary antenatal parental classes. To gain deeper knowledge about the inspirational lecture as a professional support for parents-to-be, further research is needed on the midwives' experiences from providing the lecture. The present study might be an example of how a work-integrated learning (WIL) perspective can be valuable to further explore the pedagogical approach used by the midwives providing the lecture. Future research, including a WIL perspective with specialization in healthcare pedagogics, may contribute to improved high-quality care that meets both current and future needs (63) among parents-to-be.

Randomized controlled trials are viewed as the gold standard in evaluating interventions. In this pilot study, the sampling plan was predisposed by a time aspect, and consecutive sampling was performed. Consecutive sampling has previously been described to reduce the risk of bias (32). Conducting intervention studies within clinical settings is, however, a challenge. In this study, the recruitment of participants varied from including almost all eligible parents to including around half or less of eligible parents. This variation was, among other things, explained by the high workload of the midwives at one of the antenatal clinics. Subsequently, we did not reach the targeted number of participants. Therefore, when considering the results it is important to bear in mind that this is a pilot study, and one explanation for why there is no convincing evidence of the effects of the intervention might be the small sample size. Also, we did not estimate any power analysis for this study, which could be seen as a study limitation, and the relatively short sampling period could be a potential risk for bias concerning seasonal or other time-related fluctuations (64). However, the participants within the IG and KG were relatively homogeneous, and a small sample may, therefore, be adequate (32). Also, based on previous qualitative research on parents' perceptions of the inspirational lecture (19, 20), there are reasons to expect that the independent and dependent variables will be strongly related. Despite the small sample size, this study has some interesting findings that add new knowledge to the field, implying that the inspirational lecture in combination with ordinary antenatal parental classes could be a valuable care intervention in parental preparatory professional support. Nevertheless, the results should be interpreted with caution considering the number of parents who were not invited or who declined participation. Also, when conducting intervention studies, including interventions that are not possible to blind for the participants, there might be a risk of potential desirability bias. In this study, it could be the case that the parents who "won" the ticket to extra professional support (the inspirational lecture), where thankful and wanted to give something back to the midwives providing the lecture. However, we think that such potential study bias should have been more apparent in the results.

Further, study limitations were the lack of analysis of non-responders and baseline characteristics before the intervention. In contrast, the dropout rate was relatively low and the follow-up design could be considered as a study strength. Before

conducting this study, two pilot studies were performed to test the questions and measurement clarity, as well as to test the technical issues relating to the web-based questionnaire, which could be considered as a study strength. One advantage of using the web-based questionnaire for Q2 was that participants' answers could be directly transferred to SPSS. For Q1, participants' answers were manually transferred to SPSS. To be able to reduce the risk of errors from the manual transfer, data in SPSS was carefully controlled with the participants' answers in Q1. The lesson learned from this was that web-based questionnaires should be preferable to use in future studies.

When designing this study, we used a follow-up design including repeated questionnaires, several measurements, and analyses. The reason for this was the fact that childbirth and becoming parents are life-changing experiences for the parents, and the inspirational lecture has previously been shown to have an impact on parents' feelings of being prepared for childbirth and parenthood (19, 20). When designing this pilot study, our intent was to be able to analyze the possible effects that the intervention would have on different aspects valuable for the parents, such as their birth experiences, sense of coherence, perceptions of social and professional support, and parental couple relationship. Including several measurements made it possible to, somehow, embrace the complex processes of childbirth and parental transition. However, childbirth and becoming parents are complex processes, and more research is needed to fully comprehend all aspects. Future intervention studies, evaluating the effects of professional support, are needed, and the design of such studies should be carefully considered. For better opportunities to reach statistical power and higher generalizability, a multicenter design could be preferable, for example. For future studies, the total scores obtained from the psychometric instruments in this study could be used as comparison scores for the target group. Furthermore, when evaluating the internal consistency of the included different measurements, the results showed high values for several of the measures, and lower values were shown for the MoPPS and MIRF scale, which indicates the need for improvement of the items in future studies. Within this study, we have analyzed both the index and dimensions for different measurements, as well as a few items from different measures. Therefore, it is important to interpret our results with care.

CONCLUSIONS AND CLINICAL IMPLICATIONS

The results from this pilot intervention study revealed that a combination of professional parental preparatory support between the inspirational lecture and ordinary antenatal parental classes showed a tendency to be gainful on parents' feelings of having control during birth, parental couples' relationships, and SOC, while some results were more prominent for partners. However, this professional support intervention did not strengthen social support, which all professional support actions

should aim to do. Despite the small sample, this study revealed that the concept of the inspirational lecture as large-group parental preparatory professional support seems to be a valuable care intervention in combination with ordinary antenatal parental classes. More research is needed since childbirth and transition to parenthood are complex processes that need to be comprehended, and care interventions could preferably be evaluated using a multicenter design in the future.

DATA AVAILABILITY STATEMENT

The datasets generated for this study will not be made publicly available because the authors don't have permission to share the data.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by the Regional Ethical Review Board in Gothenburg, Sweden (Dnr: 275-15). The patients/participants provided their written informed consent to participate in this study. Written informed consent was obtained from the individual(s) for the publication of any potentially identifiable images or data included in this article.

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AUTHOR CONTRIBUTIONS

ST contributed to conceptualization, data curation, formal analysis, funding acquisition, investigation, methodology, project administration, resources, software, validation, visualization, and writing of the article, which is an original draft. AE-B contributed to conceptualization, formal analysis, funding acquisition, methodology, validation, visualization, and writing of the article, which is an original draft. CB contributed to conceptualization, formal analysis, funding acquisition, investigation, methodology, resources, software, validation, visualization, and writing of the article, which is an original draft. All authors contributed to the article and approved the submitted version.

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Midwives' Experiences of Providing the “Inspirational Lecture” as a Care Intervention for Expectant Parents—A Qualitative Study

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Background: In most Western countries, ordinary parental classes exist and have become a well-established form of professional support within midwifery care, even though some of these classes lack evidence of benefits for the parents. A Swedish randomized controlled trial including an intervention as a pilot study, revealed that a type of parental preparatory professional support provided for expectant parents, the “inspirational lecture,” showed a tendency to be beneficial for parents’ birth experience, and their perceived quality of parental couple relationship. However, there is no previous research on the midwives’ experiences from providing the inspirational lecture. Carrying out research on midwives’ experiences from providing the lecture, could bring future opportunities to provide a work-integrated learning (WIL) related to professionals’ skills, and the pedagogic used.

Aim: To elucidate midwives’ experiences about providing the inspirational lecture as a care intervention for expectant parents.

Methods: Midwives were interviewed and data were analyzed using qualitative content analysis.

Results: The midwives strived to put childbirth into a comprehensive and manageable context for the expectant parents, during the inspirational lecture. For this, different approaches were used to make expectant parents understand how the parents themselves can be engaged participants in their own birth.

Conclusion and Clinical Implications: The midwives used the inspirational lecture to provide the expectant parents with knowledge about how they, as a parental couple, could cooperate and feel safe in relation to the upcoming birth. This could be understood as if the midwives were striving to facilitate the integrative power of the parental couple, which is the couples’ ability to gather their joint power. These results can assist midwives and serve as a reference for providing parental classes for expectant parents with a focus on promoting both the parents’ individual as well as mutual skills.

Keywords: transition, pregnancy, childbirth experience, parenthood, content analysis, antenatal, parental education

INTRODUCTION

In most Western countries, ordinary parental classes exist and have become a well-established form of professional support within midwifery care (1), even though evidence around the benefits of these classes for parents is lacking (1, 2). Furthermore, expectant parents lack satisfactory professional support in relation to their needs of preparation for childbirth and parenthood (3, 4). On the contrary, attendance at childbirth preparation has been associated with more women experiencing spontaneous labor onset and arriving at the hospital in active labor (5).

The extent to which ordinary parental classes are available for expectant parents, however, varies both internationally and nationally. Nationally, in Sweden, expectant parents are offered ordinary parental classes to a varying degree even though a national commission has recommended these classes for all expectant parents since 1979 (6). Currently, both small and large-group variations of ordinary parental classes are offered to expectant parents within Sweden (7). Most commonly, midwives are the leaders of these ordinary parental classes and provide expectant parents with information on how to prepare for childbirth, breastfeeding, and parenthood. A Swedish randomized controlled trial including an intervention as a pilot study allocated expecting parents to receive: (1) parental preparatory professional support provided by midwives in large groups of parents, the “inspirational lecture,” in combination with ordinary parental classes provided by midwives in small groups of parents (intervention group, $n = 66$), or (2) ordinary parental classes provided by midwives in small groups of parents (control group, $n = 60$). The results of the study revealed that the intervention, the inspirational lecture, showed a tendency to be beneficial for parents’ birth experience, and there was a statistically significant difference showing that the parents within the intervention group reported higher values regarding their perceived quality of parental couple relationship, as well as their manageability. The authors’ conclusion was that a combination between those two types of professional support (the inspirational lecture and ordinary parental classes), seems to be a valuable care intervention (8). Qualitative research on expectant first-time mothers and partners’ perceptions of the inspirational lecture have shown that the pedagogical creativity used by the midwives who provide the lecture (i.e., conveying information using humorous role-playing), increase understanding, among the expectant parents (3, 4). However, there is no previous research on the midwives’ experiences from providing the inspirational lecture.

Previous research has shown that the leadership role of parental classes seems important in terms of how parents experience the group sessions and if their parental role is affected by them after birth (9). Also, midwives’ experiences from leading ordinary parental classes have been described both as demanding (10) and enjoyable (11), and midwives need both individual skills and organizational resources to provide satisfactory parental classes (10, 11). When developing the inspirational lecture, provided as an intervention within the Swedish RCT previously mentioned (8), the intent was to

create opportunities for midwives to provide expectant parents with information about how to prepare for normal childbirth. The developers used their clinical experiences from working as labor ward midwives. In addition, the inspirational lecture was developed to provide expectant parents with information about how they can prepare for childbirth, with the focus on understanding how to manage: different labor phases (i.e., latent phase and active phase) and non-pharmacological pain relief (breathing and massage techniques, etc.). The inspirational lecture is provided for a large group of parents, approximately 80–120 parents attending, for 2 h. Further, it is an open lecture, which means that the parents do not have to apply for it and they can attend as many times as they need. Expectant parents as a couple or pregnant women together with a friend, sister, or significant other are all welcomed. In this study, the term *expectant parents* will be used when referring to attendees to the inspirational lecture, even though it is a somewhat narrow description. As mentioned, there is no previous research on midwives’ experiences from providing the lecture, and such research could generate knowledge of how midwives use their professional skills when developing, introducing and providing professional support as care interventions for expectant parents.

Carrying out research on midwives’ experiences from providing the inspirational lecture, could bring future opportunities to provide a work-integrated learning (WIL) related to professionals’ skills, and the pedagogic used by the midwives as well (12). According to Lagrosen et al. (13), a WIL approach stimulate learning through the active exchange of knowledge and reflected action. Furthermore, Pennbrant and Svensson (12) suggest that the aim with WIL is to develop tools and knowledge that increase understanding about the conditions and processes related to educations and/or workplace learning, for example. Future research on midwives’ experiences from providing the inspirational lecture could be seen as an interdisciplinary combination between the expertise of the midwives’ clinical experiences and skills, and research-based clinical evidence that could increase opportunities to achieve future high-quality care (12). Also, knowledge about midwives’ experiences of providing this type of parental class could contribute valuable knowledge for midwives who provide parental classes internationally. This is because, globally, as midwives provide professional support, they could gain further knowledge about how such care can promote health among the recipients. Therefore, the aim of the present study was to elucidate midwives’ experiences about providing the inspirational lecture as a care intervention for expectant parents.

MATERIALS AND METHODS

An explorative qualitative design using interviews (14) and a qualitative content analysis (15) was chosen to elucidate midwives’ experiences about providing the inspirational lecture as a parental class for expectant parents.

Settings and Participants

The present study was undertaken in two counties in the southwest of Sweden with two hospitals that together have

TABLE 1 | Overview with examples of the analysis process.

Statements	Codes	Sub-categories	Generic categories	Main category
<i>We present information seriously, mixed with humor, and we have noticed that humor is a very good way to reach out to the expectant parents.</i>	Present information seriously mixed with humor	Balancing humor and seriousness	Making childbirth understandable	Put childbirth into a comprehensible and manageable context
<i>The idea with the IL is that we should welcome them [the expectant parents] with open arms. And that they are free to come to the lecture one, two, or three times, if they want to. So I really like the concept.</i>	Make room for every pregnant woman and partner, and make each one of them feel welcomed	Create a sense of being welcomed	Promoting confidence in the childbirth process	
<i>They should not go to the delivery ward with the intention of having us deliver their baby. They should go to the delivery ward to give birth. They should think that we are there to strengthen them in their parenting and as a team. They should feel that they can manage it as a team, and that we are there to support them when they are giving birth.</i>	The midwives strive to strengthen the pregnant women and their partners as a team	Promote cooperation among the expectant parental couple	Facilitating the expectant parental couple's cooperation during childbirth	

approximately 6,150 births annually. Both included hospitals separately provided the inspirational lecture for expectant parents. At the time of the present study, it was only the two included hospitals that provided the inspirational lecture for expectant parents. Altogether, eight midwives worked on providing the lecture. They provided the lecture in pairs, two pairs at each hospital. The Clinical Heads of Service in the childbirth wards approved access in order to undertake the study. These Clinical Heads of Service contacted the eight midwives to ask them about their interest in participating in the present study. All the midwives agreed to participate. The included midwives varied in clinical working experience between 5 and 25 years; their present workplaces were labor ward, antenatal ward, or a combination.

Data Collection

Interviews were used to elucidate midwives' experiences about providing the inspirational lecture as a parental class for expectant parents. Prior to the interviews, all participants were contacted by the interviewer to inform about the study and the professional experience of the interviewer, as well as to establish a relationship between the participant and the interviewer. The interviewer had no previous relationship with the participants. The interviews with the midwives were conducted via telephone. All of the interviews followed a semi-structured interview guide with open-ended questions. These questions were used to encourage the midwives to describe their experiences and understanding. The open-ended questions were: *Could you describe the inspirational lecture? What is the purpose of the lecture? What is your role as a lecturer? and How do you experience the lecture?* When necessary, the interviewer asked follow-up questions for richer responses (14). Follow-up questions were, for example: *Could you explain more?* After each open-ended question, the interviewer made a brief summary that the midwives could comment on. This was done to let the midwives clarify the answers and the interviewer to confirm her interpretation (16). All interviews were held by one of the authors, between December 2015 and May 2016. The interviews

were audio taped and lasted between 24 and 51 min. Two of the authors transcribed the interviews verbatim, 113 pages (A4) in all. All of the authors had a consensus that the interviews were rigorous and met the aim of the study.

Data Analysis

Qualitative content analysis (15) was used for the data analysis process. First, each interview was read several times independently to allow each author to capture the content and essential structures of the interviews. Texts related to the aim of the study were highlighted, and open coding was conducted, which means that notes and headings were written in the text while reading it. After that, the headings were collected on coding sheets, and from these, codes were developed to explain the meaning of the text. Then, the codes were grouped into sub-categories based on similarities and differences of content. Three generic categories were developed, based on their underlying meanings. In the final step of the analysis, the main category arose (15). Three of the authors participated in each step of the analysis process. All five authors, with differing experiences of qualitative research, participated in discussions concerning the analysis, and agreed on a consensus once the analysis was complete. All of the authors participated in the process of writing the text. An overview of the analysis process is presented in **Table 1**.

Ethical Considerations

The interviews were performed according to the Swedish law stating that ethical approval is not needed when interviewing health care professionals about work-related questions (17). The Clinical Heads of Service in the childbirth wards approved access to undertake the study and provided the researchers with contact information for midwives that met the inclusion criteria. After that, the researchers contacted the midwives to inform about the study and ask for their willingness to participate. When designing the study, the potential risks were deliberated. The participants were not considered to represent a vulnerable group of individuals; their health was not considered negatively risked by participating in interviews. Thus, the potential benefits of

TABLE 2 | Overview of main category, generic categories, and sub-categories.

Main category	Generic categories	Sub-categories
Put childbirth into a comprehensible and manageable context	Making childbirth understandable	Use practical illustrations
		Balancing humor and seriousness
	Promoting confidence in the childbirth process	Create feelings of comfort and security
		Create a sense of being welcomed
	Facilitating the expectant parental couple's cooperation during childbirth	Promote cooperation between the expectant parental couple
		Create partner involvement

the study were considered to outweigh any risks. To protect participant's safety and rights, though, the Declaration of Helsinki (18) was followed, which allowed the participants: to receive information about the study and how data would be handled; right to self-determination, informed consent, and ability to withdraw participation at any time, as well as; confidentiality of personal information. The participants gave their consent to the publication of their quotes. Within the results section, quotes are provided in italics with an individual code (M1–M8) for each individual participant.

RESULTS

The analysis resulted in the following main category: *Put childbirth into a comprehensive and manageable context*. Three generic categories were found: *Making childbirth understandable*; *Promoting confidence in the childbirth process*; and *Facilitating the expectant parental couple's cooperation during childbirth*. Each generic category is based on two sub-categories, as presented in Table 2.

Main Category: Put Childbirth Into a Comprehensible and Manageable Context

According to the midwives, the intent of providing the inspirational lecture as a parental class for expectant parents was to put childbirth into a comprehensive and manageable context for the expectant parents. To achieve this, the midwives used different approaches to explain childbirth and the valuable roles played by the pregnant women and their partners. The midwives thought that if the parents understood how to prepare for childbirth, and if they understood their individual roles in the “birthing team,” it would help them to manage the upcoming childbirth. The midwives thought that when expectant parents understood the childbirth process and felt competent enough to manage it, this would increase the chance for positive childbirth experiences. Consequently, the midwives also used different approaches to facilitate cooperation in the expectant parental couple. Altogether, the midwives presented the complexity of

childbirth in an easygoing and positive way, to make expectant parents understand, feel positive about, and confident in the childbirth process.

Making Childbirth Understandable

According to the midwives, expectant parents need to understand childbirth in order to be prepared for it. Therefore, the midwives used practical illustrations, which included a balance between humor and seriousness to promote understanding about how to prepare for childbirth.

Use practical illustrations

To promote expectant parents' understanding of what situations they might be involved in when giving birth, the midwives used practical illustrations to clarify the process. For example, they showed how the expectant parents could use different practical things such as massage tools or a Pilates ball that might be used during childbirth. The midwives also wore the same clothing during the inspirational lecture as the midwives in the labor ward do. They did this with the intention to make the expectant parents feel safe from recognizing the clothing, when arriving in the labor ward to give birth.

Furthermore, the midwives role-played to illustrate in practice different situations that might occur during childbirth. During these role-plays, one of the two midwives who provided the inspirational lecture act as a birthing woman while the other one act as a partner. Then, the midwives were able to show different outcomes of the same situation, where the outcome depended on how the pregnant women and their partners acted in the exemplified situation (midwives acting to illustrate stressed or anxious expectant parents vs. midwives acting to illustrate calm or confident expectant parents).

To make childbirth understandable, the midwives not only explained how the expectant parents could act but also why. The midwives emphasized that knowing *why* to act was valuable because when expectant parents understood the underlying reason for acting, it promoted their understanding. These situations could be about the importance of nutrition, elimination, physical activity, and resting during childbirth, both from the perspective of the birthing woman and her partner.

...the word why is essential for us [the midwives who provide the Inspirational lecture]. For example, we say that it is important, what should I say... to pee... WHY is it important that you pee? Not just that, this is how it is... so that they will understand. They [the parents] are more motivated when they know what will happen if they do not do that [pee] (M 6).

The midwives experienced that different types of practical illustrations, combined with oral explanations, could facilitate understanding among the expectant parents. The visualization these illustrations provided was to facilitate for the expectant parents to remember and relate to the given information. Through this, the midwives described their intention to make the complexity of childbirth understandable for expectant parents, as well as help them understand how they could act to manage childbirth.

... we tell the expectant parents that their baby is supposed to rotate in the birth canal, and therefore it is good that the woman varies her postures during childbirth. We demonstrate this by using our hands to show what it looks like when you take off a [stiff] bracelet. You cannot just pull your arm and hand right out of it. You have to rotate your arm and hand to remove the bracelet. (M 1).

Balancing humor and seriousness

According to the midwives, using humor when presenting information could make the expectant parents laugh at something they were actually nervous about (childbirth). In the following, this could help the expectant parents relax and be more open to information during the inspirational lecture: “We present information seriously, mixed with humor, and we noticed that humor is a very good way to reach out to the expectant parents” (M 7).

When using humor, the midwives tried to create a relaxed atmosphere during the inspirational lecture. The underlying idea was that, if the expectant couples were able to relax during the inspirational lecture, it would be helpful for them to be able to relax also in their preparation for childbirth. The midwives thought that relaxation, as well as laughing, helped the expectant parents to handle or to release childbirth fears. Furthermore, relaxation and laughing were assumed by the midwives to facilitate understanding and learning abilities. However, the midwives described how it was important for them to balance humor with seriousness, to maintain the professionalism of the inspirational lecture.

Promoting Confidence in the Childbirth Process

During the inspirational lecture, the midwives tried to promote confidence in the childbirth process. To do this, the midwives experienced that it was important for them to create feelings of comfort and security as well as to create a sense of feeling welcomed in the expectant parents.

Create feelings of comfort and security

The midwives described how they tried to create feelings of comfort and security. They wanted the expectant parents to perceive the midwives as trustworthy, because they saw themselves as representatives of other midwife colleagues. To achieve this, they expressed the value of being interested in inspiring expectant parents for childbirth. Furthermore, as presenters they needed to take an interest in performing as well as liking to perform the specific concept of the inspirational lecture and to represent the midwifery profession.

I work as a midwife in the labor ward.... We [the midwives providing the Inspirational Lecture] are representatives of all our colleagues. I want them [the expectant parents] to feel like “Oh, I want to meet them [midwives] in the labor ward. I look forward to meeting them [midwives] because they [midwives] think it [childbirth] is fun and I will feel like that as well, when it is my turn to give birth.” (M 6)

During the inspirational lecture, the midwives also proposed to the expectant parents that they should create an individual mental goal. This mental goal could then be used by the parents

to cope with childbirth. The midwives thought that a mental goal could work as a positive reminder of why the parents wanted to experience childbirth; it could work as a positive reminder of the baby. Altogether, this was supposed to help the expectant parents in their feelings of excitement and mental preparation for childbirth. For this, the inspirational lecture was presented in an easygoing and positive way to make expectant parents feel confident in the childbirth process.

So, the inspiration itself is, probably, about us weaving in a little of reality; how it can be... [we] provide them with mental goal targets so that they can make an image in their head, which they can feel almost inspired from [giving birth] (M 5).

Create a sense of being welcomed

The midwives described the importance of creating an atmosphere where the expectant parents felt that they were welcomed to the inspirational lecture. The midwives saw and welcomed each one of them who arrived at the inspirational lecture, in person. The midwives thought that the expectant parents' feelings of being welcomed to the lecture could affect their feelings of being welcomed to the labor ward to give birth as well.

I want to convey such a positive feeling, so that they [the expectant parents] feel welcomed. They should feel reassured, seen, and so on. For example, we stand in the entrance when they [the expectant parents] arrive and say things like “Hello, welcome!”... (M 6)

To further create a sense of being welcomed, the inspirational lectures were held in large lecture halls, to enable everyone who came to attend the lecture. This was described by the midwives as a way of promoting feelings of having room for everyone, both in the lecture hall and in the labor ward. Further, the inspirational lecture was free of charge, scheduled in the evenings to match the expectant parents' working hours, and they could attend the inspirational lecture as many times as they wished.

Facilitating the Expectant Parental Couple's Cooperation During Childbirth

The midwives explained that one important goal of the lecture was to facilitate the expectant parental couple's cooperation during the childbirth process. To achieve this, a major part of the inspirational lecture focused on the partner, to create partner involvement and to promote the cooperation among the expectant parental couple.

Promote cooperation between the expectant parental couple

The midwives described their intention to promote cooperation between the expectant parental couple. This cooperation could create feelings of internal power within the parental couple, according to the midwives' experiences. This internal power was about the pregnant woman and her partner feeling able to manage birth together and was exemplified as: “We can do it together as a team” or “What an amazing thing we have in front of us.”

They [the expectant parents] should not go to the labor ward with the intention of having us [midwives] deliver their baby. They should go to the labor ward to give birth. They should think that we [midwives] are there to strengthen them in their mutual parenting. They should feel that they [the expectant parental couple] can manage it [childbirth and parenting] as a team, and that we are there to support them when they are giving birth. (M 1)

To create such feelings of internal power, the midwives talked about childbirth with excitement. The midwives assumed that when they presented positive feelings during the inspirational lecture, it could strengthen the expectant parents and increase their feelings of excitement about childbirth as well as their feelings of being able to manage childbirth together. Furthermore, as the inspirational lecture was given as a large group parental class, many expectant parents gathered together in the same area. This could help the parents to feel that they were not alone in having childbirth ahead of them, according to the midwives'. This was thought to facilitate feelings of being able to manage childbirth in the expectant parents.

It's the mentality that the parents feel secure and they believe in their own ability to give birth [M 2]

Create partner involvement

The midwives described that, during the inspirational lecture, the partners were as important as the pregnant/birthing women. The midwives' intention was to confirm the partner's valuable role in the "birthing team." Through this, the partner and the birthing woman could work together to cope with and experience childbirth. For this to work, the partners had to get involved and take an active role, according to the midwives'. To achieve this, the midwives explained to the partner how to be committed to this and play an active role. This was, for example, done by providing information about how to support women during childbirth, and how the partners could cope with different childbirth situations.

We focus a lot on the partner... in this Inspirational Lecture.... Partners have come to us afterwards and said that "Oh, this is exactly what I have been missing"; "You cannot read this on the Internet"; and "I thought that I couldn't do anything... that I should just sit beside, on a chair... that I should be... totally helpless and not able to do anything." And they [the partners] have expressed "thank you" and "now we know what to do." (M 2)

The midwives experienced it as essential to encourage the partners to see themselves as important. To achieve this, they reassured the partners that professionals in the labor ward valued the partners and were available to support them. To make each partner visible, the midwives used the term "partners" instead of "fathers." This was because a partner could, according to the midwives, be anyone: the expectant father or co-mother, a relative or friend, for example.

Because that's what it's all about, whether it's a father or a family member in a family relationship, or if it is a partner who is of the

same sex, all of them are supposed to get the same attention; it's their experience as well. (M 5)

In summary, the midwives saw the partner as the person/s that the pregnant woman had chosen to support her during childbirth. The midwives' intention with this was to treat all partners equally, regardless of their gender or relationship to the pregnant woman.

DISCUSSION

In the present study, midwives' experiences about providing the inspirational lecture as a parental class for expectant parents were elucidated. The main findings were that the midwives wanted to put childbirth into a comprehensive and manageable context for expectant parents. To achieve this, the midwives used their theoretical knowledge and clinical experiences as a base for the inspirational lecture. This is similar to WIL which has been described earlier (12). Further, the midwives explained that they encouraged the expectant parental couple to see themselves as a "birthing team," with valuable individual roles and an internal power focused to reach the same "mental goal." Also, the midwives experienced it as vital to make the partner's role visible. It is a well-established fact that both women and partners want professional support to include the partner's role and focus on the expectant parents as a couple (3, 4, 7, 19–21). Current findings highlight that the inspirational lecture as a parental class can facilitate the expectant parental couple's cooperation during childbirth. For this, the midwives role-played to practically illustrate different outcomes of the same situation. The outcome depended on how the expectant mothers and their partners acted in the exemplified situation (stressed or anxious expectant parents vs. calm or confident expectant parents). This brings valuable knowledge into the field, since it shows how midwives strive to make expectant parents understand how the parents themselves can be engaged participants in their own birth. It could be understood as facilitating integrative power that is the couples' ability to gather their joint power (22). To be able to become engaged participants, however, the parents' abilities to comprehend childbirth might be vital for their abilities to manage the same. Nevertheless, to gain more knowledge about how midwives can support parents in becoming engaged participants in their own birth, further exploration is needed.

The midwives within the present study were aware that they (the midwives) themselves had to provide information with security and confidence to facilitate feelings of security among the pregnant women and their partners. This points to the importance of presenters being secure in their professional knowledge (23, 24). Previous research shows, on the other hand, that midwives (10) and other health professionals (9) find leading parental classes to be challenging. Also, midwives have stated that they lack the knowledge and resources to lead parental classes (10, 11). The current findings contribute to further knowledge about how midwives approach their task of leading (or teaching) such parental classes. The approach used by the midwives who provided the inspirational lecture could be described as focused on visualizing, through practical illustrations, how the parents

could become engaged participants in their own birth. Besides this, the approach was based on the midwives' use of humor. The midwives experienced that the pregnant women's and partners' relaxation during the inspirational lecture was facilitated when information was provided through practical illustrations or humor. Moreover, this relaxation contributed to the parents' comprehension, according to the midwives. Humor has earlier been explained to create feelings of security in stressful childbirth situations (25). In addition, humor and role-play can improve learning as well, because they facilitate attention and interest in understanding information (26).

The role-play and humor used by the midwives providing the inspirational lectures have previously been shown to facilitate laughter among pregnant women and their partners. To a further extent, this laughter increases the parents' perceived abilities to absorb and understand the provided information (3, 4). Previously, humor has been associated with good health, possibly related to the release of endogenous hormones (endorphins, etc.) when laughter erupts (27). Whether or not healthcare professionals use humor may be related to both social and external circumstances, as well as to personality. Unwillingness to use humor within clinical practice could be caused by assumptions that humor is unprofessional (28). The midwives within the present study were aware of the importance of balancing humor with seriousness, to retain professionalism. Subsequently, midwives providing parental classes should present information in ways that help pregnant women and their partners to relax. This is because a feeling of being relaxed may facilitate the parents' abilities to understand information. For this reason, humor and practical illustrations could apparently be useful approaches. Nevertheless, it is valuable to bear in mind that the use of humor may not always be appropriate within care situations. Therefore, the use of humor within different international and cultural aspects may gain from further exploration.

However, expectant parents' views of childbirth differ. While some experience childbirth as a meaningful transformatory process, others experience it as a necessary part of life. The current findings illustrate how the midwives introduced childbirth as a normal life event for the expectant parents. Such an approach to childbirth could be likened to Bryar and Sinclair's (29) first model, that is: seeing pregnancy as a normal life event and as a period of growth for women, in contrast to the second model: seeing pregnancy as an illness and encouraging women to view themselves as patients (29). Pregnant women who strive to achieve normality are not strengthened by a focus on risk during childbirth (30). In addition, expectant parents need support to manage stressors that come with pregnancy. The parents need to identify both their internal and external resources required to manage those stressors. Therefore, a focus on risk during childbirth may hamper the expectant parents' abilities to manage the changes that come with childbirth. Approaching childbirth as a normal life event could be associated with salutogenesis, which aims to improve the parents' well-being or healthiness (31). Previously, Downe (32) has emphasized the need of midwives to use a more specific salutogenic approach. Furthermore, Bauer et al. (33) have proposed future salutogenic

interventions to focus on strengthening individuals' resources, promoting their comprehensible, manageable, and meaningful life experiences as well as positive health outcomes. In relation to midwifery, such a salutogenic approach or intervention could be understood as midwives supporting the parents in experiencing childbirth as a comprehensible, manageable, and meaningful life experience. This is in line with the current findings. Therefore, midwives who possess valuable knowledge about how to preserve childbearing as a normal life event, should have a central role in supporting and maintaining childbearing as a period of growth for the parents. This is because midwives who are providing professional support, such as the inspirational lecture, with the intent to strengthen parents, should be seen as providing a vital care intervention aiming at promoting mental health and sustainability among parents.

Using a qualitative inductive design and content analysis (15) for the present study was deemed to be appropriate. Conducting telephone interviews was considered to be appropriate as well, since being interviewed via telephone was deemed to be less time consuming and therefore more comfortable by the interviewees (34). However, interviewing via telephone may be challenging for both the interviewer and the research process. This is because there is no way for the interviewer to analyze body language or facial expressions among the interviewees (35). However, the interviewer had a broad experience from conducting interviews via telephone and had the ability to be attentive to oral expressions. In case of obscurity, the interviewer asked about the specific participant's experiences from being interviewed. Overall, the authors had a consensus that the interviews were rigorous and met the aim of the present study. All the researchers with their different professional backgrounds participated in the analysis process and the findings have been illustrated with quotations. Furthermore, the final analyses were discussed with other researchers possessing a variety of experiences in working with professional support for expectant parents. This contributed to the trustworthiness of the study (36). The participants were a limited number of midwives using a specific method in a limited geographic region in Sweden, which has to be taken into consideration. However, since all eight midwives who provided the Inspirational Lecture as a parental class for the time of the study were included, it could be considered to be a study strength since the participants were representative and had knowledge about the studied phenomena (37). The way midwives provide professional support and parental classes for expectant parents vary, however, not only nationally within Sweden, but also internationally. Therefore, the results of the current study may not be directly transferrable to other settings. Nevertheless, qualitative research does not intend to generalize the results into other settings (38), instead the intent with qualitative research is to gain further knowledge about the phenomena studied within the contextual circumstances for the research participants. In addition, the results from the current study increase knowledge about midwives' experiences from providing parental classes for expectant parents. Subsequently, the results can assist midwives (or other health care professionals) and serve as a reference for providing parental classes for expectant parents.

However, since the inspirational lecture is a large-group parental class, it may be difficult to meet all the support needs of expectant parents in their preparation for childbirth. Previously, Gilmer et al. (39) have claimed that it would be impossible for a single and centrally regulated program to be flexible enough to actually meet the support needs of all expectant parents. In addition, the inspirational lecture has previously been shown to be valuable for parents when provided as a care intervention for expectant parents in combination with ordinary parental classes (8). Notable is, however, that the content, strategies and philosophy outlined in the findings of the current study may be commonly used for parental classes around the world. Also, one disadvantage of the format of the inspirational lecture is having a class of 80–120 parents (40–60 couples) which could make interaction and active participation challenging. A Danish randomized controlled trial found that small parental classes may increase childbirth self-efficacy (40), which could be due to the opportunities for the parents to interact with each other (3, 4, 41) because parents need to learn from other parents (42). Therefore, the inspirational lecture, as a support for expectant parents, should not exclude other types of professional support for expectant parents, instead, the inspirational lecture should be offered in combination with other types of professional support.

CONCLUSION AND CLINICAL IMPLICATIONS

The midwives' overall experiences about providing the inspirational lecture as a parental class entailed that they wanted to put childbirth into a comprehensive and manageable context for expectant parents. To achieve this, it was essential to make childbirth understandable, to promote confidence in the childbirth process and to facilitate the expectant parental couple's cooperation during childbirth. Further, the midwives strove to support the expectant parents in their understanding of how the parents themselves can become a "birthing team" and engaged participants in their upcoming birth. This brings valuable knowledge into the field, since it demonstrates how midwives strive to make expectant parents understand how the parents themselves can be engaged participants in their own birth. It could be understood as facilitating the integrative power that is the couples' ability to gather their joint power. Subsequently, current results revealed how midwives use different approaches to increase the parents' understanding. Such knowledge is of international relevance within clinical practice, since parental classes are offered by midwives globally. However, since the inspirational lecture is a large-group parental

class, it may be difficult to meet all the support needs of expectant parents. Therefore, the inspirational lecture should be offered in combination with other types of professional support.

DATA AVAILABILITY STATEMENT

The datasets generated for this article are not readily available because we do not have permission to share data. Requests to access the datasets should be directed to caroline.backstrom@his.se.

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

CB and TS contributed to the conceptualization, data curation, formal analysis, funding acquisition, investigation, methodology, project administration, resources, software, validation, visualization, and writing the article, which is an original draft. ST and LM contributed to the conceptualization, formal analysis, funding acquisition, investigation, methodology, project administration, resources, software, validation, visualization, and writing the article, which is an original draft. MG contributed to the conceptualization, data collection, formal analysis, funding acquisition, investigation, methodology, project administration, resources, software, validation, visualization, and writing the article, which is an original draft. All authors contributed to the article and approved the submitted version.

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Efficacy, Treatment Characteristics, and Biopsychological Mechanisms of Music-Listening Interventions in Reducing Pain (MINTREP): Study Protocol of a Three-Armed Pilot Randomized Controlled Trial

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Background: Pain can severely compromise a person's overall health and well-being. Music-listening interventions have been shown to alleviate perceived pain and to modulate the body's stress-sensitive systems. Despite the growing evidence of pain- and stress-reducing effects of music-listening interventions from experimental and clinical research, current findings on music-induced analgesia are inconclusive regarding the role of specific treatment characteristics and the biopsychological mechanisms underlying these effects.

Objective: The overall aim of this pilot randomized controlled trial is to test and compare the differential effects of frequency-modulated and unmodulated music (both researcher-selected) on experimentally induced perception of acute pain and to test the efficacy of the interventions in reducing biological and subjective stress levels. Moreover, these two interventions will be compared to a third condition, in which participants listen to self-selected unmodulated music.

Methods and Analysis: A total of 90 healthy participants will be randomly allocated to one of the three music-listening intervention groups. Each intervention encompasses 10 sessions of music listening in our laboratory. Frequency-modulation will involve stepwise filtering of frequencies in the audible range of 50–4,000 Hz. Acute pain will be induced via the cold pressor test. Primary (i.e., pain tolerance, perceived pain intensity) and secondary (i.e., heart rate variability, electrodermal activity, hair cortisol, subjective stress) outcomes will be measured at baseline, post, and follow-up. In addition, intermittent measurements as well as a follow-up assessment and a range of tertiary measures (e.g., music-induced emotions) are included.

Discussion: This is the first study to systematically test and compare the effects of music frequencies along with the control over music selection, both of which qualify as

central treatment characteristics of music-listening interventions. Results will be highly informative for the design of subsequent large-scale clinical trials and provide valuable conclusions for the implementation of music-listening interventions for the reduction of perceived pain.

Clinical Trial Registration: Clinical Trials Database of the U.S. National Library of Medicine: Identifier NCT02991014.

Keywords: autonomic nervous system, cold pressor test, music, music-induced analgesia, music intervention, pain management, stress reduction

INTRODUCTION

The experience of pain is a multifaceted and highly individual phenomenon that involves sensory, affective, cognitive, social, and biological components. Perceived pain can cause serious disruptions in daily functioning and often compromises an individual's well-being and quality of life (1, 2). While acute pain is defined as a "sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage" that is mostly unpleasant, though temporary (3), chronic pain typically lasts several months or even years, occurs with or without an underlying somatic cause, and affects a large proportion of our society (4). For instance, pain conditions including low back pain and migraine are amongst the leading causes of disability and disease burden worldwide (4). In addition to the individual suffering, the treatment of chronic pain is associated with tremendously high direct and indirect costs for society as a whole (5). For these reasons, chronic pain is considered a global health challenge that needs to be treated by affordable, effective, and well-accepted interventions (6–8).

Over the last decades, music as an adjuvant treatment for the management of both acute and chronic pain has received growing interest in clinical practice and scientific research [e.g., (9, 10)]. "Music-induced analgesia" offers several advantages, since music is cost-effective, non-invasive, easy to (self-)administer and does not have the drawback of severe side effects as compared to most pharmacological treatments (11, 12). A vast body of evidence supports the pain-reducing effects of music in diverse conditions, including surgical and chronic pain. While surgical (i.e., postoperative) pain can be considered (mostly) transient and functional to a certain degree (e.g., by causing the individual to protect affected body parts), chronic pain is not (or no longer) related to actual tissue damage, exceeds the healing period and is therefore considered dysfunctional (13). In a recent meta-analysis by Garza-Villareal et al. (14) including 14 randomized controlled trials and a total of 1,178 chronic pain patients, music interventions (mostly listening to recorded music) have been shown to reduce self-rated pain and comorbid psychological symptoms with moderate to large effect sizes. Two further meta-analyses of music-based interventions for cancer patients also found effects on pain ratings in the moderate to high range and additional positive effects on symptoms of anxiety, depression, and autonomic functioning (15, 16). Moreover, various meta-analyses summarizing the empirical evidence in the context of pre-, intra-, and post-operative periods

of surgery have documented beneficial effects of music on ratings of pain and anxiety, as well as a reduction in anesthetic medication intake during postoperative recovery (12, 17, 18). In sum, the overall findings support the beneficial role of music-based interventions for the reduction of pain in diverse settings and patient populations. Nevertheless, it has been consistently emphasized that methodological shortcomings and a large study heterogeneity leave many questions unanswered [e.g., (11, 12, 14)]. Therefore, despite a growing body of promising empirical evidence, the literature on music-induced analgesia is still inconclusive with regard to the optimal treatment characteristics as well as the biopsychological mechanisms underlying the effects of music listening on pain perception [see also (10)].

In addition to clinical studies with patient populations, laboratory-based studies with healthy participants have elucidated several important moderating and mediating factors with respect to the effects of music listening on acute pain perception (outlined below). Although the evidence from these studies is certainly restricted in terms of generalizability to chronic pain patients, such approaches allow standardizing the magnitude of pain stimulation as well as keeping confounding variables to a minimum (19), which is of great advantage when investigating new treatment characteristics and mechanisms of action. For these reasons, we will conduct a pilot study that includes an experimental induction of acute pain in healthy participants in order to determine the differential efficacy of three music-listening interventions in reducing perceived pain and to examine the biopsychological mechanisms underlying the (potential) intervention effects.

