Journal of Health Sciences

REVIEW ARTICLE Open Access

Do caregivers' involvement in Type 2 diabetes education affect patients' health outcomes?: A systematic review and meta-analysis

Jeongyeon Kim[1], Jiyoun Song[2], Aluem Tark[3], Soyeon Park[4], Kyungmi Woo[1]*

[1]College of Nursing, Seoul National University, Seoul, Korea, [2]Columbia University School of Nursing, New York, USA, [3]Helene Fuld College of Nursing, New York, USA, [4]Department of Clinical Nursing Science, Korea Armed Forces Nursing Academy, Deajeon, Republic of Korea

ABSTRACT

Introduction: The prevalence of Type 2 diabetes mellitus (T2DM) is rising worldwide. Patients frequently struggle with controlling their diabetes and need the assistance of caregivers for effective self-management because managing diabetes requires a variety of strategies, including diet, glucose monitoring, and exercise. This study aimed to examine the effect of caregiver involvement in T2DM education within a community on patients' diabetes care outcomes.

Methods: Based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines, a systematic review of all published studies from the earliest record to May 2022 that reported adult caregivers of T2DM patients who participated in educational interventions concerning diabetes management and that reported one or more outcomes of the interventions were conducted. Four databases were used, including PubMed, Cochrane Library, EMBASE, and CINAHL. The meta-analysis focused on glycated hemoglobin (HbA1c) levels among randomized controlled trials (RCTs), with additional attention to lipid levels. Review Manager 5.4 was used to perform this meta-analysis.

Results: A total of 17 out of 683 studies were synthesized. Involvement of caregivers in T2DM education is shown to reduce body mass index and HbA1c. This involvement also improves patients' knowledge, physical activity, and self-efficacy, but the effect on medication adherence varies. A meta-analysis of six RCT studies shows that caregiver involvement in T2DM education reduced pooled HbA1c levels by 0.83 (95% Confidence interval: −1.27–−0.38) compared to involvement (p = 0.0003). Meta-analysis of three types of lipids (low-density lipoprotein, total cholesterol, and high-density lipoprotein) showed no strong evidence that caregiver participation in diabetes education improved lipid levels.

Conclusions: Caregivers play key roles in diabetes management and can contribute to improving patient HbA1c levels. Future research should focus on enhancing caregiver participation in T2DM education.

Keywords: Caregivers; diabetes mellitus, Type 2; education; meta-analysis; systematic review

INTRODUCTION

Type 2 diabetes mellitus (T2DM) is a major public health concern (1,2), and the International Diabetes Federation predicts that the number of T2DM patients will continue to rise (3). Although blood glucose levels can be controlled through diet, exercise, and/or medication adherence, glucose management remains challenging for those with T2DM. Community-based diabetes management programs have been implemented in response to these challenges. The previous studies show that patients who participated in community-based diabetes programs lowered their fasting blood glucose levels or improved other health indicators related to diabetes (i.e., glycated hemoglobin level (HbA1c), blood pressure, exercise behavior) (4,5). Despite these community efforts, the prevalence of T2DM-related hospitalizations is still increasing and ultimately causing high health-care expenditures (6-8), which indicates further improvements are needed in diabetes management in the community.

Diabetes education is provided to patients through a variety of channels. For example, diabetes self-management education and support (DSME/S) is provided through hospitals, health facilities, and community health center programs (9). Despite the availability of educational resources, patients continue to struggle in managing their diabetes due to the complexity of glucose management (10). To effectively manage diabetes, active efforts to change lifestyle activities such as adherence to medication, glucose monitoring, diet, and exercise are required (11). Thus, patients with T2DM often need

*Corresponding author: Kyungmi Woo, College of Nursing, Seoul National University, Seoul, Korea.
E-mail: woo2020@snu.ac.kr

Submitted: 06 May 2023/Accepted: 10 October 2023

DOI: https://doi.org/10.17532/jhs.2023.2182

UNIVERSITY OF SARAJEVO
FACULTY OF HEALTH STUDIES

assistance from their caregivers to effectively manage T2DM in the community.

Caregivers often share responsibility in managing disease. They can provide significant support to the patient in following medical treatment recommendations or in self-management activities (such as through making grocery purchases, refilling prescriptions, or transporting patients to appointments), and may also provide psychological support (12). Due to the importance of the caregiver's role, patient-caregiver involvement and education in diabetes management have recently been highlighted. Supportive caregivers (e.g., spouses or family members) can improve the quality of life and self-management of diabetes patients (13). On the other hand, a lack of support from family members could negatively impact medication compliance and blood glucose levels (12). The previous research indicates that caregiver involvement in diabetes management is a critical component of successfully managing T2DM at home and in the community. Especially given the distinctive environmental characteristics of communities as compared to hospital settings, the presence of caregivers, the degree of care participation, and caregiver education can impact the self-management of diabetes patients.

A recent meta-analysis by Kodama et al. (14) examined the effectiveness of family-oriented diabetes programs on glycemic control among both Type 1 and Type 2 diabetes patients of all ages and found that participation in the analyzed intervention programs decreased mean HbA1c (14). Despite this study providing important insights into the effects of family involvement in diabetes care, stratifying analysis and review by caregiver dynamic, diabetes type, and age group can provide a more precise picture of the relationships among various factors. Moreover, this study was conducted in 2019 with the data collection performed in 2017, and only experimental studies with HbA1c as an outcome were included in the study. According to the Cochrane Handbook, reviews are recommended to be updated approximately every 5.5 years (15). Other recent studies only looked at certain areas of diabetes management, such as foot ulcers (16). Our study not only investigates experimental studies but also observational studies with behavioral outcomes, thus providing a more comprehensive understanding of the subject area with more recent data.

The purpose of this study is to find out the effect of caregiver participation in diabetes education on patient health. To this end, we conducted a systematic literature review to examine the association between caregiver involvement in adult T2DM education within a community setting and patients' diabetes care outcomes. The outcomes focused on are biological results (e.g., HbA1c level) and self-management outcomes (e.g., diabetes knowledge). Further, a meta-analysis was conducted to determine the effectiveness of caregiver involvement in T2DM education on HbA1c levels and lipid levels. The results from this study will help diabetes educators and policymakers make decisions about whether to include caregivers in providing more effective patient diabetes education.

METHODS

A systematic literature search was conducted using four electronic databases (i.e., PubMed, Cochrane Library, EMBASE, and the Cumulative Index to Nursing and Allied Health Literature) on research published from the earliest record to May 2022. Medical Subject Headings (MeSH) terms and keywords were utilized, such as "diabetes mellitus, Type 2," "diabetes self-management education," "caregivers," "home care," and "community health." A full list of search terms used and the total number of studies identified from each database are presented in Table 1.

This study used a PICO-SD (Participants, Intervention, Comparison, Outcomes, Study Design [SD]) tool as follows: (1) Population (P), Type 2 diabetes patients and caregivers; (2) Intervention (I), patient diabetes education with caregivers (with interventions including self-management education, health education); (3) Comparison (C), usual care (without caregivers) or no control group; (4) Outcome (O), biological results (e.g., HbA1c level), self-management outcomes (e.g., diabetes knowledge); and (5) SD, interventional studies including RCTs. Furthermore, a manual search was conducted using the reference lists of all the included studies.

According to the Centers for Disease Control and Prevention, a caregiver is a person who provides care to someone who needs some ongoing assistance with everyday tasks on a regular or daily basis (17). Caregivers are referred to as either "formal" or "informal." Informal caregivers, also called family caregivers, provide care to friends or family, typically without payment (18). In this study, "caregiver" refers to informal caregivers who are not professional healthcare providers, personal care workers, or home health aides. In other words, caregivers in this study include those who live with the patient and care for the patient (e.g., spouses, adult children, friends, and cohabitants). We reviewed studies that included caregivers in the education of adults with diabetes in the home and community, but not in hospitals. The specific inclusion criteria were as follows.

Inclusion criteria were (1) adult patients (age≥18 years) with T2DM, (2) caregivers (age ≥18 years) who participated in diabetes management education, (3) interventional SD (e.g., randomized control trials or quasi-experimental study), (4) reported one or more care outcomes (e.g., physical activity, HbA1c level), (5) published in peer-reviewed journals, and (6) written in English. Exclusion criteria were (1) study protocol for a randomized controlled trial, (2) systematic reviews or meta-analysis, and (3) inpatient setting.

All identified studies were imported into a citation management tool (EndNote), then duplicate studies were removed using the "find duplicates" function and manually (19). Three authors (JK, JS, and AT) independently conducted title/abstract screening of studies using Covidence systematic review software. Then, a full-text review was conducted for the final selection. Any discrepancies were resolved through weekly discussion between all authors until a final consensus was achieved. The details of the selection process are presented in Figure 1.

