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# International Journal of Nursing Sciences

journal homepage: http://www.elsevier.com/journals/international-journal-ofnursing-sciences/2352-0132



#### Review

# Interventions for self-management of type 2 diabetes: An integrative review



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#### ARTICLE INFO

Article history:
Received 9 July 2018
Received in revised form
17 September 2018
Accepted 14 December 2018
Available online 14 December 2018

Keywords: Type 2 diabetes Interventions Research Integrative review

#### ABSTRACT

*Background:* Type 2 diabetes mellitus has been identified as one of the most challenging chronic illnesses to manage. Since the management of diabetes is mainly accomplished by patients and families, self-management has become the mainstay of diabetes care. However, a significant proportion of patients fail to engage in adequate self-management. A priority research question is how do interventions affect the self-management behaviors of persons with Type 2 diabetes?

*Purpose/Objectives:* The purpose of this integrative review is to provide a summary and critique of interventions that support diabetes self-management in the patient with Type II diabetes mellitus.

Design: An integrative review design, with a comprehensive methodological approach of reviews, allowing inclusion of experimental and non-experimental studies.

*Procedures*: A comprehensive search was conducted via Ebscohost using databases of Academic Search Complete, CINAHL, Health Source: Nursing/Academic Edition, MEDLINE, PsycArtiCLES, and PsycInfo. The final number of papers used for this review were: motivational interviewing (6), peer support/coaching (10), problem solving therapy (3), technology-based interventions (30), lifestyle modification programs (7), patient education (11), mindfulness (3), and cognitive behavioral therapy (5).

Results: Studies were examined from seventeen countries including a broad range of cultures and ethnicities. While interventions have shown mixed results in all interventional categories, many studies do support small to modest improvements in physiologic, behavioral, and psychological outcome measures. Considerable heterogeneity of interventions exists. The most commonly reported physiologic measure was HbA1c level. Outcome measures were collected mostly at 6 and 12 months. Duration of most research was limited to one year.

Conclusions: Research exploring the impact of interventions for self-management has made major contributions to the care of persons with type 2 diabetes, from offering suggestions for improving care, to stimulating new questions for research. However, implications for clinical practice remain inconclusive, and limitations in existing research suggest caution in interpreting results of studies.

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#### 1. Introduction

Type 2 diabetes mellitus has been identified as one of the most challenging chronic illnesses to manage [1]. The demands of diabetes and the integration of complex self-management regimens into daily life have been shown to produce high levels of emotional distress, and to leave people feeling overwhelmed, frustrated, and

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Peer review under responsibility of Chinese Nursing Association.

discouraged [2,3]. These demands also lead to reduced well-being, anxiety, and depression [4,5].

Since the management of diabetes is mainly accomplished by patients and families, self-management has become the mainstay of diabetes care. Self-management is the process of actively engaging in self-care activities with the goals of improving one's behaviors and well-being. Self-management includes meal planning, planned physical activity, blood glucose monitoring, taking diabetes medicines, and of managing episodes of illness and of low and high blood glucose. Self-management treatment plans are individually developed in consultation with a variety of health care professionals such as doctors, nurses, dietitians, and pharmacists [6].

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Maintaining tight glycemic control through self-management can significantly reduce complications associated with diabetes [7,8]. However, self-management of diabetes and tight glycemic control are complex, and can be further complicated by issues related to adherence to treatment plans. Most research on diabetes has found that a significant proportion of patients fail to engage in adequate self-management [9–11]. Suboptimal adherence to self-management is well documented as negatively influencing outcomes in people with diabetes [12–14].

From the State of the Science on Nursing Best Practices for Diabetes Self-Management [15], research priorities include exploring the concept of diabetes self-management. Priority research questions include asking what affects self-management in persons with diabetes (literacy, communication skills, psychosocial factors, demographics), and how do interventions affect the self-management behaviors of persons with diabetes? Therefore, the purpose of this integrative review is to provide a summary and critique of interventions that support diabetes self-management in the patient with Type II diabetes mellitus.

#### 2. Method

#### 2.1. Search method

A comprehensive search was conducted via Ebscohost using the following databases: Academic Search Complete, CINAHL, Health Source: Nursing/Academic Edition, MEDLINE, PsycArtiCLES, and PsycInfo. Search terms included diabetes mellitus, type 2 in the abstract, self care and self-management as a subject term, and "randomized controlled trial" in any field. Limits were set to include only peer-reviewed quantitative studies of adults written in the English language, and between January 2007—January 2018. In addition, the Cochrane Library was searched for a review on self-management.

The initial search yielded 98 articles that were abstracted for topics of self-management intervention. Fifty seven sources were excluded due to not meeting inclusion criteria or being duplicate. Of the remaining sources included for review, the major topics included: motivational interviewing (3), peer support/coaching (6), problem solving therapy (2), technology-based interventions (15), lifestyle modification programs (3), patient education (10), and a grouping of studies organized under psychoeducational interventions (3) that included topics of cognitive behavioral therapy and mindfulness.

Reference lists of retrieved sources were then searched. In addition, a final search of each of these topics was done using keywords and/or topics: diabetes mellitus, type 2, self care, self-management, and the name of the specific intervention topic. Review of reference lists of all included sources extended the date range from 2004 to 2018. At the completion of all searches and reviews, the final number of papers used for this review were: motivational interviewing (6), peer support/coaching (10), problem solving therapy (3), technology-based interventions (30), lifestyle modification programs (7), patient education (11), mindfulness (3), and cognitive behavioral therapy (5).

# 2.2. Inclusion criteria and quality appraisal

Three doctorally prepared nurses knowledgeable in the area of diabetes independently screened all retrieved sources for inclusion criteria and quality. After independent screening, the three nurses met to discuss inclusion criteria and quality appraisal, and to come to consensus.

To be included in the final review, each article was screened for the following inclusion criteria: Included only adults with type 2 diabetes, identified an intervention, provided quantitative empirical (Meta-analysis, systematic review, RCT, quasi-experimental, cohort study, or descriptive) evaluative support, and included an outcome variable of self-management, operationalized as: physiological indicator (i.e., blood glucose level, HbA1c, blood pressure, weight, cholesterol), psychosocial indicator (i.e., depression, emotional adjustment, stage of change, stress, or support), self-management outcomes (i.e., diet, exercise, medication, SBGM pattern), and knowledge.

To evaluate the quality of the papers included in this review, papers were assigned a grade according to the American Diabetes Association (ADA) evidence grading system for clinical practice recommendations [16]. Studies needed to qualify as a Grade A, B, or C to be evaluated. We used the grading system to evaluate the quality of the evidence and selected only those studies of higher quality for inclusion in this review as these are studies that are well supported for changes in practice. Grade C studies were included because although it is a lower level of evidence, some of these research studies provided additional helpful insight and information about specific interventional categories. The quality of evidence for this review can be summarized as follows: for motivational interviewing, four grade A, and two grade C studies; for peer support/coaching, eight grade A, and two grade C studies; for problem solving therapy, three grade A studies; for technologybased interventions, 22 grade A, four grade B, and four grade C studies; for lifestyle modification programs, seven grade A studies; for patient education, ten grade A, and one grade C studies; , for mindfulness, one grade A, and two grade C studies; and for cognitive behavioral therapy, four grade A, and one grade C studies.

#### 3. Results

# 3.1. Intervention categories

The purpose of this integrative review is to provide a summary and critique of interventions that support diabetes self-management in the patient with type 2 diabetes mellitus. The results will be presented as follows: 1) Overview of the intervention, 2) research of the intervention in chronic disease populations, including type 1 diabetes, and 3) empirical evidence of the intervention specific to type 2 diabetes.

#### 3.1.1. Motivational interviewing

Motivational interviewing (MI) is a patient-centered approach to facilitating behavior change by helping patients explore and resolve their ambivalence about changing behavior. Developed by Miller and Rollnick [17], the goal of MI is to explore the patient's ambivalence to behavior change in a way that the patient is more likely to change behavior in the desired direction. MI is based on the following principles: motivation to change is a state, not an individual trait, that may fluctuate over time and between situations, and can be influenced to change in a particular direction; it is the patient's task to resolve this ambivalence to change, rather than the practitioner's; and the practitioner's role is to recognize this ambivalence and be directive in helping the patient to explore and resolve this ambivalence [17].

MI has been used in health care consultation in the treatment of a variety of health problems, including alcoholism, substance abuse, smoking cessation, eating disorders, and psychiatric treatment adherence [18]. Systematic reviews examining the impact of MI on a broad range of chronic diseases, including diabetes (both type 1 and type 2), asthma, substance and alcohol abuse, addiction, and psychiatric disorders, have produced mixed results. MI has been evaluated to be effective in helping patients change behaviors related to disease self-management, even in brief encounters [19].

On the other hand, another systematic review of eight RCTs using MI to improve health behaviors in persons with both type 1 and type 2 diabetes concluded that the evidence does not support the use of MI to improve self-management behaviors [20].

For this integrative review, one systematic review, four randomized controlled trials (RCTs), and one descriptive study were

reviewed (see Table 1). Locations of research included four studies in the United States and one in Taiwan. In a systematic review aimed at exploring the gaps in what is known about MI and its impact on behavior change and clinical outcomes, 14 RCTs were reviewed. Results suggest that MI has some impact on diet behavior changes and weight loss [21]. Four RCTs included one MI session,

