Evaluation of the effectiveness of Persian diabetes self-management education in older adults with type 2 diabetes at a diabetes outpatient clinic in Tehran: a pilot randomized control trial

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Abstract

Purpose The effectiveness of diabetes self-management interventions has been more generally demonstrated in adults, but there is little evidence of diabetes self-management specific to older adults situated in Iran. The purpose of this study was to evaluate the effectiveness of Persian Diabetes Self-Management Education on self-efficacy, quality of life, self-care activity, depression and loneliness in older adults with type 2 diabetes.

Methods In pilot randomized controlled trial, a total of 34 participants ≥ 60 years with type 2 diabetes were randomly assigned into intervention ($n = 17$) and control ($n = 17$) group in an outpatient diabetes clinic in Tehran. To assess the primary outcome of participant experiences, the Diabetes Management Self-efficacy Scale (DMSES) was the method of measurement. The Diabetes Quality of Life-Basic Clinical Inventory (DQoL-BCI), Patient Health Questionnaire-9 (PHQ-9), Diabetes Self-Management Education Scale (DSMES), and adult Social-Emotional Loneliness Scale Short form (SELSA-S) were used as secondary outcomes. Participants' evaluations were completed at baseline, while measurements were conducted two and four weeks after allocation, using repeated measurements of Univariate and multivariate ANOVA (adjusted for baseline values) to analyze the data.

Results In the multivariate model, there was a significant difference between the control and intervention groups regarding reported quality of life ($p = 0.04$) and the medical-domain's reported self-efficacy ($p = 0.02$). However, there were no significant differences in the reported self-management, depression, loneliness, as well as the other domain of self-efficacy; as compared between the two groups before and after intervention.

Conclusion The study depicts a promising impact on older adults, imparted by the pertinent program. The finding showed PDSME has a positive effect on quality of life and medical control domain of self-efficacy. This pilot study showed that the program is feasible and duly beneficial if delivered to older adults. This pilot proves appealing to begin further testing within a larger sample population.

Keywords Aged · Self-management · Diabetes mellitus · Type 2 · Chronic disease

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Introduction

Diabetes mellitus is among the top 10 causes of death worldwide, accounting for 4.2 million deaths annually [1]. Due to urbanization and low mobility, the prevalence of diabetes worldwide is increasing [2]. It affects not only developed countries, but also afflicts developing countries, where industrialization and urbanization continue to rapidly increase [3]. The highest incidence of diabetes worldwide is endemic to the Middle East and North Africa (MENA) region [4]. Iran is one of the most populous countries in the Middle East, where diabetes management is currently inadequate. Studies have shown that unmanaged hyperglycemia is defined as 55.9% (in terms of A1C) among Iranians [5] and the population

density of older adults is also increasing in Iran. The results of prior systematic reviews indicate that people aged >55, especially woman, are associated with deteriorated management of diabetes in the Iranian population [6], while the overall prevalence of diabetes in older Iranian adults is currently estimated at 14.4% [7].

Additionally, older adults are at an added risk of functional disabilities. Conditions including cognitive impairment, depression, urinary incontinence, risk of falling, and chronic pain affecting individuals' quality of life, can further impact the outcomes associated with diabetes [8, 9]. Diabetes is a lifelong chronic illness that requires daily care and, if not managed by older adults or their caregivers, worsens individual's overall health, reduces quality of life, proves detrimental to organs, and ultimately increases the likelihood of mortality [10, 11]. Diabetes and other chronic complications, including cardiovascular disease, nephropathy, neuropathy, and retinopathy often have less optimistic prognoses and more severe implications in older adults [10].

Given that diabetes is a chronic disease, individuals need to consider a plan to manage their symptoms and reduce the risks of associated complications [8, 11]. In diabetes self-management, people are instructed to carry out a variety of self-management activities on a daily basis [8]. The complex care-plans that individuals with diabetes need to set up include meal patterns, insulin injections, exercise, at home management and monitoring of blood glucose levels, and other self-care behaviors. The complexity and need for these self-care behaviors highlight the need for training programs to ensure patients are educated in these diabetes management programs so they can manage their quality of life [12]. Therefore, among people with diabetes, those who have diabetes self-management routines in their daily lives are healthier relative to those with inconsistent or incomplete routines [13].

In order to self-manage their conditions, it is essential that older adults have adequate knowledge and information related to their condition in order to be able to make educated decisions towards their healthcare and more readily adapt to their conditions; otherwise they may experience long-term complications. [8]. Diabetes self-care behaviors for older adults with diabetes include the aforementioned aspects of diet, exercise, and blood-sugar regulation via use of medications. These all contribute to effective health outcomes, reduction of risk for complications, and healthy coping strategies for mental and physical concerns afflicting individuals with diabetes [14]. The specific needs of older adults and the complexity of diabetes education can make self-management difficult for this age group, as mobility and access to education become more convoluted relative to age [15, 16].

The specific medical, functional, cognitive, and social needs of older adults require an explicit framework for the clinical management and education of diabetes, especially after the age of 75 [17]. Older adults with diabetes and

concomitant depression are less likely to adhere to self-management programs and possess an increased risk of worsened complications from diabetes [18].

