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Systematic Review

Effect and quality of couple-based interventions of middle-aged and older adults with type 2 diabetes mellitus: a scoping review

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Abstract

Background: Studies have shown the existence of health concordance between patients with type 2 diabetes mellitus (T2DM) and their spouses, and also that spouses could influence the effect of self-management, benefiting patients' health. However, these studies are heterogeneous and the evidence is inconclusive.
Objective: To synthesize evidence from published randomized controlled trials: the interventional effects and the quality of study performance, also to identify the research gap and the directions for future studies.
Methods: We performed the scoping review by following the PRISMA-ScR guidance. We searched and examined the reports from MEDLINE, EMBASE, PsychInfo, CINAHL Plus by the pre-specified criteria. Key characteristics and information of eligible reports were extracted, analysed and synthesized comprehensively, and the results were presented in the form of words and diagrams.
Results: We identified 5 reports from 4 studies out of 3479 records included. Qualified studies indicated a positive effect of couple-based interventions on couples' distress. Insufficient evidence on physiological health or health behaviours was identified owing to the small number of included studies and inconsistent assessment outcomes. The methodological quality across these studies was generally low due to inadequate reporting of study process and substantial biases.
Conclusions: Couple-based interventions for patients with T2DM showed small effects on the couple's distress while the effects of other outcomes were inconclusive. Future studies should strengthen methodologies by using standard measures of core diabetic outcomes, including detailed assessments of implementation process, and taking a dyadic approach to systematically examine the effects.

Key words: Chronic disease, couple-based intervention, health promotion, scoping review, self-management, type 2 diabetes mellitus

Introduction

As estimated by the International Diabetes Federation, nearly half a billion people suffer from diabetes and the number is projected to nearly 700 million by 2045. Diabetes places a heavy burden on health care and social welfare systems in the developed and developing countries alike (1,2). To constrain the mounting medical resources and socioeconomic costs associated with diabetes, self-management has long been advocated in international clinical guidelines

Key Messages

- Spouses may play a positive role in self-management of patients with T2DM.
- The effects and mechanisms of couple-based intervention are rarely discussed.
- We reviewed RCTs to identify effect of couple-based intervention both on couples.
- The quality of study identified was low, with inconclusive treatment effects.
- Future studies should strengthen methodologies to examine the health outcomes.

(3), especially for the patients in the community. Nevertheless, the generally low adherence to self-management (4,5) indicates that the improvement of diabetic patients' self-management is a thorny task yet to be solved.

Besides the biological factors, type 2 diabetes mellitus (T2DM) is highly modulated by multiple lifestyle factors and heavily influenced by family environment. Baig *et al.*'s review found that active family involvement could improve patients' self-management while the clinical effect remained unclear (6). Studies further suggested that spouse might exert the most significant influence on patients' daily health management than other family members (7,8), owing to spousal daily physical and psychological support, such as food preparation, medication reminder and stress relief. Health concordance between spouse and diabetic patient has been identified (9), partially due to couples' similarities in health-related behaviours that were disease-related and were more likely to be changed jointly (10). Spouses of patients with T2DM were found to have significantly higher risks of glucose intolerance and T2DM than these with non-diabetic spouses (11). Therefore, interventions targeted at the couples may not only prevent complications for patients, but also prevent the development of diabetes of the spouses at risks.

Nevertheless, previous systematic reviews on couple-based interventions for chronic disease management identified small effects on patients' depressive symptoms (12,13) but the evidence of health behaviour change remained inconclusive (14). Prior studies also largely overlooked the psychological outcomes (12) neither for patients nor for the spouse (12,13). The extent to which couple-based interventions would have an impact on diabetes management was unclear because of the rarity of studies as there was only one randomized controlled trial (RCT) published in 1991 (12). In this way, more evidence about the effectiveness of couple-based intervention is needed to identify the gap of research and map the directions guiding the future studies.

Scoping review is a rapid-developing methodology in the spectrum of evidence synthesis (15). By incorporating a series of studies in a specific field through systematic search of the literatures, scoping reviews best serve to identify the types of available evidence in a given field, examine how research is conducted on a certain topic or field, as well as identify and analyse knowledge gaps (15,16). Compared with systematic review, scoping review works better in reviewing literature body comprehensively and exhibiting heterogeneous nature (17). Considering higher hierarchical evidence provided by RCTs than observational or other trial designs (18), we employed the methodology of scoping review to synthesize the best available evidence on the interventional effects of couple-based T2DM interventions from previous RCTs, to identify the knowledge gap by examining the study quality and to provide a clear implication of couple-based interventions on T2DM management.

