Effect of locally-contextualized nurse-led diabetes self-management education on psychosocial health and quality of life: A controlled before-after study

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ABSTRACT

Our study evaluated the potential of nurse-led, locally contextualized diabetes self-management education (DSME) to modify psychosocial symptoms and health-related quality of life (HRQoL) in a resource-limited setting. Thus, a controlled, two-group, before-after study was conducted among people with type 2 diabetes mellitus (T2DM). At the baseline, 116 participants were randomly assigned to the intervention, and 104 to the comparison group. The intervention consisted of six interactive DSME sessions administered by nurses for six months.

At the endline, data from 78 (67%) intervention and 64 (62%) comparison group participants were included in the final analysis. Statistically, no significant differences were observed in depressive symptoms, stress, and HRQoL. Even though statistically not significant the proportion of participants who had eye examination at the endline was slightly greater in the intervention group, which is clinically significant in reducing the risk of diabetes retinopathy complication. Moreover, intervention group participants reported the DSME sessions to be helpful for the management of stress and depressive symptoms. We discuss different reasons that may explain the non-significant findings, most specifically, gaps in the adaptation of the education materials for a resource-limited setting, and modifications for low-literacy. Despite the non-significant findings in this part of our study, our overall project paved a way to design and test contextualized DSME programs in resource-limited settings of Africa.

This clinical trial was retrospectively registered on ClinicalTrials.gov (Identifier: NCT03185689) on June 14, 2017. https://clinicaltrials.gov/ct2/show/NCT03185689

1. Introduction

Diabetes mellitus is a chronic condition that demands extensive involvement of patients and their families in day-to-day self-management, which places a significant burden on both patients and their families. The burden contributes to a greater prevalence of psychosocial symptoms (depression and anxiety) and deteriorating health-related quality of life (HRQoL) among diabetic patients compared to non-diabetic patients (Anderson, Freedland, Clouse, & Lustman, 2001; Cochran & Conn, 2008; Lloyd, Dyer, & Barnett, 2000; Rubin & Peyrot, 1999). Among type 2 diabetes mellitus (T2DM) patients, the

psychosocial burden attributes to the development of complications, lengthier hospitalization, increased healthcare expenditure, and in due course, poor HRQoL (Black, Markides, & Ray, 2003; Davies et al., 2008; Whitworth et al., 2016). In turn, poor HRQoL can be associated with less-effective emotional self-management practices, inappropriate blood glucose management, and greater reported diabetes symptoms (Rubin, 2000).

Diabetes self-management education (DSME) can be defined as 'an ongoing process of facilitating the knowledge, skills, and abilities necessary for prediabetes and diabetes self-care (ADA, 2014; Haas et al., 2012). Diabetes-related self-management interventions with education

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programs focusing on depressive symptoms and stress are tested mainly in high- and upper to middle-income countries. Approaches of diabetes education interventions reported from these countries vary from group-based or one-on-one to institution-based or home-based to education-supported with telephone follow-up or counselling (Concha et al., 2009; Davies et al., 2008; Naik et al., 2012; Pauley, Gargaro, Chenard, Cavanagh, & McKay, 2016). Nurse-led DSME tested in high- and upper to middle-income countries showed improved psychosocial outcomes (Hunt, 2013; Maissi et al., 2011).

Health-related quality of life (HRQoL) is a complex concept that could be affected by individuals' subjective perception of physical and psychosocial wellbeing (Cochran & Conn, 2008; Rubin, 2000). In diabetic patients, quality of life is reduced over time and can be linked with poor glycaemic control (Cochran & Conn, 2008). Poor HRQoL could also be intensified with the presence of depression and stress (Egede & Ellis, 2010). Moreover, HRQoL seems to deteriorate among T2DM patients, with the least deterioration seen among patients on diet treatment alone, then more so among patients on oral antidiabetic agents, and most among patients on insulin injections (Cochran & Conn, 2008; Rubin & Peyrot, 1999). However, the effectiveness of diabetes self-management interventions in improving psychosocial symptoms and HRQoL is not yet well established (Cai & Hu, 2016; Concha et al., 2009; Garcia, Brown, Horner, Zuniga, & Arheart, 2015; Wagner et al., 2016), especially not in LIMC settings.

