



Development and Implementation of Couple-Based Collaborative Management Model of Type 2 Diabetes Mellitus for Community-Dwelling Chinese Older Adults: A Pilot Randomized Trial

OPEN ACCESS

Edited by:

Stuart Gietel-Basten,
Hong Kong University of Science and
Technology, China

Reviewed by:

Aimin Yang,
The University of Hong Kong, China
Ying-Chun Li,
National Sun Yat-sen
University, Taiwan

*Correspondence:

Jing Liao
liaojing5@mail.sysu.edu.cn

†These authors have contributed
equally to this work and share first
authorship

Specialty section:

This article was submitted to
Aging and Public Health,
a section of the journal
Frontiers in Public Health

Received: 26 March 2021

Accepted: 26 May 2021

Published: 13 July 2021

Citation:

Liu Y, Xiao X, Peng C, Zhao T, Wu Y,
Yu W, Ou L, Chen X, Wu X, Xu DR and
Liao J (2021) Development and
Implementation of Couple-Based
Collaborative Management Model of
Type 2 Diabetes Mellitus for
Community-Dwelling Chinese Older
Adults: A Pilot Randomized Trial.
Front. Public Health 9:686282.
doi: 10.3389/fpubh.2021.686282

Yuyang Liu^{1,2†}, Xiaocun Xiao^{3†}, Chaonan Peng³, Tianyi Zhao³, Yanjuan Wu^{1,2},
Wanwen Yu⁴, Liping Ou⁵, Xiongfei Chen⁶, Xueji Wu⁶, Dong Roman Xu⁷ and Jing Liao^{1,2*}

¹ Department of Medical Statistics, School of Public Health, Sun Yat-sen University, Guangzhou, China, ² Sun Yat-sen Global Health Institute, School of Public Health and Institute of State Governance, Sun Yat-sen University, Guangzhou, China,

³ School of Nursing, Sun Yat-sen University, Guangzhou, China, ⁴ Qichuang Social Work Service, Guangzhou, China, ⁵ Panyu District Community Health Service Management Centre, Guangzhou, China, ⁶ Division of Primary Health Care, Guangzhou Centre for Disease Control and Prevention, Guangzhou, China, ⁷ School of Health Management, Southern Medical University, Guangzhou, China

Background: To mobilize family's positive involvement in improving and sustaining self-management activities of older adults with diabetes, we developed a couple-based collaborative management model (CCMM) for community-dwelling older Chinese.

Methods: The model was developed stepwise through applying theoretical models, interviewing older couples and community healthcare workers, as well as incorporating expert reviews. A 3-month pilot study was conducted to test the model's feasibility and its treatment effects by linear regression on 18 pairs of older couples aged 60 years+, who were equally divided into a couple-based intervention arm and a patient-only control arm.

Results: The developed CCMM covered four theory-driven intervention modules: dyadic assessment, dyadic education, dyadic behavior-change training, and dyadic monitoring. Each module was delivered by community healthcare workers and targeted at older couples as the management units. Based on interviews with older couples and healthcare workers, 4 weekly education and training group sessions and 2-month weekly behavior change booster calls were designed to address older adults' main management barriers. These modules and session contents were evaluated as essential and relevant by the expert panel. Furthermore, the CCMM showed good feasibility and acceptability in the pilot, with non-significant yet more positive changes in physiological outcomes of diabetic participants and couples' well-being and exercise levels of these in the intervention arm than their controlled counterparts.

Conclusion: We systematically developed a couple-based collaborative management model of diabetes, which was well-received by healthcare practitioners and highly feasible among older Chinese couples living in the community. The model's treatment effects need to be verified in fully powered randomized controlled trials.

Clinical Trial Registration: <http://www.chictr.org.cn/showproj.aspx?proj=42964>, identifier: ChiCTR1900027137.

Keywords: coupled-based intervention, chronic disease management, model development, feasibility, implementation assessment

INTRODUCTION

China's ever-increasing diabetes burden of the older population exceeds its capacity of healthcare services (1). Under the coronavirus disease 2019 (COVID-19) pandemic, prioritizing healthcare resources and personnel into infectious disease control and treatment as well as national level quarantine measures made it even difficult for older adults with diabetes to maintain their routine treatment and healthcare services (2). Although self-management has long been recommended by Chinese clinical guidelines as an effective manner to control blood glucose levels and prevent complications, adherence to self-management activities is generally low among older adults in China (3, 4). Diabetes self-management requires lifelong commitments to multiple care regimens, which permeate daily routines and interacts with living context (5). Evidence-based interventions addressing behavioral and environmental barriers should be identified to promote self-management activities of older adults with diabetes.

Accumulating evidence has suggested that family-engaged interventions, especially these motivating support from the spouse (6), significantly improved the self-management activities of older people with diabetes (7). Marital relationship is a well-established factor for couples' health that should be considered and leveraged in disease management (7). Previous couple-based interventions on chronic disease management have revealed significant treatment effects on the depressive symptom, pain, and marital functioning of the patients (8), while evidence has been inconclusive regarding improvements in the patients' or their spouse's physical health (9–11) or their health behavior (12).

Less is clear about the effects of couple-based interventions on diabetes management. Our scoping review on couple-based random controlled trials (RCTs) of type 2 diabetes mellitus (T2DM)¹ showed insufficient evidence neither on glucose control (13, 14) or changes in self-management activities of the participants with diabetes (14, 15), nor significant changes in diet or exercise levels of their spouse (16). Most of these studies

provided no theoretical bases for their intervention design and were subjected to implementation and reporting bias. Further studies equipped with theory-driven interventions and outcome measures targeting at both the participants with diabetes and their spouse are needed to clarify the treatment effects of couple-based diabetes management (10).

This paper was an interim report of the project on the couple-based collaborative management model (CCMM) of T2DM for community-dwelling older adults in China, which is a community-based multicenter RCT aiming to systematically develop and validate a CCMM integrating health professionals and family supporters (17). This report provided detailed information on the development of CCMM, grounded in theories, and tailored to the care needs of older Chinese couples with T2DM.