All authors independently conducted data extraction and quality assessments of the included studies. The following variables were extracted and used to synthesize the findings: SD/setting, country of study origin, study aim, sample size, and eligibility for study participation, characteristics of

TABLE 1. Search terms

	PubMed	
1	"Diabetes Mellitus"[Mesh] OR "Diabetes Mellitus, Type 2" [Mesh] OR "Diabetes Mellitus" [Title/Abstract] OR "Diabetes Mellitus" OR "diabetes" [Title/Abstract] OR "diabetes" OR "T2DM"[Title/Abstract] OR "T2DM" OR "diabetic" [Title/Abstract] OR "diabetic" OR "type 2 diabetes" [Title/Abstract] OR "type 2 diabetes"	871,580
2	"Independent Living" [Mesh] OR "independent living" OR "community-dwelling" OR "community based multicenter" OR "community health" OR "Home Care Services" [Mesh] OR "Home Care Services, Hospital-Based" [Mesh] OR "Home Care Agenes" [Mesh] OR "Home Nursing" [Mesh] OR "Home Care Agenes" [Mesh] OR "Community Health Services" [Mesh] OR "home care" OR "community setting" OR "community" OR "outpatient"	1,223,512
3	Patient Education [MeSH Major Topic] OR Self-care [MeSH Major Topic] OR "patient education" OR "diabetes education" OR "diabetes self-management education" OR "diabetes patient education" OR "diabetes education program" OR "education program" OR "health education" OR "educational intervention" OR "supportive educational intervention" OR "Early Intervention, Educational" [Mesh]	262,788
4	"patient's family" OR "family-based" OR "couple-based" OR "care-partner" OR "in-home supporter" OR "Friends" [Mesh] OR "caregiver" OR "supporter" OR "care giver" OR "spouse" OR "family caregiver" OR "informal caregiver" OR "care taker" OR "Caregivers" [Mesh] OR family [MeSH Major Topic]	275,356
5	"Diabetes Mellitus, Type 1" [Mesh] OR "T1DM" [Title/Abstract] OR "T1DM" OR "type 1 diabetes" [Title/Abstract] OR "type 1 diabetes" OR "Child" [Mesh] OR "Child"	2,517,622
6	1 AND 2 AND 3 AND 4 NOT 5	103
	CINAHL	
S1	TI "diabetes" OR TI "diabetes Mellitus, Type 2" OR TI "T2DM" OR TI "diabetes mellitus"	115,667
S2	"Independent Living" OR "independent living" OR "community-dwelling" OR "community based multicenter" OR "community health" OR "Home Care Services" OR "Home Care Agencies" OR "Home Nursing" OR "Home Care Agencies" OR "Community Health Services" OR "home care" OR "community setting" OR "community" OR "outpatient"	451,784
S3	((MH "Patient Education") OR (MH "Education") OR (MH "Adult Education") OR (MH "Education, Non-Traditional")) OR ("diabetes education" OR ("education in diabetes" OR "nursing education" OR "patient education"))	163,502
S4	(MH "Dependent Families") OR (MH "Family") OR "family caregiver" OR "supporter" OR "spouse" OR "family caregiver" OR "informal caregiver" OR "caretaker" OR "caregiver" OR "patient's family" OR "family-based" OR "couple-based" OR "care-partner" OR "in-home supporter" OR "supporter" OR "care giver" OR "spouse" OR "family caregiver" OR "informal caregiver" OR "care taker"	102,265
S5	(MH "Diabetes Mellitus, Type 1") OR (MH "Child")	528,906
S6	S1 AND S2 AND S3 AND S4 NOT s5	35
	EMBASE	
#1	"diabetes mellitus" OR "non insulin dependent diabetes mellitus" OR "diabetes" OR "T2DM" OR "diabetic" OR "type 2 diabetes"	1,465,363
#2	"independent living" OR "community-dwelling" OR "community dwelling person" OR "community based multicenter" OR "community health" OR "community care" OR "home care services" OR "home care" OR "community setting" OR "outpatient care"	383,209
#3	"patient education" OR "patient engagement" OR "self-care" OR "self management support" OR "diabetes education" OR "diabetes self-management education" OR "diabetes patient education" OR "diabetes education program" OR "education program" OR "health education" OR "educational intervention" OR "supportive educational intervention" OR "medical education" OR "early intervention"	807,962
#4	"caregiver" OR "informal caregiver" OR "informal caregiving" OR "family" OR "patient's family" OR "family-based" OR "supporter" OR "care partner" OR "couple-based" OR "in-home supporter" OR "spouse"	1,671,672
#5	"child" OR "pediatrics" OR "insulin dependent diabetes mellitus" OR "t1dm" OR "type 1 diabetes"	3,882,593
#6	#1 AND #2 AND #3 AND #4 NOT #5	460
	MEDLINE	
1	Diabetes Mellitus/or Diabetes Mellitus, Type 2/ or "non insulin dependent diabetes mellitus". mp. or t2dm.mp. or type 2 diabetes.mp.	31,2471
2	Independent Living/or community-dwelling.mp. or Community Health Services/or community based.mp. or community health.mp. or community care.mp. or Home Care Services/or home care.mp. or outpatient care.mp. or Ambulatory Care/	258,765
3	Patient Education as Topic/or diabetes education.mp. or Health Education/ or Early Intervention, Educational/ or self-management education.mp. or education program.mp. or educational intervention.mp.	168,117
4	Caregiver.mp. or Caregivers/ or informal caregiver.mp. or informal caregiving.mp. or family.mp or family-based.mp. or supporter. mp. or care partner.mp. or couple-based.mp.	1,037,498
5	Diabetes Mellitus, Type 1/or type 1 dm.mp. or insulin dependent diabetes mellitus.mp. or t1dm.mp. or type 1 diabetes.mp. or Child/ or child.mp.	2,316,571
6	(1 and 2 and 3 and 4) not 5	80

study participants (e.g., demographics and comorbidities), type of caregiver involved (e.g., partner, adult children), characteristics of caregiver (e.g., demographics), the intervention of caregiver education utilized, outcome measurement, and reported study outcomes.

Based on the SD, two appraisal tools were used to evaluate the quality of included studies. A Cochrane risk-of-bias tool (RoB) was used for RCTs, and a Risk of Bias Assessment Tool for Non-Randomized Studies (RoBANS) was used for non-randomized studies (20,21). The quality appraisal was validated by three authors (JK, JS, and AT), and any discrepancies were resolved during group discussions.

This study was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (22). The included literature was qualitatively synthesized and the results of randomized controlled trials (RCTs) that studied the effect of caregiver involvement in diabetes education on HbA1c and lipids were included for meta-analysis. Qualitative synthesis was performed to meet the synthesis without meta-analysis guidelines (23).

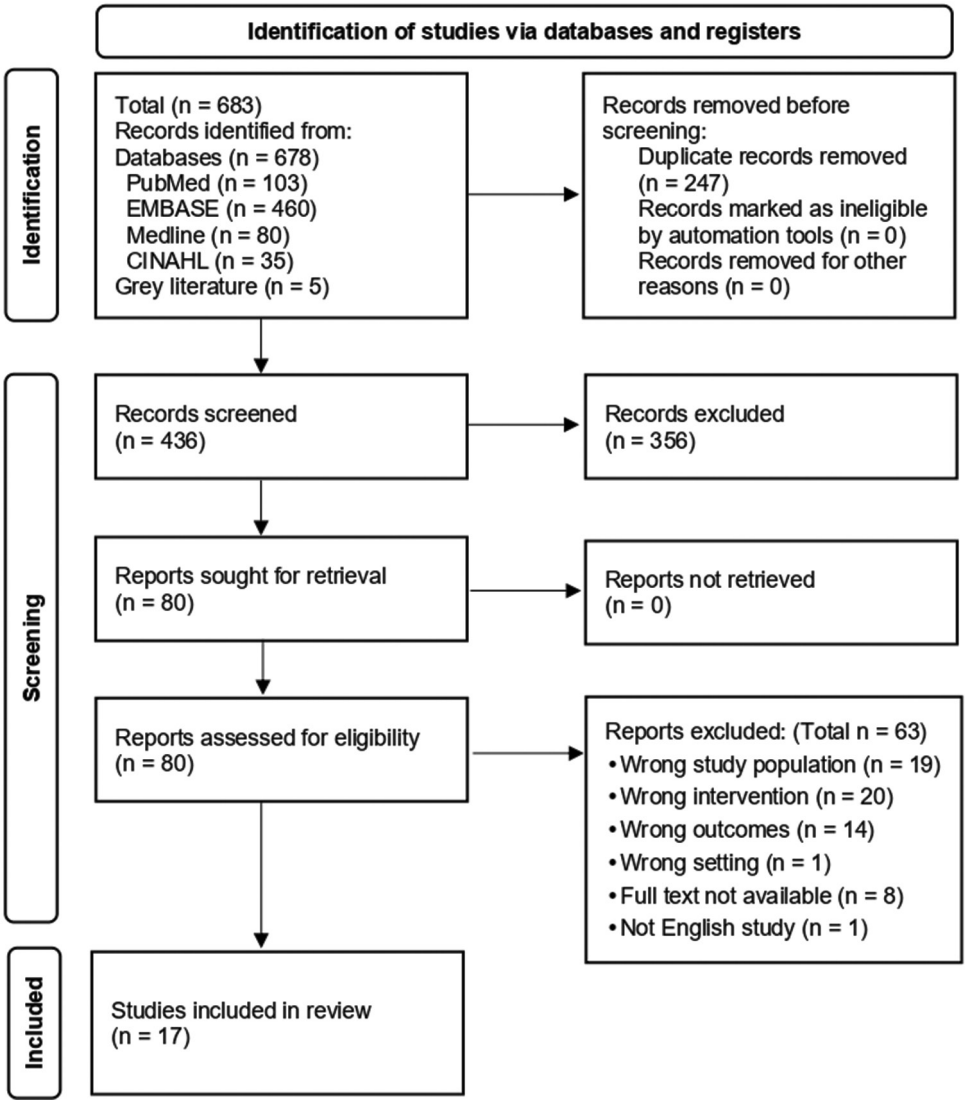

FIGURE 1. Flow diagram of the literature search according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines.

A descriptive analysis was performed on the characteristics of all the participants in the included studies (n = 17) if made available by those studies, using the mean and standard deviation (SD). However, for the following demographics, the mean and SD values were calculated and presented only for the studies that provided the relevant information. Those characteristics are diabetes duration (n = 8), comorbidity (n = 10), mean age of caregivers (n = 6), and gender of caregivers (n = 6).

The results of the qualitative synthesis were primarily divided into two groups: Biological indicators and behavioral indicators (or self-management indicators). This is because the characteristics of clinical results and behavioral outcome indicators are distinct. Thus, we as clinical experts, including a certified diabetes educator, determined that it would be more appropriate to analyze the biological and behavioral indicators separately in examining the impact of the intervention. In addition, many studies examined behavioral outcomes for caregivers' participation in diabetes education, thus excluding these studies would lead to a loss of significant scientific evidence. Therefore, we determined that presenting behavioral results rather than just the clinical results would make the research findings more comprehensive. Since HbA1c is directly related to the level of diabetes, it is considered the primary outcome among clinical indicators in our study. The results of the qualitative synthesis were presented as the mean (standard deviation), median, and range of each result value. The summary of the effect estimates pre- and post-intervention is also supplied, together with the *p*-value.

