Effectiveness of an adapted diabetes nutrition education program on clinical status, dietary behaviors and behavior mediators in adults with type 2 diabetes: a randomized controlled trial

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ABSTRACT

Purpose: This study evaluated the effectiveness of an adapted social-cognitive theory underpinned diabetes nutrition education program (NEP) on: clinical (HbA1c, BMI, blood lipids, blood pressure) and selected dietary behaviors (starchy foods and energy intake, vegetables and fruit intake) and behavior mediators (knowledge and diabetes management self-efficacy) in patients with type 2 diabetes mellitus (T2DM).

Methods: A tertiary hospital outpatient adults (40–70 years) with poorly controlled (HbA1c ≥ 8 %) T2DM were randomized to either intervention group (*n = 39*: NEP, 7-monthly group education sessions, bi-monthly follow-up sessions, 15-minute individual session, workbook + education materials) or control group (*n = 38*: education materials only). NEP aimed to improve clinical status through improved dietary behaviors and behavior mediators. Outcomes and changes in diabetes medication were assessed at six and 12 months. Intention-to-treat analysis was conducted. ANCOVA compared the groups (baseline values, age, sex adjustments).

Results: Forty-eight (62.3 %) participants completed the study. Intervention group compared to the control group had lower (-0.53 %), clinically meaningful HbA1c (primary outcome) at 6 months, albeit not sustained at 12 months. Compared to the control group, the intervention group had significantly lower: (i) systolic blood pressure at six and 12 months (ii) diastolic pressure at 12 months, (iii) energy intake at six-months, (iv) up-titration of insulin at six and 12 months and higher diabetes knowledge scores at six months.

Conclusions: NEP had limited effects on HbA1c, targeted dietary behaviors and behavior mediators but showed positive effects on blood pressure. The NEP health cost savings potential supports the need for improving program participation.

Trial registration: ClinicalTrials.gov. number NCT03334773; 7 November 2017 retrospectively registered.

Keywords: Type 2 diabetes . Nutrition education program . Randomized controlled trial . South Africa . Dietary behaviors . Diabetes management self-efficacy . Diabetes knowledge

INTRODUCTION

Diabetes mellitus is an ever-growing global health problem, with a greater impact in low and middle income countries (LMIC) [1]. South Africa is among the top ten countries in Africa in terms of people living with diabetes [1], contributing significantly to the burden of disease. In 2015, diabetes was the second most important cause of death in South Africa [2]. The shifting burden of non-communicable diseases in developing countries requires urgent and concerted efforts to prevent and reduce complications.

Intensifying diabetes self-management education (DSME) as a way to preventing complications among people living with diabetes (PLD) is a recognized need in developing countries [3,4,5]. DSME is a core component of cost-effective diabetes care [6, 7] and a feasible intervention strategy in resource limited settings [8]. DSME, including nutrition education [9] is known to improve behavior mediators such as knowledge [6, 10] promote appropriate self-care for example dietary [9], improve metabolic outcome [11], and quality of life in PLD [12]. In LMIC countries structured DSME is not widely available [13,14,15]. In addition, DSME programs beyond primary healthcare are limited [13,14,15]. In South Africa, this challenge is present despite poor diabetes control being a problem at other levels of health care [16, 17]. Evidence from a tertiary health care facility indicated that fewer than 20 % of patients with type 2 diabetes (T2DM) achieved metabolic control despite being on appropriate pharmacotherapy [17]. The authors of that study noted that PLD struggled to adhere to lifestyle recommendations, calling for more focused advice on lifestyle interventions [17]. Indeed, adherence to appropriate dietary behavior, a major lifestyle component that affects metabolic control [9, 18] is a recognized problem in T2DM patients [19] that requires attention. However, data on dietary behavior focused DSME and the impact thereof on diabetes outcomes in sub-Saharan Africa particularly in tertiary healthcare settings are limited.

To address the gap, a diabetes nutrition education program (NEP) was adapted from a primary health care setting to a tertiary health care setting in South Africa [20]. The NEP was adapted after engaging with the tertiary setting stakeholders through qualitative methods to understand the needs and preferences for diabetes nutrition education for T2DM patients [20]. The needs assessment revealed diabetes-related knowledge deficits, struggle with treatment adherence particularly diet and multiple factors contributing to poor adherence [21]. From the needs' assessment, desirable characteristics of a NEP were identified, including monthly group meetings with approaches to enhance learning and strategies to enhance motivation to change behavior [20]. Further, the Social Cognitive Theory (SCT) that guided the original NEP [22], was retained to underpin the implementation of the adapted NEP. The SCT proposes that behavior, personal factors and the environment interact to explain and predict behavior [23]. The personal factors influence the way individuals perceive and act towards health behavior [23] and include knowledge, outcomes expectations, attitudes, skills and self-efficacy [23, 24]. The environment factors are those external to an individual including the social context (e.g. family) [23] while behavior is the response to stimuli to achieve goals [23, 24] e.g. eating smaller starchy food portions to aid blood glucose control. Based on the SCT tenets, key dietary behaviors and behavior mediators of intervention focus were identified as well as the behavior change techniques/strategies to employ as means to effecting change [20]. Behavior mediators are factors that can facilitate or impede behavior change [24]. These include person-related psychosocial factors (beliefs, attitudes, knowledge, skills, self-efficacy) and environmental-related factors (physical/structural and social) [24].

