A nurse-led, community-based self-management program for people living with type 2 diabetes in Western Ethiopia: A feasibility and pilot study protocol

Running title: Nurse-led, community-based self-management program for people living with type 2 diabetes.

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Abstract

Aim: To develop and examine the preliminary effects of a nurse-led, community-based diabetes self-management education and support program on clinical outcomes, self-care behaviours, quality of life, and family support through a pilot randomized controlled trial among adults living with type 2 diabetes in Western Ethiopia.

Methods: A two-arm parallel-group pilot randomized controlled trial involving patient-caregiver dyads will be conducted. A total of 76 dyads will be recruited, with 38 dyads randomly allocated to the intervention arm receiving six sessions of the diabetes self-management education and support program supported by an educational handbook, flier, and video on top of the usual care; the control arm will continue to receive the usual care. The intervention will be guided by social cognitive theory and related international guidelines for diabetes management, addressing misconceptions, using culturally tailored foods, and involving family members in the intervention. Subjects will be recruited at Nekemte

Specialized Hospital over two months. Nurses will deliver the intervention in the community in Nekemte, western Ethiopia. Diabetes self-care behaviour, quality of life, family support, glycosylated haemoglobin, body mass index, blood pressure, and lipid profiles will be assessed. Generalized estimating equation models will be computed to test for the preliminary effectiveness of the diabetes self-management education and support program on the outcomes, and Cohen's d will be computed to estimate the effect size.

Trial registration: The Chinese Clinical Trial Registry prospectively registered the trial, and the registration number was ChiCTR2000040292.

KEYWORDS

Diabetes, diabetes self-management education and support, DSMES, nurse-led self-management program.

Novelty statement

What is already known?

- Studies on the effects of diabetes self-management interventions on blood pressure, body mass index and total cholesterol showed significant results, whereas the effect on glycated haemoglobin was inconclusive among adult people living with diabetes in Africa.
- In Ethiopia, most people consume traditional foods that are high in carbohydrates, and it is a cultural practice to eat food together. It is difficult to change behaviour with respect to cultural food and eating traditions.

What will this study address?

- This study will examine the feasibility and preliminary effects of a nurse-led, community-based diabetes self-management education and support program addressing cultural foods, misconceptions and family support and their effects on blood pressure, body mass index, lipid profiles, glycated haemoglobin, self-care practice, family support behaviour and quality of life among adults living with type 2 diabetes.

INTRODUCTION

Diabetes has become a global public health problem with frighteningly increasing rates of morbidity and mortality.[1, 2] An International Diabetes Federation Atlas report in 2019 showed that 463 million, 19.4 million and 1.7 million adults were living with diabetes in the world, Africa, and Ethiopia, respectively.[1] Diabetes is one of the toughest chronic illnesses in African health systems, posing a 'double burden' of infectious and chronic diseases.[3-5]

Sub-Saharan Africa has many challenges related to diabetes management.[4] Like other countries in sub-Saharan Africa, people in Ethiopia use traditional medicine; different cultural beliefs about diabetes exist and are potential barriers to its effective management.[6] There are four major challenges to effective diabetes management in Ethiopia: food, misconception about the disease, family support, and the health care system. Lack of understanding about food intake remains the main challenge in the management of diabetes.[7] Diet in Ethiopia is mainly composed of cereals, tubers, and root crops.[8] 'Injera', the national dish of Ethiopia, is a flatbread prepared of teff flour made from teff, which is native to the horn of Africa.[9] It is a staple food and the mainstay of every meal in Ethiopia, but it can raise blood sugar.[7] Perhaps due to a lack of knowledge about the source of nutrients and the ability to buy a variety of foods,[7] people living with diabetes do not follow nutritional recommendations.

Family support is a specific aspect of social support that is crucial in self-care. Previous studies have reported that the family may play a supportive[10-12] or non-supportive role in diabetes self-care behaviour.[13, 14] In Ethiopia, it is a tradition, especially at lunch and dinner time, to consume food together with all family members from a communal plate. Eating together is an essential part of Ethiopian culture and a sign of love.[9] Thus~~As a result~~, it may not be possible to heed the dietary preferences and needs of people living with diabetes. This makes it difficult for them to change ~~participant's~~ behaviour and modify ~~their~~ dietary practice.