Of all the included studies, only RCTs that examined HbA1c and lipids as an outcome were included for the meta-analysis. RCT studies were excluded from the synthesis if they met the following criteria: A study that received a low-quality rating in the quality assessment (e.g., one in which a high bias was identified in most domains according to the RoB) (24); a study in which pre- and post-outcome values were not sufficiently presented to perform meta-analysis (25); a study difficult to compare with other studies due to the presence of numerous intervention groups (26). The size of the effect was calculated using Review Manager 5.4 (RevMan) provided by The Cochrane Collaboration (27) and heterogeneity was estimated using the χ^2 test and the standard I^2 test. The Cochrane Handbook defines moderate heterogeneity as 50–75% between studies (28,29). Because of some heterogeneity between studies, a random-effects meta-analysis model was used to calculate the effect size for each study and the pooled HbA1c effects across the studies.

The effect size of the result value was presented as mean difference. To identify potential causes of heterogeneity, subgroup analyses were performed. Meta-analysis was considered for other indicators, but only HbA1c and lipids were found to be eligible.

RESULTS

The study selection process is depicted in Figure 1. A total of 683 studies were initially identified: 678 studies from the database search and five studies from the manual search. After duplicates were removed (n = 247), additional studies were excluded after title and abstract screening (n = 356). A total of 80 studies were included in full-text reviews, and 63 studies were excluded for failure to meet inclusion criteria. In total, 17 studies were included for qualitative analysis in this systematic review, and six RCTs were included for quantitative analysis in the meta-analysis (30-35). HbA1c levels in all six studies were analyzed, but only some of the six were used in the analysis of lipids, depending on the type(s) examined in a given study. More specifically, low-density lipoprotein (LDL) and High-density lipoprotein (HDL) were analyzed using two articles (30,34), while total cholesterol (TC) was analyzed using three articles (30,34,35).

Of all the studies, 9 *(*52.9%) were RCTs (24-26,30-35), and 8 *(*47.1%) were quasi-experimental or pre-post studies (36-43), published between 2002 and 2020. Studies were conducted in seven different countries: Chile (n = 1), China (n = 2), Iran (n = 2), Ireland (n = 1), Taiwan (n = 1), Thailand (n = 2), and the United States (n = 8). The combined total number of study participants was 2350 with a median of 140 (range 27–268). All studies were conducted in outpatient or community settings (e.g., home or church). The major aim of the included studies was to investigate the effectiveness/impact of caregiver-involved educational intervention on T2DM patient outcomes. A full list of data extraction is shown in Table 2.

The risk of bias for the nine RCT studies is shown in Figure 2. Overall, the risk of bias in most domains was low for all of the studies except one (24). The most frequently reported "low risk of bias" domain was selective reporting, and the most commonly reported "high or unknown risk of bias" domain was blinding of participants and personnel. Figure 3 shows the risk of bias for eight non-RCT studies. Among non-RCT studies, selective outcome reporting bias was the most frequently reported "low risk" area. In most studies, the risk of bias was low in the participant selection and measurement exposure domains, and it was "unclear" in blinding of outcome assessment domain.

All 17 studies included in our qualitative analysis reported the age, gender, and HbA1c levels of the patients. Overall, the mean age of the included patients (n = 1816) was 55.15 years (SD 4.59). More than half of patients were female (62.74%). In general, the diabetes of patients was poorly controlled, with an average HbA1c of 8.67% (SD 1.17; range 6.0–10.46%). The duration of diabetes was reported in eight studies and was 7.66 years on average (SD 2.37; range 3.4–10.6). In addition, ten studies reported patient comorbidity, with over 60% of patients having at least one comorbidity (e.g., hypertension, hyperlipidemia,

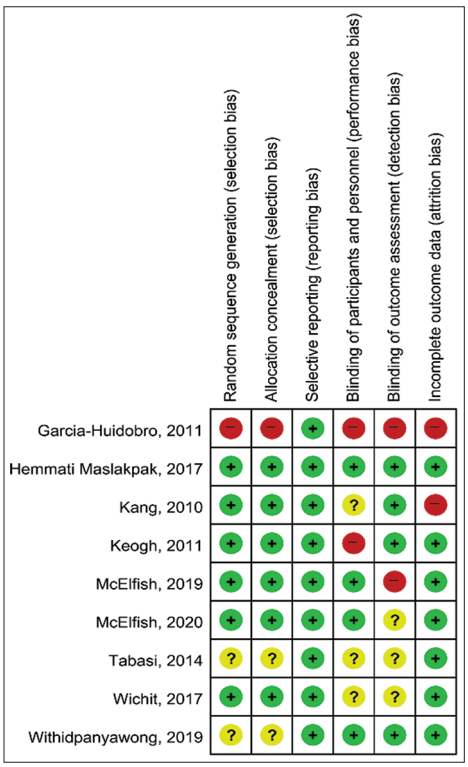

FIGURE 2. Methodological quality assessment based on the Cochrane Risk of Bias (RoB) tool for randomized controlled trials. Note: +: low risk; -: high risk; ?: unclear risk.

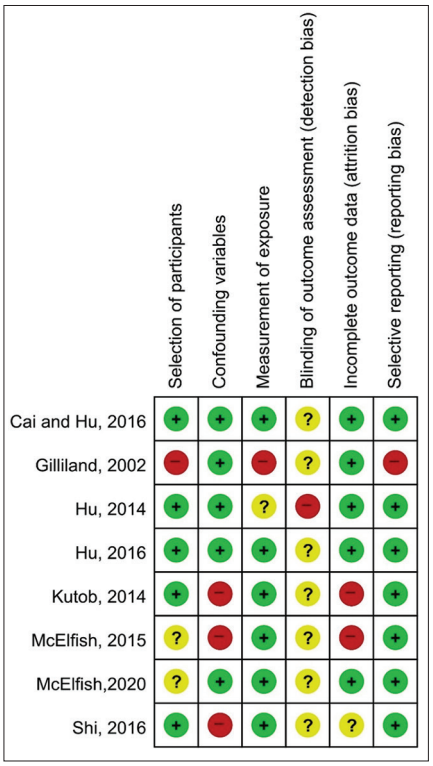

FIGURE 3. Methodological quality assessment based on the Risk of Bias Assessment tool for Non-randomized Studies (RoBANS) for non-randomized studies. Note: +: low risk; -: high risk; ?: unclear risk.

cardiovascular disease). Among the studies that provided caregiver demographic information (n = 6), the mean age of caregivers was 51.1 years (SD 7.17), and 63% were female. All 17 studies presented the caregiver as a family member, but the type of family member designated varied from a spouse, relative, or significant other, including friends. In

TABLE 2. Characteristics of included studies

Author (year)	Partipants (n)/Eligibility/ Characteristics	Type of Caregiver and Characteristics	Intervention/ Duration	*Biological* Outcomes Measured/Results	*Behavioral* Outcomes Measured/Results
Cai and Hu, (2016) China	• n=57 (IG=29; CG=28) • Eligibility: (1) self-reported a diagnosis of T2DM for more than 1 year (2) age ≥ 18 years (3) HbA1c ≥ 7.0% • Patient characteristics: Age (mean, years) 65.3, Female: 61.4%, Mean duration of DM: 7.18 years, treatment of medication: 78.5%, Complications (e.g., coronary artery disease, retinopathy, or renal damage): 61.4%, Baseline HbAlc: 7.74%	• Type: Family members (1) living in the same household with the partipant with T2DM; and (2) age ≥ 18 years. • Characteristics: mean age 63.4 years	• Diabetes knowledge and self-management activities based on 4 prinpal sources of self-efficacy. • Intervention Duration: (1) IG had 7 one-hour sessions, with 2 homes (sessions 1 & 7 visits and 5 weekly group sessions 2-6); (2) CG had usual care, including 10-15-minute home visits every quarter. • Study Duration: 3 months	• HbA1c reductions in the IG: HbA1c 7.93% to 6.93% (p<0.001) • BMI reduction in the IG: 24.39 kg/m2 to 23.27 kg/m^2 • Waist rcumference reduction in the IG: 86.8 cm to 84.1 cm	• Improved diabetes knowledge in the IG: significantly improved diabetes knowledge (F=92.77, p<0.001) • Improvement in self-efficacy and self-care activities in the IG: F=66.73 and F=63.35, respectively, all p<0.001 • Improved health-related quality of life: Partipants with T2DM in the intervention group significantly improved both physical (F=21.73, p<0.001) and mental (F=26.72, p<0.001) components of health-related quality of life
García-Huidobro et al., (2011) Chile	• n=243 • Eligibility: (1) T2DM, (2) age between 18 and 70 years (3) recent HbA1c ≥7.0% in past 3 months, (4) living with a significant family member, (5) not hospitalized in 3 months preceding the Hb1AC measure • Patient characteristics: 1. IC: n=83; Female % (n): 61 (73); Age (years): 53.4 (±8.1); HbA1c (%): 10.3 (±2.0) 2. CC1, n=76; Female % (n): 50 (65); Age (years): 53.5 (±9.8); HbA1c (%): 9.5 (±2.2) 3. CC2 n=84; Female % (n): 53 (62); Age (years): 56.2 (±9.4); HbA1c (%): 9.3 (±1.6)	• Type: Family members (1) living in the same household, (2) significant family • Number of family members in the same house: IG=3.9 (±2.4), CC1=3.4 (±1.7), CC2=4.0 (±2.4)	• Intervention group: Each patient should have had partipated in 2 family meetings or home visits, 1 individual counseling session, 1 counseling session with relatives, 1 multi-family educational session • Intervention Duration: 12 months • Study Duration: 12 months	• HbA1c reductions: Significantly reduced in the intervention clinic from 10.3 to 9.2% (p<0.001) and in Control Clinic 1 from 9.5 to 8.6% (p<0.01): not significantly different between clinics • During the second 6-month period, the patients in the intervention clinic significantly improved their HbA1c (p<0.001) compared to the control patients • A statistically significant reduction of 0.9% in HbA1c after the implementation of a family program in the intervention clinic for 12 months	• Improvement in Depressive symptoms: Significant reduction in depressive symptoms in the intervention clinic compared to CC1/ CC2 • No significant changes between groups in family functioning style, health behaviors, medication adherence, and knowledge of diabetes (between baseline and 12 months)
Gilliland et al., (2002) USA	• n=104 • Eligibility: All Native American with T2DM, >18 years, physically and mentally able • Patient characteristics: 1. FF: Age 60.2 years, Female:72%, Duration of DM 8.1 years, HbA1c 8.3%,	• Type: Family and friends: • Characteristics: N/S	1. FF group: received culturally appropriate DM education materials, skill building, and soal support provided by FF	• HbA1c: The UC arm showed a statistically significant increase in adjusted mean HbA1c change (1.2%, p=0.001)	N/S

(*Contd*...)