This manuscript reports on the effectiveness of the adapted structured NEP on clinical status, dietary behaviors, and behavior mediators on adults with poorly controlled diabetes at a tertiary health care setting in South Africa. The primary outcome hypothesis was that the adapted theory-based NEP would induce at least a 0·5 % reduction in HbA1c at six months and 12 months. A 0.5 % reduction in HbA1c levels over six months is clinically significant [25]. For the secondary outcomes (blood pressure, blood lipids, BMI, dietary behaviors and potential behavior mediators), we hypothesized that the intervention group when compared to the control group would achieve significantly better outcomes at six months and that the improved outcomes would be sustained at 12 months.

METHODS

Study setting

This study was conducted at a diabetes outpatient clinic of a public tertiary teaching hospital located in Pretoria, South Africa. Patients with poorly controlled diabetes or diabetes complications are referred to the clinic from the hospital or catchment health facilities. Most of the patients are on insulin therapy. Patients generally visit the clinic every three to six months and to collect medication from the hospital pharmacy every month. The diabetes outpatient clinic did not offer structured DSME at the time of the study. Most of the education at the clinic is offered on an individual basis based on the needs of the patient as assessed by the physician. Cases deemed to need lifestyle intervention are referred to a dietitian for further counselling.

Study design and participants

A one-year randomized controlled (RCT) design with two parallel groups was used. Participants included men and women with T2DM who met the following criteria. Aged between 40 and 70 years, glycated hemoglobin (HbA1c) of ≥ 8 %, at least one year living with diabetes, able to understand English, not pregnant, not employed full time, not planning to be out of the study site in the next year and without major complications, e.g. proliferative retinopathy, severe renal insufficiency (GFR < 15 mL/min per 1·73 m^2) and amputations. Participants were personally recruited at the clinic through convenience sampling. Recruitment stretched over 11 months (January 2017 to November 2017).

Sample size

Sample size was computed based on the primary outcome (HbA_{1c}). A sample of 140 patients (70 per group) was required to detect a 0·5 % difference in HbA_{1c} at six months with 80 % power at the 5 % level of significance, assuming a standard deviation (SD) of 1·0 % and allowing a 10 % attrition rate. The SD was based on values previously estimated from the setting.

Randomization and blinding

Participants were randomized to the intervention or control group using random permuted blocks generated by a computer. Randomization was stratified based on sex and age, totaling four strata. Sealed sequentially numbered opaque envelopes per stratum were used. Upon confirmation of a participant's eligibility and completion of baseline data collection, the next envelope in sequence was opened and the treatment allocation entered on a randomization list. The principal investigator (PI) allocated each treatment.

The health professionals (doctors and nurses) serving the participants at the diabetes clinic, the research assistants involved in data collection and hospital personnel involved in collection and analysis of blood specimens were masked to the treatment groups. The participants, the PI and one research assistant involved in the training sessions could not be blinded. Communication between the control and intervention groups was minimized by instructing intervention participants not to share information with other diabetes patients [26] at the hospital (clinic and pharmacy). In addition, the education took place in a hospital location far from the diabetes clinic.

Interventions

Both the control and intervention groups received education materials comprising of a pamphlet and a wall/fridge poster. The content of the material included the basics of diabetes such as risk factors, symptoms and consequences (pamphlet) and dietary guidelines (poster) based on the South African food based dietary guides (SAFBDGs) [27]. Both groups continued with usual medical care at the diabetes outpatient clinic. Participants in the control group had no further encounters except for outcome assessments.

The intervention group received the adapted NEP which comprised four components: (i) seven-monthly group training (curriculum) sessions, (ii) one individual counselling and goal setting session, ii) group follow-up sessions (bi-monthly sessions), and iv) a workbook. Participants were encouraged to bring a family member along during the sessions. The NEP group sessions were offered in seven groups of four to seven intervention participants. The groups were formed based on when the patients were recruited. The first group commenced in March 2017 and the last group completed in December 2018.

The NEP was implemented over one year, like the original NEP [20, 22]. The adapted NEP aimed to improve glycemic control (HbA1c) and other clinical outcomes (BMI, lipid profile, blood pressure) through improved dietary behaviors and behavior mediating factors (diabetes knowledge and diabetes management self-efficacy). The specific objectives were to: (i) increase vegetable and fruit intake to at least 3 servings per day, (ii) decrease starchy food intake (servings per day) to 6–11 servings, (iii) enhance balance in meals evidenced by macronutrient contribution to energy within the acceptable macronutrient distribution range (AMDR) i.e. carbohydrates 45–65 %; proteins 10–20 %; fats ≤ 30 %, and (iv) improve diabetes knowledge and diabetes management self-efficacy (DMSE).