Depression is less common among persons with diabetes who receive greater social support than those who receive less [19–23]. Performing self-care behaviors such as monitoring blood glucose levels, proper adherence to recommended diets, and seeking help from trusted supports, all require sufficient physical and cognitive abilities. Therefore, older adults who have more social and familial interactions can potentially benefit from their support networks for assistance in self-care activities. Studies have also shown that the best intervention for reducing social isolation in older adults is group-centered interventions that require active individual participation, such as in workshops [24]. The essential goal of diabetes self-management in older adults is improvement to quality of life, whilst the main goal in young patients is the reduction of risk for the onset of chronic complications [25].

While the desire to provide self-management programs in chronic diseases is increasing with emerging evidence that diabetes is more becoming more prevalent in older adults, most randomized controlled trial (RCT) studies in diabetes exclude people over the age of 60 or 65. This is due to concerns about the effects of comorbidities, possible cognitive changes, and other implications that could potentially impose possible occlusions to results of RCT studies [17]. In addition, studies that include older adults often do not analyze the data by age [26], and less than 1% of clinical trials on diabetes are pertinent to older adults resulting in disproportional representations [27]. Since educational programs are age-dependent as well as often culturally-dependent [28], the lack of proportional and explicit representation for older adults situated in Iran, diminishes the healthcare awareness towards diabetes self-management centric to this group. Prior studies have examined the relationship of self-management programs with correlated self-care behaviors, quality of life, and other psychological factors such as depression and loneliness in people with diabetes.

Persian Diabetes Self-Management Education Program (PDSME) is a theory- and evidence-based, culture-oriented intervention. This program is specifically developed for diabetes in Iran to provide a modified version of the American Association of Diabetes Educators (AADE) curriculum, based on seven criterion of diabetes self-management. The self-management criterion includes: (i) healthy eating, (ii) being active, (iii) monitoring blood glucose, (iv) taking medication, (v) adaptability, (vi) reducing risks and (vii) adopting healthy coping mechanisms. The PDSME comprises eight 2½-h educational workshops offered over a 4-week period that facilitates the continuous process of education, acquiring disease-management skills, and proactive behaviors needed to reduce

risks of diabetes complications. These workshops also introduce support networks and activities that help individuals implement and maintain these behaviors to better ameliorate their symptoms, on an ongoing basis [29].

The impact of the PDSME on a variety of clinical and psychological factors in adults (but not exclusively in older adults) has been previously investigated in Iran, although the impact of PDSME and similar programs on the psychological factors associated with diabetes in older adults has not been explicitly investigated [29]. Therefore, the aim of this study is to specifically evaluate the efficacy of the Persian Diabetes Self-Management Education (PDSME) program on diabetes self-efficacy, self-care activity, quality of life, depression, and loneliness compared against current-care control groups. Other controls used in this study include weight and vital signs, oral medication and insulin dosage, as well as prior laboratory tests and assessments of diabetic foot neuropathy. Any prior education in diabetes-management will be noted for the participants to prevent confounding.

Methods

Study design

This study was a pilot randomized controlled clinical trial to assess the effectiveness of the PDSME on self-efficacy, self-care activity, quality of life, as well as depression and loneliness in older adults with type 2 diabetes. This program was deemed feasible as assessed from recruitment and retention rates in diabetes clinics for older adults.

Acceptability was determined via informal feedback from participants while effectiveness was measured as relative scores for primary and secondary outcome measures.

In this study we reduced the number of treatment groups to 9–13 compared to the original study (20–25 people in the main study), the duration of the treatment program was reduced to about 2 h (instead of 2 and a half hours). This appeared to be sufficient to educate, share experiences, and answer participants' questions, while limiting the interview length to better suit participants' comfort.

Setting and sampling

This RCT was carried out on the participants with type 2 diabetes, who were referred to an academic diabetes outpatient clinic affiliated with Tehran University of Medical Sciences in 2019. This accessible sampling method was used to recruit participants. A sample size of 34 was calculated by considering a power of 80%, $p = 0.05$ resulting in an effective size equal to 0.35, for the main outcome of self-efficacy [29].

Participants

The participants were invited to the study through announcements in the Tehran University of Medical Sciences diabetes clinic. Forty older adults; consented to participate in the study. Thirty-four participants with diabetes who met the inclusion and exclusion criteria were included.

The inclusion criteria was limited to participants aged ≥ 60 years old with type 2 diabetes [according to the American Diabetes Association (ADA), 2017], who were diagnosed with diabetes [30] according to the PDSME inclusion criteria in the original study [29], at least six months prior to the study. Exclusion criteria included those unwilling to participate and individuals with logistical complications resulting from diabetes; such as a macro vascular disease like Coronary Artery Disease (CAD), Stroke, amputation, if any of these complications resulted in mobility issues preventing attendance to the diabetes self-management program), and cognitive impairment (Abbreviated Mental Test < 7). Participant loss due to follow-up in our study, was defined as an absence from more than two sessions (due to incomplete of instruction), hospitalization at the time of study, or those who later chose to opt out of the program. The causes of participants being lost to follow-up were recorded for future analysis. This study used stratified sampling based on age and gender (age < 70 and age > 70).