Although various theories have been proposed with respect to the *psychological and biological mechanisms underlying music-induced analgesia*, the mediating processes are still not yet very well-understood (9, 10). The processing of pain is modulated via descending pathways, neurotransmitter systems, and neuronal/synaptic activity changes involving cortical and subcortical brain regions, the brainstem, and the spinal cord [see (20) for review]. Psychological processes, especially changes in attention and emotional state, are suggested to influence the processing of pain (21, 22). In this context, many researchers emphasize the distracting abilities of music and posit that music binds cognitive capacities, diverts the listener's attention, and consequently inhibits pain sensations [e.g., (23–25)]. In addition, emotional engagement with music might explain its pain-reducing effects. Particularly pleasurable music has been shown to induce positive emotions (e.g., joy, pleasure)

in the listener and to modulate mood states (e.g., enhance feelings of relaxation, decrease feelings of anxiety) (26–28), which are assumed to be associated with a downregulation of pain experiences (29–31). In addition, research in the fields of neuroscience and psychoneuroendocrinology has revealed that music affects a multitude of cortical and subcortical areas in the brain, many of which are also involved in the processing of pain, indicating that music-induced analgesia involves the descending pain modulation pathway (9, 32). For example, previous experimental studies applying imaging techniques and pharmacological manipulations (33–35) have substantiated the idea that pleasurable music affects dopaminergic and endogenous opioid pathways that are associated with the brain's reward system. The release of dopamine and endogenous opioids in response to pleasurable music could therefore qualify as a possible biological pathway that leads to pain relief [see also (36)].

Furthermore, a biopsychological mediation model has been advocated that proposes that the autonomic nervous system (ANS) and subjective stress mediate the effects of music on pain perception (37, 38). In line with this idea, four recent systematic reviews and meta-analyses have underlined the effectiveness of music in decreasing biological and subjective markers of stress (39–42). The ANS is responsible for rapidly adapting the individual to internal and external threats via a coordinated interplay of its sympathetic and parasympathetic branch (43). Consequently, the ANS is involved in the body's processing of and response to pain, which is reflected by changes in biomarkers of the ANS such as heart rate, blood pressure, and respiration rate (44–46). Particularly heart rate variability and skin conductance are of special interest, since these indicators allow a relatively fine-grained interpretation of sympathetic and parasympathetic activity (47–49). Interestingly, the ANS is also highly sensitive to musical stimulation (50, 51). A prominent model explaining the effects of music on ANS suggests that music modulates activity in the limbic and paralimbic regions including the hippocampus and the amygdala, which are also involved in the regulation of ANS activity and the processing of pain (9, 52). To the best of our knowledge, only few studies have investigated the effects of music on autonomic functioning in the context of pain [e.g., (53–56)]. In addition, we are not aware of any experimental or clinical study that has explicitly aimed at testing changes in ANS activity as a potential mediator between music listening and pain perception. One exception to this is a previous ambulatory assessment study from our own lab, in which women diagnosed with fibromyalgia (i.e., a condition characterized by chronic widespread pain) reported on experiences of pain, stress, and their natural (i.e., experimentally not manipulated) music listening behavior multiple times per day over a duration of 14 days (38). The findings indicated that control over pain was significantly enhanced by music listening, but no effects on biological or subjective levels of stress were found [in contrast to similar studies in healthy subjects, e.g., (57)]. Therefore, the authors abstained from conducting a mediation analysis. It is noteworthy that observational studies conducted in patients' everyday life are of high value with regard to ecological validity (58); however, many parameters in daily life research cannot be controlled for, particularly in

patient populations, and might have masked effects of music on ANS activity. This, again, underlines the necessity for controlled laboratory-based experimental studies with acute pain induction in healthy participants in order to unravel mechanisms of action underlying the effects of music listening on pain perception.

Next, we argue that *structural elements of music* and *choice over musical selection* are two pivotal treatment characteristics in music-listening interventions that lack a systematic investigation in previous studies (10, 59). In a recent meta-analysis by Martin-Saavedra et al. (60), the common neglect of reporting musical characteristics (e.g., tempo, instrumentation, presence of lyrics) in previous randomized controlled trials investigating music for pain management was criticized, since no clear conclusions can be drawn based on the current literature. In this regard, in their analyses of three experimental pain studies using participants' self-selected music, Knox et al. (61) found that timbral and tonal aspects were significantly correlated with measures of experimentally induced pain perception, indicating that structural elements of music might differentially moderate the effects of music on pain reduction.

In contrast to the relative lack of conclusive findings in the field of pain management, musical characteristics such as sound intensity, tempo, timbre, and arousal level have been shown to affect ANS activity in a plethora of studies (62–68). However, only recently, audio frequencies, which constitute another inherent feature of music, have been brought into focus of scientific investigations (69–72). From a technical perspective, the term frequency describes the number of oscillations per time unit, i.e., for audio frequency, it is the number of vibrations per second that determines the pitch of a sound and is measured in Hertz (Hz). Music can be defined as a combination of a fundamental frequency and multiple partial overtones, which are suggested to be translated from the cochlea into neural activity in a first step, followed by a pre-processing in the auditory brainstem, and are then analyzed in the auditory cortex and other brain regions (52). Nowadays, diverse commercial and free-to-listen compositions with frequency-modulated music are available that are claimed to exert a positive influence on the cognitive, emotional, social, and physiological domains of their consumers. Typically, these diverse programmes are based on different ideas about which frequencies might be particularly beneficial or detrimental to the human body and brain, with each programme thus justifying its specific approach of frequency modulation (e.g., amplification or filtering of certain frequencies) (73). Besides anecdotal evidence on the potential benefits of these methods, scientific research within this field is just in its infancy. For example, in the study by Nakajima et al. (71), 12 healthy women underwent a stress-inducing procedure three times in a row and listened to one of three versions of the Horn Concerto in E-flat major, K.417 by Mozart, afterwards. The respective conditions comprised the music piece modulated in the high-frequency spectrum (equal of above 3.5 kHz), in the low-frequency spectrum (below 0.5 Hz), or not modulated at all. Heart rate variability (HRV) was measured as dependent variable indicating autonomic recovery during music listening. Results indicated that particularly the modulation of high-frequency components was more effective in supporting autonomic recovery compared to the other

conditions. In another study, Akimoto et al. (69) tested so-called “solfege frequency music.” In their study, nine participants listened to 5 min of “regular” relaxing piano music, i.e., tuned to the international standard reference tone of 440 Hz, on 1 day, and to the same piece tuned to a reference tone of 444 Hz (which results in the inclusion of 528 Hz), on a different day. Biomarkers of the ANS were assessed during and after exposure to music. Results indicated subtle differences in HRV and significant reductions in negative mood states in the 444 Hz (528 Hz), but not in the 440 Hz music condition. Thus, findings from both studies support the notion that specific frequency components in music might be capable of differentially modulating the activity of the ANS and psychological outcomes. Certainly, it is necessary to interpret the data with caution and to recognize their limited generalizability, particularly since both studies focused on short-term effects of frequency-modulated music within a single session and a small number of participants.

In addition to these experimental studies, recent investigations applied a music intervention labeled “Audiovisuelle Wahrnehmungsförderung” (AVWF®)¹, that involves a repeated exposure to frequency-modulated music, in a clinical setting (74, 75). The authors found beneficial effects of this frequency-modulated music intervention on HRV (74) and on the cortisol-awakening response (i.e., indicator of the endocrine stress system) in psychosomatic inpatients (75). These findings, though preliminary, could indicate that the AVWF method might have a beneficial impact on biological indicators of stress in patients suffering from chronic conditions (74, 75). However, patients were not randomly assigned to treatment and control groups in the study. Thus, it remains unclear whether improvements in the variables of interest were actually caused by the frequency modulation in the music, since the mere act of music listening or other confounding aspects (e.g., selection and performance bias) cannot be ruled out based on the current findings (74, 75). Consequently, in line with the evidence reviewed above, it would be a critical endeavor to test if the beneficial impact of music on pain perception can actually be enhanced by a modulation of certain frequencies in music. Only a randomized controlled trial that compares frequency-modulated music with the same music in an unmodulated version and in which both participants and examiners are blinded with regard to frequency modulation allows drawing firm conclusions.

Furthermore, previous research is limited with regard to systematic comparisons of the effects of control over choice of music selection, i.e., researcher- vs. participants’ self-selected music. Self-selected music might increase feelings of emotional and cognitive involvement during music listening (31, 55, 76). Self-selected music in contrast to pre-selected music is assumed to better capture the listener’s personal preferences and is therefore thought to be associated with a higher liking of and familiarity with the music, as well as an increased sense of control, all of which have been related to pain-reducing effects (29, 31, 77). However, in some settings (e.g., hospital, rehabilitation), it might be more practical to make use of predetermined music selections. Therefore, some researchers

have opted for pre-selected (i.e., researcher-selected) music pieces in the context of pain management such as slow, classical music, since this is believed to be perceived as relaxing and pleasant by most individuals [e.g., (78)]. Others offered participants to choose pieces from a variety of musical genres in order to permit some degree of personal preference [e.g., (79, 80), see also (81)]. Overall, self-selected music has been shown to be superior to music chosen by researchers/clinical staff for pain alleviation in patients with chronic pain conditions (14) and to be superior to other distracting and emotionally engaging stimuli in experimental studies with healthy participants (24).

A final shortcoming in previous research concerns the fact that the existent body of studies is inconclusive with respect to the *stability of these effects* (14). In previous laboratory-based studies, experimental pain induction and music listening are typically administered concurrently and in one session only [e.g., (31, 55, 82)]. Although this is a valuable approach for investigating the short-term impact of music on pain perception when processed in parallel, these results are of limited validity with regard to longer-lasting benefits of music for pain management. Knowledge on the required length and amount of an intervention is necessary in order to optimally balance spending of resources (e.g., temporal, financial) and desired health outcomes. In the context of music interventions for pain management, however, previous studies are characterized by a remarkable variation in length and frequency of music-listening sessions and whether pain-reducing effects of music-based interventions last over several weeks or even months have been examined only rarely. For example, Finlay (83) found short-term, but no long-term or cumulative effects of music listening on perceived pain intensity and unpleasantness in chronic pain patients, whereas other research groups found a steady increase in music-induced analgesia over 2 (78) and 4 (84) weeks, respectively. However, none of these studies included a follow-up assessment to test whether the beneficial effects of music on pain perception lasted even after cessation of the intervention period. In order to close this research gap, we chose a long duration and high number of music-listening sessions in addition to the inclusion of a (1 month) follow-up assessment in order to be able to investigate the potential intermediate stability of the effects of music listening on measures of pain perception.

STUDY AIMS AND HYPOTHESES

This study addresses a number of open research questions with regard to the overall efficacy, role of specific treatment characteristics and biopsychological mechanisms of music-listening interventions in reducing perceived pain.

First, we will investigate the pain-reducing effects of frequency-modulated vs. unmodulated music, which are both researcher-selected, within a randomized controlled, laboratory-based, double-blind trial. Additionally, we include a third study arm, in which participants will listen to their self-selected (unmodulated) music. Since all study procedures (e.g., duration and number of sessions and measurements) will be conducted in parallel to the researcher-selected music-listening interventions,

¹ A corresponding English translation is “Audiovisual Perception Enhancement”.

we will be able to directly compare the differential effects of all three music-listening interventions on measures of pain perception. Furthermore, besides measures of pain perception, we will investigate the effects of these three music-listening conditions on biomarkers of the ANS and other stress-related biological and subjective markers. In addition, we will test whether changes in these markers of stress mediate the effects of the music-listening interventions on perceived pain. We will apply a laboratory-based, experimental paradigm for the induction of acute pain (i.e., cold pressor test) at baseline, post, and follow-up, as well as intermittently during the intervention period.

Considering the complexity in design, assessments, and procedure and the relative lack of conclusive previous findings, we consider the current study a preliminary, though extensive, pilot trial. The results of this pilot randomized controlled trial (pilot-RCT) will be highly informative for the design and evaluation of subsequent large-scale trials.

This pilot-RCT targets the following main hypotheses:

1. Listening to researcher-selected frequency-modulated music and self-selected unmodulated music will result in stronger increases in pain tolerance and stronger decreases in perceived pain intensity from baseline to post-intervention compared to listening to researcher-selected unmodulated music.
2. Stronger decreases in biological and subjective markers of stress from baseline to post-intervention are expected in the researcher-selected frequency-modulated music and self-selected unmodulated music-listening conditions than in the researcher-selected unmodulated music-listening condition.

Since there is no previous literature indicating a superiority of researcher-selected frequency-modulated or self-selected unmodulated music, we will test these comparisons in a two-sided manner.

3. Changes in pain tolerance and perceived pain intensity will be mediated by changes in biomarkers of the ANS and subjective stress.

In addition to these main hypotheses, we will examine whether reductions in measures of pain perception and markers of stress persist until the follow-up assessment (4 weeks after the post-assessment) aiming at investigating the potential intermediate stability of the effects.

Moreover, we plan to conduct additional exploratory analyses in order to unravel further health benefits as well as mediating and moderating factors in association with the music-listening interventions. For example, previous music research indicates that music interventions might improve sleep quality (85), reduce fatigue (86, 87), and enhance mood (88). Moreover, empirical evidence underlines the role of music-induced emotions and memories (26, 89), perceived musical valence and arousal (38, 57) as well as liking of and familiarity with the music (31, 90, 91) among other music-related aspects for the effects of music listening on perceived pain. Moreover, person-specific characteristics such as cognitive style of music listening (92, 93) and music-related mood regulation strategies (94) have been suggested to influence measures of pain perception and markers

of stress (82, 95). Consequently, the current study aims at investigating following additional questions: are the expected pain- and stress-reducing effects stable after cessation of the interventions? Do the interventions benefit further health-related parameters, such as sleep and fatigue? What roles do music-induced perceptions (i.e., emotions, memories, chills), perceived music attributes (valence, arousal), changes in mood states, as well as liking of and familiarity with the music play in relation to measures of pain perception and markers of stress? Do the habitual cognitive style of music listening and music-related mood regulation habits moderate the effects of the music-listening interventions on measures of pain perception and markers of stress? In order to investigate these additional questions, we will assess a comprehensive set of tertiary variables.

METHODS

Study Design

The study is a laboratory-based, (double-)blind, randomized controlled trial with three parallel arms: frequency-modulated researcher-selected music, unmodulated researcher-selected music and unmodulated self-selected music. Double blinding with respect to frequency modulation will be achieved in the researcher-selected music conditions, and participant blinding will be ensured regarding frequency modulation within the self-selected music condition. **Figure 1** displays the study flow chart.

Overall, 90 participants (30 participants per intervention condition) will attend a baseline assessment, followed by 10 sessions of music listening conducted within 3 consecutive weeks. Finally, post and follow-up assessments will be conducted. We do not anticipate protocol modifications. Nevertheless, if any trial modifications should be considered necessary, all changes in design, measures, or eligibility criteria will be recorded in the online protocol registration entry and will be included in the final manuscript for journal submission.

Following the study preparation phase (April–November 2016), recruitment and testing started in December 2016 in Marburg, Germany. Due to the move of our lab from Marburg, Germany, to Vienna, Austria, recruitment and testing needed to be paused as of January 2018 for 9 months. Testing continued in October 2018 and is presumed to be accomplished in December 2022.

Study Setting and Procedure

All 13 appointments (baseline, 10 music-listening sessions, post-intervention assessment, follow-up assessment) will be held in our laboratory. Since previous research indicates that chronobiological rhythms influence perceived pain and stress parameters (96, 97), the appointments will be scheduled exclusively between 12 and 6 p.m. The 10 music-listening sessions (intervention period) will be scheduled within 3 consecutive weeks. Baseline and post-assessments will be held as closely in time as possible to the first and last music-listening session, respectively. Some degree of variability between participants will

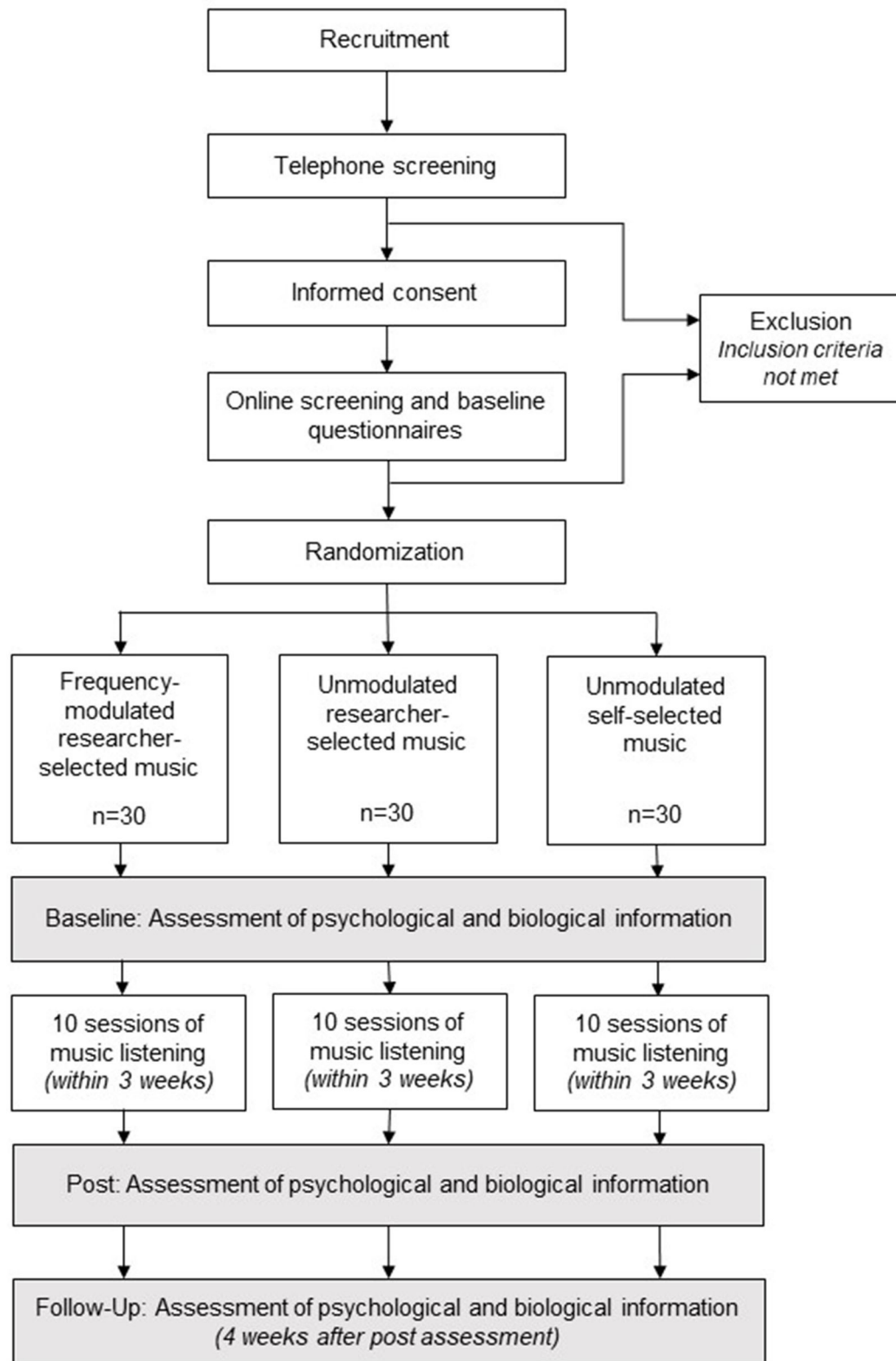


FIGURE 1 | Study flow diagram.

BOX 1 | Instructions for study appointments

- No intake of analgesic medication on days of study appointments
- No use of body lotion or other fatty agents in the chest area (before the appointment) to minimize artifacts in ECG recordings on days of study appointments
- No consumption of alcoholic and/or energizing beverages or food, no smoking, no excessive exercise or relaxation techniques (i.e., meditation, yoga) for at least 1 hour prior to study appointments
- Wearing of comfortable clothing during appointments.

be accepted in order to better enable participants to fit the large number of appointments into their daily schedules.

After a telephone-based screening and upon inclusion, participants will be scheduled a baseline appointment and receive an email with instructions that they are asked to comply with in order to prevent any interference with behavioral and physiological measures (see **Box 1**).

Participants allocated to the self-selected music condition will also receive an email attachment instructing them to compile 120 min of their favorite music pieces. This self-selected music compilation should be brought to the first baseline assessment on a portable device and handed to the examiner. At the end of the baseline appointment, the examiner and participant arrange further appointments for the subsequent 10 sessions of music listening within the next 3 consecutive weeks.

At the beginning of each appointment, participants will be asked to indicate whether any of the behaviors mentioned in Box 1 (drinking alcoholic or energizing beverages, smoking, etc.) apply. Additionally, the examiner will document whether participants state being in a currently stressful phase (i.e., exams), had poor sleep quality or short sleep duration during the previous night, or have any current illness. Affirmation of intake of analgesic medication at baseline, music-listening sessions 1, 3, 6, 10, post-, or follow-up assessments will lead to rescheduling of the respective session since acute pain will be induced at these appointments. The detailed protocol and timeline for baseline, post, and follow-up appointments is displayed in **Figure 2A**, the protocol and timeline for music-listening sessions 1, 3, 6, and 10 is depicted in **Figure 2B**. The examiner will be blind regarding frequency modulation and will be in charge of instructing the participants during the course of the study. An independent second scientific staff member, unblinded with regard to intervention conditions, will be in charge of adjusting the music delivery systems (described below) according to the respective music-listening intervention. This person will not interact with the participants face-to-face at any time.

Study Population

Eligibility criteria are age between 18 and 35 years, body mass index between 18.5 and 30 kg/m², fluency in speaking and reading German, and ability to attend our laboratory for 10 appointments within 3 consecutive weeks. Participants of both genders will be included (15 women and 15 men per group).

The following exclusion criteria are specified to ensure an accurate delivery of the music-listening interventions:

- Perfect pitch
- Music-related studies (i.e., university level education) or profession
- Impairment of hearing capability (e.g., chronic/acute tinnitus, hearing loss).

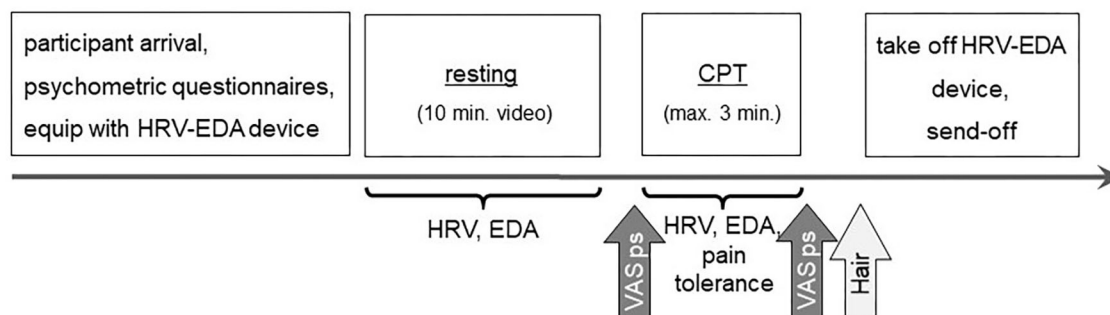
Additionally, since our primary and secondary outcome measures are susceptible to a range of lifestyle factors and health conditions (98, 99), and in order to reduce any potential risk related to participation in the study, the following further exclusion criteria will be applied based on participant self-report:

- Cardiovascular disease
- Artery occlusive disease
- Hyper-/Hypotension
- Diabetes
- Extreme visual impairment
- Chronic pain condition
- Raynaud syndrome
- Irregular menstrual cycle
- Pregnancy or breastfeeding
- Inability to refrain from smoking for more than 2.5 h
- Regular and problematic alcohol consumption
- Regular intake of pain medication and/or psychotropic drugs
- Mental disorders: current major depression/anxiety disorder; current eating disorder or eating disorder within the past 5 years, current substance abuse or substance abuse within the past 2 years; current or previous psychosis, schizophrenia, or bipolar disorder
- Premenstrual syndrome
- Inability to self-identify as a man or woman.

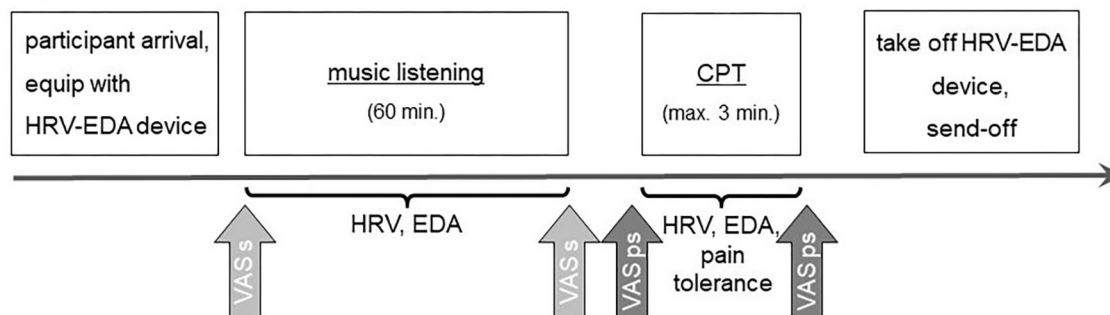
Recruitment, Screening, and Consent

Participant recruitment will be conducted by advertising on public notice boards, internet classified ads, social media sites and via announcements in university classes. The study will be presented to the public as “Music for stress management: A music-based intervention study,” and a study email address will be given for contact purposes. Interested potential participants will be asked to send an email including their telephone number in order to establish a first contact.

A two-step screening approach will ensure that only healthy participants are included. First, prospective participants will complete a telephone-based screening interview to check for inclusion and exclusion criteria with regard to medical conditions and lifestyle factors. Thereafter, the detailed study information and an online link to confirm or decline study participation will be sent to the positively screened participants. In the case of confirmation, participants will be emailed a subsequent link leading to an online survey including a battery of questionnaires with further in-depth inclusion and exclusion criteria. If participants screen positive for depression, pre-menstrual syndrome or any psychiatric disorders apply [either based on self-report within the telephone screening or based on the online questionnaires, e.g., Patient Health Questionnaire (100),

A

Protocol and timeline at baseline, post, and 1-month follow-up. Heart rate variability (HRV) and electrodermal activity (EDA) are collected during a resting period and the cold pressor test (CPT). VAS ps = Visual analog scales for pain intensity and momentary stress. Hair for the analysis of cortisol is collected at baseline and follow-up only.

B

Protocol and timeline at music-listening sessions 1, 3, 6, and 10. Heart rate variability (HRV) and electrodermal activity (EDA) are collected during music listening and the cold pressor test (CPT). VAS s = Visual analog scale for stress, VAS ps = Visual analog scales for pain intensity and momentary stress.

FIGURE 2 | Protocol and timeline for study appointments: **(A)** baseline, post, and follow-up, **(B)** music-listening sessions 1, 3, 6, and 10.

Beck Depression Inventory-II (101), Premenstrual Syndrome Questionnaire (102)], they will be excluded from the study. If no exclusion criteria apply, participants will be randomly allocated to one of the three music-listening interventions, and the baseline appointment will be scheduled. The informed consent obtained online will be corroborated by a personal signature at baseline. Participants will be compensated for completion of the study with 80 €. In the case of pre-mature termination of the study, participants will be compensated proportionally.

Randomization

We will use a block randomization stratified by gender using the blockrand package (103) and the statistical software R, version 3.4.2 (104). Block lengths will vary randomly between 3, 6, and 9. The randomization procedure will be performed by an independent researcher unrelated to the study. The resulting 90 computer-generated notes stating participant gender and

experimental condition will be placed into separately sealed envelopes and stored in a locked cabinet. Upon inclusion of a new participant, the project coordinator will draw an envelope containing the note with the respective condition to which the included participant will be assigned. This information will be shared with the scientific co-worker who will be in charge of setting the music-delivery systems (see below) during the course of the intervention period, but not with the experimenter.

Blinding

To ensure that all participants across all conditions have similar beliefs in terms of treatment expectancy, participation in the study (as stated in the study information) implies random assignment to either frequency-modulated or unmodulated music, irrespective of selection of music (researcher- vs. self-selection). The modulation of frequencies in our intervention is not or only barely audible as confirmed in a pilot study conducted

in our own lab. Therefore, participants will be unable to detect whether the music they listen to is frequency-modulated (or not), and we will check participants' assumptions concerning their assigned condition at the end of the study (as described below).

With regard to frequency modulation in the researcher-selected conditions, the participants and the examiner (who will be in charge of instructing and interacting with the participants throughout the study sessions) will be fully blinded. Similar to participants in the researcher-selected music conditions, participants in the self-selected music condition will expect to hear either frequency-modulated or unmodulated music. Due to technical constraints, however, frequency modulation will not be applied in this study arm and participants will be exclusively listening to unmodulated music. In this case, the examiner interacting with the participants will be aware of the fact that no frequency modulation will be applied. Consequently, apart from the examiner's and participants' awareness of researcher-selected vs. self-selected music, the study features a double-blind design (examiner and participant) with regard to the frequency modulation within the researcher-selected music arms and a single-blind design (participant only) with regard to the self-selected music arm. The scientific co-worker who will be in charge of the music-delivery systems and administering the correct music intervention to the participating subjects will be fully aware of the respective conditions. Moreover, the study coordinators will also be unblinded since they will be in charge of assigning participants to examiners and scientific co-workers. Neither scientific co-workers nor study coordinators will interact directly with the participants.

Debriefing

At the end of the post-assessment, participants will be asked to indicate which condition they believe they were allocated to (i.e., frequency-modulated or unmodulated music) in order to check if blinding has been successful. After termination of the study (i.e., after the completion of the follow-up assessment), participants will be debriefed with regard to their intervention allocation. They will be further debriefed with regard to the study goals and the fact that no frequency modulation occurred in the self-selected music-listening condition. In the case of premature study termination, participants will be debriefed accordingly.

Music-Listening Interventions

Each of the three music-listening interventions consists of 10 sessions of music listening within 3 consecutive weeks. There is no pre-defined minimum number of sessions per week in order to ensure integration of the intervention into participants' schedules. We chose a highly concentrated number of intervention sessions since we assume a dose-dependent effect on measures of pain perception and markers of stress (38, 105). Each music-listening session will encompass 60 min of music listening and 10–20 min for additional data assessments before and after music listening. Participants will receive the intervention individually. During music listening, each participant will be in a reclined position on a lounge chair and will listen to the allocated music via headphones.

Frequency-Modulated Researcher-Selected Music

Frequency modulation and music pieces used in this arm are comparable to the procedures of applications of AVWF-based music interventions in previous clinical studies (74, 75). Six different mixes of music pieces are chosen that cover a wide range of genres such as classic, instrumental, pop, rock, and world music (see **Box 2** for details). Three of these mixes are compositions of known artists of which two also contain vocals. The remaining three of the music mixes are instrumental music pieces that were directly composed, recorded, and provided by the developer of the AVWF method. Four of the six mixes will be presented repeatedly within the 10 music-listening sessions. Each mix has a length of 60 min. According to the AVWF method, the applied music is modulated within the audible frequency range of 50–4,000 Hz via a software system. This involves filtering the harmonic overtones of low frequencies of the music pieces presented in music-listening sessions 1–7. In sessions 8–10, modulation will be additionally applied to frequencies in the high spectrum. The modulated music will be transferred onto a music delivery system (described below) which is equipped with hardware components and additional modulating features, increasing the magnitude of modulation from session to session. This treatment is based on the assumption that listening to music modulated in the low- and high-frequency spectrum improves stress regulation and benefits the ANS via indirect stimulation of afferent and efferent nerves within the auditory passage (106).

For persons with average hearing ability, the frequency modulation is typically not detectable according to the AVWF developer. We conducted a pilot study with a convenience sample of 10 healthy subjects (seven women, three men, all psychology students) in order to test whether participants would be able to guess correctly if they listened to frequency-modulated or unmodulated music. We randomly assigned participants to one of the two conditions (5 per group) and chose a composition of classic instrumental music that was self-composed by the AVWF developer for both conditions. Moreover, for the frequency-modulated music condition, we decided to apply a modulation stage that would be usually played during the sixth session (i.e., advanced modulation of frequencies compared to the first sessions). Participants listened to the respective music for a duration of 20 min in sitting position via headphones. Afterwards, they filled out a paper-pencil questionnaire asking them (a) to indicate whether the music they listened to was presumably frequency-modulated or unmodulated and (b) to estimate how confident they feel in their answer on a VAS ranging from 0 to 100%. One participant did not provide answers, leaving data from nine participants for evaluation. Three participants (33.3%) allocated to the frequency-modulated music made the correct guess with an average confidence level of 50.3%. It is notable that one of these three participants had visual impairments and reported extremely good hearing abilities. Moreover, three participants (33.3%) who were allocated to unmodulated music, guessed wrongly and reported having been listening to frequency-modulated music with an average confidence level of 43.0%. Furthermore, one participant (11.1%) reported correctly having listened to unmodulated music with a confidence level of 15.0% and

BOX 2 | Overview of the music used in each music-listening session in the researcher-selected music conditions.

ML session	Title of Album(s)	Artist(s)
1	Well-balanced	Oliver Shanti
2	AVWF—Classics I	AVWF®
3	QE2; Earth Moving	Mike Oldfield
4	Violine Volume I	AVWF®
5	The Beatles; The Beatles	Munich Symphonic Sound Orchestra; Classic Dream Orchestra
6	See session 1	
7	See session 4	
8	See session 5	
9	See session 3	
10	Guitar I	AVWF®

Participants will listen to a mix of music pieces of the specified album and artist for 60 min in each session. Frequency modulation increases with session number in the frequency-modulated researcher-selected music-listening (ML) condition.

two participants (22.2%) thought they listened to unmodulated music although they had been allocated to the frequency-modulated music, with an average confidence level of 42.5%. In summary, considering the 50% chance of guessing correctly and that those who did guess correctly were not overall confident in their estimation, we concluded from these results that there was no systematic identification of frequency-modulated music, confirming the notion that frequency modulation is typically undetectable.

Unmodulated Researcher-Selected Music

The same music pieces in identical sequence as in the frequency-modulated researcher-selected music condition (see **Box 2**) will be presented to participants. However, music pieces will not be frequency-modulated and will be presented via a music delivery system without modulating features.

Unmodulated Self-Selected Music

Participants will receive an email before their baseline appointment instructing them to compile 120 min of their favorite music, irrespective of genre or other musical characteristics (e.g., tempo, instrumental, vocal). Participants will be assured that their personal selection will not be judged in any way and that they should select songs or musical excerpts that they will be able to enjoy listening to for 60 min. Participants will also be advised to bring their compilation on a portable memory device in mp3 format at their baseline appointment, when the examiner will transfer the music onto the study server and onto the music-delivery system without modulating features for the subsequent 10 music-listening sessions. During the intervention period, the self-selected music will be played in shuffle mode in order to ensure variation across and within sessions. On every occasion, the current playlist will be recorded by the scientific co-worker for our internal records.

Materials and Equipment

Music-Delivery Systems

Music will be presented via two different non-commercially available music-delivery systems [as described in (75)]. One of these will modulate the music via specific hardware components while the other will play music unaltered. Both systems consist of a computer with touch display and an amplifier built into a wooden case and equipped with Windows media player software. All participants will listen to their respective music via over-ear headphones (beyerdynamic, Heilbronn, Germany).

Pain Induction

The cold pressor test (CPT) is a safe, reliable, and frequently applied method to induce cold pain in experimental settings (107, 108). The CPT apparatus consists of a plastic bucket filled with crushed ice and water. A metal grid placed into the bucket holds the ice at the bottom of the bucket, and an electrical pump constantly circulates the water to maintain a constant temperature within the bucket. The target temperature is 1°C and is controlled by a thermometer. Participants are asked to immerse their dominant hand into the water up to their wrist without moving their hand or making a fist. Participants are instructed to keep their hand in the water for as long as they can stand it. In this study, participants will be facing a wall, and the examiner will turn away from the participant in order to eliminate confounding due to social desirability. When extracting their hand from the water, the participants will be asked to signal this verbally to the examiner. After a maximum duration of 3 min, participants will be asked to pull their hand out of the water in order to prevent any potential tissue damage. Moreover, participants do not know after which of the music-listening sessions they will be exposed to the CPT in order to avoid anticipation effects.

Outcome Measures

Course of Assessments

Table 1 reports the assessment schedule for measures of pain perception as well as for biological and subjective markers of stress. See **Figure 2A** for the protocol and timeline for baseline, post, and follow-up appointments and **Figure 2B** for the protocol and timeline for music-listening sessions 1, 3, 6, and 10. In accordance with our hypotheses regarding measures of pain perception and markers of stress, primary and secondary outcomes will be measured at baseline and post-intervention. Furthermore, to investigate the intermediate stability of potential benefits of the music-listening interventions, we have included a follow-up assessment 4 weeks after the post-assessment.

The intervention period encompasses 10 sessions of music listening, each for a duration of 60 min, within 3 consecutive weeks. Music-listening sessions 1, 3, 6, and 10 will also include assessments of perceived pain in response to cold pain (induced via the CPT after music listening) and continuous measurements of biomarkers of the ANS as well as measurements of momentary subjective stress before and after music listening, as well as before and after the CPT. Furthermore, we will assess a range of tertiary variables during the course of the study (e.g., music-induced emotions, mood). The detailed assessment schedule including all

TABLE 1 | Assessment schedule for measures of pain perception and markers of stress.

Measures		Online survey	BL	Intervention period										Post	FU
				M1	M2	M3	M4	M5	M6	M7	M8	M9	M10		
Pain perception	Pain tolerance (seconds)		x	x		x			x				x	x	x
	Perceived pain intensity ^a (VAS)		x	x		x			x				x	x	x
Subjective stress	Momentary stress ^b (VAS)		x	x	x	x	x	x	x	x	x	x	x	x	x
	Chronic Stress (SSCS)	x												x	x
	Stress reactivity (PSRS)	x												x	x
Biological stress markers	HRV ^c		x	x		x			x				x	x	x
	EDA ^c		x	x		x			x				x	x	x
	Hair cortisol		x												x

The intervention period comprises 10 sessions of music listening (for a duration of 60 min each) scheduled within 3 consecutive weeks. Perceived pain will be induced via the cold pressor test (CPT) at baseline (BL), music-listening sessions (M) 1, 3, 6, and 10 (after music listening, respectively), at post, and at follow-up (FU). Music-listening sessions 2, 4, 5, 7, 8, and 9 comprise music listening only and no subsequent pain induction.

^aPerceived pain intensity will be assessed pre- and post-CPT.

^bMomentary stress will be assessed pre- and post-music listening and pre- and post-CPT.

^cHRV and EDA will be derived from resting state (=10 min) at baseline, post, and follow-up; in addition, HRV and EDA will be measured continuously throughout music-listening sessions 1, 3, 6, and 10.

EDA, electrodermal activity; HRV, heart rate variability; PSRS, Perceived Stress Reactivity Scale; SSCS, Screening Scale for Chronic Stress; VAS, visual analog scale.

measured variables (primary, secondary, tertiary) is reported in the **Supplementary Tables 1, 2**.

Primary Outcomes

Pain tolerance and perceived pain intensity: Pain tolerance will be operationalized via time in seconds elapsed from immersion until extraction of the hand during the CPT. It will be recorded by the examiner using a stopwatch. Perceived pain intensity will be measured before and after the CPT via paper-and-pencil visual analog scales (VAS). Participants will be provided with a piece of paper containing the sentence “I am in pain” and a 10 cm line ranging from 0 to 100. They will be instructed to mark the line accordingly (0 = no pain, 100 = maximal pain). Additionally, after the CPT, participants will be asked to report how painful they perceived the CPT to be by responding to the sentence “The test was painful” and again marking a VAS corresponding to their experience (0 = not at all painful, 100 = maximally painful). Measures of pain perception will be assessed at baseline, post, and follow-up as well as after music listening in sessions 1, 3, 6 and 10 (see **Table 1** and **Figure 2**).

Secondary Outcomes

Since stress is a multidimensional phenomenon, we consider biological (autonomic, endocrine) as well as subjective indicators that operationalize different aspects and time-varying characteristics of stress as our secondary outcomes (109).

Autonomic and Endocrine Stress Markers

Heart Rate Variability We will record an electrocardiogram (ECG) at a sampling rate of 256 Hz for the analysis of heart rate variability as an indicator of ANS activity using Equivital EQ02 Life Monitors and Equivital Life Shirts (Hidalgo Limited, Cambridge, UK). Time domain (e.g., square root of the mean squared differences between successive RR intervals, RMSSD; percentage of successive RR intervals that differ by more than

50 ms, pNN50) as well as frequency-domain (e.g., high-frequency band, HF; low- to high-frequency ratio, LF/HF) indices (110) will be calculated. At baseline, post, and follow-up, ECG recordings will take place at rest for 10 min while watching a video featuring landscapes (111) with the sound turned off. At the same appointments, ECG will be additionally recorded continuously (i.e., including pain induction). In music-listening sessions 1, 3, 6, and 10, ECG will be recorded constantly throughout the whole session (i.e., including music listening and pain induction).