Table 1. Nutrition education program

Session/ Month	Topic	Content and activities
1	What is diabetes mellitus & how is it treated? (Issue of education materials)	Nature of disease (explanation of what happens when one has diabetes, including body's response to food in diabetic/non-diabetic states, insulin action, causes/risk factors, types; symptoms; complications • Diet, physical activity & medication and their roles in treatment • Aim for treatment and targets for good control • Causes, symptoms and management of hypoglycemia & hyperglycemia • Importance of goal setting in diabetes management and how to set good goals **Activity**: Guided self-evaluation of baseline laboratory results; Reflection on current practices that affect diabetes control; group discussion and goal setting
2	Balancing the meals for health: Dietary guidelines*	• Overview of the food groups and contribution to overall health based on South African Food based dietary guidelines • Focus on variety, balance and selection of healthier options; highlight food groups that affect blood glucose **Activity**: View food groups on display; reflection on current dietary practices plus goal setting and group discussion
3	Balancing the portions	• Discussion on importance of portion control • Guidelines for meal pattern/frequency and portion sizes and the relation to medication **Demonstration**: portion sizes (household measures, plate model, Zimbabwe hand jive) **Activity**: • Practice portioning various commonly used foods • Discussion about portion sizes and associated issues such as hunger • Reflection on food portioning, goal setting and group discussion
4	Improving intake of vegetables, fruits and legumes	• Discussion on the importance of vegetable, fruits and legumes to general health and diabetes control • Tips on how to improve the intake of vegetables, fruits and legumes **Activity**: • Discussion on barriers to vegetable, fruit and legumes intake and how to overcome them, group goal setting • Display and tasting of one hot legume dish kept hot with a locally made & relatively cheap food warmer/cooker
5	Planning meals on a tight budget	• Planning meals on a limited budget including tips, emphasize variety and balance within available resources **Activity**: • Group identify strategies that could be used to plan healthy meals within their resources • Do costing for sample meals of commonly consumed foods • Plan a day's menu based on available resources and calculate the cost • Reflection and group discussion
6	Preventing complications and improving quality of life	• Good control through balancing between diet, physical activity and medication to prevent hypo-and hyperglycemia • Other self-care areas: foot, eyes, managing stress, etc. • Positive living with diabetes
7	Summary and evaluation	• Question and answer • Facilitator directed discussion on key issues covered in the curriculum • Group and individual evaluation of the curriculum component • Brief individual feedback on 6- months HbA1c results

5–10 minutes of group exercise at the end of each session to encourage individual exercise at home

* Commence individual consultations

The NEP curriculum content is presented in Table 1. Like in the original NEP, the SAFBDGs were used to teach the dietary content. In addition, messages that addressed multiple dietary behaviors were capitalized on. For example, consuming mixed meals (combination of at least 3 food groups: starchy foods, protein foods and vegetables in at least the main meals) as encouraged by the SAFBGS was a specific message aimed at improving meal balance (energy intake within AMDR) and vegetable intake while reducing excessive intake of starchy foods.

The NEP sessions were facilitated by one of the investigators (JM), a qualified and experienced dietitian, assisted by a MSc nutrition student. A training manual was used to enhance optimal delivery and consistency across the seven intervention groups. The sessions were offered in an interactive manner and included demonstrations and hands-on activities. In addition, the workbook contained a summary of key messages for each session and activities to engage participants between group sessions. The application of the SCT to improve targeted behavior mediating outcomes and behaviors are reported elsewhere [20]. Briefly, the following were employed for improving dietary and other self-care self-efficacy: (i) goal setting for dietary behaviors, (ii) addressing barriers to dietary and other self-care through group discussions, (iii) modelling/observation learning through facilitator demonstrating desired behavior(s), followed by practice by one or more participant, (iv) verbal persuasion, e.g. giving praise for accomplishment, (v) group activities including hands-on activities to enhance social support for positive behavior, (vi) vicarious learning through testimonials from successful stories, and (vii) encouraging and supporting problem-solving through behavior and outcome monitoring. Providing information on desirable levels of self-monitored glucose and the fridge/wall poster were used as cues to appropriate dietary and related behaviors for the intervention group [20].

Participants in both groups were reimbursed their transport costs during all the outcome assessment periods and during the education sessions for the intervention group. They were also offered healthy snacks. Control group participants who completed the program were offered a two-and a half hour group education session covering the main content of the NEP.

Measures

Except for demographic and medical history, all data were measured at baseline, 6-months and 12 months. Self-report and reviews of medical records were used to obtain data.

Clinical outcomes

The primary outcome (HbA1c) was measured from venous blood samples, if there were no recent results (≤ month) available from routine clinical care. The most recent (≤ 6 months) full lipid profile (total cholesterol, LDL-cholesterol, HDL-cholesterol, triglycerides) data were obtained from medical records. Blood chemistry analysis was done at the National Health Laboratory Services core laboratory. Weight and height were measured using standard techniques with participants barefooted and in light clothing [28]. Weight was determined to the nearest 0·1 kg using a calibrated electronic scale (Seca 872). Height was measured to the nearest 0·1 cm using a portable stadiometer (Seca 208). The average of two measurements each of weight and height were used for BMI calculations. BMI (kg/m^2) was calculated by dividing the participant's mean body weight by the square of his/her mean height. Blood pressure was measured according to standard guidelines [29] using a digital pressure monitor (Omron M4-1). Two measurements were taken and in cases where there was a difference of more than 5 mmHg between the readings, one or two more measurements were taken. The mean of the two closest measurements was used to determine mean blood pressure.

Dietary behavior

Two face-to-face 24hr multiple-pass diet recalls (1 weekday and one weekend day) on non-consecutive days assessed dietary intake. Three stages of the multiple-pass recalls were conducted: a 'quick list', a 'detailed description of food and beverage items consumed including quantities' and a review [30]. Portion estimation aids including bean bag mounds, fruit models and standardized commonly used household measures (cups, glasses, spoons, bowls etc.) were used to assist participants to quantify food/fluids portions. The interviews were conducted by a qualified dietitian, a masters student in nutrition and a qualified PhD nutritionist all who were trained.

Diabetes knowledge and management self-efficacy

The Simplified Diabetes Knowledge Scale (SDKS) [31] was used to assess diabetes knowledge. The SDKS is a 20-item instrument designed to measure general diabetes knowledge. The questions were read to the participants in a one-on-one interview and participants answered (true/false/don't know). The total number of correct or incorrect (including don't know) scores were calculated to a total percentage score. The SDKS is reliable and valid measure that is relatively easy to administer [31].

