Original Article

Effectiveness of Diabetes Self-Management Education on Distress and HbA1C among Indian Type 2 Diabetes Mellitus Patients: A Randomized Controlled Trial

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Abstract

Introduction: The interrelationship of diabetes with mental illness has increased in recent years. Diabetes-related distress is the emotional burden, stress, and worries associated with diabetes, which does not reach the threshold for depressive disorder. A diabetes self-management education (DSME) is a structured educational approach to improve glycemic control and diabetes-related distress. This study aimed to assess the effectiveness of DSME in comparison with usual diabetes care in improving glycemic control and diabetes-related distress. **Material and Methods:** This is a single-center, parallel randomized controlled trial. A total of 106 participants were recruited for both intervention and control groups with 53 participants each. The control group received only routine outpatient department (OPD) care. The intervention group received DSME in addition to routine OPD care. Diabetes-related distress and HbA1C were assessed after 3 months. The data were analyzed using IBM Statistical Package for the Social Sciences (SPSS) version 25. Per-protocol analysis was done. **Results:** Of 127 patients screened, 106 met the eligibility criteria and were randomized. At 3-month follow-up, the reduction in mean HbA1C, fasting blood sugar (FBS), postprandial blood sugar (PPBS), and diabetes distress were significant in the intervention group compared with the control group (p 0.001). The mean HbA1C reduction in the intervention group was significant (mean difference: -1.3, SD: 0.4). The mean DDS had decreased significantly in the intervention group from 2 to 1.2 (mean difference: -0.8, SD: 0.1). **Conclusion:** The DSME was effective in improving the glycemic control, diabetes-related distress, and self-care among type 2 diabetes (T2DM) mellitus patients.

Keywords: Diabetes-related distress, DSME, HbA1C, type 2 diabetes mellitus

Introduction

Diabetes mellitus is a chronic condition with a major impact on the lives and well-being of individuals, families, and communities worldwide. Around 77 million people in India are living with diabetes at present, and it is projected to reach 101 million by 2030 and 134 million by 2045.[1] Diabetes-related distress is the emotional burdens, stress, and worries associated with diabetes, which does not reach the threshold for depressive disorder as per the Diagnostic and statistical manual of mental disorders (DSM) and International classification of diseases(ICD) classification.[2,3] Diabetes distress remains largely undiagnosed because most patients do not raise their emotional concerns. Prolonged and un-addressed diabetes distress impairs the glycemic control and makes the patient more prone to micro- and macrovascular complications of diabetes.[4]

Diabetes self-management education (DSME) is defined as the "ongoing process of facilitating the knowledge, skills, and ability necessary for diabetes self-care as well as activities that assist a person in implementing and sustaining the behaviors needed to manage this condition on an ongoing basis, beyond or outside of formal self-management training."[5] DSME helps to improve glycemic control of the patients, decrease diabetes-related distress, and also improve diabetes self-care behaviors such as medication adherence, foot care, blood sugar

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monitoring, risk reduction behaviors, healthy coping, and good problem-solving skills.[6-10]

One of the challenges of diabetes management in the Indian setting is the lack of patient-centered care.[11] Provider-centered approach ignores the concerns of the patient that may lead to diabetes-related distress. Illiteracy, ignorance, and poor patient knowledge of diabetes are the other challenges in India. In India, though there is an integration of major noncommunicable diseases under the National Program for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS), mental health care was not a part of diabetes care.[12] DSME is rarely practiced in India, and we lack national standards for the same.[11] Research studies examining the impact of education interventions on metabolic control are limited in Indian settings. With this background, our study aimed to evaluate the effectiveness of DSME on glycemic control and diabetes-related distress among patients with diabetes mellitus in a tertiary care center in North India.