The continent of Africa has a high number of premature deaths related to diabetes mellitus (IDF, 2017). Moreover, the prevalence of depressive symptoms and stress among diabetic patients across the continent is high (Engidaw, Wubetu, & Basha, 2020; Mendenhall et al., 2015). However, studies on the effectiveness of locally contextualized DSME to improve depressive symptoms, stress, and HRQoL are limited. To the best of our knowledge, few experimental studies were conducted in Africa related to diabetes self-management, and they did not adequately address psychosocial health symptoms and HRQoL outcomes (Abaza & Marschollek, 2017; Essien et al., 2017; Gathu, Shabani, Kunyiha, & Ratansi, 2018).

In the context of a resource-limited setting of Ethiopia, we evaluated the effect of the nurse-led DSME intervention package composed of an illustrative teaching handbook and fliers, take-home activities and experience sharing. The effect of the program was evaluated from three dimensions, including clinical, behavioural and psychosocial outcomes. Clinical outcomes (Hailu, Hjortdahl, & Moen, 2018), and other outcomes, including knowledge, self-care behaviours, and self-efficacy (Hailu, Moen, & Hjortdahl, 2019), were reported in previous papers. In the current paper, we hypothesized that a locally contextualized nurse-led DSME program would improve depressive symptoms, perceived stress level, HRQoL, and the use of healthcare support among T2DM patients in a resource-limited setting.

2. Materials and methods

2.1. Study design, setting, and period

This paper is part of a controlled before-after study conducted in a resource-limited setting in Ethiopia. The study was conducted in Jimma Medical Centre (JMC), which is 355 km Southwest of the capital city serving over 15 million in the catchment area. We conducted the baseline survey from February to May 2016. With a change in the setting from the old hospital to the new operating hospital, JMC and other logistic constraints, the initiation of the DSME intervention was delayed by five months. It eventually began in November 2016 and ended in July 2017. Six DSME sessions, each lasting for approximately 90 min, were provided over six months, followed by three months with no DSME sessions. Finally, the endline survey was conducted from August to October 2017. This study adheres to the Consolidated Standards of Reporting Trials (CONSORT) reporting guidelines and the CONSORT checklist has been completed (Supplementary Material 1).

2.2. Sampling and participant recruitment

Before recruitment of the study participants, a fresh sample frame of adult diabetic patients on active follow-up at the JMC diabetic clinic was prepared over three months. The fresh sample frame was prepared related to the inconsistencies of the manual registration of patients on follow-up at the diabetes clinic. Patients were asked for their willingness to provide information for registration. The information required from the patients was read aloud to them. Accordingly, with verbal consent obtained from each patient, 447 adult T2DM patients were registered. The sample size was then calculated using an online program, Epi info_7. exe (Dean et al., 2013), with the assumptions of increasing the proportion of people with target glycated haemoglobin (≤7%) in the intervention group from 18% to 33% with a power of 80%, which was reported in the previous paper focusing on clinical outcomes (Hailu, Hjortdahl, & Moen, 2018). Because glycated haemoglobin had never been done routinely in the hospital, we used the finding of the previous study that reported the proportion of T2DM patients with target blood sugar level using fasting blood sugar (FBS) as a reference measure of glycaemic control (Angamo, Melese, & Ayen, 2013). From these parameters, the power analysis indicated a sample of 204 and adding 15% contingency, we sought to recruit 240 participants.

Participants were recruited proportionally based on their residence, considering Jimma city and Jimma zone rural districts around Jimma city. Using Excel random number generator and a given individual code number, 67 participants from Jimma city and 53 participants from Jimma zone districts were randomly selected for the intervention group. Similarly, for the comparison group, 66 participants from Jimma city and 54 participants from Jimma zone districts were randomly selected. Therefore, 120 participants were assigned to the intervention group and 120 participants to the comparison group. Whereas at the baseline, 220 participants agreed to participate in the study, and 116 from the intervention group and 104 from the comparison group gave data. At the endline, 78 participants in the intervention group and 64 in the comparison group provided data (Hailu, Moen, & Hjortdahl, 2019).