Electrodermal Activity Electrodermal activity (EDA) will be recorded at a sampling rate of 16 Hz using Equivital EQ02 Life Monitors and corresponding EQ-ACC-034 EDA sensors (Hidalgo Limited, Cambridge, UK). EDA will be derived from the intermediate phalanx of the middle and index finger of the non-dominant hand using pre-gelled Biopac EL507 electrodes with Ag/AgCl contacts (Biopac Systems Inc., Goleta, CA, USA). Recording will take place analogously to ECG recordings.

Hair Cortisol Cortisol is the main effector hormone of the hypothalamic-pituitary adrenal axis, an important stress-sensitive system besides the ANS. The secretion of cortisol is increased upon exposure to environmental stressful situations and accumulates in hair, reflecting a measure of chronic stress exposure (112). Hair samples for the subsequent analysis of hair cortisol will be taken at baseline and follow-up assessment. Three strands of hair will be taken scalp-near from the posterior vertex region. The most scalp-near 1 cm of hair will be analyzed as this represents cortisol secretion in approximately the last month and thus gives insight into each individual's cumulative stress exposure over the month before sampling. In the context of this study, we will thus be able to assess chronic biological stress in the 4 weeks before baseline and in the 4 weeks before follow-up (reflecting the timeframe between the post-measurement and follow-up assessment).

Subjective Stress Measures

Subjective Momentary Stress We will measure momentary subjective stress via VAS (paper-and-pencil) before and after music listening in all 10 music-listening sessions and before and after conducting the CPT (i.e., at baseline, music-listening sessions 1, 3, 6, 10, post, and follow-up). On each occasion, participants will be asked to respond to the sentence “I am feeling stressed” using a VAS ranging from 0 (not stressed at all) to 100 (maximally stressed).

Chronic Stress We will use the Screening Scale for Chronic Stress (SSCS) comprising 12 items of the Trier Inventory of Chronic Stress (TICS) (113) at baseline, post, and follow-up assessment to measure subjective chronic stress. We have adjusted the reference period in the instructions of the SSCS from 4 weeks to 1 week so that baseline and post-assessment will not overlap. The TICS encompasses 57 items on six subscales (work overload, worries, social stress, lack of social recognition, work discontent, intrusive memories) and will be used at baseline, too.

Stress Reactivity Stress reactivity will be measured by the German version of the Perceived Stress Reactivity Scale (PSRS) (114), administered at baseline, post, and follow-up assessment. The PSRS consists of five subscales (Prolonged Reactivity, Reactivity to Work Overload, Reactivity to Social Conflicts, Reactivity to Failure, Reactivity to Social Evaluation) which can be combined into one overall scale.

Tertiary Variables

Tertiary variables will be assessed throughout the study. These may serve as outcome, control, moderator and/or mediator variables in exploratory analyses related to the study. The assessment schedule for tertiary variables is displayed in the **Supplementary Tables 1, 2**.

In each music-listening session, momentary mood [short scale of the Multidimensional Mood Questionnaire, MDMQ-short (115)] will be assessed directly before and after music listening. Additionally, based on previous literature investigating the impact of music on measures of pain perception and stress, we developed a questionnaire assessing music-related perceptions concerning the respective music that was listened to. The questionnaire will be provided after music listening in each session. It includes questions on music-induced emotions, perceived valence and arousal of the music, music-induced memories, and is also thought to control for mind-wandering or sleeping during the music-listening sessions (see questionnaire 1 in online **Supplementary Material**). Furthermore, musical engagement between sessions will be assessed (see questionnaire 2 in online **Supplementary Material**) as a potential control variable.

At baseline, post, and follow-up assessments, the following additional variables will be assessed via questionnaires: emotion regulation strategies [Emotion Regulation Questionnaire, ERQ (116)], fatigue [Multidimensional Fatigue Inventory, MFI-20 (117)], sleep quality [Pittsburgh Sleep Quality Index, PSQI (118)], and depressive symptoms [Beck Depression Inventory-II, BDI-II (101)]. Moreover, at baseline only, cognitive style

of music listening (Music-Empathizing-Music-Systemizing (ME-MS) Inventory), music preferences [revised version of the Music Preference Questionnaire, MPQ (119)], personality traits [openness to experience, conscientiousness, extraversion, agreeableness, neuroticism, Big Five Inventory-10 (120)], perceived social support [subscale of the Berlin Social Support Scales, BSSS (121)], and menstrual cycle phase (self-report) will be assessed.

For the purpose of monitoring the participants during the intervention period, they will receive paper-and-pencil questionnaires with open-ended questions at the end of music-listening sessions 1, 3, 6, and 10. This will enable them to report whether they felt any disturbances associated with the music-listening session and whether they had any specific thoughts during the CPT in order to control for cognitive pain-coping strategies.

At the end of the post-assessment, participants will receive a paper-and-pencil post-monitoring questionnaire, asking them to indicate which condition (i.e., frequency-modulated or unmodulated music) they believe they were assigned to and how confident they are in this belief. Moreover, participants will be asked whether they perceived increased self-awareness due to study participation, whether any positive or negative changes in well-being, mood, or general health occurred during the course of the intervention, and to state how compatible study participation was with their individual schedules. At the follow-up assessment, final post-monitoring and control questions regarding musical engagement, previous familiarity with and use of music-listening interventions and study conformity will be assessed.

Sample Size Determination

Previous investigations employing a comparable design are lacking and we consider the current study a pilot trial in order to yield sufficient precision for a sample size calculation in a subsequent full trial. Therefore, following the recommendations mentioned in (122, 123) and (124), we decided to test 30 participants in each group. A power analysis using G*Power 3 (125) suggested that this sample size will be sufficient to achieve a medium effect ($f = 0.25$) in a repeated-measures analysis of variance ($\alpha = 0.05$, power $(1-\beta) = 0.80$) with condition as the between-subject factor (frequency-modulated researcher-selected vs. unmodulated researcher-selected vs. self-selected) and time (baseline vs. post) as the within-subject factor. In the case of dropouts, we will continue recruitment and repeat the randomization procedure until at least a number of 30 participants is collected in each group. Thus, the final number of participants in each group might slightly differ.

Statistical Analysis

Repeated-measures analyses of variance will be conducted to test our main hypotheses 1 and 2. Mediation hypotheses will be tested with continuous time modeling procedures. P -values of ≤ 0.05 will be considered statistically significant. Analyses for comparisons between the researcher-selected frequency-modulated and self-selected unmodulated music conditions will be conducted in a two-sided manner. Any further exploratory analyses will be specified in future publications. We will perform

both per-protocol and intention-to-treat analyses. Missing data will be imputed in accordance with (126).

Ethical Considerations

The study has been approved by the Local Ethics Committee of the Department of Psychology of the University of Marburg (2016–27k) and the Local Ethics Committee of the University of Vienna (00331). It is preregistered on ClinicalTrials.gov (Identifier: NCT02991014). The study has begun in Marburg (recruitment and testing from December 2016 until December 2017) and will be continued in Vienna. Potential participants will be informed about the procedure and general aims of the study. Participants will be told that they will be randomly assigned to a researcher-selected or self-selected music-listening condition; they will be told that their respective music might be frequency-modulated. In fact, only researcher-selected music will be frequency-modulated. This deception is necessary to avoid any confounding effects due to expectancy bias. Written informed consent will be obtained from all participants. Participants can withdraw from the study at any time. All participants will be debriefed upon completion of or withdrawal from the study.

Conducting the CPT will be painful. Nevertheless, in order to study effects of music-based interventions on pain, it is essential to evoke pain. Participants can withdraw their hand at any time. Maximum immersion time will be limited to 3 min to ensure the safety of the procedure. To further rule out any risk, persons suffering from conditions like cardiovascular diseases, Raynaud syndrome or high or extremely low blood pressure will be excluded from participation.

Dissemination

Results of this research study will be presented at national and international conferences and published in a peer-reviewed journal. In accordance with the recommendations of the German Psychological Association (DGPs) (127), primary data of this study will be made available in an electronic online repository.

Data Monitoring and Management

A data monitoring committee has not been established since this study is considered to be of minimal risk. Questionnaires that are administered electronically will be saved in a password-protected online database. Paper-and-pencil questionnaires will be stored in a locked cabinet. They will be entered into and saved in electronic files on a regular basis. Access to study data will be limited to research staff who require direct access.

Confidentiality

After inclusion of a new participant (i.e., after online confirmation of study participation and successful online screening), the participant will be allocated a unique study code (sequential number), which will be used for all further study documentation to ensure confidentiality. All data analysis will be performed via study code only. The master files that connect the unique participant codes with sensitive person-related information will be stored separately in a locked cabinet with limited access.

DISCUSSION

Music-listening interventions are an effective adjuvant for the management of pain and stress. There is still uncertainty concerning the role of particular treatment characteristics for the effects of music-listening interventions on measures of pain perception and markers of stress. Some authors argue that certain frequencies in music might be especially useful for alleviating perceived pain and stress, and suggest that musical stimuli should be modulated accordingly. Moreover, some researchers emphasize the importance of high standardization in the design of music-listening interventions and thus argue in favor of music selection by researchers, while others advocate self-selection of musical stimuli by participants to achieve beneficial effects. Furthermore, very few studies have investigated both measures of pain perception and markers of stress together, making it difficult to unravel the potential role of stress in pain perception.

This study aims to determine potential influences of frequency modulation as well as of self- vs. researcher-driven selection of music stimuli in terms of the efficacy in reducing perceived pain and markers of stress. Moreover, while there is inconclusive evidence of direct effects of music-based interventions on pain perception, we seek to investigate whether these effects might be mediated by changes in biomarkers of the ANS and subjective stress and whether this can result in long-term benefits. To address these open questions, we designed a randomized controlled, laboratory-based, double-blind pilot trial comparing frequency-modulated researcher-selected music with unmodulated researcher-selected music. In addition, we included a third condition, in which participants will listen to their self-selected unmodulated music.

Certain limitations of our study warrant consideration. Due to technical constraints, we will not have the opportunity to conduct frequency modulation on music, which is self-selected by participants. Thus, our design does not allow us to test a possible interaction between frequency modulation (modulated or unmodulated) and selection (self-selected or researcher-selected). In addition, the procedures for participants randomized to the self-selected music condition are not entirely comparable to the procedures for participants in the researcher-selected music conditions: participants in the self-selected music condition will spend time and effort in selecting their favorite pieces of music whereas this does not apply to participants in the researcher-selected music condition. In case of significant differences between these two conditions, we cannot completely rule out that the effects depend, in part, on the act of listening to music that one has chosen in an effortful process or other confounding aspects instead of the music *per se*. Examining these mechanisms lies, however, beyond the scope of the current study and has been discussed elsewhere with suggestions on how to disentangle the confounding variables (e.g., increased control over choice, familiarity) in studies investigating self- and researcher-selected music (10). Furthermore, due to the repeated exposure to the CPT, the possibility of desensitization effects needs to be considered. There are not many studies that

investigated intervention effects on cold pressor pain including a repeated exposure to the CPT. However, those that did, found that there were no desensitization effects with respect to pain tolerance (128). Furthermore, considering biomarkers of the ANS, Minkley et al. (129) found no desensitization effects on blood pressure during repeated exposure to the (socially evaluated) CPT, however, desensitization of heart rate was documented. Other studies suggest that ANS activity remains unaffected by repeated exposure to the cold pressor test if the recovery period is long enough (130), which applies to the present study. Importantly, if desensitization effects should occur in the present study, we would assume that these affect participants across conditions due to the randomization and would thus apply to all three conditions. Therefore, systematic differences in pain perception between the conditions should stay unaffected. Moreover, we are only able to investigate the effect of one specific method of frequency modulation. However, we chose to investigate this particular approach, since the AVWF method has been applied in clinical research with patients suffering from stress-associated disorders with first positive results (74, 75). Consequently, it seems a reasonable starting point to test specifically the AVWF method and to investigate its potential to reduce perceived pain and markers of stress in a pilot-RCT. Another limitation concerns the lack of a non-musical control condition (e.g., listening to an audio book or another type of non-musical auditory stimulation). However, adding such a group would be of limited use because this would merely allow us to test whether music *per se* has an effect compared to non-musical auditory stimuli. The effectiveness of music *per se* in reducing pain (14, 17) and stress (39, 41) has already been shown in various studies. Thus, given the costs of including an additional control group, we did not deem such a group necessary in order to answer our study questions within the current pilot-RCT. Furthermore, considering the 4 weeks between the post- and follow-up assessments, it might be argued that this is a rather short timeframe in order to investigate the stability of potential benefits of the music-listening interventions. However, in the context of our study, stability needs to be considered in the context of the experimental nature of the study, such that it might provide initial evidence on how long potential effects could last in healthy participants. If our results reveal preliminary evidence for effects enduring for 4 weeks after termination of the interventions, this would clearly underscore the importance of further examinations of such effects in a subsequent study, which may include chronic pain patients and a longer duration until follow-up assessment. Finally, we will only recruit healthy young adults in a laboratory setting using experimentally induced pain, which obviously differs from real-life pain conditions in several ways, such as the individual's possibility to stop the pain-inducing procedure at any time (19). Thus, the generalizability of findings will be limited. Nevertheless, in order to investigate biopsychological mechanisms, we consider it important to examine potential effects in a well-controlled, highly standardized design first, before conducting studies with clinical populations in more naturalistic settings.

Apart from the above-mentioned limitations, there are several strengths of our study. To the best of our knowledge, this is the first study to test effects of frequency-modulated music vs. researcher-selected music on experimentally induced acute pain using a longitudinal, randomized controlled and double-blind design. By including a third condition, i.e., self-selected unmodulated music we will be able to compare the differential effects of the three music-listening interventions and to fill research gaps that have been documented in the literature (9, 10, 14). Moreover, by including measures of biological and subjective stress, the current study will address secondary variables that have been proposed to mediate the effects of music on pain perception (37, 38). Unlike most previous studies, we will not investigate effects on measures of pain perception during concurrent music listening but will instead test whether even after cessation of listening to music an effect on pain perception can still be achieved. This will enable us to investigate the potential stability of the pain-reducing effects of music listening—at least within an intermediate time-frame, an aspect that is currently highly under-researched (14). Moreover, we will measure a great variety of tertiary variables such as sleep quality, fatigue, mood, and music-related perceptions, allowing us insights into the effects of music on many domains of health.

Consequently, this study is the first important step toward a deeper understanding of the efficacy, the role of treatment characteristics (i.e., frequency modulation, control over selection of music) and biopsychological mechanisms underlying the phenomenon of music-induced analgesia. The results from the current pilot-RCT will provide important information on the differential effects and effect-sizes on perceived pain as well as the potential biopsychological mechanisms underlying the effects of the three employed music-listening interventions on perceived pain. These findings are pivotal for the sound design of future large-scale randomized controlled trials focusing on the effects of particular music-listening interventions for the reduction of pain. In addition, although preliminary, results from this study will be highly informative for the implementation and improvements of music-listening interventions offered to acute and chronic pain patients.

ETHICS STATEMENT

The study has been reviewed and approved by the Local Ethics Committee, Department of Psychology, University of Marburg, Marburg, Germany (2016–27k), and the Local Ethics Committee, University of Vienna, Vienna, Austria (00331). All participants will provide their written informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

AF, MK, BD, DO, and UN designed the study. AF, MK, and RM wrote the first draft of the manuscript. All authors reviewed and edited the manuscript and approved its final version.

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SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: <https://www.frontiersin.org/articles/10.3389/fpsy.2020.518316/full#supplementary-material>

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Caring for Persons With Intellectual Disabilities and Challenging Behavior: Staff Experiences With a Web-Based Training Program

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Background: Clear and effective communication is a prerequisite to provide help and support in healthcare situations, especially in health, and social care services for persons with intellectual disabilities, as these clients commonly experience communication difficulties. Knowledge about how to communicate effectively is integral to ensuring the quality of care. Currently, however, there is a lack of such knowledge among staff working in the disabilities sector, which is exacerbated by challenges in the competence provision in municipal health and social care services. Therefore, the aim of the study was to explore staffs' experience of web-based training in relation to their professional caring for persons with intellectual disabilities and challenging behavior. The intention is to move toward well-evaluated and proven web-based training in order to contribute to competence provision in this specific context.

Methods: Fourteen semi-structured interviews were carried out with individual staff members to gather data regarding their experiences with web-based training in relation to their profession. The collected data were analyzed using qualitative content analysis with a focus on both manifest and latent content.

Results: The staff's experiences with the web-based training program were presented as a single main theme: "Web-based training for staff initiates a workplace learning process by promoting reflections on and awareness of how to better care for persons with intellectual disabilities and challenging behavior." This theme contained three categories which are based on eight sub-categories.

Conclusion and clinical implications: The benefits of web-based training for workplace learning could clearly be observed in the strengthening of professional care for persons with intellectual disabilities and challenging behavior. Staff members claimed to have gained novel insights about how to better care for clients as well as about the importance of interactions in their encounters with clients. Professional teamwork is crucial to providing effective care for persons with intellectual disabilities and challenging

behavior. Hence, future research aimed at investigating the views of other healthcare professionals, such as registered nurses, is recommended to improve the competence provision within municipal health and social care services and thereby enhance the quality of care.

Keywords: professionals, health and social care services, web-based training, intellectual disability, communication, workplace learning, quality of care

INTRODUCTION

Persons with an intellectual disability (ID), particularly those who have moderate or severe intellectual impairment, need professional care and support in their everyday lives. This assertion is in accordance with the Swedish Act Concerning Support and Service for Persons with Certain Functional Impairments (1). Functioning communication is a prerequisite to provide help and support in healthcare situations and is a valuable contributor to better outcomes and improved quality of care (2). Poor communication, on the other hand, is perceived to be a barrier to effective healthcare for both healthcare professionals and persons with an ID (3). Therefore, for healthcare professionals, knowledge about how to communicate effectively is integral to ensuring optimal health outcomes (4). However, persons with an ID commonly experience difficulties with communication to varying degrees (5–8). Such communication difficulties are considered to be among the underlying causes of challenging behavior (CB) in persons with IDs (9–11). It has been shown that the severity of CB is usually proportional to the extent of communication difficulties experienced by persons with an ID (7, 9, 10). CB is often an expression of an unfulfilled desire or a manifestation of an unmet need, both of which typically culminate in frustration. Frustration occurring as the result of clients feeling ignored or misunderstood by healthcare professionals is the most commonly reported reason for engaging in CB (12).

CB describes a wide range of behaviors that may be harmful to both the individuals who engage in such behaviors and to those in proximity to these individuals, including healthcare professionals. Examples of CB include aggressiveness, self-injury, non-compliance in care situations, persistent screaming, and overactivity (13). Healthcare professionals who work with persons with IDs report as CB problems behaviors that they frequently witness or experience and/or struggle to manage (14, 15). The inability to address CB in the preferred manner may cause stress, fear, anger, and a sense of powerlessness among healthcare professionals in residential settings and may increase the risk of burnout (15–17). As a consequence, healthcare professionals tend to develop ineffective coping strategies, like avoidance, which in turn can adversely affect their interactions with persons with IDs and thereby degrade the quality of care the professionals can provide (18). Communication and interaction have been mentioned as key factors for ensuring the quality of care providing by healthcare professionals who work with persons with IDs in a residential facility (19). In

a review, educational training for healthcare professionals in general communication with persons with IDs was identified as a priority (20). Nonetheless, healthcare professionals do not always have access to such training nor to the resources needed to practice skillful communication when supporting persons with IDs (21).

Persons with IDs value the time they spend interacting with healthcare professionals (22). As such, productive conversations with and attentiveness to persons with IDs could help mitigate or reduce the incidence of difficult situations and emotions (23). Therefore, developing knowledge about effective communication and interaction among healthcare professionals would likely have direct, beneficial impacts on the quality of care for persons with IDs.

In a situation report, both the Health and Social Care Inspectorate (IVO) and the Swedish National Board of Health and Welfare stated that there is currently a lack of knowledge required to provide care for the clients among healthcare professionals working in the sector of disabilities. In addition, challenges concerning the competence provision likely further contribute to the lack of knowledge among healthcare professionals. These knowledge deficiencies have negative consequences for clients (24). As good-quality care has been characterized as being person-centered, equal, and safe, promoting more active participation by clients should be prioritized (4, 25). This contention corresponds with the findings of previous research, which have demonstrated that the capacity to communicate one's own will and fully experience participation can improve the quality of life for persons with IDs who live in residential facilities (19, 26). Yet again, knowledge about how to communicate effectively forms the basis of encounters with clients and the quality of care they consequently receive. Communication deficiencies should therefore be clearly understood and addressed, as otherwise they can jeopardize patient safety (25).

More specifically, training in effective communication and interaction with persons with IDs is particularly valuable for healthcare professionals working in residential settings (21, 27), where persons with IDs typically live. However, in Sweden, municipal health and social care services are currently experiencing a shortage of healthcare professionals in general (28) and healthcare professionals working within residential facilities for persons with IDs in particular (hereafter in this work, those healthcare professionals who work in these facilities will be referred to as *staff*). Unfortunately, as a consequence of such under-staffing and associated economic circumstances (24), enrolling current staff in training at off-site locations would adversely impact the quality of care for clients and

Abbreviations: ID, Intellectual disability; CB, Challenging behavior.

would also unduly increase the already substantial workload of non-enrolled staff. Therefore, when planning training programs, a tradeoff between staff training and workload must be adequately considered and addressed. Earlier research has shown that web-based training for staff within healthcare settings can generate good results (29–31). In addition to being able to participate during work hours (31), staff can also overcome access issues in the delivery of training (30).

Internationally, various training programs, for both groups and individuals, have yielded positive outcomes and have had beneficial impacts on the quality of communication between healthcare professionals and persons with IDs (32). In Sweden, a pilot study was conducted on a web-based training program designed to improve the communication and interaction abilities of staff at a residential facility for adults with IDs (33). In this program, a causal modeling approach was applied as the design and evaluation framework (34). The content of the web-based training program was based on a theoretical model that included the assumption that CB is caused by interrupted communication between staff and persons with IDs. By raising awareness and enhancing understanding among staff members of their own values, emotional reactions, skill repertoires, and thoughts concerning individuals with IDs, as well as by expanding their perception of the physical environment and workplace culture in which they operate, the likelihood of achieving and sustaining effective and productive interactions with clients was expected to increase (35). In the pilot study it was shown that web-based training produces beneficial outcomes and is greatly appreciated by the participants (33). Given these previous results, conducting a larger study based on the knowledge derived from the results would greatly benefit communication and interaction between staff and clients with IDs and CB. It is for this reason that the present study was developed and carried out. More precisely, this study sought to facilitate a deeper understanding of staff experiences with web-based training in relation to caring for persons with IDs and CB. In addition, it was hoped that this study would contribute to the further development of the web-based training program with the ultimate aim of achieving more individualized and better-quality care for persons with IDs and CB in the health and social care settings. Therefore, the aim of the current study was to explore staff experiences with a web-based training program in relation to their professional care for persons with intellectual disabilities and challenging behavior.

METHODS

Design

In order to accomplish the study's objective, a qualitative and inductive approach was applied. Data collection was carried out via individual semi-structured interviews. The collected data were assessed by conducting qualitative content analysis with a focus on both manifest and latent content (36).

The Web-Based Educational Intervention

The web-based training program consisted of a text section and a streamed-lecture section. The construction of the program proceeded from the same basis used to develop the pilot

study (33). In the pilot study, the web-based training program was assessed in terms of several topics, e.g., definitions and characteristics of IDs and CB, as well as their possible causes and consequences, including deteriorated mental health. Likewise, the importance of communication and interaction, in addition to the availability of coping and prevention efforts, were highlighted and discussed with regard to the quality of care and support. Similarly, focus was placed on the values, feelings, and abilities of the staff themselves, especially with respect to the workplace culture and physical environment in relation to the development of CB in persons with IDs. To stimulate reflections, cases of encounters between staff and persons with ID and CB were included (33).

The present study differed from the pilot study described above in its enhanced emphasis on streamed lectures and in-depth scientific scrutiny aimed at enhancing learning for a multi-professional group. Both the text section and streamed-lecture section covered a range of knowledge, from basic information to more theoretical discussions and reasoning linked to relevant scientific findings within the area. In total, 12 streamed lectures were included, varying in duration from 4.5 min to 14 min. The text section consisted of three chapters, each of which ended with opportunities for self-reflection. The participants were encouraged to share and discuss these self-reflections with co-workers. Lastly, they were given access to previous research in the area.

Setting

A total of 20 residential facilities for persons with IDs, aged 18 and over, in a medium-size city in Sweden were included in the current study. The staff employed in these facilities worked weekdays as well as weekends, including daytime, evening, and nighttime shifts. The individuals who lived in the facilities (referred to hereafter as *clients*) had access to staff around the clock for support and assistance in structuring their everyday lives, e.g., when to work, when to pursue other daily activities, and when to do housework. Depending on how many clients lived in the residential facility, the severity of their ID, and the time of day, there were between one to six staff members on duty at any time. Most of the facilities had an office with one or two computers, which were used mainly for documentation. These computers were also intended for use in the web-based training program. Some facilities did not have an office; in these facilities, the staff carried out the web-based training in a breakroom.

Most of the facilities held regular staff meetings, e.g., every 2 weeks, with the service manager to discuss ongoing work activities. Some facilities offered a web-based introduction for new employees; otherwise, no regular training programs for the staff were conducted.

Procedure and Data Collection

Two of the co-authors (CA and HA) attended the workplace meetings in which the web-based training program and subsequent interviews were introduced. All staff members who were permanently employed in the facilities were offered the web-based training program during their work hours. Some facilities

even offered this training to temporary employees. The web-based training occurred from spring 2018 until autumn 2018 after receiving approval from the administration manager and from the service managers of the residential facilities.

After completing web-based training, the participants were once again asked, verbally during staff meetings and in writing by email, to participate in an interview. The informants were either working in the residential facilities or were responsible for providing education and supervision concerning workplace issues with respect to persons with IDs and CB. Fourteen informants (11 women and 3 men) aged 27–55 agreed to participate in the study. Of the nine informants who had received upper secondary school education, five had specialized in the care of persons with IDs. More precisely, one informant had received higher vocational education, whereas the remaining four had received university education in the social sciences. The work experience with persons with IDs ranged from 8 to 30 years.

The semi-structured interviews were conducted by the first author (AT) and two of the co-authors (CA and HA) at a location chosen by the informants. The interviews were based on two open-ended questions: “*What is your experience of attending the web-based training?*” and “*What do you think about the web-based training in relation to your daily work with persons with IDs and CB?*” Follow-up questions were directed in such a way as to encourage the staff to freely share their experiences. All of the interviews were recorded with the permission of the informants. The duration of the interviews ranged from 30 to 77 min (mean = 53 min).

A pilot interview was used to test the efficacy of the interview guide. The results of the pilot interview indicated that only minor changes needed to be made to the interview questions to facilitate more in-depth depictions. Accordingly, the pilot interview and its findings were included in the final analysis.

Analysis

The interviews were transcribed verbatim by the first author (AT). The transcriptions were read as the corresponding audio files were simultaneously played in order to cultivate a better sense of what the informants were seeking to express. Thereafter, the transcriptions were reviewed several times in order to ensure that the full content of the text was comprehensively assessed and its findings were fully elicited (36).

In the following step, all statements that corresponded to the aim of the study were underlined. Meaning units were identified before being condensed and were subsequently labeled with codes, which in this case constituted brief descriptions or essential summaries of the statements. The created codes were first discussed among all the authors and then further developed in relation to the original text, if needed. In the next step, the codes were collated with regard to similarities and differences and were accordingly grouped into subcategories. All of the codes within a subcategory were connected to a common denominator, which was assigned as the name of that subcategory. From these subcategories, the categories were created that represented the manifest content of the data. The analysis process consisted of several iterative steps by which an understanding of the data was gained. Throughout the analysis process, attempts were made to

TABLE 1 | Categories with subcategories and theme as they emerged from interviews with the staff.

Subcategory	Category	Theme
Independence	Web-based training provides freedom but also requires responsibility, both of which affect the learning outcome	Web-based training for staff initiates a workplace learning process by promoting reflections on and awareness of how to better care for persons with IDs and CB
Individual responsibility		
Fundamental prerequisites		
Stimulation of reflections and discussions within the work group	The learning process contributes to generating insights about caring through reflection	
Structured planning to enhance learning		
Gaining of awareness and understanding about caring for persons with IDs and CB	The mutual impact of training and the opinions of staff about learning for the care of persons with IDs and CB	
The pedagogical arrangement		
Perceptions and attitudes about training		

capture the latent content of the data, which was represented by a theme corresponding to the aim of the study (see **Table 1**). The generation of the categories, and single main theme was accomplished cooperatively by all authors.

Ethical Considerations

Approval to conduct the study was obtained from the Swedish Ethical Review Authority, Dnr 35517. In the study, ethical principles were followed in accordance with the Helsinki Declarations (37). Ultimately, the study provided staff with the opportunity to acquire valuable knowledge that would support their work with persons with IDs and CB, thereby improving the clients’ quality of care. The facilities and their staff were provided with all necessary information about the research in writing as well as verbally. Participation was voluntary, and written consent was required from participants before their involvement in the study. The confidentiality of each informant was ensured by removing any information from the data that could be used to identify the participants.

RESULTS

The staff’s experiences with the web-based training program in relation to their professional care for persons with IDs and CB were presented as a single main theme: “*Web-based training for staff initiates a workplace learning process by promoting reflections on and awareness of how to better care for persons with IDs and CB.*” This theme contained three categories: “*Web-based training provides freedom but also requires responsibility, both of which affect the learning outcome,*” “*The learning process contributes*

to generating of insights about caring through reflection,” and “The mutual impact of training and the opinions of staff about learning for the care of persons with IDs and CB.” These categories were based on eight sub-categories (Table 1). Each category and associated subcategories are presented in this work by using quotations to illustrate the subjective experiences of the staff.

Web-Based Training Provides Freedom but Also Requires Responsibility, Both of Which Affect the Learning Outcome

This category encompassed informants’ thoughts about taking part in web-based training during work hours. The informants appreciated the freedom they had to organize their own training sessions. However, they also realized the magnitude of demands placed upon them, as well as their responsibility to complete the web-based training, provided they had access to a device and were reasonably digitally literate.

Independence

The informants appreciated having the freedom to organize their own training sessions; for example, they did not have to be in any particular place to take part in them; a web-enabled digital device was all they needed to obtain access to the training. They also felt free to complete the training at their own pace. As the informants did not need to take other learners into consideration and were not faced with disturbances by others, they could regulate their own training under completely different conditions as compared to a normal classroom education. As one informant mentioned:

“And if it is a (classroom) lecture that just goes on like this, then you can’t pause or go back to write things down, then... you can miss a lot.”

Under traditional training circumstances, informants might sometimes not feel like they wanted to attend courses due to heavy or otherwise incomplete workloads, which would have left them frustrated by the lack of time needed to take part in the course. Being able to choose when to complete the training thus increased their motivation to do so, thereby providing them with better opportunities to implement their training. As one informant remarked:

“Ok, now I cannot take this part, so now I can focus on these here. And then you will go into it wholeheartedly.”

This independent nature of the training also enhanced access to the program for the whole work group, meaning that everyone had the same likelihood of acquiring the requisite knowledge. Accordingly, independence was considered to be beneficial from these points of view.

Individual Responsibility

Individual responsibility was required to complete the training. In other words, each informant had to develop their own plan for completing the training and for ensuring that they finished the training based on their own initiative. One informant described this unspoken responsibility as follows:

“No one telling you what to do... when to do it. You got to take it when you know you actually can...”

The informants drew up a plan in agreement with their co-workers and took turns completing the training program. They each had to find moments in which they could participate in the training, which often took time. It was about undertaking and finishing the training according to each person’s own responsibility.

Fundamental Prerequisites

Some technical concerns were raised about the training. Although most of the informants were familiar with web-based training, some had never before engaged in such training and consequently did not feel very comfortable with computers, requiring additional effort and time to address. During the training, these informants had to ask for help from their younger co-workers. One informant described this feeling as being a burden to others:

“There were some... young people who were high-tech. They just, chop chop! It was almost done, you know? Pressing here and there... and another almost got sweating of the hands, you feel... sweat on your forehead, you know? And you need to ask for help...”

Additionally, some informants also mentioned that it was difficult to find a peaceful place to train and/or gain access to a digital device at the workplace, as most facilities only had one computer for the entire work group to share.

The Learning Process Contributes to Generating Insights About Caring Through Reflection

With the training, the informants were given opportunities for self-reflection and discussion of these self-reflections with other co-workers. They also had the chance to express their thoughts about daily work concerning the care of clients and to receive fresh insights as a result. At the same time, requests were made for additional group discussions, and the desire for better planning to enhance learning among the staff was expressed.

Stimulation of Reflections and Discussions Within the Work Group

Being able to undertake training during work hours was considered beneficial. The participants could pause to consider and express their thoughts about their daily work, often resulting in the generation of novel insights concerning various work aspects. Training amidst everyday work facilitated self-reflection and made it easier to connect reflections and instructions from the training to their actual job tasks. This connection was emphasized by one informant:

“When you do a web training, you usually do it in daily work. Then, reflection may occur more easily...”

Furthermore, the training was conducive to encouraging reflections and spontaneous discussions about how to best care

for clients even within the work group. The informants discussed various training lessons and insights with each other, which in turn prompted interesting and fruitful conversations. By having such discussions with co-workers, the informants could each learn from each other, thereby reinforcing their cohesion and solidarity as a work group.

Structured Planning to Enhance Learning

Comments were made about the need for more supportive planning from the organization to enable training and learning. Further, emphasis was placed on the need for a clearer and more effective training framework. This is because not all of the informants had sufficient time to complete the training. Even when time was allocated by organizations, it differed in duration among the units. Therefore, it was suggested that the training be better planned and streamlined with respect to work schedules; doing so would, according to the informants, help them to stay focused when participating in the training. Moreover, the planning of follow-up training as well as its actual implementation should be more overt, providing equal time for collaborative work and individual training, which would help increase commitment to learning. The absence of follow-up training was noted by one informant:

"The training has a prerequisite that is not used by the workplaces. I have talked to others; no one has felt that you are discussing it in different groups, maybe in a workplace meeting. I think it's sad, I think it is wasteful if you don't..."

The informants emphasized the importance of sharing their experiences with others in a collaborative setting. They believed that knowledge can spontaneously emerge in such settings, and that collaborative discussions might lead to unique combinations of knowledge.

The Mutual Impact of Training and the Opinions of Staff About Learning for the Care of Persons With IDs and CB

This category included informants' reflections on the impact of the training on themselves as well as their opinions about the learning required for completing their daily work with respect to caring for clients. The informants were pleased that issues pertaining to difficulties they experienced in their daily work with clients had been brought to light. Their increased understanding of clients also made them feel more confident in their encounters with the clients. The arrangement of the training components and the relative amount of time allocated to each were considered well-balanced and appropriate. That said, some were of the opinion that the training could be extended to cover a greater range of needs on various levels. Likewise, there was agreement that the content and lessons provided by the training could be more tangible.

Gaining of Awareness and Understanding About Caring for Persons With IDs and CB

The training and its set-up encompassed the knowledge needed by the informants to handle the types of CB they faced in

their everyday work. The informants felt strengthened by the training, as it gave them the opportunity to review their previous knowledge. The level of the training program was considered acceptable for new temporary staff, and even for staff originating from foreign countries, for whom it was regarded as especially valuable. The training could then be more effectively absorbed. All of the informants received the exact same content and knowledge, which they used to discuss and argue about their different views, about which one informant remarked:

"At my level, I think it's just right; it's just good for me. We are different. I have Swedish as the second language."

Since the training, problems in their daily work have inevitably surfaced, and the informants have expressed appreciation that their profession was finally receiving adequate attention. Their feeling of being exposed to violence in their daily work, for example, was validated. They gathered the courage to talk openly about it, such as the following informant:

"... and I think that is part of the training, that it is... that you dare to lift it. I feel that way."

After undertaking training, the informants' understanding of client behaviors was enhanced. They realized that some of these behaviors were not caused by them, by what they had said or done in problematic situations. In this way, they felt more confident about their encounters with clients. Their increased awareness and understanding also changed the ways in which they worked with the clients.

The staff desired training so they could acquire greater knowledge and receive advice that would help them identify concrete solutions to existing problems in the daily care, for instance problem with self-harm. They also wanted to learn additional strategies that would help their clients. This concern was stressed by one informant:

"... as he who banged his head against the wall and the wardrobe doors,... if you could find some strategy to change that behavior to something else... less harmful..."

The informants were hopeful for more training as a result of experiencing web-based training first-hand.

The Pedagogical Arrangement

The training arrangement and its various components were considered to be well-balanced and appropriate. Likewise, the design offered many ways to assimilate the training which was considered pedagogically. Some informants found that pleasant simply sitting there and listening to the streamed-lectures while others preferred to read the texts by themselves. At the same time, concerns were raised about the content and lessons, which informants thought should be more tangible. A concern was also raised about the presentation of the content, which some informants thought should be better designed to capture the interest of participants and provoke novel thoughts and curiosity. The informants preferred for the lecturer to speak more vividly

about the topic and not place too much text on a PowerPoint presentation. An alternative, such as showing some pictures to better explicate the lessons, was considered.

Some informants expressed the desire for a better division of training components and a reduction in the number of components overall. Doing so would, according to these informants, make it easier to accurately perceive various aspects of the training. Take the following thought expressed by one informant:

"... and you have finished this part and still have all these left... you almost get tired of seeing how much you have left to go through.... the movies talk about the same thing a lot; why not merge into a few instead of so many?"

Moreover, mixed activities, e.g., text and streamed lectures, could be better integrated with some reflection questions or cases. Likewise, including more concrete issues associated with the daily work with which informants engage would help them to understand underlying theory and connect it with their job duties.

Perceptions and Attitudes About Training

Some informants expressed concern that the training did not meet their needs and expectations. These informants went on to state that they were not concerned about potential threats and violence in their residential facility and therefore did not require training on such issues. As one informant commented:

"I think the arrangement was great. You could certainly have used it, if we had a lot of threats and violence, then you can work with that,... but right now we do not have that... So it is a little difficult. Otherwise, it was great."

Volition and interest on the part of individuals were essential, as was the opportunity to be involved. Some informants claimed that they already possessed sufficient information about the topics presented in the training, as they had been working in the sector for years. Sitting in front of a computer was tiring, some said, but they simply had to accept the development. Some informants went on to reveal that the staff tended to get stuck in their work methods, and that not everyone was comfortable with the changes.

Web-Based Training for Staff Initiates a Workplace Learning Process by Promoting Reflections on and Awareness of How to Better Care for Persons With IDs and CB

Overall, the web-based training program for staff initiated a workplace learning process by promoting reflections on and awareness of how to better care for persons with IDs and CB. The staff claimed that they had gained novel insights into the profession and into the caring process for persons with IDs and CB. Opinions about clients and CB changed somewhat, and the staff were inspired to adopt new ways of working. For instance, they allowed themselves to take a step back, giving clients the room and time to express themselves when they were experiencing an emotional outburst. At the same time,

the explicit need for prerequisites, such as access to a device and learning-supported planning, was expressed. Furthermore, staff members called for the expansion of training to better meet the needs of staff, such as methods for dealing with clients who engage in self-harm. Also, informants claimed that more effort was needed to work with the understandings and the attitudes of staff, and that the importance of learning and knowledge as integral components in the care of clients should be further emphasized. Healthcare organizations could play a key role in this process by announcing and encouraging training, which could in turn promote greater commitment to training among their staff. These factors were considered essential to training and to assisting staff in acquiring a more useful knowledge base.

DISCUSSION

The aim of the present study was to explore the experiences of staff with a web-based training program in relation to their professional care for persons with IDs and CB. Our findings showed that the program initiated a workplace learning process by promoting self-reflections and awareness of how to better care for persons with IDs and CB. The staff claimed that they gained novel insights concerning the care of their clients. For instance, some staff members realized that stepping back and giving clients room and time to express themselves when they are experiencing an emotional outburst can ultimately benefit interactions. They were also inspired by the new knowledge they obtained concerning the dynamics underlying CB. The web-based training program strengthened the ability of staff to meet the individual needs of persons with IDs and CB. Furthermore, staff members called for the expansion of training to better meet the needs of staff, such as methods for dealing with clients who engage in self-harm. Also, informants claimed that more effort was needed to work with the understandings and the attitudes of staff, make it clear that learning and knowledge were integral to the care of clients and should as such be further emphasized. Healthcare organizations could play a key role in this process by announcing and encouraging training, which could in turn promote greater commitment to training among their staff.

The results of this study demonstrated how staff members realized that stepping back and giving clients room and time to express themselves when they are experiencing an emotional outburst can ultimately benefit interactions. Communication and interaction have been mentioned as key factors for healthcare professionals who work with persons with IDs in a residential facility, ensuring the quality of care (19). Therefore, educational training for staff in general communication with persons with IDs is a priority (20). In addition, one prior study revealed that CB could predict emotional exhaustion and was correlated with increased stress and burnout rates among staff, which were in turn associated with relative levels of commitment by staff to their work. Therefore, the importance of interventions that enable staff to better manage CB among their clients should be stressed (14). This emphasis is congruent with findings from another study on nurses who work with people with IDs (38).