Allocation procedures

All of the participants were categorized into four groups: women under 70, women over 70, men under 70, and men over 70. Each group was then randomly divided into one of two subgroups for intervention and control. Both intervention and control subgroups included approximately the same number of applicable participants across each group. This was done because the control and intervention groups were matched for gender and age and to prevent potential confounding of intervention between participants in terms of age and sex.

Allocation was performed over two rounds. Each round included 17 participants through simple random sampling using a STATA 12 package. Random allocation was completed through three trained research assistants. One assistant was responsible for the allocation sequence, another assigned participants into the intervention and control groups according to the allocation sequence, and the remaining assistant performed the baseline assessment and follow-ups for those blind to the allocation groups.

The intervention

Individuals in the intervention group participated in the PDSME program designed by Shakibazadeh [29]. It is the first

and only evidence-based and culture-oriented intervention developed for diabetes in Iran. It is culture-oriented because the educational programs are relevant to the specific culture. For example, participants are instructed on the common cultural misconceptions about nutrition in diabetes; such that they do not need to entirely deviate their diet from their family members' diets. Specific to this cultural context, the rice and breads that are staple-foods for Iranians do not need to be eliminated, rather they need to better understand moderation and healthy preparation techniques. Additionally, to continue to participate in social gathering in which an abundance of food is provided, people managing their diabetes can learn how to proactively adjust their diet, while not fasting or lacking food intake, during the day so that they can still enjoy the similar foods as their family and friends. In terms of physical activities, since most older Iranian women are reluctant to exercise in public spaces such as parks, they can be directed to affordable sports clubs that can accommodate their needs for privacy. This program provides a modified version of the curriculum of American Association of Diabetes Education (ADA) based on seven core aspects of diabetes self-management including: (i) healthy eating, (ii) being active, (iii) blood glucose monitoring, (iv) taking medication, (v) problem solving, (vi) reducing risks and (vii) healthy coping. The PDSME is comprised of eight 2-h educational workshops offered over a 4-week period in this study.

The team of educators included an occupational therapist, a nurse educator, a dietitian, and a general practitioner from an outpatient diabetes clinic in Tehran. A nurse and a general practitioner were certified in diabetes care and education.

An occupational therapist ensured that the educators used in this study adhered to the appropriate instruction guidelines. According to the American Diabetes Association (ADA), occupational therapists are members of the diabetes self-management team. As occupational therapy practitioners are experts at analyzing the functional skills needed to engage in individuals' daily activities, they can provide the necessary education and training for people with diabetes. Occupational therapists do this by targeting maladaptive habits and routines, in turn providing corrections to help individuals develop a healthier lifestyle and reduce the overall progression of the disease. In this program, each member of the education team was first trained on the general principles, necessary rules, as well as the goals and procedures of the PDSME program. Training for the education team members was overseen by the occupational therapy practitioner, who understands the material at an exceptional depth, has exemplified mastery of the program, and was present in each of the education sessions. Furthermore, education team members were additionally trained in their specialized task through protocols derived from the main PDSME guidelines. Each session was attended by 9–13 participants.

This program derived from the PDSME protocol included eight, 2-h self-management diabetes education workshops that were offered over the four week period [29]. There were two sessions per week with 3-day intervals between sessions.

The topics covered in each workshop, alongside the pertinent educators are shown in Table 1. Workshops were meant to be as highly interactive as possible, involving discussions of patients' concerns, their involvement in the programs, and their progress achieved. Moreover, visual aids such as power points were used for some sessions to ensure various forms of communication were utilized. The sequence of each program session proceeded as follows: (i) Evaluation of diabetes self-care behaviors, exploration of participants' motivation, and barriers to change; (ii) active learning of diabetes topics; (iii) setting practical goals to facilitate changes to behavior: participants set 'SMART' goals (i.e. specific, measurable, achievable, realistic and time-bonded) overseen by the assistant of the educator, which contributes to patient participation while increasing sense of self-efficacy [31]; and (iv) answering clinical questions to provide information about diabetes and self-management.

The control group participated in two 30-min routine education sessions. Both sessions were educational and non-interactive and also conducted by the occupational therapist. At the end of each control class, participants' questions were answered by the educator. The first session provided a brief overview of diabetes, and the second session briefly explained the role of nutrition in diabetes (Table 1).

It is important to note that the control group only participated in two non-interactive education sessions, while the intervention group received a PDSME program over eight sessions. This difference allowed us to compare the two intervention groups that participated in the diabetes PDSME and the control group that received routine diabetes education.

Data collection

Before the start of the first diabetes self-management workshop, all baseline measurements were completed. The first and final follow-up evaluations were then performed after the two-week and four-week marks from the start of the program, for all the participants, through a blind evaluator. If participants could not attend these sessions, they were contacted by telephone. Since the baseline assessments were filled in at the beginning of these sessions, participants who missed more than two sessions were considered as a lost to follow-up. Participants were then called, only to record the reason for cessation. The control group participated in two 30-min education sessions in the second and fourth weeks of the program as well as the final evaluations performed the end of the control program, by the blind evaluator. The team verified willing respondents for eligibility and obtained written informed consents.