2.3. Inclusion and exclusion criteria

In relation to the burden of T2DM and to focus our study, only people with diagnosed T2DM attending the diabetes clinic at the study site were included in the study. Diagnosis of T2DM and T1DM (type 1 diabetes mellitus) based on human leukocyte antigen–antibody and other genetic tests are unavailable in the study setting. Thus, by consulting literature and physicians working in diabetes mellitus clinic we used the following criteria to identify patients with T2DM. T2DM patients 30 years of age or older at the time of diagnosis, who were taking oral hypoglycaemic agents (OHAs), or possessed a record of OHAs or a record of both insulin and OHAs were eligible for inclusion in the study. Individuals with T1DM, gestational diabetes, or severe mental or physical incapability were excluded from the study.

2.4. Intervention

Our nurse-led DSME package consists of an illustrative teaching handbook and fliers, interactive discussion of experience sharing, and specific take-home activities. The teaching handbook focusing on psychosocial health issues was prepared by consulting the "Diabetes Education Training Manual for Sub-Sahara Africa," developed by the International Diabetes Federation (IDF, 2006), recommendations by Lorig et al. (2012), and the American Diabetes Association (ADA, 2015). Using these materials, which were tested in developed countries, we contextualized management recommendations of depressive symptoms and stress to the resource-limited local Ethiopian context and for low-literate T2DM patients.

The DSME sessions were facilitated by two nurses, wherein an average of 8–12 people attended each session. The intervention group

attended six DSME sessions, of which the fifth session focused specifically on strategies to prevent and control depressive symptoms and stress. During the session, the facilitators introduced common manifestations and self-management recommendations of stress and depressive symptoms, and the participants could share their experiences related to those manifestations and management. This was followed by a summary of the suggested recommendations from the teaching handbook. Moreover, the "Do's and Don'ts" reminders related to stress and depressive symptom management were discussed. Finally, the facilitators concluded the session by providing take-home activities. With this, we assumed that patients would acquire adequate knowledge and be more confident in undertaking self-management practices related to depressive symptoms and stress and in turn, improving patients' psychosocial wellbeing (Hill, 2017; Wu et al., 2013).

The participants in the comparison group continued their usual care, including having their blood pressures and weights checked, consulting with physicians, and collecting medicines.

2.5. Data collection and analysis

Seven nurses who completed one day of training collected data using interview-administered questionnaires. None of the data collectors participated in the intervention, nor were they informed about the participants' group assignments. For data collection, we used validated tools, including the Patient Health Questionnaire 9 (PHQ-9) for depressive symptoms (Cronbach's α of 0.89) (Gelaye et al., 2013; Kroenke & Spitzer, 2001), the perceived stress scale (PSS) for stress (Cronbach's α 0.89) (Cohen, Kamarck, & Mermelstein, 1983; Mitchell Ann, Patricia Crane, & Yookyung Kim, 2008), the generic HowRU tool for HRQoL (Cronbach's α 0.89) (Benson et al., 2010), and the revised healthcare utilization tool developed by the Stanford Self-Management Resource Centre for source of healthcare support (Table 1). Since the participants of this study were low-literate, each question was read aloud during the interview. Moreover, we used coloured visual aids prepared in a ladder fashion for the PHQ-9 and PSS and a coloured smiley face pictograph for the HowRU tool.

All tools were translated to the widely used local languages, Afan Oromo and Amharic, and then translated back into English for quality check purposes. Before the actual data collection commenced, all questionnaires were pre-tested on 27 T2DM patients not included in the main study. Based on the pre-test, a few modifications were made to the tools to improve clarity by choosing more locally comprehendible terms and expressions.

Data were entered into the EpiData entry client/manager (v.4.2.0.0) and then transported to StataSE 15 for analysis. A normality distribution test was performed for all continuous outcome variables. For the within-group before and after differences in HRQoL, PHQ-9, and PSS scores, which are normally distributed or have a moderate violation of normal distribution on a normal distribution curve, we used an independent sample t-test. For the "source of healthcare support" parameter, we used the nonparametric Wilcoxon-rank sum test for two independent samples. For the between groups difference in sociodemographic characteristics, a chi-square test was performed. We considered p-values of less than 0.05 as being statistically significant within or between groups.

Intervention group participants who took an instruction handbook and fliers but did not attend DSME sessions before the end of the intervention period were included in the endline analysis based on their initial group assignment using an intention-to-treat analysis principle. Use of the generic tools, which are diabetes non-specific, to measure depressive symptoms, perceived stress, and HRQoL among people with diabetes might not capture diabetes-specific psychosocial experiences. Thus, to deepen the insight of the study and to collect information that might not be captured by the diabetic non-specific tools, field notes were taken during the feedback sessions of the intervention at the end of the study period. The participants were asked to report their experiences with the DMSE.