The English version of the Korean diabetes management self-efficacy scale (K-DSME) [32] was used to measure self-efficacy. The K-DSME consists of 16 items measuring diabetes self-management efficacy clustered into four sub-scales: nutrition (6 items), physical exercise/body weight (4 items), medical treatment (3 items), and blood sugar (3 items). An additional item "I am able to examine my feet for cuts/wound", that was present in the original DMSE scale [33] but removed in the K-DSME, was included as it was found essential in the target population. The item was added to the blood sugar subscale to form "blood sugar/feet check" sub-scale.

The SDKS and K-DSME were pretested with ten patients like the study population and adjustments were made to some wordings to suit the local context.

Changes in diabetes medication and hypoglycemic incidence

Change in diabetes medication over the study period was assessed at six and 12 months. A medication increase was defined as an increase in the dose or number of oral glucose-lowering agents and/or insulin dose while a decrease was defined as a reduction in the insulin dose and/or number or quantity of the oral agents.

Incidence of hypoglycemia (self-monitored blood glucose < 4 mmol/L) for the previous month (None/<3/ > 3 times) and the perceptions of intensity in comparison with prior experiences to joining the study (more/less/same) were assessed through self-report at baseline and the two assessment periods.

Dietitian consultation

Consultation with the hospital dietitian(s) before and during the study was assessed at baseline and at the two assessment periods.

Program adherence

Intervention participant attendance of the NEP was recorded at each session. Participants were given dates for NE sessions on cards and reminded of the same through telephone. Both intervention and control groups were reminded of their six month and 12-month assessments via telephone with up to four follow-up contacts in case of non-attendance.

Data analysis

The South Africa Medical Research Council FoodFinder3® diet analysis software was used to analyze the 24-hour diet recalls. Stata® version 15·1 was used for all statistical analyses. An intention-to-treat analysis using the last observation carried forward [34] was used. ANCOVA was used to compare the intervention group and control group on the measured outcomes post-intervention with adjustments for age and sex. Rank ANCOVA [35] was used for the triglycerides and dietary intake except for energy intake due to non-normality of data. The level of significance was set at $\alpha < 0{\cdot}05$ for a two-tailed test.

RESULTS

Participants' profile

Figure 1 presents the flow of participants through the study. Seventy-seven patients were enrolled, of which 48 completed (38 % attrition). Table 2 summarizes the participants' characteristics which were similar between the two groups. The mean age at baseline was 57.2 years (*SD* = 6.6) and a median diabetes duration of 14 years (7–21 interquartile range (IQR) for the sample. In both groups, participants comprised mainly of black (≥ 50 %) and white (≥ 20 %) races. The majority (> 75 %) were women, married (> 45 %), unemployed (> 65 %) and had at least high school education (> 85 %). A large proportion of participants were on insulin therapy (> 90 %), mainly in combination with oral hypoglycemics (> 55 %). Hypertension was the most common co-morbidity (> 90 %) followed by hyperlipidemia (> 55 %).