**Table 1**Motivational interviewing intervention studies.

Study & Location	Design	Sample	Outcome Measures	Intervention (I) and Control (C) Groups	Results
Smith-West et al. (2007) [22] US	RCT	N=217 Female: 100% Mean age: 53 African American: 38%	Weight, BMI, HbA1c, collected at baseline, 6, 12, and 18 months.	Participants enrolled in a group-based weight control program, receiving 42 sessions (weekly for 6 months, then biweekly for 6 months, then monthly for 6 months for total of 18 months). (I): (N = 109) Five MI sessions offered (the first session before the first group meeting) at baseline, 3, 6, 9, and 12 months. Sessions lasted 45 min. Led by psychologists; (LTA = 6); Intervention delivered by psychologist; Intervention fidelity addressed. (C): (N = 108) [Attention Control group] Educational sessions (not MI sessions), the same number and length as the intervention group's MI sessions, that focused on topics of womens health; (LTA = 9).	MI group: significantly more weight loss at 6 and 18 months; significant HbAlc reduction at 6 months (0.8%), but not at 18 months.
Chen et al. (2012) [23] Taiwan	RCT		HbA1c, self-management, self-efficacy, QOL, depression, anxiety, & stress, collected at baseline and 3 months post-intervention.	•	Significant improvements in self-management, self-efficacy, QOL, and HbA1c (8.97 $\pm$ 2.17 decreased to 8.16 $\pm$ 1.73). Depression Anxiety Scale showed no significant change.
Welch et al. (2011) [24] US	RCT	N = 234 Female: 59% Mean age: 55.7 Caucasian: 84%	HbA1c, distress, self-care behaviors (SMBG, diet, exercise, & medication adherence), depression, satisfaction, & self-efficacy, collected at baseline and 6 months.	(C): (N = 110) Usual care; (LTA = 15). 4 groups: (1) DSME + MI with webtool; (2) DSME + MI without webtool; (3) DSME with webtool; (4) DSME without webtool. Intervention groups N = 118 (LTA = 28). Intervention delivered by Certified Diabetes Educator; Intervention fidelity addressed.	period in total sample (reduction of
Calhoun et al. (2010) [25] US	Descriptive		Glucose, HbA1c, & self-reported psychological (distress, locus of control, QOL, depression, stages of change), exercise, & diet, collected at baseline and 3 months post-intervention.	Control groups $N = 116$ (LTA = 22). (I): $(N = 20)$ A program with a baseline assessment, two MI sessions within 3 weeks of baseline (each session lasting 30 min), then 3 months postintervention assessment. (LTA = 0). Intervention delivered by "trained interventionist"; Intervention fidelity not addressed.	symptoms, fatalism, treatment
Hokanson et al. (2006) [26] US	RCT	N = 114 Female: 43% Age range: 21- 80 White: 88%	Prevalence of smoking, self-efficacy, HbA1c, weight loss, lipids, & BP collected at baseline, 3 and 6 months follow-up.		No significant differences between groups at 6 months in smoking cessation. No significant differences in psychosocial variables. HbA1c improved in both groups (from >7% to <7% at 6 months).
Ekong & Kavookjian, (2016) [21]	Systematic review		Health behaviors for diabetes and any targeted clinical outcome.	Studies varied in length and frequency of MI sessions. Outcome variables included self-management behaviors of diet, physical activity, alcohol reduction and smoking cessation, HbA1c, BP, BMI, weight reduction, and cholesterol levels.	and weight loss, and may show promise

 $<sup>^{\</sup>rm a}$  LTA = Lost to attrition.

and two included four and five MI sessions. Studies showed improvements in self-management behaviors related to diet, weight loss, and HbA1c [22–24], self-efficacy and quality of life [23,25]. One study showed weak support for MI due to improvement seen in both the intervention and control groups when MI was added to standard DSME [22]. Improvements in depression and smoking cessation were not reported [23,26].

#### 3.1.2. Coaching/peer health coaching/peer support

Coaching, peer health coaching, and peer support use health care providers or volunteers, collectively referred to as coaches or peer supporters, to provide self-management support for persons who may be considered peers or who have the same health condition [27,28]. These coaches and peers can include patients, community health workers, lay educators, family members, and health care professionals. Peer health coaching is based on the idea that a patient will connect to others who have similar experiences [29]. Regardless as to the type of coaching or peer support, the goal is to engage and motivate patients in self-management.

Coaching and peer support interventions have been well documented in diabetes education. In the context of diabetes support, coaches and peers can have multiple roles, including educator, advocate, cultural translator, mentor, case manager, and group facilitator [27]. Peer coaching and support is most commonly delivered by a trained peer, and focuses on self-management interventions that are time limited and based on a scripted standardized curricula [30]. In terms of effectiveness, peer health coaching and support have been successful in improving self-management and in lowering HbA1c [31]. Because of these favorable results, peer health coaching and support has received increased interest as a model for more long-term diabetes self-management support interventions.

For this integrative review, ten randomized controlled trials (RCT) were reviewed (see Table 2). Locations of research included seven studies in the United States, and one in the Netherlands, Thailand, and Australia. Six studies compared peer-led interventions, two compared health professional-led interventions, one compared a CHW intervention, and one used a family-oriented approach to self-management, with all intervention groups being compared to usual care. The duration of the interventions ranged from 4 weeks to 18 months. Studies showed improvements in self-efficacy and knowledge of self-management [32–36]. Results for reduction in HbA1c were mixed. Four studies described reductions in HbA1c levels in peer-led intervention groups and CHWs [1,28,31,37]; three studies showed no significant reduction in HbA1c levels [32,33,38].

### 3.1.3. Problem solving therapy/problem solving

Problem solving therapy (PST) is an intervention approach for behavior change that entails a series of cognitive operations used to figure out what to do when the way to reach a goal is not apparent [39]. The goal of PST is to facilitate behavior change, aiming to facilitate positive emotional reactions and reduce negative emotional reactions [40]. PST involves teaching the patient a step-by-step process to solving life problems, generally broken down into two major parts: applying a problem solving orientation to life, and using problem solving skills [41]. PST is based on teaching the following skills: (1) identifying a problem, (2) defining the problem, (3) understanding the problem, (4) setting goals related to the problem, (5) identifying alternative solutions, (6) evaluating and choosing best alternatives, (7) implementing alternatives, and (8) evaluating the effort at problem solving [42].

PST has a long history in clinical and counseling psychology to address multiple mental health disorders, family and relational distress, stress management and coping skills, and substance abuse

[39]. PST has been a frequently used component of interventions within diabetes education and care, usually one component of a larger diabetes self-management intervention. PST has been recognized as an important process, intervention, and skill in diabetes self-management [43].

For this integrative review, three studies were reviewed: a RCT, a systematic review, and a meta-analysis (see Table 3). Locations of research included the United States, with systematic reviews including studies from English and Chinese electronic databases. The RCT compared an intensive program including eight PST session to a condensed program including just one PST session. Results showed a significant difference in HbA1c (0.71%) in the intensive PST group [44]. The systematic review assessed 56 papers exploring the association of PST to diabetes self-management and control. Six studies used PST as an intervention for adults. Results of the review suggest that evidence for the effectiveness of PST on HbA1c is weak [45]. The meta-analysis assessed 16 RCTs of interactive selfmanagement interventions, with seven being specific to PST. The studies specific to PST showed a mean difference of -0.39% when comparing intervention to control groups, demonstrating a significant reduction in HbA1c [46].

#### 3.1.4. Technology-based interventions

Technology based interventions involve the use of equipment, devices, or tools to augment care through improved communication and increased ability to process information. Often referred to as telehealth, these various modalities include telephone, teleconferencing by video, computer, and internet/web-based technology [47]. Technology based interventions incorporate various technological modalities to monitor outcomes, provide self-management education, and deliver self-management strategies.

In general, technology based interventions have been used to provide support for patients with multiple health conditions including heart disease, chronic lung disease, and diabetes [48]. These telehealth interventions have been developed in response to access to care issues in various rural and regional communities [47]. The telephone is a customary technology that is commonly available for communication with patients [49]. More advanced telephone management includes mobile phone-based applications, referred to commonly as apps, which allow smart-phone applications and texting in addition to basic telephone components. Videoconferencing requires even more complex technology, such as webcams and software to communicate by video. Computerassisted modules (CAM) typically include computer hardware and software that provide programs for education and/or support. CAMs can be further stratified to include web-based interventions. A final category includes mixed modalities of these various components. Systematic reviews of technology interventions for mixed populations of type 1 and type 2 diabetes have shown limited to no impact on hemoglobin HbA1c [47,50,51]. For this integrative review, 30 studies were reviewed (see Table 4). Research on telehealth yielded articles on telephone/mobile phone (16), computerassisted modules (2), web-based interventions (7) and mixed modalities (5). Locations of research included eleven studies in the United States, and thirteen studies done in eight different countries.

For telephone interventions, a systematic review with metaanalysis of seven RCTs examining the impact of telephone follow up interventions on glucose control found little impact on glycemic control, with a mean weighted difference in HbA1c of -0.44% in favor of the intervention [35]. Eleven RCTs studied the impact of telephone interventions on glycemic control, symptoms, and selfmanagement behaviors. Two RCTs that explored the impact of automated response systems showed no improvement in HbA1c [49,52]. Nine RCTs examined live telephonic interactive interventions that involved a consultation, counseling, or coaching