TABLE 2. (*Continued*)

Author (year)	Partipants (n)/Eligibility/ Characteristics	Type of Caregiver and Characteristics	Intervention/ Duration	*Biological* Outcomes Measured/Results	*Behavioral* Outcomes Measured/Results
Gilliland et al., (2002) USA	2. One-on-One (OO): Age 59.9 years, Female: 74%, Duration of DM: 8.3 years, HbA1c 9.2%, 3. UC: Age 60.2 years, Female: 91%; Duration of DM: 10.0 years; HbA1c: 7.9%		2. OO group: same intervention but in one-on-one appointment) 3. UC group: usual medical care and delayed intervention 1 year • Intervention Duration: 6 weeks apart session for 10 months • Study Duration: 4 years	• Decreased BP in FF group: Diastolic blood pressure decreased by 6 mmHg in the FF arm of the intervention and remained unchanged in the OO and UC arms (p=0.02)	
Hemmati Maslakpak et al., (2017) Iran	• n=90 patients, equal groups of 30 members in three groups: (1) a face-to-face education group, (2) a telephone-based education group, (3) a control group • Eligibility: (1) patients having a known history of type 2 (noninsulin requiring) diabetes confirmed by a specialist. (2) 18 ≤ age ≤ 55 (3) patients having no underlying health problems (4) patients and their family members having reading and writing literacy • Patient characteristics: Age (mean, years) 49.9, Female: 43.3% Overall self-care by each group: control (58.83), face-to-face (49.36), phone (56.13); HbA1c by each group (%): control (1.7), face-to-face (1.5), phone (1.1) • Duration of DM: 10.3 years	Designated family member (one fixed member for each patient) • esignated family N/S	Interventions: appropriate diet and exerse, blood glucose monitoring, foot ulcer prevention, and adherence to medication Two experimental groups via different delivery methods: Group 1: face-to-face family-oriented education; Group 2: telephone-based family-oriented education group; Group 3: control group received usual education • Intervention Duration: 3 months • Study Duration: 3 months	• Fasting blood glucose and HbA1c: despite the decreasing trend in the intervention groups, this change did not reach statistical significance Improved Triglycerides (p=0.003) and Cholesterol after the intervention (p=0.02)	• Self-care scores: 1. Significant differences among group 1 (100.82±14.56), group 2 (92.93±11.09), and group 3 (49.46±16.35) (p=0.0001) 2. Overall self-care scores: significantly higher in face-to-face education group than the telephone-based group (p=0.011) • Dietary adherence: significantly higher mean score in the face-to-face group than in the telephone- based group (p=0.043) • Physical activity: significantly higher scores in the face-to-face group than in the telephone- based group (p=0.04)
Hu et al., (2014) USA	• n=73 (36 patients and 37 family members) • Eligibility: (1) self-identification as Hispanic, (2) age ≥18 years (3) self-report of a medical diagnosis of T2DM, and (4) an adult family member willing to partipate • Patient characteristics: Age (mean, years) 50 (SD=11), Female: 75%, average BMI: 35.1±5.6 kg/m², Average HbA1c=8.1% (65 mmol/mol)±2.2 (range, 5.3% [34 mmol/mol] to 13.0% [119 mmol/mol]), and 60% had HbA1c >7.0% (53 mmol/mol), 72% had fewer than 12 years of education	• n=37 family members • Eligibility: (1) residence in the patient's household and (2) age ≥18 years. Partipants and family members had to be able to speak either Spanish or English • Age (years.) 40.6 (SD=13.1); Female 70%, BMI 32.7±4.9 kg/m² Obese: 70%	• Patients and family members attended a culturally tailored diabetes educational program taught in Spanish • Intervention Duration: 8 weeks • Study Duration: 3 months (1 month follow-up)	• HbA1c reductions: HbA1c decreased by 0.41% (percent change: −4.9%) on average among patients from pre-intervention to 1-month post-intervention (p=0.0683) • BP: Systolic blood pressure significantly improved (p=0.0124). • LDL reduction: decrease in LDL of 10.6 mg/dL after 1 month, but not statistically significant (p=0.0788)	• Significant improvements in diabetes self-efficacy (p<0.0001) • Significant improvements in diabetes knowledge score (mean difference=5.89, p<0.0001)

(*Contd*...)

TABLE 2. (*Continued*)

Author (year)	Partipants (n)/Eligibility/ Characteristics	Type of Caregiver and Characteristics	Intervention/ Duration	*Biological* Outcomes Measured/Results	*Behavioral* Outcomes Measured/Results
Hu et al., (2016) USA	• n=186 (Hispanic patients with Type 2 diabetes and their family groups; 92 patients and 94 family members) • n=92 patients (51 in intervention, 41 in control) • Eligibility: (1) community-dwelling, (2) self-identification as Hispanic, (3) age ≥18 years. (4) self-identification as having a medical diagnosis of T2DM, and (5) an adult family member willing to participate in the study • Patient characteristics: Patients (n=92): Age (mean, years.) 49.4, Female: 59%, Baseline mean HbA1c: 74 mmol/mol (8.9%), about half of patients were on lipid lowering (49%) and hypertensive (52%) medications	• n=94 family members (52 in intervention, 42 in control) • Eligibility: (1) residence in the same household as the participant with diabetes and (2) age ≥18 years • Characteristics: N/S	• 8-week culturally tailored diabetes educational program delivered in Spanish: total 12 hours of information on risk factors, symptoms, medications etc. • Intervention Duration: 8 weeks • Study Duration: 3 years	• HbA1c reductions: Mean HbA1c in the intervention group from baseline 8.5% [65 mmol/mol] to 7.7% (61 mmol/mol) and from baseline 9.4% [79 mmol/mol] to 8.7% (72 mmol/mol) in the attention control group at post-intervention (p=0.020) Significant differences between groups at 1-month post-intervention follow-up: (I mean=7.7% [61 mmol/mol] vs. C mean=9.0% [75 mmol/mol], p=0.005)	• Self-management: significant changes in diabetes knowledge scores (p<0.001), Self-efficacy scores (p=0.007), and family support scores (p=0.028) over time
Kang et al., (2010) Taiwan	• n=67 FPIC group (n=33) and to the CC group (n=34) • Eligibility: (1) Age >20 years, (2) T2DM, (3) on oral hypoglycemic therapy, (4) poor glycemic control (HbA1c >7.0%) • Patient characteristics: Age (mean, years.) 53.5, Female: 46.4%, HbA1c (%):9.25 Mean duration of DM: 3.4 years, Baseline mean HbA1c: 9.15%, comorbidities: 87.5% with hypertension or hyperlipidemia, living with family member: 98.2%	Primary family members co-habited with patients before intervention. (e.g., spouse, parent, significant other, or additional important relative) • Characteristics: Women (71.4%), Most of them are spouses (78.5%), adult children (17%).	Three individual educational sessions, 2-day long group educational sessions, a monthly telephone discussion with question-and-answer session (25–30 min) All participants were given diabetes handouts about diet, medication, physical activity and exercise, and eye and foot self-care • Intervention Duration: 6 months • Study Duration: 23 months	• HbA1c: Family partnership intervention care group patients HbA1c level decrease more than conventional care group (mean difference 1.35% vs. 0.93%) but no significant differences in the reduction of hemoglobin HbA1c levels (p=0.46) • BMI: a small reduction in BMI but not significant (p=0.35)	• Significant differences in the scores of positive and negative family-supportive behaviors, knowledge of diabetes, attitudes about diabetes between the groups (all p<0.05) Family partnership intervention care group presented more development in diabetes self-care behaviors than conventional care group but not statistically significant between two groups (p=0.605)
Keogh et al., (2011) Ireland	• n=121 (IG=60; CG=61) • 1) CGGt al., (1) age ≥18years, (2) T2DM more than 1 year (3) poor glycemic control (HbA1c >8.0%) • Patient characteristics: Age (mean, years) 58.63, Female: 36.4%, Baseline mean HbA1c: 9.18%, comorbidities: hypertension 40.2%, Mean duration of DM: 9.4 years	• Tomor: Family members (1) must be ≥)18 years (2) have no history of diabetes (3) defined as a person who has a close relationship with the patient and makes regular contact (No need to live together or be blood relative) • Characteristics: Age (mean, years) 51; Female: 69.1%, Spouses (76.4%), adult children (23.5%)	• 3 weekly sessions provided by a health psychologist, 2 sessions held at the patient regular contact (No need to live together or be blood relative)-minute follow-up telephone call • Intervention Duration: 3 weeks • Study Duration: 6 months	• HbA1c reductions: −0.65% in IG; group difference in changes in HbA1c was −0.4% (IG: 8.4% [SD=0.99%] vs. CG: 8.8% [SD=1.36%]; p=0.04) The intervention was most effective in those with the poorest control at baseline (HbA1c>9.5%) (intervention 8.7% [SD=1.16%, n=15] vs. control 9.9% [SD=1.31%, n=15]; p=0.01) • No differences in Blood pressure and BMI	• Statistically significant improvements in beliefs about diabetes, psychological well-being, diet, exercise, self – efficacy, and family support (p<0.01)