Table 1 programs in intervention and control groups

Group	Topic of workshops	Educator(s)	Duration of workshops	concepts
Intervention	General diabetes	Occupational therapist	2-h	Evaluation of diabetes self-care behaviors, their motivation and barriers to change
	Nutrition and healthy eating	Nutritionist Occupational therapist		
	Sports and relevant physical activity	Occupational therapist		
	Monitoring blood glucose	Registered nurse Occupational therapist		Active learning of diabetes topics
	Diabetic foot	Occupational therapist		Setting ‘SMART’ goals
	Diabetes and medication	Registered general practitioner Occupational therapist		Answering clinical questions to provide information about diabetes and self-management
	Overcoming self-management barriers to diabetes	Occupational therapist		
	Stress management	Occupational therapist		
Control	Brief overview of general diabetes	Occupational therapist	30 min	Giving brief knowledge answering clinical questions
	Brief overview of nutrition	Occupational therapist		

Measurements

Primary and secondary outcomes

Demographic information and clinical characteristics included: age, gender, highest education level, employment status, marital status, time since diagnosis with diabetes, and main mode of current treatment. Diabetes complications including neuropathy, retinopathy, nephropathy, and cardiovascular problems were completed at the interview session for those who were eligible (Table 2).

The primary outcome was the change in the self-efficacy score as measured by the Diabetes Management Self-Efficacy Scale (DMSES) questionnaire [32]. Secondary variables were validated and reliable questionnaires, Diabetes Quality of Life-Basic Clinical Inventory (DQoL-BCI), Patient Health Questionnaire-9 (PHQ-9), Diabetes Self-Management Education Scale (DSMES), and adult Social-Emotional Loneliness Scale-Short form (SELSA-S).

The Diabetes Management Self-Efficacy Scale (DMSES) includes 20 questions. The Persian version of the questionnaire divides the questions into five factors: specific nutrition, general nutrition, blood glucose management and weight control, exercise activity, and medical self-efficacy. Self-efficacy is defined as measures of the extent to which respondents are confident that they can manage their blood glucose level, foot care, medication, diet and level of physical activity. A response to a 5-point scale (1 to 5) from “I cannot do at all” to “I’m sure I can do it” was designated. Higher scores indicate better self-efficacy [32]. This questionnaire was translated into Farsi and then validated. Questionnaire validity and reliability were previously assessed in Iran by Noroozi and Tahmasebi in 2014 while internal consistency was confirmed with a

Chronbach’s alpha coefficient of 0.92. The construct validity of the instrument was determined using factor analysis and criterion validity. Criterion-related validity showed that the DMSES was a significant predictor of the diabetes self-management ($R = 0.61$; $P < 0.001$) [33].

Self-care activity were assessed using the Diabetes Self-Management Scale (DSMS), which was prepared by Rahimian Booger [2013] based on the Summary of Diabetes Self-Care Activity measure (SDSCA) [34, 35] and the six items of the Chinese self-management diabetes scale [25]. The DSMS includes 14 items (9 items of weekly self-management, two items of monthly self-management, and three items of annual self-management). A higher total score indicated higher levels of self-management behaviors. Cronbach’s alpha ($n = 500$) for weekly, monthly and annual self-management subscales was 0.95, 0.86, and 0.67 respectively, and for the total scale, 0.95 was obtained. Additionally, four-week interval test-retest reliability of person with diabetes for the weekly, monthly, and annual self-management behavior was 0.92, 0.90, and 0.97, respectively, indicated the higher reliability of scale [36].

Quality of life was measured using a Diabetes Quality of Life-Brief Clinical Inventory scale (DQOL-BCI). It is comprised of 15 questions in two sets which are graded based on a 5-point Likert scale. One set of questions, rated from 1 (completely satisfied) to 5 (completely dissatisfied), inquired about participant satisfaction with diabetes treatment and their quality of life. The other set of questions inquired about the frequency of the negative effects of diabetes itself or any associated treatments, with scores ranging from 1 (never) to 5 (always). Questions within the sets were divided into two categories: Participants’ satisfaction with their diabetes management and predictors of involvement in self-care regimens.

Table 2 Characteristics of participants at baseline

Variable	Intervention group (n = 17)	Control group (n = 17)	Test	p value
Age				
Mean (SD)	66.29 (6.44)	69.12 (7.77)	t test	0.267
Gender n (%)				
Female	8 (47.06)	6 (35.29)	χ^2	0.49
Male	9 (52.94)	11 (64.71)		
Highest education level n (%)				
Less than secondary school	5 (29.41)	7 (41.18)	χ^2	0.924
Secondary school	4 (23.53)	4 (23.53)		
Higher than secondary school	8 (47.06)	6 (35.29)		
Employment status n (%)				
Unemployed/housewife	5 (29.41)	5 (29.41)	χ^2	0.881
Job at present	2 (11.76)	3 (17.65)		
Retired	10 (58.82)	9 (52.94)		
Marital status n (%)				
Single			χ^2	0.29
Married	14 (82.35)	16 (94.12)		
Divorced				
Widowed	3 (17.65)	1 (5.88)		
Duration of diabetes n (%)				
< 5	4 (23.53)	6 (35.29)	χ^2	0.257
5–10	6 (35.29)	2 (11.77)		
> 10	7 (41.18)	9 (52.94)		
Main mode of treatment n (%)				
Food diet	1 (5.88)	1 (5.88)	χ^2	0.443
Oral hypoglycemic	10 (58.82)	6 (35.29)		
Insulin	3 (17.65)	2 (11.77)		
Oral hypoglycemic and insulin	3 (17.65)	8 (47.06)		
Retinopathy n (%)				
Yes	5 (29.41)	3 (17.65)	χ^2	0.419
No	12 (70.59)	14 (82.35)		
Nephropathy n (%)				
Yes	2 (11.76)	5 (29.41)	χ^2	0.203
No	15 (88.24)	12 (70.59)		
Neuropathy n (%)				
Yes	2 (11.76)	4 (23.53)	χ^2	0.368
No	15 (88.24)	13 (76.47)		
Cardiovascular n (%)				
Yes	8 (47.06)	8 (47.06)	χ^2	1:000
No	9 (52.94)	9 (52.94)		