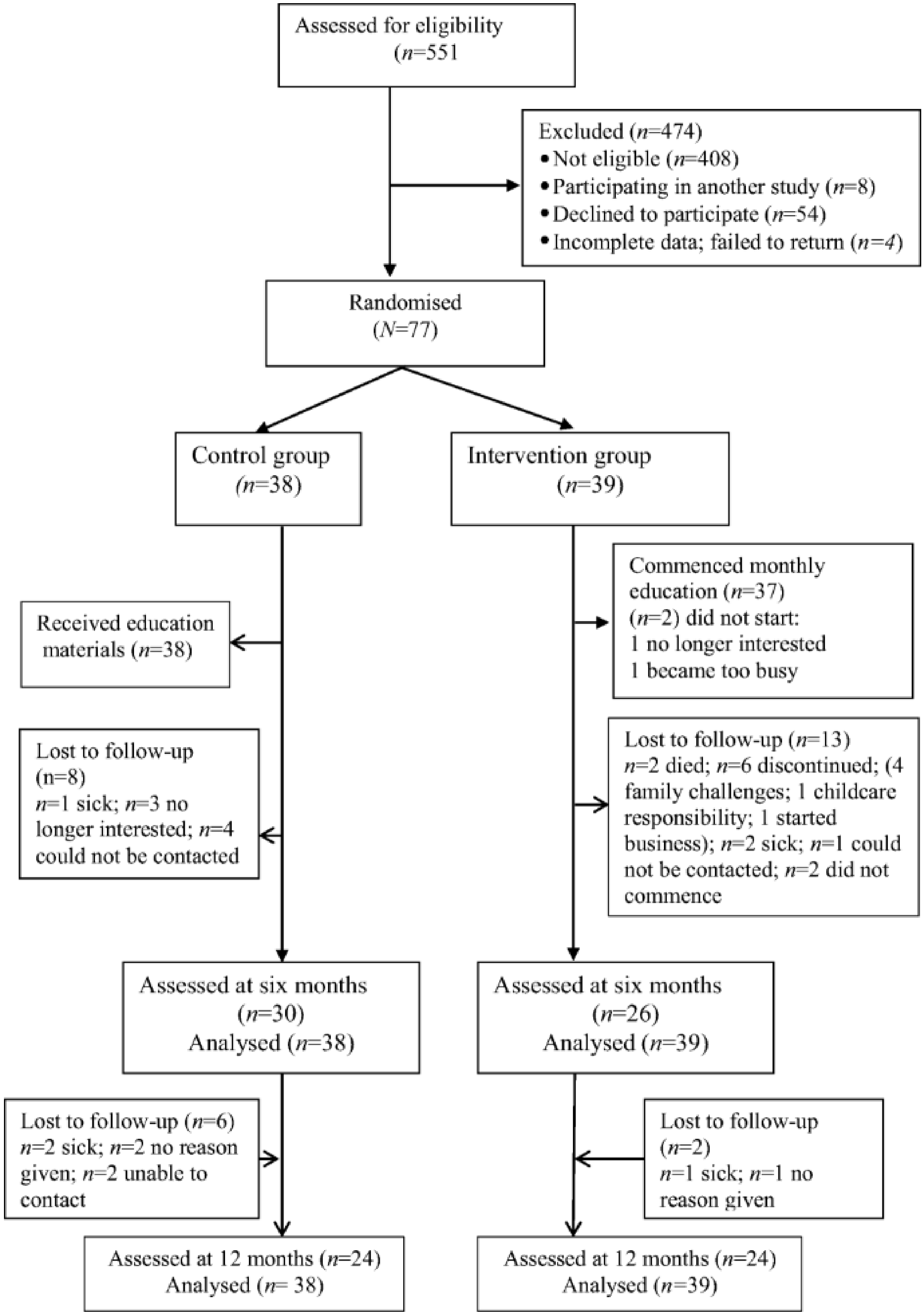

Fig. 1. Participants flow through the study

Table 2. Participants' demographic and medical profile

Characteristic	Intervention group (n=39)	Control group (n=38)	P-value
Age Mean (SD) (years)	57.6 (6.8)	56.9 (6.4)	0.62[a]
Diabetes duration (Median (IQR)) (years)	12 (6–20)	17 (9–23)	0.27[b]
Ethnicity	n (%)	n (%)	0.51[c]
Black Africans	25 (64.1)	19 (50.0)	
White	8 (20.5)	10 (26.3)	
Colored	4 (10.3)	4 (10.5)	
Indian	2 (5.1)	5 (13.2)	
Gender	30 (76.9)	30 (78.9)	0.83
Female			
Age-gender (years)	6 (15.4)	6 (15.8)	1.00
Males 40–60	5 (12.8)	4 (10.5)	
Males 61–70	16(41.0)	17 (44.7)	
Females 40–60	12 (39)	11 (29.0)	
Females 61–70			
Marital status	6 (15.4)	5 (13.2)	0.93
Single	19 (48.7)	20 (52.6)	
Married	9 (23.1)	7 (18.4)	
Widowed	5 (12.8)	6 (15.8)	
Separated/divorced			
Living situation	36 (92.3)	34 (89.5)	0.85
Live with family	2 (5.1)	2 (5.3)	
Live alone	1 (2.6)	2 (5.3)	
Other			
Education level	1 (2.6)	3 (7.9)	0.32
Primary school	34 (87.2)	34 (89.5)	
High School	4(10.3)	1 (2.6)	
Tertiary			
Employment status	26 (66.7)	27 (71.0)	0.68
Not employed			
Diabetes medication	3 (7.7)	0	0.92
Oral hypoglycemics (OHAs)	14 (35.9)	13 (34.2)	
Insulin	22 (56.4)	25 (65.8)	
OHAs+Insulin			
Co-morbidities	38(97.4)	36 (94.7)	0.62
Hypertension	12 (30.8)	11 (29.0)	0.86
Heart diseases	24 (61.5)	22 (57.9)	0.74
Dyslipidemia	5 (12.8)	4 (10.5)	1.00
Nephropathy	2 (5.1)	2 (5.3)	1.00
Retinopathy			
Hypoglycemia (last month)	8 (20.5)	8 (21.1)	0.99
Less than 3 times	15 (38.5)	14 (36.8)	
>3 times	16 (41.0)	16 (42.1)	
None			
Lifestyle	7 (18.0)	5 (13.1)	0.56
Alcohol	4 (10.3)	3 (7.9)	1.0
Smoking			
Attended diabetes group education	1 (2.6)	0	1
Previously seen dietitian	31 (79.5)	30 (79.0)	1.0
Duration since dietitian consultation (years)	16 (51.6)	10 (32.3)	0.42
<1	10 (32.3)	11 (35.5)	
1–4	3 (9.7)	4 (12.9)	
>4–10	2 (6.5)	6 (19.4)	
>10			

IQR: Interquartile range [a] Based on t-test [b] Based on Mann Whitney test [c] Based on Chi2 test

Adherence to the nutrition education program

Two intervention participants did not attend any education session. Of those who started the education sessions, 67·6 % attended at least four of the seven monthly sessions, representing program adherence. Only 18·9 % attended all monthly sessions and 46 % attended all bi-monthly sessions. Individual consultations were achieved for fewer than 50 % of participants who commenced the education sessions (41 %, 15/37).

Dietitian consultation

Most participants (~ 80 %) in both groups had been referred to- and seen a dietitian at the hospital's outpatient clinic at baseline, with no group differences (Table 2). Few participants in both groups consulted with the dietitian between baseline and six months (1 vs. 2) and six and 12 months (1 vs. 2) for the intervention and control groups respectively (data not shown).

Changes in diabetes medication and hypoglycemic incidences

At six months, 14 intervention and 21 control group participants had their insulin dose increased ($P = 0{\cdot}18$). At 12 months, five intervention and 15 control group participants had their insulin dose increased ($P = 0{\cdot}008$). The increase in insulin units was significantly higher in the control group at six months ($P < 0{\cdot}04$) and at 12 months ($P = 0{\cdot}009$). Two participants in the intervention group had their insulin dose decreased at each of the assessment periods (data not shown).

At baseline, over a third of participants in each group reported more than three hypoglycemic episodes in the previous month, but no group differences were seen ($P > 0.05$). At six and 12 months few participants reported more than three hypoglycemic episodes in the previous month (< 7 per group) or perceived an increase in hypoglycemic events during the study compared with before (< 3 per group).