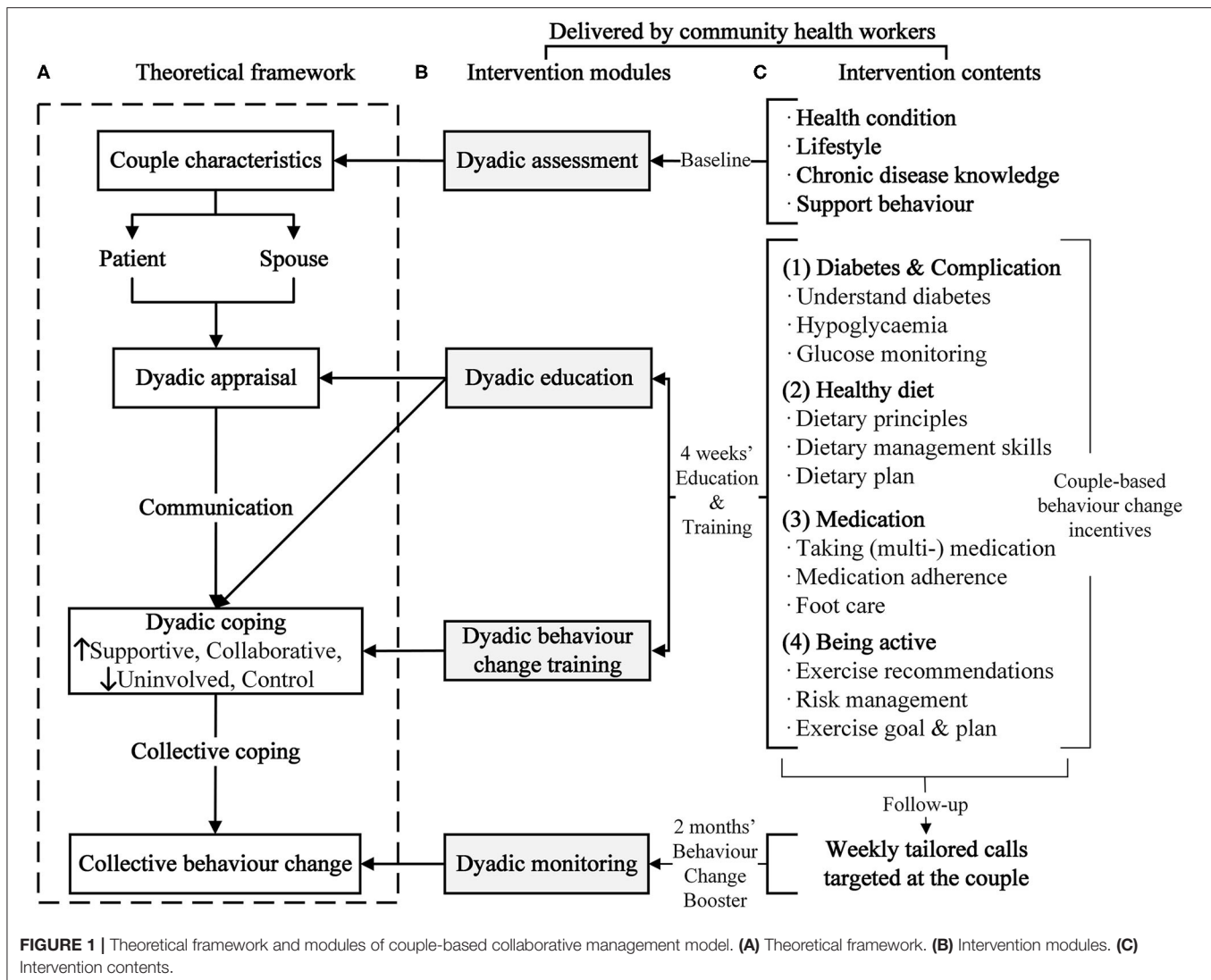
MATERIALS AND METHODS

Step 1: Theory-Driven Model Development

The CCMM was developed based on Berg and Upchurch's dyadic model of coping with chronic illness (DMCCI) (18) and Bandura's social cognitive theory (SCT) (19). DMCCI describes couples' dyadic appraisal of the illness severity, ownership and management responsibility, and dyadic coping strategies ranging from uninvolved (patient coping alone), supportive (spouse taking a supportive role), collaborative (spouse actively involved and the couple coping jointly) to control (spouse dominating the care responsibility) (18). If the couple both appraised the chronic disease as a shared problem needed to be coped together, a communal coping would be formed (20), which would boost their collective efficacy in managing chronic diseases, in addition to the patient's self-efficacy emphasized in the SCT (19). The collective efficacy of the couple can be strengthened by successful experiences of jointly developing and achieving management goals, alternative experiences such as acting as each other's role model, as well as language persuasion and positive physiological feedbacks (21). Intervention modules targeted at these key theoretical components were formed, with intervention contents further developed in line with the community diabetes self-management education program (22) and the Chinese clinical guideline for T2DM prevention and treatment (3). The community healthcare centers' current services were also integrated into CCMM to maximize its normalization into their routine practices.

Abbreviations: CCMM, couple-based collaborative management model; RCT, random controlled trials; T2DM, type 2 diabetes mellitus; DMCCI, the dyadic model of coping with chronic illness; SCT, social cognitive theory; HbA1c, glycosylated hemoglobin; BMI, body mass index; NPT, normalization process theory.

¹Wang C, Wu M, Yang Y, Liao J. Effect and quality of couple-based interventions of middle-aged and older adults with type 2 diabetes mellitus: a scoping review (Unpublished) (2020).