(*Contd...*)

TABLE 2. (*Continued*)

Author (year)	Partipants (n)/Eligibility/ Characteristics	Type of Caregiver and Characteristics	Intervention/ Duration	*Biological* Outcomes Measured/Results	*Behavioral* Outcomes Measured/Results
Kutob et al., (2014) USA	• n=39 participants (20 primary participants, 19 accompanying support) • Eligibility: Participants between the ages of 18 and 70; have at least one risk factor for T2DM as defined by the American Diabetes Association • Patient characteristics: Age (range in years): 49.2±11.0, Female (n)=13 (65%), White (non-Hispanic) (n)=11 (55.0%), Education: College graduate (n)=9 (45.0%), Health Insurance: Group plan (n)=12 (60.0%). Baseline HbA1c: 6%	• Type: Adults support person (family member or friend) (n=19) • Characteristics: Age (range in years): 46.4±13.7, Female (n)=14 (73.7%), White (non-Hispanic) (n) = 13 (68.4%) Education: Some College (n)=12 (63.2%) Health Insurance: Group plan (n)=11 (57.9%)	• Participants had group office visits to be educated in behavior modification on reducing lifestyle-related risk factors • Intervention Duration: 6 months (office visit every 2 weeks, total 12 visits) • Study Duration: 12 months	• Reduction in the total number of predefined, modifiable risk factors (i.e., body mass index n25 kg/mbody masscircumference c88 cm [women], s102 cm [men]; blood pressure 140/90 mm Hg; HbA1c ≥5.7%; fasting insulin ≥15 μU/mL; glycemic index ≥52.5% [women], ≥53.4% [men]; and physical activity <150 min/wk) • Primary participants' risk factors decreased approximately 15% immediately after the 6-month intervention (absolute reduction of 1.1 risk factors) and increased to ~20% reduction 1-year post-intervention (absolute reduction of 1.4 risk factors)	• Weight Loss: For those who completed the group visit intervention, regardless of paired status at the intervention's end, 15% achieved a 5% or greater weight loss immediately post-intervention. • Decreased of fasting insulin use: In post-intervention, fasting insulin delinked by 4.8 μU/mL in the 16 participants without diabetes and with baseline insulin u 15 μU/mL (95%, –12.1, 2.6).
McElfish et al., (2015) USA	• n=27 participants • Eligibility: n/s • Patient characteristics: Age (range in years): 18 -44 (57%), Female: 77%, Education: High school graduates or less (71%), Uninsured (56%), Baseline HbA1c: 8.1%	• Type: Family members • Characteristics: N/S	• Participants received a total of 10 hours of diabetes education • Intervention Duration: 6 weekly sessions • Study Duration: 6 weeks	• HbA1c reductions: post-intervention data showed a decrease of 0.7% (percent change of −7%) • BMI: pre-intervention 31.2±5.0, post-intervention: 31. ±5.6 (not significant)	N/S
McElfish et al., (2019) USA	• n=221 participants (Adapted-Family diabetes self-management group (in home setting) = 110, Standard diabetes self-management group (community setting) = 111) • Eligibility: (1) aged 18 and older, (2) Participants in the adapted DSME arm were required to invite one or more adult (aged 18 and up) family members • Patient characteristics: Age (median age 52, range 31–80 years), Female: 58.8%, Baseline mean HbA1c: 10.46%	• Type: Family members age ≥18 years • Characteristics: N/S	• 10 hours of education covering eight core elements across sessions • Adapted-Family diabetes self-management group: education with community-based participatory research approach received in home setting with family members Standard diabetes self-management group: education received in community setting without family members • Intervention Duration: 8 weeks • Study Duration: 3 years	• HbA1c Participants in the adapted DSME arm had significantly lower mean HbA1c levels immediately (-0.61%; p = 0.038) and 12 months (-0.77%, p = 0.013) later than those in the standard DSME arm. • Total Cholesterol A significantly higher drop in total cholesterol than those in the control group (−12.50 mg/dL; p=0.019)	N/S

(*Contd...*)

TABLE 2. (*Continued*)

Author (year)	Partipants (n)/Eligibility/ Characteristics	Type of Caregiver and Characteristics	Intervention/ Duration	*Biological* Outcomes Measured/Results	*Behavioral* Outcomes Measured/Results
McElfish et al., (2020) USA	• n=221 participants (Adapted-Family diabetes self-management group (in home setting) = 110, Standard diabetes self-management group (community setting) = 111) • Eligibility: (1) aged 18 and older, (2) Participants in the adapted DSME arm were required to invite one or more adult (aged 18 and up) family members. • Patient characteristics: Age (median age 52, range 31–80 years), Female: 58.8%, Baseline mean HbA1c: 10.46%	• Type: Family members • Characteristics: N/S	• 10 hours of education covering eight core elements across sessions • Adapted-Family diabetes self-management group: 10 hours of education covering eight core elements with community-based participatory research (CBPR) approach. Focusing heavily on the importance of engaging all family members • Intervention Duration: 8 weeks • Study Duration: 3 years	• HbA1c Adapted family DSME group was associated with greater reductions than the Standard DSME group The hours of intervention received (hours of attendance) have significant effect on reduction of HbA1c (p=0.046)	N/S
McElfish et al., (2020) USA	• n=20 (Participants, T2DM patients (n=10), their family members (n=10) • Eligibility: (1) Marshallese (2) 18 years of age or older (3) T2DM (HbA1c ≥l6.5%) (4) at least 1 family member willing to partipate in the study (5) partipants were excluded if they had previously partipated in DSME within the past 5years • Patient characteristics: Age (mean 59.3 year), Female: 70%, Education (80% less than a high school education), Baseline HbA1c: 9.1%	• Type: Family members • Characteristics: Age: (mean 55.8 years), Female (50%) Education (70% less than a high school education)	• 10 hours of Adapted-Family DSME delivered over 8 weeks (eight classes of 75 minutes each) • Intervention Duration: 8 weeks • Study Duration: 12 weeks	• HbA1c reduction: mean decrease HbA1c of 0.7% but not statistically significant • BMI increase: mean increase BMI of 0.2kg/m2 but not statistically significant • LDL reduction: mean decrease LDL of 2.1 mg/dL but not statistically significant (p>0.05) • HDL increase: mean increase HDL of 2.7mg/dL but not statistically significant • SBP and DBP decrease: mean decrease SBP of 10.9 mmHg and DBP of 1.0 mmHg but not statistically significant	N/S
Shi et al., (2016) China	• n=120 (FIG, n=60 and SIG, n=60) • Eligibility: (1) T2DM, (2) completed education courses for 4 times, (3) age >18 years old • Patient characteristics: Age (mean, years): FIG=57.8 (±13.5); SIG=57.10 (±11.4), Male (%): FIG 32 (53.3); SIG 26 (43.3), baseline HbA1c (%): FIG 9.73 (±2.00); SIG 10.05 (±1.68)	• Type: Family members • Characteristics: 47 spouses (78.3%), 6 parents, 5 children (8.3%), 2 siblings	FIG: health education for both patients and their family members SIG: health education for patient alone • Intervention Duration: 4 months (4 lessons with a monthly cycle) • Study Duration: 2 years	• HbA1c reduction: −4.29% in FIG; −2.34% in SIG • BMI decrease: −1.78 in FIG, −0.5 in SIG	• Improvement in self-management measured by KAP (Knowledge, Attitude, Practice) score: +32.6 in FIG, while +20.9 in SIG • Improvement in Quality of life measured by SF-36: +14.3 in FIG, while +3.2 in SIG

(*Contd*...)

TABLE 2. (*Continued*)