Studies on the effectiveness of diabetes self-management interventions showed small to modest improvements in diabetes outcomes, reflecting mixed results with substantial variations across studies.[15, 16] Recent~~ly, a~~ systematic review s reported that ~~and meta-analysis among African Americans with type 2 diabetes reported that~~ diabetes self-management education was ineffective in reducing glycated haemoglobin and improving quality of life among African Americans with type 2 diabetes,[16] and ~~people living with diabetes in Africa demonstrated that~~

has mixed results ~~the effects of diabetes self-management interventions~~ on physiological outcomes ~~were mixed~~among people living with diabetes in Africa.[17] Besides, none of the studies included interventions adapted to the local context – such as family, targeting misconceptions about diabetes, and the frequent consumption of cultural food – as part of the intervention, and only one study was conducted in the community.[18] These meta-analytic findings suggest a need for modifications in diabetes self-management interventions for African people living with diabetes because no attention has been paid to the barrier of local food and the facilitator of family support in self-management for this population~~the person with diabetes in Africa~~. It is suggested that locally adapted, community-based interventions engaging families as an integral part could be used to achieve diabetes management targets. Nurses were not involved in interventions in any of the randomized controlled trials ~~studies~~ conducted in Africa,[17] thus we propose to examine the effects of a nurse-led interventional study. Therefore, this proposed study will examine the feasibility and estimate effect sizes~~preliminary effects~~ of the nurse-led diabetes self-management education and support program on diabetes clinical outcomes, self-care behaviours, quality of life, and family support among adults with type 2 diabetes and nominated primary family caregivers (any relative, partner, friend, or neighbour who has a significant personal relationship with people living with diabetes).

OBJECTIVES

1. To determine the rates of eligibility, recruitment, retention, and percentage of missing data at the item level of the questionnaire of the respondents.

2. To estimate the effect sizes of the nurse-led, community-based diabetes self-management education and support program on glycated haemoglobin, lipid profiles, systolic blood pressure, diastolic blood pressure, body mass index, self-care behaviours, quality of life, and family support behaviour among adults living with type 2 diabetes.

3. To examine the effect size of a nurse-led, community-based diabetes self-management education and support program on family support behaviour among family caregivers of adults living with type 2 diabetes.

4. To explore the acceptability of diabetes self-management education and support intervention among adults living with type 2 diabetes and their family caregivers.

METHODS
Study setting

Participants will be recruited in Nekemte Specialized Hospital and the intervention will be conducted in the community of two selected *Kebeles* in Nekemte, Ethiopia. *Kebeles* ~~(which~~ is a small administrative unit ~~within Ethiopia and consisting of~~ at least 500 families ~~in each Kebele) in Nekemte, Ethiopia~~. The two selected *Kebeles* have high numbers of people living with diabetes and are easily accessible for the intervention.

Trial design

A two-arm, parallel-group pilot randomized controlled trial will be conducted, with a follow-up at two months after the intervention.

Eligibility criteria

Study participants will be dyads (people living with type 2 diabetes and one of their nominated family caregivers) living in the city of Nekemte, Western Ethiopia. ~~Eligibility screening will be performed by data collectors.~~ People living with diabetes will be included if they 1) have been diagnosed with type 2 diabetes (from their ~~(the diagnosis will be retrieved from the participant's~~ medical records), 2) are aged 18 or over, 3) come from the two selected *Kebeles* in Nekemte ~~(Kebeles that have high numbers of people living with diabetes and are easily accessible for the intervention)~~, and 4) are taking insulin and/or oral hypoglycaemic agents. They will be excluded if they 1) have a cognitive impairment (from ~~which information will be retrieved from the people living with diabetes~~ medical records); 2) are unable to nominate one family member who can support them in diabetes management; 3) are a pregnant woman living with type 2 diabetes (they will be excluded due to possible difficulty in completing the intervention and follow-up related to pregnancy-related physiological changes); 4) have a physical impairment like blindness, paralysis, etc., because they may not be able to attend the diabetes self-management education and support sessions due to these impairments; and 5) are unable to understand Afaan Oromoo.

Family members will be included if they are 1) the primary family caregiver, 2) aged 18 or over, 3) willing to provide support, and 4) living with the people living with diabetes. Family members will be excluded if they 1) have physical limitations preventing them from performing the caregiver responsibilities or 2) are unable to understand Afaan Oromoo.