Step 2: Management Barriers Assessment of Older Adults With Diabetes

To ensure intervention contents of CCMM that met the management needs of older couples, we conducted semistructured group interviews among couples aged 60+ years with at least one partner having diabetes and community health workers involving in diabetes care. Interviews were conducted between March to August 2019 in Guangzhou, Guangdong, China. These interviews explored couples' main barriers in daily diabetes management from couples' and care managers' perspectives. Each one and half an hour interview was composed of three researchers (a host, a recorder, and an observer) and five to six couples or seven to eight community health workers. Interviews were audio-recorded and transcribed verbatim. Detailed qualitative analyses of these interviews are presented in separate papers of the series of studies (5). The study was approved by the Institutional Review Board of the School of Public Health of Sun Yat-sen University (#SYSU 2019-064),

and the drafting of this manuscript adheres to the CONSORT statement (**Supplementary Table 1**) (23). All participants read and signed the written informed consent approved by the institutional review board prior to participation.

Step 3: Incorporation of Expert Reviews

To further tailor CCMM to the focus of chronic disease management in China, the expert reviews on the intervention content of model were conducted following a Delphi approach. An independent panel was convened, including 11 experts that consist of diabetes clinicians, general practitioners, community chronic disease management officials, and social workers. Every expert assessed the content of CCMM for its necessity, relevance, and clarity with quality reviews and quantity measures (24). The evaluation was synthesized and reevaluated until the panel reached 80% consensus.

TABLE 1 | Couples' sociodemographic characteristics of the 3-month pilot study (couple pairs $N = 18$).

Variables	Participants with diabetes		Spouses	
	Intervention arm ($n = 9$)	Control arm ($n = 9$)	Intervention arm ($n = 9$)	Control arm ($n = 9$)
Sociodemographic characteristics				
Age (years), mean (SD)	73.2 (8.8)	70.3 (5.5)	71.3 (8.8)	68.9 (7.1)
Male, n (%)	5 (56)	4 (44)	4 (44)	5 (56)
Primary school and below, n (%)	6 (67)	5 (56)	3 (33)	3 (33)
Retired, n (%)	8 (89)	9 (100)	9 (100)	9 (100)
Diabetes duration (years), mean (SD)	11.1 (4.5)	8.8 (7.8)	N/A	N/A
Had other diagnosed diseases, ^a n (%)	7 (78)	6 (67)	4 (44)	8 (89)

SD, standard deviation.

^aDiagnosed disease included hypertension, hyperlipidemia, cardiopathy, coronary artery disease, heart failure, kidney diseases, cerebrovascular diseases, and gout.

Step 4: Feasibility Study

A 3-month feasibility study among older couples was carried out between September and December 2019. Participants with diabetes were recruited from a community of Guangzhou by community healthcare workers if they had T2DM, with the latest fasting blood glucose level > 8.0 mmol/L or glycosylated hemoglobin (HbA1c) $> 7.0\%$, aged 60+ years, cohabited with spouses, and normal cognitive and behavioral capacity. Participants with diabetes who previously participated in a similar education group were excluded. Their cohabited spouses with no mental or physical dysfunction were also recruited. In the pilot study, the partner with higher baseline blood glucose was treated as "participants with diabetes" if the couple pair both had diabetes. All participants provided informed consent.

Out of the 24 pairs of couple screened with signed informed consent, 18 eligible couple pairs were enrolled (recruitment rate = 75%) and 1:1 simple randomized into couple-based intervention arm ($n = 9$) and individual-based control arm ($n = 9$) by an uninformed researcher. The content of interventions was delivered by two community healthcare workers targeted at both the diabetic participants and their spouses for the intervention arm while only at the diabetic participants for the control arm (17). After the interventions, semistructured group interviews were conducted to evaluate the intervention's feasibility by the couples of the intervention arm and community healthcare workers. Two-month weekly behavior change booster calls were implemented afterwards.

Study Measures

To examine CCMM's treatment effects, we measured couples' physiological health [i.e., HbA1c as primary outcome measures for patients, fasting blood glucose, lipid profiles, and body mass index (BMI)], psychological health (i.e., quality of life by the 36-item short form survey as primary outcome measures for spouses, self-efficacy by the Chinese version of the diabetes management questionnaire), and self-management behaviors by the summary of diabetes self-care activities questionnaire and physical activity by the international physical activity questionnaire-short form at baseline and 3 months after the

beginning of the intervention. Detailed outcome measures were provided in the study protocol (17).

The CCMM's feasibility was evaluated quantitatively by the attendance rates of education sessions, follow-up rates of booster calls, and acceptability scores of couples of intervention and participants with diabetes of control arm and qualitatively by semistructured group interviews with couples of the intervention arm and community health workers who delivered CCMM, guided by the normalization process theory (NPT) (interview script in **Supplementary Table 2**) (25).

Statistical Analyses

Intention-to-treat was applied to examine the treatment effects for the diabetic participants and spouses separately. Six percent to 6–17% couples missed the psychological measures, and 11–22% participants with diabetes missed the physiological measures (detailed information see **Supplementary Table 3**). Missing values were multiply imputed under the missing at the random assumption by intervention and control arms separately by arms to avoid biasing treatment effects toward the null (26). Fifty complete datasets for each arm were multiply imputed using individual demographic information, all physiological measures, and all psychological measures. Within-arm changes in health measures between baseline and 3 months were calculated by paired t -tests. Between-arm differences in the changes in health outcomes were compared by linear regression. Furthermore, differences in diabetic participants across arms and correlations between couples of the intervention arm in the implementation measures and acceptability scores were examined by Wilcoxon rank-sum test and Spearman's rank correlation, respectively, because of small sample size and non-normal distribution. All data analyses were by R Version 3.61.

RESULTS

Step 1: Theory-Driven Model Development

As shown in the CCMM theoretical framework (**Figures 1A,B**), the intervention prototype covered four modules: (1) dyadic assessment to evaluate older couples' baseline sociodemographic

TABLE 2 | Treatment effects of couple-based interventions on participants with diabetes of the 3-month pilot study (couple pair $N = 18$).