Methodology

Study design and setting

A single-center, parallel randomized controlled trial was conducted in Diabetology Clinic, AIIMS Rishikesh, Uttarakhand, from 2020 June to 2021 December. We have included Type 2 Diabetes mellitus (T2DM) patients with age ≥30 years who have been diagnosed for at least 1 year who were possessing their recent blood test results of the last three months, and with sufficient Hindi communication skills. We have excluded patients who were pregnant or lactating, have psychiatric/psychological disorders with cognitive impairments and could not complete interviews, have life-threatening diseases, have recent acute complications or injuries, and with a history of recent hospitalizations**.**

Data collection

A structured questionnaire was pilot tested, which had baseline socio-demographic details of the participants such as age, gender, occupation, education, duration of diabetes, type of treatment, and presence of and type of complications of diabetes and comorbidities. Anthropometric measurements such as height, weight, body mass index (BMI), and blood pressure were assessed by standard methods. Recent laboratory investigations such as glycated hemoglobin (HbA1C), fasting blood sugar (FBS), and postprandial blood sugar (PPBS) were collected from medical records. Translated validated Diabetes Distress Scale (DDS-17), Hindi version, was used to assess the diabetes distress. The DDS-17 consists of 17 items, which assess distress related to diabetes in four subscales: emotional burden, physician-related distress, regimen-related distress, and interpersonal distress.[13] A 6-point Likert scale rated the response to each item of the scale. Summing up all item scores and dividing by 17 give the mean item score. The interpretation of the score is as follows: <2.0 indicates "little or no distress," 2.0–2.9 indicates "moderate distress," and ≥ 3.0 indicates "high distress." Diabetes self-management questionnaire (DSMQ) was used to assess diabetes self-care activities of the participants in four dimensions such as "glucose management," "physical activity," "dietary control," and "healthcare use."[3]

The sample size was calculated using the effect of intervention on HbA1C.[14] Considering the two-way hypothesis with an alpha error of 0.05 and a power of 80%, the effect size comes to be 0.5. The sample size was calculated using G Power as 34. Considering the dropouts of 20%, the minimum sample size was 41. We enrolled 53 participants in each group with a total of 106 participants.

Data collection details are provided in Consolidated standards of reporting trials (CONSORT) format [Figure 1].[15] Among 127 patients assessed for eligibility, 21 were excluded. Fourteen were not meeting the inclusion criteria, five denied to participate and two discontinued the intervention in between. Eligible participants were randomly allocated in 1: 1 ratio to the intervention and control groups in which the control group received usual diabetes care only whereas the intervention group received DSME in addition to the usual diabetes care. We have performed permuted block randomization with fixed block sizes of 4 or 6. The randomization table was prepared by the departmental staff of Community and Family Medicine. The allocation was done using https://www.sealedenvelope.com.[16] Participants and researchers were aware of allocation. One of the diabetes educators (outcome assessor) who were asked to fill out the DDS-17 was masked for allocation. Written informed consent was obtained before the study. DSMQ was self-administered with minimum interference of researcher.

The intervention

The detailed script for DSME has been prepared before the intervention with the help of diabetologist, community medicine faculty, and two certified diabetes educators with six years of experience in diabetes training and education. The script was based on four theories: self-regulation theory, dual process theory, self-determination theory, and social learning theory.[17] Self-regulation theory includes the awareness of diabetes, cause, timeline, possible consequences, and effectiveness of treatment.[18] Dual process theory ensures the active involvement of the participants in the process of learning. The difference between controlled and autonomous motivation was explained by the self-determination theory.[19] Social learning theory explains the individuals' perceptions of their ability and follow through on action plans.