Interventions

The participants will be divided into two arms. The control arm will receive the usual care from~~provided by~~ the participating hospital, and the intervention arm will receive the usual care

and the diabetes self-management education and support program. Usual care in the hospital includes pharmacological management approaches to diabetes. Specifically, people living with diabetes attend the diabetes clinic every month in the ~~participating~~ hospital, at which history taking, physical examination conducted by nurses and physicians, and laboratory evaluation of blood glucose via fasting blood glucose are routinely conducted by medical laboratory professionals.[19] If the person is newly diagnosed with diabetes, brief oral counselling will be provided. People living with diabetes also collect prescribed drugs and home-based self-medication at the monthly visit. Th~~is usual~~e ~~cost of the~~ care is paid for by the people living with diabetes, although some of them have health insurance.

On top of the usual care ~~for people living with type 2 diabetes~~, the intervention group will receive diabetes self-management education and support. It was recommended that all components of diabetes self-management education be adopted: ≥10 h~~our~~, Short Message Services-supported face-to-face interventions and those guided by theory.[17] The engagement of family members and community-based interventions[20] was also recommended to improve~~reduce~~ clinical outcomes. The~~A~~ diabetes self-management education and support is specifically designed to enhance nutritional knowledge of cultural foods and improve family support and is intended to be conducted in the community to address diabetes challenges in Africa. The ~~diabetes self-management education and support~~ program consist~~s~~ of six 2-hour sessions, including an educational package that addresses seven self-care behaviours for diabetes management (healthy diet, physical activity, medication, self-monitoring of blood glucose, diabetes complications, healthy coping, and problem-solving), diabetes-related misconceptions, and foot care followed by home-based family support (Support file 2~~1~~). The contents of the intervention were developed from a diabetes education training manual for sub-Saharan Africa,[6] ~~and~~ the lifestyle recommendations ~~were~~ taken from the American Diabetes Association standards of care in diabetes-2020,[21] and an educational video produced on foods and drinks for Ethiopian adults with diabetes living in the United States.[22] Other components are also included to address the local context. The development of the intervention is guided by social cognitive theory (Support file 2~~1~~). ~~A diabetes self-management education and support is specifically designed to enhance nutritional knowledge of cultural foods and improve family support and is intended to be conducted in the community to address diabetes challenges in Africa. The diabetes self-management education and support program consist of six 2-hour sessions, including an educational package that addresses seven self-care behaviours for diabetes management (healthy diet, physical activity, medication, self-monitoring of blood~~

glucose, diabetes complications, healthy coping, and problem-solving), diabetes-related misconceptions, and foot care followed by home-based family support (Support file 2).

The education intervention will be given in a face-to-face, group format for six consecutive weeks, a total of 12 hours. In each group, at most seven dyads will be included, hence a total of six intervention groups will be formed based on the proximity of their homes to each other. The intervention will be delivered using a culturally tailored approach with a validated diabetes self-management education and support handbook. The handbook was validated assessed by an expert panel consisting of (four subject matter experts and four people living with diabetes) with . Tthe content validity index ofwas 1.0, indicating that the handbook is relevant, feasible, and appropriate. The expert panel gave comments to add some contents to the handbook in a culturally acceptable way. The participating family members will be equipped with the knowledge and skills to provide support to the people living with diabetes at home. The diabetes self-management education and support educational handbook will be distributed in the first session, and the flyer, which contents other important tips on signs and symptoms of hyperglycaemia, the glycaemic index of common foods, the side-effects of Metformin, common tips for foot care, and management of the sick day, will be distributed in every session. Demonstrations of how to conduct blood glucose self-monitoring and a video on foot care will be used to enhance learning. The health extension workers, who are trained staffworkers of the and government staff and, will trained act as a bridge between the community and public health institutions, and will be assigned to each *Kebele*. They will remind participants one day before every session. Family caregiverssupport is expected to provide support be given to the people living with diabetes, and they will continue the implementation of their roles and responsibilities (Support file 3). The intervention will be delivered by three experienced nurses in diabetes care who have a nursing Bbachelor degreeof Science in nursing and, work in athe participating hospital, and are experienced in diabetes care. A two-day training workshopprogram on the intervention contents will be given to the nurses by the first author. The interventiontraining will be delivered in three training centres in the community, considering the proximity of participants' homes to the training centre. It is important to boost intervention adherence, as travel cost is a barrier to receiving the intervention in the hospital, for both the person living with diabetes and the family member. Participants will receive 60 Ethiopian birr for transportation after attending each of the six sessions to boost intervention adherence as travel cost is a barrier to receiving the intervention in the hospital for participants of the study. No care will be prohibited to the participants during the intervention. The

intervention will be discontinued at the participant's request or because of any claim of serious disease or social events.