Variables of participants with diabetes	Intervention arm ($n = 9$)				Control arm ($n = 9$)				Treatment effect	
	Baseline ^a Mean (SD)	3-month ^a Mean (SD)	Difference within arm ^b Mean (SE)	P^c	Baseline ^a Mean (SD)	3-month ^a Mean (SD)	Difference within arm ^b Mean (SE)	P^c	Difference between arm ^d Mean (SE)	P^c
Physiological outcomes										
HbA _{1c} (%)	8.6 (2.1)	8.1 (2.0)	-0.3 (0.5)	0.586	7.9 (1.5)	7.8 (1.6)	-0.2 (0.4)	0.656	-0.1 (0.6)	0.848
FBG (mmol/L)	9.5 (2.3)	9.2 (2.4)	-0.3 (1.0)	0.776	8.4 (2.2)	8.6 (2.5)	0.3 (0.9)	0.781	-0.6 (1.4)	0.686
BMI (kg/m ²)	24.0 (1.3)	25.0 (2.1)	1.0 (0.7)	0.201	24.8 (2.8)	24.9 (3.1)	0.1 (0.5)	0.822	1.0 (0.9)	0.286
Total cholesterol (mmol/L)	9.8 (15.1)	5.0 (0.8)	-4.8 (4.9)	0.367	4.4 (1.0)	4.1 (0.8)	-0.2 (0.3)	0.568	-4.6 (5.0)	0.370
Triglycerides (mmol/L)	2.1 (1.0)	2.3 (1.3)	0.2 (0.4)	0.658	1.8 (1.5)	1.8 (1.4)	-0.0 (4.7)	0.987	0.2 (0.6)	0.763
LDL-C (mmol/L)	2.8 (1.0)	1.2 (0.2)	-1.7 (0.3)	0.001	2.5 (0.9)	1.3 (0.2)	-1.2 (0.3)	0.005	-0.5 (0.4)	0.415
HDL-C (mmol/L)	1.2 (0.2)	2.9 (0.9)	1.7 (0.3)	0.001	1.4 (0.3)	2.0 (0.6)	0.7 (0.3)	0.053	0.9 (0.4)	0.037
Psychosocial outcomes										
SF-36: Physical component score	49.9 (10.0)	49.7 (12.3)	0.5 (2.9)	0.868	48.6 (8.3)	49.7 (5.6)	1.0 (2.0)	0.621	-0.5 (3.5)	0.887
SF-36: Mental component score	53.0 (3.7)	53.0 (5.1)	-0.1 (2.5)	0.961	53.7 (3.8)	53.1 (2.8)	-0.6 (0.9)	0.564	0.4 (2.6)	0.872
C-DMQ score	91.6 (14.6)	101.2 (18.0)	9.7 (5.7)	0.135	82.1 (12.5)	91.6 (13.9)	9.4 (4.8)	0.092	0.2 (7.4)	0.976
Behavior outcomes										
SADCA score	33.4 (11.1)	38.2 (12.2)	4.8 (3.8)	0.252	32.4 (9.7)	38.2 (10.9)	5.8 (5.3)	0.310	-1.0 (6.5)	0.880
Metabolic equivalent scores measured by IPAQ-C (MET min week⁻¹)										
Exercise ^e	594.3 (797.1)	1,440.0 (2,459.3)	676.4 (723.8)	0.384	840.0 (1,313.3)	573.3 (857.8)	-62.6 (628.9)	0.924	739.0 (961.6)	0.456
Walking	1,277.6 (765.1)	1,254.0 (1,372.2)	-167.6 (294.7)	0.560	1,328.3 (635.8)	1,457.5 (893.9)	340.4 (486.9)	0.512	-507.9 (572.8)	0.392
Sitting	900.0 (921.1)	660.0 (761.3)	-51.3 (517.7)	0.924	945.0 (736.5)	1,120.0 (525.7)	378.0 (397.0)	0.381	-429.3 (653.6)	0.523

SD, standard deviation; SE, standard error; 95% CI, 95% confidence interval; HbA_{1c}, glycosylated; FBG, fasting blood glucose; BMI, body mass index; LDL-C, low-density lipoprotein cholesterol; HDL-C, high-density lipoprotein cholesterol; SF-36, the 36-item Short Form Survey (SF-36); SADCA, the Summary of Diabetes Self-Care Activities questionnaire; IPAQ-C, International Physical Activity Questionnaire—Chinese version; MET min week⁻¹, minutes of metabolic equivalent per week for physical activity; C-DMQ, the Chinese version of the Diabetes Management Questionnaires.

^aThe statistical description was based on complete cases without imputation.

^bThe within-arm difference was calculated as the difference between 3-month and baseline levels of given measures using the multiply imputed data.

^c P -value of the within-arm difference was tested by paired t -test, and the between-arm difference was tested by Student's t -test.

^dThe between-arm difference was calculated as the difference between intervention and control arms using the multiply imputed data.

^eThe exercise was defined as moderate to vigorous physical activity measured by IPAQ-C regarding weekly frequency and duration.

characteristics, health status, and lifestyle as the evidence base of intervention context; (2) dyadic education to address older couples' dyadic appraisal and understanding about diabetes management *via* group education base on the background of dyadic assessment; (3) dyadic behavior change training to improve couples' dyadic coping skills by promoting collaborative action for behavior change by using experience, encouragement, and positive feedback, which can enhance not only the efficacy of older adults with diabetes but also the collective behavior of couples; (4) dyadic monitoring to assess and provide timely feedback to improve dyadic behavior health. All modules had community health workers serving as care managers and older couples as management units.