The DSME consists of two sessions 60 minutes each and was conducted by the researcher along with dietician and a supporting staff trained in diabetes care. The caregivers were allowed to attend the session. The first session presents the general awareness of diabetes and two of the self-care strategies such as diet and exercise. The second session after 15 days covered foot care, medication adherence, blood glucose monitoring, risk reduction strategies, and healthy coping skills. The educational tools were designed in an appropriate manner with charts/videos/PowerPoint presentations in the Hindi language mainly. The participants were encouraged to

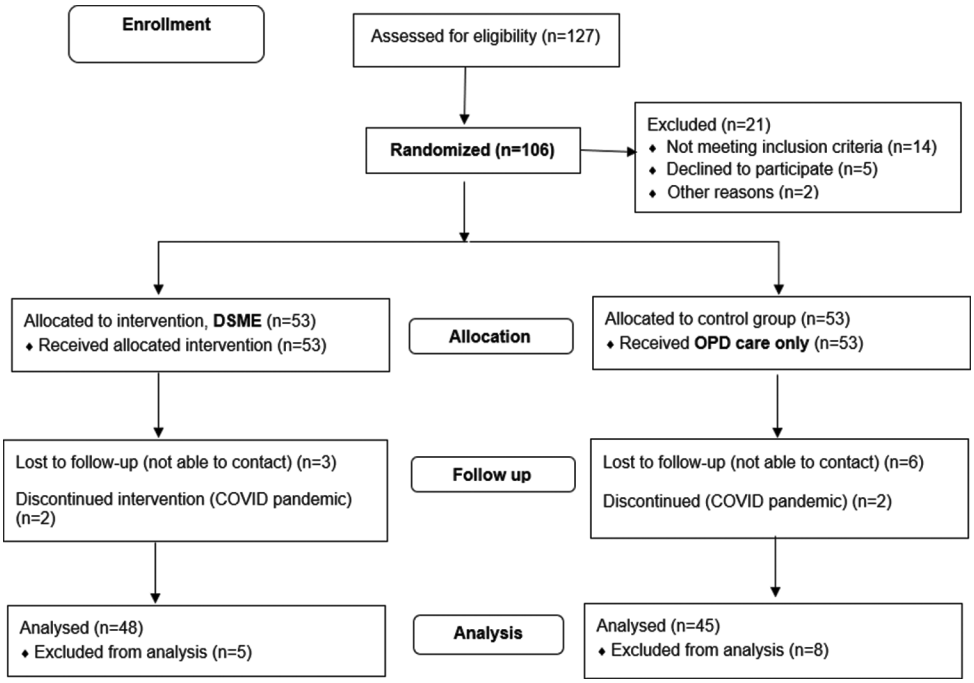

Figure 1: Diabetes self-management education intervention (DSME): Randomized controlled trial (RCT) CONSORT diagram

share their knowledge and success stories to motivate others. The sessions were conducted twice weekly in OPD in groups of 7–10 each. As a part of an ongoing self-care strategy, the participants were added to a diabetes self-care WhatsApp group to share their daily diabetes routine, blood sugar charts, success stories, and queries. Good efforts from each of the participants were appreciated on this social platform. Both groups were followed up after 3 months. FBS, PPBS, HbA1C, DDS-17, and DSMQ were completed at the follow-up.

Data entry and analysis

Data were analyzed using IBM Statistical Package for the Social Sciences (SPSS) version 25 (trial version). The change in the mean of the outcome variables was assessed within groups by paired *t*-test, and between-group comparison was done by the unpaired *t*-test. Mann–Whitney U-test was used for FBS, PPBS, and HbA1C since the data were not normally distributed. The statistical significance was considered at a *P* value of <0.05. The associations between the categorical variables were done with Pearson's Chi-squared test/Fisher's exact test. Analysis of covariance (ANCOVA) was used to adjust for baseline differences in the outcome variables. Per-protocol analysis was done. More than 20% loss to follow-up was considered threat to validity. Ethical approval was obtained from the Ethics Committee (AIIMS/IEC/20/362) of AIIMS Rishikesh. The trial was registered in the Clinical Trial Registry of India (No. CTRI/2021/03/031830). The confidentiality and anonymity of the participants were maintained throughout.