**Table 2** Peer health coaching/peer.

Female:   Fema	Study & Location	Design	Sample	Outcome Measures	Intervention (I) and Control (C) Groups	Results
Ruggiero de al. (2014)  (2014)  Wichit et al. RCT [2017]  Wichit et al	(2012) [32]	RCT	Female: 62.6% Mean age: 48.5 Hawaiian or	reported self-efficacy, & QOL, collected	self-directed support from life coach and a pharmacist. Appointments made by individual participants (LTA = 45); Intervention delivered by pharmacist and "trained" life coach (bachelor's degree in social sciences); Intervention fidelity addressed.	improved in those subjects who had 10 or
With teal. RCT (2017) Female: 128.8 (Eff. ang. eff. management activities, QOL, self. (2016) Female: 58.4 (2010) Female: 58.4 (2010) Female: 63.4 (2010) Female: 64.4 (2010) Female: 63.4 (2010) Female: 64.4	et al. (2014) [33]	RCT	Female: 68.8% Mean age: 53.2 African American: 52.6%; Hispanic/	depressive symptoms, & confidence,	(I): (N = 136) Medical Assistant coaching intervention delivered by trained MA's over a 12-month period with in-person contacts at regular clinic visits (30 min sessions), and monthly follow-up phone calls in between visits. The focus was on providing information and skills to make informed self-care choices and changes; (LTA = 43); Intervention delivered by medical assistants; Intervention fidelity addressed.	All groups reported improvements in self- care across time, but no intervention effect was found. No differences were found in HbA1c between groups or across time.
Was et al.   RCT   N=30   Female:   General   Self-reported self-efficacy, self-   With research nurse (week 1), and follow up with research nurse (week	(2017) [34]	RCT	Female: 72.8% Mean age:	efficacy, and HbA1c, collected at	(I): $(N=70)$ Family intervention consisting of three 2-h group session delivered at baseline, 5 weeks and 9 weeks. Groups of $8-12$ dyads (patient and family member); $(LTA=3)$ ; Intervention delivered by nurse; Intervention fidelity not addressed.	group. No between group differences in
Van der RCT N = 133 Self-reported self-efficacy, coping, diet. (D; (N = 68) Three monthly home visits by a text al. (2012) How an age: 54 collected at baseline, 3 and 6 months. (2013) How wells after al. (2013) How an age: 54 collected at baseline, 3 and 6 months. (D; (N = 148) Coaching intervention fidelity addressed. (C): (N = 148) Coaching intervention fidelity addressed. (C): (N = 148) Coaching intervention with per coaches intervention fidelity addressed. (C): (N = 148) Coaching intervention with a follow pup home visits by a depressive symptoms, & distress, Visit 1 explored areas of lifestyle change. Visit 2 hadparticipants assign importate and feasibility to proposed lifestyle changes, Visit 2 adparticipants assign importate and feasibility to proposed lifestyle changes, Visit 2 adparticipants assign importate and feasibility to proposed lifestyle changes, Visit 2 adparticipants assign importate and feasibility to proposed lifestyle changes, Visit 2 adparticipants assign importate and feasibility to proposed lifestyle changes, Visit 2 adparticipants assign importate and feasibility to proposed lifestyle changes, Visit 2 adparticipants assign importate and feasibility to proposed lifestyle changes, Visit 2 adparticipants assign importate and feasibility to proposed lifestyle changes, Visit 2 adparticipants assign intervention felicity addressed. (C): (N = 55) Usual care: (LTA = 5): Intervention for 12 months that included 4 home visits and 12 phone calls, and additional mailed educational agroups; (LTA = 39). Intervention delivered by "trained" chrown in the visits and 12 phone calls, and additional mailed educational agroups; (LTA = 46). (D; (N = 148) Coaching intervention with per coaches interacting with patients in person — telephone contact 2 times/month, and an inperson contact 2 or more times over 6 months. (D; (N = 148) Diabetes self-management program (Partners in Care), led by per educators, focus on knowledge and skills related to blood glucose montioring, adherence to medications, healthy addr	(2010) [35]	RCT	Female: 28.6% Mean age range: 62.7	management behavior, & knowledge, collected at baseline & 4-week follow	(I): $(N=15)$ Usual care plus peer support (Peer CDSMP). The program is 3 face to face sessions with research nurse (week 1), and follow up weeks 2–4 by peers who used weekly one telephone call and two text messages after each phone call; Intervention delivered by nurses and "trained" peers; Intervention fidelity not addressed.	found for the intervention group, but no differences between the two groups over time for self-efficacy and self-management
Earrasquillo RCT Female: 55% diet, physical activity, and medication adherence, collected at baseline and 12 months.  Sinclair et al. RCT (2013) [1] JS (201	Wulp et al. (2012) [36]	RCT	Female: 45.4%	physical activity, well-being, depressive symptoms, & distress,	peer (expert patient) with a follow up phone call or email within two weeks after each visit. Visit 1 explored areas of lifestyle change. Visit 2 had participants assign importance and feasibility to proposed lifestyle changes, and set goals related to those changes. Visit 3 evaluated goals; (LTA = 9); Intervention delivered by "trained" expert patient peers; Intervention fidelity addressed.	improved self-efficacy in patients experiencing low self-efficacy. No significant differences were found in remaining outcome variables.
Moskowitz RCT N = 299 A1c, and self-reported depression, et al. Female: 51.4 social support, literacy, & self- coaches interacting with patients in person — lowering HbA1c for patients with low medication adherence and self-management, collected at baseline and at 6 months.  Sinclair et al. RCT N = 82 A1c, height, weight, BP, & lipids, (2013) [1] Female: 63% Mean age: 53-55 Hawaii  Mean age: 53-55 Hawaii  Mean age: 53-55 Hawaii  Mean age: 53-55 Hawaii  Mean age: 51.4 social support, literacy, & self-coaches interacting with patients in person — lowering HbA1c for patients with low medication adherence and self-management person contact 2 or more times over 6 months. Intervention fidelity not addressed. (C): (N = 151) Usual care. Study attrition not addressed  (I): (N = 151) Usual care. Study attrition not addressed. (I): (N = 48) Diabetes self-management program (Partners in Care), led by peer educators. Focus on knowledge and skills related to blood glucose monitoring, adherence to medications, healthy eating, physical activity, and stress reduction; (LTA = 14); Intervention delivered by "trained" peer educators; Intervention fidelity addressed. (C): (N = 34) Wait listed for intervention;	et al. (2017) [37]	RCT	Female: 55% Mean age: 55.2	diet, physical activity, and medication adherence, collected at baseline and 12	(I): $(N=150)$ CHW intervention for 12 months that included 4 home visits and 12 phone calls, and additional monthly CHW led educational groups; (LTA = 39). Intervention delivered by a "trained" CHW; Intervention fidelity addressed. (C): $(N=150)$ Enhanced usual care that included additional mailed educational	(reduction of 0.51), compared to control. N
Sinclair et al. RCT N=82 A1c, height, weight, BP, & lipids, (2013) [1] Female: 63% collected at baseline and 6 months.  US Mean age: 53-55 Hawaii Fawaii Faw	et al. (2013) [31]	RCT	Female: 51.4 -53% Mean age:	social support, literacy, & self- management, collected at baseline and	(I): $(N=148)$ Coaching intervention with peer coaches interacting with patients in person — telephone contact 2 times/month, and an inperson contact 2 or more times over 6 months. Intervention delivered by "trained" peers; Intervention fidelity not addressed. (C): $(N=151)$ Usual care. Study attrition not	medication adherence and self-
	(2013)[1]	RCT	Female: 63% Mean age: 53-55		(I): (N = 48) Diabetes self-management program (Partners in Care), led by peer educators. Focus on knowledge and skills related to blood glucose monitoring, adherence to medications, healthy eating, physical activity, and stress reduction; (ITA = 14); Intervention delivered by "trained" peer educators; Intervention fidelity addressed.	Significant reduction in HbA1c (reduction of 1.6) and distress in intervention group at 6 months.

RCT

Table 2 (continued)

Study & Location	Design	Sample	Outcome Measures	Intervention (I) and Control (C) Groups	Results
Thom et al. (2013) [28] US		N = 299 Female: >50% Mean age: 56.1 African American: 30.7–37.5%	A1c, lipids, height, weight, BMI, & BP, collected at baseline and 6 months.	(I): (N = 148) Coaching intervention with peer coaches interacting with patients in person - telephone contact 2 times/month, and an inperson contact 2 or more times over 6 months; (LTA = 8); Intervention delivered by "trained" peer coaches; Intervention fidelity not addressed. (C): (N = 151) Usual care; (LTA = 16).	At 6 months, significant differences in HbA1c levels, with reduction of 1.07% in intervention group, and only 0.3% in the usual care group.
Tang et al. (2015) [38] US	RCT	N = 106 Female: 67% Mean age: 56.3 African American	HbA1c, lipids, BP, BMI, waist circumference, & self-reported distress, & social support, collected at baseline, 3, 9, and 15 months.	(I): (N = 54) 3 months DSME plus 12 months peer support; (LTA = 20); Intervention delivered by nurses and peer leaders; Intervention fidelity not addressed. (C): (N = 52) 3 months DSME; (LTA = 20).	No significant changes in HbA1c between groups.

interaction(s), demonstrating mixed results on self-management behaviors. Five studies demonstrated improvements in HbA1c [53–56], weight loss [56], and symptoms [57]. However, four studies found no significant change impact on HbA1c level [58–61]. In a descriptive study by Aikens et al. [62], improvements in self-management behaviors were noted (medication adherence self-monitoring blood glucose, foot care) of varying significance.

More specifically, mobile phone technology and access to these devices is increasing the use of this technology in self-management of diabetes. Two systematic reviews of mobile phone applications designed to improve glycemic control by supporting type 2 diabetes self-management report an overall mean reduction in HbA1c of 0.40% and 0.49% when compared to controls [63,64]. One systematic review with meta-analysis also demonstrated a reduction in HbA1c of 0.51% when comparing smart phone to standard care [65].

Two studies examined CAMs and the impact on physiologic and psychosocial outcomes. A systematic review of 16 RCTs examined the impact of computer-based diabetes intervention, showing only a small benefit on reduction of HbA1c level, with no other evidence of benefit noted on cardiovascular risk factors, OOL and health

status [66]. A RCT assessed the effectiveness of a computer-assisted diabetes self-management intervention, finding no significant HbA1c improvement and only small improvements in fasting plasma glucose and body weight [67].

Seven studies examined web-based interventions and the impact on physiologic and psychosocial outcomes, including six RCTs and a cohort study. Of the six RCTs, one showed significant improvement in HbA1c, weight, and waist circumference at four months [68] three showed improved HbA1c at six months [69–71], and two showed improvement in knowledge scores, healthcare behaviors, and HbA1c [72,73]. The cohort study showed a significant HbA1c reduction at six months but not at twelve month [74].

The mixed modalities studies were all CAMs & telephone and included one systematic review, two cohort studies, and two RCTs. The systematic review included six studies that found significant declines in HbA1c and an overall increase in satisfaction, personal health care, knowledge and quality of life [75]. Cohort studies showed mixed results with significant changes to HbA1c; however one found significant reductions in distress [76,77]. In the RCTs, intervention groups using telehealth with provider feedback showed significant decreases in HbA1c [78] and blood pressure, but

**Table 3** Problem-solving therapy.

Study & Location	Design	Sample	Outcome Measures	Intervention (I) and Control (C) Groups	Results
Hill- Briggs et al. (2011) [44] US	RCT	N = 56 Female: 58.9% Mean age: 61.3 African American	A1c, lipids, BP, literacy, & self-reported depression, knowledge, health problems, barriers, self-management, & satisfaction, collected at baseline, 1-week post-intervention, & 3 months.	(I - Intensive group): (N = 29) 1 session (diabetes and CVD education session + 8 PST session - delivered bi-weekly, 8–10 participants/group); (LTA = 3); Intervention delivered by "trained interventionist"; Intervention fidelity addressed. (I - Condensed group): (N = 27) CVD education session + one PST session; (LTA = 1).	
Hill- Briggs et al. (2007) [45]	Systematic review	N=52 Qualitative, quantitative, cross- sectional prospective, RCTs, and quasi- experimental designs Type 1 and type 2 diabetes	Problem solving, self-management behaviors, physiological, psychosocial, and process outcomes.	Six studies of adults (out of 52 studies) used problem solving as an intervention.	
Cheng et al. (2017) [46]	Meta- analysis	N = 16 RCTs Adults type 2 diabetes English and Chinese	A1c	Seven studies of adults (out of 16 studies) used problem solving as an intervention.	Problem solving studies showed a mean difference in HbA1c of $-0.39\%$ (95% CI: $73\%$ to $05\%$ ; p = $.03$ ).