Step 2: Management Barriers Assessment of Older Adults With Diabetes

Altogether, we interviewed 11 pairs of older couples with T2DM and 33 community health workers from four community healthcare centers. These interviews helped identify barriers in daily T2DM management from the perspectives of older adults with diabetes, spouses, and clinicians. The main barriers of older couples with diabetes included lack of knowledge about diabetes and complications prevention, short of authentic information on medication, and lack of support to properly conduct self-management activities, particularly regarding foot care, healthy diet, and exercise. Couples trusted community health workers who understand their condition at most and assessed them as the best suitable group delivered personalized education mentioned above. To make use of this information, we invited health workers as care managers for four modules. To address these management barriers, the intervention contents of education and training sessions were designed to improve the knowledge and skills of (1) diabetes and complications management, (2) healthy diet, (3) medication adherence, and (4) exercise (Figure 1C). To facilitate older couples to adopt healthy behaviors, each session further employed behavior change techniques (weekly and special training) and couple-based behavior change incentives (material and social incentives and rewards based on couples' performances). A detailed information of change techniques and incentives was shown in our protocol.

Step 3: Incorporation of Expert Reviews

The expert panel well-received the context of CCMM, evaluated as essential (the average of content validity ratio was 0.89, with a minimum acceptable value of 0.59) and relevant (the item-level content validity index was 0.72–1, and the average and union agreement of scale-level content validity index was 0.96 and 0.77, respectively, with a generally accepted value of 0.80). They commented that most of the intervention contents were well-organized and clearly presented, except for some sections that need to be tailored to the actual situation of people with diabetes (e.g., knowledge of insulin may only be useful for those using insulin). The panel further suggested that the course contents should be easily understandable by less-educated older couples. Considering expert reviews, we simplified educational content by deleting low essential and replaced one-way education with interactive activities for older couples to practice together.

Step 4: Feasibility Study

Older couples' sociodemographic characteristics were comparable between arms (Table 1). Participants with diabetes had a mean age of 70 years, half were male, had low education, and the majority were retired. They had diabetes for multiple years, and over two-thirds had diseases other than diabetes. Spouses had similar sociodemographic profiles, who tended to be younger and better educated.

The models' treatment effects were shown in Table 2 for the diabetic participants and Table 3 for the spouses. Although none of these treatment effects were statistically significant due to insufficient power (e.g., power for HbA1c was 0.1), trends in within- and between-arms differences of these measures were large as expected; namely, participants with diabetes of the intervention arm tended to have faster declines in blood glucose and lipid levels, more improvements in mental well-being, self-efficacy, and physical activities than their controlled counterparts. Nevertheless, participants with diabetes of the control arm seemed to have better outcomes in terms of BMI, self-reported physical health, and daily management activities. Similar trends showed among the spouses. Notably, spouses of the intervention arm reported increased confidence in assisting their partners in diabetes management, while an opposite tendency was shown among spouses of the control arm.

Table 4 showed the implementation measures and acceptability scores of the different arms. The intervention arm showed a higher attendance rate (83 vs. 55%) and lower dropout rate (0 vs. 22%), and refusal rate (11 vs. 33%) than the control arm. The correlation of the attendance rate between participants with diabetes and spouses of intervention arm was 0.9 ($P < 0.01$), indicating high concordance. Participants with diabetes of both arms found the interventions acceptable and helpful to improve management knowledge and skills. Correspondingly, spouses of the intervention arm rated the intervention highly (correlated spousal range from -0.2 to 0.7 , all P s > 0.05), particularly regarding promoted mutual understandings.

Group interviews guided by NPT further provided a structured analysis approach to identify facilitating and inhibiting factors of implementation of CCMM. In terms of coherence and cognitive participation, older couples and health workers all understood the purpose of CCMM and agreed to invest time and energy to practice this model, given its self-reported benefits in improving spousal interactions in daily diabetes management. Community health workers commented that a harmonious marital relationship would be critical to the implementation of CCMM. As for collective action, participants indicated that although the duration and intensity of interventions were generally acceptable, the content of some sessions was overwhelming. Healthcare workers expressed that standardized training to implement CCMM was necessary. In line with acceptability assessments, participants reflected CCMM positively. Health workers additionally suggested that the utilization of online communication tools would facilitate intervention implementation and follow-up.

TABLE 3 | Treatment effects of couple-based interventions on spouses of the 3-month pilot study (couple pair $N = 18$).

Variables of spouses	Intervention arm ($n = 9$)				Control arm ($n = 9$)				Treatment effect	
	Baseline ^a Mean (SD)	3-month ^a Mean (SD)	Difference within arm ^b Mean (SE)	P^c	Baseline ^a Mean (SD)	3-month ^a Mean (SD)	Difference within arm ^b Mean (SE)	P^c	Difference between arm ^d Mean (SE)	P^e
Psychosocial outcomes										
SF-36: Physical component score	47.0 (7.7)	46.0 (10.2)	-1.0 (2.9)	0.754	49.1 (9.4)	50.2 (7.4)	0.8 (2.6)	0.761	-1.8 (4.0)	0.657
SF-36: Mental component score	55.0 (4.5)	53.2 (5.3)	-2.0 (2.1)	0.365	56.7 (6.4)	51.8 (5.0)	-5.1 (s2.0)	0.041	3.1 (2.8)	0.297
C-DMQ score	76.7 (30.0)	84.5 (28.5)	10.0 (12.8)	0.467	87.0 (29.2)	75.8 (24.6)	-11.3 (9.8)	0.293	21.3 (16.1)	0.212
Behavior outcomes										
Metabolic equivalent scores measured by IPAQ-C (MET min week ⁻¹)										
Exercise ^e	440.0 (643.7)	1,500.9 (1,530.9)	1,131.2 (607.0)	0.112	1,680.0 (1,680.0)	2,425.7 (3,607.6)	695.0 (869.0)	0.454	436.3 (1,056.1)	0.686
Walking	1,666.5 (874.2)	1,287.0 (1,034.0)	-454.8 (564.3)	0.450	2,277.0 (1,369.4)	1,155.0 (832.9)	-1,043.1 (484.3)	0.073	588.3 (737.7)	0.439
Sitting	1,015.0 (585.2)	805.0 (708.0)	-360.7 (308.6)	0.300	1,560.0 (930.2)	870.0 (988.2)	-545.5 (432.2)	0.252	184.8 (532.9)	0.735

SD, standard deviation; SE, standard error; 95% CI, 95% confidence interval; HbA1c, glycosylated; SF-36, the 36-item Short Form Survey (SF-36); IPAQ-C, International Physical Activity Questionnaire-Chinese version; MET min week⁻¹, minutes of metabolic equivalent per week for physical activity; C-DMQ, the Chinese version of the Diabetes Management Questionnaires.