Results

Baseline characteristics

The mean age of the study participants was 53.4 (10.3) years. The socio-demographic profile and diabetes characteristics were comparable between the two groups at baseline, *P* > 0.05. The mean BP, FBS, HbA1C, and diabetes self-care scores were also comparable between the groups at baseline (*P* value >0.05). The mean PPBS, BMI, diabetes distress score total, and all other subscales except interpersonal distress were significantly higher in the control group compared with the intervention group at the baseline (*P* value <0.05). Nearly half of the study participants were having diabetes for a duration of <5 years and three-fourths oral hypoglycemic agents (OHA) alone when compared to OHA and insulin. A similar proportion of the participants had at least one complication of diabetes. Hypertension was the most commonly reported comorbidity in both groups [Table 1].

The outcome measures at 3-month follow-up

At 3-month follow-up, the reduction in mean HbA1C, FBS, PPBS, and diabetes distress were significant in the intervention group compared with the control group (p 0.001). The control group had a significant reduction in emotional burden only (p 0.03) [Table 2]. The mean HbA1C reduction after 3 months from the baseline in the intervention group was significant, from 9% to 7.7% (mean difference: -1.3, SD: 0.4), and the magnitude of this reduction significantly differed between the two groups (difference in the change: Intervention–control group is 0.48 with *P* 0.03). The mean DDS had decreased significantly in the intervention group after 3 months, from 2 to 1.2 (mean difference: -0.8, SD: 0.1), and the magnitude of this reduction significantly differed between the two groups (difference in the change: Intervention–control group is 1.15 with *P* 0.04). Loss to follow-up was 9% in the interventional group and 15% in the control group.

Table 1: Baseline socio-demographic, clinical, and metabolic profile of the participants including diabetes distress and diabetes self-care activities

Characteristics	Total (*n*=106)	Intervention group (*n*=53)	Control group (*n*=53)	*P*
Age in years, mean (SD)	53.4 (10.3)	55.30 (10.5)	51.45 (9.9)	0.06[a]
Gender, *n* (%)				