The informants reflected on and reasoned about the opportunities and challenges entailed by their work and with

regard to web-based training. Additionally, they mentioned benefiting from many novel insights about the mutual impact between training and staff members' own opinions in relation to attaining knowledge required for their profession. These aspects are further discussed below.

In this study, web-based training seemed to have had a stimulating effect on workplace learning. Carrying out the training in the workplace triggered self-reflections on and discussions within the work group that generated insights into their own profession. The results of this study also showed that more effort was needed to understand the attitudes of staff, and that it was important to stress the integrality of learning and knowledge in the care of clients. Healthcare organizations could play a key role in this process by announcing and encouraging training, which could in turn promote greater commitment to training among their staff. Van Woerkom and Poell stated that workplaces constitute a learning environment due to the opportunities they offer for combining formal education with informal learning, individual efforts, and teamwork. Furthermore, workplaces enable exchanges between novices and experts (39). By participating in activities and interactions in the workplace, various kinds of ongoing learning arise (40). Learning comprises two elements: a social process that occurs in interaction with the environment, and an inner psychological process that transpires within individuals (41). Hence, sharing self-reflections with group members in addition to individual study is essential for stimulating and consequently extracting knowledge from training. This process was also demonstrated in another study in which the outcome of web-based training in combination with group-based discussions was compared to web-based training alone. Both groups gained significant knowledge from the training. The group that, in addition, could discuss the client scenarios of its members and continue to promote its most productive ideas reported having better training outcomes and improved practices compared with the group that experienced only web-based training (42). This demonstrates the importance of both individual processes and larger interactions with one's social surroundings, a consideration that should be included in planning as well. In this study, close attention was paid to how to enable both individual and the social processes but, judging from the results, further developments should focus on optimizing the effect of social interaction. Arranging discussions with supervisors to clarify the connections between the training and the daily practices could increase learning among staff even further.

As our results showed, the independence offered by web-based training made it easier for many informants to complete their training. A similar result was also found in an earlier study that revealed the flexibility of web-based courses in allowing participants, especially adult learners, to choose when to start and complete certain assignments (43). At the same time, web-based training places greater emphasis on the personal responsibility and accountability of participants. This dimension was illustrated by Federman (44), who stated that e-learners are free to decide the pace and timing of their training and are as such ultimately key to their own training. As the web-based training in the current study was completely self-regulated, it was crucial for

participants to be willing and motivated to take responsibility for themselves in their training. For some, it was not easy to use a computer; hence, their training did not proceed as smoothly as it did for other informants. Furthermore, access to the devices needed for the training was not always optimal in the workplace. In this respect, there have been warnings about the implications of the unrestricted introduction of information technology into the educational context in recent years. In this view, greater use of information technology in educational settings will not necessarily improve the quality of education—quite the opposite, technology is likely to exacerbate social inequality by disenfranchising those with less access to digital devices and/or less training in the use of such technology (45). Our results indicate that far more attention should be paid to overcoming the abovementioned obstacles. Doing so would especially benefit staff within municipal residential care services. Besides, as shown by our results, not everyone prefers web-based learning. Other studies have indicated that students who like web-based learning will likely receive more effective instruction than those who dislike it. Thus, each student's preferred mode of learning should be taken into consideration (46, 47). We should keep this in mind when offering competence provision by way of web-based training. Nevertheless, the informants in the present study agreed that the job of caring for persons with IDs is not easy to perform, and that more knowledge is thus needed in health and social care services. The informants also found it regrettable that accessibility to education and training within the sector has been reduced in recent years due to financial circumstances. Finally, research on designing learning through supportive web-based lectures has only just begun (48), and as such it would be wasteful not to look for opportunities to make use of the potential of such technology in competence development for the benefit of health and social care services in municipalities.

The informants in this study shared their thoughts about web-based training in relation to their own needs and everyday work. Some found the training to be helpful, strengthening them as professionals and making them more confident in their encounters with clients. In another study, reflections, and discussions in connection with training were considered to be related to local resources, beliefs, and methods participants would likely choose to improve work pathways (42). These considerations are in agreement with the basic assumptions concerning web-based training in the current study. One assumption was that by working with the staff's own values, and when accompanied by the cultural and skill repertoires of the staff, interactions with clients would be improved (35). This effect was identifiable in statements made by the informants in our study. The informants appeared to be more confident in their encounters with clients, and their interactions with clients with regard to the basic conditions of person-centered care and the fundamental idea of promoting clients' participation in and influence over their own care were enhanced (25). Person-centered care is based on the fact that clients are people who have their own wills, abilities, and needs. In addition, the capacity to personally relate with clients, i.e., forming a partnership with clients for the furtherance of care, has been emphasized (49). Fredriksson proposed that communication in

a care context is the basic prerequisite for understanding the patient's experience of their own reality. Hence, it has enormous significance in a complex world. Besides, communication enables the development of productive relationships between staff and their clients, which in turn permits a higher degree of well-being for both parties (50). Persons with IDs value the time they spend interacting with healthcare professionals (22). As such, productive conversations with and attentiveness to persons with IDs could help mitigate or reduce the incidence of difficult situations and emotions (23). Confident encounters would constitute the foundation of such partnerships, in which clients could receive the support they need and staff could provide the support as intended, which would in turn cultivate the partnership even further. Consequently, it is our opinion that web-based training can create the partnerships required for person-centered care. The provision of person-centered care may also culminate in better well-being and job satisfaction among professionals working with persons with IDs (51). These researchers remind us that considering the welfare of healthcare professionals is equally crucial, as they might otherwise experience significant work stress and increased rates of burnout (51).

In contrast, concerns were raised in this study about the quality of training, which did not meet some informants' expectations. Accordingly, suggestions were made for improving the design and procedures of the training. Some informants believed that they did not need the topical knowledge offered by the program, or they were already well-informed about such topics. However, Damschroder et al. argue that the capacity to meet the different knowledge needs in large, heterogeneous groups which itself is a challenge. The complexity of this issue shows to increase as the number of potential organizational targets or people increase (52). This finding is in line with the results and contexts of the present study. Even though the units were all municipal residential facilities for adults with IDs, they nonetheless diverged with respect to direction of ID. The clients also varied in terms of age, severity of ID, and so on, meaning that the extent and severity of CB also differed widely among them. Furthermore, differences with regard to staff members' backgrounds and predispositions, e.g., education, work experience, sense of responsibility and motivation, can also play a key role in this connection. Fulfilling all the requests made within a single training session might be difficult, and as such further development and customization of the training program is warranted.

Nonetheless, knowledge is, to a certain extent, about cognitive growth, which depends not just on knowing more but also on restructuring what is already known in order to make connections with new forms of knowledge (53). Moreover, knowledge does not exist in objects or events themselves but rather only emerges in our descriptions or analyses of such objects or events (54). Based on these arguments, knowledge generated from the web-based training program in this study constituted knowledge only to the extent that participants actively, cognitively worked with it and established connections between it and (restructured) prior knowledge, which is known as the acquisition process (41). Only then does progress in

learning truly arise. Without these consciously applied activities, there would only be "*a lot of trees but no wood*" (53). Further, learning demands the mobilization of mental energy. Everything we learn also has an emotional side, on which both the acquisition process and the learning outcome depend (41). Illeris propose in his research that adults typically react with resistance to learning when they are faced with pressure or forced into learning courses for which they subjectively cannot see the point or in which they have no interest, or when other, subjectively unacceptable conditions apply (41). This statement is in accordance with the findings by Luceys study that shows that useful knowledge applicable to the learner's current career, along with interesting course materials relevant to real-world issues, are motivating factors for adult learners to actively pursue training (43). In addition, organizational supports appear to be relevant for improving learning outcomes (42). Previous studies have illustrated significant differences in perceived workplace learning support via participant reports from different occupational groups. Higher-status occupations offer a workplace environment that is more conducive to learning than that of lower-status occupations (55). These aspects must be addressed and overcome to fully develop the competence provision and counteract potential negative consequences. Only then can the quality of care in municipal health and social care services for persons with IDs and CB be substantively improved.

Methodological Considerations

Efforts were made to ensure the trustworthiness of the research data by abiding by the three crucial aspects of *credibility*, *dependability*, and *confirmability* in the different stages of the study. Interviewing individuals who have first-hand experience with a phenomenon and are thus able to accurately discuss it in detail increases the *credibility* of the study (56). Likewise, choosing informants of various genders, ages, and experiences can more comprehensively address the research questions by approaching them from a variety of angles (36). In this study, all of the informants, who constituted a mix of men and women, participated in the web-based training program. One informant was also of foreign descent. The informants were of mixed age, represented a variety of educational levels, and had varied durations of work experience with persons with IDs. As such, this sample might reflect contemporary variations in the current healthcare sector. Interview questions were first tested through a pilot interview, which has been described as enhancing a study's *credibility* (57). The fact that the interviews were conducted by three researchers could be considered a limitation in terms of *dependability*, as follow-up questions could have been asked in various ways depending on the divergent subjective traits of each researcher. Conversely, employing three researchers may have in fact captured useful variations in the experiences of the participants (58). Similarly, throughout the analysis process, regular discussions on various issues were held between all researchers in the author group until consensus was reached. This process was undertaken to manage our pre-understandings and mitigate our underlying subjective biases, thereby preventing them from adversely impacting our interpretations (56). Such pre-understandings and biases emerge

out of lessons and experiences tied to one's profession, subject area, educational background, and other types of training. Therefore, assembling a multidisciplinary team helped us to manage such underlying assumptions. Ultimately, it is the voice of the participants that should be emphasized, as doing so greatly improves the *dependability* of the study. All authors were involved in the analysis of the results in this study. The transcriptions were read as the corresponding audio files were simultaneously played in order to cultivate a better sense of what the informants were seeking to express. We took notes, for instance, about silence, laughter, and gestures, which were included in our interpretations of the informants' statements. Doing so likely enhanced the *confirmability* (57) of our research. While organizing and grouping the data into subcategories and categories, the first author (AT) repeatedly reviewed all the previous steps to identify all meaning units, sometimes even in the original interview text. This was done to ensure, as much as possible, that the content was not taken out of context, which is a consideration to which a researcher should pay particular attention during the analysis process (58).

An interview is an exchange of views between two persons who talk about a topic of mutual interest; the knowledge that consequently arises is thus constructed in and by the interaction between these parties (58, 59). The topic in this case was the evaluation of web-based training, about which the informants shared their experiences in interviews with the researcher who developed the training program. This knowledge could have been perceived as a mental obstacle to the informants, who may not have felt free to express themselves fully. To overcome this obstacle, strenuous efforts were made to encourage the informants to share their experiences with training, both positive and negative, as honestly and comprehensively as possible.

CONCLUSIONS AND CLINICAL IMPLICATIONS

The benefits of web-based training for workplace learning clearly included the strengthening of professional care for persons with IDs and CB. The staff claimed to have gained novel insights about how to care for clients as well as about the importance of interaction in encounters with their clients. For instance, they allowed themselves to take a step back, giving clients the room and time to express themselves when they were experiencing an emotional outburst.

Our findings illustrate the complexity of providing staff training for the workplace through web-based training program. Beyond the benefits of web-based training for workplace learning, some challenges also emerged. We conclude that web-based training, workplace organization, and individuals' opinions each have an important impact on the learning outcome. To reach the best possible outcome, however, resources need to be invested in all three parts concurrently. This knowledge can contribute to the development of competence provision in municipal health and social care services more generally, where

similar circumstances in terms of a notable downward trend in competence provision prevail, a pattern which could ultimately jeopardize the quality of care.

In addition to knowledge, cooperation in both healthcare and social services was also highlighted in order to improve care for persons with IDs and CB, by Swedish Association of Local Authorities and Regions (60). In order to better meet their needs, professional teamwork is critically important. Hence, future research should investigate the views of other healthcare professionals, e.g., registered nurses, to further improve the competence provision within municipal health and social care services and thereby improve the overall quality of care. This approach would enrich our knowledge and understanding of how the competence provision could be enhanced to provide the best possible care for vulnerable groups in our society.

DATA AVAILABILITY STATEMENT

The datasets presented in this article are not readily available because of the participants' requests for confidentiality. Requests to access the datasets should be directed to correspondent of this article.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by Swedish Ethical Review Authority, Dnr 35517. The patients/participants provided their written informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

AT contributed to data collection, data curation, data analysis and interpretation, as well as to drafting the article, critically revising the article, and obtaining final approval of the version to be published. CA and HA contributed to the conception of the work, to data collection, to data analysis and interpretation, to critical revision of the article, and to obtaining final approval of the version to be published. AE-B contributed to data analysis and interpretation, to critical revision of the article, and to obtaining final approval of the version to be published. All authors contributed to the article and approved the submitted version.

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Parents' Experiences of Receiving Professional Support Through Extended Home Visits During Pregnancy and Early Childhood—A Phenomenographic Study

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Background: While becoming a parent can be challenging for all, it can particularly be challenging for those parents and children who are in a vulnerable situation—e.g., in families whose members have problems related to health, relationships, or socioeconomic status. It is essential for health care professionals to identify the more vulnerable families at an early stage. Home visits are one cost-effective way of identifying and supporting such families. This study describes the parental experiences of an intervention that involves professional support in the form of extended home visits. The aim of the study is to describe the parents' understanding of their experiences of receiving professional support through extended home visits both during pregnancy and the first 15 months of their child's life.

Methods/Design: A phenomenographic approach was used. Semi-structured interviews were conducted with 12 parents who had received the intervention. The interviews were analyzed using the seven-step phenomenography model described by Sjöström and Dahlgren.

Results: The following three descriptive categories emerged from the analysis: (1) *conceptions concerning the meaning of the physical environment*, (2) *conceptions concerning extended home visits promoting feelings of self-confidence in the parental role*, and (3) *conceptions concerning extended home visits promoting parental participation and relations*.

Conclusion and Clinical Implications: Extended home visits as a form of professional support appear to promote parental self-confidence in parenting ability, giving parents a feeling of security that facilitates conversation with professionals. Children and their entire families had natural roles during home visits, which allowed the children to behave more characteristically. Furthermore, the home visits were understood to facilitate social support through social activities at the child health center as well as integration into

Swedish society for migrant parents. Professional support should be adjusted to the unique individual needs of parents, which demands a variety of supportive interventions—for example, reorganizing one or two of the regular clinical visits currently being scheduled as home visits instead.

Keywords: mother, father, labor, parental transition, child health care nurse, midwife, nurse, social service

INTRODUCTION

While being a parent can be challenging for anyone, it is especially so for parents and children who are in a vulnerable situation—for example, in families whose members have problems related to health, relationships, or socioeconomic status. In Sweden, there is free professional support available for expectant and new parents at both individual and group levels. Professional support is provided for parents and their children during pregnancy and until the child's school age. Access to high-quality family planning services is fundamental for realizing the rights and well-being of women, men, and children (1). The antenatal and child health service program in Sweden is based on the Conventions on the Rights of the Child (2), maintaining a focus on the child perspective and the child's best interest.

It is essential to identify the more vulnerable families at an early stage. Home visits represent a cost-effective way of identifying and supporting such families (3–5). Home visits can help strengthen relationships between parents and children, children and child healthcare (CHC) nurses, and parents and CHC nurses (6). Home visits provide opportunities for professionals to pay attention to the environment in which a family lives in, making it possible for them to increase their understanding of the family and to support the family's unique needs (7). Furthermore, extended home visits can strengthen parental knowledge, skills, and motivation related to parenting and are favorable for the family's health and function—supporting children during both childhood and adolescence (3). Previous research has reported that home visits provide early, individual, and family-centered support (8), which strengthens both the self-confidence and social networks of parents (9). For instance, it has been found that parental confidence, knowledge of social services, and local family resources can be strengthened for migrant fathers (10). In addition, home visits have been shown to reduce the incidence of child abuse (11).

Most expectant parents have both positive and negative feelings connected to the role changes encountered during the transition from one stage of life to the next (12). Seay et al. (13) defined positive parenthood as a continuous relationship between parents and children that includes care, nurture, teaching, training, and leadership as well as communication that consistently and unconditionally secures the needs of the child. The transition to motherhood is considered to be a pivotal and paradoxical life experience for women, which entails the processing of existential questions such as what the meaning of life is and what makes life worth living (14). Men's transition to fatherhood seems guided by the social context in which they live and work as well as by their personal characteristics. Men

struggle to reconcile their personal and work-related needs with those of their new families (15). Expectant and new fathers may lack relevant information, role models, or guidelines to help them during the transition to parenthood and the fathering role (16). Resilience refers to a person's long-term ability to handle change and continue to develop, which is of great importance in parenting (17). Bäckström et al. (18) reported that childbirth and the transition to parenthood have a positive impact on the abilities of parents to cope with life.

In Sweden, midwives are independently responsible for managing healthy pregnancies (19). Midwives at antenatal units offer expectant parents six to nine antenatal visits (20), which can be described as health check-ups for detecting any pregnancy-related complications (19). Moreover, individual support needs of parents are meant to be identified during these visits, especially in terms of parents who are showing signs of mental and social illness, which may make it challenging for them to fulfill their upcoming parental role (19).

When a baby is born, its family is entitled to CHC. In Sweden, this area is staffed by professionals, such as child health nurses, who provide families with access to physicians, psychologists, dieticians, social workers, and speech therapists (21). The goal is to promote child health by providing health examinations, guidance, and vaccinations for all children as well as parental support. Additional goals are to monitor the mental health of parents, strengthen social relationships in the family, and facilitate responsive parenting (22). Child health nurses first meet the children and their parents upon birth and the families receive a total of about 13 visits throughout the first 6 years of their children's lives. Of these visits, two are home visits (the first one and the one that occurs when the child is 8 months old), while the remaining visits take place at a CHC center.

In most Western countries, professional parental support is offered to expectant parents within antenatal care and to new parents within CHC. Professional support—promoting the parental role construction—provides guidance for the parents and a safe growing environment for the children while also developing a trusting relationship and can facilitate the transition to parenthood (23). Bäckström et al. (24) reported that professional support contributes to expectant parents' mental preparedness for both childbirth and parenting. In a review of effective new-parenting interventions, Gilmer et al. (25) showed that multiple approaches are of value when they allow expectant and new parents' access to information or education at a time and in a format that suits them. In Sweden, there are also so-called family centers that offer professional support coordinated at the central level in the municipality. It is a collaboration that includes open preschool, antenatal health, CHC, and social services

focused on promotion (22). Open preschool is a unique form of preschool because the children attend it with their parents, it costs nothing, and no prior registration is required. Visitors choose when they want to come and go. The organization of the family centers is based on a national strategy for community assistance and is intended to support parents in their parenthood (26). The Swedish social service is a municipal administration ordered by the municipality's social committee and regulated by the Social Services Act [(27): 453]. The primary purpose of social services is to promote the foundation of democracy and solidarity, as well as people's economic and social security, equality in living conditions, and active participation in social life [(27): 453]. Family supporters working in social services are responsible for protecting children from growing up in poor conditions and must do so through outreach activities.

In Sweden, the goal is to create societal conditions for good and equal health throughout the population [(26): 131]. However, there are substantial health inequalities in the country (28). Children's health and well-being are affected, for example, by their home environment, parents' health, and social relationships (29). Today, antenatal and CHC services reach almost all pregnant women and parents with a newborn child in Sweden—nevertheless, some parents need more professional support. Welsh et al. (29) showed that interventions in family settings are successful in building the strengths of children and supporting parenting, which may have positive outcomes on child health, both universally and within disadvantaged groups. During the first 15 months of a child's life, the parental transition to parenthood is shaped (30). From a health equity perspective on early childhood development, Barboza et al. (4) reported that home visits can strengthen the roles and relations within a new family unit. Pålsson et al. (31) argued that cross-sectional collaboration between professionals possessing complementary knowledge may be one way to resolve issues lacking topical skills. Furthermore, introduction to different professionals could increase the parents' awareness of how professional support can be accessed both before and after their baby is born. To the best of our knowledge, there is a lack of research on how the skills and experiences of expectant and new parents can be strengthened during their parenthood *via* collaboration with professionals in antenatal health, CHC, and social services. Hence, this study aimed to describe the parents' understanding of their experiences of receiving professional support through extended home visits during pregnancy and the first 15 months of their child's life.

METHODS AND DESIGN

This study was derived from an intervention initiated in the *Reinforced Parenting—Extended Home Visits* project. This intervention included professional home visits to parents during pregnancy and the first 15 months of parenthood. It is described in more detail below.

In order to answer the aim of the study, we used a qualitative method and an inductive and phenomenographic approach. Qualitative research is used to gain an understanding of how groups of people describe a phenomenon. Data are

usually collected in a natural setting that is sensitive to the people and places under study (32). Both deductive and inductive approaches can be used in qualitative research. For the current study, an inductive approach was employed to allow the facts to be acquired from the participants' narratives (33). Phenomenography is suitable when conducting research on a broad range of various experiences for a specific phenomenon (34). Using the phenomenographic approach allows for investigating the different ways in which people make sense of, experience, and understand phenomena. The intention is to discover the underlying structure of variance in the perceptions of a phenomenon rather than the phenomenon's core—the latter being the focus of other qualitative research methods (34). The phenomenon examined in this study was parental understanding of their experiences of receiving professional support through extended home visits during pregnancy and the first 15 months of parenthood.

Intervention

For the intervention, public antenatal, CHC, and social services introduced extended home visits for parents in two regions in southwestern Sweden. This home visit service was conducted by professionals—e.g., midwives working within antenatal care, district nurses working in CHC, and family supporters working in social services. The two regions were chosen for the intervention because they generally included parents from a lower socioeconomic status and with higher professional support needs that were determined according to the Care Need Index (35), which is a social deprivation index. In the two regions, there were also well-functioning family centers, which provided a valuable aspect for the intervention. These family centers included antenatal and CHC centers and social services that practiced mutual cooperation. The development of the intervention was based on the Swedish national strategy for community support and assistance to parents in their parenting [(26): 131]. The aim of the intervention was to strengthen the self-confidence of parents and to promote their trust in antenatal care and CHC as well as social services. Furthermore, the intervention aimed to promote equality and participation among the parents and to identify families with extra professional support needs at an early stage.

The intervention consisted of extended home visits for expectant and new parents. Participants were consecutively selected for the intervention because the recruitment process was tailored to a specific period (May 2018–May 2019). In total, 100 children were estimated to be born within the setting during the specified time period and, therefore, 100 families were targeted for the intervention. The inclusion criteria were that the parents lived in one of the two included regions and that they were expecting their first child to be born in Sweden (i.e., the parents could have had another child previously in another country). Midwives who worked at antenatal wards within the regions asked the parents who met the inclusion criteria about their willingness to participate in the intervention during a prenatal assessment between the 29th and 32nd week of pregnancy. However, the targeted number of families was not recruited because fewer than 100 children were born in the setting during

the chosen period. In addition, the midwives provided different reasons because of which they did not ask certain families about their willingness to participate—e.g., heavy workload or forgetting to inform families about the study. In total, 70 families were informed about the intervention and were invited to participate; 20 refused and 50 agreed to participate. Some of the families that declined to participate explained that they were not in need of professional support in the form of extended home visits. The intervention took place from 2018 to 2020 and the extended home visits provided to the parents participating in the intervention are described in detail in **Table 1**.

The intervention included five home visits between the 34th week of pregnancy and 15 months after birth (**Table 1**). A family supporter working for a social service center participated in each home visit. The five home visits included in the intervention differed from standard care in the following manner:

- 1) The first home visit (in 34th week of pregnancy) was conducted by a midwife in addition to standard care, while the subsequent four home visits were conducted by a child health nurse;
- 2) In standard care, parents are provided a home visit 2 weeks after birth—for the intervention, a family supporter working for social services was present during the standard care home visit 2 weeks after birth;
- 3) At 4 months after birth, the parents who were included in the intervention were provided a home visit instead of visiting a CHC unit, which is included in standard care;
- 4) In standard care, parents are provided a home visit 8 months after birth—for the intervention, a family supporter working for social services was present during the home visit 8 months after birth;
- 5) At 15 months after birth, the parents who were included in the intervention were provided a home visit instead of visiting a CHC unit, which is included in standard care.

Parents who declined to participate in the intervention were offered standard care.

Settings and Participants

The current study was carried out in two regions in southwestern Sweden, which have a population of ~15,000 inhabitants. Parents who met the inclusion criteria and parents who had participated in the *Reinforced Parenting—Extended Home Visits* project were informed about the current study and invited to participate. In total, 40 parents had completed the intervention at the time of recruitment and 12 (transgender) parents agreed to participate in the current study (eight females and four males). The participating parents were 23–57 years of age, seven had a university education, and four were born in Sweden, while the rest were born in Syria, Cameroon, or Morocco. The number of children that the participants had ranged from one to seven. Nine of them were first-time parents, while the others had two to seven children each. The participants comprised parents who participated individually from a parental couple and parental couples in which both parents participated. The participants represented a broad variety of parents who had knowledge about

the topics of interest for this study. Therefore, the number of participants was deemed to be satisfactory.

Data Collection

The responsible managers at public CHC centers gave written approval for parents who took part in the intervention to be asked about their interest in participating in interviews for the current study. A semi-structured interview guide was created, which was initially tested in two pilot interviews in order to explore informant interpretation of the questions. After the pilot interviews, one question was revised to increase clarity. The two pilot interviews were included in the data analysis because the interviewees met the inclusion criteria. Examples of the questions included within the interview guide are: *Could you describe your experiences with the extended home visits? What meaning have the extended home visits had for you?* Examples of follow-up questions are: *Could you describe this further? Could you give an example?* All the interviews were conducted between January and March 2020; three interviews were held with the parental couple, while the other interviews were held with individual parents. The participants could choose whether they wanted to be interviewed individually or with their partner. They were also able to choose the interview setting—in their homes or at the CHC center. Two of the authors (ACF and JP) carried out the interviews. Seven interviews were conducted in Arabic with a professional translator, one was conducted in English, and the rest were conducted in Swedish. The interviews lasted 22–64 min and were all recorded digitally and transcribed verbatim (the transcribed interviews total 66 pages in A4 format). From the interviews conducted in Arabic with a professional translator, the transcriber transcribed the Swedish words. The interview conducted in English was transcribed in English.

Data Analysis

Data analysis was performed by three of the authors in accordance with the phenomenographic approach (34) and the seven-step model described by Sjöström and Dahlgren (36). In the first step (*familiarization*), the transcribed interviews were read several times. Subsequently, the narratives from all participants concerning their experiences of receiving professional support through home visitations during pregnancy and the first 15 months of parenthood were gathered into statements, representing the second step (*compilation*). In the third step (*condensation*), the statements were concentrated to obtain a representative description of the participants' experiences. Similar statements were grouped together in the fourth step (*grouping*), while the groups were compared to find similarities and differences in the experiences in the fifth step (*comparison*). In the sixth step (*naming*), the conceptions and emerging descriptive categories were named, while the logical relationship between the descriptive categories was analyzed in the seventh step (*contrastive comparison*), resulting in a hierarchical arrangement among the categories that was presented as an outcome space. Three of the authors (CB, ACF, and JP) initially participated in each step of the analysis process. Thereafter, all authors discussed the analysis and the

TABLE 1 | Overview of the intervention consisting of extended home visits for parents during pregnancy and the first 15 months of parenthood.

Extended home visit	Time point	Professionals responsible for the extended home visit	Issues brought up during extended home visit
1. To become a parent	Pregnancy week 34	Midwife working within antenatal care, and family supporter working within social services	Relation to and support from partner; social network such as family, friends and significant others; the expected child and her/his needs; first time at home after birth; parenthood; emotional changes/reactions; breastfeeding; and skin-to-skin contact.
2. To meet and receive the child	Two weeks after birth	Child health nurse working within child health care, and family supporter working within social services	The child's sleeping position; safety of the child; the child's eating; how to comfort a sad child; the parent's health and well-being, alcohol and tobacco use; the parental couple relationship; violence in close relations; the parent's social network; child health service and professional caregivers available for the family
3. To be together	Four months after birth	Child health nurse working within child health care, and family supporter working within social services	The child's well-being; routines for the child's eating and sleeping, and language development as babbling and laughing; safety of the child; infections and self-care; the library and children's book; the parent's health and well-being, alcohol and tobacco use; the parental couple relationship; violence in close relations; social medias; child health care and professional caregivers available for the family
4. To lead and follow	Eight months after birth	Child health nurse working within child health care, and family supporter working within social services	The child's language development; daily routines and feelings of security; safety of the child; infections and self-care; dental care; kindergarten/preschool; parental leave; the parent's health and well-being; violence in close relations
5. To be a family	Fifteen months after birth	Child health nurse working within child health care, and family supporter working within social services	The child's eating and sleeping-routines; the child's communication, language development, and digital screen time; what the child likes to do; infections and self-care; the parental couple relationship; the parent's time for own interests; violence in close relations

different steps of the analysis process were repeated to verify the results. All authors contributed with their experiences of qualitative research when discussing the analysis to reach a consensus. The analysis and interpretation of the results were also discussed continually among a group of MSc students during the analysis process. All authors participated in the process of writing the text. The parents' socioeconomic status, gender, birth country, and parity were not generally considered when conducting the analysis—however, when the results showed any participant understanding that only represented a specific group of participants (e.g., mothers/fathers, first-/second-time parents), this was clarified in writing in the results section. Overall, the authors agreed that the participants represented a diverse group of individuals regarding the characteristics mentioned. All data were analyzed in Swedish, except for the interview transcribed in English which was analyzed in English. The authors CB, ACF, and JP checked the transcriptions and the recordings were available during the analysis. No computer program was used for the analysis.

Ethical Considerations

The participants received both written and verbal information about the study before they provided their informed consent to participate. Prior to the interviews, the participants could ask questions about the study. This was done to ensure that the aim of the study was understood and that participation was voluntary.

The study complied with Swedish law and was approved by the Regional Ethical Review Board in Gothenburg (Dnr 2019:03906).

RESULTS

The interviews with the participants were analyzed. Three descriptive categories emerged with their attendant conceptions of receiving professional support through extended home visits during pregnancy and the first 15 months of parenthood (Table 2).

Conceptions Concerning the Meaning of the Physical Environment

The participants conceptualized that, for the extended home visits, the physical environment—the participants' home—was meaningful. This was because they considered their home to be a safe place, which affected the entire family and facilitated conversation with professionals. Furthermore, the home environment affected both the content of the professional support and the participants' conceptions of it. The participants described that the professional support received during the extended home visits facilitated feelings of manageability and meaningfulness as well as a sense of coherence. The first descriptive category consisted of the following two conceptions: (1) *the home environment is a safe place that facilitates*

TABLE 2 | Overview of descriptive categories and conceptions.

Descriptive categories	Conceptions
Conceptions concerning the meaning of the physical environment	The home environment is a safe place that facilitates conversation The home environment creates conditions for the child to have a more natural place in the meeting
Conceptions concerning extended home visits promoting feelings of self-confidence in the parental role	Extended home visits facilitate professional support that reassures the parental role Extended home visits facilitate professional support that is based on the individual
Conceptions concerning extended home visits promoting parental participation and relations	Extended home visits facilitate a close and equal relationship with the professionals Extended home visits facilitate parental participation, togetherness, and integration

conversation and (2) the home environment creates conditions for the child to have a more natural place in the meeting.

1) The Home Environment Is a Safe Place That Facilitates Conversation

The participants conceived the home environment to be a safe place that facilitated their conversation with professionals. The home environment enabled the participants to feel calm and behave more naturally because their home was their natural place in comparison to antenatal or CHC centers or social services, which were considered to be the arenas of healthcare professionals. From the statements, it was clear that the meetings with the healthcare professionals tended to be more relaxed during home visits than at healthcare centers. In addition, the home environment facilitated a more personal feeling, which allowed for more open and permissive conversation. In contrast, meeting professionals at healthcare centers was described as more inflexible and official, which limited the participants' conversation. Altogether, the home environment was conceptualized to convey a calm that allowed the participants to behave more naturally, honestly, and spontaneously—making it easier for them to remember what issues they wanted to discuss. This conception was common among the participants. They described it as a prerequisite for them to be able to receive professional support regarding sensitive or difficult issues, as pointed out by one of the fathers (first child):

When they come to meet me at home, it feels more open. It is more... it is the environment and it is mine, I feel at home... It is easier to answer questions, it is easier to open up, and it is easier for my wife, who thinks it is easier to open up, sort of, when it [the care meeting] occurs at home. That is what I mean by "positive," that it is nice in that manner.

The home environment also allowed for discussions to take place that felt more current at the moment of the care meeting. The participants conceptualized that the conversations with the professionals were more extensive and detailed. They had opportunities to show the professionals things and to talk about what was essential for them in the family's natural

environment. The participants described that extended home visits allowed them to receive professional support in line with the family's contextual circumstances, which facilitated feelings of manageability. This was the case for both first-time parents and parents with other children, corroborated by one of the first-time mothers:

It is good... You remember what you wanted to ask about issues when you are at home and visually see everything.

Furthermore, one of the mothers conceived that home visits provided opportunities for professionals to investigate a child's home environment, allowing them to detect children who are in potential danger:

I also think it's good that the family supporter is involved and that they come home and see a little how it is at home because then, maybe, it is possible to discover if something is not right. Now the visits are scheduled, so that you can prepare your home, but, still, it may be possible to notice a little more warning signals... I am thinking of children who may be in danger... There are four visits instead of two, so you can see it a little easier, maybe, hopefully.

2) The Home Environment Creates Conditions for the Child to Have a More Natural Place in the Meeting

The participants conceptualized that the home environment created conditions for the children to have a more natural place in the meeting. During the extended home visits, the children were in their natural environment and, consequently, acted more genuinely. One of the participants described that she let her child play on the floor during the home visits, which she did not allow the child to do during visits at the CHC centers:

It felt somehow better at home because, when you are at the child healthcare center, you do not let her down on the floor in the same way and she is not allowed to crawl around but, at home, she can lie on the floor... and then they [the professionals] can see... how she moves, compared to when she sits in the baby seat.

Moreover, the entire family (parents, child, and potential siblings) was seen in its natural environment, making the lives of each unique family more visually evident for the professionals. This was especially so for participants with other children. The participants who had other children conceptualized that siblings had a more prominent role in the conversations with the professionals during home visits than during the meetings at healthcare centers. The needs of the entire family became more visible and every individual in the family was given the same important role as the new child, which facilitated feelings of meaningfulness. A non-Swedish-speaking participant described this as follows:

During the first visit, we sat there, my wife and I. They [the professionals] started to tell us how we should handle the newborn child, how we should think regarding the big brother, considering his sensitivity. How we should handle him and how we should, we should see that both children are feeling ok. So, not just the baby. That was important information for us.

The participants described the value of the extended home visits in allowing the professionals to evaluate the children's development in their natural environment. Children were described as showing their true selves to a more considerable extent during the home visits than at visits taking place at healthcare centers. The participants conceptualized that the children played more easily, naturally, and spontaneously; they were not hindered from doing so during the home visits. This facilitated feelings of security among the participants because they knew that the children had been given the opportunity to show their real development. One first-time mother described it as follows:

So, I can imagine that it is more fun for the child, too. That [the child] feels safer. That feels good [for me]. It is really crucial for me that she feels safe, then it becomes more fun if it is possible to have meetings like this, meetings in which she is extra safe.

Conceptions Concerning Extended Home Visits Promoting Feelings of Self-Confidence in the Parental Role

The participants conceptualized that extended home visits allowed professional support that was reassuring and based on the individual. As a result, they felt that their self-confidence in the parental role increased. The second descriptive category contains the following two conceptions: (1) *extended home visits facilitate professional support that is reassuring* and (2) *extended home visits facilitate professional support that is based on the individual*.

1) Extended Home Visits Facilitate Professional Support That Is Reassuring

The participants conceptualized that, during the extended home visits, their parental role was put in its real context and, hence, made more visible to the professionals. The professionals reinforced the function of the home environment and the parenthood provided within it. The participants conceptualized that their daily lives were naturally linked to their parenthood. From this, the professionals could see how the participants' parental role worked for both them and their children, which was considered to be valuable. One of the non-Swedish speaking mothers described this in the following manner:

They also showed me how to put the baby to bed in the first weeks after birth. She [the child] was very sad and just cried at night. They told me: "When you put her on your stomach or next to your chest, she hears your heartbeats"...it was very good and it helped. She slept well afterward.

The extended home visits facilitated the participants' abilities to take in the advice and information provided by the professionals. From the statements, it was clear that—regardless of their gender, Swedish language skills, or number of children—the participants felt that they were seen and cared for as unique individuals. Furthermore, they conceptualized that home visits allowed professional support, which was reassuring and strengthened their parental role. One of the fathers described this:

I feel happiness due to the feeling of security. Moreover, that you feel calm, that it will be ok. There is help to receive. You feel that other persons... will engage with our child. They will help us. They are there for us. We can turn to them when needed.

2) Extended Home Visits Facilitate Professional Support That Is Based on the Parent as an Individual

The participants conceptualized that extended home visits provided room for their individual needs and that the professionals' agenda did not overshadow their needs. Furthermore, they described that extended home visits allowed for a calmness that made it possible for them to share their thinking; also, when they asked questions, there was time for the professionals to listen and answer. The home environment made it possible for the professionals to provide support based on the participants as unique individuals and on the specific requirements that their families had. During the home visits, the professionals brought up issues that were related to the real situation that the family was currently experiencing. One of the participants described, for example, how the professionals recognized the family's dogs during a home visit:

She got to see our dogs and talk a little about them and so on. It [the conversation] was on another level, perhaps.

Home visits also allowed the participants to illustrate points in their home practically (a changing table, for example) and the information that the professionals gave verbally was strengthened when they also showed the parents how to handle an issue (a diaper change, for example). This led to the participants perceiving that extended home visits facilitated their feeling of being well-informed so that they felt prepared, calm, and secure. This was especially so among the non-Swedish-speaking participants, as one of the mothers related:

What was good, really important for me, was that we spoke. She spoke beforehand, gave me information beforehand, so that all information I received was ahead of the visit, so that I felt prepared... That felt important for us, it gave my family and me everything we needed without having to ask for it...so it was super complete.

Conceptions Concerning Extended Home Visits Promoting Parental Participation and Relations

The participants conceptualized that the extended home visits facilitated their participation within the care meeting, their relations with the professionals, and their other social connections (their partner or other parents). The third descriptive category covers the following two conceptions: (1) *extended home visits facilitate a close and equal relationship with professionals* and (2) *extended home visits facilitate parental participation, togetherness, and integration*.

1) Extended Home Visits Facilitate a Close and Equal Relationship with the Professionals

The participants conceptualized that the extended home visits enabled a closer, more personal, and more equal relationship between them and the professionals. The relation to the professionals was described as closer because home visits enabled care meetings to be conducted on a more personal level. This was described as essential by the participants who did not have their families or relatives within a close geographic area:

It felt like personal; it was like a family member coming home to me, a cousin, a family member who asks how I feel... and provides me with support... I have no one here. I have no contacts... It is not easy... It was good for me.

Those participants conceptualized their relationship with the professionals as complementing the absence of their family and social network in some manner. Such a close and personal relationship was seen as valuable support that facilitated feelings of security and togetherness, which was subsequently valuable for them in their parental role:

That was strengthening for us because we are alone in Sweden; we do not have any social network. We do not have our parents here. We are new to this country, so it has been a great support... how to say it, emotionally... So, it has been good support for us since we are alone here.

The participants also conceptualized that the home visits enabled them to meet the professionals on a more equal level than at healthcare units. By “equal level,” the participants were referring to the social equality condition—finding themselves to have the same status and respect as the professionals. This occurred because the professionals came to visit them in their homes, arriving as guests, which established a feeling of the visit being a meeting of equals between the participants and the professionals. The participants also described care meetings at the healthcare units as being implemented with professional authorization that caused an imbalance, where the participant was at a disadvantage. The feelings of equality that arose during home visits made it easier for the participants to ask questions that were perceived to be uncomfortable—questions they may not have otherwise dared to ask at the healthcare center. The participants described that the healthcare centers functioned as a barrier during the care meetings because the participants felt like they were meeting healthcare professionals as authorities in these cases. In contrast, the participants conceptualized that, during home visits, they were meeting a person. This was a common conception among the participants, described by one of the mothers:

It becomes a bit different, when you come into a healthcare environment at the primary healthcare center, it is a bit more... she has working clothes on then and behaves differently, and it is more apparent that she has a professional role in some manner. When she comes to the house, she has ordinary clothes on and it becomes more like if you have a meeting with a person, different, I would say. Yes, it feels more personal.

The participants also described that they did not distinguish between the professionals regarding their assignment. Instead,

the participants conceptualized the professionals—e.g., midwives working within antenatal care, district nurses working within CHC, and family supporters working within social services—as a cohesive group or as a whole.

2) Extended Home Visits Facilitate Parental Participation, Togetherness, and Integration

The participants described that the home environment provided them with opportunities to participate in the meeting with the professionals to a more considerable extent in comparison to meetings with the professionals at the healthcare center. These feelings of participation were based on the feeling of being seen as an individual. In addition, the participants conceptualized a feeling of not only receiving professional support but also of having the opportunity to ask for support more easily than during a care meeting at the healthcare unit. Thus, the participants expressed that they felt free to ask for further support from the professionals during the home visits. A common understanding among the participants was that they felt free to ask for extended professional support, such as extra appointments with family supporters working within social services, during the home visits:

They have told me: “Whenever you need to ask us something, if you need advice or support, we are always here.”