Higher scores indicate higher quality of life [37]. This questionnaire was translated into Farsi by Mirfeizi (2012). The questionnaire's validity and reliability were evaluated within an Iranian population and content was credited with good validity (CVI values >0.75 and CVR values >0.99), internal consistency ($\alpha = 0.75$) and test–retest reliability (ICC = 0.81). The reliability was determined using Cronbach's alpha ($\alpha = 0.78$) [38].

The Patient Health Questionnaire-9 (PHQ-9) used to assess depression consisted of 9 items. PHQ-9 scores range from 0 to

27 and utilizes a three-point Likert spectrum. Scores below 5 indicate psychological well-being and no symptoms of depression while scores ranging from 5 to 9 indicate mild depression, scores between 10 to 14 indicate moderate depression, and scores 15 and above indicate severe depression. PHQ-9 is the most appropriate tool for screening and diagnosing depression in chronic diseases [39]. The PHQ-9 used was translated into Farsi and its validity and reliability were assessed by Dadfar et al. (2018), indicating high internal consistency using Cronbach's alpha ($\alpha = 0.88$). One-week test-

retest reliability was 0.79. The PHQ-9 correlated 0.64 with PHQ-15, −0.35 with WHO-5, and 0.70 with BDI-13, indicating good construct and criterion-related validity [40].

Social-Emotional Loneliness Scale-Short form (SELSA-S) consists of 15 items and three subscales of romantic loneliness (five items), family loneliness (five items), and social loneliness (five items). Emotional loneliness scores were obtained from the cumulative scores of romantic and familial subscales, however, this questionnaire consists of both social loneliness and emotional loneliness. For both social and emotional loneliness, a score above 15 indicated marked loneliness [41]. Validity and reliability of the SELSA-S have been previously studied in Iran by Jowkar et al. (2011) [42]. The resulting correlation of this scale with other measures shows favorable convergent and divergent validity of the questionnaire. Furthermore, Cronbach's alpha coefficient was used to measure the reliability of the questionnaire. They reported Cronbach alpha values of 0.92, 0.84 and 0.78 for romantic, social, and familial subscales, respectively.

Statistical analysis

The normality of distribution was assessed and because the distribution of main outcomes was near to normal, univariate and multivariate ANOVA repeated measurement tests was subsequently utilized. Due to the similarity between intervention and control group in terms of age, sex, education, time since diagnosis with diabetes, and method of treatment, statistical adjustments were only performed for baseline values of main outcomes. *P*-values <0.05 were considered as statistically significant outcomes.

Ethical consideration

Written permissions were obtained from authors of tools used in this study. All patients were informed of the study outline, were assured confidentiality of their collected data, and each participant completed and signed a waiver of informed consent. The study was approved by Shahid Beheshti University of Medical Sciences Ethics Committee (IR.SBMU.RETECH.REC.1398.015).

Results

Feasibility

Of the 40 people who volunteered to participate in the study, 34 participants were eligible and randomly allocated into control and intervention groups during recruitment. A rationale was provided by individuals who refrained from participating in this study, which included: one instance of hospitalization, three patients lacking availability to participate, and two

patients were traveling at the time of the study. The Baseline assessment was carried out for the 34 eligible participants (Fig. 1).

The participant retention rate was thus 100% ($n = 34$) for the 4-week study period; 14 participants in the intervention group had 100% attendance at all study sessions. Reasons for absences were not related to the intervention (e.g., travel, doctor appointment and caring of grandchild).

Acceptability

Finally, participants in the intervention group were asked to write their holistic evaluation of the program and share their experiences, comments, and suggestions. The comprehensive result of these participant evaluations indicated that participants held the program in a unanimously positive regard, with no negative evaluations. The information imparted from this feedback indicated that participants were highly receptive to the Persian diabetes self-management education in its adaptation to older adults. One participant responded, "I like the group setting and I'm glad I was able to use the experiences of my peers to [prompt me to] follow-up [on] my foot ulcers". Another participant responded, "By participating in this program, I was able to regulate and increase my physical activity program". Two participants responded, 'I figured out how to adjust my diet and know my misconceptions about nutrition' while another participant commented, 'I like the program and how much better it would be if I could [have] participated in this program from the beginning of the diagnosis of diabetes'. The remaining patients did not provide further comments.