Table 1
Description of data collection tools.

Tool	Description	Coding
Patient Health Questionnaire 9 (PHQ-9; Kroenke & Spitzer, 2001)	The questionnaire included interest to do something, mood, sleep, energy, appetite, self-concept, concentration, suicidal ideation and thoughts. The nine items can be used to diagnose depressive symptoms and to grade the severity of depressive symptoms.	Responses ranged from "0 = Not at all" to "3 = Nearly every day" with a sum ranging from 0 to 27. The greater the sum score, the more severe the symptom.
Perceived stress scale (PSS; Cohen et al., 1983)	The scale elicits data about being upset with unexpected happenings, ability to control things important in one's life, feeling nervous, dealing effectively with life hassles, effectively handling personal problems, controlling time spent, and overcoming difficulties over the last month.	Responses range from "0 = Never" to "4 = Very often." Before summing-up for analysis, responses of the seven positively stated items (item numbers 4, 5, 6, 7, 9, 10, and 13) were reversed as "0 = 4, 1 = 3, 2 = 2, 3 = 1, and 4 = 0." The greater the sum score, the more severe the symptom.
Generic HowRU tool (Benson et al., 2013, 2010; Hendriks et al., 2015)	The HowRU is a short and more readable generic patient-reported outcome measure that tracks and compares patients' perceptions of how they feel and what they are able to do in the last 24 h. This tool has four items addressing discomfort (physical symptoms), distress (emotional symptoms), disability (work, home, and leisure activities), and dependence (need for help from others).	Responses are rated using four ordinal scales of 0 to 3: extreme = 0, quite a lot = 1, a little = 2, and none = 3. The sum is calculated by adding the scores for each item, ranging from 0 to 12; the lesser the sum, the poorer the quality of life.
Healthcare utilization tool developed by the Stanford Self-Management Resource Centre (SMRC, 2015)	The tool has items related to physician visits, emergency department visits, and nights hospitalized. We also included items related to spiritual care support.	The tool has yes or no and frequency response items.

3. Results

Even though people with T2DM are at higher risk of psychosocial health problems, the few diabetes self-management studies conducted in Africa have often overlooked interventions to address those problems. The following findings, therefore, include a change in self-reported depressive symptoms, perceived stress level, HRQoL, and the source of healthcare support among intervention and comparison groups.

From 116 participants in the intervention group and 104 participants in the comparison group at the baseline, 78 (67%) participants from the intervention group and 64 (62%) participants from the comparison group provided data for the endline analysis.

3.1. Sociodemographic characteristics

Out of the total intervention group and comparison group participants included in the endline analysis, 31% and 33% were respectively females. At the baseline, there was no statistically significant difference in sociodemographic and clinical characteristics between the two groups.

At the endline, except for the "source of finance for healthcare" parameter, there was no significant difference between the intervention and comparison group participants in terms of sociodemographic characteristics. The proportion of comparison group participants who paid out of pocket for health care at the endline was significantly (p = 0.027, chi2 = 9.199) higher in the comparison group (Table 2).

3.2. Psychosocial symptoms

The self-reported depressive symptoms and perceived stress at the baseline and endline were not statistically different between the intervention and comparison groups.

Similarly, as shown in Table 3, there were no statistically significant differences within groups in those two outcomes in both the intervention and comparison groups. Even though quantitative data showed no statistically significant difference in mean depressive symptom score and stress, at the end of the DSME sessions, intervention group participants reported the sessions were helpful. One of the participants stated, "I was hopeless with my diabetes and usually felt depressed. With education and listening to the experience of others, I usually go for exercises, especially walking. Now I am feeling healthy".

Another participant added, "When I am anxious because of some disagreement at the workplace, I go to my home for sleep, but other stressful conditions may be there at home too. For which I used to be more anxious. With being involved in education, instead of going home and sleeping, I would go out walking."

Engaging in physical exercise like walking and jogging, is one of the strategies recommended by our DSME intervention to prevent, control, or alleviate stress and depressive symptoms. Even though the change in stress level and depressive symptom scores was not statistically significant, such reports indicate that the participants benefited from the DSME intervention.