Clinical status

Table 3 presents the mean baseline clinical data and the age and sex adjusted outcomes at six and 12 months. There were no group differences at baseline for all clinical outcomes. For HbA1c, no group differences were found at both six months and 12 months ($P = > 0.05$), though intervention group had lower levels at six months. The NEP achieved the hypothesized reduction of at least 0.5 % in HbA1c levels at six months (-0.53 %). No group differences were found in the proportion of participants who achieved the HbA1c target (< 7 %) at the two time periods ($P > 0{\cdot}05$). In both groups, the BMI was in the obese category at baseline and with no changes over the study period or group differences. Systolic blood pressure was significantly lower in the intervention group at six − 6·6 ($P = 0{\cdot}049$) and 12 months − 9·4 ($P = 0{\cdot}004$), and diastolic blood pressure − 4·11 ($P = 0{\cdot}016$) at 12 months.

Baseline and follow-up lipids were available for a small subset of each group ($n = 23$–28). None of the lipids was significantly different between the groups at six or 12 months.

Table 3. Clinical outcomes: differences between the intervention and control groups from baseline to post-intervention

	Baseline			6 months				12 months			
Outcome	Intervention (*n*=39)	Control (*n*=38)	*P* value[a]	Intervention (*n*=39)	Control (*n*=38)	Difference (95% CI)	*P* value[b]	Intervention (*n*=39)	Control (*n*=38)	Difference (95% CI)	*P* value[b]
HbA1c, mean (SD/SE)	10.3 (1.9)	10.6 (1.9)	0.47	9.88 (0.2)	10.4 (0.2)	-0.53 (-0.11- 1.2)	0.10	9.91 (0.2)	9.92 (0.2)	-0.02	0.96
Body mass index (kg/m^2)	34.5 (5.6)	34.1 (5.2)	0.76	34.2 (0.2)	34.5 (0.2)	-0.37 (-0.1- 0.82)	0.11	34.4 (0.3)	34.3 (0.3)	-0.1 (-0.9-0.79)	0.88
Systolic blood pressure (mm Hg)	130.8 (14.2)	135.0 (16.9)	0.23	130.7 (2.3)	137.2 (2.3)	-6.6 (0.01–13.1)	0.049	128.2 (2.3)	137.6 (2.2)	-9.4 (3.2–15.6)	0.004
Diastolic blood pressure (mm Hg)	71.1 (7.3)	73.0 (7.6)	0.28	72.3 (1.3)	73.8 (1.3)	-1.56 (-2.1- 5.2)	0.40	71.6 (1.2)	75.7 (1.2)	-4.11 (0.79–7.4)	0.016
Total cholesterol (mmol/L)	4.19 (0.96)	4.75 (1.54)	0.11	3.94	4.47	0.53 (-0.4- 1.1)	0.07	3.98 (0.19)	4.17 (0.19)	-0.20 (0.36–0.75)	0.48
LDL-cholesterol (mmol/L	2.29	2.61	0.13	2.13 (0.14)	2.39 (0.14)	0.25 (-0.17-0.68)	0.24	2.19 (0.16)	2.49 (0.16)	-0.34 (0.12–0.80)	0.15
HDL- cholesterol (mmol/L)	1.12 (0.29)	1.1 8 (0.30)	0.50	1.07 (0.05)	1.15 (0.05)	-0.08 (0.07–0.23)	0.28	1.07 (0.04)	1.10 (0.04)	-0.09 (-0.03-0.20)	0.14
Triglycerides (mmol/L)	1.54[c] (1.2–2.2)	1.76 (1.2–2.4)	0.50[d]	1.6 (1.0-2.3	1.46 (1.2–2.4)	-	0.76[e]	1.36 (1.0-2.2)	1.39 (1.1-2.0)	-	0.22[e]

Baseline data are mean (SD); 6 and 12 months are mean (SE)

[a] Based on student's t-test

[b] Based on ANCOVA

[c] Median (Interquartile range (IQR))

[d] Based on Mann Whitney test

[e] Based on rank ANCOVA)

Dietary behavior

Table 4 shows the baseline and age and sex adjusted post-intervention dietary behavior outcomes for the intervention and control groups. There were no group differences at baseline for any of the dietary behavior outcomes. Post-intervention, only intake of energy at six months was significantly lower in the intervention group when compared to the control group (-125.0 Kcals, $P = 0{\cdot}042$). Macronutrients contribution to energy were within the AMDR for both groups throughout the study and no group differences were observed. Intake of vegetables and fruits was very low at baseline and at the two assessment periods with no group differences.

Diabetes knowledge and diabetes management self-efficacy

Table 5 presents baseline and age and sex adjusted diabetes knowledge scores and diabetes management self-efficacy scores, respectively. There were no group differences at baseline in the scores of these two outcomes. At six months the intervention group had significantly higher mean diabetes knowledge scores than the control group + 1.29 ($P = 0.013$). However, this difference was not sustained at 12 months. Post-intervention, there were no significant group differences in the diabetes management self-efficacy mean scores for the total scale and sub-scales, except for the blood sugar and feet check sub-scale at 6-months where the intervention group had a higher score + 0.53 ($P = 0.02$) compared to the control group.