Author (year)	Partipants (n)/Eligibility/ Characteristics	Type of Caregiver and Characteristics	Intervention/ Duration	*Biological* Outcomes Measured/Results	*Behavioral* Outcomes Measured/Results
Tabasi et al., (2014) Iran	• N = 91 (IG = 45; CG = 46) • Eligibility: (1) Age >30 years., (2) T2DM, (3) poor glycemic control (HbA1c> 7.0%), (4) on oral hypoglycemic therapy or insulin • Patient characteristics: Age (mean, years.) 53.6 (7.58), Female: 52.7%, Mean duration of DM: 10.56 years, Baseline HbA1c: 8.35%	• Type: Family members were defined as those over 18 years old, having a blood relative and to be living with a patient and were identified by the patient • Characteristics: The main supporting family member is spouses in both groups (82.35%)	• The key persons of family members in the intervention group are divided into small groups (2–20 persons) according to their educational needs. Education on the importance of medication adherence and family support behavior was carried out. • Intervention Duration: 3 sessions about 40–60 min • Study Duration: 3 months	• HbA1c reduction: The mean change of HbA1c decreased 1.2%±0.96 in intervention group and increased to 0.3%±0.91 in control group (p<0.001)	• Significant difference in medication adherence scale: the mean score of before and after intervention MMAS (Morisky medication adherence scale) in intervention group (p<0.001) • Significant difference in diabetes soal support questioner: Significant difference in the mean score of before and after intervention DSSQ in both group (p<0.001)
Wichit et al., (2017) Thailand	• n=140 • (IG=70; CG=70) • Eligibility: (1) age ≥35 years, (2) T2DM, (3) fasting plasma glucose levels ≥ 140 mg/dl • Patient's characteristics: Age (mean, years) 58.4, Female: 72.9%, Baseline mean HbA1c: 6.7%, comorbidities: 80.7%, taking two or more hypoglycemic agents: 72.2%, Duration of DM: 5.7 years	• Type: Family member included: (1) living in the same residence with the patient, (2) being a spouse, child, grandchild, sibling, or friend, (3) aged ≥ 18 years • Characteristics: N/S	Family-oriented self-management program • Intervention Duration: 9 weeks (three education sessions delivered at baseline, week 5, week 9) Study Duration: 13 weeks	HbA1c: no decrease in IC nor CG, but significant risk (1% increase) in CG after 13 weeks	• The intervention arm had significantly better self-management, self-efficacy, outcome expectations, and diabetes knowledge than the controls (p<0.001, respectively). • IG increased the diabetes knowledge score by 3.3 points self-management score by 14.3 points self-efficacy score by 10.8 points
Withidpanyawong et al., (2019) Thailand	• n=180 (IG=88, CG=92) • Eligibility: (1) age ≥ 30 years, (2) T2DM, (3) on oral meds, (4) poor glycemic control (HbA1c >7.0%) • Patient characteristics: Age (mean, years) 59.3, Female: 76.8%, Baseline mean HbA1c: 9.14%, comorbidities: hypertension 67.2%, hyperlipidemia 87.8%, CVD 4.4%, Duration of DM: 5.9 years	• Type: Family members (1) living in the same household, (2) a spouse or significant relative, (3) aged ≥ 18 years • Characteristics: Age (mean, years) 49.5; Female: 43.8%; More than half of the family members were spouses (62.25%), Adult children (30.65%)	Education package for participants and their relatives • Intervention Duration: 9 months (4 visits) • Study Duration: 9 months	• HbA1c reductions: −1.37% in IG; group difference in the changes of HbA1c was −1.16% • LDL reduction: −0.43 mmol/L in IG (p=0.002); group difference −0.36 mmol/L (p=0.041) • Decrease in systolic/ diastolic BP: group difference −5.83 mmHg in Systolic BP, −4.06 mmHg in Diastolic BP	• Improvement in knowledge for both patients and caregivers in IG and patients in CG. • Improvement in positive family support in IG: change of 9.6 in IG; group difference 3.18 • Improvement in pill count (%): change of 92% in IG; group difference 3.83% • Improvement in self-efficacy: change of 4.4 in IG; group difference 0.98

addition, nine studies required that family members live in the same residence as patients in their SDs, whereas the remaining eight studies did not require cohabitation or did not present residency status as inclusion criteria. Of these different types of family caregivers involved, the majority were spouses (63%) followed by adult children (13.5%). On the other hand, three studies included friends as caregivers along with family members (33,37,40).

The duration of the intervention ranged from 3 weeks to 12 months. The majority of the educational interventions aimed to enhance family members' knowledge of diabetes and their active support. The contents of education programs included an introduction to diabetes, healthy dietary options (e.g., healthy fats, reducing consumption of sugar-sweetened beverages, high-quality protein), increasing physical activity, and coping strategies (26,30,31,33-39,41,42). Seven studies included educational content on the importance of medication adherence in diabetes management (30,32,35,36,38,39,42). One study focused on individual counseling, group counseling with relatives, or multi-family educational sessions (24). The educational program in another study concentrated on skill-building and social support (40).

HbA1c and body mass index (BMI) decreased as a result of caregiver involvement in T2DM education; however, the effects on lipid profiles were inconsistent. Involving a caregiver in T2DM education could also significantly increase a patient's diabetes knowledge, level of physical activity, and self-efficacy, but the impact on medication adherence varied.

All studies measured changes in HbA1c as a metric of the effectiveness of caregiver education. Overall, HbA1c significantly decreased by 1.21% after a given educational intervention (range 0.41–4.3%). However, three studies reported that there was no statistically significant improvement between intervention versus control groups, although HbA1c levels decreased over time (26,30,38).

Nine studies examined changes in patients' lipid profiles. Some studies found that after caregiver participation in T2DM education, patients exhibited significant improvement in LDL, TC, and triglycerides (26,34,35). However, most studies showed no statistically significant change between pre- and post-tests or between intervention and control groups. LDL was used as an outcome indicator in five studies, and in one study, LDL decreased by 0.36 mmol/L (p = 0.041) following intervention (34). In four studies, LDL was lowered, although the reductions were not significant (p > 0.05) (30,38,41,43). Five studies treated HDL as an outcome indicator, and HDL value increased or decreased depending on the study, but none of the findings were statistically significant (p > 0.05) (30,34,36,41,43). In two of the five studies that used TC as an outcome indicator, it was significantly decreased by 18.24 mg/dL (range: 12.50–23.97 mg/dL) (p < 0.05) (26,35). In the rest of the three studies, TC dropped, but it was not significant (p > 0.05) (30,34,40). Triglycerides were treated in four studies, and only one study found significant improvement compared to the control group (p = 0.003) (26). In the other three studies, there was no statistically significant change between the intervention and control groups (34,40,41).

Nine studies reported weight-related patient outcomes, and the results varied. Two studies reported significant reductions in BMI by 1% after caregiver involvement in T2DM education (range 1.12–1.28%) (41,42). Three studies reported a reduction in BMI, but it was not significant (30,35,38). Two studies reported no difference in BMI in the group with caregiver involvement in T2DM education (31,34). Two studies reported a slight but not statistically significant increase in BMI (36,43).

Six studies that reported on diabetes knowledge revealed variations in patient knowledge before and after interventions. The caregiver involvement in T2DM education group had significantly higher diabetes knowledge scores in two studies that examined diabetes knowledge using the Diabetes Knowledge Questionnaire (33,34). Other studies that assessed diabetes knowledge using the Spoken Knowledge of Diabetes in Low Literacy Patients with Diabetes tool also revealed gains in diabetes knowledge over time (38,39). In addition, Cai and Hu found that between pre- and post-intervention, the mean diabetes knowledge score increased by 161% (41). Likewise, where Kang et al. utilized knowledge and attitude toward the diabetes questionnaire, authors reported an increase in the mean difference score for patients in the family partnership intervention care group compared to the control group (5.32 vs. 2.32, respectively) (30).

Physical activity was examined in four studies. In two studies (26,31), physical activity significantly improved by a minimum of 1.55 times to a maximum of 2.18 times after family participation intervention (p < 0.01), while the other two studies found no significant difference (24,38). Physical activity was measured using various questionnaire items, such as the number of physical activity days, the number of walking days per week, and the degree of participation in moderate-intensity activities or sedentary activities. Physical activity was queried as one in a set of health behavior questions, or with questionnaires such as the Summary of Diabetes Self-Care Activities (SDSCA) and the International Physical Activity Questionnaire.

Adherence to diabetes medication was measured in two studies (26,34). One study used the Morisky Medication Adherence Scale and found that the intervention group participants showed greater score increases than those in the control group (34). However, the other study, which observed differences in medication adherence using SDSCA measures, did not report any improvement in medication adherence (26).

In three studies (31,33,39), the intervention group showed a significant improvement in diabetes self-efficacy compared to the control group. In a study conducted by Cai and Hu, compared to the control group, the intervention group demonstrated a statistically significant improvement in diabetes management self-efficacy when observed from baseline to 3-month follow-up (41). Similarly, Withidpanyawong et al. (34) investigated diabetes self-efficacy and reported that at 9 months follow-up, self-efficacy scores were significantly higher in the intervention group with a group difference of 0.98 (0.68 vs. 1.67). The study by Hu et al. (39) reported that self-efficacy in the intervention group increased by 33%.

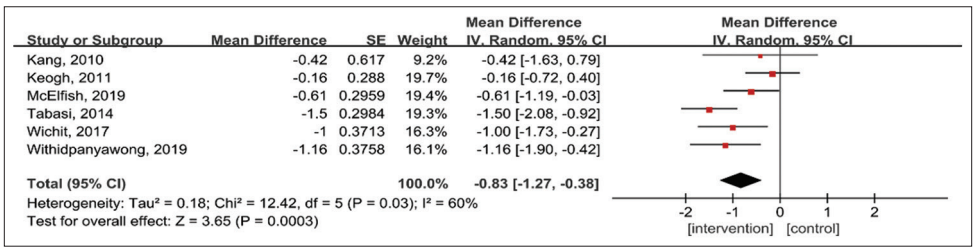

FIGURE 4. Meta-analyses on the effect of caregiver involvement in T2DM education on HbA1c.

As a result of HbA1c meta-analysis, the heterogeneity between studies was moderately heterogeneous with an I^2 value of 60%. The meta-analysis for six RCT studies showed that the group with caregiver involvement in T2DM education was associated with pooled HbA1c levels 0.83 (95% Confidence interval [CI]: −1.27–−0.38) lower than the control group (p = 0.0003) (Figure 4). Subgroup analyses were performed to identify the potential source of heterogeneity. We checked subgroups of patients' gender, study duration (3 vs. 6 vs. ≥8 months), duration of diabetes (≤6 years vs. >6 years), and types of caregivers (family vs. family and friend). We found no statistically significant differences except types of caregivers. However, a far smaller number of trials and participants contributed data to the family and friend subgroup (One trial, 70 participants) than to the family subgroup (Four trials, 227 participants), meaning that the analysis is unlikely to produce useful findings. The results of the meta-analysis of three types of lipids (LDL, TC, and HDL) showed no strong evidence that caregiver participation in diabetes education improved lipid levels. The p-value for LDL was 0.15 (95%: −13.68–2.07), the p-value for TC was 0.18 (95%: −12.39–2.36), and the p-value for HDL was 0.82 (95%: −1.47–1.85). Heterogeneity (I^2) was 0% in all three cases. A meta-analysis was not possible for triglycerides given that of the four studies that reported triglyceride as an indicator, there were only two RCT studies, and one of the RCT studies had multiple intervention groups, making them unsuitable for comparison with other studies.