^aThe statistical description was based on complete cases without imputation.

^bThe within-arm difference was calculated as the difference between 3-month and baseline levels of given measures using the multiply imputed data.

^c P -value of the within-arm difference was tested by paired t -test and the between-arm difference was tested by Student's t -test.

^dThe between-arm difference was calculated as the difference between intervention and control arms using the multiply imputed data.

^eThe exercise was defined as moderate to vigorous physical activity measured by IPAQ-C regarding weekly frequency and duration.

TABLE 4 | Implementation assessments of the 3-month pilot study (couple pair $N = 18$).

Variables	Participants with diabetes			Spouses of intervention arm		
	Intervention arm ($n = 9$)	Control arm ($n = 9$)	P for arm difference ^a	Intervention arm ($n = 9$)	Spousal correlation coefficient ^b	P for spousal correlation ^b
Implementation measures						
Group education attendance rate (%), mean (SD)	0.8 (0.3)	0.6 (0.4)	0.082	0.8 (0.3)	0.9	0.003
Booster call follow-ups						
Dropout rate, n (%)	0 (0)	2 (22)	0.470	–	–	
Refusal rate, n (%)	1 (11)	3 (33)	0.576	–	–	
Acceptability scores^c, median (25%,75% quartiles)						
Taking this course						
Improved my awareness of diabetes	4.0 (2.5,4.0)	3.0 (3.0,4.0)	0.861	3.0 (3.0,4.0)	0.7	0.065
Improved my control/assistance of blood glucose monitoring	3.0 (3.0,4.0)	4.0 (3.0,4.0)	0.928	4.0 (3.5,4.0)	0.5	0.203
Improved my diabetes management skills	4.0 (3.0,4.0)	3.0 (3.0,4.0)	0.470	4.0 (3.0,4.0)	–0.2	0.721
Increased my awareness of feet care	4.0 (3.0,4.0)	3.0 (3.0,4.0)	0.723	4.0 (4.0,4.0)	0.3	0.453
Participated in the intervention together with my spouse						
Helpful for us	4.0 (3.5,4.0)	NA	NA	4.0 (4.0,4.0)	0.7	0.117
Enhanced awareness of diabetes	4.0 (4.0,4.0)	NA	NA	4.0 (3.0,4.0)	0.6	0.090

SD, standard deviation; NA, not applicable.

^a P -value of arm difference was tested between participants with diabetes of intervention and control arms by Student's t -test, Fisher test, and Wilcoxon rank-sum test.

^bCorrelation between participants with diabetes and spouses of intervention arm was computed by Pearson correlation and Spearman's rank correlation.

^cAcceptability was evaluated as the extent to which participants found CCMM were helpful to improve their knowledge and ability to conduct (or to assist, for spouse) diabetes management activities and to promote positive interactions with their partner (for the intervention arm only) on a scale from 1 (strongly disagree) to 4 (strongly agree).

DISCUSSION

Our study developed CCMM of T2DM based on theoretical models and tailored to the care needs of older couples with diabetes in China. The constructed model was well-received by health practitioners and public health experts and demonstrated its feasibility in the small-scale pilot, with promising treatment effects on older couples to be further confirmed.

The CCMM was systematically constructed in line with the Medical Research Council's guidance for complex interventions' development and evaluation (27), including theory and evidence identification, needs assessment, and piloting. Previous studies have documented the development process of couple-based interventions on coronary artery disease (28), osteoarthritis (29), low-density lipoprotein cholesterol (30), and heart failure (31). Compared to prior couple-based models (**Supplementary Table 4**), CCMM was theoretically grounded, with four intervention modules designed correspondingly. While few studies assessed participants with disease and health practitioners' management barriers (30, 32), our intervention contents were tailored to older couples' specific needs and learning capacity. To ensure active spousal participation, CCMM engaged the spouses of participants with diabetes *via* couple-level discussions and skill practices and communal behavior change goals set, which were selectively employed by prior models (15, 28, 30) and innovatively incorporated couple-based behavior change incentives to promote collaboration between couples.

Our pilot generated interesting findings on the treatment effects of CCMM that were worth further validation. Despite statistically non-significant treatment effects identified due to the small sample size, the results also fitted the theoretical model well. In line with the DMCCI, we found that participants with diabetes and spouses in the intervention arm had a higher attendance rate and lower lost to follow-up rate than those in the control arm, which showed that spouses had the positive effect of dyadic coping in helping daily diabetes management (18). Positive dyadic coping brought improvement to self-efficacy of participants with diabetes and spousal efficacy to assist their partners with diabetes, which was shown by the better C-DMQ scores change in the intervention arm than that in the control arm (20). Furthermore, according to the self-efficacy in SCT, better self-efficacy of couples can improve the couple's health and quality of life, which was also shown in the more improvement of several physiological measures and exercise levels among participants with diabetes of the intervention arm than their controlled counterparts, alongside positive changes in spousal mental well-being and exercise levels (19). Previous studies mainly identified the psychological benefits of couple-based interventions, with mixed findings on clinical (13, 14, 30) and behavioral outcomes (14, 15) of people with diabetes, and less is clear about spousal health (16). Our follow-up studies will validate CCMM in a multicenter RCT (17), adopting adequate outcome measures for both the participants with diabetes and their spouses to provide high-quality evidence to the couple-based chronic disease management literature (11).