Methods

Our scoping review was performed by systematically searching, selecting and synthesizing existing evidence by following the recommendations according to the Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) (19) as below in detail.

Databases and search terms

We searched four major databases: MEDLINE (OvidSP), EMBASE (OvidSP), PsychInfo (EBSCOhost), CINAHL Plus (EBSCOhost) with the latest search executed on 22 March 2020. We re-checked these databases before submitting (December 2020), and found no new RCT to the date. There was no language limitation in our search strategies. Reports identified were imported into bibliographic software Endnote X8, and the search strategies are available in Supplementary Table A.

Study selection process

Two researchers, MW and CXW, independently screened titles and abstracts of identified articles. Duplicated articles were excluded and potentially eligible articles were enrolled for the full-text inspection. References of the eligible reports were also screened and retrieved if meeting inclusion criteria. Any inconsistency of results was judged and solved by a third researcher (JL).

Inclusion and exclusion criteria

The inclusion criteria were: (i) RCTs targeted at T2DM (with or without comorbidities) management; (ii) interventions for both patients and spouses; (iii) community dwellers as participants, with the age of above 50 years old. The exclusion criteria were: (i) studies involving other chronic diseases (e.g. T1DM); (ii) family-based studies which were unable to distinguish couple effect; (iii) participants who were institutionalized.

Data extraction and synthesis of results

The researchers developed an electronic data collection form in an Excel 2016® format, and all authors identified the key characteristics of eligible reports. Two members (MW and CXW) read the reports, extracted and input the pre-specified information in the collection form individually. Interventional components and implementation measures were checked to provide insights into couple-based trial design. The quality of study performance was examined with the bias assessment tool according to Cochrane Handbook for Systematic Reviews of Intervention (20). Any inconsistency was judged and determined by a third author (JL). Based on the reporting of couple-based interventions and measures of outcome indicators included in the eligible studies, we have categorized the interventions into three categories (diabetes knowledge education, cognitive

training and behavioural training) and classified the measures into three categories (physiological/clinical measures, psychosocial measures and behaviour measures) for a comprehensive description.

Results

Study characteristics and trial design

Three thousand four hundred and seventy-nine reports from databases and reference lists were identified, and 22 of them were enrolled for full-text examination after screening titles and abstracts. We excluded 17 of them for not meeting the criteria, and 5 reports from 4 studies were included for final assessment. Results of two reports (21,22) from a same study (one about patients' outcomes while the other about spouses') were integrated together. The selection process is shown in Figure 1. All but one of the included studies were conducted in the USA, with the only one study was performed in China. Two studies recruited participants in clinical settings, namely hospitals or health care centres (23,24) while the other two recruited participants directly in community by advertisements (21,25). The sample size of couples across the studies varied from 37 to 268 (median = 108.5) with a slight predominance of male (F/M ratio: 0.83). Table 1 summarizes the characteristics of included studies.

Regarding trial design, half of the studies adopted a standard two-arm, parallel-group design, with 1:1 allocation, comparing couple-based intervention and individual-based intervention (25) or care as usual (namely with no additional intervention) (23). The other two studies by Trief *et al.* (21) and Wooldridge (24) adopted a three-arm design, with a third group to differentiate the effects between individual-based intervention and care as usual.

In terms of the length of follow-up, half of these studies examined treatments effects right after interventions, while the rest two followed participants for over 1 year after baseline (21,25). The reporting of recruitment and retention rates were inadequate, only two studies (21,24) provided the figures. Table 1 illustrates the detailed information about trial characteristics of included studies.

Characteristics of intervention

Table 2 shows the characteristics of interventions contents of these studies. The duration and frequency of intervention varied