Male	73 (68.9)	39 (73.6)	34 (64.2)	0.40[b]
Female	33 (31.1)	14 (26.4)	19 (35.8)	
Level of education, *n* (%)				
Primary	25 (23.6)	12 (22.6)	13 (24.5)	0.57[b]
High school	28 (26.4)	16 (30.2)	12 (22.6)	
Intermediate	18 (17)	9 (17)	9 (17)	
Graduate	22 (20.8)	8 (15.1)	14 (26.4)	
Postgraduate	13 (12.3)	8 (15.1)	5 (9.4)	
Duration of diabetes in years, *n* (%)				
1–5	50 (47.2)	24 (45.3)	26 (49.1)	0.93[b]
6–10	31 (29.2)	16 (30.2)	15 (28.3)	
>10	25 (23.6)	13 (24.5)	12 (22.6)	
Treatment, *n* (%)				
Only oral hypoglycemic agent (OHA)	79 (74.5)	42 (79.2)	37 (69.8)	0.27[b]
Insulin+/-OHA	27 (25.5)	11 (20.8)	16 (30.2)	
Presence of complications of diabetes, *n* (%)	53 (50)	29 (54.7)	24 (45.3	0.33[b]
Types of complication				
Diabetic neuropathy	34 (32.1)	16 (30.2)	18 (33.9)	
Diabetic nephropathy	2 (1.9)	2 (3.8)	0	
Diabetic retinopathy	3 (2.8)	2 (3.8)	1 (1.9))	
Others	1 4 (13.2)	9 (16.9)	5 (9.4)	
Presence of comorbidity, *n* (%)	52 (49.1)	28 (52.8)	24 (45.3)	0.56[b]
Type of comorbidity				
Hypertension	31 (29.2)	17 (32.1)	13 (24.5)	
Cardiovascular disorders	7 (6.6)	5 (9.4)	2 (3.8)	
Dyslipidemia	7 (6.6)	5 (9.4)	2 (3.8)	
Hypothyroidism	7 (6.6)	1 (1.9)	6 (11.3)	
BMI, mean (SD)	26.4 (5.6)	25.2 (4.6)	27.7 (6.3)	0.02
Body mass index (BMI), *n* (%)				
Normal and underweight	28 (26.4)	15 (28.3)	13 (24.5)	0.83[b]
Overweight and obese	78 (73.6)	38 (71.7)	40 (75.5)	
Systolic BP, mean (SD)	136.2 (19.6)	136.2 (22.4)	136.3 (16.6)	0.98[a]
Diastolic BP, mean (SD)	77.7 (11.6)	76.7 (11.6)	78.7 (11.7)	0.37[a]
FBS (mg/dl), mean (SD)	181.6 (83.0)	171.8 (66.2)	191.9 (97.2)	0.22[a]
PPBS (mg/dl), mean (SD)	256.9 (105.4)	231.9 (66.1)	281.0 (128.9)	0.02[a]
HbA1C (%), mean (SD)	9.4 (2.7)	9.0 (2.2)	9.9 (3.1)	0.12[a]
Total DSMQ score, mean (SD)	26.7 (3.1)	26.4 (3.2)	27.0 (3)	0.27[a]
Glucose management	4.9 (1.1)	4.8 (1.1)	4.9 (1.2)	0.33
Dietary control	5.6 (0.9)	5.5 (1.1)	5.6 (0.9)	0.69
Physical activity	6.0 (1.1)	5.9 (1.1)	6.0 (1.2)	0.85
Healthcare use	5.7 (1.4)	5.7 (1.3)	5.7 (1.5)	0.81
Total DDS score, mean (SD)	2.2 (0.6)	2.0 (0.5)	2.4 (0.7)	0.01[a]
Emotional burden	1.8 (0.5)	1.6 (0.4)	1.9 (0.6)	0.01
Physician distress	2.5 (0.8)	2.4 (0.7)	2.7 (0.9)	0.03
Regimen distress	2.9 (1.0)	2.6 (0.9)	3.1 (1.1)	0.01
Interpersonal distress	1.4 (0.6)	1.4 (0.5)	1.5 (0.6)	0.30