DISCUSSION

This study aimed to explore the association between caregiver involvement in T2DM education interventions and patient care outcomes. Through this review, we have identified that caregiver involvement in T2DM education reduced HbA1c by 0.83 (95%: −1.27–−0.38) (p = 0.0003). Our findings regarding the impact of caregiver intervention on the reduction of HbA1c are also supported by a previous meta-analysis study that examined the impact of peer support interventions (44). Thus, although not a causal relationship, this suggests that diabetes education in which caregivers participated improved the patient's physical activity and medication intake and indirectly led to improvement in HbA1c. There was no strong evidence that caregiver participation in diabetes education improved lipid levels. Since only two or three limited studies were used in the lipid meta-analysis, additional research on the effect of the intervention is needed.

Caregivers play key roles in the management of diabetes not only by enhancing patient knowledge of diabetes but also by reinforcing the patients' self-care skills (45,46). The majority of included studies focused on imparting knowledge on T2DM, such as introduction to diabetes or the importance of both healthy dietary options and increasing physical activity. Only one included study, conducted by García-Huidobro et al., focused on skill-building or social support in addition to knowledge (24). However, knowledge is not enough to manage T2DM; rather, self-care skills are more critical to improving glucose control. Therefore, cultivating patient and caregiver skills should be taken into consideration in caregiver involvement in T2DM education. Such skills may include carb counting ability for a diabetes meal plan or monitoring glucose levels using a glucometer. In addition, only two studies focused on counseling or social support (24,40). Given that caregiver burden can affect patient outcomes (47-49), individual counseling or social support should also be included in caregiver education programs for successful T2DM management.

In the included studies, several patient characteristics and performance measurements were inconsistent, thereby possibly contributing to discrepancies in the study results. For example, the care patients' duration of T2DM varied from 3.4 to 10.6 years. As the duration can influence the effectiveness of DM self-management, caregiver education on managing glucose and modifying patient behavior may be less effective for patients with long-standing T2DM (50). Therefore, educational interventions for the caregiver should take into consideration patients' duration of disease and should be individually tailored to be regular, more intense, and reinforced with sustained encouragement.

In addition, family participation has been emphasized in diabetes management, but previous meta-analysis research did not examine in detail the characteristics of the family (14). The present study comprehensively explored different types of caregivers with a scope not limited to the family, and their demographic characteristics. We also investigated whether a tailored intervention takes these caregivers' factors into account during the intervention. The type of caregiver varied from family members, including those living in the same residence, to friends. A family member who mostly stays with the patient in the same place has more opportunities to encourage beneficial patient behavior based on the knowledge they learned from caregiver education (51). Moreover, the majority of caregivers were spouses or adult children. Considering the included studies were conducted in different countries, the expectations and role of caregivers may differ across cultures. For example, adult children of Asian ethnicity are socialized to have a greater sense of filial obligation and caregiving burden where such is a strong cultural norm (52,53). Hence, the participation

of caregivers in patients' diabetes education should be tailored to each country's situation and role expectations to improve outcomes. Caring for a loved one with a chronic disease such as T2DM involves a number of challenges, both physical and mental. Therefore, to reduce caregiver burden while achieving optimal outcomes in patient care, caregiver characteristics including demographics, cognitive function, physical condition, and psychological profiles should be considered when developing educational programs.

There are several limitations to this systematic review that are worth noting. First, as we only have six RCT studies in the meta-analysis, we did not analyze the funnel plot. If there are under ten studies eligible for analysis, the Cochrane Handbook advises against using the funnel plot to observe publication bias. The authors conducted a formal search of the gray literature, which may have otherwise helped overcome publication bias. Second, as is the nature of the caregiver-involved intervention, all included studies have a potential performance bias due to incompletely blinded research. Third, there was significant variability in the study outcome measurements, impairing the confidence that can be drawn from the results. Fourth, this study provided only an overview of the effectiveness of various caregiver-involved interventions, with the interventions very briefly summarized. Therefore, clinicians will need to refer directly to cited articles to gain a sufficiently detailed understanding of the interventions studied for potential application. Fifth, as both a pilot study and its associated RCT study targeting the same population were included in the study, the results of the family intervention effect may have been somewhat inflated (35,43). Finally, only six articles with small sample sizes were included in this meta-analysis; therefore, homogeneity power and effect size were limited in this review. Despite the limitations of this study, the results imply that caregivers are not simply supporters and observers but important subjects to be considered along with patients for diabetes education. Therefore, community health-care providers and policymakers should consider involving caregivers at an early stage when educating people with diabetes. In addition, when organizing an education program, it is vital to consider the content for improving caregiver skills so that the caregiver can effectively support the patient's self-management and in turn improve health outcomes.

CONCLUSIONS

This review found that the included studies generally report improvement in most biological and self-management outcomes. In addition, the intervention group in which the caregiver involvement in T2DM education significantly decreased HbA1c compared to the control group from the meta-analysis. The findings of this study suggest that caregiver involvement in education leads to improvement in glycemic control, diabetes knowledge, self-efficacy, and physical activity. Caregiver participation in diabetes self-management education depends on a variety of factors, including caregiver characteristics, lifestyle, and education needs. Therefore, future research should focus on enhancing caregiver participation and incorporating caregiver involvement in T2DM education efficiently and effectively. Furthermore, no studies were found that investigated the effect of caregiving education on complications and/or hospitalizations. Since many studies focus on limited health indicators, we recommend that the impact of caregiver involvement in T2DM education be investigated in relation to a broader range of health markers with a longitudinal study.

FUNDING

This work was supported by the New Faculty Startup Fund from Seoul National University [grant numbers 810-20200018]. The content is solely the responsibility of the authors and does not necessarily represent the official views of SNU.

DECLARATION OF INTEREST

Authors declare no conflict of interest.

REFERENCES

1. Haghighatpanah M, Nejad AS, Haghighatpanah M, Thunga G, Mallayasamy S. Factors that correlate with poor glycemic control in Type 2 diabetes mellitus patients with complications. Osong Public Health Res Perspect 2018;9(4):167-74. http://10.24171/j.phrp.2018.9.4.05
2. Milibari AA, Matuure EY, Gadah EM. Prevalence, determinants and prevention of Type 2 diabetes mellitus (t2dm) in arabic countries: A systematic review study. J Health Sci 2020;14(2):98-115. https://doi.org/10.34172/hpp.2020.18
3. International Diabetes Federation. IDF Diabetes Atlas Belgium: Dunia; 2019. Available from: https://www.diabetesatlas.org/upload/resources/material/20200302_133351_IDFATLAS9e-final-web.pdf [Last accessed on 2022 Oct 20].
4. Philis-Tsimikas A, Gallo LC. Implementing community-based diabetes programs: The scripps whittier diabetes institute experience. Curr Diab Rep 2014;14(2):462. https://doi.org/10.1007/s11892-013-0462-0
5. Higgs C, Skinner M, Hale L. Outcomes of a community-based lifestyle programme for adults with diabetes or pre-diabetes. J Prim Health Care 2016;8(2):130-9. https://doi.org/10.1071/hc15038
6. Cannon A, Handelsman Y, Heile M, Shannon M. Burden of illness in Type 2 diabetes mellitus. J Manag Care Spec Pharm 2018;24(9-a Suppl):S5-S13. https://doi.org/10.18553/jmcp.2018.24.9-a.s5
7. Yoo H, Choo E, Lee S. Study of hospitalization and mortality in Korean diabetic patients using the diabetes complications severity index. BMC Endocr Disord 2020;20(1):122. https://doi.org/10.1186/s12902-020-00605-5
8. Lara-Rojas CM, Pérez-Belmonte LM, López-Carmona MD, Guijarro-Merino R, Bernal-López MR, Gómez-Huelgas R. National trends in diabetes mellitus hospitalization in Spain 1997-2010: Analysis of over 5.4 millions of admissions. Eur J Intern Med 2019;60:83-9. https://doi.org/10.1016/j.ejim.2018.04.005
9. Powers MA, Bardsley J, Cypress M, Duker P, Funnell MM, Fischl AH, et al. Diabetes self-management education and support in Type 2 diabetes: A joint position statement of the American diabetes association, the American association of diabetes educators, and the academy of nutrition and dietetics. Diabetes Educ. 2017;43(1):40-53. https://doi.org/10.1016/j.jand.2015.05.012
10. Gregory NS, Seley JJ, Dargar SK, Galla N, Gerber LM, Lee JI. Strategies to prevent readmission in high-risk patients with diabetes: The importance of an interdisciplinary approach. Curr Diab Rep 2018;18(8):54. https://doi.org/10.1007/s11892-018-1027-z
11. Asif M. The prevention and control the Type-2 diabetes by changing lifestyle and dietary pattern. J Educ Health Promot 2014;3:1. https://doi.org/10.4103/2277-9531.127541
12. Mayberry LS, Osborn CY. Family support, medication adherence, and glycemic control among adults with Type 2 diabetes. Diabetes Care 2012;35(6):1239-45. https://doi.org/10.2337/dc11-2103
13. Tang TS, Brown MB, Funnell MM, Anderson RM. Social support, quality of life, and self-care behaviors amongAfrican Americans with Type 2 diabetes. Diabetes Educ 2008;34(2):266-76. https://doi.org/10.1177/0145721708315680
14. Kodama S, Morikawa S, Horikawa C, Ishii D, Fujihara K, Yamamoto M, et al. Effect of family-oriented diabetes programs on glycemic control: A meta-analysis. Fam Pract 2019;36(4):387-94.

https://doi.org/10.1093/fampra/cmy112

15. Higgins JP, Thomas J, Chandler J, Cumpston M, Li T, Page MJ, et al. Cochrane Handbook for Systematic Reviews of Interventions. Version 6.3; 2022. Available from: https://training.cochrane.org/handbook/PDF/v6.4 [Last accesed on 2023 Jul 22].
16. Suglo JN, Winkley K, Sturt J. Prevention and management of diabetes-related foot ulcers through informal caregiver involvement: A systematic review. J Diabetes Res 2022;2022:9007813.