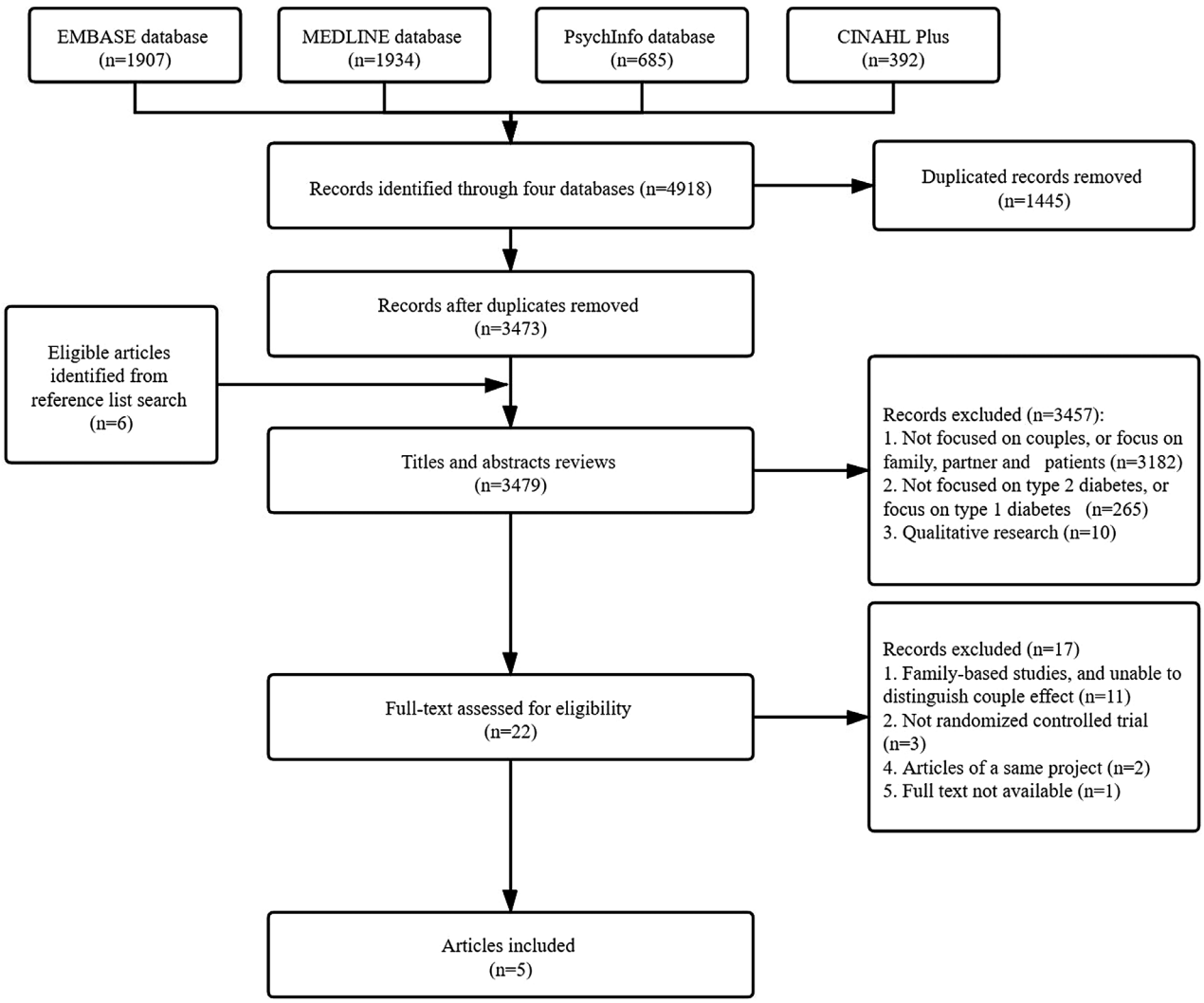

Figure 1. Flow diagram of studies selection process.

Table 1. Study characteristics and trial design

Reports	Country	Study population	Baseline age (mean ± SD, years)	Sample size (male rates among patients)	Trial designs	Length of follow-up	Recruitment rates	Drop-out rates
Trief *et al.* (21,22)	USA	Patients with type 2 diabetes and their spouse	Patients: 56.8 ± 10.9 Spouses: 55.8 ± 11.7	268 (61.6%)	Couple-based intervention (n = 97) versus individual intervention (n = 93) versus diabetes education (n = 78)	Baseline-3 months intervention-12 months follow-up	80.0%	4.3%
Jing and Zhaoxia (23)	China	Patients with type 2 diabetes and their spouse	Patients information only: 69.2 ± 8.1 Intervention arm Control arm 68.9 ± 7.6	168 (51.8%)	Intervention arm (43 men and 41 women) versus control arm (44 men and 40 women)	Baseline-3 months intervention	NR[a]	NR
Wooldridge (24)	USA	Patients with type 2 diabetes and their romantic partners	Patients: 53.9 ± 9.4 Spouses: 53.5 ± 10.13	37 (56.8%)	Couple-based intervention (n = 15) versus individual intervention (n = 15) versus diabetes education (n = 7)	Baseline-6 weeks intervention	22.8%	10.8%
Wing *et al.* (25)	USA	Obese diabetic patients with obese spouses (diabetic or non-diabetic)	Patients alone: 51.2 ± 7.3 Patients together: 53.6 ± 7.7 Spouses alone: 51.6 ± 9.9 Spouses together: 53.4 ± 8.3	49 (36.7%)	Couple-based intervention (n = 24) versus individual intervention (n = 25)	Baseline-20 weeks intervention-72 weeks follow-up	NR	Patient: 12.3% Spouse: 14%