Outcomes

Feasibility outcomes
Eligibility rate, recruitment rate, retention rate, and percentage of missing data at the item level will be calculated.

Intervention fidelity
Intervention fidelity, ~~This is~~ the extent to which the intervention is delivered as it was intended,~~.~~[23] will be assessed with ~~A~~a 13-item self-developed checklist, administered ~~will be used to assess intervention fidelity~~ at each of the 36 diabetes self-management education and support sessions (six groups times six sessions).

People living with diabetes and Family Outcomes
Four groups of ~~T~~the people living with diabetes outcomes ~~of this intervention~~ will be collected~~classified into four groups~~: 1) clinical outcomes, including glycated haemoglobin, lipid profiles, systolic blood pressure, diastolic blood pressure, and body mass index; 2) behavioural outcomes; 3) quality of life, and 4) receiving family support. The family outcome will be family behaviour, which assesses the support provided to the people living with diabetes by the family caregiver. The translated, culturally adapted, and psychometrically tested Afaan Oromoo version of all scales will ~~be used to~~ measure the self-reported outcomes.

Primary outcomes
a) The glycated haemoglobin of the people living with diabetes, a gold standard measure of blood glucose, measured after obtaining a venous whole blood sample, analysed using a COBAS C311 fully automated clinical chemistry machine and reported in %.
b) The family member's family behaviour will be measured using the validated 16-item Diabetes Family Behavior Checklist.~~, with internal consistency ranging between 0.71 and 0.74.~~[24]

Secondary outcomes from people living with diabetes
a) The lipid profiles ~~of the people living with diabetes~~ – composed of the levels of total cholesterol, high-density lipoprotein, low-density lipoprotein, and triglycerides – will be measured after obtaining a venous serum sample; they will be analysed using the COBAS C311 fully automated clinical chemistry machine and reported in mg/dL.

b) The blood pressure ~~of the people living with diabetes~~ will be measured using an aneroid sphygmomanometer on the left upper arm and reported in mm Hg.

c) The body mass index ~~of the people living with diabetes~~ will be calculated from their weight and height, which will be measured using the TCS-200LP stadiometer.

c) The self-care behaviours ~~of the people living with diabetes~~ will be measured using the Summary of Diabetes Self-care Activities-Expanded scale.~~,~~[25]~~. whose internal consistency has been calculated as 0.62.~~[26] The score for the <u>scale</u>~~summary of diabetes self-care activities~~ will be calculated from the mean numbers of days the person living with diabetes practised self-care activities in the previous seven days for ~~ ~~all items.

d) The quality of life ~~of the people living with diabetes~~ will be measured using a <u>validated</u> 46-item Diabetes Quality of Life scale, with lower scores indicating better quality of life.[27] ~~The scale has demonstrated good reliability.~~

<u>e)</u> The family support reported by the people living with diabetes will be measured using the <u>validated</u> Diabetes Care Profile Support scale.~~,~~[28]~~ which has acceptable to excellent reliability for African Americans, ranging from 0.70 to 0.97.~~[29]

<u>Secondary outcome from the dyads</u>

~~e)~~<u>f)</u> The acceptability of the intervention to participants will be assessed using the <u>validated 6-item</u> credibility and expectancy questionnaire.[30] The scale has two sets of questions that address the thinking and feeling about what will happen after receiving therapy. ~~The scale has six items, each of which has nine responses ranging from 1 to 9. It has been shown to have good to excellent reliability.~~

The sociodemographic characteristics of gender, age, educational status, employment status, monthly income, the relationship between family caregiver and family, and the presence of comorbidity will be obtained from the dyads.

Timeline

Data collection is expected to be completed in ten months. The recruitment, intervention, and post-intervention follow-up will take six months (Support file 4).

Sample size determination

The sample size was determined according to Hertzog's recommendation for a pilot interventional study [S1]. Accordingly, 30 dyads per group are needed to estimate the variance in the between-group difference. Allowing for a 20% attrition rate, 38 dyads per group will be recruited to the study, for a total of 76 dyads.