https://doi.org/10.1155/2022/9007813

17. Centers for Disease Control and Prevention. Caregiving; 2022. Available from: https://www.cdc.gov/aging/caregiving/index.htm [Last accessed on 2022 Oct 20].
18. JohnsHopkins Medicine. Being a Caregiver: Johns Hopkins Medicine Web; 2022. Available from: https://www.hopkinsmedicine.org/health/caregiving/being-a-caregiver [Last accessed on 2022 Sep 15].
19. Bramer WM, Giustini D, de Jonge GB, Holland L, Bekhuis T. De-duplication of database search results for systematic reviews in EndNote. J Med Libr Assoc 2016;104(3):240-3.

https://doi.org/10.3163/1536-5050.104.3.014

20. Higgins JP, Altman DG, Gøtzsche PC, Jüni P, Moher D, Oxman AD, et al. The cochrane collaboration's tool for assessing risk of bias in randomised trials. BMJ 2011;343:d5928.

https://doi.org/10.1136/bmj.d5928

21. Kim SY, Park JE, Lee YJ, Seo HJ, Sheen SS, Hahn S, et al. Testing a tool for assessing the risk of bias for nonrandomized studies showed moderate reliability and promising validity. J Clin Epidemiol 2013;66(4):408-14.

https://doi.org/10.1016/j.jclinepi.2012.09.016

22. Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: An updated guideline for reporting systematic reviews. Int J Surg 2021;88:105906.

https://doi.org/10.1016/j.ijsu.2021.105906

23. Campbell M, McKenzie JE, Sowden A, Katikireddi SV, Brennan SE, Ellis S, et al. Synthesis without meta-analysis (SWiM) in systematic reviews: Reporting guideline. BMJ 2020;368:l6890.

https://doi.org/10.1136/bmj.l6890

24. García-Huidobro D, Bittner M, Brahm P, Puschel K. Family intervention to control Type 2 diabetes: A controlled clinical trial. Fam Pract 2011;28(1):4-11.

https://doi.org/10.1093/fampra/cmq069

25. McElfish PA, Long CR, Bursac Z, Scott AJ, Felix HC, Schulz TK, et al. Diabetes self‐management education exposure and glycated haemoglobin levels among Marshallese participants in a randomized controlled study. Diabet Med 2020;37(2):319-25.

https://doi.org/10.1111/dme.14189

26. Hemmati Maslakpak M, Razmara S, Niazkhani Z. Effects of face-to-face and telephone-based family-oriented education on self-care behavior and patient outcomes in Type 2 diabetes: A randomized controlled trial. J Diabetes Res 2017;2017:8404328.

https://doi.org/10.1155/2017/8404328

27. Manager R. RevMan Version 5.4 [Computer Program]. London: The Cochrane Collaboration; 2020.
28. Higgins JP, Thompson SG, Deeks JJ, Altman DG. Measuring inconsistency in meta-analyses. BMJ 2003;327(7414):557-60.

https://doi.org/10.1136/bmj.327.7414.557

29. Higgins J. Cochrane Handbook for Systematic Reviews of Interventions. Version 5.1. 0; 2011. Available from: https://www.cochrane-handbook.org [Last accessed on 2023 Mar 15].
30. Kang CM, Chang SC, Chen PL, Liu PF, Liu WC, Chang CC, et al. Comparison of family partnership intervention care vs. Conventional care in adult patients with poorly controlled Type 2 diabetes in a community hospital: A randomized controlled trial. Int J Nurs Stud 2010;47(11):1363-73.

https://doi.org/10.1016/j.ijnurstu.2010.03.009

31. Keogh KM, Smith SM, White P, McGilloway S, Kelly A, Gibney J, et al. Psychological family intervention for poorly controlled Type 2 diabetes. Am J Manag Care 2011;17(2):105-13.
32. Khosravizade Tabasi H, Madarshahian F, Khoshniat Nikoo M, Hassanabadi M, Mahmoudirad G. Impact of family support improvement behaviors on anti diabetic medication adherence and cognition in Type 2 diabetic patients. J Diabetes Metab Disord 2014;13(1):113.

https://doi.org/10.1186/s40200-014-0113-2

33. Wichit N, Mnatzaganian G, Courtney M, Schulz P, Johnson M. Randomized controlled trial of a family-oriented self-management program to improve self-efficacy, glycemic control and quality of life among Thai individuals with Type 2 diabetes. Diabetes Res Clin Pract 2017;123:37-48.

https://doi.org/10.1016/j.diabres.2016.11.013

34. Withidpanyawong U, Lerkiatbundit S, Saengcharoen W. Family-based intervention by pharmacists for Type 2 diabetes: A randomised controlled trial. Patient Educ Couns 2019;102(1):85-92.

https://doi.org/10.1016/j.pec.2018.08.015

35. McElfish PA, Long CR, Kohler PO, Yeary KH, Bursac Z, Narcisse MR, et al. Comparative effectiveness and maintenance of diabetes self-management education interventions for Marshallese patients with Type 2 diabetes: A randomized controlled trial. Diabetes Care 2019;42(5):849-58.

https://doi.org/10.2337/dc18-1985

36. McElfish PA, Bridges MD, Hudson JS, Purvis RS, Bursac Z, Kohler PO, et al. Family model of diabetes education with a pacific islander community. Diabetes Educ 2015;41(6):706-15.

https://doi.org/10.1177/0145721715606806

37. Kutob RM, Siwik VP, Aickin M, Ritenbaugh C. Families United/Familias Unidas: Family group office visits to reduce risk factors for Type 2 diabetes. Diabetes Educ 2014;40(2):191-201.

https://doi.org/10.1177/0145721714520722

38. Hu J, Wallace DC, McCoy TP, Amirehsani KA. A family-based diabetes intervention for hispanic adults and their family members. Diabetes Educ 2014;40(1):48-59.

https://doi.org/10.1177/0145721713512682

39. Hu J, Amirehsani KA, Wallace DC, McCoy TP, Silva Z. A family-based, culturally tailored diabetes intervention for hispanics and their family members. Diabetes Educ 2016;42(3):299-314.

https://doi.org/10.1177/0145721716636961

40. Gilliland SS, Azen SP, Perez GE, Carter JS. Strong in body and spirit: Lifestyle intervention for native American adults with diabetes in New Mexico. Diabetes Care 2002;25(1):78-83.

https://doi.org/10.2337/diacare.25.1.78

41. Cai C, Hu J. Effectiveness of a family-based diabetes self-management educational intervention for Chinese adults with Type 2 diabetes in Wuhan, China. Diabetes Educ 2016;42(6):697-711.

https://doi.org/10.1177/0145721716674325

42. Shi M, Xu MY, Liu ZL, Duan XY, Zhu YB, Shi HM, et al. Effectiveness of family involvement in newly diagnosed Type 2 diabetes patients: A follow-up study. Patient Educ Couns 2016;99(5):776-82.

https://doi.org/10.1016/j.pec.2015.12.018

43. McElfish PA, Long CR, Scott AJ, Hudson JS, Haggard-Duff L, Holland A, et al. Pilot implementation of adapted-family diabetes self-management education into a clinical setting. J Prim Care Community Health 2020;11:2150132720931289.

https://doi.org/10.1177/2150132720931289

44. Patil SJ, Ruppar T, Koopman RJ, Lindbloom EJ, Elliott SG, Mehr DR, et al. Peer support interventions for adults with diabetes: A meta-analysis of hemoglobin A1c outcomes. Ann Fam Med 2016;14(6):540-51.

https://doi.org/10.1370/afm.1982

45. Baig AA, Benitez A, Quinn MT, Burnet DL. Family interventions to improve diabetes outcomes for adults. Ann N Y Acad Sci 2015;1353(1):89-112.

https://doi.org/10.1111/nyas.12844

46. Deakin T, McShane CE, Cade JE, Williams RD. Group based training for self-management strategies in people with Type 2 diabetes mellitus. Cochrane Database Syst Rev 2005(2):Cd003417.

https://doi.org/10.1002/14651858.CD003417.pub2

47. Lebrec J, Ascher-Svanum H, Chen YF, Reed C, Kahle-Wrobleski K, Hake AM, et al. Effect of diabetes on caregiver burden in an observational study of individuals with Alzheimer's disease. BMC Geriatr 2016;16:93.

https://doi.org/10.1186/s12877-016-0264-8

48. Kuzuya M, Enoki H, Hasegawa J, Izawa S, Hirakawa Y, Shimokata H, et al. Impact of caregiver burden on adverse health outcomes in community-dwelling dependent older care recipients. Am J Geriatr Psychiatry 2011;19(4):382-91.

https://doi.org/10.1097/JGP.0b013e3181e9b98d

49. Bidwell JT, Lyons KS, Lee CS. Caregiver well-being and patient outcomes in heart failure: A meta-analysis. J Cardiovasc Nurs 2017;32(4):372-82.

https://doi.org/10.1097/JCN.0000000000000350

50. Ko SH, Park SA, Cho JH, Ko SH, Shin KM, Lee SH, et al. Influence of the duration of diabetes on the outcome of a diabetes self-management education program. Diabetes Metab J 2012;36(3):222-9.

https://doi.org/10.4093/dmj.2012.36.3.222

51. National Academies of Sciences Engineering and Medicine. Family caregiving roles and impacts. In: Families Caring for an Aging America. Washington, DC: National Academies Press; 2016.
52. Guo M, Kim S, Dong X. Sense of filial obligation and caregiving burdens among Chinese immigrants in the United States. J Am Geriatr Soc 2019;67(S3):S564-70.

https://doi.org/10.1111/jgs.15735

53. Cho J, Nakagawa T, Martin P, Gondo Y, Poon LW, Hirose N. Caregiving centenarians: Cross-national comparison in caregiver-burden between the United States and Japan. Aging Ment Health 2020;24(5):774-83.

https://doi.org/10.1080/13607863.2018.1544221