[a]NR indicates certain characteristics was not reported.

extensively, and half of the studies lasted for 12 weeks (ranging 6–20 weeks) while interventions were carried out ranging from once a week to every 3 weeks. Components of couple-based intervention were classified into three categories: diabetes knowledge education, cognitive training and behavioural training. These intervention contents were utilized jointly (21,22) or selectively in different arms. In these studies, the interventional and controlled groups were treated differently in terms of for instance diabetes education, setting different goals, and promoting health conditions for both patients and their spouses. Most interventions were implemented through face-to-face group education, except for one study being carried out via telephone calls by trained clinicians and nurses (21,22).

Treatment effects of couple-based intervention on patients and spouses

There was lacked reporting and inconsistent selection of the patient's or spouse's health outcomes across the studies. We also found discrepant use of outcomes between patients and spouses in the core outcomes of T2DM interventions across the studies. The physiological, psychosocial and behaviour outcomes of both patients and spouses are shown in Table 3.

Effects on patients. All studies reported surrogate or biomedical but not clinical outcomes of diabetes treatment in the clinical outcome measures. The studies of Trief *et al.* (21) and Wing *et al.* (25) both reported blood glucose measures, and found neither statistically significant changes in HbA1c nor fasting glucose. None of them identified substantial improvements in body mass index or waist circumference between groups. A potential gender-specific effect was suggested by Wing *et al.* that female patients were more likely to lose weight if companied by their husbands during intervention (25). Treatment effects on patients' distress reduction were reported uniformly in two studies (21,23), while evidence was still contradictory regarding self-efficacy. Regarding behavioural outcomes, Wing *et al.* (25) failed to find significant changes in dietary control, while Wooldridge (24) elaborated improved physical activity levels immediate after 6-week intervention. The sustainability of couple-based intervention and its long-term effects on behaviour changes were thus yet to be established.

Effects on spouses. Trief *et al.* (22) found a significant reduction in diastolic blood pressure (P = 0.007) but not body weight among spouses in the couple-based intervention group. An opposite conclusion was drawn by Wing *et al.* (25), finding spouses in 'together condition' lost more weight than those in alone condition (31.1 ± 22.5 versus 5.1 ± 9.2 lb, P < 0.001). Trief *et al.* (22) found couple-based intervention significantly decreased spousal distress (4, 8 months, P < 0.001; 12 months, P < 0.05). Furthermore, a statistically significant effect in promoting healthy diet was reported by Wing *et al.* (25), such that the spouses in couple-based intervention arm had greater changes in using eating behavioural strategies assessed by the Eating Behavior Inventory than the spouses in the individual condition [(F(1,38) = 6.4, P < 0.02)].

Implementation process and quality of study performance

In view of the substantial differences in treatment effects, we further checked the quality of performance in these studies. Intervention fidelity was only briefly reported by two studies. Trief *et al.* (21) audiotaped phone-calling sessions for supervision and selected a random sample to verify treatment fidelity. Wooldridge (24) evaluated participants' commitments to physical activities plans by examining the

Table 2. Comparison of intervention contents of included studies

	Trief *et al.* (21,22)	Jing and Zhaoxia (23)	Wooldridge (24)	Wing *et al.* (25)
Intervention duration	12 weeks	12 weeks	6 weeks	20 weeks
Intervention frequency	Weekly	Biweekly	Every 3 weeks	Weekly
Intervention component				
Diabetes knowledge education				
Dietary management				
Drug management				
Exercise management				
Stress management				
Cognitive training				
Problem-solving skills				
Enhance couple mutual support				
Behavioural training				
Individual behaviour goal-setting				
Couple-based behaviour goal-setting				
Self-monitoring blood glucose				
Physical activity improvement				
Dietary change				

Components used in intervention and control arms.
Components used in couple-based intervention arm only.
Components used in individual intervention arm only.