**Table 4** Technology based interventions.

Study & Location	Design	Sample	Outcome Measures	Intervention (I) and Control (C) Groups	Results
Wu et al. (2010) [35]	Systematic review & meta- analysis	N=7 RCTs, ≥16 years old Type 2 diabetes White: 81%	A1c	Telephone follow up interventions directed at improving self-management in comparison with a control group in which the telephone was the only difference in the intervention being provided. (I): $N = 1020$ . (C): $N = 744$ .	Standardized effect of the telephone follow up showed a mean weighted difference in HbA1c of -0.44% in favor of the intervention.
Graziano et al. (2009) [49] US	RCT	N = 120 Female: 45% Mean age: 62 White: 77%	A1c, medication changes, SMBG, & self-reported perceived severity, perceived susceptibility, perceived benefits, barriers, & attitudes, collect at baseline and 90 days.	(I): $(N=62)$ Usual care plus a daily automated prerecorded voice message relaying a short (less than 1 min) message focused on self-care behaviors to influence attitudes and beliefs, and reduce barriers for self-care behaviors; $(LTA=1)$ ; Intervention delivered by "investigator"; Intervention fidelity not addressed.	No significant change in HbA1c or secondary outcomes between groups, except for SMBG. The telephone group had significant increase in frequency of SMBG.
Williams et al.(2012) [52] Australia	RCT	N = 120 Female: 37% Mean age: 57.4 Australian born: 70%.	A1c, & self-reported health-related QOL, collected at baseline and 6 months.	(TLC) with automated interactive	The intervention group had a significant reduction in HbA1c (0.8%) compared to the control group (0.2%), and in mental health related QOL.
Lim et al.(2011) [53] Korea	RCT	<i>N</i> = 154 Females: 55.8% Mean age: 67.5 Korean	A1c, weight, BMI, glucose levels, lipids, & SMBG, collected at baseline, 3 and 6 months.	Three groups: (I-1): $(N = 51)$ SMBG	U-healthcare group had significant improvement in HbA1c and SMBG, but did not meet study goal of less than 7% for HbA1c. No other significant findings.
Walker et al. (2011) [54] US	RCT	N = 526 Female: 67.1% Mean age: 55.5 Black: 62%; Hispanic: 23%; 77% foreign born	A1c, medication adherence (pill counts), & self-reported self-management behaviors, collected at baseline and 12 months.	(I): (N = 262) Telephone intervention involving 10 calls at 4–6 week intervals from a health educator over a 12-month period. Focus was on	reduction in HbA1c (0.23% $\pm$ 1.1%) over 1 year, and improved medication adherence among those not taking insulin. No significant changes in self-
Trief et al. (2016) [55] US	RCT	N = 280 Female: 38.4% Mean age: 56.8 30% self-described minority	A1c, BMI, BP, distress, self-efficacy, depressive symptoms, & satisfaction collected at baseline, 4, 8, and 12 months.	Three arms: (IC): $(N = 94)$ Individual call group, with 2 phone sessions, plus 10 additional calls (50–55 min) addressing self-management;	•

Table 4 (continued)

Study & Location	Design	Sample	Outcome Measures	Intervention (I) and Control (C) Groups	Results
Goode et al. (2015) [56] Australia	RCT	N = 302 Female: 72% Mean age: 57.8 Caucasian: 43.7%	Weight, PA, HbA1c, & diet collected at baseline, 6, 18, and 24 months.	(I): $(N = 135)$ 18-month intervention with 27 phone calls, weekly for first 4 weeks, then every 2 weeks for 5 months, then monthly for the remaining 12 months. Counseling to increase PA, diet, and weight loss provided. Given pedometer and digital scales; $(LTA = 33)$ ; Intervention delivered by counselors with bachelor's-level training in nutrition and dietetics; Intervention fidelity addressed. (C): $(N = 144)$ Usual care plus educational brochures; $(LTA = 13)$ .	
Sacco et al. (2009) [57] US	RCT	N = 62 Female: 58% Mean age: 52 Caucasian: 77% African American: 14.5% Hispanic: 8.1%	A1c, BMI, and self-report of symptoms, depression, knowledge, self-efficacy, awareness of goals, and adherence to diet, SMBG, foot care, & medications, collected at baseline and 6 months.	(I): $(N=31)$ Telephone coaching call weekly for 3 months, then bi-weekly for additional 3 months. Telephone	adherence, diabetes-related medical symptoms, and depression Symptoms. No significant effects on
Anderson et al. (2010) [58] US	RCT	N = 295 Female: 58% Age: > 18 White: 26–27% Other: 62–65% with majority being African American or Hispanic	self-reported overall health, depressive symptoms, diet and physical activity, collected at baseline,	(I): (N = 146) One-year of telephonic disease management with phone calls including a brief clinical assessment, self-management discussion. Patients were called weekly, bi-weekly or monthly depending on a risk-stratification, or if the patient requested a change in call frequency; (LTA = 52); Intervention delivered by nurses; Intervention fidelity not addressed.	other secondary outcome measures after 12 months.
Frosch et al. (2011) [59] US	RCT	N = 201 Female: 50% Mean age: 55 Latino: 55%; African American:16%; White: 20%	A1c, lipids, BP, BMI, & prescribed medications, and self-reported knowledge of self-management behaviors, collected at baseline, 1 and 6 months.	The telephone sessions varied in length from 15 to 60 min with a cap of 150 min total. Time intervals between calls determined collaboratively; (LTA = 17); Intervention delivered by nurses; Intervention fidelity not addressed.	outcome measures were nonsignificant.
Nesari et al. (2010) [60] Iran	RCT	N=61 Female: 71.7% Mean age: 51 Iranian	A1c, and self-reported disease characteristics, diet, exercise, medications, foot care, and SMBG, collected at baseline and after 12 weeks.	weeks, twice weekly for the first month and then weekly for second and third months. Each session averaged 20 min and each person received 16 phone calls. Calls included self-management education, and medication adjustments coordinated by the nurse and consulting endocrinologist; (LTA = 0); Intervention delivered by nursing student; Intervention fidelity not addressed.	
Wayne et al. (2015) [61] Canada	RCT	N = 131 Female: 72% Mean age: 53.2 Black: 45%; Caucasian: 27%	A1c, weight, BMI, & waist circumference collected at baseline, 3 and 6 months.	(C): $(N=30)$ Usual care; $(LTA=1)$ . (I): $(N=67)$ 6-month intervention using a health coach and smart phone, with $24/7$ access to coach; $(LTA=19)$ ; Intervention delivered by behaviorchange counseling specialist; Intervention fidelity not addressed. (C): $(N=64)$ Using health coach, but no smart phone; $(LTA=15)$ .	reduced HbA1c (-0.84

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Table 4 (continued)

Study & Location	Design	Sample	Outcome Measures	Intervention (I) and Control (C) Groups	Results
Cui et al. (2106) [63]	Systematic review	N=13 Adults with type 2 diabetes from 7 countries: Finland, Norway, US, Korea, Spain, Canada, Netherlands	A1c Baseline and at study completion	Thirteen RCTs compared mHealth smart phone applications to control groups receiving usual care only. Studies included a primary outcome variable of HbA1c, and measured change in HbA1c.	Significant reduction in HbA1c by $0.40\%$ (p < .01) mean difference, when compared to control group.
Wu et al.(2018) [65].	Systematic review & meta- analysis	N = 17 Adults with type 2 diabetes	A1c Baseline and at study completion	Seventeen RCTs of smartphone technology that used apps or internet access via the smartphone or personal digital assistants, compared to a control group receiving usual care only. Outcome variable of HbA1c, and measured change in HbA1c.	comparing smartphone technology to usual care.
Aikens et al.(2015) [62] US	Descriptive comparative study	Male: 92.8% Mean age 66.7	Self-reported self-management behaviors, physical & mental functioning, depressive symptoms, & distress, collected at baseline, 3 and 6 months.	Two intervention groups: a 3 month group ( $N = 108$ ), and a 6 month group ( $N = 193$ ). The intervention was an	functioning), and in self-management behaviors of medications, SMBG, and foot care. Duration of study had no significant effects on IVR outcomes.
Hou et al. (2016) [64]	Systematic review	N = 14 RCTs Adults with type 1 or type 2 diabetes	A1c (baseline and follow up, and not self-reported)	Ten RCTs (out of 14) were of type 2 diabetes, and using a total 9 different apps for type 2 diabetes. Apps were designed to improve selfmanagement by providing personalize feedback on selfmonitoring of blood glucose, diet, and physical activity	a mean reduction in HbA1c of 0.49%
Pal et al. (2014) [66]	Systematic review	N = 16 RCTs(UK) Adults with type 2 diabetes	A1c, BP, lipids, weight, death, health- related QOL, changes in cognition, behaviors, social support, emotional outcomes, adverse effect, complications, & economic data.		Computer-based interventions had a small effect on HbA1c, with a pooled effect of $-0.2\%$ , with the sub-group of mobile phone-based interventions having a larger effect ( $-0.50\%$ ) on HbA1c. No evidence of benefit for other biological, cognitive, behavioral or emotional outcomes.
Jaipakdee et al. (2015) [67] Thailand	RCT	<i>N</i> = 403 Females: 76.7% Mean age: 61.3	A1c, glucose, weight, BMI, BP, waist circumference, and self-reported depressive symptoms, self-management behaviors, & QOL, collected at baseline, 3 and 6 months.	(1): ( <i>N</i> = 203) DSMS over 6 months with computer-assisted instruction (CAI) that included educational sessions by computer plus a monthly 3 h educational session; (LTA = 9); Intervention delivered by nurses; Intervention fidelity addressed. (C): ( <i>N</i> = 200) Usual care; (LTA = 16).	Significant improvements in HbA1c (reduction of 0.34), fasting blood glucose, health behaviors, and QOL in
Pacaud et al. (2012) [75] Canada	RCT	<i>N</i> = 79 Female: 52.9% Mean age: 54.2	A1c, diabetes knowledge, self-efficacy, self-care behaviors, satisfaction, QOL, collected at baseline, 3, 6, 9, & 12 months.	Two intervention conditions: (I-1): $(N = 18)$ Web static group; (I-2):	Significant findings when comparing website use, such that higher website use was associated with higher knowledge, self-efficacy, and lower HbA1c.

Table 4 (continued)