3.3. Health-related quality of life

The ultimate goal of all diabetes self-management strategies was for diabetic patients to achieve a better quality of life. Therefore, we evaluated the effect of nurse-led DSME on HRQoL.

However, the self-reported HRQoL at the baseline and endline showed no statistical differences between and within groups (Table 4).

Table 2
Endline sociodemographic characteristics.

Variables	Intervention (n = 78)		Comparison (n = 64)	
	Frequency	Percent	Frequency	Percent
Gender				
Male	54	69	43	67
Female	24	31	21	33
Marital status				
Married	66	85	49	77
Widow	6	8	8	12
Never married	4	5	3	5
Divorced	2	2	4	6
Financial sources for health care *				
Out of pocket	39	50	43	67
Paid by district	18	23	16	25
Insured	17	22	4	6
Other	4	5	1	2
Residence				
Urban [†]	55	71	49	77
Rural	23	29	15	23
Household food insecurity				
Insecure	29	37	28	44
Secure	49	63	36	56

* P-value = 0.027 and Pearson chi2 = 9.199, [†] Towns having municipality.

Table 3
Self-reported psychosocial symptoms within-group mean difference before and after DSME intervention.

Depressive symptoms					
Group	n	Mean	Standard Deviation	Confidence Interval	
Intervention	78	−1.82	6.53	−3.29	−0.35
Comparison	64	−3.45	5.77	−4.89	−2.01
Difference		1.63		−0.43	3.69
Significance level	0.1207				
Perceived stress level					
Intervention	57	2.00	10.38	−0.75	4.75
Comparison	46	1.07	8.68	−1.51	3.64
Difference		0.93		−2.86	4.73
Significance level	0.6264				

Table 4
Self-reported health-related quality of life within-group mean difference before and after DSME intervention.

Group	n	Mean	Standard deviation	Confidence interval	
Intervention	78	0.60	2.76	−0.02	1.23
Comparison	64	1.14	3.23	0.33	1.95
Difference		−0.54		−1.53	0.46
Significance level	0.2868				

3.4. Source of healthcare support

The following result encompasses sources of healthcare support, including frequency of visits to healthcare providers, foot examinations, eye examinations, and visits to traditional healers or sought spiritual care by the intervention and comparison groups at the baseline and endline.

There was no statistically significant difference between the intervention and comparison groups at the endline related to the frequency of visiting healthcare providers, frequency of visiting emergency rooms, and frequency of foot examinations by healthcare providers in the previous six months (Table 5).

Even though the results were not statistically significant, the proportion of participants who had an eye examination by a healthcare provider at the endline was slightly higher in the intervention group compared to the comparison group (Fig. 1).

Patients with chronic diseases such as T2DM may use traditional healers and spiritual care in addition to modern health care. Our study did not demonstrate a statistically significant difference in the proportion of participants in the intervention group and the comparison group that sought spiritual care and traditional healers (Table 6).

Table 5
Sought healthcare support of intervention and comparison group participants at the end of DSME intervention.

| Group	Observation	Rank sum	Expected
Endline healthcare provider visit frequency in the last six months (excluding visit for emergency)			
Intervention	78	5552	5577
Comparison	64	4601	4576
z = -0.112		p = 0.911	
Frequency of emergency room visits in the last six months			
Intervention	78	5818	5577
Comparison	64	4335	4576
z = 1.911		p = 0.056	
Frequency of foot examination by healthcare provider in the last six months			
Intervention	78	5775	5577
Comparison	64	4378	4576
z = 0.957		p = 0.339	
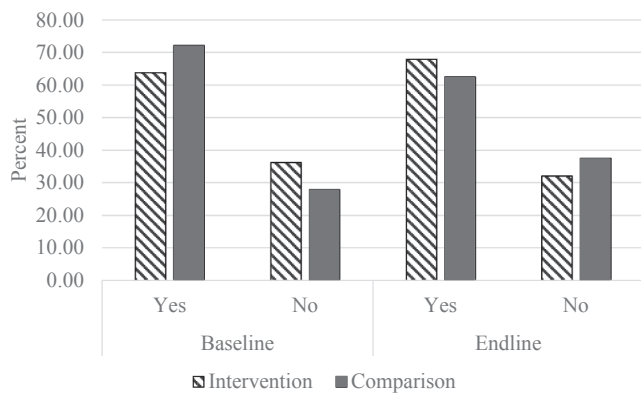
Fig. 1. Proportion of participants who had eye examinations.