Moreover, a non-Swedish speaking mother described participating in activities for new parents, arranged by professionals at the healthcare unit, to a larger extent after receiving the home visits:

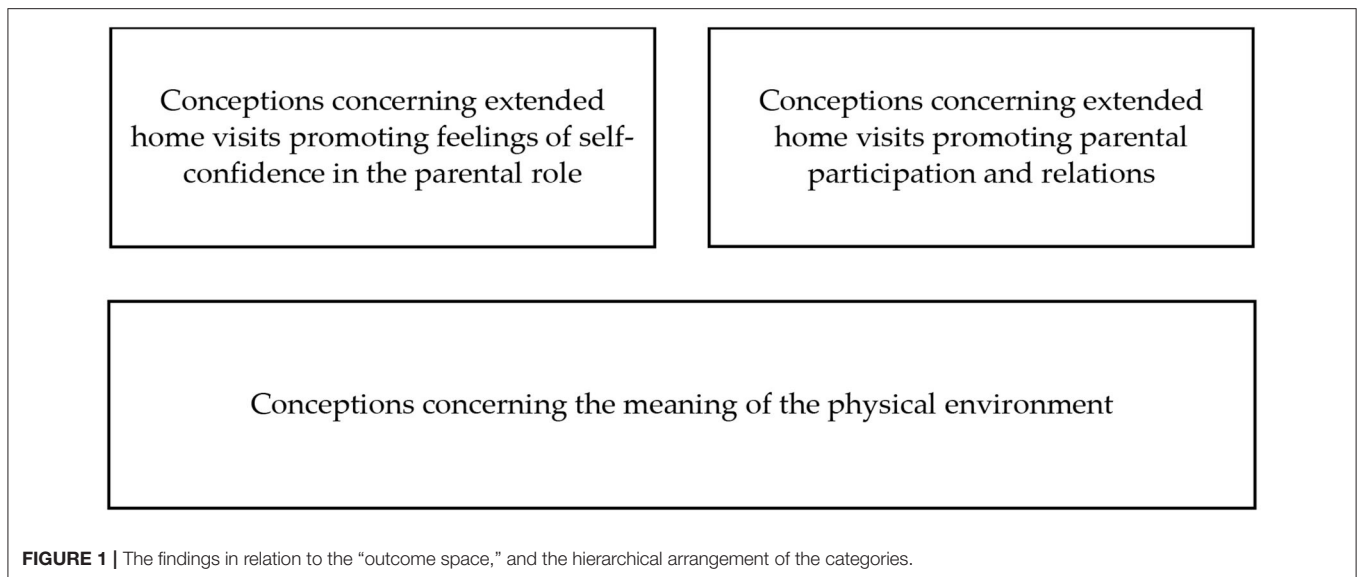
We talked about different activities that we could participate in... they had an arranged activity in the library in which children of all ages could participate. They could listen to someone reading a book. There was also another activity where mothers gather and talk and the children play together... They told me about it, it was something new, and I learned from it.

As a result, the participants described feeling that society engaged with them and provided them with the support they required. The participants who had a migration background conceptualized that the home visits facilitated their integration into the Swedish society because they learned about Swedish society and how to manage parenthood in Sweden.

It is a feeling that society engages with you, that it cares for you. That they will help you. It facilitates the integration into society and you feel welcomed—that you are being supported, that you are able to become integrated. You feel togetherness somehow. You feel so comfortable, relaxing in your home, and they come home to you. So, it makes it more accessible.

The Outcome Space

Using a phenomenographic approach allows for an analysis of the underlying structure of variance in the conceptions of and the relationship between the descriptive categories that arise during data analysis. This relationship is presented in an outcome space, where each descriptive category forms part of a larger whole.



For this study, a hierarchical arrangement of the relationship between the descriptive categories arose and this arrangement illustrates the participants’ understanding of their experiences of receiving professional support through extended home visits during pregnancy and the first 15 months of parenthood. The hierarchical arrangement—shown in **Figure 1**—is based on the theoretical assumption described below.

According to the participants’ understanding of their experiences of receiving professional support through extended home visits during pregnancy and the first 15 months of parenthood, the descriptive category *conceptions concerning the meaning of the place of the meeting* formed the basis within the hierarchical arrangement. The participants considered the home to be a safe place in which to meet the professionals and this affected the entire family. The extended home visits facilitated the participants’ feelings of manageability, meaningfulness, and a sense of coherence. From a theoretical perspective, such feelings promoted the participants’ feelings of strengthened parenthood as well as their parental participation and relations. Subsequently, the second (*conceptions concerning extended home visits promoting feelings of strengthened parenthood*) and third (*conceptions concerning extended home visits promoting parental participation and relations*) descriptive categories were placed above the first descriptive category in the figure that illustrates the outcome space (**Figure 1**).

DISCUSSION

Home as a Safe and Natural Meeting Place

The results from our study reveal that the place in which care meeting occur, as well as their form, seem to influence how parents perceive meaningfulness and manageability of their own parenthood, which also seems essential for their conceptualization of the support they were offered. Parents described that their home environment provided them with a sense of security, and the meaning of the meeting place was

revealed to be the basis of the outcome space of our results. This is in line with earlier research that had described home visits as supporting parents in their parental role because support is applied in a natural environment (i.e., the parents’ home) (4). Leirbakk et al. (7) pointed out that home visits increase the professionals’ understanding of how families handle the challenge of parenthood. Other studies describe the importance of home visits to support the family in lifestyle matters because parents play an important role in children’s health (9). Barboza et al. (4) also described home visits as a way to strengthen relationships within a new family. In line with this, Turnbull et al. (37) described the importance of securing the social situations of families so that they can receive support and be strengthened in their parental role. It is important to remember that, while the results of our study indicate that the home is a safe meeting place, this may not always be the case (e.g., in cases of domestic abuse). However, home visits may offer professionals a broader arena for identifying and supporting the parents and children in these situations, which could be a reason why home visits reduce the incidence of child abuse (11).

The parents participating in our study described that their home meant security for them. In addition, it also meant that the child had a natural place during in the care meeting, which was viewed as essential by parents. Their parental role, as well as the support they needed, became more apparent, positively influencing both parents and children. In line with this, Barboza et al. (4) described that home visits and the home environment are essential aspects of the support provided by professionals for new parents in their parental role. This is because professional support can then be provided in the natural environs of families. Studies have also described home visits as promoting the parents’ ability to ask questions in contrast to meetings at healthcare centers (7, 10), increasing their support concerning their babies’ needs (10). This is in line with Rautio (8), who described home visits as providing a basis for safe and trustworthy relationships with professionals. Parents felt heard

and expressed that professionals had more time in their meetings, giving them a safe arena in which to ask questions. Leirbakk et al. (7) pointed out that all parents need professional support and that seemingly well-functioning parents also need an arena in which they can ask questions. These results point out the importance of creating a space in which parents feel safe to ask any question that will help them develop their parental role. This also implies that extended home visits represent important interventions that should be provided as a regular part of care during pregnancy and early childhood in order to promote self-confidence in parents because this is a challenging time in the life of a parent.

Home Visits With a Focus on the Whole Family

Extended home visits involve an increased focus on the whole family. In the current study, the information that the parents received was described as being appropriately adapted and in line with the family's needs and situation. It was essential for the parents that they also received the information they needed in advance so that they could prepare. These results are in line with Barimani et al. (38), who stated that the relaxed attitude of professionals in meetings promotes the parents' ability to receive the support provided. Their results also stressed the importance of professionals having the time and ability to act reassuringly, allowing parents to raise uncomfortable issues. This, in turn, enabled professionals to provide support in accordance with the unique needs of parents. Reticena et al. (23) described a variety of professional support dimensions, such as promoting the development of the parental role, creating a safe environment for their children's upbringing, and providing guidance in life as parents. Together, these results stress the importance of support for both parents, which is in line with previous research that highlights the value of individual parent communication with the non-birthing parent to support family health and the child's upbringing (39). When planning future interventions for expectant and new parents, both the form of professional support and the types of the actual professionals involved in the provision of this support need to be taken into consideration. In the *Reinforced Parenting—Extended Home Visits* intervention, the extended home visits provided a safe place for parents and an arena in which the professionals were allowed to listen to parents in order to understand their life circumstances better.

Home Visits Promoting Self-Confidence in Parenting

In our study, the participating parents noted that their self-confidence in relation to parenting was strengthened through the reassurance and safety experienced during the extended home visits. They described feeling well-informed and prepared in their parental role, secure in the idea that they could access professional support when they needed it. This is in line with other studies (4, 40) that reported that home visits lead to increased security in the parental role, increased trust in healthcare professionals, and a decrease in visits to the casualty department. In our study, parents also described extended home visits as a form of professional support that was individualized

and reassuring. The home visits established a calm atmosphere that helped parents speak their thoughts. MacKenzie Bryers and van Teijlingen (41) and Wiklund et al. (42) described the importance of professional support adapted to the needs of parents and children and their unique situations. They stressed the importance of having professional support built on continuity. Such individualized support is essential for strengthening the parents' sense of security and safety during pregnancy and in early parenthood because this time of life is challenging. However, professional support should also aim to strengthen social support (43) and, in our study, home visits were also found to promote the idea of parents joining activities with other parents within CHC, thus promoting social support as well. Put together, it is essential to consider these results when care and support for new parents and their children are planned. Extended home visits and support in the parental home environments are likely to strengthen the parents on a more comprehensive level than the results of our study show. For the parents' satisfaction, it is essential that they feel a well-established sense of security in their current situation because becoming a parent is a challenging life event.

Home Visits Creating Mutual Trust Between Parents and Professionals

The results of our study revealed that parents conceptualized the extended home visits as society's interest in and engagement with them as parents and as a family. The home visits were described as a crucial form of professional support, something all parents should be offered. For migrant parents, the extended home visits were seen as helping them with their integration into Swedish society. The parents also described the extended home visits as a form of replacement for the social support they lacked as a result of family and friends living far away. This is in line with Rautio (8), who described that parents need to have a trustworthy and safe relationship with professionals. Burström et al. (44) stated that support from and building relations with professionals are important measures for integration—which means that it is very important to offer extended home visits to migrant parents during pregnancy and early parenthood. In particular, our results show that extended home visits especially promoted social support for migrant parents.

The parents in our study described that a close and more equal relationship was created between them and the professionals through the extended home visits. They also described that increased participation and presence was created. Stubbs and Achat (6) pointed out the importance of the early identification of needs for extended support in order to promote and strengthen the relationship between parents and children, within the family as a whole, and between parents and professionals. Turnbull et al. (37) described home visits as a tool that can be used to gain a deeper understanding of a family's social situation and to secure it. This is in line with Marttila et al. (40), who related the experience of social workers, concluding that home visits allowed them to become better acquainted with new parents and their children, creating a sense of mutual trust. This could be important if contacts were needed later on in a child's life. In

our study, parents did not differentiate between the different job functions of the professionals during home visits, which is essential because parents may hesitate to contact social workers but a visit from a midwife or CHC nurse is expected for childbirth and early parenthood in Sweden. This is especially important because social services provide support, such as family counseling, if parents are having difficulties in their relationships.

Home Visits Promoting Parents' Meaningfulness and Manageability

The results of our study reveal that parents experienced meaningfulness and manageability of parenthood when professional support was provided in their homes. The participants pointed out that the professional support was more evident and that it felt more real when their parental role was actualized in their home environment, which meant that the parents could anchor the support to their lives and proper context. These results are in line with Bäckström et al. (18), who described how a sense of coherence can strengthen the quality of couple relations, which can affect the parents' ability to handle stressful situations and challenges in life. According to Mansfield et al. (45), this ability could be understood as resilience, which refers to a person's ability to handle stress, demands, and emotions as well as to solve problems and be adaptable. According to Masten and Barnes (17), resilience is a long-term ability that aids people in handling changes and continuing to develop. Mansfield et al. (45) conveyed that resilience refers to being able to seek and accept support and to having the ability to create and promote relations. Many of the experiences described by parents in our study could be understood as resilience factors that would strengthen and protect both the parents and the children in a family. The parents noted the importance of social support, of their care for their children, and of receiving support in their parental role during their children's upbringing. They also stressed the importance of professional support concerning parenthood, the child, and society. Earlier research has shown that positive parenthood can be understood as a resilience factor, together with engaged parents and social support in a variety of forms such as family, friends, and society (46). According to Seay et al. (13), positive parenthood facilitates the parents' ability to unconditionally meet the needs of their child. These researchers defined positive parenthood as a continuing relationship between the parents and children that includes care, nurture, teaching, training, leadership, and communication. Earlier research thus strengthens the importance of the results obtained in our study regarding the parents' experiences of extended home visits. Fritz et al. (46) showed that interventions that enhance the life situations of individuals and families—in combination with social support and resilience factors—can contribute to preventing difficulties during childhood. Aronen and Arajärvi (3) stressed the importance of early interventions for promoting health in children, with extended home visits being one example of such early interventions. The results of our study suggest that the parents experienced extended home visits as a form of professional support that strengthened their abilities to fulfill their parental role. It was essential for them to receive

individualized support concerning their specific situations. Professional support for parents needs to adapt to the needs of today's parents.

A limitation of our study could be that some of the interviews were conducted in Arabic, which required an interpreter to be present. Performing interviews with an interpreter could affect the quality of the data. However, our data were rich and varied and provide results that increase our understanding of the parents' experiences of extended home visits. The number of participants was deemed to be satisfactory because our informants had diverse characteristics in terms of age, gender, education level, country of origin, and number of children, which is a strength of our study (47). The analysis focused on parents' understanding of their experiences of receiving professional support through home visits, and parents' socioeconomic status, gender, birth country, and parity were not generally considered, which might be a limitation in our study. Also, further exploration is needed regarding migrant families' needs and understanding of professional support. Phenomenography was considered to be a useful method for this study because it provided us with a broader understanding of the parents' experiences of extended home visits as a phenomenon (34). Another strength of our study was that the analysis was performed in a team and that all authors were engaged in its final steps. However, further studies that utilize various methods are needed in order to further deepen our understanding and develop knowledge of the impacts and benefits of home visits for both parents and children.

Conclusions and Clinical Implications

Extended home visits—as a form of professional support—appear to promote the self-confidence of parents in their parenting ability, giving them a feeling of security that facilitates conversations with professionals. Moreover, parents feel that their children behave more characteristically during home visits because both the children and the entire family have a natural role in the home setting. The results of this study indicate that professional support during home visits is conceptualized as reassuring and individualized, making it easier to understand information and receive support from professionals, thus improving social support through social activities at child health centers. Furthermore, it is also found that home visits may facilitate parental participation and integration into Swedish society for migrant parents. Cooperation between professionals is found to be important. Professional support should be adjusted to the unique individual needs of parents, which demands a variety of supportive interventions—for example, reorganizing one or two of the regular clinical visits currently being scheduled as home visits instead.

DATA AVAILABILITY STATEMENT

The datasets generated for this article are not readily available because we do not have permission to share data. Requests to access the datasets should be directed to caroline.backstrom@his.se.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by the Regional Ethical Review Board in Gothenburg (Dnr 2019:03906). The patients/participants provided their written informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

CB contributed to the study's conceptualization, formal analysis, investigation, methodology, validation, and visualization, as well as to writing the article, which is an original draft. A-CF and JP contributed to the conceptualization, data curation, formal analysis, funding acquisition, investigation, methodology, project administration, resources, software, validation, visualization, and writing of the article. ST and ML contributed to the

conceptualization, formal analysis, validation, and writing of the article. All authors contributed to the article and approved the submitted version.

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To Live, Not Only Survive—An Ongoing Endeavor: Resilience of Adult Swedish Women Abused as Children

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Background: A significant proportion of individuals exposed to maltreatment in childhood adapt positively in adulthood despite the adversities, i.e., show resilience. Little is known about resources and processes related to adulthood that promote resilience. Since women are overrepresented as victims of intrafamilial violence, understanding resilience among adult women is important.

Objective: To explore experiences of resilience among adult women who perceive well-being and well-functioning although being exposed to maltreatment during childhood.

Participants and Setting: This study included 22 women with experiences of childhood maltreatment, mean age of 48 years, living in Sweden.

Methods: Individual interviews were conducted and analyzed according to constructivist grounded theory.

Results: The process of resilience was experienced as an ongoing endeavor to live, not only survive, an internal process that interacted with external processes involving social relations and conditions. This endeavor was built on four interrelated resources: establishing and maintaining command of life; employing personal resources; surrounding oneself with valuable people; and reaching acceptance. These worked together, not in a linear or chronological order, but in up and down ways, turns and straight lines (now and then), through the process from maltreatment to well-being.

Conclusion: Resilience was found to rest on intrapersonal and interpersonal resources. Individual's inherent capabilities can be, depending on life circumstances and available resources, realized in a way that promote well-being and well-functioning despite severe adversities. Therefore, public health initiatives, social services, and policies should provide conditions that help women maltreated in childhood to live fully rather than merely to survive.

Keywords: resilience, well-being, childhood maltreatment, adult women, public health, qualitative

BACKGROUND

Childhood maltreatment, a major public health concern, violates children's rights to health, safety, and development and can negatively affect health and socialization that can last into adulthood (1). Therefore, society must establish and maintain effective initiatives that prevent child abuse and minimize the negative consequences of maltreatment. This strategy requires genuine understanding of processes and resources that promote resilience.

Between 1 and 16% of children in high-income countries are estimated to have been exposed to some kind of physical, sexual, or emotional maltreatment (1). A prior review suggests that in the Nordic countries, about 1% of children have experienced sexual abuse by a parent or a step parent, 3–9% have experienced physical abuse, and 7–12% have witnessed domestic violence (2, 3). Women are overrepresented as victims of all types of intrafamilial violence (1–4). Furthermore, women who experience poly-victimization (i.e., being victimized by more than one person such as parents and partners) tend to have more mental health problems during young adulthood (4). In addition, especially for women, being subjected to violence during childhood increases the risk of being subjected to violence later in life (5, 6). Well-known negative consequences of childhood maltreatment include criminality, mental health problems, and risky consumption of alcohol (1, 7). However, not all children who experience maltreatment experience negative consequences to the same extent. Some adapt positively despite severe adversities—i.e., they develop and display resilience behaviors (8–10). Previous research suggests that of those who experience childhood maltreatment, 15–47% develop appropriate social functioning and good mental health—i.e., 15–47% are assessed to experience resilience. This wide range of resilience rates is potentially explained by the use of different criteria for resilience (11). When studying what promotes resilience, previous research has mainly focused on resources related to childhood rather than adulthood (8, 12).

Originally considered mainly a personal trait, resilience is now considered a dynamic process that embraces individuals' interactions with their surroundings and manifests at different points in one's life (8, 10). The importance of increased understanding of the mechanisms and the resources needed to support resilience has been emphasized as a way to develop prevention practice and policy (9, 10). In childhood, emotional intelligence, problem-solving abilities, effective schooling, and positive relationship with competent and supportive adults have been identified as factors that contribute to resilience (8, 9). However, research regarding resilience resources for adults who experienced childhood maltreatment is scarce (12), but activities that enable victimized adults distance themselves from these adverse experiences and create positive opportunities that enhance their coping strategies seem to promote resilience (9). Furthermore, health-promoting behaviors and social resources in adulthood—e.g., appraisal, belonging, self-esteem, and tangible social support—might buffer negative effects of childhood adversities, including childhood maltreatment (13–15).

In summary, few studies have investigated resilience processes in adults. Given the higher prevalence of childhood abuse among girls, studies of women are especially important, also as more women than men experience mental illness. Because welfare practices and public health policies need a sound knowledge base, studies conducted in national context are needed. Thus, the aim of this study was to explore experiences of resilience among adult women in Sweden who perceive well-being and well-functioning although being exposed to maltreatment during childhood.

METHODS

Study Design

This explorative qualitative study relies in constructivist grounded theory (16). Using purposive sampling, this study targeted women between 30 and 65 years old (i.e., working-aged women), an age when women are assumed to have had a reasonable chance to finish their education, build a family, or in some other way shape their adult life. The initial data analysis and data gathering were conducted simultaneously to allow for adding new themes to the interview guide if needed. Memos were also written after each interview, including the interviewers' summaries and preliminary codes. Constant comparisons were made throughout the process both between the interview notes of the two interviewers and between codes and categories in each step of the analysis. Data gathering was ended when the data were considered rich enough to compile a conceptual framework of the women's experiences of resilience.

Participants

The women were recruited through an advertisement on Facebook with University of Gothenburg as a consigner (see @AWAREstudyGU on Facebook) that began with the following question: Have you been abused or neglected during your childhood? The advertisement was posted for 2 weeks in the Facebook news feed of female users between 30 and 65 years old and who lived in the middle and western regions of Sweden. Women were invited to participate if they were between 30 and 65 years old, had witnessed domestic violence or experienced any kind of physical, emotional, or sexual abuse and/or were neglected by a close adult during their childhood, and defined themselves as experiencing well-being and having a well-functioning life as an adult. The women responded to the advertisement by contacting one of the interviewers (first author or last author) by either e-mail or telephone. The women had the interpretative prerogative of their experiences of both the childhood maltreatment and the well-being/well-functioning when assessing who was to be included in the study. Two women opted out after the initial contact since they reappraised their situation as not experiencing well-being. The final participants included 22 women between 31 and 64 years old (mean age = 48 years). Of these 22 women, 13 described themselves as having been physically abused by their biological, step, or foster father as a child, and nine described having witnessed severe physical violence by their biological or stepfather against their mother. Nineteen described having been neglected by their primary guardian (most commonly

their mother), and this was mainly emotional neglect. Nine had been psychologically/verbally abused by a parent and/or other household member. Five had been raped or sexually abused by their biological father and six by another household member or relative. Therefore, the vast majority described having been victimized in multiple ways as a child, repeatedly and during a substantial part of their childhood. No one described only occasional event of maltreatment.

Data Collection

Data were collected during individual interviews between March and June 2018. All interviews were face-to-face in a place chosen by each woman, most often in a separate room at the University of Gothenburg or Örebro University, but some women chose to be interviewed in their home or at a café. The interviews were structured around three themes. In the first theme, the women were asked to describe how they defined and described their own well-being and well-functioning and why they chose to volunteer for the study. In the second theme, the women were asked to share their adversities in childhood. In the third theme, the women were asked to reflect on their life course and describe what experiences they perceived enabled their journey toward well-being and well-functioning. For example, they were asked to describe particular periods of life, events, persons, and activities that they perceived of as having specific importance. Follow-up questions were asked if needed, but primarily the women were encouraged to share their stories freely. The first and last author conducted 11 interviews each, lasting between 47 and 110 min. The interviews were audiotaped and transcribed verbatim.

Analysis

The analysis was guided by the procedures of grounded theory as described by Charmaz (16). The analysis began during the data collection as the interviewers discussed the meaning of each interview, compared their understanding of the women's life stories and wrote memos immediately after the interviews. After all the interviews were completed, the transcriptions were read and systematically analyzed using the steps of initial, focused, and axial coding as well as constantly comparing the data [see Charmaz (16)]. The analyses were conducted in five steps. In the first step, the first author read and analyzed two interviews conducted by the last author and the last author read and analyzed two interviews conducted by the first author. During the reading the focus was on identifying processes and activities (initial coding) contributing to resilience according to the participants' life-stories from childhood to the day of the interview. To come to consensus regarding the meaning of the data in the first interviews, the processes and activities identified were compared, specifically focusing on their meaning and possible concepts that could capture the meaning. A picture of a pattern of the experiences of resilience started to emerge. In step two, the first and the last author read and analyzed two more interviews, one conducted by the first author and one conducted by the last author. Comparisons were made between the processes and activities identified by the both authors and consensus was reached about the understanding of processes and activities where the meaning was unclear. In addition,

the processes and activities identified were compared to those coded in the two first interviews. During the second step, the codes were sorted into categories to capture different aspects of the resilience experienced (focused coding) in an attempt to clarify the pattern. Next, the procedure was repeated with two more interviews. In the third step, the first author read and analyzed the remaining interviews according to previous procedures and constantly compared this analysis to previously identified codes and categories as well as the emerging pattern. Specific attention was made to processes and activities potentially contrasting or challenging the categories previously constructed and the emerging pattern in order to be open to new aspects or dimensions. In the fourth step, the first and the last author together explored the properties of the codes and constructed subcategories reflecting different dimensions of the women's experiences of resilience (axial coding). In the fifth step, the first and the last author together with co-authors scrutinized the emerging results to make sense of all the processes and activities described. Eventually, the results were compiled into a conceptual framework of women's experiences of resilience explaining their well-being and well-functioning in adulthood despite abuse and neglect in childhood (theoretical coding). See **Table 1** for example of the coding procedure.

Ethics

The study was approved by the regional board of ethical vetting in Gothenburg (dnr: 258-17). After being assigned to the study, the participants were provided written information via e-mail. The same written information was presented during the interview at which time they also could ask questions and, were informed about the possibility at any time to withdraw from the study. These issues were presented before they signed an informed consent document.

RESULTS

To Live, Not Only Survive—An Ongoing Endeavor

During the analyses, an ongoing endeavor to live not just survive emerged as a core process of resilience. Surviving refers to basic needs and managing everyday duties of life. Living, on the other hand, refers to the right to experience joy and create emotional distance from negative childhood experiences by not letting those experiences define one's life or well-being. To live, not only survive incorporates the ability to function well and experience well-being despite childhood abuse, an attitude expressed in the following quotation: "Previously, I just was surviving, now I'm living" (Woman Q).

The core of the resilience processes associated with living not just surviving had to be constantly re-experienced—i.e., it was an ongoing endeavor. Therefore, the core category "to live, not only survive—an ongoing endeavor" captures resilience as a process without a defined beginning or an end: "It has been a fairly long process, so it is difficult to say an exact time, but I see it more as something that continues to evolve all the time" (Woman E).

This endeavor was found to rest on four important types of resources. Not all women described having used all four

TABLE 1 | Example of the coding procedure.

Quotation	Initial coding	Focused coding-category	Axial coding-subcategory
<i>I am happy with myself, and it takes a lot for me to get angry or change that mood, but of course you have to work consciously with it and that, I think, starts with oneself and how one perceives things and chooses to perceive them. If you have that ability then, of course. So, I've probably always emphasized the positive things.</i>	I am happy with myself—I have probably always emphasized the positive things.	Employing personal resources	Embracing the joy of living
<i>And Mom could not cope. And I can see that; I didn't understand it back then. I was pretty angry with her for a while. However, I could see this later on; I understand that she could not cope. He knocked the shit out of her.</i>	I can see that; I didn't understand it back then. I understand that she could not cope.	Reaching acceptance	Finding explanations
<i>After all, I chose a man [...] a man who doesn't keep on rubbing up against me and doing other stuff. I chose a man who wouldn't keep going on with sexual abuse and stuff like that. I chose a man who is calm and caring and careful. Which may have its drawbacks in not being so adventurous [laughter]. But I made a choice there. A safe choice.</i>	I chose a man who is calm and caring and careful.	Establishing and maintaining command of life	Making strategic life choices

types of resources, but all described having used more than one and it was clear that the resources typically enabled each other. Hence, we conceptualized the ongoing endeavor of living, not only surviving, as interrelated parts of a machinery with the different types of resources that drive the process of resilience (**Figure 1**). The resources enabling living are related to the women's intrapersonal efforts as well as interactions with others. These resources are described in the following categories: *establishing and maintaining command of life*; *employing personal resources*; *surrounding oneself with valuable people*; and *reaching acceptance*. These resources trigger or drive one another, but not in a specific order or as a chain of causality.

Although there are limits to how well the process of resilience can be conceptualized as machinery, we believe this metaphor illustrates that the resources can enable each other and that resilience is dynamic rather than static. For examples, *establishing and maintaining command of life* may demand *employing personal resources* and *surrounding oneself with valuable people* who activate a person's personal resources and ultimately *reach acceptance*. Allocating responsibility for the abuse to the abusing parent can help women accept the abusing parent's personal and environmental limitations. Furthermore, the intensity of the different resources varied over different periods of life, and the women described these resources to different extents. For some, the ongoing endeavor of living rather than just surviving began in childhood; for others, an additional trauma or other tough life experiences during adulthood triggered a turning point where they began their journey of ongoing living. For this latter group, after a period of experiencing a relatively smooth life even though primarily in the form of survival, something traumatic happened that urged these women to sort out their experiences and inner chaos:

[I]t has been this process, that you [...] just like you do a puzzle. You find a piece there "ah, okay," and then you find a piece there. And then more [...] that's what it has been like for me – that the more pieces I have found, the greater peace I have found within myself (Woman T).

The next section describes the types of resources and their dimensions in more detail. At the end of the description of each resource, the interrelations to the next resource described is considered.

Establishing and Maintaining Command of Life

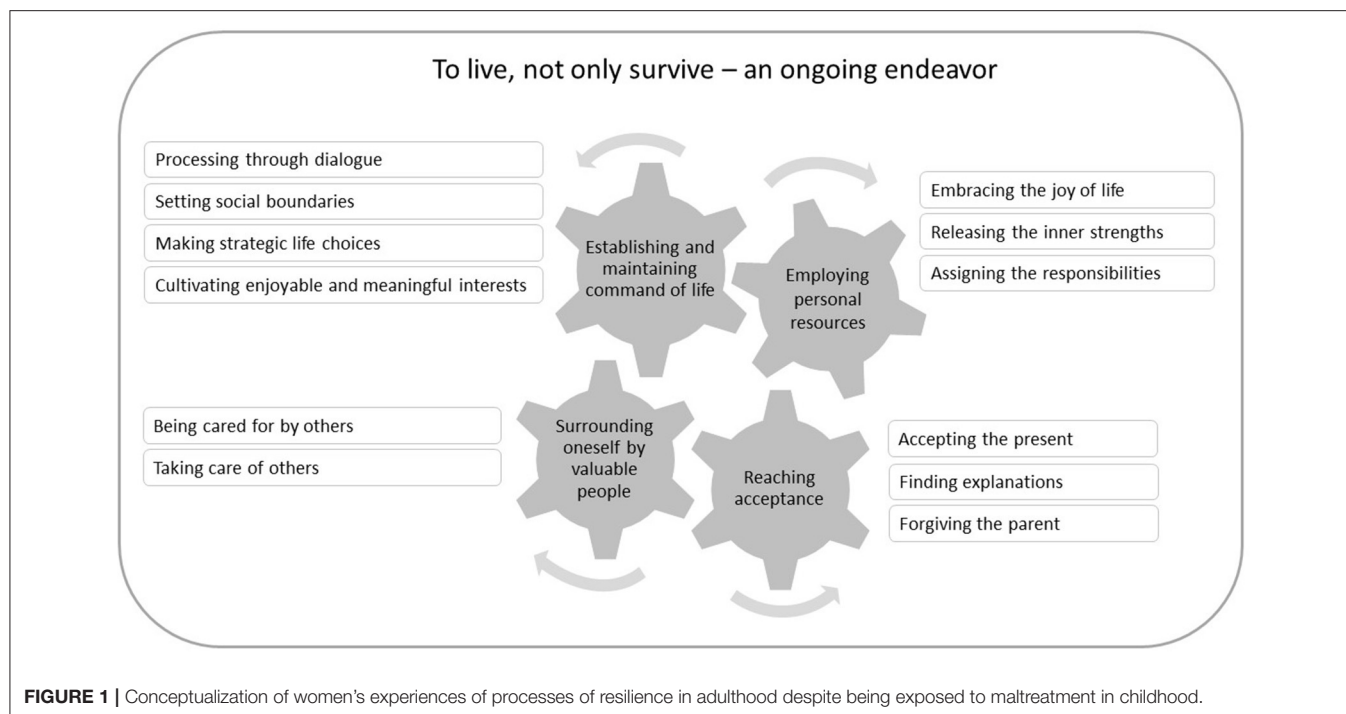
To establish and maintain command of life emerged as an important resource for the ongoing endeavor of living, not only surviving. The command of life could be established and maintained through processing experiences of abuse or neglect, managing feelings through dialogue with others or reflections within oneself, and setting social boundaries with others, mainly abusive parents. The command of life could also be established and maintained by making strategic life choices concerning education, work, living arrangements, family building, and partaking in enjoyable and meaningful interests.

Processing Through Dialogue

Processing through dialogue was important for establishing and maintaining control of life and comprised both internal dialogues and external dialogues with others. External dialogues included therapeutic conversations with professionals, informal conversations with friends, and sharing experiences with others with similar experiences. Being open and putting one's experiences and feelings into words was experienced as healing. The internal dialogue—i.e., self-reflection—was processed by writing letters or self-biographical notes or through meditation, all techniques used to confront one's feelings and to reach an understanding of the effects these experiences had on well-being and behavior:

For me, it has been like, the more I talk about it, the more understanding and distance I get to what it is [...] to what it was like. It does not define me as a person today, but I carry it with me, I do, and always will (Woman T).

However, to put feelings into words, or “to dare to meet oneself” as one woman described it, required a different kind of effort



and assistance. Some women did it mostly by themselves with minimal support from friends, relatives, or a professional. Others, however, tried a range of therapies before finding the one that suited them or met many professionals before finding someone they could trust. Whatever path they chose, the essence was to process their experiences actively, to do it with someone they trusted, and to distance themselves from the experiences of abuse even though they could not leave their experiences completely behind.

Setting Social Boundaries

The necessity of setting boundaries to focus on one's own needs and development or to protect oneself from abuse was highlighted. This necessity referred both to the relationship with the abusing parent[s] and to relations with others. Sometimes, setting boundaries included breaking contact with an abusing parent[s]. One woman described the strength she experienced by setting clear boundaries with her abusive father:

I didn't want anything to do with [my] dad [...]. And I said to him, straight out and bluntly, "you can go to hell, I never want to see you again. You have ruined so much in my life." And it made me feel so strong (Woman P).

At the same time, permanently breaking contact with parents was not described as a simple solution; it was described as challenging as emotional ties appeared to be strong. The woman cited above described how she later re-established contact with her father as she started to feel guilty over breaking contact. Another woman described the permanent break with her parents as a large hole in her life, but she believed she had no choice. She believed she needed to break from her parents so as not to be

dragged down by their destructive behaviors. Although painful, the permanent break became her rescue. Setting boundaries also included clarifying distinctly for the parent that certain types of behaviors would not be accepted anymore, which especially was found needed when the women felt it necessary to protect their own children from their abusing parent[s]. One woman also described a fulfillment in being able to clearly set boundaries and speak her opinions or voice her needs, at times aggressively, to protect her (or even her friends') private sphere, a response to a threat she was unable to marshal as a child. Hence, control over one's life required setting boundaries in relation to others, establishing a few close friends instead of pressing oneself to interact with too many people, and, not the least, making all this clear to others.

Making Strategic Life Choices

Making strategic life choices embraced how women in young adulthood or in the transition to adulthood made choices and took actions to make the best out of their lives. One woman described how her choice of a husband was a strategic choice to ensure safety.

After all, I chose a man [...] a man who doesn't keep on rubbing up against me and doing other stuff. I chose a man who wouldn't keep going on with sexual abuse and stuff like that. I chose a man who is calm and caring and careful. Which may have its drawbacks in not being so adventurous [laughter]. But I made a choice there. A safe choice (Woman J).

Making strategic life choices could also be about owning an apartment early in life, getting an education, and/or finding a job. It could also be about taking an opportunity to move on

and try something new when an opportunity presented itself. Furthermore, making strategic life choices comprised choosing which relations were worth investing time and energy in. Overall, making strategic life choices required making choices to engage in things that contributed positively to one's life as well as opting out of things that did not benefit one's well-being.

Cultivating Enjoyable and Meaningful Interests

Women expressed that one part of controlling their life was to cultivate enjoyable and meaningful interests as engaging in activities and hobbies was described as contributing to well-being. These interests include cultural, physical, and cognitively-demanding activities such as solving a crossword puzzle, taking a course, and reading a book. In addition, taking care of animals was described as bringing delight and peace into one's life:

And the horse makes demands. It gives a lot, but it also makes demands. You have to be present. You have to be calm. If you are not calm, the horse is not calm. So horses have been my salvation. And now they are my joy. And now I have my own horse (Woman U).

That is, the importance of not only engaging in activities but also in finding pleasure in small things in life was acknowledged.

The resilience resource of establishing and maintaining command of life enabled and forced the women to actively and strategically choose actions such as processing experiences, seeking help, setting boundaries, or filling life with meaningful activities. To choose such actions together with other resources contributed to the resilience process. In the next section, employing personal resources will be even more obvious and highlighted as an important resilience resource.

Employing Personal Resources

An important part of the ongoing endeavor of not only surviving but also living was being able to use personal resources, innate or acquired, throughout the life course. Personal resources included the ability to embrace the joy of life, release one's the inner strengths, and allocate the responsibilities for experiences and situations in the past (the abuse) and the present (to live) to whom they belong.

Embracing the Joy of Living

Embracing the joy of living includes the importance of being able to feel joy and cheer even during the hardest of times. Some women described the ability to feel joy as an innate gift—i.e., they believed they were born happy. However, the ability to feel joy was also described as an active decision and skill acquired through life—i.e., an adapted approach. Embracing the joy of living could also be used strategically by rewarding oneself with enjoyable things when challenges had been managed:

I am happy with myself and it takes a lot for me to get angry or change that mood, but of course you have to work consciously with it and that, I think, starts with oneself and how one perceives things and chooses to perceive them. If you have that ability then, of course. So, I've probably always emphasized the positive things (Woman B).

Therefore, taking advantage of the innate joy of living or making decisions to highlight the joyful things in life was considered an important contribution to well-being and well-functioning.

Releasing Inner Strength

The perception of an inner strength was also an important contributor or an explanation for why the women experienced well-being and well-functioning in everyday life in spite of their childhood adversities. The internal strength had both a dimension of an innate personal trait that had been of great help in childhood and a dimension of a quality they were adapted or was released because of the difficulty they were experiencing. One woman described this experience as her "lifeblood": No matter how exposed or how broken she felt, her "lifeblood" always kept her up.

I have given a name to this thing that I don't really know what it is. I call it my lifeblood, and it is completely unyielding. So, it doesn't matter how much of a difficult position I am in or how much I [...] no matter how hard life has been, somehow it has bounced back again (Woman F).

In general, however, the women found it difficult to explain their internal strength; that is, this internal strength was hard to put into words.

Assigning the Responsibilities

Assigning the responsibilities for past and present actions to where they belonged was an important personal resource. That is, these women embraced the conviction that they were not the cause of their parents' harmful acts nor deserving of the abusive treatment: their parents were the problem and they were innocent victims of the circumstances. To achieve well-being and a well-functioning life, it was important to clarify for oneself that the parents were responsible for the abusive treatment, but the responsibility to go on with life and convert the negative experiences to something useful was their own:

It's all about, like, getting oneself out of this. And, that is not done by just sitting and feeling sorry for oneself. I also have a responsibility; I have to get a hold of my life (Woman R).

For some women, this had always been very clear; for others, it took them a long time to come to this insight. Assigning the responsibilities also included the present and the ability to move beyond victimhood, as pondering on victimhood was perceived to hinder well-being.

The resilience resource of employing personal resources could be enhanced by a significant person in the women's lives. At the same time, personal resources such as inner strength enabled them to establish valuable relationships, for example, with their children and to enjoy life even during hard times. The next section goes into detail about how other people can become resiliency resources.

Surrounding Oneself With Valuable People

Surrounding oneself with valuable people was an important resource for being able to live and not only to survive and

consisted of two dimensions: one describing the importance of opening up to being cared for by others and the one describing the importance of taking care of others. Being cared for by others embraced the importance of supportive relationships, both intimate relationships and relationships with professionals and others outside the women's immediate social circle, and the availability of others who can support the woman when needed. Taking care of others embraced the value of being responsible for the well-being of others, which made life worth living. Although the availability of valuable people, and particularly their care, was not described as completely up to the individual as surrounding oneself with valuable people demands being open to establishing such relationships and encouraging these relationships as well as finding people who would reciprocate these desires. These women had in one respect or another chosen to be surrounded with valuable people.

Being Cared for by Others

This dimension embraced the nurturing bonds the women managed to establish and maintain. A trustworthy relationship with a person they shared their life with, a husband or a partner, emerged central for the ongoing endeavor. A partner who was respectful and accepting, who the woman could rely on and build a new better life with, with or without children, was considered to contribute substantially to the well-being and well-functioning they experienced. Being cared for by others also embraced professional relationships, employers and/or colleagues, who recognized and acknowledged their abilities, confirming that they had value and a self-worth. These relationships also helped the women believe in themselves in a way they had not experienced. In addition, friend and sibling relationships were sources of support. The importance of being seen by someone outside their immediate social circle could be essential for the women's well-being and well-functioning—i.e., someone recognized the women's needs and/or their potential need for help or support, for example, a health professional or employer:

She [the child health care nurse] kept calling me to meetings anyway; she wouldn't give up. And then, after a year she got me start talking [...]. So I mean, for me, it was a salvation that she understood. She was the only one who had seen and had understood (Woman A).

Being cared for by others also embraced how someone had taken action, for example, by not giving in even though the woman was not ready to talk or receive the help offered, but waited and tried again until she became ready or by putting a foot down and making the call, for example, to arrange someone professional to talk to.