Table 4 (continue	u)				
Study & Location	Design	Sample	Outcome Measures	Intervention (I) and Control (C) Groups	Results
Hansel et al. (2017) [68] France	RCT	<i>N</i> = 120 Female: 66.7% Mean age: 57	Weight, waist circumference, BMI, lipids, HbA1c, aerobic fitness, & self-reported diet, physical activity, & satisfaction collected at baseline and 4 months.	designed to improve lifestyle habits, including diet and PA. Participants	Significant improvements in HbA1c, weight and waist circumference in intervention group at 4 months.
Avdal et al. (2011) [69] RCT Turkey		<i>N</i> = 122 Female: 50.8% Mean age: 51.5	A1c & rate of attendance at health check visits were collected at baseline and 6 months.	(I): $(N = 61)$ Web site intervention	
Glasko et al. (2012) [70] US	RCT	N = 463 Female: 50% Mean age: 58 White: 72%, African American: 15%, Latino 21%	A1c, BMI, lipids, BP, health literacy, and self-reported diet, physical activity, medication adherence, self-efficacy, problem solving, supportive sources, health status, distress, collected at baseline, 4 and 12 months.	3 arm trial using CASM, an internet- based computer assisted self-	
Lorig et al. (2010) [71] US	RCT	<i>N</i> = 761 Female: 76% Mean age: 54.3 White: 76%	A1c, and self-reported health status, health care utilization, patient activation, self-efficacy, distress, & physical activity, collected at baseline, 6, and 18 months.	lattereset.  3 arm trial: (Group 1): (N = 259) Internet-based Diabetes Self- Management Program (IDSMP) that included a 6-week asynchronous training program with 6 weekly sessions and a reference book; (LTA = 50). (Group 2): (N = 232) IDSMP plus e-mail reinforcement; (LTA = 46). Intervention delivered by "trained" peer facilitators; Intervention fidelity not addressed. (C): (N = 270) Usual care; (LTA = 32).	Significant improvements in HbA1c, patient activation, and self-efficacy at 6 months, and self-efficacy and patient activation at 18 month, for the intervention groups. No changes in other health or behavioral indicators.
Heinrich et al. (2012) [72] Netherlands	RCT	N = 99 Female: Mean age:	Diabetes self-management knowledge, and use of website intervention, collected at baseline and two weeks.	(I): (N = 43) Web-based Diabetes Interactive Education Programme (DIEP) that provides an overview of type 2 diabetes in seven chapters; (LTA = 7); Interventions delivered by research team; intervention fidelity not addressed. (C): (N = 56) Usual care; (LTA = 2).	Significant improvement in knowledge scores in the experimental group at post-test. The total time spent on the website averaged 58 min, and was not correlated to increased knowledge.
(2013) [74] US	Cohort study	Female: 40% Mean age: 54 White: 59% Asian: 21% Hispanic: 10%	A1c, BP, lipids, cardiovascular risk, and self-reported knowledge, distress, depression & treatment satisfaction, collected at 6 and 12 months.	(I): $(N=202)$ : An online, disease management support system that included wirelessly uploaded home glucometer readings with graphical feedback, comprehensive patient-specific diabetes summary status report, nutrition and exercise logs, insulin record, online messaging with the health team; $(LTA=9)$ ; Intervention delivered by nurses and dieticians; Intervention fidelity not addressed. (C): $(N=213)$ Usual care; $(LTA=24)$ .	
Jackson et al. (2006) [75]	Systematic review	N = 26 RCTs & observational studies Type 1 & type 2 diabetes	A1c, weight, BP, micro-albumin, lipids, creatinine, depression, hematocrit, & health care utilization, self-care behaviors, satisfaction, & cost.	14 out of 26 studies were RCTs. Studies used various technologies including internet (3 RCTs), telephone (4 RCTs), and computer-assisted integration of clinical information (7 RCTs).	Six out of 14 RCTs showed significant declines in HbA1c (>1%) when compared with controls. Overall increases in patient satisfaction with the interventions, personal health care, perceived support, QOL, and knowledge.  (continued on next page)

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Table 4 (continued)

Study & Location	Design	Sample	Outcome Measures	Intervention (I) and Control (C) Groups	Results
Fisher et al. (2013) [76] US	Cohort study	N = 392 Female: 53.8% Mean age: 56 White: 40% Asian: 19% African American: 16% Hispanic: 11%	A1c, & self-reported diabetes distress, & self-reported physical activity, diet, & medication adherence, collected at baseline, 4 and 12 months.	received live phone calls at weeks 2, 4,	Significant reductions in distress across all three groups without
Noh et al. (2010) [77] Korea	Cohort study	N=44 Female: 22.5% Mean age: 42 Koreans	A1c, fasting and post-prandial blood glucose levels, collected at baseline and 6 months.	(I): ( $N = 24$ ), eMOD intervention is a web-based system providing diabetes education that participants can log into when convenient by either cell phone or computer; (LTA = 4); Intervention delivered by research team; Intervention fidelity not addressed. (C): ( $N = 20$ ) Received education books with content similar to eMOD	
Greenwood et al. (2015) [78] US	RCT	<i>N</i> = 90 Female: 23% Mean age: 58 Caucasian 64%	A1c, diabetes knowledge, self- management activities, & self-efficacy collected at baseline and 6 months.	website; (LTA = 0). (I): $(N = 45)$ A telehealth remote monitoring system using a tablet connected to a modem and a glucometer that has a touch screen to answer daily health questions. Data is sent to a certified diabetes educator. 84 daily sessions delivered; (LTA = 4); Intervention delivered by certified diabetes educators; Intervention fidelity not addressed.	Both groups lowered HbA1c with a significant difference $(41\%)$ at 6 months, with greater reduction in the intervention group.
Wild et al. (2016) [79] UK	RCT	N = 321 Female: 33.3% Mean age: 61 Ethnicity/race not reported		(C): (N = 45) Usual care; (LTA = 5). (1): (N = 160) 9-month telehealth intervention using remote monitoring equipment for weight, BP, and blood glucose, with the information being delivered via modem to nurses. Advice then given to participant based on data at weekly intervals, and as needed; (LTA = 14); Intervention delivered by research team; Intervention fidelity not addressed. (C): (N = 161) Usual care; (LTA = 22).	No differences between groups in

no differences in weight, self-management adherence behaviors, or QOL [79].

# 3.1.5. Lifestyle modification programs

Lifestyle modification program (LMP) is a general description given to an intervention designed to promote health through lifestyle and behavior change. LMPs can include a wide range of topics, including diet, exercise, medications, and stress; can occur in a wide range of settings, including healthcare organizations, workplaces, and the community; and can be delivered through a variety

of mediums ranging from face-to-face, to telephonic, to online technologies. LMP's have a long history in diabetes care, and typically combine interventions targeting diet, exercise, medication management, and behavior modification. Individualizing LMPs has been identified as a key to their success.

Seven RCTs were reviewed with various LMP interventions (see Table 5). Locations of research included three in the United States, and one in the United Kingdom, Canada, and the Netherlands. Programs ranged from twelve months to two years in length. Of these seven, only one study had a short-term statistically

significant impact on HbA1c but this did not persist over the duration of the study [80]. Of the multiple LMP outcome variables, the most positive impacts were noted in diet (6/7 studies) [10,80–84]; physical activity (4/7 studies) [10,81,83,84]; self-efficacy (2/6 studies) [80,85]; and stress (2/6 studies) [82,83].

#### 3.1.6. Education

Identified as a critical element in the care for all people with diabetes, diabetes self-management education (DSME) has been a long-standing intervention in the care of persons with diabetes [86]. DSME has evolved over time to include behavioral and affective strategies [87], and biopsychosocial treatment models addressing both medical and psychosocial needs of persons with diabetes [88]. Educational interventions can be administered by peers or professionals, to individual or groups, in short term or extended sessions, and by different modalities. Current thought on optimal diabetes self-management is that DSME needs to be followed by diabetes self-management support (DSMS) [89]. DSMS involves several essential components that must be maintained long-term to prevent diabetes-related complications: adherence to diet, physical activity, treatments, and monitoring checks [90].

The National Standards for Diabetes Self-Management Education and Support are reviewed and revised approximately every five years by a Task Force jointly convened by the American Association of Diabetes Educators (AADE) and American Diabetes Association (ADA) [86]. While there are many models of DSME, the standards do not endorse any one approach, but rather, specifies what constitutes effective self-management strategies [86]. Many studies have explored the impact of DSME on self-management with outcomes measures covering a range of physiological, behavioral, and psychosocial variables. Research suggests that DSME is associated with changes in diabetes knowledge, clinical outcomes, self-efficacy, and quality of life [91].

For this review, eleven sources were reviewed: one systematic review, two meta-analysis, and eight RCTs. Locations of research included the United States, Sweden, Australia, Saudi Arabia, Japan, and Norway. Looking specifically at HbA1c as the outcome, a systematic review of 118 DSME interventions found that DSME resulted in a significant decrease in HbA1c [91]. Two meta-analyses analyzing RCTs specific to persons with type 2 diabetes show that the benefits of DSME are modest [92] and that the positive effects tend to gradually decline over time [93]. Eight RCTs conducted in six countries were reviewed with various educational interventions (see Table 6). Sample sizes ranged from 75 to 670 participants with the intervention groups ranging from 36 to 335 individuals in the RCTs. Statistically significant improvements in select biophysical, psychosocial, and self-management measures, including knowledge [94,95], distress and quality of life [96,97], and physiologic outcomes [98,100]. One study found no differences in biophysical or self-management behaviors [101].

# 3.1.7. Mindfulness

Mindfulness is a type of meditation practice that has been described as being attentive to the present moment in an open and non-judgmental way [102]. Described as both a trait that can vary between persons, and a skill that can be learned, the concept of mindfulness has measureable aspects including: non-reacting, observing, acting with awareness, describing, and non-judging [103]. Mindfulness as an intervention engages and strengthens an individual's internal resources for optimization of health through self-awareness and taking responsibility for one's life choices [104]. Mindfulness interventions emphasize different practices, depending on the philosophy of mediation practice used, and can incorporate components of stress reduction therapy, cognitive behavior therapy, and spiritual components. However, while mindfulness

interventions take on a variety of forms, most follow a systematic procedure for developing self-awareness, and have clear learning objectives based on theory and science [105].

Mindfulness interventions have be used in chronic disease care to address symptom management and the emotional distress caused by disease and its management. Research suggests that mindfulness has a negative association with both anxiety and depression symptoms in a sample of 666 persons with type 1 and 2 diabetes [106], and was negatively correlated with depression and positively correlated with health-related quality of life in a sample of 75 adults with type 2 diabetes [107]. A mindfulness-based cognitive therapy intervention has been shown to reduce emotional distress and increase quality of life in persons with type 1 and 2 diabetes [108]. In a systematic review of 45 studies using meditation interventions for chronic disease, Chan and Larson [105] conclude that meditation improved symptoms of anxiety, depression, and chronic disease; but conclude that the lack of consistency across diseases and types of meditation interventions warrants further research.

For this integrative review, mindfulness was studied as an intervention in three studies. Locations of research included the United States and Germany. The frequency and length of mindfulness interventions included a one-day workshop, to two 90-min session two months apart, and weekly meetings for 8 weeks. In a RCT of 81 persons from the community with type 2 diabetes, providing education and teaching mindfulness and acceptance of diabetes, compared to providing education alone resulted in improvements in HbA1c at three months post-intervention [109]. However, two other RCTs did not find improvements in physical measures of diabetes. An 8-week mindfulness-based intervention compared to a control group demonstrated lower levels of selfreported depression and improved health status at a one-year follow up, but no differences in albuminuria [110]. In a cohort study, a mindfulness-based eating intervention was compared to an educational intervention over a six-month period, resulting in no significant differences between groups for change in weight or diet intake [111]. See Table 7.

### 3.1.8. Cognitive behavioral therapy

Cognitive behavioral therapy (CBT) is a form of psychotherapy focused on problem-solving through improving negative thinking and behavior [112]. In CBT, the therapist focuses on the impact that dysfunctional thoughts have on current behavior and future functioning. CBT is aimed at evaluating, challenging, and modifying a patient's dysfunctional beliefs (cognitive restructuring) [113]. CBT is used as an intervention for multiple disorders including but not limited to, anxiety, depression, panic disorder, phobias, obsessive compulsive disorder, post-traumatic stress, schizophrenia, anger, eating disorders, somatic disorders, and chronic pain syndromes [114].