Table 6
Proportion of participants that visited spiritual care and traditional healers before and after DSME intervention.

Group	Baseline, n (%)		Endline, n (%)	
	Yes	No	Yes	No
Intervention	17 (14.66)	99 (85.34)	10 (12.82)	68 (87.18)
Comparison	12 (11.54)	92 (88.46)	9 (14.06)	55 (85.94)
Significance	Chi-square = 0.466p = 0.495		Chi-square = 0.829p = 0.829	

During DSME sessions, participants shared how they used to believe that manifestations of acute diabetes complications were related to some bad spirit, for which they preferred to visit or call spiritual healers or religious leaders. To illustrate this, one of the older participants shared the following experience: "On one of the days, I was confused, did not know what to do, and started to shout aloud. Then my family called a priest for prayer. As time goes on, I rather become sleepy and lost my conscious. Then they started to prepare me for post-mortem care. Finally, I woke-up but cannot talk […] and started to move my fingers." With tears in his eyes, he continued, "Now they recognized that I was alive. They gave me some food, and after a while, I started to talk. My family and I don't know the manifestations and management of hypoglycaemia, and usually, I don't use homemade remedies or consult the nearby health facility to manage a drop in blood sugar level."

This may show the extent to which patients and their families are challenged with the difficulties of handling acute diabetes-related complications, especially in the presence of inadequate self-management knowledge and skill. In which case, they prefer to look for spiritual care instead of or in addition to getting healthcare services at health facilities. Therefore, the identification, prioritization, and the appropriate use of different, available sources of healthcare support, including scheduled eye and foot examinations and visiting healthcare providers routinely or for emergency conditions, are complicated, according to the study participants and their families. Despite these observations and reported experiences, there was no significant difference within the groups before and after DSME intervention and between the groups at the endline in the use of healthcare support.

4. Discussion

Comorbid depressive symptoms and stress are consistently remained high among diabetic patients (Anderson et al., 2001; Grigsby, Anderson, Freedland, Clouse, & Lustman, 2002), especially in Sub-Saharan Africa and Ethiopia (Engidaw et al., 2020; Mendenhall et al., 2015). This is associated with increased suffering and serious deterioration in HRQoL (Cochran & Conn, 2008; Egede & Ellis, 2010). To alleviate these psychosocial health problems and improve quality of life, DSME contextualized to resource-limited areas in African may help. Our developed

nurse-led DSME package with an illustrative teaching handbook and fliers contextualized to low-literate T2DM patients in the resource-limited setting of Ethiopia is an example (ADA, 2015; IDF Africa Region, 2006; Lorig et al., 2012, 2020). Like other DSME sessions of our program, the specific session about depressive symptoms and stress was facilitated by nurses. The participants in the session shared experiences related to manifestation, precipitating factors, and the management of stress and depressive symptoms. By undertaking the suggested take-home activities and participating in the subsequent revisiting sessions, we assumed that participants would better undertake emotional self-management roles using the recommendations of depressive symptom and stress management, which would contribute to reduced depressive symptoms and stress. However, our study showed no statistically significant difference within and between groups in terms of depressive symptoms, perceived stress level, and HRQoL.

4.1. Psychosocial symptoms

The current study showed no statistically significant difference between and within groups in the depressive symptoms scores, measured by the PHQ-9. This finding is in line with the findings of diabetes education provided by nutritionists and diabetes nurse educators supported with counselling and telephone calls (Wu et al., 2011). Our finding is also consistent with the finding of the study that tested home-based, one-on-one diabetes self-management support (DSMS) provided by personal support workers (Pauley et al., 2016).

However, group-based education for newly diagnosed diabetic patients (Davies et al., 2008) and DSMS delivered by telephone coaching for patients with uncontrolled diabetes (Naik et al., 2012) showed a statistically significant decrease in depressive symptoms from month six to 12. Yet, the reduction in depressive symptoms may not be sustained over a longer period (Khunti et al., 2012). A decrease in depressive symptoms with group-based diabetes interventions might be related to the opportunities that the intervention group participants have to share their experiences with one another. This might help participants to learn potential strategies from their peers to help comprehend or control their symptoms.