Table 3. Study outcomes and treatment effects for patients and spouses by the included studies

	Trief *et al.* (21,22)	Jing and Zhaoxia (23)	Wooldridge (24)	Wing *et al.* (25)
Patients' outcomes				
Physiological/clinical measures				
HbA1c (%)	=	NR	NR	=
FG (mg/dl)	NR	NR	NR	=
BMI (kg/m^2)	=	NR	NR	=
Weight loss	NR	NR	NR	= male; ↑ female
WC (cm)	=	NR	NR	NR
BP (mmHg)	=	NR	NR	NR
Psychosocial measures				
Distress	↓	↓	NR	NR
Depressive symptoms	=	NR	NR	NR
Self-efficacy	=	↑	=	NR
Behaviour measures				
Eating Behavior Inventory	NR	NR	NR	=
Physical activity	NR	NR	↑	NR
Spouses' outcomes				
Physiological/clinical measure				
Weight loss	=	NR	NR	↑
Psychosocial measures				
Relationship satisfaction	=	NR	NR	NR
Distress	↓	NR	NR	NR
Depressive symptoms	↓	NR	NR	NR
Behaviour measures				
Eating Behavior Inventory	NR	NR	NR	↑

BMI, body mass index; BP, blood pressure; FG, fasting glucose; HbA1c, haemoglobin A1c; WC, waist circumstance.
'=' means no significant difference between couple-based intervention and control arms.
'NR' indicates certain outcome was not reported.
'↓' means significant decreases between arms.
'↑' means significant increases between arms.

extent to which participants fulfilled their plans using self-reported checklists, and evaluated intervention's feasibility and acceptability by measuring some indicators like recruitment, refusal rates and using an attitude scale, respectively.

We illustrated the results of risk of bias assessments in Figure 2. Despite that all studies reported random sequence generation which were unlikely to incur selection bias, half of the studies (23,25) were susceptible to attrition bias and reporting bias, and three (23–25) failed to report allocation concealment or blinding to clinical staff conducting outcome assessments. It was noticed half of these studies only or mainly used self-reported psychosocial or behavioural outcomes which were likely to incur recall, and social desirability bias

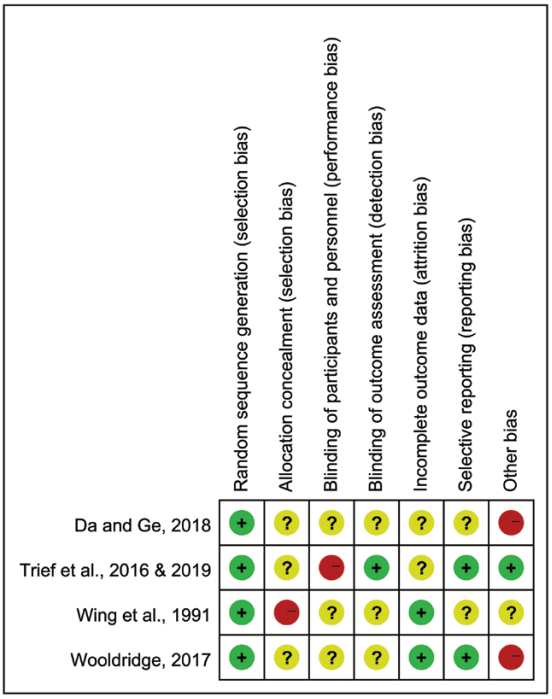

Figure 2. Risk of bias graph of studies reviewed.

while other physiological outcome measured by objective methods in other studies.

Discussion and conclusion

Discussion

The present study is a scoping review of RCTs with couple-based intervention for T2DM to identify issues on treatment effect of couple-based intervention on patients and their spouses which was rarely reported previously. Taking the advantages of the scoping review, we could have better understanding of the research in this field. We found four studies which provided inconsistent findings on the interventional effects of couple-based intervention on diabetic patients' or their spouses' physiological, psychological and behaviour health. The quality of these studies was relatively low since majority of them are not methodologically robust or control potential bias rigorously.