In relation to the study of diabetes, CBT has been used as an intervention to treat depression due to its association with glycemic control and self-management. The incidence of major depression as a comorbid condition in both type 1 and type 2 diabetes is well documented, estimated to affect 15–20% of persons with diabetes [115]. Furthermore, depression, even at low levels, has been associated with suboptimal adherence, worse diabetes control, and risk of complications [116]. In an early study done by Lustman et al. [117], the use of CBT with supportive diabetes education demonstrated effectiveness in treatment for major depression and potential improvement in glycemic control in persons with type 2 diabetes. Following this work, other studies have explored the use of CBT for treatment of depression and the impact on glycemic control. CBT has been explored in studies of both type 1 and type 2 diabetes mellitus, demonstrating positive effects of CBT

Table 5
Lifestyle modification programs.

Study &		Sample	Outcome Measures	Intervention (I) and Control (C) Groups	Results
Location				(-, and control (c) droups	
Rosal et al. (2011) [80] US	RCT	N = 252 Female: 76.5% Age: > 18 Latino	waist circumference, medication intensity,	management, cultural tailoring; (LTA = 19); Intervention delivered by a nutritionist or health educator and "trained" and lay individuals; Intervention fidelity not addressed.	months (reduction 0.88), but not at 12
Clark et al. (2004) [81] UK	RCT	N = 166 Female: 42% Mean age: 59.5 United Kingdom	of change, barriers, & self-efficacy,	with interventionist at baseline, and weeks 12, 24, and 52, for goal setting and MI techniques for behavior change. Follow up phone calls by interventionist at weeks 1, 3, and 7; (LTA = 2); Intervention delivered by an "interventionist"; Intervention fidelity not addressed.	
Thoolen et al. (2009) [10] Netherlands	RCT	<i>N</i> = 227 Female: 45% Mean age: 62	BMI, & self-reported intentions, self-efficacy, proactive coping, self-care behaviors, physical activity, diet, & medications, collected at baseline, 3 and 12 months.	Taught a 5-step proactive coping plan, involving goal setting and planning processes; (LTA = 11); Intervention delivered by nurses; Intervention fidelity not addressed.	Diet and physical activity behavior improved, resulting in significant weight loss at 12 months; proactive coping was a better predictor of long-term self-management than intentions or self-efficacy.
Toobert et al. (2007) [82] US	RCT	N = 289 Female: 100% Mean age: 61 Post-menopausal women	Self-reported lifestyle behaviors (diet, physical activity, smoking, stress management), social support, problem solving, self-efficacy, depression, QOL, & cost analysis, collected at baseline, 6, 12, and 24 months.		problem solving ability. Improvements noted in physical activity, social resources, and self-efficacy.
Toobert et al. (2011) [83] US	RCT	N = 280 Female: 100% Mean age: 55.6 -58.7 Latina	Problem solving (coded by interviewers), and self-reported self-efficacy, social support, diet, stress management, & physical activity, collected at baseline, 6 and 12 months.	(I): $(N=142)$ Usual care plus Viva Bien program - a 12-month lifestyle modification program addressing diet, stress management techniques, exercise, smoking cessation, problem solving. Involves a 2 and a half days retreat followed by weekly 4-h meetings for 6 months, then twice monthly for 6 months. Intervention delivered by "study staff"; Intervention fidelity not addressed. (C): $(N=138)$ Usual care. LTA: 23.2% intervention group; 21.7% control group.	Significant improvements in behavior change (diet, practice of stress management, exercise, and engagement in social support), and HbA1c; however, these changes were not maintained at 12 months. Improvements in psychosocial outcomes (problem solving, self-efficacy, and perceived support).
McGowan (2015) [85] Canada	RCT RCT	N = 361 Male: 54–64% Mean age range: 63.8–64.6	HbA1c, lipids, weight, BMI, BP, waist circumference, self-reported self-efficacy, attitudes, behaviors, health status, & QOL, collected at baseline, 6 and 12 months.	Three groups: (I-1): $(N = 130)$ DSMP program - lead by pairs of trained lay leaders, groups of $10-16$ meet once a	

Table 5 (continued)

Study & Design Location	n Sample	Outcome Measures	Intervention (I) and Control (C) Groups	Results
Markle- Reid et al. (2018) [84] Canada	N = 159 Female: 55.9% Age: 30% aged 65 to 69, 40% aged 70 to 74, and 30% aged 75 and older.		(I): $(N = 80)$ Participated in a community-based lifestyle modification program focused on self-efficacy, self-management, holistic care, and individual and caregiver engagement. The program, delivered by trained nurses, dietitians, program coordinator, and peer volunteers, involved 3 in-home visits, monthly group sessions, monthly case conferences, and on-going nurse-led care coordination. (LTA = 5). Fidelity addressed. (C): $(N = 79)$ Usual care. (LTA = 13).	quality of life and self-management and reduced depressive symptoms.

on depressive symptoms, but with mixed findings on the impact on glycemic control. In a study of 94 outpatients with diabetes and depressive symptoms, improvements in depressive symptoms and HbA1c, and in self-reported depressive symptoms, anxiety, well-being, and diabetes-related distress were found [118]. Additional studies of both type 1 and type 2 diabetes using CBT interventions show improvements in depression, but are inconclusive regarding the impact on improving self-management and physical health outcomes [119,120].

For this integrative review, five studies examined the use of CBT for depression and the relationship to type 2 diabetes selfmanagement: Three RCTs, one systematic review, and one metaanalyses (see Table 8). Two of the RCTs were done in the United States, and one in Germany. One study included five weekly 90-min CBT sessions, and two studies included eight to twelve one-hour weekly CBT sessions. All RCTs compared the intervention group to usual care that included diabetes self-management education. The RCTs show improvements in depression and distress [121,123], but only one study showed improvements in glycemic monitoring and control [123]. In a systematic review and meta-analysis of RCTs of psychological interventions to improve glycemic control in persons with type 2 diabetes, 23 out of 25 RCTs examined CBT as the intervention. Results suggest that there are improvements in longterm glycemic control and psychological distress, but not in weight control and blood glucose level [124]. In a meta-analyses of 45 RCTs assessing efficacy of psychological interventions for selfmanagement of type 2 diabetes in adults from mainland China, 33 studies focused on CBT as the intervention. Analysis suggest that CBT was more effective than the control condition in reducing HbA1c, depression, and anxiety [125].

### 4. Synthesis

### 4.1. Impact of interventions

This integrative review examined 70 studies (8 systematic reviews, 3 meta-analyses, 53 RCTs, 4 cohort, and 2 descriptive), summarizing eight categories of interventions targeting physiologic, behavioral, and psychological outcomes in patients with type 2 diabetes. Studies were examined from seventeen countries including a broad range of cultures and ethnicities within the research, including Caucasian American, African American, Native American, Hispanic/Latino, European, Canadian, Australian, Middle-Eastern, and Asian populations.

While interventions have shown mixed results in all interventions categories, many studies do support small to modest improvements in physiologic, behavioral, and psychological outcome measures. Interventions have shown small to modest improvements for HbA1c. Often the significant HbA1c change was

only within the intervention group, but not significant when compared between groups. Levels of improvement ranged from 0.13% to 1.6% reductions, with the highest reductions seen in peer support/coaching and technology-based interventions. Small to modest improvements were also seen in physiologic outcomes of weight loss, behavioral outcomes of self-reported diet and physical activity, and psychological outcomes of self-reported improvement in self-efficacy and reduction in distress.

#### 4.2. Attributes of interventions

In addition to a wide variety of interventions being tested for self-management of type 2 diabetes, considerable heterogeneity of interventions exist within similar types of interventions. Areas of heterogeneity included length, duration, and number of sessions, content, method of delivery (i.e., in-person and technology-based, individual or group-based), and facilitation (i.e., self-directed, health care professional, peer). For example, motivational interviewing interventions ranged in length from one 60-min session to five 45-min sessions over one year, could be either individual or group based sessions, including face-to-face and self-directed internet based sessions. Considerable variation was found in all intervention categories in this review. This heterogeneity makes it difficult to aggregate findings on specific interventions.

A wide range of professionals and non-professionals were used for intervention delivery. Out of 59 studies, 18 (30%) had nurses facilitating the interventions, with most being education or technology interventions. Twenty-three studies used non-specified personnel to deliver the intervention, including health educators, trained personnel, and peer and/or lay persons. Most of these studies included a peer or coaching intervention, or a lifestyle modification program. Ten studies indicated that a research team delivered the intervention, mostly of which were technology-based interventions. Other types of professionals delivering interventions included certified diabetes educators, psychologist/counselors, pharmacists, dieticians and nutritionists, exercise physiologists and trainers, and social workers, medical assistants, physicians, and students. While only 30% of the studies had nurses as interventionists, they are well positioned to contribute to all intervention types. As it was noted with the exception of mindfulness, nurses were the only professionals used as interventionists across all types of interventions in this review. However, it is also to be noted that components of mindfulness have been embedded within some larger multi-modality and education interventions that have been led by nurses.

In addition to heterogeneity, many intervention approaches are multi-modal, and include components of different categories of intervention in one intervention program. For example, a life style management program may include components of education,