a: Unpaired *t*-test or Mann–Whitney *U*-test. b: Chi-square test

An ANCOVA was run to determine the effect of DSME on post-intervention diabetes distress after controlling for pre-intervention distress and baseline BMI. After adjustment for pre-intervention distress and BMI, there was a difference in post-intervention diabetes distress, which is statistically significant between the two groups, F (1,93) = 59.5, partial $\eta 2 = 0.4$, P value 0.001. The *post hoc* analysis was performed then with a Bonferroni adjustment. The post-intervention

Table 2: Changes in glycemic control, diabetes self-care activities, and diabetes distress of the study participants at 3-month follow-up

Outcome variable	Intervention group			*P*[a]	Control group			*P*[a]
	Baseline Mean (SD)	3 months Mean (SD)	Mean difference Between baseline and 3 months Mean (SD)		Baseline Mean (SD)	3 months Mean (SD)	Mean difference Between baseline and 3 months Mean (SD)	
HbA1C	9.0 (2.2)	7.7 (1.4)	1.3 (0.4)	0.001	9.9 (3.1)	9.8 (2.9)	0.1 (0.6)	0.17
FBS	171.8 (66.2)	126.1 (41.5)	45.7 (10.7)	0.001	191.9 (97.2)	185.4 (68.8)	6.5 (16.4)	0.55
PPBS	231.9 (66.1)	180.6 (51.8)	51.3 (11.5)	0.001	281.0 (128.9)	252.4 (88.1)	28.6 (21.4)	0.90
Total DSMQ score	26.4 (3.2)	24.5 (2.6)	1.9 (0.6)	0.001	27.0 (3)	26.9 (3.7)	0.1 (0.7)	0.90
Glucose management	4.8 (1.1)	6.2 (0.9)	-1.4 (0.2)	0.001	4.9 (1.2)	4.9 (1.2)	0 (0.2)	0.79
Dietary control	5.5 (1.1)	5.6 (0.9)	-0.1 (0.2)	0.001	5.6 (0.9)	5.7 (0.8)	-0.1 (0.2)	0.31
Physical activity	5.9 (1.1)	4.2 (1)	1.7 (0.2)	0.001	6.0 (1.2)	5.9 (1.2)	0.1 (0.2)	0.18
Healthcare use	5.7 (1.3)	4.8 (0.8)	0.9 (0.2)	0.001	5.7 (1.5)	5.8 (1.4)	-0.1 (0.3)	0.77
Total DDS score	2.0 (0.5)	1.2 (0.3)	0.8 (0.1)	0.001	2.4 (0.7)	2.3 (0.8)	0.1 (0.1)	0.13
Emotional burden	1.6 (0.4)	1.0 (0.3)	0.6 (0.1)	0.001	1.9 (0.6)	1.7 (0.6)	0.2 (0.1)	0.03
Physician distress	2.4 (0.7)	1.4 (0.4)	1 (0.1)	0.001	2.7 (0.9)	2.7 (1)	0.1 (0.9)	0.37
Regimen distress	2.6 (0.9)	1.3 (0.4)	1.3 (0.1)	0.001	3.1 (1.1)	3.0 (1.3)	0.2 (1.1)	0.24
Interpersonal distress	1.4 (0.5)	1.0 (0.2)	0.4 (0.5)	0.001	1.5 (0.6)	1.4 (0.7)	0.1 (0.6)	0.37

a: Paired *t*-test

Table 3: ANCOVA results after adjusting for the covariates

Characteristics	*F*	Partial eta-squared	*P*	MD (control vs intervention)	95% confidence interval
Total DDS score	59.5	0.4	0.001	0.9	0.65–1.10
Emotional burden	36.6	0.3	0.001	0.5	0.35–0.70
Physician distress	54.9	0.4	0.001	1.1	0.78–1.35
Regimen distress	57.5	0.2	0.001	1.4	1.03–1.77
Interpersonal distress	15.6	0.1	0.001	0.4	0.18–0.54

distress was statistically significantly greater in the control vs intervention group (mean difference of 0.9, 95% CI: 0.65–1.10) [Table 3].

Discussion

A structured DSME module adapted to Indian standard was found to be acceptable to participants and effective in reducing diabetes distress and improving the glycemic control. The DSME had a detailed interactive session with the participants, which ensured the self-regulation and dual process theory. In our settings, patients play a passive role with the practitioners. The investigator made use of charts and videos in the local language to provide relevant information. The sessions were interactive rather than one-to-one session. Self-determination theory was ensured by setting a goal, which is specific, realistic, and time-limited by the participant themselves based on their recent blood sugar status and self-care efforts. The emphasis was on participants' autonomy. The concept of self-confidence was ensured by reinforcing self-care efforts through a WhatsApp platform.

Our doctor-led DSME recruited a total of 106 participants. A systematic review of group-based DSME vs routine treatment reported the number of participants within a range of 36 to 314.[20] Thirteen of 21 studies in this systematic review recruited <150 participants. There are studies on DSME that involved participants in a similar age group and a similar duration of diabetes as that of our study.[9,20-22] Thirty-two percent of the participants in our study reported a history of peripheral neuropathy. A recent study in India reported the same results in type 2 diabetes mellitus (T2DM) patients (31.1%).[23] Hypertension was the most prevalent comorbidity (29%) in our participants. A study from India also reported similar findings (21%).[24] Most of the previous studies assessed only HbA1C for glycemic control, but we have assessed FBS and PPBS also. The significantly higher PPBS at the baseline in the control group has been attributed to the presence of 3–4 patients with extreme blood sugar values. HbA1C mean level was 9.4%, similar to other studies (9.9%).[21] The baseline diabetes distress was higher for regimen-related distress followed by physician distress. The deviated results can be attributed to the impact of the coronavirus disease 2019 (COVID-19) lockdown, which might have affected medication adherence and subsequent follow-ups. The control group had higher distress in all domains except that of interpersonal distress. We have addressed this difference in analysis by calculating the effect

size and adjusting for the covariates at baseline. A similar difference in baseline distress was found in a study assessing the effectiveness of DSME on psychological distress.[25]