Our study failed to identify conclusive treatment effects of couple-based interventions on health outcomes of middle-aged and elderly diabetic patients. Owing to limited number and inconsistency of health outcomes across the included studies, there was insufficient evidence to suggest that couple-based collaborative intervention would improve diabetic patients' physiological or behaviour outcomes. For instance, we could not draw a clear conclusion on the effect of couple intervention on patients' HbA1c only basing on two RCTs with blood glucose measures (21,25). The review by Spencer-Bonilla *et al.* (26) suggested a favourable effect of social support on short-term HbA1c. Different from our study, their study not only included research on family or couple, but also other social relationships (e.g. friends, communities) into review, failing to specify the effect of couple-based intervention alone. In partial agreement with a review of couple-oriented interventions for chronic illness (12), we found consistent effects of couple-based interventions on reducing patients' distress levels (21,23), but not depressive symptoms (12). The limited number of included studies suggests that more couple-based interventions on T2DM management are needed to clarify the effects with adequate outcome measures. Beyond that, none of the indicators we summarized for outcomes and treatment effects was examined in all four reports. This highlights the importance of adopting outcomes of Core Outcome Set for diabetic studies. The poor performance of these reports on bias control may be another reason why we could not identify consistent effects. For example, none of these reports had made good use of the blinding, which may had affected the veracity of subjective outcome. It is usually difficult for researchers to blind participants for behaviour change-related interventions, but bias can still be reduced by blinding the outcome assessors or using objective outcome measures to minimize the limits of this type of intervention.

We also found insufficient number of studies with limited spousal outcome measures. Compared with patients, spouses received less attention from researchers and spousal outcome was primarily focussed on psychological perspective. The only two studies assessed spousal health were confined to psychological and behavioural outcomes, showing positive effects on relieving spouses' distress and depression. This was in concordance with a previous review of family involvement in psychological interventions for chronic diseases (7). This may be attributed by researchers' presumptions that most spouses are not diabetic and their physiological health changes may be of fewer interests for previous studies. However, the high health concordance between couple has been well documented, particularly regarding metabolic syndrome that is heavily dependent on lifestyle shared by couple (27). Some cohorts in Asia have identified a 1.12- to 1.31-fold increased risk of metabolic syndrome of spouses of diabetic patients compared with their counterparts with healthy partners (28,29). Our study identified this research gap, highlighting that future studies should pay equivalent attention to patient's spouses who are also susceptible to and may already suffer from diabetes or pre-diabetes, and properly treat the couple as the intervention and assessment unit (30).

Our scoping review additionally revealed the considerable heterogeneities in the trial design with a generally low quality. The evaluation supported the result of review by Spencer-Bonilla *et al.* (26) concluding that the body of evidence of social network intervention on T2DM was subjected to moderate risk of bias, heterogeneous and inconsistent findings. Half of the reports reviewed by our review did not provide detailed descriptions of intervention fidelity, with common failure to control potential bias rigorously. The reasons for the risks of bias could be attributed to inadequate reporting or poor compliance to reporting guidelines. We suggest that future studies should have clear assessments of implementation process and bias control, alongside reported health outcomes for patients routinely, and abide by the reporting guideline (31).

As we know, this is one of the first scoping reviews to explore effects of couples' collaborative interventions on T2DM, with evaluations on health outcomes and methodological quality. Nevertheless, some limitations are worth noting. First, due to strict inclusion and exclusion criteria, trials other than RCTs exploring the effects were not included. This approach may lead to the small number of studies identified in the current review, while findings generated by RCTs are most reliable in the hierarchy of evidence. Additionally, we only searched RCTs targeted at T2DM management, and these focussed on multiple health conditions with T2DM were beyond our review's scope. Multimorbidity is increasingly common among older adults which deserves further exploration in couple-based interventions (32). Finally, the databases we chose would only allow us to screen published reports. Although we conducted grey literature research and included one unpublished dissertation (24), our study may still be at risk of publication bias.

Conclusion

Our scoping review of couple-based interventions on T2DM found inconclusive interventional effects on diabetic patients or their spouses. Despite of limited number of studies with generally low quality, we made contributions to identify the inconclusive effects of couple-based intervention for middle-aged and older patients with T2DM and their spouse. In the future, studies on this topic should strengthen methodologies by, for example, using standard measures of diabetic outcomes, including adequate assessments of the implementation process, and even taking a dyadic approach to systematically to examine the effects.

Supplementary material

Supplementary material is available at *Family Practice* online.

Declaration

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Ethical approval: not applicable.
Conflict of interest: none.

Data availability

The data underlying this article are available in the article and in its online supplementary materials.

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