Table 6

Study & Location	Design	Sample	Outcome Measures	Intervention (I) and Control (C) Groups	Results
Chrvala, Sherr, & Lipman (2016) [91]	Systematic review	N = 118 RCTs >18 years, type 1 and type 2 diabetes.	Must have HbA1c as outcome variable.	Out of 118 RCTs, most reported on a single discrete DSME intervention with follow up HbA1c level at 3 months or greater. Several RCTs compared 2 or 3 methods of DSME to a control condition.	change in HbA1c, with an average reduction of 0.57. Education hours <10
Klein et al. (2013) [93]		N = 52 RCT Type 2 diabetes, age > 18.	HbA1c values at baseline and post- intervention.	Of the 52 RCTs, 17 had 13 weeks or less for length of intervention, 17 had 14–16 weeks of intervention, and 19 had 27 or more weeks of intervention.	
Adolfsson et al. (2007) [94] Sweden	RCT	N = 101 Female: 41%	HbA1c, BMI, and self-reported confidence in diabetes knowledge, self-efficacy, & satisfaction, collected at baseline and 1- year follow up.	had 4-5 empowerment group education sessions, and a follow up session within 7 months; (LTA = 8); Intervention delivered by "trained" doctors and nurses; Intervention fidelity addressed.	
Campbell et al. (2013) [95] Australia	RCT	N = 670 Female: 46.3% Mean age: 55.7 Australia	Self-reported self-efficacy, and self-management behaviors, collected at baseline, 4 weeks, and 6 months.	(C): (N = 46) Usual care; (LTA = 5). (1): (N = 335) Received Fact Sheets and DVD comprising patient narratives of type II diabetes management during a 3-week intervention; (LTA = 49); Intervention delivery personnel and intervention fidelity not addressed. (C): (N = 335) Received diabetic Fact Sheets only; (LTA = 23).	
Beverly et al. (2013) [96] US	RCT		HbA1c, weight, BMI, waist circumference, BP, pedometer readings, fitness assessment, blood glucose, and self-reported self-care, symptoms, coping, distress, QOL, confidence, and health literacy, collected at baseline, 3, 6, and 12 months.	(I): $(N=68)$ Four 1-h group education sessions each with a different topic (diabetes overview, healthy eating, BGL monitoring, natural course of diabetes); (LTA = 10); Intervention delivered by RNs	Intervention group had modest improvement in HbA1c at 3 months (reduction of 0.4%), with no maintenanc of improvement at 6 and 12 months. Control group had no improvement of HbA1c at any time. Both groups improved frequency of self-care, QOL, distress and frustration over time.
Sugiyama et al. (2015) [97] US	RCT		HbA1c, and self-reported mental and physical health-related QOL, & social support, collected at baseline and 6 months.	All given 2 h training on SMBG. (1): $(N = 258)$ Six weekly small group self-care sessions based on empowerment model. Sessions were for 2 h, with 8–10 persons per group; (LTA = 55); Intervention delivered by trained "health educators"; Intervention fidelity addressed. (C): $(N = 258)$ Six lectures on geriatric topics unrelated to diabetes; (LTA = 62).	Education increased health-related QOI and significant reduction in HbAlc (0.4% compared to control.
Mohamed et al. (2013) [98] Saudi Arabia	RCT	N = 430 Female: majority Mean age: 53.5 Saudi Arabia	HbA1c, fasting glucose, lipids, BMI, BP, albumin/creatinine ratio, and self-reported knowledge, attitudes, & practice, collected at baseline, 6 and 12 months.	(I): $(N = 215)$ CSSEP (culturally sensitive structured education program), consisting	Significant improvements in interventic group in HbA1c reduction (0.55%), fastis blood sugar, BMI, albumin/creatinine ratknowledge, attitude & practice.
Moriyama et al. (2009) [99] Japan	RCT	N = 75 Female: 54% Mean age: 65.8 Japan	Weight, abdominal circumference, BP, fasting blood glucose, HbA1c, lipids, and self-reported QOL, stage of change, goal attainment, & self-check, collected at baseline and 3, 6, 9, and 12 months.	(c). (N = 213) Osdal Care, (LTA = 34).  (I): (N = 50) Monthly face-to-face individual sessions, 30 min each, after clinical exam. Required patient setting behavioral goals on exercise and diet and contact every 2 weeks to check if practicing goal setting behaviors over the next 12 months; (LTA = 8); Intervention delivered by "educator"; Intervention fidelity addressed.  (C): (N = 25) Usual care; (LTA = 2).	Intervention group had significant improvements in weight, HbA1c reduct (0.55%), self-efficacy, dieting and exerci stages, QOL, diastolic BP, total cholester and complication prevention behaviors

Table 6 (continued)

Study & Location	Design	Sample	Outcome Measures	Intervention (I) and Control (C) Groups	Results
Sperl- Hillen et al. (2011) [100] US	RCT	N = 623 Female: 49.4% Mean age: 61.8 Caucasian: 65.2%; Hispanic: 22.1%	HbA1c, weight, waist circumference, BP, and self-reported depression, general health, support, attitudes, caring ability, distress, understanding, empowerment, diet, & physical activity, collected at baseline, 1, and 4 months.	3 groups: (I-1): ( $N$ = 243) Group education using Conversation Maps in four 2-h sessions with groups scheduled at 1 week intervals, 8–10 people per group; (LTA = 29). (I-2): ( $N$ = 246) Individual education; 3 sessions, 1 h each, one month intervals; (LTA = 37). Intervention delivered by "trained" nurses and dieticians; Intervention fidelity addressed. (C): ( $N$ = 134) Usual care (LTA = 13).	education or usual care. Individual education improved physical health, but not mental health scores.
Rygg et al. (2012) [101] Norway	RCT		reported patient activation, QOL, distress, global health, diabetes knowledge, & self-management skills, collected at 6 and 12	(I): (N = 73) DSME group of 8–10 patients, 15 h of education over 3 sessions, one week between each session; (LTA = 9); Intervention delivered by "trained" nurses; Intervention fidelity not addressed. (C): (N = 73) Usual care; (LTA = 4).	No difference in primary outcomes between groups at 12 months. Diabetes knowledge and some self-management skills improved significantly in the intervention group.
Ferguson et al. (2015) [92]		N = 13, with 11 included in meta- analysis. Hispanic or Latino majority.	A1c Baseline and at follow up. Follow up periods ranged from 6 months to 5 years.	Studies included a DSME intervention in combination with primary care. Seven RCTs included culturally tailored DSME; 9 reported the level of involvement of the primary care provider. Five of 13 studies reported statistically significant changes in HbA1c in the intervention group; Six found no significant changes in HbA1c between groups.	The pooled effect across studies was and HbA1c reduction of $-0.25$ (95% CI, $-0.42$ to $-0.07$ , $P=.01$ ), indicating a greater improvement in glycemic control for the intervention group at 6 months $-12$ months.

**Table 7** Mindfulness.

Study & Location	Design	Sample	Outcome Measures	Intervention (I) and Control (C) Groups	Results
Gregg et al. (2007) [109] US	RCT	N = 81 Female: 46.9% Mean age: 50.9 Hispanic: 28.4%	A1c, and self-reported self-management (diet, exercise, and blood glucose monitoring), knowledge, treatment satisfaction, & acceptance, collected at baseline and 3 months.	(I): ( <i>N</i> = 43) The ACT condition, involving a one-day workshop with education, acceptance, and mindfulness training; (LTA = 10); Intervention delivered by "author of manual"; Intervention fidelity not addressed. (C): ( <i>N</i> = 38) Education alone; (LTA = 3).	ACT condition more likely to use the coping strategies, to report better diabetes self-care, and to have HbA1c values in the target range. ACT had no significant effect on HbA1c.
Hartmann et al. (2012) [110] Germany	RCT	N=110 Males: 78.1% Mean age: 59 European	Albuminuria, and self-reported psychiatric comorbidity, levels of Depression, & stress, collected at baseline & 12 months.	(I): ( <i>N</i> = 53) Mindfulness based stress reduction (MBSR) intervention, groups of 6 –10 participants, meeting weekly for 8 weeks, with a booster session after 6 months; (LTA = 10); Intervention delivered by psychologist and resident physician; Intervention fidelity not addressed. (C): ( <i>N</i> = 57) Usual care; (LTA = 6).	The MBSR group showed significant reduction in psychosocial distress, but not on albuminuria. <i>No</i> significant reduction in HbA1c.
Miller et al. (2014) [111] US	Cohort	N = 68 Female: 63.5% Mean age: 54 Caucasian: 76.5%	Weight, & self-reported diet, knowledge, outcome, expectancy, self-efficacy, anxiety, depression, & mindfulness, collected at baseline, post-intervention, then again 1 month and 3 months after the second data collection.	Group 1: ( <i>N</i> = 32) Mindful based eating awareness training (MB-EAT), 2 CDs to guide mindfulness meditation, encouraged to meditate 6 days/week and to practice minimeditations at other times, basic information on self-management; (LTA = 5). Group 2: ( <i>N</i> = 36) Smart Choice (SC) intervention which is behavioral DSME and in-depth nutrient information. All groups had 90 min 1 and 3 month follow up session reviewing key principals of interventions; (LTA = 11);. For both groups, intervention delivered by dietician and social worker; Intervention fidelity addressed.	efficacy, and cognitive control regarding eating behaviors.

**Table 8**Cognitive behavioral therapy.

Study & Location	Design	Sample	Outcome Measures	Intervention (I) and Control (C) Groups	Results
Hermanns et al.(2015) [121] Germany	RCT	N = 214 Female: 56.5% Mean age: 43.3 German- speaking	Self-reported depressive symptoms, distress, self-care activities, well-being, QOL, diabetes acceptance, & treatment satisfaction, collected at baseline, immediately after intervention, then 6 and 12 months.	(I): (N = 106) DIAMOS program, delivered by psychologist using CBT, comprised of five 90-min lessons; (LTA = 13); Intervention delivered by "certified" psychologist; Intervention fidelity not addressed. (C): (N = 108) Usual care, consisting of a group-based diabetes education program; (LTA = 20).	
Penckofer et al. (2012) [122] US	RCT	N=74 Females Mean age 54.8 White 63%; Black 29%; Hispanic: 8%	Fasting glucose, HbA1c, & self-reported depression, anxiety, anger, health related QOL, & knowledge, collected at baseline, 3 and 6 months.	(I): $(N=38)$ One hour CBT intervention done in group sessions, delivered by a nurse, weekly for 8 weeks; $(LTA=12)$ ; Interventions delivered by nurses; Intervention fidelity addressed. (C): $(N=36)$ Usual care; $(LTA=2)$ .	CBT significantly reduced depression, anxiety, and anger symptoms compared to usual care, but there were no significant differences between groups on HbA1c levels.
Safren et al. (2014) [123] US	RCT	N = 87 Female: 50%	A1c, medication adherence, SMBG, distress & self-reported depression, collected at baseline, 4, 8, and 12 months.	(I): $(N = 45)$ CBT for adherence & depression + ETAU (enhanced treatment as usual). Received 9–12 CBT sessions over 4 months; (LTA = 5); Intervention delivered by a "therapist"; Intervention fidelity not addressed. (C): $(N = 42)$ ETAU with series of diabetes support and adherence interventions (included one meeting with nurse educator, two with dietician, one with adherence counselor); (LTA = 4).	medication adherence, SMBG, reduction in HbA1c (0.63%), & improvement in depression score. At 8 & 12 months medication adherence, HbA1c and SMBG
Ismail et al. (2004) [124]	Systematic review	N = 25 RCTs Psychological interventions for Type 2 diabetes control	A1c, blood glucose, weight, BMI, & psychological distress.	23 studies of adults (out of 25 studies) used CBT as an intervention in relation to diabetes control in type 2 diabetes.	In persons receiving psychological therapies, there are improvements in long term glycemic control (mean HbA1c reduction of 0.32%), and psychological distress, but not in weight or blood glucose level.
Chapman et al. (2015) [125]	Meta- analysis	N = 45 RCTs(US and China) Psychological interventions for type 2 diabetes control	HbA1c, blood glucose, anxiety, depression, & QOL.	33 studies of adults (out of 45 studies) used CBT as an intervention in relation to diabetes control in type 2 diabetes.	CBT was more effective than the control condition in reducing HbA1c (SMD $=-0.97$ ), depression, and anxiety.

motivational interviewing, and technology. Technology interventions, while focusing on the use of the specific technology, may include education, problem solving, and peer coaching. And while the use of multi-modal approach may be beneficial to helping to improve self-management, this overlap makes it challenging to separate out impact of specific interventions. And lastly, fidelity of interventions is another area of consideration. Out of 59 studies, only 21 (35.5%) addressed procedures for intervention fidelity.