All the eligible participants completed the study. The mean age of participants was 67.53 ± 7.23 years and 42.28% of them were female. Just 45% of the participants had >10-years of experience living with diabetes mellitus. More than 70% of participants had no retinopathy, 79.41% had nephropathy, and 82.35% had neuropathy complications. Moreover, 67.65% of the participants had at least one diabetes related complications (retinopathy, neuropathy, and etc.). There was not any statistical difference between control and intervention groups in terms of age, sex, education, duration of diabetes, and other preexisting diseases (Table 2).

Primary outcome measures

The repeated test measures showed a significant improvement in the medical self-efficacy domain, particularly for the intervention group as compared to the control group ($p = 0.02$). However, the significance of repeated test results after two weeks was less notable than the changes elucidated after the four week duration. There was no significant difference between the intervention and controls group in the other domains of self-efficacy and questionnaire scores (Table 3).

Fig. 1 CONSORT Flow Diagram

Secondary outcome measures

The overall DQOL score increased significantly more in the intervention group than the control group (mean difference between baseline and final score in intervention 4.41 ± 6.30 and control group 0.82 ± 5.27) ($p < 0.05$). With respect to secondary outcome domains: satisfaction of treatment

improved from 22.82 ± 3.28 to 24.29 ± 3.10 after the four-week follow-up ($p < 0.05$), but there was no significant difference between intervention and control groups in the domain of predictors for self-care behavior.

After the final follow-up, the participants of both groups showed an overall increase in the mean self-care scores compared to the baseline. An even greater improvement was

Table 3 clinical outcome showing changes over time and group

OUTCOME	Baseline data		Two-week data		Four-week data		Mean difference c ^a	
	Intervention group (SD) (n = 17)	Control group (SD) (n = 17)	p value	Intervention group (SD) (n = 17)	Control group (SD) (n = 17)	p value	p value a [*]	p value b [*]
Perceived self-efficacy								
General nutrition	19.41(3.89)	22.12(3.04)	0.03	18.79(3.52)	22.00(2.85)	0.01	20.24(4.55)	22.12(2.96)
Specific nutrition	17.24(4.41)	19.53(4.36)	0.14	17.00(3.32)	19.24(4.59)	0.11	17.94(4.05)	19.53(4.77)
Blood sugar	11.71(3.27)	13.71(1.36)	0.03	11.00(1.66)	13.88(12.27)	0.02	12.76(1.39)	13.88(1.495)
Medical control	18.65(2.18)	19.59(0.71)	0.10	18.60(1.70)	19.71(0.59)	0.03	18.76(1.75)	19.76(0.56)
Physical activity	10.56(3.10)	12.88(2.595)	0.03	11.54(2.53)	12.88(2.31)	0.12	12.53(1.74)	13.06(2.38)
Overall score	77.65(11.56)	87.82(10.16)	0.01	77.93(10.35)	87.71(9.82)	0.01	82.24(10.82)	88.35(10.43)
Self-care activity								
Weekly	45.29(7.92)	42.29(11.56)	0.38	48.77(3.38)	45.53(9.58)	0.29	49.24(9.95)	43.00(9.14)
Monthly	10.76(6.25)	12.00(5.85)	0.56	10.52(6.39)	15.12(4.30)	0.02	12.18(6.435)	13.94(4.175)
Annually	2.47(0.62)	2.47(0.72)	1.00	2.68(0.58)	2.53(0.72)	0.50	2.76(0.44)	2.53(0.62)
Overall score	58.19(11.07)	56.76(12.14)	0.66	61.94(12.26)	63.18(11.50)	0.77	64.44(13.81)	59.47(10.76)
Depression	10.53(6.41)	7.35(6.17)	0.15	8.59 (7.380)	7.53(5.68)	0.64	8.35(7.26)	7.00(4.78)
Quality of life								
Predictor of self-care behavior	31.59(5.37)	33.47 (6.55)	0.33	33.385(5.08)	33.71(5.52)	0.09	34.53(5.30)	34.53(4.89)
Satisfaction of treatment	22.82(3.28)	23.24(4.25)	0.75	24.12(2.78)	21.82(3.97)	0.06	24.29(3.10)	23.00(3.26)
Overall score	54.41(7.73)	56.71(8.9)	0.43	57.5(6.99)	55.53(8.6)	0.47	58.82(7.71)	57.53(7.21)
Loneliness								
Social	14.59(2.88)	10.59(3.62)	0.01	14.45(4.97)	10.71(4.43)	0.03	14.00(4.18)	11.12(3.87)
Familiar	11.59(4.925)	8.65(2.96)	0.04	12.40(4.97)	9.24 (3.09)	0.03	10.53(4.50)	8.82(2.53)
Romance	14.76(5.345)	12.47(3.68)	0.15	15.10(4.43)	12.35(3.67)	0.06	13.94(4.085)	13.18(3.64)
Overall score	40.94(11.56)	31.71(8.21)	0.01	41.95(10.25)	32.29(8.61)	0.01	38.47(10.74)	33.12(7.57)

a^{*}: Without adjustingb^{*}: Adjusted for the baseline valuesc^{*}: Mean difference between baseline and four-week data

observed in the intervention group compared the control group, although the mean difference between two groups was not statistically significant. The results showed no significant difference between the intervention and control groups ($p = 0.71$).