Subject recruitment

Subjects will be recruited, using convenience sampling, on the day of their monthly check-up at the participating hospital. ~~The dyads will be the sampling unit. A convenience sampling technique will be used to select eligible participants.~~ According to the hospital registration, ~~Among a total of 993 people living with diabetes,~~ 461 ~~of them~~ people are living with type 2 diabetes ~~(according to hospital registration)~~. An average of five dyads per day will be recruited via face-to-face interviews until we have 76 dyads. Their participation will be ensured before they leave the hospital after completion of the monthly visit. If the family member attends the hospital with the people living with diabetes, both will be approached and invited to participate in the study. After explaining the project, the data collectors will obtain written consent from the dyad~~both the people living with diabetes and the family member~~. If the ~~primary~~ family caregiver is not with the people living with diabetes during recruitment, the phone number of the nominated family member will be obtained, and they will be contacted for recruitment. The baseline assessment will then be conducted. If the family member is recruited via telephone, oral consent will be obtained first, and the baseline assessment will be conducted via telephone after obtaining oral consent. Written consent will be sought by the health extension worker during the proactive visit before the first session of the diabetes self-management education and support program.

Randomization and blinding of subjects

After baseline assessment, dyads will be randomly allocated to either the control group~~, to receive the usual care,~~ or the intervention group~~,~~ to receive their respective diabetic care ~~diabetes self-management education and support~~ at a 1:1 allocation ratio with a block size of 4. Before the start of subject recruitment, an independent team member who will not be involved in subject recruitment and will not have contact with potential participants will generate a randomization list using an online research randomizer software (https://www.randomizer.org/), and prepare~~.~~ ~~A~~a separate sequence of the group identified based on the computer-generated random codes ~~will be prepared~~ and placed the codes in serially numbered opaque sealed envelopes ~~before the start of the study~~. Data collectors will open the sealed envelope and pass the dyads' information to the intervention facilitator if they are assigned to the intervention group. Participants assigned to the intervention group will be informed of the date of the first educational session after randomization, and the health extension worker will remind them one day before the session. To monitor information

contamination, the intervention and control groups will attend the hospital for follow-up visits on a monthly basis, on different dates. Due to the nature of the intervention, participants and intervention providers cannot be blinded. However, the data collectors and the~~a~~ data analyst will ~~also~~ be blinded to the group allocation through coding.

Data collection procedure

Outcome measurement will be conducted at three time points: baseline (T0: after recruitment), immediately after the diabetes self-management education and support intervention (T1: post-intervention), and two months after the intervention (T2) (Support file 5). Data for all the dyads~~people living with diabetes and participating family members~~ will be collected at all three time points during their monthly follow-up at the hospital. If the family members do not visit the hospital with the people living with diabetes, they will be contacted by telephone. Clinical outcomes will be retrieved from ~~the people living with diabetes~~ medical records as far as possible. If glycated haemoglobin and lipid profiles are not available from ~~people living with diabetes~~ medical records, a medical laboratory technologist, ~~who is~~ a ~~member of~~ staff of the participating hospital and ~~will be~~ recruited as a part-time staff ~~member~~ of the study,~~research project~~ will~~to~~ collect blood samples and perform the tests. All laboratory tests will be done at the hospital~~Nekemte Specialized Hospital~~, and the blood samples will be monitored by a~~the~~ medical laboratory technologist according to the national standards of Ethiopia.

Statistical analysis

Data will be ~~entered into and~~ analysed by the SPSS version 26 software package. The intention-to-treat principle will be used whenever applicable. A p-value < 0.05 will be considered statistically significant. Descriptive statistics~~analysis~~ will summarize the sociodemographic variables of the dyads; people~~'s~~ living with diabetes' clinical outcomes, self-care behaviours, ~~and~~ quality of life and~~;~~ the level of family support;~~,~~ and family caregivers' behaviours; and the acceptability level~~, with means and standard deviations for continuous variables and counts and percentages for categorical variables~~. Independent sample t-tests for~~if~~ normally distributed continuous variables, or Wilcoxon's rank-sum test for~~if~~ non-normal ~~for~~ continuous variables and Chi-square tests for categorical variables will ~~be computed to~~ examine the comparability of groups in terms of demographics produced by randomization. Feasibility outcomes using proportions/rates/percentage and effect size estimation using between-group Cohen's d ~~and separate generalized estimating equations~~ will be computed. ~~Generalized estimating equations will be adjusted for demographic characteristics if statistically significant group differences are~~

~~observed at the baseline. A significant "time x group" interaction term will provide preliminary support on the effects of diabetes self-management education and support.~~

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