Table 5. Diabetes knowledge and diabetes management self-efficacy: differences between the intervention and control groups from baseline to post-intervention

Outcome	Baseline			Six months				12 months			
	Intervention group (*n*=39)	Control group (*n*=38)	*P*[a] value	Intervention Group (*n*=39)	Control group (*n*=38)	Difference (95% CI)	*P*[b] value	Intervention Group (*n*=39	Control Group (*n*=38)	Difference (95% CI)	*P*[b] value
Knowledge*	11.2 (1.98)	11.9 (2.6)	0.17	15.0 (0.36)	13.8 (0.36)	-1.29 (-2.1- -1.2)	0.013	16.1 (0.51)	14.7 (0.51)	-1.38 (-2.82-0.07)	0.061
Diabetes management self-efficacy**											
Total scale	7.9 (1.3)	7.9 9 (1.4)	0.88	8.5 (0.1)	8.2 (0.1)	-034 (-0.74- 0.01)	0.055	8.7 (0.2	8.4 (0.2)	-0.30 (-0.74-0.2)	0.22
Sub-scales**											
Diet self-efficacy	7.1 (2.0)	6.9 (2.2)	0.77	7.9 (0.2)	7.6 (0.2)	-0.30 (-0.9-0.3)	0.29	8.0 (0.21)	7.8 (0.21)	-0.23 (-0.84-0.38)	0.45
Physical activity & weight	7.1 (2.3)	7.0 (2.3)	0.72	7.9 (0.2)	7.3 (0.3)	-0.66 (-1.4-0.04)	0.07	8.2 (0.4)	7.7 (0.4)	-0.56 (-1.8- 0.7)	0.36
Medical treatment	9.7 (0.64)	9.9 (0.0.3)	0.14	9.8 (0.1)	9.9 (0.1)	0.02 (-0.13-0.2)	0.77	9.9 (0.1)	9.7 (0.1)	-0.14 (-0.38-0.1)	0.22
Blood sugar & feet check	8.3 (1.5)	8.2 (1.3)	0.82	8.8 (0.2)	8.2 (0.2)	-0. 53 (-0.97–0.1)	0.02	8.7 (0.14)	8.6 (0.14)	-0.26 (-0.7-021)	0.22

Baseline values are mean (SD); Six and 12 months mean (SE)

[a] Based on t-test;

[b] Based on ANCOVA

[*] Maximum score = 20

[**] Maximum score = 10

Discussion

This study tested the effectiveness of an adapted NEP to improve clinical outcomes through improved dietary behaviors and behavior mediators guided by the SCT. The main hypothesis that the NEP would induce a reduction in HbA1c of at least 0.5 % at six months is supported by our results that showed a 0·53 % reduction in HbA1c. However, this reduction was not sustained at 12 months unlike in the original NEP [22]. The positive result at six months is clinically meaningful [25, 36] in view of the demonstrated 37 % reduction in microvascular complications for every 1 % decrease in HbA1c by the United Kingdom Prospective Diabetes Study (UKPDS) [37]. The reduction in HbA1c at six months is comparable to that achieved at four months (0.59 %) in an activity and nutrition intervention for obese T2DM patients [38]. The reduction in our study is higher than that reported for the LOADD study, a nutrition intervention for uncontrolled T2DM patients on maximum hypoglycemics dose (-0·4 %) [39]. The reduction is also higher than that reported for lifestyle interventions (-0·37 %) in a meta-analysis [40], and a systematic review and meta-analysis, (diet component: -0·30 %) [41]. The reduction in HbA1c is slightly lower than achieved in the original NEP (~ 0·6 %) [22] and lower than for a sub-set of poorly controlled (HbA1c 7–10 %) (-0·76 %) participants in the plate model teaching arm [42], an approach used teach food portions in the current study.

Our results do not support the hypothesis of the NEP achieving a significant reduction in the primary outcome (HbA1c) post-intervention. The non-significant results could possibly be explained by several reasons. Intervention participants did not satisfactorily attend the group education sessions nor the individual session, which could have led to inadequate diet self-efficacy and unsatisfactory dietary self-care, which is evidenced in our study. Diet self-efficacy is a strong predictor of dietary self-care behavior and both are reported to predict better glycemic control among T2DM patients [43, 44]. It is also likely that the impact of medication as a result of greater up-titration of insulin dose in the control group at both six and 12 months would have reduced the effect of the NEP.

Our secondary outcomes hypothesis regarding clinical outcomes is only supported for systolic blood pressure, whereby a significant reduction was induced at six months and sustained at 12 months. Diastolic blood pressure was only significantly lower in the intervention group at 12 months. The results showing improved blood pressure agree with those of a systematic review and meta-analysis for dietary interventions [41] and a meta-analysis for lifestyle interventions including diet [40] as well as for a South African group DSME intervention in primary health care [45]. The positive effect on blood pressure is an important outcome, given the associated cardiovascular disease (CVD) risk and mortality reduction [46, 47]. As reported in most lifestyle interventions for T2DM patients, our NEP had no effect on BMI [41], emphasizing the challenge of losing weight among overweight and obese people with T2DM [48].

Regarding dietary behaviors, only energy intake at six months was significantly lower in the intervention group compared to the control group. This is contrary to the original NEP which achieved significant results for starchy food intake at six months and 12 months, in addition to a significant outcome for energy intake at 12 months [22]. It is however worth noting that the reported starchy food intake of participants in the current study was within the desired targets and much lower than for participants in the original NEP [22]. No interventions targeting starchy food intake behavior among people with T2DM were found. The level of energy intake reduction at six months is comparable to that reported for a dietitian led study among poorly controlled T2DM participants [49]. The non-significant difference in macronutrients contribution to energy was also reported by the study by Huang et al. [49]. Macronutrient contribution to energy in our study was within the AMDR for both groups, meaning not much change would have been expected. Overall, given the obese status of participants in our study, under reporting of dietary intake cannot be ruled out as it is common among obese adults [50] including those with T2DM [51].