After the two-week follow-up, loneliness increased in both the intervention and control groups. However, after four weeks, the intervention group showed a decline in loneliness, indicating improvement in this variable, whereas the control group trend continued to increase. Ultimately, the results showed no significant change in the control and intervention groups in terms of loneliness after controlling for baseline data ($p = 0.75$).

Results showed that 82.7% of participants in the intervention group and 52.9% of participants in the control group had some degree of depression (mild, moderate, and severe). After four weeks of intervention, this percentage reached 64.6% and 58.8% in the intervention and control groups, respectively (Table 3). Reported depression in the intervention group continued to improve over time, while worsening in the control group after two weeks before eventually decreasing after four weeks. Despite the PHQ-9 score decrease in the intervention group after the four week duration, there were no significant differences between the control and intervention groups after the four-week follow-up ($p = 0.38$) (Table 2).

Discussion

This pilot-study shows that implementing a PDSME is both feasible to the target community and acceptable in the program design. One of the goals of the pilot study was to demonstrate that this intervention could successfully recruit and retain participants. The trial protocol was acceptable in execution and retention rates were excellent over the four-week duration (100%).

The purpose of this study was to evaluate the overall effectiveness of PDSME on quality of life, self-efficacy, self-management, and reported depression and loneliness in older adults with type 2 diabetes in the targeted demographic. Results show that the PDSME could improve the quality of life and the domain of medical self-efficacy in this population.

A previous study has shown that the PDSME is effective in clinical and psychosocial contexts in adults with diabetes. In this prior study, participants included adults aged >18 years old, however, the authors did not analyze the results based on the age groups, which may limit the direct application to older demographics [29]. As different sectors of health management can be challenged with increasing age, there is considerable heterogeneity in the results of studies related to older adults that require specific education and health care [43].

Quality of life

In this study we observed that the PDSME can be effective in improving the quality of life of older adults with diabetes. This positive result is consistent with previous studies that indicate diabetes self-management education can improve quality of life in both older [44] and younger adults with type 2 diabetes [45]. Diabetes is a known class of chronic diseases that markedly decreases individuals' quality of life [46, 47]. Lower quality of life is associated with infrequent involvement in treatment and therefore reported increases in diabetes complications and mortality [46]. Whereas the main purpose of diabetes management is reduction risk or delay of diabetes complications in younger adults, the essential aim in older adults is diabetes self-management, and improvement of quality of life.

Self-efficacy

Our results also indicated that the domain of medical self-efficacy notably improved in the intervention group, while no significant changes were observed with respect to other domains of self-efficacy (exercise, diet and blood sugar). Goode (2016) demonstrated that participants had more confidence in the domains of medication management and glucose self-monitoring. In their study, the domains in which adults with type 2 diabetes showed lower confidence were nutrition and physical activity [48] and these result was consistent with our study. According to the findings of this study and the feedback received from the participants during their evaluation and intervention session after treatment, it has been elucidated that on average, older adults have more confidence, trust, and dependence on the medical and pharmaceutical system than in their own self-efficacy. For example, in the case of rising blood sugar they prefer to see their doctor to change their medication, rather than increase physical activity or change their diet.

Before adjusting baseline values, the repeated test measures indicated a significant difference in the mean score of self-efficacies compared over the test intervals. Perhaps, if the sample size were considerably larger, changes to self-efficacy would be markedly positive after controlling for baseline values. Initially, results showed that after two weeks the mean scores of some self-efficacy domains decreased before eventually increasing after four weeks. After inquiring the evaluator, it was suspected that this was due to the "reconceptualization response shift" concept. This refers to the participants' growth in understanding new instructions to a concept that was previously meaningless to them [49]. After the first evaluation, despite direct instruction, the participants may not have fully comprehended the concept of self-efficacy, but after attending two weeks of workshops, they likely gained a deeper understanding of self-efficacy in diabetes management. Therefore, it is possible that after two weeks they gained

a better understanding of self-efficacy. This potentially explains the phenomenon of scores dropping and then increasing across sessions, by the end of the study.

In addition, our intervention had an effect on some domains of self-efficacy scores but not on all of them. Nutrition and physical activity were less affected by our intervention needs and more so by decision making and planning skills. Studies have shown that executive functioning skills, such as decision making and planning skills, decline with age [50]. Since the self-management program used in this study had been adapted from programs designed for younger people, further adjustments are needed to continue to make this program more applicable to older demographics.

Self-care behavior

This study showed no significant improvement in self-care behaviors. Results are consistent with Zhang et al. (2019) and Jie et al. (2015) studies previously conducted on adults with type 2 diabetes, in China [51, 52]. Realistically, the results of these studies are not entirely comparable to the demographic present in this study. Because the Chinese study utilized various interventions and measurements for assessing self-care behavior, and this study used a self-efficacy tool developed by a researcher, the prior study did not consider separate domains for diabetes self-management behaviors. On the other hand, various studies, in addition to being defined as a dependent variable in diabetes self-management, depression has been previously considered as a barrier that confounds. Glasgow et al. (2001) conducted a study to identify psychosocial barriers to diabetes self-management and quality of life. They stated that depression as a barrier could be related to diabetes self-management. In the present study, older adults with diabetes in the intervention group had some degree of depression which can be considered as a factor that has hindered the improvement diabetes self-management during self-efficacy programs [53].