In relation to the perceived stress level, the current study of group-based nurse-led DSME showed no statistically significant difference within and between groups. This finding is in line with the findings of home-based, one-on-one diabetes self-management coaching provided weekly by paraprofessionals (personal support workers) over six weeks, which reported no significant reduction in stress level (Pauley et al., 2016). However, the findings in our study were not consistent with the previous findings of diabetes self-management interventions that used psychological education and support complimented with a participatory patient education strategy and telephone follow-up sessions (Concha et al., 2009). On the other hand, during the feedback section intervention group participants in our study reported a better understanding of their situation and the benefits of attending DSME sessions. They reported the benefits of using some of the strategies to recognize, prevent, alleviate, or control stress and depressive symptoms.

4.2. Health-related quality of life (HRQoL)

The current study indicated statistically a non-significant difference within and between groups in self-reported HRQoL. Our findings are consistent with diabetes self-management interventions offered to low-income diabetic patients (Nelson et al., 2017), peer-led DSMS (McGowan, 2015), and diabetes education supported with counselling and telephone follow-up sessions, which also indicated no significant difference in HRQoL (Wu et al., 2011). Similarly, our findings are also in line with the non-significant change in HRQoL of group-based structured diabetes education provided for newly diagnosed diabetic patients (Davies et al., 2008). Nevertheless, some studies have shown significant improvements in HRQoL, including DSME provided by nurses for 18 h

over six months for T2DM patients with uncontrolled glucose (Jaipakdee, Jiamjarasrangsi, Lohsoonthorn, & Lertmaharit, 2015); DSMS supported with a pharmacotherapeutic care plan (Cani et al., 2015); and DSME for older female diabetic patients (Jahromi, Ramezanli, & Taheri, 2015). Similarly, home-based diabetes self-management interventions, including home-based stress management education (Wagner et al., 2016), one-on-one symptom-based diabetes education supported with telephone follow-up sessions (Garcia et al., 2015), and diabetes education involving family members, indicate a significant change in HRQoL (Cani et al., 2015). Our comprehensive group-based DSME provided over six months was assumed to improve quality of life, which is a multifaceted subjective construct associated with the wholesome effect of management strategies, social and economic challenges, and the presence of psychosocial comorbidities (Cani et al., 2015; Rubin & Peyrot, 1999). Thus, it could be problematic to demonstrate a significant change or effect with a single-site intervention, such as ours.

4.3. Source of healthcare support

It is recommended for diabetic patients to have a complete foot and eye examination at least every three to six months (IDF Africa Region, 2006). Even though statistically not significant, the proportion of intervention group participants who had an eye examination increased by 4% and decreased by 10% in the comparison group at the endline. These statistically non-significant findings, however, could be significant for their overall self-management activities (Amrhein, Greenland, & McShane, 2019). The JMC diabetes clinic was not specifically equipped with a specially trained team of healthcare providers to provide specialized care and support for diabetes patients. Thus, patients might not be routinely scheduled or advised to have foot and eye examinations at regular time intervals. Patients must often request these examinations themselves, which suggests that the self-management and awareness promoted through the DSME intervention would explain the pattern of increased eye examinations.

4.4. Explaining the lack of significant findings

The non-significant difference in depressive symptoms, stress, and HRQoL may be attributed to different factors, including little tailoring of the intervention package to an individual or structural challenges. These may be including the fact that our DSME intervention package prepared for the local context, which includes low-literate participants. Our DSME intervention may also be unable to address subjective multifaceted psychosocial health problems, and that the providers of the DSME sessions were not specially trained in mental healthcare or psychosocial counselling. Thus, the DSME intervention providers may have lacked the knowledge and skills necessary to equip patients with the required coping mechanisms for depressive symptoms and stress (Massimi et al., 2017). Furthermore, there was only a relatively short duration to measure the effect of our intervention after the DSME sessions focusing on depressive symptoms and stress, which occurred at the fifth DSME session in the series of six sessions (Wu et al., 2011). The findings can also be related to the use of generic tools (PHQ-9, PPS, HowRU, and the healthcare utilization tool) that may not be sensitive enough for diabetes-specific problems among a low-literate population in a resource-limited setting (Steed, Cooke, & Newman, 2003). The non-significant findings may also be related to the challenge of integrating stress and depressive symptom self-management strategies into the participants' daily lives, norms, and values (De Man et al., 2019).