We found that DSME helps patients with T2DM in reducing FBS, PPBS, and HbA1C and attain good glycemic control. A systematic review by Ernawati U *et al*.[26] reported similar results that DSME has improved self-efficacy and glycemic control of T2DM patients with regard to blood glucose levels, HbA1C, etc. They have included 15 studies related to DSME and concluded that DSME has a positive effect on the health status, clinical profile, and lifestyle of diabetes patients. The review also mentioned that the implementation of DSME can be influenced by various factors such as limitation of resources, DSME providers, accessibility, and availability of the services. Our outcomes are in accordance with other similar studies.[8,27] A nurse-led DSME intervention conducted in India also concurs with our study results.[28] The glycemic control was significant both within and between groups in our study, whereas a study from Kenya reported that the magnitude of the reduction in mean HbA1C did not differ between the groups ($P = 0.37$).[21] A multicenter RCT conducted in an urban low-resource setting by Lamptey R *et al*.[29] studied the association between structured DSME and glycemic control. They found that structured DSME was not associated with a change in HbA1C at follow-up in low-resource settings. Similar to our results, they have observed a significant reduction in HbA1C in the intervention group only (-0·9%), not in the control group.

The diabetes distress score has reduced significantly in the intervention group in our study. A study by Pen Purcell *et al*.[25] highlighted the potential of DSME programs to have an impact on psychological health, which can lead to better diabetes outcomes. Heise M *et al*.[30] conducted a nationwide population study among ever-DSME vs never-DSME participants to find the association of knowledge and diabetes distress with DSME. They found that DSME training was not associated with reduced distress. They recommended that DSME should rethink the psychological approaches to reduce the distress related to diabetes and coping mechanisms. Our study showed a significant improvement in diabetes self-care. A study from India with a nurse-led intervention also showed similar results.[28] Among the subscales of self-management, all the self-management domains except diet improved significantly in the experimental group. A study conducted by Jadawala HD in Surat City, India, concluded that housewives, single/ever married, and insulin treatment rather than oral hypoglycemic agents were associated with good dietary activity.[31] All of the participants in our study were married, male being the majority (68%), and employed, and nearly three-fourths of the participants were on oral hypoglycemic agents justifying the reason for the noncompliance to the diet modification in our study. The high dropout rate in our study was attributed to the impact of the COVID-19. Most of the lost to follow-up were from the hilly regions of Uttarakhand where the laboratory and transport facility were interrupted by the COVID-19 second wave.

Conclusion and recommendations

The structured DSME module was well drafted and effective in improving diabetes-related distress and glycemic control among T2DM patients, which can be effectively used in clinical settings in addition to medical management and can be effectively incorporated in national health programs such as the National Program for Prevention and Control of Non-Communicable Diseases (NP-NCD).

Strengths and weaknesses

The structured DSME module was acceptable to the participants since it used a wide variety of platforms such as interactive sessions, demonstration, charts in Hindi language, individualized diet chart, and videos of exercises and social media platforms for the continuum of care. The reinforcement was achieved through the WhatsApp group on a daily basis.

We found difficulty in conducting the second session since the regular follow-up time was after 3 months. Maintaining the COVID-19 protocol during the session was difficult. The effectiveness was assessed for the short term. Periodic reinforcement is necessary to achieve behavioral changes and sustainability.[6]

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Nil.

Conflicts of interest

There are no conflicts of interest.

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