Taking Care of Others

Taking care of others embraced the role children and family have played in the women's lives. Building one's own family could be a strategy to replace the family they never had as a child or a reason to live, strengthening their desire to keep struggling during hard times or when feeling life was meaningless. Although taking care of others could mean the women put their own feelings

on hold, it could trigger the processing of adverse experiences from childhood.

It has always been kind of my salvation, I would say, the kids and things. And in that way, I'm very grateful that I had a child early because I don't know if I'd have been here today if I hadn't had him to take care of (Woman E).

Becoming a mother also brought to light how wrong their parents had treated them during their childhood, and this could eventually bring strength and eagerness to never treat her children in same way.

Thus, being surrounded by valuable people who enabled the women to accept their experiences and life situations helped them process their experiences and feelings. In time, this also gave them strength to attempt to understand why they had been exposed to neglect. At the same time, acceptance of their situation and experiences could make them more receptive to the care of the valuable people with whom they were surrounded. The fourth aspect, the resilience resources encompassing acceptance, is further described in the next section.

Reaching Acceptance

Acceptance could be reached through a better relationship with oneself (i.e., being a friend with oneself) and the life one was living. The process of acceptance was enabled by finding explanations for their childhood experiences and for some by forgiving their parents. Attempts to understand or find explanations to why their parents treated them the way they did was also a part of reaching acceptance, and some women even embraced reconciliation or forgiveness.

Consenting the Present

Consenting the present included accepting one's strengths and weaknesses and embracing the perception of being good enough no matter what. Consenting the present was described as the ongoing desire to battle one's problems, contributing to one's own well-being by living a life rather than just surviving. Similarly, being genuine about one's potential for chaos rather than presenting a calm façade was highlighted as important for attaining well-being:

You have to allow yourself to be sad and think things are shitty, because sometimes it is. It is really shitty. But you have to remember to recall, even when it is at its worst, that it will get better again. It will be brighter again (Woman R).

Furthermore, consenting the present included embracing life as it is, with its ups and downs, and realizing that life naturally includes challenges that should be met with humility and serenity.

Finding Explanations

Finding explanations embraced the need to understand or explain why their parents were abusive. The explanations could be in the form of the parent having alcohol or psychological problems that triggered the abusive behavior or their parents' abusive behavior being the result of their parents' childhood

abuse or neglect. Especially the father's abusive behavior was explained by illnesses or previous experiences being the cause, in part, of his lack of control. At the same time, it was found to be more difficult to explain why their mothers did not protect their children from their abusive fathers. This lack of maternal protection was explained by their mother being so totally broken down that she had to use all her energy just to survive. In the cases where the mother primarily was the abusing or neglecting one, the lack of protection from the father was more easily explained by his own vulnerability.

And Mom could not cope. And I can see that; I didn't understand it back then. I was pretty angry with her for a while. However, I could see this later on; I understand that she could not cope. He knocked the shit out of her (Woman U).

Finding explanations could lead to the conclusion that the parents did the best they could given the circumstances, a realization that was experienced as important for well-being.

Forgiving the Parent

The explanations and understandings of the parents' actions and situations could lead to forgiveness since, as one woman put it, *"you can love a parent at the same time you hate him or her"* (Woman 20). Receiving a request for forgiveness was perceived as a significant event and was found to be very relieving. Similarly, a parent's confession or insight about what he/she had done was wrong provided some relief:

There came some kind of "sorry" in his own little way. And, for the first time, there, on his deathbed, I chose to actually sing for him of my own volition. It was big (Woman P).

Thus, even a modest indication of regret that could be interpreted as the parent asking for forgiveness was described as very important. The resilience resource of reaching acceptance enabled the women to establish and maintain command of life at the same time enabled them to process their experiences through dialogue, ultimately facilitating their ability to reach acceptance.

DISCUSSION

This study adds to the research of resilience among adult women by exploring the process from childhood abuse and neglect to adulthood well-being and well-functioning. We found that this process was an ongoing endeavor to live, not only survive, an internal process that interacted with external processes involving social relations and conditions. This endeavor was built on four interrelated resources: establishing and maintaining command of life; employing personal resources; surrounding oneself with valuable people; and reaching acceptance. These four resources worked together, not in a linear or chronological order, but in up and down ways, turns and straight lines (now and then), through the process from abuse to well-being. Thus, this study found that resilience was something that continued throughout life with support of four important types of resources. Our findings regarding an ongoing endeavor agree with previous

work conceptualizing resilience as a dynamic process (8, 9) and conclusions about resilience and recovery being an ongoing process (17, 18). Our findings contribute to earlier studies by providing more details that explain resilience as an interactive process consisting of four resources. The resources employing personal resources and reaching acceptance capture processes at an intrapersonal level that allowed the women to establish and maintain command of life and surround oneself with valuable people. The latter resources capture processes at an interpersonal level, activities that are done with others and depend on social conditions that also enable the internal processes. That is, these four resources work together and promote the ongoing endeavor for living, not only surviving. These results are in line with previous conceptualizations of resilience as a dynamic intrapersonal developmental process enhanced by interpersonal relationships and interaction with the environment (8, 9, 19). Our result that the ongoing endeavor is not linear agrees with Thomas and Hall (18), who identified three main patterns of trajectories when exploring recovery among women who experienced childhood sexual abuse. They identified a pattern of relatively steady upwards progression, a pattern of a lengthy roller coaster pattern with many ups and downs, and a pattern of struggle characterized by stagnation or downward progression. The steady upward progression and the roller coaster patterns illustrate a dynamic process of resilience and similar patterns could be glimpsed in the life stories of the women in our study. Our results extend Thomas and Hall's results by elucidating the ongoing endeavor to live a well-functioning life such that the trajectories move toward resilience and recovery rather than struggle and stagnation.

Previous research has concluded that turning points, including both positive and negative life-changing events, cause shifts and changes in directions of life trajectories that are central for developing resilience and the process of recovery (17, 18). Although our results did include occasional descriptions of additional trauma or other tough life experiences that in times could trigger the endeavor to live, not only survive, these did not emerge as sufficient for the process.

In our results, the rendering of resilience as an ongoing endeavor for living and not only surviving was found to rest on four resources. Some of the resources found in our study—e.g., releasing an inner strength, making strategic life choices, and being cared for by others—resemble previously described childhood resilience resources such as emotional intelligence, problem-solving personality, and positive relationship with competent and supportive adults (8, 9). The resources embracing the joy of life and releasing inner strength include being aware of one's own personal characteristics that can enable the resilience process, e.g., the perception of being born happy or perceived internal strength. These relate to personality traits, i.e., ego-resiliency, which previously have been described to play an important role in the process of resilience (8). Furthermore, our results include resources such as processing through dialogue, taking care of others, as well as being cared for by others that highlight the importance of social relations for the ongoing endeavor of living. These results agree with previous research that shows that safe and supporting relationships buffer the effects of

maltreatment in childhood on various health outcomes among adult women (13, 15). Especially processing through dialogue accentuates the importance of having access to someone to talk to, someone with whom to process experiences. The women in our study described a variety of therapeutic contacts they used to process their experiences as well as informal contacts with friends, family members (e.g., partners or siblings), and colleagues. Thus, our results suggest that access to low threshold opportunities to diverse therapeutic methods may be a relevant public health initiative aimed at promoting resilience among women maltreated in childhood. Furthermore, in our results, the resources making strategic life choices and setting social boundaries reflect how the women used their internal resources in interaction with the environment (by moving away from the abusive context, getting an education, and/or finding a job) to find ways to distance themselves from their experiences and enhance their resilience. Thus, equal access to housing, employment, and education can be considered important for enabling the process of resilience. However, further research is needed to establish such evidence. Our results further add to the understanding of adult resilience resources by revealing the importance of pleasurable activities embedded in the endeavor of living, not only surviving, captured by the resources cultivating enjoyable and meaningful interests and embracing the joy of life. These results have not been prominent in previous research of adult resilience resources although some studies have described engaging in creativity and sports as useful resources for becoming less controlled by previous events (20).

The observed pattern of how the women explain their abuse differed for their fathers and their mothers, possibly reflecting gendered structures in society. Although the father or another male relative was the perpetrator in most cases, the women found it more challenging and complicated to explain why their mothers did not protect them from their abusive father than to explain their father's abusive behavior *per se*. These experiences might reflect the social construction of motherhood, including the expectation that mothers have the main responsibility for the care of the children. This perspective is particularly evident in the context of domestic violence where women's mothering has been framed as a determining factor in the protection of children and how the children are affected by the violence perpetrated by the father (21, 22). The lack of protection from the father in case of an abusive or neglecting mother was more easily explained by the father's own previous vulnerability. This view could be understood in the light of hegemonic masculinity where expectations of fathers are not mainly related to their engagement in the care of the children but rather in their position of dominance in the family (23).

Strengths and Limitations

In our study, the women had the interpretative prerogative when assessing their childhood experiences, well-being and well-functioning, which can be considered a strength since it captures their own interpretations of resilience constructed in their own reality. However, it can also be considered a limitation since nuances in descriptions may have been lost and the

chronological order of experiences may have been less precise, which can make the results even harder to transfer or compare to other women with experiences of childhood maltreatment. Nevertheless, memories of emotional events and traumatic experiences are suggested to be better recalled than more neutral events and experiences (24, 25). The initial purposive sampling (age, subjective well-being and well-functioning, and experience of childhood maltreatment) could be criticized for being too specified for grounded theory in that the defined borders already set the stage for the inductive theory. However, as stated by Breckenridge and Jones (26), researchers need some idea of where to start, and initial sampling can be a part of theoretical sampling before moving into simultaneous data collection and analysis based on constant comparison. The level of positive adaptation as criterion for resilience is a debated issue within the field: some researchers believe positive functioning in multiple domains of life is a requirement for resilience, whereas others believe positive functioning in only one domain is sufficient for resilience, depending on type of adversity (11). Furthermore, it has been argued that resilience should be assessed in terms of functioning that is relatively better compared to others with experiences of adversities at the same level (9) or based on other's views of how well the exposed individual is doing (27). However, resilience often becomes operationalized merely as the absence of psychopathology (11), which can be considered a narrow definition of positive adaption. Assessing resilient outcomes at different levels of life (e.g., intrapersonal, interpersonal, and/or societal) is another way of operationalizing resilience, allowing for wider understanding of positive adaption. Our study contributes to a wider understanding of positive adaption by exploring women's own interpretations of their well-being and well-functioning despite experiences of childhood maltreatment.

Several measures were taken to enhance the trustworthiness of the study, primarily through an accurate description of the performed procedures. To achieve credibility, we recruited participants with their own experiences of childhood maltreatment who were able and willing to share their stories, and we continued gathering data until we considered the data rich enough to provide a comprehensive answer for the study's focus. Confirmability was addressed by including several researchers in the data analysis (two in the initial steps and four in the last steps), opening up for alternative interpretations. In addition, quotes from the respondents were generously provided. The women included in this study were verbal, Swedish speakers, and active users of social media, who appreciated the opportunity to share their experiences as survivors rather than victims of childhood maltreatment. This should be kept in mind when the results are transferred or compared to other women with experiences of childhood maltreatment. To improve transferability, we provided information about the women's age, living context and type of childhood maltreatment they experienced up to an extent that would not risk revealing their identity.

Implications

In prevention and health promotion within public health and social work, it is important to work from a knowledge base

developed by systematic research. This qualitative study suggests that resilience is an ongoing process and that women use different types of resources to support this process. Several aspects of our results can inspire policy making and planning of health and social services. For example, available and affordable housing may be helpful for young women who need to set boundaries for themselves and flee abusive family situations. Furthermore, access to available and affordable counseling services may help women to process experiences of abuse and neglect. Furthermore, opportunities to cultivate meaningful interests and meet like-minded people are suggested as important resources for enabling women to distance themselves from their negative experiences and strengthen their social network, further developing their resilience. However, further quantitative research is needed to confirm the role of the identified resources in enhancing resilience among women maltreated in childhood.

Future Directions

To advance the understanding of resilience among women exposed to childhood abuse or neglect, future studies should further explore how women perceive their well-being and well-functioning. To better understand gendered patterns, future studies should explore how men who experience childhood abuse or neglect develop resilience.

CONCLUSIONS

The main result of this study—i.e., resilience is an ongoing endeavor to live, not only survive—supports the conceptualization of resilience as a dynamic process. Our results show that resilience among women who experience childhood abuse or neglect rests on intrapersonal and interpersonal resources. Furthermore, the results show that an individual's inherent capabilities, depending on life circumstances and available resources, can be vitalized/realized in a way promote well-being and well-functioning. Therefore, public health initiatives, social

services, and policies should aim to create conditions with variety of resources available that help women who have experienced childhood abuse or neglect to live fully rather than merely to survive.

DATA AVAILABILITY STATEMENT

The dataset presented in this article are not readily available because the participants were guaranteed that only the research group at University of Gothenburg and Örebro University would have access to the interview material. Requests to access the dataset should be directed to hildur.gunnarsdottir@gu.se.

ETHICS STATEMENT

The study was reviewed and approved by Regional board of ethical vetting in Gothenburg (dnr: 258-17). The patients/participants provided their written informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

HG and ÅK were responsible for the data gathering and the initial analysis. JL and GH contributed to the data analysis. HG drafted the main manuscript. All authors contributed with writing and intellectual feedback, contributed to the design of the study, and approved the submitted version.

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Evaluation of a Short-Term Digital Group Intervention to Relieve Mental Distress and Promote Well-Being Among Community-Dwelling Older Individuals During the COVID-19 Outbreak: A Study Protocol

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Older individuals are at an increased risk of experiencing adverse social and health consequences due to both the COVID-19 pandemic and the measures taken to manage it, such as social distancing. To promote community-dwelling older individuals' well-being during this time, the aims of the current project are to develop effective strategies in order (a) to increase older individuals' digital literacy, and (b) to help them acquire behavioral and cognitive skills that will improve their coping abilities with the stressful situation created as a result of the pandemic, as well as reducing adverse mental health effects. The project comprises an intervention arm that includes digital group sessions for older individuals meant to improve their digital literacy, promote their effective coping, and relieve their mental distress and loneliness. Subjects receive a short-term (seven sessions), twice-weekly, digitally guided group intervention through Zoom (a video conferencing app), and WhatsApp (instant messaging app). The wait list control-group participants receive twice-weekly telephone calls from a research assistant during a parallel period. Web-based questionnaires are filled in pre- and post-participation. The effectiveness of the intervention will be analyzed by comparing pre- and post-measures, between intervention and control groups. This protocol offers a model for helping to support vulnerable populations during the COVID-19 pandemic. However, it is applicable regardless of the outbreak of a global health crisis or the imposition of lockdown rules; in fact, it has the potential to contribute to the social inclusion of vulnerable populations during routine times as well as during emergencies. Furthermore, ideas for future expansion include the integration of multilingual facilitators in order to reach seniors from underserved minority groups in various social contexts, even across borders.

Keywords: older individuals, COVID-19, mental health and well-being, digital group interventions, cognitive-behavioral skills

INTRODUCTION

The outbreak of the COVID-19 pandemic, which erupted in Wuhan, China, and which has spread quickly throughout the world, infecting millions, and claiming the lives of more than 2.5 million people (to date) (1), is at the center of concern for public health and healthcare agencies worldwide. Epidemiological investigations clearly indicate that increased mortality from COVID-19 is generally associated with older age and with the presence of chronic illnesses among this population, compromising their ability to deal with the myriad effects of the novel coronavirus (2, 3). Thus, the older population is especially at risk, in particular those who are frail and very old. Many countries around the world are advocating preventive measures such as social distancing, and governments are instructing at-risk populations, such as, older individuals, to self-isolate as much as possible by staying home. Although, these measures may be effective in preventing infection, morbidity, and death, they can also lead to increased loneliness and alienation (4, 5), potentially bearing dire health consequences both from a mental and physical health point of view (6). In many municipal jurisdictions, volunteers take care of delivering groceries and medications to the doorsteps of these populations; however, such efforts do not alleviate loneliness. An extensive body of knowledge suggests that loneliness among older people is strongly and independently associated with depression, high blood pressure, sleep disorders, prolonged and heightened stress responses, and even deterioration in cognitive function (6, 7). Other evidence suggests that loneliness among older adults is a major public health issue, and is associated with an increase in ongoing healthcare utilization (e.g., physician visits) (8) for chronic or acute non-COVID-19 conditions.

The use of new information and communication technology (ICT) (e.g., Skype, Facebook, WhatsApp, Zoom, and many more) offers a convenient alternative. In times such as the one we are currently living through, ICT enables the remote maintenance of social connections (9–12), and the conveyance of digital interventions over which therapeutic techniques and skills can be learned and practiced to promote effective coping, as well as alleviate loneliness, distress, and other mental health conditions (13–15). An extensive body of knowledge indicates the beneficial effects of digital interventions for diverse populations and conditions, using various communication modes. Therapeutic interventions delivered *via* digital platforms have been found to meet the same professional practice standards and outcomes as face-to-face delivery, and online delivery is particularly useful for people who are socially isolated (16–18). A meta-analysis that evaluated the clinical significance of guided digital interventions for patients with depression concluded that participating patients reported higher rates of remission compared to controls. In addition, older participants were more

likely to respond to treatment than were younger participants (19). The results partially corresponded to those of another meta-analysis that examined the effect of digital interventions on loneliness and depression among older adults and reported a significant improvement only for the loneliness measure (20). Another study conducted in the U.S. described a significant improvement in measures of depression, quality of life, social support, and self-efficacy among older adults with diabetes who received a digital intervention guided by a nurse (21). However, the studies described above refer mostly to one-on-one rather than group interventions. Additionally, they were not conducted during a pandemic: a unique public health emergency that has necessitated social isolation and, as such, has posed an additional threat to the well-being and quality of life of at-risk populations such as older adults. Another recent study that was conducted in Germany among older individuals who had been traumatized as children found that a therapist-guided digital group intervention during which participants received cognitive-behavioral therapy (CBT) was associated with a substantial reduction in posttraumatic stress symptoms and with an increase in coping resources (22). Another study, conducted in South Africa, reported a significant reduction in loneliness levels among older adults who received a cognitive-behavioral group intervention *via* an instant messaging application (WhatsApp) (23).

There has been some debate regarding the effectiveness of group interventions compared with one-on-one activities among older adults (24), as well as regarding which modes of communication work better for delivering interventions to this population (25). Previous studies have usually referred to the utilization of a single digital platform such as email (26), forums and blogs (27, 28), and more recently, instant messaging (23) and videoconferencing (29). Given that each of these platforms has different, and often complementary functions, the integration of more than one platform for conveying therapeutic interventions also merits exploration. In the current protocol we evaluate the unique and common contribution of two digital platforms, WhatsApp (instant messaging app) and Zoom (videoconferencing app).

The importance of using ICT currently, during the COVID-19 crisis, can hardly be overstated; yet older people are likely to have what is commonly called an *age divide* (30), reflected in at least two levels of a digital divide between younger and older internet users. The first is internet connectivity, which differentiates between users and non-users, whereas the second is related to the skills and abilities required for ICT use (12, 31, 32). Moreover, a recent study documented a first-level digital divide within the senior citizen sector itself, the so-called *gray divide*, as reflected in connectivity and frequency of ICT use. That is, this study indicated that the major gap did not lie between what might be called the “pre-seniors” (50–59 years) and those younger, but rather between the “old seniors” (70+) and the rest of the populace (33). A study that explored the acceptance of health information technology among community-dwelling elders reported a variety of barriers related to familiarity and access, need for assistance, trust, privacy issues, design issues, and physical issues such as sight and hearing loss, loss of tactile

Abbreviations: COVID-19, Coronavirus disease 2019; ICT, information and communication technology; CBT, Cognitive behavioral training; CBS, Central Bureau of Statistics; OECD, Organization for Economic Co-operation and Development; QOL, Quality of life; DSM-V, Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition.

senses, and cognitive and memory issues. The authors concluded that custom design and provision of relevant training can assist in overcoming these barriers (34). Nevertheless, the transition of many services to ICT may deepen the digital divide and increase social isolation if not properly tailored to the population of older adults (34–37). As such, future endeavors in the field of online therapeutic interventions should address this issue extensively if targeting older adults (34).

Despite the existence of the abovementioned substantial barriers, conducting interventions in an online format for older individuals appears feasible. Recent evidence shows growing rates of their embracing internet use (34). The COVID-19 pandemic has further highlighted how necessary and often inevitable it is to deliver therapeutic interventions through digital platforms. These platforms enable access to various health services that may otherwise be inaccessible (38), and if performed in a group manner, such interventions can reduce social isolation (39) at times such as these.

The aims of the current project are therefore to develop for at-risk populations, such as, older individuals, effective strategies in order to (a) increase their digital literacy, and (b) provide them with the tools and skills necessary for improving their coping abilities with the stressful situation created as a result of the pandemic, as well as reducing adverse mental health effects.

METHODS/DESIGN

Study Design and Setting

A prospective cohort intervention study among community-dwelling older adults.

Inclusion and Exclusion Criteria

Eligible participants are adults aged 65 and older residing in the community who are proficient in Hebrew and can provide informed consent. Additional inclusion criteria are having an active internet connection, possessing at least one device that enables online communication, and having a minimal ability to operate this device (i.e., turning it on and off). Excluded from the study are participants who screen positive for major clinical depression on the Patient Health Questionnaire-9 (the PHQ9), defined as a sum score of $15 <$ or score $\neq 0$ on item 9. Participants are personally contacted by a member of the research team with clinical training in mental health care, in order to provide initial psychological support and information regarding appropriate further treatment options in the community. This procedure is a precautionary measure aimed at the early detection of, among other things, suicidal tendencies.

Recruitment Procedure

Recruitment of study participants commenced in the month of April (2020) and will continue for 14 months, until June 2021, given the expectation that there will be additional COVID-19 waves (40). The main recruitment routes are advertisements to WhatsApp groups established by a local NGO responsible for promoting digital literacy among older adults. The advertisement contains information about the project and a link to a registration form for those interested in participating. In addition, we

contacted relevant agencies responsible for the social care of older adults in several municipalities in the southern region of Israel (as these agencies have previous working collaborations with the research team) in an effort to widen the recruitment net. Social workers in these agencies were asked to refer relevant applicants, subject to the applicant's approval. In this manner, we have also been able to recruit participants with potentially low levels of digital literacy. All applicants are randomized on an 80:20 ratio into either the intervention or the control group, which is actually a waitlist for the intervention group, using a table of random numbers with no further constraints. The applicants referred by social services and those signing up voluntarily are randomized separately to ensure that an equal proportion of participants attained *via* both recruitment channels end up in both groups.

After randomization, research assistants contact the participants to: (1) fill in the questionnaires (T0), and (2) ensure that the ZOOM platform is installed on their computer or smartphone, and that their skill level of operating it is satisfactory. If necessary, remote assistance (*via* telephone) is provided in downloading and installing the app, and individual training is conducted in order for the participant to be able to independently hold a conversation. At this point, participants classified to the intervention group are assigned to small groups of up to seven participants. This sub-classification is done in accordance with three guidelines: (a) gender ratio; (b) maximum age difference of ~ 10 years; and (c) marital status balance (i.e., 50:50 ratio between participants who live alone vs. those who are married or have a common-law partner). The rationale underlying this sub-classification is an attempt to create small groups with a certain degree of basic similarity that will facilitate the participants' communication and connection to one another. We expect to see a higher application rate for women as their proportion among this age group ($65 <$) is higher compared with men (41). Following this classification, the group moderator (a clinical social worker) is provided with his/her participants' contact details and information (name, phone number, age, and marital status). Each moderator establishes a WhatsApp group for the participants in his/her group in order to allow for ongoing communication between the participants themselves and/or with the moderators during and also between sessions.

Digital Intervention Group to Relieve Mental Distress and Promote Well-Being

The online project comprises an intervention arm and wait list (control) group.

The intervention includes seven twice-weekly online guided group sessions *via* Zoom. In parallel, the participants can communicate with each other and with the moderator through a designated WhatsApp group. The main purpose of the intervention is to create a safe virtual learning space for participants to share their hardships in a supportive atmosphere, and acquire skills related to coping with the pandemic and the measures taken against it (i.e., social distancing). During each session participants learn and practice behavioral and cognitive techniques to reduce mental distress and promote well-being. The duration of each online session is between 60 and 90 min,

and it consists of two parts: (a) a guided group discussion, and (b) learning and practicing cognitive-behavioral techniques and skills (CB intervention) such as, relaxation, guided imagery of a “safe place,” identifying non-adaptive cognitive schemas using Beck (42) and Ellis (43) categorization, cognitive restructuring, and constructing positive self-talk (15, 44, 45). Mindfulness techniques are taught as well, as part of positive self-talk and distancing strategies. All techniques are learned and practiced during the session (synchronized learning) under the guidance and supervision of the group’s moderator, who also provides feedback to the participants. A schematic description of the entire intervention structure and the content, techniques, and skills delivered in each session is depicted in **Figure 1**.

The WhatsApp group is established 1 day prior to the first session. In addition to this platform’s role as a channel for ongoing communication between the participants and their moderator, it also serves as (1) a tool for group management and data collection, by sending reminders and invitation links for the sessions, (2) a way to forward the links for the online questionnaires, and (3) a learning aid, *via* the sending of supplementary materials (video and audio files) for practicing the techniques taught in the sessions and tips for using Zoom and WhatsApp. During the first session, the moderator and the participants formulate a contract that defines the rules of conduct in the WhatsApp group in terms of content that can or cannot be shared, times of operation, and adherence to respectful discourse.

The online group moderators are clinical social workers with previous experience in delivering online cognitive-behavioral-based therapeutic interventions. A social work student in his/her final year is assigned to each moderator. The student takes part in all sessions and is responsible for assisting in administrative issues such as collecting data regarding emotional distress at the beginning and at the end of each session. Each moderator is provided with instruction once a week by a senior clinical social worker. The instruction sessions are focused on adapting the techniques and strategies to the needs of each group member.

The wait list control-group participants receive twice-weekly telephone calls (that is, “old-fashioned,” one-on-one, telephone calls, with no video accompaniment) from a research assistant during a parallel period.

All the participants fill out online questionnaires at three timepoints: pre-participation (T0); immediately post-participation (T1); and one-month post-participation (T2), in order to enable the evaluation of the intervention’s effectiveness and the duration of impact. The link to the online questionnaire (web-based survey, <https://www.qualtrics.com>) is distributed by the groups’ moderators to the participants’ mobile phone or email, depending on their preference, near the start and end of the intervention: that is, no more than 48 h pre- or post-participation. The questionnaires assess digital literacy, social presence through technology, satisfaction with the use of computer-mediated communication, loneliness, self-reported depression symptoms, social support, resilience, self-efficacy, compliance with regular medication regime, adherence to social distancing practices, self-assessment of health status, and quality of life. Levels and changes of mental distress are monitored before and after each session. The waitlist control group

participants are assessed twice before entering the intervention group, completing a total of four measurements (compared with three measurements in the intervention group) (see **Figure 2**).

Measures to Assess the Effectiveness of the Online Intervention

Outcomes used to assess the effectiveness of the intervention procedure are described below. All measures are taken through web-based questionnaires at each of the abovementioned timepoints.

Primary Outcome Measures

Mental Distress

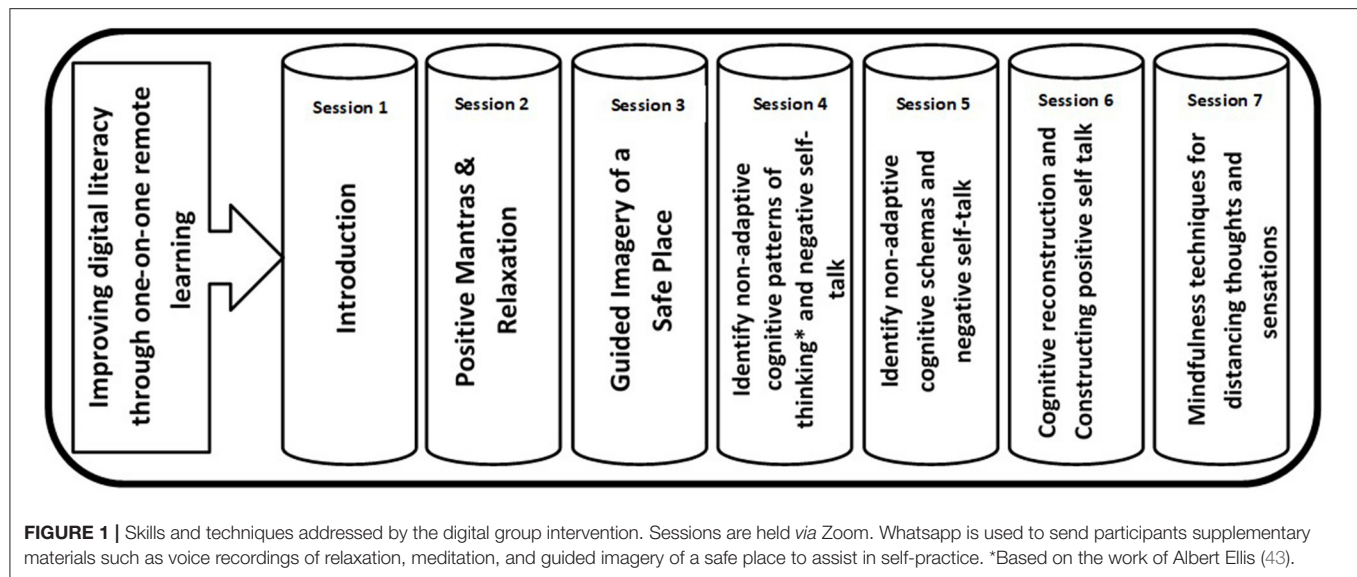
Mental distress is monitored and assessed using two scales: (1) The Subjective Units of Distress Scale (SUDS) (46), to assess changes in distress levels pre- and post- each session. The SUDS provides a quick and simple way to measure distress in a given moment. The respondents are required to estimate the severity of their emotional distress before and after each session by giving a numerical value ranging from 0 (*totally relaxed*) to 10 (*highest distress that you ever felt*). The SUDS is a common tool for measuring the effect (pre- and post-) of therapeutic interventions (47, 48) and has been previously used among older individuals (49). (2) The short form of the Perceived Stress Scale (PSS-4) (50, 51). This scale is a commonly used tool which measures mental distress. The PSS-4 consists of four items that evaluate the degree to which individuals believe their life has been unpredictable, uncontrollable, and overloaded during the previous month, on a scale ranging from 0 (*never*) to 4 (*very often*). The responses are summed, resulting in a maximum total score of 16. Higher scores are correlated with more distress.

Loneliness

One of the main concerns related to protective measures such as, social distancing during the COVID-19 outbreak, especially among older individuals, has been an increase in loneliness. Our hypothesis is that participation in group sessions using a videoconferencing app will alleviate levels of loneliness. We use the Short Scale for Measuring Loneliness (52) which comprises three items examining perceptions related to lack of companionship, social exclusion, and social isolation. The response categories are coded as 1 (*hardly ever*), 2 (*some of the time*), and 3 (*often*). The responses are summed, with higher scores indicating greater loneliness.

Digital Literacy

The ability to operate and communicate *via* ICT is measured using questions from Israel’s Central Bureau of Statistics (CBS) survey of web and computer use (53). These questions assess elements related to: (a) a first-level digital divide: the possession of digital devices such as computers, smartphones, etc., and an active internet connection package (two items); (b) a second-level digital divide: level of use and competence in operating web applications such as, email, search engines, social networking sites and apps, and using ICT such as, videoconferencing apps and instant messaging apps (10 items rated on a 5-point Likert



scale ranging from 1 [*not at all*] to 4 [*to a high extent*]), and (c) barriers for ICT use (two multiple choice questions).

Secondary Outcome Measures

Health and Well-Being

Perceptions of personal health status and health-related quality of life are examined *via* three questions from Israel's Central Bureau of Statistics (CBS) survey of health indicators (54). These questions relate to three health-related perceptions: (a) self-reported health, rated on a 4-point Likert scale; (b) self-reported independence in daily functioning, rated on a 5-point Likert scale; and (c) self-reported chronic morbidity, rated by a dichotomous question (yes/no) related to regular medication use.

Well-being is assessed using two questions from the OECD better life initiative (55) related to: (a) self-reported perception of quality of life (QOL), rated on a 5-point Likert scale; and (b) life satisfaction, rated on a 0–10 scale.

Self-Efficacy

The short form of the General Self-Efficacy Scale (GSE-6) (56, 57) contains six items, ranked on a 4-point Likert scale. The total score is calculated by finding the sum of all the items. For the GSE, the total score ranges between 6 and 24, with a higher score indicating more self-efficacy. The GSE is correlated with positive emotions, optimism, and life satisfaction. Negative coefficients have been reported for depression, stress, health complaints, burnout, and anxiety.

Resilience

The Conjoint Community Resiliency Assessment Measure (CCRAM) (58, 59) is a tool suitable for use in both routine and emergency times. The brief instrument includes 10 items measured on a 5-point Likert scale. The items were shown in a previous study (59) to form constructs of five factors: trust in leadership, collective efficacy, preparedness, place attachment, and social trust. The CCRAM score is composed of the average

score of the constructs of these factors, each being assigned equal weight.

Social Support

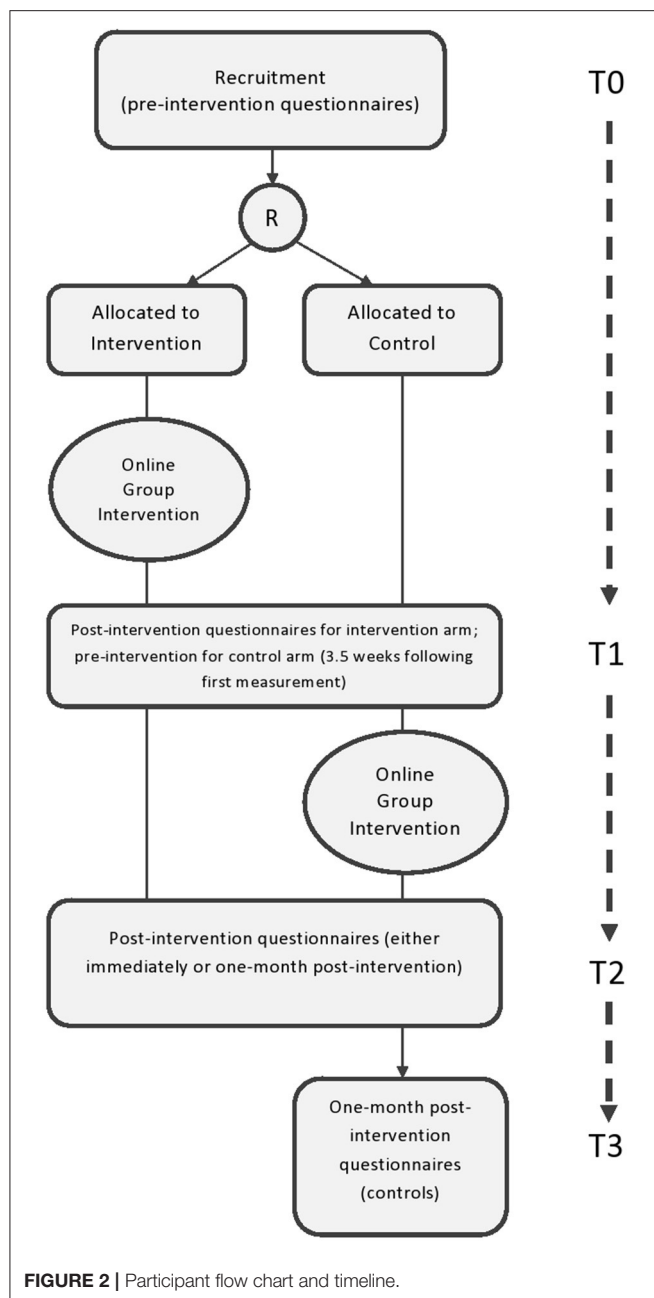
Group interventions have the potential to enhance social support as a result of the interaction between the participants. We assess this notion using the Duke-UNC Functional Social Support Questionnaire (60) which is a validated tool for measuring social support among various populations, among them older adults (61). The tool contains eight items, rated on a 5-point Likert scale, that address both emotional support and functional support. An average score is calculated: The higher the average score, the greater the perceived social support.

Depression

High rates of depressive symptoms are generally common among older adults both during routine times and especially during and following crises. Depression and severity of relevant symptoms are assessed using a 9-item depression severity measure. This measure is part of the Patient Health Questionnaire (PHQ-9), and it is used as a diagnostic instrument for common mental disorders (62). The PHQ-9 scores each of the DSM-V criteria as 0 (*not at all*) to 3 (*nearly every day*). The responses are summed, resulting in a maximum total score of 27. Scores of 5, 10, 15, and 20 represent mild, moderate, moderately severe, and severe depression, respectively. The last item of the PHQ-9 targets suicidal inclinations and is utilized as a screening measure for suicidality in primary care. The PHQ-9 has previously been tested among the Israeli population (63).

Adherence to Social Distancing Practices

To assess the ability of the online intervention to increase adherence to social distancing practices, the research team developed 10 specific questions which are based on Israel's Ministry of Health guidelines, and which are published and regularly updated on the ministry's website (64). The participants



are asked to report how often they performed eight activities such as, leaving their homes for stocking up on groceries, replenishing medication supplies, and exercising; how often they used others (family members or paid help) for those same tasks in order not to leave their homes; and how often they physically met with family and friends. The items are rated on a 5-point Likert scale ranging from 0 (*not at all*) to 4 (*once a day or more*). The responses are summed, resulting in a maximum total score of 40, with a lower value indicating higher compliance. Another item relates to the level of adherence to guidelines for using personal protective equipment (e.g., facial masks) and is assessed by a multiple-choice question. The last item relates to the perception

of social distancing effectiveness in protecting participants from getting infected with COVID-19. This item is rated on a 7-point Likert scale, ranging from 1 (*not at all*) to 7 (*highly agree*).

Sample Size Calculation

The Perceived Stress Scale (PSS-4) score is used as the primary outcome for sample size calculation. Harrer et al. (65) found a score of 7.43 (SD = 2.93) for the intervention group and 9.49 (SD = 3.06) for the control group in their study. They reported a decrease of 33% in the PSS-4 score post-intervention. We expect we will find similar results for our online intervention program, namely to find a decrease of between 20 and 30% in the total PSS-4 score. The target was set slightly lower in this study, because of the unique pandemic circumstances and social distancing practices which were absent in previous studies. Based on a power of 0.8, and a 2-sided alpha of 0.05, a sample size of 77 + 21 older people is needed, or 98 in total. This number was increased to $n = 125$ to account for a dropout rate of 25% in the intervention group and a 40% dropout rate in the control group.

Quantitative Data Analysis

The differences in the outcome measures between the intervention and control groups will be measured using statistical tests comparing the change from baseline in outcome to immediately post-intervention and one-month post-intervention (for example, a paired *T*-test). Our participants' (self-enrolled and invited) data will be analyzed separately in light of the fact that potential differences in the degree of motivation may lead to a selection bias in the outcomes.

Multivariable regression models will also be conducted, and interaction effects between the study's primary and secondary outcomes will be examined. The analyses will be performed using SPSS (version 26, SPSS Inc., Chicago, IL, USA), an alpha level of 0.05 being accepted as significant. Analyses will be controlled for covariates such as gender, age, marital status, education, and household composition.

Qualitative Data Analysis

All sessions will be recorded and transcribed verbatim. WhatsApp group correspondence will be mined as well. Both of these data components will be analyzed by content analysis, using ATLAS.ti (ATLAS.ti Scientific Software Development, Berlin). At least two researchers will scrutinize the qualitative data and participate in their interpretation.

Ethical Considerations

Using internet-based platforms to deliver mental health interventions raises a number of ethical issues and challenges. First, in order to ensure confidentiality and privacy during the online sessions and minimize cybersecurity risks, the collection and storage of data comply with the Israeli Protection of Privacy Regulations (Data Security): All data collected will be stored in a secured server and only the main investigators will have access to the final datasets. The second issue relates to distress management or the risk that the topics discussed during the sessions may exacerbate distress among some participants. This risk is addressed by guiding the group's moderators, who are

trained clinicians, to monitor the participants' affect and if deemed necessary to conduct a brief risk assessment and provide additional support following the end of the session.

DISCUSSION

This study aims were to develop a short-term online group intervention utilizing Zoom and WhatsApp to increase digital literacy, relieve adverse mental health effects and promote better coping and well-being among community-dwelling older individuals who have been shut in during the COVID-19 pandemic. Promoting the well-being of older people during a global health crisis requires an understanding of the target group and the specific hardships with which they struggle during routine and emergency situations. These individuals may find it difficult to navigate through the sea of online resources, and are thus highly vulnerable in scenarios where social distancing and isolation are required, and in which digital tools become a primary source of communication. Thus, developing an intervention that enhances both digital literacy and coping skills can be central to their resilience and well-being during such times, and provide valuable information regarding their abilities to adapt and strive in times of public health crises. Identifying those who are the better adaptors and those who struggle with difficulties can enhance preparedness for future events.

Furthermore, as older people are generally considered particularly susceptible to loneliness and mental distress (66, 67), the digital and coping skills acquired can be applied also during routine daily life or during future disease outbreaks. Thus, this project stands to make an even greater contribution in terms of the known and global phenomenon of social isolation among older individuals, and its potentially dire health and social consequences (66–68).