# 4.3. Outcome measures and attrition

The studies in this review examined the impact of a self-management intervention on the major outcomes of physiologic measures of disease control, self-management behaviors, and psychological outcomes. The most commonly reported physiologic measure of disease control was HbA1c level. Other commonly used physiologic measures included weight, BMI, waist circumference, and blood lipid levels. The most commonly reported behavioral outcomes were for diet and physical activity. Other behavioral outcomes included SMBG and medication adherence. In addition, behavioral outcomes were mainly self-report. The most commonly reported psychological outcomes were self-efficacy and distress, and as in behavioral outcomes, these outcomes were also mainly

self-reported.

Outcome measures were collected mostly at 6 months (19 studies) and 12 months (22 studies) follow up. Twelve studies collected outcome data at three to four months, two at 18 months, and two studies at 24 months. Overall, duration of most research was limited to one year.

In terms of attrition rates, the majority of studies (64.4%) had less than 20% attrition at final data collection time. Approximately 25% had 1.2–10% attrition, and 39% had 10.0–20% attrition. Three studies had attrition rates between 32.6 and 37.7%, with study duration lasting between 12 and 15 months. The majority of studies report attrition as a number or percentage, with limited information about participant characteristics and attrition. Five studies did not report attrition.

# 5. Discussion

# 5.1. Impact of interventions

The results of the integrative review support prior reports from the literature on diabetes self-management. A vast amount of literature exists describing intervention research for diabetes selfmanagement. Interventions in general have demonstrated shortterm improvements in glycemic control [126,127], and in promoting knowledge, self-efficacy, and in distress reduction [46]. However, results of intervention effectiveness are inconsistent [45], with many studies producing mixed results in relation to physiological, behavioral, and psychosocial outcomes.

The levels of improvement of HbA1c in this integrative review ranged from 0.13% to 1.6%. To elaborate on those findings, most studies that showed improvements in HbA1c had reductions of approximately 0.50%. Of the four studies that had showed HbA1c reductions of greater that 1.00%, three of them collected outcome data at 6 months, and two had sample sizes less than 65 subject. These finding bring consideration to the question of statistical versus clinical significance. It has been suggested that 0.5% HbA1c is a clinically significant change [128]. This reference to this reduction in HbA1c is drawn from the earlier work of the Diabetes Control and Complications Trial Research Group [129], and the UK Prospective Diabetes Study [7]. A difference in HbA1c of only approximately 2% between intensive and standard treatment groups demonstrated significant differences in outcome risks [129], and even lower differences in HbA1c (7.0% intensive vs 7.9% conventional treatment) demonstrated significant reduction of microvascular complications in persons with type 2 diabetes [7].

# 5.2. Intervention heterogeneity and fidelity assessment

The results of this integrative review demonstrated that in addition to a wide variety of interventions being tested for selfmanagement of type 2 diabetes, there is considerable heterogeneity of interventions that exists within similar types of interventions. This result is also reported in systematic reviews on interventions for self-management of type 2 diabetes [23,124,125] describing considerable variability in studies with respect to methods of intervention delivery, duration, and intensity, and in measurement of outcome variables and follow-up interval [91]. In addition, many intervention approaches are multi-modal and include components of different categories of intervention in one intervention program. This overlap makes it challenging to separate out impact of specific interventions, and makes it challenging to aggregate findings and draw solid conclusions on the impact on outcomes of physiologic, behavioral, and psychological outcomes [35,91].

Fidelity of interventions is another area of consideration. In this integrative review, out of 59 studies, only 21 (35.5%) addressed procedures for intervention fidelity. Intervention fidelity has been identified as a limitation in diabetes self-management research, with issues concerning inconsistency in intervention delivery, quality in training to assure fidelity, and lack of fidelity assessment [21, 44, [125]. A systematic review specific to intervention fidelity in diabetes self-management interventions reported that intervention fidelity of interventions remains under-investigated [130], with most fidelity assessment done through direct observation, and with intervention dose being assessed by self-reported measures [130].

#### 5.3. Outcome measures

The most commonly reported physiologic measure of disease control was HbA1c level. This is consistent with the diabetes literature on treatment and research [7,131], with HbA1c being considered the gold standard for glycemic control. HbA1c reflects average glycemia over approximately 3 months and has strong predictive value for diabetes complications [132], and provides the most objective and reliable information about glucose control of patients with type 2 diabetes. Most studies in this review reported HbA1c value changes between groups from points in time, as opposed to identifying target HbA1c reduction value. While a

specific number or percentage considered to be the target value for reduction has not been identified or consistently used in reference for HbA1c reduction, the common approach has been consistency in lowering HbA1c. Consistent with the literature, studies in this review referenced the American Diabetes Association [132] goal for HbA1c for most adults to be 7%, and presented HbA1c results in terms of reductions towards that goal.

The most commonly reported self-management behavioral outcomes were for diet and physical activity. Diet and physical activity are two of the four major cornerstones of care for selfmanagement of diabetes [133]. Poor diet and physical inactivity are major contributors to disabilities that result from diabetes. The importance of proper nutrition and physical activity in reducing rates of disease and death from chronic diseases has been wellestablished [8,134]. The balancing of diet and physical activity are well-established keys to managing diabetes [132], and in many cases, the most challenging of the self-management behaviors to manage due to being complicated and difficult to integrate into daily life [135]. In addition, they can be challenging to measure, with most measures in research studies being self-report. Selfreport measures may present certain limitations in capturing aspects of dietary and physical activity behavior, with over-reporting being a known problem [68,136].

The most commonly reported psychosocial outcomes were selfefficacy and distress. Self-efficacy and distress have received considerable attention in the chronic disease and diabetes literature. Self-efficacy has been defined as the judgment of capabilities to organize and execute courses of action required to attain desired types of performance and expected outcomes [137]. Diabetes distress has been described as unique emotional issues directly related to the burdens and worries of living with a chronic disease [11]. Both self-efficacy and distress have been associated with diabetes self-management and HbA1c levels [138,139]. In general, a broad range of interventions have favorable impact on both selfefficacy and distress, however, sustaining impact on glycemic control and self-management behaviors remains a challenge. Successful treatment and management of emotional needs of patients is needed so that people can be successful with diabetes selfmanagement [122]. And as in the measurement of diet and physical activity, measures of self-efficacy and distress are self-reported, thus the risk of over-reporting on these variables exists.

Outcome measures were collected mostly at 6 months (19 studies) and 12 months (22 studies) follow up. For studying the impact of interventions on physiologic, behavioral, and psychological outcomes, this timeline presents limitations. Research suggests that results of interventions begin to diminish over twelve months [46], and that longer follow up periods extending beyond twelve months are needed [75]. However, the challenges of longitudinal studies are well documented. Challenges such as incomplete and interrupted follow-up with study participants, attrition with loss to follow-up over time, and the generally increased time and financial demands associated with longitudinal research are implicit in study designs [140].

# 5.4. Limitations of this review

Because this was an integrative review we chose to include systematic reviews, meta-analyses, RCTs, and descriptive work. This was done in order to not miss nuances found within individual studies that can sometimes occur with larger review studies. However, because some of the RCTs may have also been in larger review studies, there may be some duplication of findings and enhanced or diminished intervention impact. Because of the exhaustive nature of the literature on this topic, it is challenging to stay informed of the entirety of the body of work in this area. Thus,

not every piece of evidence, nor every aspect of intervention success/failure maybe completely accounted. And lastly, because of the multi-modal aspects of interventions, it was difficult to initially categorize the broad array of interventions. In each selected category, there may be other interventions. Thus the true impact of a singular category (i.e.: coaching, technology-based, etc.) is difficult to separate out and report outcomes.

## 5.5. Recommendations for future research

Based on the synthesis of findings from this review, the following recommendations for future research are offered. To address the concerns of multi-modal interventions, research that includes a theoretical basis/model of investigation would be beneficial to explicitly describe and provide rationale for the foundation of the intervention. Complex interventions need to be developed based on theoretical frameworks, which is important because a simple explanation or model applied to a complex intervention risks overstating the causal contribution of the intervention [141]. All elements of a complex intervention need to be identified and described, giving the intervention its theoretical and pragmatic basis that is thought to account for the effectiveness of the intervention [142,143]. Using a theoretical framework provides a guide to appropriately implement, and analyze the intervention [144].

Research studies need to include full protocols/descriptions of the interventions to provide researchers with the details for comparison and reproduction of the intervention. Many intervention descriptions are too brief or ambiguous, making it difficult to identify specific actions taken, and in turn, making replication challenging. Often words such as self-management, education program, or healthy lifestyle are used with little clarity into what exactly constitutes the intervention. Mixed modality approaches make it difficult to sort out contributions of components of intervention, or to examine the association of components with each other and the impact on outcomes. For example, tech-based interventions may be enhanced by adding coaching components.

Long-term studies and analysis are needed to assist in evaluating the ways in which study variables impact self-management behavior. Longer follow up may provide participants more opportunity to implement strategies targeting behavior change. Prolonged follow up is needed to monitor maintenance of skills gained, many of which may improve over time (i.e. problem solving skills, CBT). In addition, research incorporating more objective measures of self-management is needed. Much of the self-management behaviors are self-report. More objective measures, in addition to HbA1c, for self-management are needed. Objective measures of physical activity and diet are needed.

While efforts have been made to expand the diversity of research participants, many groups continue to be under-represented in diabetes research. More strategies for recruiting representative numbers of ethnic minorities and underserved populations, and research seeking to determine whether interventions are equally effective in these groups is needed. There is a need for new strategies to control the growing diabetes epidemic in the underserved and marginalized population, to better understand diabetes self-management patterns and correlates, and to identify and overcome barriers to self-care in an effort to identify effective culturally tailored self-management interventions [33].

And lastly, care delivery models that incorporate what is known about effective interventions in the management of diabetes is an area of nursing research wide open for investigation. Specifically, the role of the registered nurse in the management of diabetes care. An interesting point to consider about the issues with intervention heterogeneity, fidelity, and duration focuses on the role of the nurse

in the primary care setting. All of the interventions included in this review fall within the scope of practice of general practice nurses in the primary care setting. The RN can be uniquely positioned as part of an inter-professional team to take on expanded primary care functions in managing the complex care of patients with diabetes, leading complex care management teams, and comprehensive care coordination between the primary care home and providers of care services [145].

#### 6. Conclusion

Diabetes is a global health problem, as evidenced by the findings of this integrative review. The vast amount of research exploring the impact of interventions for self-management has made major contributions to the care of persons with type 2 diabetes, from offering suggestions for improving care, to stimulating new questions for research. However, implications for clinical practice remain inconclusive [126], and there remain limitations in the existing body of research, suggesting caution in interpreting results of studies. Moving research forward with attention to intervention development, study design features, and exploring innovative care delivery models offers potential to move this body of research forward to achieving impactful and sustainable physiologic, behavioral, and psychosocial outcomes, and improve the health of those with type 2 diabetes.

## **Funding or conflicts of interest**

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

#### Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijnss.2018.12.002.

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