Contrary to the study by Deakin et al. that found increase in fruit and vegetable intake [52], our results show no impact of the NEP on these dietary behaviors. In the current study, it was noted that participants were reluctant to set goals and to action plan for these dietary behaviors, while these techniques are considered effective in changing dietary behavior [53], even among people with T2DM [54]. Participants' reasons for unwillingness to engage in the two activities included not being solely responsible for meals and costs concerns. This indicates that self-efficacy for these dietary behaviors was unchanged despite the NEP addressing barriers to healthy eating including cost. It does also appear that the outcome expectation from the emphasis of the benefits of vegetable and fruit consumption did not adequately outweigh participants' perceived cost barrier. The importance of family support for appropriate self-care behaviors including diet [55] is well recognized. In our study, however, few participants were able to bring a family member due to unavailability. This is contrary to the expectation given that in the needs assessment, involving family members was recommended [21]. In addition, the NEP education sessions were offered during the preferred times (i.e. weekdays and during the mornings) [21].

While cost is recognized to contribute to low vegetable and fruit consumption as reported in a recent multi-country study including South Africa [56], the very low intake by participants in this study (≤ 1 serving/day; ≤ 80 g/day) compared to the those of the original NEP (1.3–2.2 servings/day) [22] and South African adults aged ≥ 45 years (2.2–2.74 servings/day) [57] is concerning and requires further investigation. Adequate intake of vegetables and fruits is beneficial in reducing CVD risk [58] for which PLD are at high risk [47], and in contributing to dietary fiber. High fiber diets have been shown to reduce absolute values of HbA1c by 0.55 % in a systematic review and meta-analysis of RCT [59]. Further, lower levels of HbA1c and triglycerides have been reported among elderly Japanese men consuming ≥ 200 g/day of vegetables in the Japanese Elderly Diabetes Intervention [60].

Regarding behavior mediators, unlike in the original NEP where diabetes knowledge scores were significantly higher in the intervention group at the two time periods [61], it was only significant at six months in this study, although the intervention group had higher scores at 12 months. The results at six months agree with those of a culturally adapted NEP [62]. The non-sustained outcome at 12 months could possibly be explained by the low program participation by the intervention group. The NEP had very limited impact on diabetes management self-efficacy, with only the blood sugar and feet check sub-scale reaching significant levels at six months. The results of the current study correspond with those of a South African study conducted in primary care that found no effect on self-efficacy for group DSME in T2DM adults [45].The results are contrary to those of a self-efficacy program that included diet education for Taiwanese T2DM patients that found significant improvement in self-efficacy using the same scale used in the current study [63]. The results are also contrary to those a theory-based nutrition education intervention among older adults (≥ 65 years) with T2DM that reported significant improvements in nutrition related self-efficacy [64]. The lack of significant improvement in self-efficacy especially related to diet self-efficacy is an unexpected outcome given the multifaceted strategies employed to improve self-efficacy [53, 54] including behavior enablement techniques such as barrier identification, goal setting, action planning, problem solving and cues to action [20]. More intensive efforts to keep participants engaged between education sessions, for example through telephone contacts as had been done in the Taiwan study [63] might have been needed. In the Taiwan study, the telephone contacts which lasted 10–15 minutes offered health professionals an opportunity to promptly deal with participants challenges [63].

This study has several strengths including using an RCT design and the assessment of multiple outcomes known to impact on metabolic control of PLD. The assessment of other factors that were likely to influence the outcomes such as changes in glucose lowering medications, perceptions about hypoglycemia incidence and participants consultation with the dietitian is an additional strength. Establishing the participants' perceptions regarding incidence of hypoglycemia was important because of the possibility of compensatory measures for preventing the occurrence such as increased energy intake or decreasing insulin dose with a negative consequence on glycemic control [65]. The additional insight regarding lower need for medication increase in the intervention group is an important finding because of the health costs implication. Further, the study was long enough to assess stability of outcomes beyond six months.

Limitations of this study include insufficient power to detect a 0.5 % change in the primary outcome. Recruitment into the study however posed a challenge, with 41 % of eligible participants refusing to participate mainly because of lack of interest and time, reasons noted for non-participation in DSME programs [66]. The small sample of participants assessed for the lipid profile was another limitation beyond the investigators control due to limited resources. Inability to obtain three 24hr diet recalls, the optimal number recommended for assessing group energy intake [67] as initially planned [20] could also be viewed as a limitation. However, an analysis of dietary intake of close to a third of participants (n = 21) for whom three recalls at baseline were obtained, revealed no difference in energy intake when compared with two 24hr recalls (1814.5 vs. 1812.4 kcal/d, P = 0.90).

Seemingly, the adapted NEP had a lower impact than the original program. Although the intensity and contact time of the adapted NEP was reduced to meet the needs of the tertiary patients, the requisite number of sessions, contact time and intervention duration reported to contribute to DSME effectiveness was met [68, 69]. It does appear low program participation could have played a major role indicating a need for novel strategies for enhancing participants' motivation and program participation at the tertiary setting. This is particularly because program completers of the current study (unpublished data) indicated high program satisfaction suggesting that low program participation was not due to the program per se. A system level approach to align group DSME and patient outpatient activities could help overcome the challenge experienced in the current study of scheduling group education during medicine collection days as initially planned.

Conclusions

The adapted NEP had limited effects on HbA1c, selected SCT behavior mediators and dietary behaviors but appeared beneficial on blood pressure. The health cost savings potential of the NEP supports the need for improving program participation.

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Data availability

Data are available from the corresponding author upon reasonable request.

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