The current study further advanced the literature by testing the implementation process and analyzing implementation

barriers and facilitators. In concordance with a systematic review of trials involving people with a disease and a support person (33), we found higher attendance and retention rates of couple-based than individual-based arms, which may be largely attributed to the spousal companion as indicated by the high spousal concordance score. Trief and colleagues studied challenges in the implementation of couple-based interventions for T2DM management *via* telephone calls. Similar to their study (32), our pilot study revealed challenges of independent assessments and spousal engagement from both intervention recipients' and providers' perspectives and the importance of adequate staff training and monitoring in maintaining intervention fidelity. Our planned RCT will modify implementation strategies incorporating challenges identified: (1) equivalent attention will be paid to recruit, assess, and engage the spouse; (2) care managers will receive 10-h training prior to group education and be equipped with a standardized intervention material package; and (3) education sessions will be recorded by structured fieldnotes and taped for fidelity evaluation.

We constructed CCMM according to the recommended practices and evaluated feasibility in a pilot study with high recruitment and retention rates. However, limited to the small sample size and short duration, the pilot study was underpowered to verify the model's treatment effects. We also did not pay equal attention to collect spouses' blood samples, which would provide objective measures to indicate spousal behavior changes in diet and physical activity. The failure to record spouses' retention rates of booster calls further prevented us from exploring spousal correlations in treatment adherence over time. We set our recruitment age of the couples with diabetes at 60+ in line with China's official retirement age to promote their participation. This approach, however, may lead our study population to an older-aged group that was more likely to be widowed and weaken the model's prevention values for these middle-aged adults at high risks for developing T2DM.

CONCLUSION

We developed a theoretically grounded couple-based collaborative model for diabetes management, addressing the main management barriers of community-dwelling older Chinese. Large-scale studies with sufficient statistical powers and longer follow-ups are needed to verify the model's long-term effectiveness in improving management behaviors and clinical outcomes of older adults with diabetes and their spouse. This model has the potential of not only enhancing diabetes management activities of older adults with diabetes but also serving as a primary prevention tool for their spouse.

DATA AVAILABILITY STATEMENT

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

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by Institutional Review Board of the School of Public Health of Sun Yat-sen University. The patients/participants provided their written informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

JL, DX, and YL conceptualized the study, analyzed the results, and wrote the first draft of the manuscript. XX, CP, and WY were responsible for designing education and training sessions. TZ oversaw the booster calls. YW conducted the interviews and analyzed NPT result. LO, XC, and XW contributed to the study design and implementation. All authors contributed to revising the manuscript, have read, and approved the final manuscript.

REFERENCES

- Xiaoli Z. Problems and considerations in the current management of chronic diseases in the elderly in communities in China. *J Commun Med.* (2017) 15:81–2.
- Bornstein SR, Rubino F, Khunti K, Mingrone G, Hopkins D, Birkenfeld AL, et al. Practical recommendations for the management of diabetes in patients with COVID-19. *Lancet Diab Endocrinol.* (2020) 8:546–50. doi: 10.1016/S2213-8587(20)30152-2
- Chinese Diabetes Society China. *Guidelines for Prevention and Treatment of Type 2 Diabetes in China*. Shanghai: Chinese Diabetes Society China (2011).
- Tan P, Dong J. Research progress in self-management of diabetes patients. *Chin J Prev Control Chronic Dis.* (2011) 19:435–9.
- Tu J, Liu Y, Wu X, Xu D, Liao J. Dyadic appraisal and coping with illness among older Chinese adults with type 2 diabetes mellitus: a qualitative study. *Age Ageing.* (2021) 50:928–35. doi: 10.1093/ageing/afaa245
- Withidpanyawong U, Lerkiatbundit S, Saengcharoen W. Family-based intervention by pharmacists for type 2 diabetes: a randomised controlled trial. *Patient Educ Counsel.* (2019) 102:85–92. doi: 10.1016/j.pec.2018.08.015
- Wu M, Liao J. Older couple-based studies on collaborative management of chronic diseases: basic theory and findings. *Chin J Geriatr.* (2020) 39:106–10. doi: 10.3760/cma.j.issn.0254-9026.2020.01.021
- Stahl ST, Rodakowski J, Saghabi EM, Park M, Reynolds CF, Dew MA. Systematic review of dyadic and family-oriented interventions for late-life depression. *Int J Geriatr Psychiatry.* (2016) 31:963–73. doi: 10.1002/gps.4434
- Voils CI, Coffman CJ, Yancy WS Jr, Weinberger M, Jeffreys AS, Datta S, et al. A randomized controlled trial to evaluate the effectiveness of CouPLES: a spouse-assisted lifestyle change intervention to improve low-density lipoprotein cholesterol. *Prev Med.* (2013) 56:46–52. doi: 10.1016/j.ypmed.2012.11.001
- Martire LM, Helgeson VS. Close relationships and the management of chronic illness: associations and interventions. *Am Psychol.* (2017) 72:601–12. doi: 10.1037/amp0000066
- Martire LM, Schulz R, Helgeson VS, Small BJ, Saghabi EM. Review and meta-analysis of couple-oriented interventions for chronic illness. *Ann Behav Med.* (2010) 40:325–42. doi: 10.1007/s12160-010-9216-2
- Arden-Close E, McGrath N. Health behaviour change interventions for couples: a systematic review. *Br J Health Psychol.* (2017) 22:215–37. doi: 10.1111/bjhp.12227
- Trief PM, Fisher L, Sandberg J, Cibula DA, Dimmock J, Hessler DM, et al. Health and psychosocial outcomes of a telephonic couples behavior change

FUNDING

This work was supported by the National Natural Science Foundation of China (#71804201) and the Natural Science Foundation of Guangdong Province (#2018A0303130046). The funders have no role in the design of the study, collection, analysis, and interpretation of data or in writing the manuscript.

ACKNOWLEDGMENTS

The authors thank two community healthcare workers, Aiwu Cai and Feng Chen, who helped recruit the participants and organized education and training sessions.

SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: <https://www.frontiersin.org/articles/10.3389/fpubh.2021.686282/full#supplementary-material>

- intervention in patients with poorly controlled type 2 diabetes: a randomized clinical trial. *Diabetes Care.* (2016) 39:2165–73. doi: 10.2337/dc16-0035
- Wing RR, Marcus MD, Epstein LH, Jawad A. A “family-based” approach to the treatment of obese Type II diabetic patients. *J Consult Clin Psychol.* (1991) 59:156. doi: 10.1037/0022-006X.59.1.156
- Wooldridge JS. *A Couples-Based Approach for Increasing Physical Activity Among Couples with Type 2 Diabetes*. Denver: University of Colorado (2017).
- Trief PM, Fisher L, Sandberg J, Hessler DM, Cibula DA, Weinstock RS. Two for one? Effects of a couples intervention on partners of persons with Type 2 diabetes: a randomized controlled trial. *Diabetic Med.* (2019) 36:473–81. doi: 10.1111/dme.13871
- Liao J, Wu X, Wang C, Xiao X, Cai Y, Wu M, et al. Couple-based collaborative management model of type 2 diabetes mellitus for community-dwelling older adults in China: protocol for a hybrid type 1 randomized controlled trial. *BMC Geriatr.* (2020) 20:123. doi: 10.1186/s12877-020-01528-5
- Berg CA, Upchurch R. A developmental-contextual model of couples coping with chronic illness across the adult life span. *Psychol Bull.* (2007) 133:920–54. doi: 10.1037/0033-2909.133.6.920
- Bandura A. Health promotion by social cognitive means. *Health Educ Behav.* (2004) 31:143–64. doi: 10.1177/1090198104263660
- Helgeson VS, Jakubiak B, Seltman H, Hausmann L, Korytkowski M. Implicit and explicit communal coping in couples with recently diagnosed type 2 diabetes. *J Soc Pers Relat.* (2017) 34:1099–121. doi: 10.1177/0265407516669604
- Vassilev I, Rogers A, Kennedy A, Koetsenruijter J. The influence of social networks on self-management support: a metasynthesis. *BMC Public Health.* (2014) 14:719. doi: 10.1186/1471-2458-14-719
- Ji L, Li M, Liu Y. *Structured Treatment and Education Program for Patients With Type 2 Diabetes not on Insulin*. Beijing: Peking University Press (2016).
- Schulz KE, Altman DG, Moher D, CONSORT Group. CONSORT 2010 statement: updated guidelines for reporting parallel group randomized trials. *Ann Intern Med.* (2010) 152:726–32. doi: 10.7326/0003-4819-152-11-201006010-00232
- Zamanzadeh V, Ghahramanian A, Rassouli M, Abbaszadeh A, Alavi-Majd H, Nikanfar AR. Design and implementation content validity study: development of an instrument for measuring patient-centered communication. *J Caring Sci.* (2015) 4:165–78. doi: 10.15171/jcs.2015.017
- Murray E, Treweek S, Pope C, MacFarlane A, Ballini L, Dowrick C, et al. Normalisation process theory: a framework for developing, evaluating and implementing complex interventions. *BMC Med.* (2010) 8:63. doi: 10.1186/1741-7015-8-63
- Sullivan TR, White IR, Salter AB, Ryan P, Lee KJ. Should multiple imputation be the method of choice for handling missing data in randomized

- trials? *Stat Methods Med Res.* (2018) 27:2610–26. doi: 10.1177/0962280216683570
27. Senn B, Kirsch M, Sanz C, Karlou C, Tulus K, De Leeuw J, et al. Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ.* (2013) 59:587–92. doi: 10.1136/bmj.a1655
 28. Sher TG, Bellg AJ, Braun L, Domas A, Rosenson R, Canar WJ. Partners for Life: a theoretical approach to developing an intervention for cardiac risk reduction. *Health Educ Res.* (2002) 17:597–605. doi: 10.1093/her/17.5.597
 29. Martire LM, Schulz R, Keefe FJ, Rudy TE, Starz TW. Couple-oriented education and support intervention for osteoarthritis: effects on spouses' support and responses to patient pain. *Fam Syst Health.* (2008) 26:185–95. doi: 10.1037/1091-7527.26.2.185
 30. Voils CI, Yancy WS Jr, Kovac S, Coffman CJ, Weinberger M, Oddone EZ, et al. Study protocol: couples partnering for lipid enhancing strategies (CouPLES) - a randomized, controlled trial. *Trials.* (2009) 10:10. doi: 10.1186/1745-6215-10-10
 31. Trivedi R, Slightam C, Fan VS, Rosland A-M, Nelson K, Timko C, et al. A couples' Based self-Management Program for heart Failure: results of a Feasibility study. *Front Public Health.* (2016) 4:e00171. doi: 10.3389/fpubh.2016.00171
 32. Trief PM. Challenges and lessons learned in the development and implementation of a couples-focused telephone intervention for adults with type 2 diabetes: the diabetes support project. *Transl Behav Med.* (2011) 1:461–7. doi: 10.1007/s13142-011-0057-8
 33. Trivedi RB, Szarka JG, Beaver K, Brousseau K, Nevins E, Yancy WS Jr, et al. Recruitment and retention rates in behavioral trials involving patients and a support person: a systematic review. *Contemp Clin Trials.* (2013) 36:307–18. doi: 10.1016/j.cct.2013.07.009

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.

Copyright © 2021 Liu, Xiao, Peng, Zhao, Wu, Yu, Ou, Chen, Wu, Xu and Liao. This is an open-access article distributed under the terms of the Creative Commons Attribution License (CC BY). The use, distribution or reproduction in other forums is permitted, provided the original author(s) and the copyright owner(s) are credited and that the original publication in this journal is cited, in accordance with accepted academic practice. No use, distribution or reproduction is permitted which does not comply with these terms.