From a broader public health perspective, providing older individuals with the knowledge and ability to independently communicate online with their significant others and/or with various caretakers can contribute, even if indirectly, to their adherence to protective guidelines of physical distancing and to minimizing their exposure to the coronavirus or other infectious diseases.

If this protocol is proven effective, it can be expanded to other populations such as, older individuals living in assisted living frameworks or nursing homes, people with disabilities, or any population at high risk of experiencing mental distress during a continuous public health emergency (69, 70) such as the COVID-19 pandemic. Additionally, although the current protocol is addressed solely to Hebrew-speaking older individuals, another future potential expansion could involve the integration of multilingual facilitators in a specific social context in order to reach underserved older adults from other ethnic groups who might benefit from both improving digital literacy and coping skills. For example, in the Israeli context, the integration of Arabic, Russian, and Amharic speaking moderators would help make the intervention more accessible, and more socially sensitive (71) to all of the sub-populations that comprise Israeli society.

The surge of interest in and acceptance of digital tools among both health and social care providers and consumers that has been triggered by the COVID-19 global crisis (72) offers a unique and important opportunity to explore the effectiveness and full potential of various digital initiatives that offer support and mental health care (73). In this regard, developing high-quality protocols to evaluate these digital initiatives is particularly crucial in order to provide clear evidence of their efficacy and benefits on the one hand, and/or to expose potential risks and pitfalls on the other. We feel that our protocol offers a robust design for the evaluation of a digital group intervention to improve mental health indicators. It can easily be adapted to evaluate other digital initiatives in this field or similar fields (e.g., “lifestyle interventions,” such as those focused on physical exercise, diet, etc.) (74) that might also be impacted during long periods of isolation.

Challenges and Limitations

There are several challenges in the implementation of this intervention. First, the current recruitment procedure may potentially lead to a selection bias. Using digital platforms as a primary source for recruitment may lead to the exclusion of ICT non-users, people of low socioeconomic status, and other marginalized groups who may well be most in need of these kinds of interventions. It is our current goal to establish a structured infrastructure for participants' enrollment through Israel's Ministry of Social Affairs and Social Services, as well as through local municipalities. Doing so will allow for an internal mapping of older individuals across Israel in order to locate people who live alone, and/or have background morbidities (i.e., people who constitute the most vulnerable subgroup of older individuals in the current pandemic context). In the event of a second outbreak, this kind of mapping will enable a rapid implementation of the protocol.

Another challenge relates to the time and resources required to offer such interventions. Although, we believe that the benefits of the program detailed above outweigh these challenges, we see much importance in investing more research to reduce costs and make the program sustainable.

And finally, the scope of the intervention is also worth discussing. As this intervention focuses on mental health as a way to promote well-being, it may have a limited impact on individual lifestyle behaviors in the long run, especially if learned strategies are not practiced on a daily basis. Important other determinants of health and well-being such as physical exercise, good dietary management, and cultural activities – the likely lack of which have all had an impact during the pandemic outbreak (74, 75) – are not addressed by the current online intervention, although, there may be some indirect positive effect of our program on older people's approach to these issues. To this end, we did use the WhatsApp groups as a channel to inform participants of other initiatives and events in these domains. Hence, the digital group intervention offered here is only one element of an integrated, system-wide approach required for the successful support of vulnerable populations during an ongoing public health emergency such as that which has been caused by the current eruption of COVID-19.

ETHICS STATEMENT

Ethical approval to conduct this study was obtained from the Ben Gurion University of the Negev (BGU) Human Subjects Research committee (ID: 1885-1). Informed consent will be obtained from all study participants at baseline. Research assistants will send the form *via* email or WhatsApp and the participants will then provide their written informed consent.

AUTHOR CONTRIBUTIONS

SS, DY-K, GG, LA-D, AMC, and OS are members of the research team and contributed to the design of the study. SS, DY-K, LA-D, AMC, and OS developed the study protocol. OS and GG developed the cognitive-behavioral intervention protocol. SS wrote the manuscript. All authors provided comments and approved the final manuscript.

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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.

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Assessment of Need for Recovery and Its Relationship With Work Characteristics and Health in a Sample of Chinese Doctors: A Cross-Sectional Survey

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Background: China is launching an unprecedented health care system reform. However, the long-term interests of doctors seem to have been ignored during this process especially considering that the work environment and work-life balance for doctors have severely deteriorated over the past decade. Their well-being and health are facing substantial threats due to heavy workloads and inadequate recovery opportunities. This study aimed to investigate the extent of need for recovery (NFR) among Chinese doctors and to examine their work-related fatigue. The study also examines the relationship of NFR with workplace satisfaction and health outcomes among Chinese doctors.

Methods: A total of 2,617 doctors from 30 administrative regions in China participated in this study to assess the need for recovery and its relationship with work characteristics and health. A cross-sectional survey was conducted using the Chinese version of the Need for Recovery Scale (NFRS). Participants were invited to complete an anonymous online survey during May 2016. Data were analyzed using descriptive statistics, one-way ANOVA, reliability analysis, Pearson correlations, and hierarchical multiple regression analysis.

Results: Significant differences in NFR scores were found across demographic characteristics such as age, service years, hospital levels, educational attainment, professional positions, work shifts, and working time. Regardless of any illnesses they might be experiencing, about 70.0% of participants remained at their job even though many doctors (22.1%) must continue working under the policies of the organization, which led to more pronounced NFR ($P < 0.001$). Further, a higher NFR was negatively related to workplace well-being and self-reported health outcomes of participants.

Conclusions: Work-induced fatigue is a growing threat to doctors in China and their recovery opportunities are extremely limited in the workplace. High NFR exerts a considerable effect on their workplace well-being and health. China's hospital managers should pay close attention to the fact that doctors have little chance of recovery, and

should offer doctors' positive encouragement and support to enhance well-being. To improve doctors' working conditions, targeted prevention policies must be introduced by policymakers to control this spreading crisis.

Keywords: need for recovery, cross-sectional survey, Chinese doctors, workplace well-being, self-reported health outcomes

BACKGROUND

Over the past decade, China has undertaken a series of reforms to promote an equitable and efficient health care delivery system (1). Despite numerous achievements that have been realized to some extent, a number of critical issues have still not been solved (2), and new problems and dilemmas are constantly emerging. Violence against healthcare staff in hospitals has become a prevalent public health problem (3) and has attracted considerable attention from citizens, the media, scholars, and China's government (4). As a result, how to deal with the doctor-patient relationship is raising a new and additional source of stress among doctors in China. As a consequence, working conditions and work-life balance among Chinese doctors continues to deteriorate (5).

China's government declares that their reforms follow a principle that is referred to as a "Person-Centered Framework"; however, most of the policies developed in the area of healthcare reform during recent years seem to only exhibit a patient-centered approach. Further, the various policies aimed at reducing the cost of healthcare services and enhancing the quality of health services are continually adding increased pressure on public hospitals. In order to comply with the policy goals, Chinese doctors are suffering from diverse challenges; increased workload without increased revenue in the public hospital setting has caused more complaints and burnout among physicians. The occupational health and wellness of Chinese doctors escape the notice of policy-makers notice all the time, which, in turn, results in a vicious circle: if the participation of doctors is absent, any series of reforms to China's healthcare system cannot proceed smoothly (6).

Recently, Kelly et al. proposed an Employee-Centered Care Model and suggested that the promotion of healthcare providers' health and wellness contributed to enhancing benefits in the areas of health care costs, access, and patient satisfaction (7). In reality, however, the workload and fatigue of doctors has received little attention (8) in China. In short, a focus on doctors' working environments, occupational health and safety, and labor rights, as an important component of the healthcare system, should be emphasized in healthcare reforms.

During workdays, individual physical and mental resources are often used and depleted to meet work-related requirements (9). Work-induced fatigue is a major topic in the domain of occupational health (10) and is a common experience for healthcare staff (11), especially for doctors, who work under an organizational environment characterized by long working

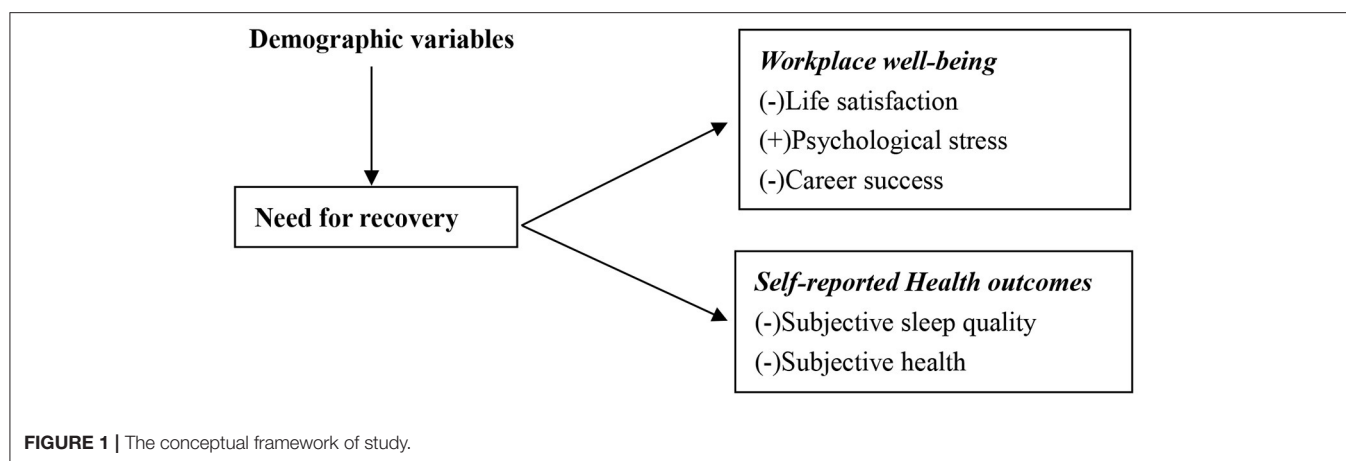
hours, shift work, frequent night duty, heavy workloads, high work stress, inadequate sleep, and short breaks between shifts (3). In addition, doctors need to engage in emotional labor strategies, as a means of displaying organizationally appropriate emotions in the hospital setting including deep acting, surface acting, and the suppression of naturally felt emotions (12), in order to create close relationships with their patients and patients' relatives, which will increase their fatigue-related risks. These issues are especially problematic in urban public hospitals in China due to increasing medical service demands and an insufficient number of doctors (2). A large number of patients force Chinese doctors into hectic work schedules (13), in which their role is to promote patients' wellness, rather than their own (14). Accordingly, it is a common and inevitable outcome that, along with depletion of psychological resources that can counter negative psychological states such as depression, anxiety, and other psychiatric or medical disorders (15), Chinese doctors frequently suffer from prevalent fatigue (16). One issue for Chinese policymakers is how to help doctors maintain work-recovery balance and avoid burnout while promoting excellent patient care (14).

Need for recovery (NFR) is one topic regarding the work-related fatigue issue that has attracted considerable attention from both scholars and practitioners. NFR refers to a variant of the fatigue experience (17). It is regarded as an early diagnosis of chronic fatigue and is a breakthrough point in the prevention of chronic fatigue (17). Thus, as an early sign of employees' prolonged fatigue and an indication of the need to take a break and recuperate from work demands (18), NFR is frequently investigated in various fields such as sociology, organizational psychology, and occupational health psychology (19). Previous studies have demonstrated that NFR is reflected in subjective evaluations of short-term effects by self-reported statements regarding a working day (20). It is induced when employees lack time to recover during periods of work (21). NFR can also be identified as an indicator of failing to recover from the effects of fatigue, which is similar to an initial stage of a continuous process of fatigue (17).

Numerous studies have investigated the causes of NFR, which mainly include work characteristics (22) (e.g., pace and amount of work, physical effort, skill utilization, task autonomy, relationship with colleagues, relationship with direct supervisor, and job security), work-family conflict (23), job stressors (24), low quantity of sleep/rest (25), and poor psychological detachment (24). In short, due to an imbalance between job demands and available resources, both elevated job demands (26) and reduced job control and resources (support) (27) show a robust prognostic value for the level of NFR.

It is reasonable and understandable that hospital managers encourage their doctors to work diligently, so as to improve

Abbreviations: ECHMU, Ethics Committee of the Harbin Medical University; NFR, need for recovery; NFRS, need for recovery scale.



the efficiency and quantity of the doctor's service, especially in these times characterized by a shortage of human resources in the healthcare system. However, it has been shown that the effect of job involvement is a double edged sword for the staff (28), considering that doctors' time and energy is limited. Similar to "recharging the batteries," recovery is indispensable for all doctors because it enables them to meet and be ready for new challenges. Their energy and attention both need to be restored, and suitable rest and relaxation are required for fatigued doctors. Moreover, higher levels of job involvement will consume their physical strength and mental resources under continuously uninterrupted work duties, resulting in inadequate recovery opportunities in the hospital workplace. If high NFR can't be relieved, NFR may be an indicator of well-being, health, safety, and performance problems. Although these are serious and realistic problems, they have not been the subject of extensive academic study to this point. The present research is the first to examine the subject of NFR among Chinese doctors, associated factors, and its effects.

RESEARCH HYPOTHESES

Previous studies have indicated that accumulated NFR contributes to more serious costs in terms of "load effects" (29), which in turn led to a collection of emotional, cognitive, and behavioral symptoms characterized by motivational deficits, feelings of work overload, social withdrawal, irritability, subjective health complaints (26), lack of energy for new efforts, and reduced performance. Further, if a doctor's NFR is not addressed, sleep deprivation and overfatigue are likely to occur, which in turn can lead to greater risk of clinical burnout (30). In summary, if the NFR is not adequately addressed it can have very negative consequences in many areas of doctors' lives. Thus, the following hypotheses are proposed in this study conducted with a group of Chinese doctors.

Hypothesis 1: There Is a Negative Association Between NFR and Life Satisfaction of Doctors

High workload is related to poor psychological detachment and the ability to relax during non-work time, which in turn hinders daily recovery for doctors (24). Thus, the time for leisure activities and social activities are sharply reduced for doctors. As a consequence, a prolonged activation of negative affect related to clinical work will be induced (31). Moreover, a doctor who does not have the opportunity for adequate recovery may have poor psychological detachment and the inability to refrain from job-related thoughts, which results in an increasing risk of emotional exhaustion (32). Thus, NFR can result in doctors maintaining a state of prolonged activation when at home or during leisure time, which is then associated with thinking and ruminating about work-related issues (33). This suggests that the doctor may feel overwhelmed and will often result in a situation where they continue to think about clinical duties to be accomplished even when they are at home or during leisure time. This may lead to a situation in which doctors' energy is constantly consumed which in turn increases their psychological stress. This leads to our second hypothesis:

Hypothesis 2: NFR Is a Positive Predictor of Psychological Stress Among Doctors

Recovery experiences can protect and foster personal resources that are necessary to achieving work goals, may reduce job demands and the associated physiological and psychological costs, and motivate growth, learning, and development among doctors (31). Thus, adequate recovery assists in meeting the basic psychological needs of autonomy, belongingness, and competence, which are important job resources for doctors; meeting these can also be intrinsically motivating for them. In addition, recovery experiences engender a feeling of mastery; doctors with an adequate recovery are likely to perceive having greater control over leisure time (34), which can help them to address new challenges or learn new things during leisure time. As a consequence, recovery experiences can foster a positive

satisfaction regarding the aspect of doctors' career evaluation. Conversely, high levels of NFR suggest that the doctor doesn't devote enough time to continuously improve on their own and the sense of their development and competence may be limited. Therefore, the following hypothesis is proposed in this study:

Hypothesis 3: NFR Reduces Doctors' Sense of Career Success

A misalignment between the internal circadian rhythm and the work schedule has been found to be a crucial cause of sleep disorder (35). Due to long working hours and overtime, doctors with lack of recovery opportunities have insufficient breaks. In this case, NFR can trigger disturbances of biological and social circadian rhythms (36). High NFR as a sign of occupationally-induced fatigue is prone to lead to a vicious circle, in which doctors might give extra effort at the beginning of each working period to rebalance the suboptimal state and to avoid faulty operation (37). As a result, doctors who have insufficient time to recover remain vulnerable to sleep loss. Thus, the following hypothesis is proposed in this study:

Hypothesis 4: NFR Is Related to Poor Subjective Sleep Quality

Numerous studies have demonstrated that people with long-term inadequate recovery during non-work time are more likely to experience a series of risks of physiological problems such as cardiovascular diseases (38), neuroendocrine reactivity (20), physical symptoms (39), muscular tension (40), and musculoskeletal problems (41). Indeed, the hazards caused by NFR have been widely studied and the relationship between NFR and health appears to be quite robust. However, even though a large number of Chinese doctors are suffering from overload, their high NFR and its associated impact get very little attention. Therefore, the following hypothesis is proposed in this study:

Hypothesis 5: NFR Is a Positive Predictor of Low Levels of Self-Reported Health Among Doctors

In summary, the purpose of present study is to gain further insight on the status of NFR among Chinese doctors and associated factors, and to clarify the relationship between NFR, workplace well-being and self-reported health outcomes of Chinese doctors. A conceptual framework of the study is provided in **Figure 1**.

METHODS

Participants and Procedures

An anonymous online cross-sectional survey was completed by doctors across the country during May 2016 in 30 of the 34 Chinese administrative regions. Participants did not include doctors from Tibet, Taiwan, Hong Kong, and Macao (Macau). Approximately 50 doctors from the authors' unit were recruited as original respondents to our survey, while the other participants were colleagues or classmates invited by the original survey respondents. The authors' unit is a well-known medical college

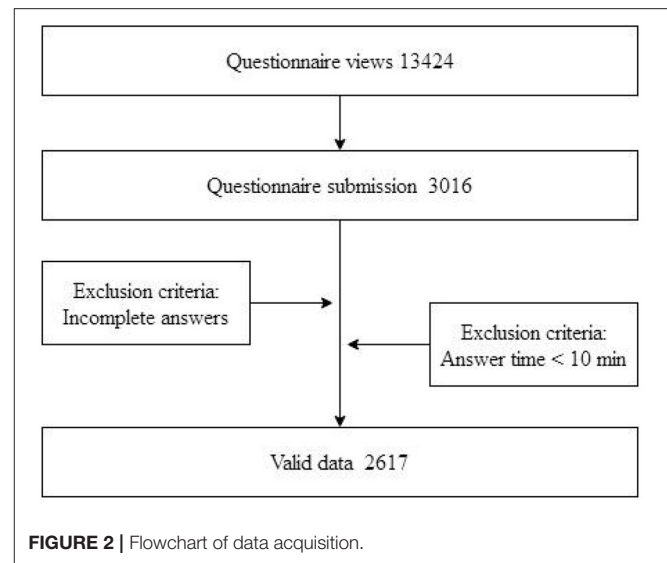


FIGURE 2 | Flowchart of data acquisition.

which has a great number of graduates who have worked throughout the country and have formed a vast alumni network which could be accessed to assist in data collection. Thus, a “snowball” sampling method (word of mouth) using the alumni network was employed. Since the social media platform WeChat has been widely used in China, it was very easy to send a website link (<https://www.wjx.cn/>) about our survey to the mobile phones of potential participants. This link was sent to 13,424 people, and 3,016 questionnaires have been submitted successfully. A total of 2,617 valid questionnaires have been obtained, excluding incomplete answers and questionnaires that take <10 min to answer. The effective recovery rate of the questionnaire was 86.8%. The specific data acquisition process is shown in **Figure 2**.

The research described in the present article meets the ethical guidelines of the ethics committee of the College of Public Health, Harbin Medical University and was approved by the Ethics Committee of the Harbin Medical University (ECHMU). Written informed consent could not be obtained because of the anonymous survey approach; hence, oral informed consent for the survey was approved by the ECHMU and obtained from each doctor. Before distributing the questionnaire, we informed participants of the anonymity and privacy protection measures of the questionnaire. Dialogue and alert pop up boxes were used to remind participants who agreed to complete the survey to send their replies to our research group. Thus, once a questionnaire was completed, it was assumed that the doctor had verbally agreed to participate in our survey by reference to the Wen's criteria (3).

Measures Need for Recovery

The NFR was assessed by using The Need for Recovery Scale (NFRS) which includes 11 items developed by Sluiter (37); the Chinese version of NFRS was translated by Qi Xin-liang (42). The items of the NFRS measure symptoms with yes/no questions to indicate the short-term effects of a day of work; thus, each item is dichotomously scored (no = 0, yes = 1). The total NFRS

score is calculated by summing up the scores of the 11 constituent dichotomous items, resulting in a score ranging from 0 to 11, with higher scores indicating a higher degree of NFR. The Cronbach's alpha for the scale was 0.850.

Workplace Well-Being

Three variables including life satisfaction, psychological stress, and subjective career success were selected to represent the workplace well-being of doctors. With reference to previous research (43), life satisfaction (44), psychological stress (45), and subjective career success (46) were each measured using one item. Items were rated on five-point Likert scales: life satisfaction–1 = extremely unsatisfied, 5 = quite satisfied; psychological stress–1 = not at all, 5 = very much; subjective career success–1 = least successful, 5 = most successful.

Self-Reported Health Outcomes

Two single items were used to measure doctors' self-reported health outcomes. Based on research by Fein and Skinner (47), overall subjective health was estimated by a widely used single-item measure ("In general would you say your health is": 4 = excellent, 3 = very good, 2 = good, 1 = poor). Subjective sleep quality (48) was measured by the question "How would you evaluate last night's sleep?"; the response format ranged from 1 = very bad to 4 = very good.

In addition, this study also collected demographic information from doctors including gender, age, service years, hospital level, marital status, and educational attainment. Further, the following occupational factors were considered: hours of work, shift work, psychological detachment from work during non-work time, and continuously working while suffering from illness. A single-item question was provided to participants to assess psychological detachment during non-work time: "Do you still need to think about work when you are resting?"; the response format ranged from 5 = No detachment (I must pay close attention to my responsibilities in my department) to 1 = Overall detachment (I don't need to care about my responsibilities in my department at all).

Statistical Analysis

The NFR score were examined using one-way ANOVA. Pearson's correlation coefficients were used to estimate correlations between the NFR, workplace well-being, and self-reported health outcomes. Hierarchical linear regression analysis was performed to test the effects of groups of independent variables on workplace well-being and self-reported health outcomes. The demographic variables related to NFR in univariate analyses ($P < 0.05$) were entered into step 1 of the hierarchical regression analysis model, to eliminate their interference on the dependent variables. We also addressed the relative impact of each category of all variables on workplace well-being and self-reported health outcomes by this analysis model. In the step 2, both the demographic variables and NFR were entered into the model to test NFR's explained variance in the dependent variables. We provided data including F , and ΔR^2 . Standardized regression coefficient (β) and P -value for each step in the regression model. In this study, statistical

significance was set at $P < 0.05$ (two-tailed). All of the analyses were conducted using SPSS 24.0 (SPSS, Inc., Chicago, IL, USA) for Windows.

RESULTS

Demographic Information

Demographic variables of participants and the ANOVA models for the NFR of Chinese doctors are shown in **Table 1**.

Of the 2,617 doctors surveyed, most (66.6%) of the participants were from tertiary hospitals. The age of participants ranged from 20 to 53 years. Females made up 52.3% of the sample. Most (82.1%) participants were married. As for educational background, 51.7% obtained bachelor's degrees and 38.1% obtained master's or doctorate degrees. A total of 306 (11.7%) participants were without professional titles, 564 (21.6%) resident doctors, 898 (34.4%) attending physicians, 569 (21.8%) associate chief physicians, and 270 (10.4%) chief physicians. The representativeness of the responding doctors was evaluated by comparing characteristics of the study participants with those of Chinese doctors which were published in Chinese Health and Family Planning Statistical Yearbooks (CHFPSY), regarding age groups distribution (22.40% under 30 years in study participants vs. 22.10% in the CHFPSY report), gender (47.40 vs. 55.90% males), service years (16.50% under 30 service years in study participants vs. 23.40% in the CHFPSY report) and education level (44.30 vs. 51.70% bachelor in the CHFPSY report). Thus, sampling bias is also potential interference factor, resulting in an overreported doctors' dissatisfaction and/or those who complain of their professional situation.

A total of 2,617 (86.8%) respondents reported their NFR status. The median score of the overall level of NFR of Chinese doctors was nine points (range = 0–11). This result indicates that Chinese doctors have severe work-related fatigue.

As shown in **Table 1**, the differences in NFR scores for gender and marital status were not statistically significant ($P > 0.05$). With respect to age, the highest NFR was found among participants aged 31–40 years ($P < 0.001$). Length of service between 11 and 20 years had higher NFR scores than groups of other service years ($P < 0.001$). Doctors working in the large-scale general hospitals had higher levels of NFR than those in low-level hospitals. Doctors with master's and doctoral degrees reported significantly higher NFR than all others ($P < 0.001$) and attending physicians had higher NFR scores than all others ($P < 0.001$). Approximately 79.8% of participants reported working more than 8 h a day. Over one-half (61.6%) of participants who often worked at night had higher NFR scores than those with less night duty ($P < 0.001$). Respondents reporting prolonged working times had higher levels of NFR ($P < 0.001$). Most of the doctors reported low levels of psychological detachment (no detachment = 57.9%, little detachment = 29.8%); they also had higher NFR scores ($P < 0.001$). Approximately 70.0% of participants reported they generally continued to work when they are ill, and 22.1% of participants must continue to work long hours; they reported higher NFR scores than those who choose to rest ($P < 0.001$).

TABLE 1 | Characteristics of the respondents ($n = 2,617$).

Characteristics	N	%	Median(Q1,Q3)	F	P
Overall level					
NFR scores	2,540	97.06	9.00(7.00-10.00)		
Missing value	77	2.94			
Age				9.69	P < 0.001
≤30	587	22.43	9.00 (6.00-10.00)		
31-40	1,224	46.77	9.00 (7.75-10.25)		
41-50	658	25.14	9.00 (6.00-10.00)		
≥51	119	4.55	8.00 (6.00-10.00)		
Missing value	29	1.11			
Service Years				10.28	P < 0.001
≤10	1,088	41.57	9.00 (7.00-10.00)		
11-20	720	27.51	10.00 (7.00-11.00)		
≥30	376	14.37	9.00 (6.00-10.00)		
Missing value	433	16.55			
Hospital level				10.85	P < 0.001
Large-scale general hospital	1,740	66.49	9.00 (7.00-10.00)		
General hospital	733	28.01	9.00 (6.00-10.00)		
Primary hospital	139	5.31	9.00 (5.00-10.00)		
Missing value	5	0.19			
Gender				0.59	0.441
Male	1,240	47.38	9.00 (7.00-10.00)		
Female	1,369	52.31	9.00 (7.00-10.00)		
Missing value	8	0.31			
Additional degrees to MD				12.35	P < 0.001
No additional degree	291	11.21	8.00 (5.00-10.00)		
Bachelor	1,350	51.59	9.00 (7.00-10.00)		
Master	692	26.44	9.00 (7.00-10.00)		
Doctor	277	10.58	9.00 (7.00-10.25)		
Missing value	7	0.27			
Marital status				2	0.136
Single	397	15.17	9.00 (7.00-10.00)		
Married	2,148	82.08	9.00 (7.00-10.00)		
Divorced or Widowed	70	2.67	10.00 (8.00-10.00)		
Missing value	2	0.08			
Professional position				14.13	P < 0.001
Without professional title	306	11.69	8.00 (5.00-10.00)		
Resident doctor	564	21.55	9.00 (7.00-10.00)		
Attending physician	898	34.31	10.00 (7.00-11.00)		
Associate chief physician	569	21.74	9.00 (7.00-11.00)		
Chief Physician	270	10.32	9.00 (6.00-10.00)		
Missing value	10	0.38			
Shift work				62.13	P < 0.001
Dayworker	503	19.22	8.00 (5.00-10.00)		
Dayworker, but occasional work at night	500	19.11	8.50 (5.00-10.00)		
Night shift	1,613	61.64	8.67 (8.00-11.00)		
Missing value	1	0.04			
Working time (hours)				74.43	P < 0.001
≤8	528	20.18	7.00 (4.00-10.00)		
9-10	1,297	49.56	9.00 (7.00-10.00)		
11-12	504	19.26	10.00 (8.00-10.00)		
≥13	285	10.89	10.00 (9.00-11.00)		
Missing value	3	0.11			

(Continued)

TABLE 1 | Continued

Characteristics	N	%	Median(Q1,Q3)	F	P
Psychological detachment				55.12	$P < 0.001$
None detachment	1,514	57.85	10.00 (8.00-11.00)		
Little detachment	781	29.84	8.00 (6.00-10.00)		
Partly detachment	102	3.90	8.00 (5.25-10.00)		
Most detachment	182	6.95	7.00 (3.00-10.00)		
Overall detachment	35	1.34	8.00 (5.00-10.00)		
Missing value	3	0.11			
Continuous working under status of sickness				100.21	$P < 0.001$
Rest by organization's suggestion	39	1.49	5.00 (3.75-7.25)		
Rest by self-decision	169	6.46	6.00 (2.00-9.00)		
Generally, to continue working	1,831	69.97	9.00 (7.00-10.00)		
To continuous working by force	578	22.09	10.00 (9.00-11.00)		

TABLE 2 | The information of distribution of each variable.

Variables	Mean	SD	Median	IQR
1. Need for recovery	8.17	2.94	9	1-11
2. Life satisfaction	2.48	1.03	3	1-5
3. Psychological stress	3.33	0.86	3	1-5
4. Subjective career success	2.87	0.89	3	1-5
5. Subjective sleep quality	2.29	0.76	2	1-4
6. Subjective health	2.47	0.64	3	1-4

SD, standard deviation; IQR, inter-quartile range.

Information on and Distribution of all Variables

The means, standard deviations, medians, and IQRs are provided in Table 2.

Correlations Between Study Variables

Pearson correlation coefficients between the continuous variables are shown in Table 3. As indicated in the table, all variables were significantly correlated with each other. NFR was positively correlated with psychological stress ($r = 0.470$, $P < 0.001$), and negatively correlated with life satisfaction ($r = -0.409$, $P < 0.001$), career success ($r = -0.245$, $P < 0.001$), subjective sleep quality ($r = -0.398$, $P < 0.001$) and subjective health ($r = -0.428$, $P < 0.001$).

Hierarchical Linear Regression Models

Two hierarchical regression analyses were performed to examine the influence of NFR on workplace well-being (Table 4) and self-reported health outcomes (Table 5) after controlling for the effects of the demographic variables. Need for recovery was posed as a independent variable in this study, and workplace well-being (life satisfaction, psychological stress, and career success) and self-reported health outcomes (subjective sleep quality and subjective health) as dependent variables, respectively. Step 1 explained the influence of demographic variables (age, service

years, hospital level, education level, professional title, shift work, working time, psychological detachment, and continuous working under sickness status) on each dependent variable. Step 2 explained joint influence of demographic variables and explanatory variable on response variable.

As shown in Table 4, NFR accounted for an additional 7.0% of the variance in the prediction of life satisfaction in step 2. The test of ΔR^2 was significant, indicating that NFR was a significant predictor of life satisfaction. NFR was negatively associated with life satisfaction ($\beta = -0.293$, $P < 0.001$). A positive correlation between NFR and psychological stress was observed in our respondents ($\beta = 0.374$, $P < 0.001$). We found that NFR was negatively associated with career success ($\beta = -0.219$, $P < 0.001$). In consideration of all of the above-mentioned factors, these results suggest NFR had a negatively association with the workplace well-being of Chinese doctors.

As indicated in Table 5, NFR accounted for an additional 9.1% of the variance in the prediction of subjective sleep quality in step 2. The test of ΔR^2 was significant. Thus, these data are consistent with the notion that NFR is a significant predictor of subjective sleep quality ($\beta = -0.332$, $P < 0.001$). Consistent with the above results, NFR was also negatively associated with subjective health ($\beta = -0.370$, $P < 0.001$). Overall, these two findings demonstrated that NFR also had a negative association with doctors' self-reported health outcomes.

TABLE 3 | Means, standard deviations (SD), and correlations of continuous variables.

Variables	1	2	3	4	5	6
1. Need for recovery	1					
2. Life satisfaction	−0.409**	1				
3. Psychological stress	0.470**	−0.389**	1			
4. Subjective career success	−0.245**	0.352**	−0.223**	1		
5. Subjective sleep quality	−0.398**	0.350**	−0.471**	0.227**	1	
6. Subjective health	−0.428**	0.379**	−0.464**	0.278**	0.524**	1

** $P < 0.001$.**TABLE 4 |** Hierarchical linear regression models for workplace well-being.

Variables	Life satisfaction		Psychological stress		Career success	
	Step1(β)	Step2(β)	Step1(β)	Step2(β)	Step1(β)	Step2(β)
Control variables						
Age	0.076	0.074	0.031	0.033	−0.019	−0.020
Service Years	0.009	−0.003	0.014	0.031	0.120*	0.110
Hospital level	−0.007	−0.017	−0.008	0.003	0.008	0.002
Education level	0.041	0.043	0.009	0.007	0.050	0.051*
Professional title	−0.104***	−0.090**	0.018	−0.001	0.128***	0.139***
Shift work	−0.090***	−0.064**	0.032	0.000	−0.100***	−0.081***
Working time	−0.117***	−0.074**	0.157***	0.103***	−0.044	−0.012
Psychological detachment	−0.085***	−0.038	0.182***	0.120***	0.050*	0.086***
Continuous working under sickness status	−0.277***	−0.210***	0.224***	0.138***	−0.135***	−0.085***
Need for recovery		−0.293***		0.374***		−0.219***
<i>F</i>	44.666***	62.933***	45.257***	80.312***	27.370***	35.349***
ΔR^2		0.070***		0.115***		0.039***

* $P < 0.05$.** $P < 0.01$.*** $P < 0.001$ (two-tailed).**TABLE 5 |** Hierarchical linear regression models for self-reported health outcomes.

Variables	Subjective sleep quality		Subjective health	
	Step1(β)	Step2(β)	Step1(β)	Step2(β)
Age	0.054	0.053	−0.050	−0.052
Service years	−0.083	−0.099	0.008	−0.009
Hospital level	−0.009	−0.019	0.017	0.006
Education level	0.083***	0.085***	0.069**	0.071**
Professional title	0.009	0.026	−0.027	−0.008
Shift work	−0.064**	−0.036	−0.047	−0.015
Working time	−0.165***	−0.117***	−0.139***	−0.086***
Psychological detachment	−0.087***	−0.033	−0.085***	−0.025
Continuous working under sickness status	−0.185***	−0.109***	−0.189***	−0.104***
Need for recovery		−0.332***		−0.370***
<i>F</i>	29.452***	53.123***	25.049***	55.390***
ΔR^2		0.091***		0.113***

* $p < 0.05$.** $p < 0.01$.*** $p < 0.001$ (two-tailed).

DISCUSSIONS

In the present study, a cross-sectional survey was conducted to examine the extent of NFR of Chinese doctors. This study also investigated whether NFR differs in terms of doctors' demographic variables. Another purpose of this study was to examine the relationship between NFR, workplace well-being, and subjective health outcomes. These cross-sectional data demonstrated that the median score of the overall level of NFR of Chinese doctors was nine points (range = 0-11). Given that the maximum score on this scale is 11, this indicates that the respondents experienced a high level of NFR. There are no data available in previous studies providing the distribution of NFR scores in the general population, which makes it difficult to determine if the level of NFR among Chinese doctors is comparatively high. However, the results still indicated that participants exhibited serious work-induced fatigue without being adequately recovered, as the findings indicated that almost two-thirds (61.6%) of the participants often work during the night and 79.8% of them needed to work more than 8 h every day; 10.9% of participants even reported they had to work more than 13 h every day. As a consequence, the workloads of Chinese doctors are very heavy (3), which tend to cause tiredness and even sudden death for some doctors (8). Previous research has suggested that most doctors object to their next generation working in the medical industry (49).

The present study provided further insight into work-induced fatigue and NFR of Chinese doctors. This study's results demonstrated that the highest NFR was found among attending physicians, doctors aged 31-40 years, and those with 11-20 years of work experience; these findings are consistent with previous studies (19) indicating that increasing age is associated with NFR. However, there is a further explanation for this result. In China, attending physicians aged 31-40 with 11-20 years work experience undertake more work roles and extreme work overloads (5). They often take more on night duty and have less time for rest and leisure; along with increasing higher psychosocial job demands, these factors all contribute to their fatigue.

The data in this study illustrated that higher educational and hospital levels are associated with higher NFR. Tertiary hospitals and high educational levels are scarce resources in China. It is understandable that doctors with higher educational levels in tertiary hospitals are the busiest. To provide quality healthcare services to a large number of patients (3), they are limited in opportunities for rest time. This is also a reflection of an insufficient quantity of high quality medical resources in China. The population of China is huge, which means that the medical needs of patients are very large as well. High-level hospitals solve this problem by increasing service quantity and the workload of doctors. In this case, better doctors become busier, which leads to the fact that their risks of fatigue and health burdens also become higher. Shift work as an important predictor for NFR was verified in our study; a similar result was observed by Maastricht Cohort Study (50). Moreover, another study among physicians reported that shift work of emergency physicians can lead to disturbed sleep and increased fatigue and neurohormonal results (51).

Although the negative health effects of on-call work have been demonstrated in previous research (52), our investigation illustrated that 61.6% of participants were often working during the night in China. This means that they likely have inadequate time to recuperate from work-related efforts because of their on-call duties, which was also an important reason for their fatigue. Results from **Tables 4, 5** also indicate that doctors who engage in longer work times are more likely to experience low life satisfaction, high levels of psychological stress, and poor sleep quality and health. Likewise, the present study also found that prolonged work hours are associated with high levels of NFR. This conclusion is strikingly similar to HÄRMÄ's (53), who found that doctors who must deal with prolonged or repeated exposure to stress, often experience a sustained arousal without the opportunity for adequate recovery (53). High job demands may result in doctors being unable to control their duties (54), which in turn increases the risk of negative health-related outcomes (33). Our regression results also suggest that shift work is more likely to threaten doctors' perceived life satisfaction and subjective career success, and even trigger sleep problems. In addition, the present findings also suggest that for many doctors it was very difficult to attain psychological detachment from work during off-job time (no detachment was 57.9%, little detachment was 29.8%), which suggests that doctors were still occupied by work-related duties during off-job time, in turn leading to higher NFR. As a partial mediator between job stressors and low work-home boundaries on the one hand and strain reactions (emotional exhaustion, need for recovery) on the other hand (24), psychological detachment refers to a specific cognitive-emotional state in which individuals mentally disconnect or psychologically detach from work and do not need to deal with job-related issues during their off-job time (55). Thus, insufficient psychological detachment is a potential explanatory mechanism for the relationship between NFR and workplace well-being (24). The stressor-detachment model suggests that work stressors from doctors' duties or demands are a serious impediment to the psychological detachment of doctors from work during non-work time, which will further cause doctors' strain reactions and negatively impact affective states, psychological reactions, and workplace well-being (56). Additionally, the results of the two regressions (**Tables 4, 5**) also indicate that a doctor with a state of psychological detachment during non-work time is likely to experience better workplace well-being and self-reported health outcomes. Additionally, when doctors were uncomfortable or experiencing illness, 70.0% of participants reported they generally continued working, and 22.1% of participants must continue working under the policies of the organization, resulting in higher NFR scores than those who are able to rest. This finding indicates that not only psychological detachment of doctors was difficult to obtain in non-working time, but also doctors' bodies can't get rest even when they are ill. This has seriously affected the interests, well-being, and health-related outcomes of doctors. A considerable amount of research has been conducted on many careers during the last decade, but few have been conducted with doctors. This study found that doctors with elevated NFR had lower workplace well-being (57) and health status (26), and that this was closely related to their quality of

life. These results are similar to previous studies (58), but those findings were reported in professional fields other than medicine. In fact, other studies have demonstrated that NFR plays an important mediating role on the relationship between overtime or overload and health of employees (31, 57). High workload combined with lack of control (59), together with unreasonable work arrangements, reduces the recovery opportunity of doctors, resulting in the body and mind experiencing long-term NFR (31), so their well-being and health are adversely affected. The cognitive activation theory of stress (60) provides more insights and explanations of this association. Overtime work and excessive workload easily lead to sustained activation, combined with insufficient recovery from work. This can result in negative load consequences, followed by damaged individual well-being and health. Relevant pathophysiological mechanisms were also reported in previous findings (61). Overall, the main contribution of our study is to highlight that there is considerable NFR among Chinese doctors, causing considerable of work-induced fatigue. In China, doctors face a heavy workload, prolonged work times, frequent shift work, lack psychological detachment, and even have no choice but to continue working when they are ill, all of which result in reducing the work life quality of doctors. These are all considerable risks for elevated NFR, which in turn will damage the interests, well-being, and health-related outcomes of doctors. These effects even spread to medical service results (3). Corresponding interventions and policies for reducing work-induced fatigue have been introduced in many developed regions such as Australia, New Zealand, Europe, and the USA (62). Unfortunately, these issues aren't on the agenda in China. It remains poorly understood that these factors are of great importance for doctors' individual well-being and the country's health-care system. In this study, five suggestions were put forward from three aspects of individual doctors, hospitals and institutions to relieve the fatigue of doctors in tertiary hospitals who work for a long time. First of all, doctors should develop hobbies outside work. We encourage doctors to spend more time on sports, leisure and entertainment to relieve work pressure. Second, we suggest that doctors use mindfulness to adjust their inner state and timely recover their mind. Third, it is suggested that the hospital optimize the shift system in order to allow doctors in the tertiary hospitals to get sufficient rest. Fourthly, we suggest that the hospital organize medical staff to carry out "employee assistance plan" to help each other to reduce the pressure of life. Fifthly, the hierarchical diagnosis and treatment system needs to be continuously promoted in order to reduce the workload of doctors in tertiary hospitals. It is earnestly hoped that this study can motivate some policy makers in China to address doctors' occupational health and well-being, as well as lead to the development of specific targets for prevention of fatigue and high NFR.