Structural challenges, including frequent stock-out of medications, which are assumed to be readily available for patients at the JMC, either at a cheaper price or for free, may increase the risk of stress and depressive symptoms and a deteriorating quality of life. Another structural challenge causing stress may have been acquiring transport during the rainy season for those coming from rural districts (Hailu, Moen, & Hjortdahl, 2019). As an individual factor, poorer self-care practice

associated with severe depressive symptoms and lack of commitment to undertake self-care could also contribute to the non-significant findings (Gonzalez et al., 2007; Mosnier-Pudar et al., 2010). The interplay of these individual and structural factors could increase the risk of psychosocial health problems, that could not be addressed with a single current DSME intervention. On the other hand, on the continuum of DSME outcomes, health status, which can be measured by the quality of life, is a long-term outcome least affected by one-time diabetes education (Mulcahy et al., 2003). Despite the lack of statistically significant findings in the current study, we may argue for the clinical significance of the intervention, as some of the intervention group participants reported that the DSME added insights and meaningful values to their self-management of diabetes-related conditions.

4.5. Limitations and strengths

This study was conducted in a sample of low-literate T2DM patients with low economic status in a resource-limited setting. The DSME intervention package supported with an illustrative instruction handbook and fliers was adapted to try to meet the needs of low-literate diabetic patients in the resource-limited settings of Ethiopia and Sub-Saharan Africa. This package should be considered as a reference for further related experimental studies. The study sought to evaluate the effectiveness of DSME on stress, depressive symptoms, and quality of life, which are among the most challenging outcomes to document – due to their largely subjective nature – for desired changes with a single-site and one-time longitudinal study.

Interpretation of the current study's findings should take into account limitations like the possibility of information contamination, higher attrition seen as lower attendance towards the end of the DSME intervention, and social desirability bias, as also reported from our study (see Hailu, Hjortdahl, & Moen, 2018; Hailu, Moen, & Hjortdahl, 2019). The generic, diabetes non-specific tools used to measure psychosocial symptoms and HRQoL might not be sensitive enough for participants in the JMC setting and hence might not capture their reports of disease-specific problems (Steed et al., 2003). Thus, the use of these diabetes non-specific and subjective tools would affect the interpretation of our results, and it would also affect comparisons with studies that used diabetes-specific tools. Moreover, some of the questions from the PHQ-9 and PSS may be intimidating, requiring participants to recall past experiences, or comprehend beyond their actual level of literacy. Answering to a person who read the questions to them might also influence their responses. These factors might ultimately introduce response bias.

Additionally, the study may be underpowered due to the loss of participants during the intervention period, and the fact that power calculation was based on numerical changes in glycated haemoglobin levels and not psychosocial outcomes or HRQoL. This could have contributed to Type II errors or to the non-significant findings in this part of our study.

5. Conclusion

The nurse-led DSME education supported with illustrative education materials and experience sharing reported in this paper was well received by the participants but our study could not demonstrate significant differences between and within groups related to depressive symptoms, stress, and HRQoL. For further achievements of DSME in a resource-limited setting and low-literate population of Africa, our field notes demonstrate value and come with a potential to undertake a more comprehensive, qualitative approach to better understand psychosocial symptoms and HRQoL related to the self-management behaviour of T2DM patients. Furthermore, we recommend exploring interpretations and perspectives using diabetes-specific and culturally sensitive instruments.

6. Relevance for clinical practice

The current study has shown an example of new self-management strategies in Africa that should be further contextualized and tested to help diabetic patients to recognize and manage stress and depressive symptoms. The benefits of attending DSME sessions reported by the intervention group participants to prevent and control psychosocial symptoms and acute complications of diabetes would be clinically important. Moreover, even though statistically not significant, an increase in the proportion of the intervention group who had eye examinations would be clinically important in reducing the risk of diabetic retinopathy. This finding could also indicate more active health-seeking behaviours among the intervention group participants.

To our knowledge, diabetic patients attending the JMC diabetic clinic were not given any organized diabetes education since being diagnosed with diabetes. For this reason, diabetic patients might need screening for unmet psychological therapy that should be provided by expertise in the area.

7. Availability of data and materials

The datasets used and analysed in the current study, and the study protocols are available from the corresponding author upon reasonable request.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijans.2021.100325.

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