Depression

In our study, 82.7% of participants in the intervention group and 52.9% of the participants in control group had some degree of depression (mild, moderate, or severe). The results of this study demonstrated that the depression score in the intervention and control groups did not change significantly. This result is consistent with the result of study Zagarins et al. (2012) who showed that diabetes self-management education caused a change in hemoglobin A1C in adults and older adults with type 2 of diabetes after six months of intervention. This is important to note as increases of HbA1C are correlated with increases to depressive symptoms and in some cases mortality. This change also reduced emotional distress associated with diabetes during this period but there was no change in

depressive symptoms [54]. Depression is a complex condition that can be influenced by various factors. Since participants in this study were older adults and depression is a common condition in this age group, longer-term and multi-approach interventions may be needed to address this issue [53]. In addition, self-management education-based interventions typically do not directly target depression [54]. Thus, interventions that specifically focus on the treatment of depression may also be needed for older adults. Furthermore, some older adults in this study also had comorbidities, such as Parkinson's and cardiovascular disease that can exacerbate depression. Therefore, this self-management program is not suited to address the complex sources and emotional complexities of depression. Thus, it is recommended that the program be broadened to include mental health sessions, such as Cognitive Behavioral Therapy (CBT).

Loneliness

Loneliness is one of the major factors affecting the development of depression. Studies have also shown that depression is associated with an increase in HbA1c level, a risk of diabetes complications and mortality [55–60]. In our study, during the education and evaluation sessions, we received a large number of reports of patients reporting hardships in their marriage. Most participants' dissatisfied with their marital affairs stated; 'My husband/ wife does not understand my physical and emotional state and I receive no compassion or satisfaction in my relationship with him/her'. The lack of targeted improvement in the romantic domain of loneliness also echoes this finding. A prior qualitative study that explored the factors affecting diabetes self-care in Iranian patients, identified the lack of family support as a main barrier to wellbeing, given the significant negative effects of loneliness in older adults with type 2 of diabetes [61]. It is suggested that family attendance at workshops be included in the older adults' self-management education. Since the results of this study elucidate the impact of loneliness in older adults, especially in the romantic domain, it seems that the attendance of family members, especially for romantic partners, in education sessions greatly contributes to the success of these programs. Familial and social supports can increase mutual information and comprehension of the condition for older adults with type 2 diabetes, ultimately contributing to an increase in patient participation in self-management programs.

Participants often expressed that involvement in the group-based PDSME enabled them to share, and make better use of the experiences of their peers. Additionally, those participating in these sessions, performed in the diabetes clinic, have better access to the health care team as well as to accessing periodic checkups. Moreover, they acknowledged that the attendance of family members, especially the spouse, during this program motivates them to pursue a self-care program.

In addition, most participants, especially men, said in the assessment sessions that they had difficulty with sex due to their diabetes and required education on this subject, however, the program did not include sex education. Given the potential impact of diabetes on sex, especially in older individuals, it seems that sex education should be considered in diabetes self-management education programs for older adults with diabetes.

Strengths and limitation

According to our knowledge, this study is the first RCT in older Iranian adults patients with type 2 diabetes that draws comparisons against a control group, considered a wide range of health and psychological outcomes, and had all evaluation steps performed in a single blind manner. The other strength of our study is the use of a theory- and culture-based diabetes self-management program.

Because of the small sample size, despite the randomly assigned control and intervention groups, there was a difference between the two groups in some domains at the baseline. Therefore, we had to adjust for baseline values. We observed non-significant improvement in some outcome scores. Perhaps studies with larger sample sizes could detect a significant effect using otherwise similar parameters. The results of this study can be used for sample size calculation for future studies. In this study, most of older adults had some degree of depression that influenced the different outcomes. Since depression is one of the most common diseases in older adults and has both direct and indirect impacts on diabetes self-management, future studies should include medical and non-medical programs to control depression in older adults with diabetes. Short-term effects of this program on different outcomes were evaluated. Long-term effects on older adults with diabetes need to be examined as well. Our program focused on older adults within a given community. As the life context has a significant impact on health conditions of older adults, future programs may consider the impact of self-management education in different contexts, such as home-care or day-care centers for older adults.

Conclusion

Overall, this pilot study indicates that a PDSME appears to be a feasible and acceptable way to provide patients with necessary information to aid self-management in older people with diabetes type 2.

Results indicate that the PDSME shows promising results in improving the quality of life ($p < 0.04$) and medical control domain of self-efficacy ($p = 0.02$) in older adults with type 2 of diabetes. However, this is not enough to recommend utilizing it in clinical settings for improvement of diabetes

management. Convincing evidence is needed to ensure this program has the potential to improve other domains of self-efficacy. Moreover, interventions that focus on the treatment of depression and family attendance at workshops may also need be included to improve the older adult self-management program before recommendations can be given to care providers. In order to generalize the results, a larger study population with long term follow-up is required.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

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