LIMITATIONS

Although there are significant findings in the present study, the study has several limitations. First, a convenience sample was used in this study, which raises the potential for sampling bias resulting in a non-random sample of a population in which all individuals were not equally likely to have been selected. Thus, we

cannot provide complete confidence in the results of the overall investigation. Second, a cross-sectional design prevented the determination of causation related to the relationship between the NFR, workplace well-being, and health; thus, one important direction is that longitudinal studies should be conducted in the future. Third, the data were collected from self-reports of doctors, which introduces the possibility of response bias from social desirability or negative affect. The doctors might have overestimated or underestimated the association between the study variables. Moreover, using online questionnaires in an unmonitored setting is more likely to result in those experiencing difficulties responding. Further, it is not known whether those returning incomplete questionnaires differed in any significant way from those who completed them.

CONCLUSIONS

To our knowledge, this is the first investigation to measure the prevalence and status of the NFR and associated factors among Chinese doctors, which seems to be often ignored although it is a very important dimension. This paper also indicated that the need for recovery is significantly related to workplace well-being and subjective health of doctors. The present study also provides insight into work overload, psychological detachment, and continuous working in spite of illness of Chinese doctors, which suggests some new perspectives for future research. In summary, we have identified that Chinese doctors are caught in a pattern of inadequate recovery outside work and are suffering considerable work-induced fatigue; their interests and well-being are facing serious challenges, and their health is threatened. The results in the present study suggest that some necessary actions should be implemented to put an end to the spreading crisis.

DATA AVAILABILITY STATEMENT

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

ETHICS STATEMENT

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

TS conceived, designed, and performed the experiments and wrote the paper. TS, YS, DY, and SZ analyzed the data. TS, YS, DY, and XW contributed reagents, materials and analysis tools. TS and XW approved the final manuscript for publication. All authors contributed to the article and approved the submitted version.

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Yoga as Complementary Care for Young People Placed in Juvenile Institutions—A Study Plan

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Recent studies have established yoga practice as a mainstream complementary clinical tool within correctional environments. It is shown that regular yoga practice is coupled with improved impulse control, sustained attention, attenuated antisocial and self-harm behaviors, reduced stress, and psychological distress. No academic research until now has provided evidence of mental health benefits of yoga for institutionalized young people. In Sweden, each year more than thousand adolescents receive compulsory care at juvenile institutions run by the Swedish National Board of Institutional Care. These young people are characterized by substance abuse, aggressive and antisocial behaviors, high frequency of self-harm, and the experience of abuse. Most of them manifest attention problems, depression, anxiety, and impulsivity. They have a dramatically increased risk for recidivistic criminal behavior, continuous medical, and social care and untimely death. The present study plan aims at evaluating, with previously validated psychological measures, in a quasi-experimental design, the effects of yoga practice for institutionalized adolescents. Adolescents' experiences of participating in yoga practice will also be assessed by semi-structured individual interviews. Ethical approval was given by the Swedish Ethical Review Authority. It is hypothesized that yoga practice (in combination with the standard treatment within institutional care) will reduce institutionalized adolescents' aggression, antisocial behavior, anxiety, depression, and negative affect, and increase their cognitive flexibility (in the form of increased impulse control).

Keywords: adolescents, aggressive antisocial behavior, juvenile institutional care, mental health, substance use, yoga

INTRODUCTION

Young People Placed in Juvenile Institutions

The Swedish National Board of Institutional Care (Statens institutionsstyrelse, SiS) runs special residential homes and provides individually tailored compulsory care for young people with psychosocial problems, substance abuse and aggressive antisocial behaviors. Care is provided under the terms of the Care of Young Persons (Special Provisions) Act (LVU) (1990:52) and the Secure Youth Care Act (LSU) (1998:603). The social services of the municipalities are responsible for handling and placing these young people into SiS, as well as taking care of their needs and support after their release from SiS. SiS runs 23 special residential homes in Sweden that currently holds about 700 adolescents in need of special, compulsory care (Personal communication with SiS statistic unit, January 2021).

Every year, the Social services commit over a thousand young people between 15 and 21 years old to SiS's juvenile institutional care due to drug abuse, criminal activity, and/or other socially destructive behaviors. According to SiS (1) the average length of special care in 2019 was 164 days per young person, amounting to ~206,000 care days a year. In 2019, Swedish municipalities alone spent 1.44 billion Swedish crowns (SEK) on young people's care committed to juvenile institutions.

Within this population of children and young adults, the majority has at least one but most often several coexisting psychiatric diagnoses (2), even though the primary reason for the compulsory care is their antisocial behavior, which hampers individual development. The most common diagnosis for both young males and females is Attention-Deficit Hyperactivity Disorder (ADHD), followed by Substance Use Disorder and Post-Traumatic Stress Disorder (PTSD). During the peculiar circumstances of the year 2020, due to the COVID-19 pandemic, a substantial proportion of Swedish adolescents reported more substance use (3) suggesting a possible increased pressure on SiS services in following years.

About half of the young people in the SiS juvenile institutional care report having experienced depression for a longer period of time, attention difficulties, and/or severe anxiety/tension. Almost every other female (47%) and more than 10% (13%) of males has attempted suicide. More than one in three has been the victim of physical and/or psychological abuse by a parental figure. About 40% report having witnessed violence against someone close to them, and nearly half of the females have been victims of sexual abuse (4).

A majority of the young people in SiS care have failed at school, have difficulties keeping up with the teaching, and/or have poor attendance. Their challenges are often complicated, and their environment (family relations, the circle of friends) has often had a substantial impact on their current situation.

The special residential homes run by SiS are the only treatment facilities in Sweden that have the right to forcibly detain individuals who have been taken into compulsory care according to the LVU Act. This right encompasses the options to place individuals under lock and key and/or physically restrain them if they pose a danger to themselves or others. In 2019, physical restraint was used 1,152 times in the residential homes run by SiS (1). According to SiS, most of these events involved a small number of young people and the common factor was a low functioning level, neuropsychiatric disorders, and comorbid psychiatric illness.

Recent research has shown that this population of adolescents has an increased need for improved and integrative treatments. A 3-year follow-up study of institutionalized young people found dramatically increased rates of criminal recidivism, use of inpatient care, and untimely death among young people in institutional care compared to an age-matched general population group (5). The past year's (COVID-19 pandemic) dramatic changes resulted in increased stress, insecurity, fear of illness, risk of an imbalance between school-work and private life, and social isolation. Adolescents reply to these type of traumatic events with an increased incidence of anxiety-, eating disorders, depression, self-harm, suicide, and illegal substance use. A

general increase in crime, where violence in close relationships and cyberbullying are some of the most frequent problems, is predicted. These are realities that high schools, social services, health cares, and families have to be prepared to face.

Psychological/Behavioral Changes Induced by Yoga

In recent decades numerous research studies have investigated the effects and action mechanisms of yoga, often inclusive meditation and specific breathing techniques. Those studies suggest that such activities can have a significant impact on somatic and mental health. It has been shown that yoga increases psychological well-being, self-compassion, and resilience (6–8). For instance, some results suggest that yoga, including meditation and specific breathing techniques, can effectively reduce psychological distress (9, 10), anxiety, and depression (11–13). Yoga combined with controlled, same rhythm breathing was associated with a reduction in suicidal ideation for patients diagnosed with major depressive disorder (14). A specifically developed yoga intervention (trauma-informed yoga) has shown a reduction of symptoms in treatment-resistant PTSD (15).

There are also indications that yoga (including meditation and specific breathing techniques) can have beneficial effects on an individual's neurobiology and increase the capacity to regulate emotions by modulating the activity and connectivity in the prefrontal cortex, anterior cingulate cortex, insular cortex, and the amygdala (16, 17). Yoga improves the sympathetic nervous system's regulation and the hypothalamic-pituitary-adrenal system, which are essential in response to stress (18).

Today it is well-established that the environment (physical, psychological, social, and/or cultural) induces distinct gene expression changes, which can be studied by the emerging field of psychosocial genomics (19) focusing on the relationship between the body, mind, and behaviors. Studies on yoga and other mind-body interventions suggest that these practices positively affect gene expression profiles; for example, they may lead to a reduced risk of inflammation-related diseases (20). Multiple lines of evidence (preclinical, genetics, and bioinformatics) show an activation of immune system molecules and pathways that can contribute to psychiatric disorders' pathogenesis (21–23).

Last year a new review was published of randomized controlled trials testing the effects of yoga with youth (24), which concluded that there is growing evidence that yoga is a promising intervention for children and youth.

Yoga in Correctional Settings—Our Previous Results

The above-described physiological changes may explain those behavioral and psychological changes observed in our previous study on yoga in the Swedish Prison and Probation Services (9, 25). In recent years, yoga has become popular in many correctional institutions worldwide as a complementary rehabilitation tool offered to inmates. The popularity can be partly explained by its cost and time efficacy compared to other non-pharmacological treatments, such as psychological

therapies. Our study shows that regular yoga practice is associated with an increased level of impulse control (25), attenuation of aggression and antisocial behaviors (25), and a significantly decreased level of paranoid ideations (9), each of these phenomena being an essential variable related to criminal behavior. Furthermore, improvements on variables that can increase offenders' abilities to participate in treatments have also been observed, for example, that yoga significantly can increase positive emotional states and decrease emotional states that are negative (25), sustain attention (25), reduce depression, anxiety, and obsession (9), and very importantly, can increase personality traits, that can be interpreted as character maturity (26). Conclusively, our results, as well as other research summarized in a systematic review (27), show that yoga has a strong potential to strengthen the inmates' self-acceptance, purposefulness, and sense of responsibility. These are qualities that promote a more peaceful and safer environment in the correctional settings, providing a foundation for the development of a prosocial lifestyle upon release.

Role of Yoga for Children and Young Adults at Juvenile Institutions

The overall goal of the treatments offered in SiS's juvenile institutions is to help adolescents adapt to social and cultural norms and become prosocial, healthy citizens. The adolescents' responsivity to such treatments is highly influenced by their sustained attention, compliance, and general mental health. Compulsory care providers experience a great need for new, cost, and time-effective non-pharmaceutical methods that can enhance the responsivity (attention, compliance) of young adults to the methods currently used to change antisocial behavior and treat substance-related syndromes. The most frequently used methods at juvenile institutions are Cognitive Behavioral Therapy, Aggression Replacement Treatment, Relapse Prevention, and Motivational Interview, each of which requires highly educated personal and longer treatment time. Importantly, we do not suggest yoga instead of any well-established treatment methods within SiS, but as a complement where yoga may promote and enhance the effects of ongoing psychological treatments. Yoga may also provide a positive coping tool for adolescents in SiS and potentially offer a prosocial activity upon release from institutions.

There is a lack of research measuring yoga's effects on adolescents' mental health, cognitive psychological characteristics, and deviant behaviors in residential/institutional care. One pilot study examined yoga's effects as a complementary care component in an institutionalized youth population (28). In that study, a multimodality intervention consisting of yoga poses, breathing exercises, and meditation was offered to institutionalized adolescents daily. The results indicate that yoga practice (combined with breathing techniques and relaxation/meditation) may improve stress resilience and self-control in an incarcerated youth population (28). In another pilot study, yoga intervention resulted in decreased alcohol consumption and improved social skills in a population of young people with high-risk behavior (29).

Contemplative preventative practices (manualized meditation-, mindfulness-based intervention) have been suggested in residential psychiatric care for children with severe psychiatric disabilities to reduce their need for physical intervention in response to dangerous behavior (30). A few studies have reported decreased anxiety and/or depression in children and adolescents (not institutionalized) having participated in yoga programs (31–35). It was proven that yoga and mindfulness-based interventions positively affect inattention and hyperactivity in young people with ADHD (36). Notably, a recent review of randomized controlled trials (RCTs) of yoga suggested improvement in behavioral and/or cognitive and/or physiological functioning in children and youth (ages 5–18; not institutionalized) (24).

METHODS

Participants

Computer required sample size analysis for repeated measures ANOVA within-between interaction, with an effect size of 0.25 [medium effect size; average from effect sizes in changes by yoga in previous studies (9, 25)], a power of 0.80, an alpha error probability at 5%, for two groups (yoga and comparison) and two measurements (pre- and post-intervention) suggested a sample size of 34 for each sex.

We aim to collect complete data from at least 34 participants of both sexes (34 male and 34 female clients) to perform gender-specific analyses. Gender analyses will only be performed, if this number of participants can be reached.

Based on previous experience working with participants within correctional settings, we know that the attrition rate can reach 50%; therefore, our aim is to include approximately 120 participants.

Three institutions at the South West in Sweden have at this stage declared interest in participating in the study. Data collection is planned to take place for one and a half years' time, based on an estimated three months per institute (**Figure 1**). This three months period includes spreading advertisements and information about the study, collecting informed consents, six weeks of intervention (including pre- and post-intervention tests), and time for qualitative interviews to assess individual experiences of yoga classes. As the average time spent within SiS is calculated to be eight months, we will be able to perform intervention and data collection in each participating institute twice, six months apart during the planned data collection period (one and a half years) (**Figure 1**).

Inclusion criterion: All young people arriving at the juvenile institutions will be offered to participate in the study.

Exclusion criteria: Serious physical illness prohibiting participation in physical activities. Inability to read and understand at least one of the following languages: Swedish, Arabic, or Dari (variety of Persian spoken in Afghanistan).

Inclusion criterion for the qualitative data collection: Participation in the yoga intervention.

Exclusion criteria for the qualitative data collection: Inability to understand and speak Swedish language.

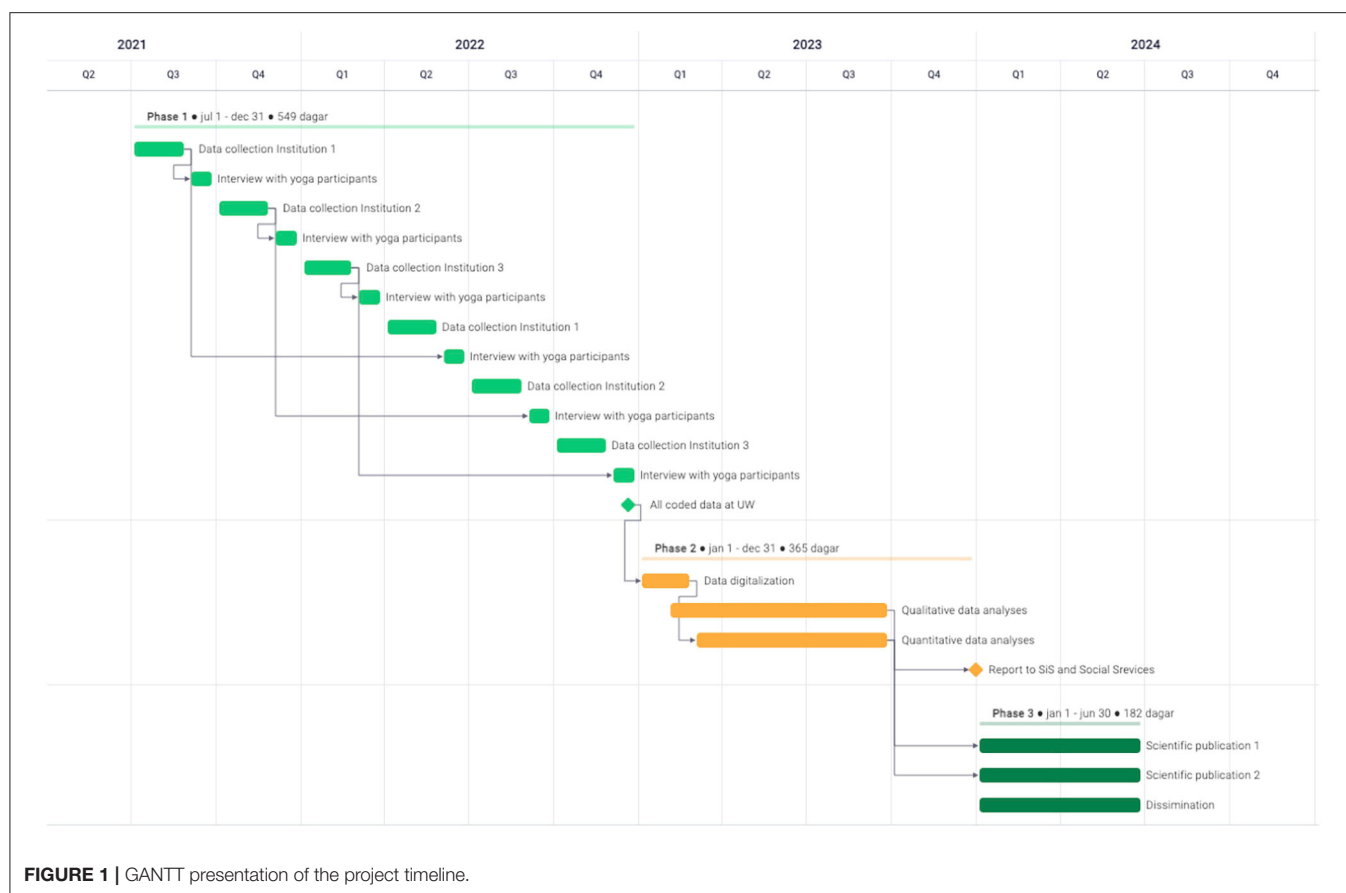


FIGURE 1 | GANTT presentation of the project timeline.

Procedure

Upon placement to the juvenile institution, the young people will be offered to participate in the study. Participation is voluntary, and SiS clients are ensured that participation in yoga or in a comparison group or non-participation should not affect the care they receive at SiS. All data is coded (pseudo-anonymized) and the code keys will be kept securely at each juvenile institution under the institution directors' responsibility, following SiS regulations. Upon completion of data assessment code keys will be destroyed. Only anonym data will be handled outside each SiS facility. With this procedure we assure that there is no possibility of identifying the individual from the collected information.

The study has a *quasi-experimental* design. Participants will receive a numeric code and will participate in the pre-intervention assessment, after which they will chose to participate in yoga classes (belonging to the "yoga group") or not to participate in yoga classes (belonging to the "comparison group") (Figure 2). The yoga group will participate in a 75 min yoga session, twice a week, for six weeks—as their leisure-time physical activity. During the same six-week period, the comparison group will participate twice a week (~1 h) in any, at the institution offered leisure-time physical activity (e.g., walking, gym training, and physical education class). Participants of the comparison

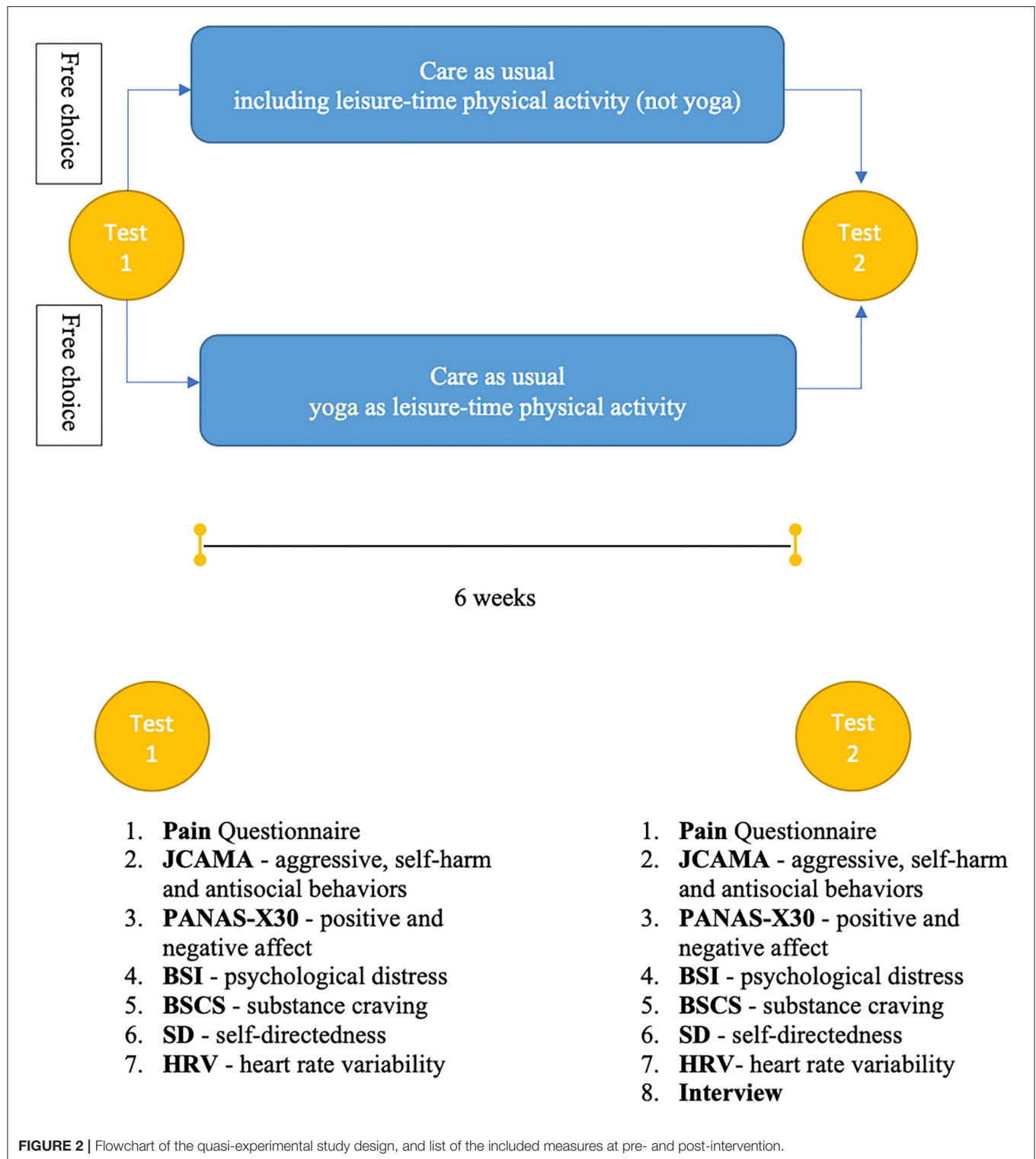
group are asked to include ~10–15 min of relaxation at the end of their leisure-time physical activity.

Ethnicity

An essential aspect of our study is the inclusion of all major ethnic groups who are SiS clients. We have investigated how many languages spoken by most of the young people placed in SiS institutional care. As a result, we will offer the various test materials in Swedish, Arabic, and Dari, thus ensuring that almost 100% of the presumptive participants can take part in the study, independently of their ethnic belonging.

Yoga Classes

The yoga classes held twice a week consist of trauma-informed yoga methods including inviting language, freedom of choice by offering options, a set routine for predictability and recognition, counting down in challenging poses for a sense of control and guidance toward practical interoceptive awareness. The relaxation offered is a progressive muscle relaxation adapted for ADHD and high anxiety levels. The aim is to increase resilience, promote relaxation and to provide self-regulation skills for stress and overwhelming emotions and reactions promoting self-empowerment and impulse control. The class will be set up in a circle to provide a sense of safety with no outer disturbances



for triggering responses and will always be offered on a voluntary basis for the participants.

A yoga class is 75 min long and consists of yoga methods such as physical movement, static yoga postures, balance exercises, and breathing practices. The instruction intends to increase the

interoceptive awareness with practically adapted mindfulness and guided trauma-informed progressive relaxation. The class includes intervals of raising and lowering heart rate and breathing to provide self-regulating skills. The classes do not consist of potential triggering poses, no physical adjustments or

practices that can bear a resemblance to sexual abuse or practices that can over-activate the sympathetic nervous system.

Each class is built up as follows:

- Warm-up 15 min: At least 10 min of warm-up exercises to release muscular tension, discharge high-stress levels, restlessness, and anxiety, increase blood circulation, and increase proprioceptive awareness.
- Opening sequence 15 min: large energizing dynamic movements.
- Balancing poses 10 min.
- Dynamic Sequence 15 min: a combination between dynamic energizing movements and powerful postures where the participants hold the pose for at least two min (impulse-control). The importance of synchronized breathing and movements.
- Closing 20 min: including the last 10 min with guided mindfulness-based relaxation.

The instructors have completed a special training program in trauma-informed yoga and yoga for mental health, and they are trained in how to manage overwhelming emotions in a class. The classes are adapted to the most common mental health issues presented within the juvenile institutional system, such as PTSD, anxiety disorders, depression, ADHD, and autism.

The yoga manual is standardized, and all yoga instructors are qualified by a specific yoga-informed education course, held by licensed yoga therapist Josefin Wikström (e-RYT 500, YACEP, and TCTSY-F), founder of Trauma-adapted (informed) Yoga Sweden. She is the main teacher and Program director for the Prison Yoga Project Europe, recognized as a part of Trauma Research Foundation Therapeutic Alliance.

Assessment

There will be two main testing periods: pre-intervention (Test 1) before the intervention and post-intervention (Test 2) after six weeks of intervention (Figure 2). All the measures described below will be included in the pre- and post-intervention tests.

Measures

Three different origins of data are included as measurements: (A) self-reported measures in the form of a survey, (B) heart rate measure, and (C) register data. A and B applied both at pre-intervention (Test 1) and post-intervention (Test 2), while the data from SiS's register will be combined with data only for those participants who complete all parts of the study.

The pre-intervention survey includes a question on yoga expectations, and the post-intervention assessment includes a question on time spent on yoga and the experience of yoga.

A. Self-Reports

The self-report survey will include six previously validated instruments available in the Swedish, Arabic, and Dari languages.

Juvenile Care Adjusted Measure of Aggression

It is a SiS environment adapted version of the Prison Adjusted Measure of Aggression (PAMA), which assesses the self-reported frequency of state aggression and antisocial behavior in subjects

within correctional settings (37). The Juvenile Care Adjusted Measure of Aggression (JCAMA) scale consists of nine items. The items are distributed over three subscales: a five-item Aggression scale, a two-item Antisocial Behavior scale, and a two-item Self-directed Aggression scale.

The Aggression subscale measures overt aggression and includes items on temper tantrums, verbal and indirect aggression, non-specific fighting, and physical assault against people. The Antisocial Behavior subscale consists of items on disciplinary problems at school and conflicts caused by own antisocial behavior. The Self-directed Aggression subscale includes items on self-injurious behavior and suicide attempts.

All the items are rated on a six-point scale based on the total number of occurrences over the past month: no occurrences = 0, one event = 1, two or three events = 2, four to nine events = 3, 10 or more events = 4, more events than can be counted = 5. The JCAMA score is the sum of the ratings on all nine items (total score) or the specific items in a certain subscale (subscale score). The JCAMA total score can range from 0 to 45; the Aggression subscale scores from 0 to 25; the Antisocial behavior scores from 0 to 10; and the Self-directed Aggression scores from 0 to 10.

The original PAMA's validity has previously been shown to be acceptable, and its test-retest reliability has been measured as fair (37), while the JCAMA reliability has not yet been tested.

Positive Affect and Negative Affect-Extended

The Positive Affect and Negative Affect-Extended (PANAS-X) instrument consists of 30 items and captures the valence (positive and negative) and the arousal (activated or deactivated) of the mood descriptors. As a result, PANAS-X30 makes it possible to measure positive (pleasant) and negative (unpleasant) and within both activated and deactivated affect states. This distinction is relevant in yoga studies, where effects are likely to be found in pleasant, deactivated emotions such as feeling calm, content, and relaxed. The following are examples for all four categories. Positive activated: *active, enthusiastic, excited, inspired* and, *proud*; Positive deactivated: *at ease, serene, calm, relaxed*, and *content*; Negative activated: *afraid, scared, hostile, guilty*, and *ashamed*; Negative deactivated: *tired, sluggish, drowsy, dull*, and *bored* (38).

The four scales' internal consistency is acceptable, with Cronbach's alphas ranging from 0.77 to 0.88 (25).

Brief Symptom Inventory

The Brief Symptom Inventory (BSI) is a self-rated measure of general psychopathology and psychological distress (39). The BSI contains 53 items reflecting psychological symptom patterns of psychiatric patients and non-patients. It comprises nine primary symptoms' scales and the global severity index (GSI). The primary symptom scales are: Anxiety, Depression, Interpersonal Sensitivity, Hostility, Obsessive Compulsiveness, Psychoticism, Paranoid Ideations, Phobic Anxiety, and Somatization. The answers are given on a five-point scale, from 0 = "not at all" to 4 = "extremely." The BSI subscales and its GSI have high internal reliability (0.71–0.85) (9, 40, 41) and test-retest reliability, as well as high convergent, discriminant, and construct validity (42).

Pain

The Pain assessment instrument uses verbal and numerical assessment scales, where the participant describes their pain during the last two weeks using words (*no pain; mild pain; moderate pain; severe pain; very severe pain; unbearable pain*) and using numbers between 0 and 10, where 0 (zero) represents no pain, and 10 represents the worst possible pain. The type of pain and its location is marked by the participants on a standard image of a man or a woman (43).

Brief Substance Craving Scale

There have been multiple recommendations that craving should be included as a standardized outcome in treatment studies (44). The Brief Substance Craving Scale (BSCS), designed by Somoza et al. (45), will be used in the present study to measure the intensity, frequency, and lengths of cravings in the participants. BSCS measures craving for the primary substance, including alcohol and drugs. This short, self-report measure has previously been used and tested for psychometric properties (46, 47).

Self-Directedness

Self-directedness (SD) is a personality trait of self-determination. It captures the participant's ability to regulate, control, and adapt his/her behavior to situational requirements with the aim to achieve personally chosen goals. It is one dimension in Cloninger's Temperament and Character Inventory (TCI) (48). Cloninger has described SD as "willpower." It captures to what extent a person identifies themselves as an integrated, purposeful, self-sufficient, self-acceptant, responsible, reliable, and effective individual. SD contains 20 questions of the TCI-R140 scale.

Interviews

After the intervention (six weeks of yoga) qualitative information will be gathered about the participants' experience of yoga and possible health effects (please see the **Supplementary Material** for the semi-structured interview guide).

B. Heart Rate Variability

Heart rate variability (HRV), or the beat-to-beat alteration in heart rate, offers a noninvasive indicator of the autonomic nervous system's activity (49). HRV has been used as a proxy for health and fitness and as an indicator of autonomic regulation. Low HRV—indicating reduced parasympathetic cardiac control—was associated with sleep problems and difficulty regulating emotions (50), while yoga practice was associated with increased HRV (51).

HRV can be measured with a good quality activity bracelet and an App belonging to that, recording an electrocardiogram. At the moment we do not know which algorithmic approach for operationalizing HRV will be used. Data will be recorded during the first and last occasions of the intervention (yoga class). HRV data for the comparison group will be recorded with an identical time interval, during leisure time physical activity.

C. Register Data

Register data concerning the participants' medications during the intervention, their school attendance and participation in

physical activity classes during the study will be assessed based on registers kept by SiS.

Data Analysis

If the required number of male and female participants (at least 34 of each gender) is reached, then we will analyze the data separately by gender. Otherwise, the data will be pooled, and no gender-specific results will be presented.

All statistical analyses will be conducted using a significance level of $p < 0.05$. Only complete post-attrition data will be analyzed. The comparison of the attrition rates between the two groups ("yoga" group and "comparison" group) will be calculated using Fisher's exact test. The Test 1 and 2 scores within the groups will be compared using the Wilcoxon signed-rank test. Mean changes and standard deviations will be calculated to identify differences within the groups. Mann-Whitney U -tests will be used for the continuous variables and Fisher's exact test for the categorical variables to compare differences between them. The effect sizes (Cohen's d) will be calculated to identify differences between the groups; an effect size of 0.2 will be considered a small effect, 0.5 a medium effect, and 0.8 a large effect. As data will be collected from three institutions, generalized estimating equations (GEE), that adjusts standard regression estimators for clustering, will be applied. The primary outcome is the level of psychological distress (BSI). Secondary outcomes' (craving, pain, affect, and aggressive antisocial behaviors) mediating and moderating effect will be also explored by conditional process analyses. We plan to conduct a mid-point analysis (about nine months after that data collection has started) to allow for better modeling of change trajectories.

To describe the adolescents' experiences of participating in yoga practice, with the help of a semi-structured interview guide (**Supplementary Material**), individual interviews will be performed. The adolescents will be contacted within 2 weeks after completing the yoga intervention. Content analysis will be used as a method for analyzing the interviews (52). The qualitative content analysis is performed stepwise identifying meaning units, condensing the meaning units, labeling meaning units with codes and thereafter identifying subcategories, categories and themes. Content analysis makes it possible to describe the adolescents' experiences on both manifest and latent levels.

DISCUSSION

While there is a growing body of evidence in favor of the unique and significant positive effects of yoga as a form of complementary care for vulnerable populations (such as people with psychiatric conditions and/or people in correctional settings), there is a lack of research measuring the effects of yoga in the population of adolescents in residential/institutional care. The Swedish National Board of Institutional Care (Statens institutionsstyrelse, SiS) offers compulsory care for young people who manifest psychiatric disorders, substance use disorder and criminal behavior (2). The average age of an institutionalized young (fe)male is 16 years old, and (s)he meets the criteria for at least one psychiatric diagnosis. The most frequent diagnoses are ADHD, Substance Use Disorder, PTSD, Conduct

Disorder, and Autism Spectrum Disorder. Depression and anxiety are usually co-existing diagnoses. One in four of these young people has attempted suicide. This population of adolescents has an increased need for effective treatments that can prevent the development of persistent mental ill-health, substance dependence, recidivistic criminal behavior, social marginalization, and untimely death. The young people's mental ill-health in SiS is substantial and extensive medical and psychological treatments are provided during their stay. SiS's goal and vision is, that the young people undergoing various SiS treatment programs should have gained by the end of their stay at SiS increased resources to live their lives without crime and abuse.

According to a follow-up study (5) today's institutional care is not sufficiently effective. Half of these young people have a history of at least one inpatient treatment episode, 60% are reconvicted for criminal acts, and 3% die within three years of their release from the institution.

Therefore, the planned study's impact can be measured from the aspects of the individual, the organizations, and the society.

Disruptive behaviors and high levels of psychological distress often hamper treatment responsiveness. The suggested positive effects of yoga (decreased levels of psychological distress and less aggressive and antisocial behavior) may result in increased treatment responsiveness, which may reduce the number of care days. This positive outcome may entail considerable benefits in terms of significantly decreased economic burdens on SiS and the society.

Reduced recidivism and substance use are not only valuable from a socioeconomic perspective, but they are also necessary for the promotion of a safe society for all and, of course, represent a vital benefit for the individual. The study population comprises a highly relevant group from the perspective of basic societal needs. There are about 550,000 15–19-year-old Swedish citizens today. 0.2% of these adolescents are institutionalized in SiS care yearly (4). The care provided to this small fraction of adolescents represents a considerable annual cost for society (1.6 million SEK/person for medication and 2.1 million SEK/person for placement in SiS care). If this vulnerable group's care and rehabilitation are not successful, it will continue to represent a considerable burden on society at several levels: criminality, medical health problems, social support needs, pain, and suffering of the individual and others.

An active heroin addict costs society 2.1 million and an amphetamine addict about 1.5 million SEK/year from an economic perspective. These figures encompass the expenses for their active use (criminality, legal authorities, and financial aid), medical and social care, and costs for their family's support.

In the event the present study can provide evidence on the positive effects of yoga for the clients of SiS institutions, it will provide a basis and rationale for making a strategic investment at the national level.

The positive effects of yoga at the individual level are proposed from strong scientific evidence. Studies have proven in adult populations that yoga can strengthen the practitioner's self-acceptance, purposefulness, and sense of responsibility (26). These qualities promote a more peaceful and safer environment in institutional settings and offer higher effectiveness of other

treatments and school education programs. Yoga can also provide a foundation for the development of a prosocial lifestyle upon release. In other words, there is evidence that yoga empowers the individual yoga practitioner and thus improves his or her mental health and prosocial lifestyle. These novel effects of yoga practice emphasize the importance of testing yoga as complementary care for young people with behavioral and mental health problems.

The duration and the type of yoga in the present study have been adjusted to the population. We use a shorter intervention time but more frequent training (six weeks twice a week, implying 12 yoga sessions) to optimally adapt to the participating institutes' possibilities. Several studies have proven that 8–10 weeks (once a week, therefore, 8–10 sessions) yoga has positive effects on mental health, behaviors, and self-control of adults in correctional setting (9, 25–27, 53). As our study population includes adolescent, it is essential to recognize that the brain goes through pruning (anatomically improving its efficiency) during this developmental period [see e.g., (54)]. During this time, the brain is increasingly susceptible to environmental effects; therefore, we speculate that eventual changes in adolescents' mental health and behaviors will be recognizable already after six weeks (12 sessions) of training. There are results indicating that short-term intensive interventions (four weeks, three times a week yoga classes) have a positive effect on adults' anxiety, depression, and stress (55). Importantly we use a specifically developed yoga (trauma-informed yoga), adapted to the most common psychiatric disorders (ADHD, PTSD, anxiety, and depression) in the adolescent study population.

The proposed study fills a gap in knowledge focusing on young people population in institutional care. If the study's hypothesis is confirmed, our results will verify and strengthen earlier findings in Sweden (9, 25, 26) regarding the benefits of yoga for a marginalized population, thus indicating the usefulness and value of yoga within juvenile institutional care at a national level.

One limitation of the proposed study is the fact that we won't be able to randomly distribute participants between groups, with other words, we could not rationalize a randomized controlled trial (RCT) design. A quasi-experimental design was chosen in agreement with the clinical and institutional experts, who predicted an unacceptable high attrition rate (80–90%) in case of not giving the possibility to the young clients to freely choose their participation in yoga classes.

Future RCTs should confirm our findings and prospective longitudinal studies need to investigate if yoga within SiS can potentially offer a prosocial activity upon release from institutions for young people.

Ethics and Dissemination

Young people placed in SiS institutions are in many respects in a vulnerable position because of their deprived situation. From an ethical research perspective, therefore, it should be taken into account that this position may affect their propensity to decline to participate in the study due to fear of negative consequences. However, this risk may be considered small. Therefore, great emphasis will be placed on the research ethical principles regarding information, consent, confidentiality, and

usefulness. Consequently, all participants will be informed, both orally and in writing, about the purpose and structure of the study, that participation is voluntary, and that they have the right to end their participation at any time. Written consent will be obtained from all study participants before inclusion in the study. All data and information gathered will be treated with the highest possible confidentiality. In this context, it should also be clear from the information that the decision to participate or not in the study, will not affect the young person's treatment plan in any way.

The National Ethical Review Authority has approved the study with the registration number: 2019-04589. We applied for a change in the original ethical approval as we have changed—based on last year's feedback on our grant applications—the study design from RCT to quasi-experimental design, and we included qualitative interviews in the project. The new ethical approval is registered with Dnr: 2021-00088.

This project is carried out in close collaboration with the Swedish National Board of Institutional Care (Statens institutionsstyrelse, SiS), an independent Swedish government agency operating a multidisciplinary activity. The care and treatments offered within SiS institutions must be based on the individual's needs (person-centered care). On a national level, only methods for which there is scientific support are used. Yoga is offered already in some SiS institutions, but not included in care, because of the lack of research and evidence.

The project will take part in University West's academic environment, where the (in Sweden) unique Social Psychiatric Care candidate program is established. The Social Psychiatric Care program covers the interfaces between social services, psychiatric healthcare, the police, correctional centers, schools, and non-governmental organizations. The project is also coupled to the research center for Child and Youth Studies at University West (56), which is part of a network of similar research environments at Stockholm University, Linköping University, University of Gothenburg, and Malmö University. The purpose of the network is to gather and promote research in the interdisciplinary field of child and youth studies.

The project is supported by the Prison Yoga Project (PYP) (57), a non-profit organization that supports incarcerated people worldwide with trauma-informed yoga and mindfulness programs. The PYP Community includes a wide range of professionals (academics, certified yoga instructors, prison employees, medical doctors, etc.) with a common aim to promote social change, transforming the systems and culture to create a more inclusive, equitable, and just world.

Information about the project is disseminated using several channels: producing reports to SiS, open accesses peer-reviewed

scientific articles, giving scientific and popular scientific lectures at national and international forums, and using the above-described collaborations.

ETHICS STATEMENT

The National Ethical Review Authority has approved the study with the registration numbers: 2019-04589 and 2021-00088. Written informed consent to participate in this study will be provided of the legal guardian (in case of the participants is under the age of 15) and all the participants.

AUTHOR CONTRIBUTIONS

NK is the project leader who has planned the study and developed the study protocol in cooperation with national agents and SiS employers.

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SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: <https://www.frontiersin.org/articles/10.3389/fpsy.2021.575147/full#supplementary-material>

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Conflict of Interest: The author declares that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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