EFFECTS OF A NURSE-LED, COMMUNITY-BASED SELF-MANAGEMENT PROGRAMME FOR PEOPLE WITH TYPE 2 DIABETES IN WESTERN ETHIOPIA: A PILOT RANDOMISED CONTROLLED TRIAL

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A THESIS SUBMITTED IN PARTIAL FULFILMENT OF THE REQUIREMENTS FOR THE DEGREE OF DOCTOR OF PHILOSOPHY

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CERTIFICATE OF ORIGINALITY

I hereby declare that this thesis is my own work and that, to the best of my knowledge and belief, it reproduces no material previously published or written, nor material that has been accepted for the award of any other degree or diploma, except where due acknowledgement has been made in the text.

__________ (Signed)

DIRIBA Dereje Chala (Name of student)

DEDICATION

This thesis is dedicated to my family, especially to Sian Dereje.

ABSTRACT

Background

Diabetes is becoming a public health threat, with more than a half-billion adults living with this illness globally. Ethiopia ranks fourth based on the number of diabetes cases in Africa, with type 2 diabetes (T2D) as the most prevalent type. Effective management is necessary to curb this disease. In Africa, the management of diabetes is suboptimal and challenged by the lack of understanding of local foods, misconceptions, lack of family support and a poor healthcare system. Meanwhile, amongst African Americans, diabetes self-management interventions (DSM) are ineffective in controlling glycosylated haemoglobin (HbA1c) and improving self-management behaviours. However, the interventions' feasibility and effectiveness on Ethiopians with diabetes are unknown.

Aim

The aim of the pilot randomised controlled trial (RCT) was to examine the feasibility, acceptability and preliminary effects of a nurse-led, community-based DSM education and support (DSMES) programme on the clinical, behavioural, psychological and environmental outcomes of people with diabetes and their family caregiver's supportive behaviour.

Methods and materials

The doctoral study is divided into three phases. In Phase I, a systematic review and a meta-analysis were conducted based on 11 RCTs to review and synthesise the effectiveness of DSMES interventions on the diabetic-related outcomes on Africans with diabetes. Lack of the culturally specific nutrition knowledge, misconception about diabetes and its management, gap in family support, lack of practical tools to educate the self-care activities and lack of community-based intervention were identified as the gaps. The findings from this review were then used to guide the intervention development of the pilot RCT. In Phase II, a DSEMS programme was developed based on social cognitive theory (SCT) and the Phase I results. In Phase III, a two-arm parallel-group pilot RCT was conducted for people with diabetes–family caregiver dyads. Seventy-six dyads were recruited in Nekemte Specialised Hospital over three months, with 38 dyads randomly allocated either to the intervention arm to receive 12 hours of DSMES programme intervention besides the usual care or to the control group to continue the usual care. The intervention was delivered by nurses in the community setting and supported with an educational handbook, flyers and videos.

The feasibility outcomes (recruitment, retention and item-level missing data rates) and the preliminary efficacy of the DSMES programme on the clinical, diabetes-related quality of life (DQOL), self-management practise, support status and family caregiver's supportive behaviour were assessed. Furthermore, the intervention fidelity and acceptability were assessed for the intervention group. The feasibility outcomes were computed using rates/percentages. Independent t-tests and chi-squared tests were computed to examine the groups' comparability in demographics as produced by randomisation. Generalised estimating equations models were computed to test for the preliminary effects of the DSMES programme on the outcomes, and Cohen's d was calculated to estimate the between-group effect size of the intervention.

Results

The results of the pilot RCT showed the feasibility of recruiting and retaining the participants in the study. The eligibility rate, recruitment rate, intervention compliance rate of the study was 39.2%, 85.4% and 97.4% respectively. The item-level missing rate ranges between 0 to 3.5%. The study found that the DSMES programme can produce promising preliminary results in improving

HbA1c, triglycerides, self-management practise, DQOL, support needed and support received and family caregiver's supportive behaviour. The effect sizes ranged from small to large. The DSMES programme is acceptable to the participating dyads receiving the DSMES programme.

Conclusion

The SCT-guided, nurse-led and community-based DSMES programme can produce a promising positive effect on controlling blood glucose, improving self-management behaviours and enhancing the quality of life of people with diabetes. It can also produce promising positive effects on the perceived support from their family/friends and improving the family's supportive behaviour.

PRESENTATIONS AND PUBLICATIONS ARISING FROM PhD STUDY

Conference session presentations

1. Diriba, D.C., Leung, D.Y.P., & Suen, L.K.P. (2020). The Effects of Diabetes Self-management Interventions on Physiological Outcomes in Peoples Living with Diabetes in Africa: A Systematic Review and Meta-Analysis (Abstract and Oral Presentation). Paper presented at the *2nd World Congress on Diabetes and Endocrinology* (July 31-August 01, 2020), SCOTLAND.
2. Diriba, D.C., Leung, D.Y.P., & Suen, L.K.P. (2021). Effectiveness of a nurse-led community-based self-management program among adults with diabetes-family dyads in western Ethiopia (Abstract and poster presentation). *IDF 2021 Virtual Congress*; (December 6-11, 2021), International Diabetes Federation, Brussels, BELGIUM.
3. Diriba, D.C., Leung, D.Y.P., & Suen, L.K.P. (2022). Effects of culturally tailored self-management education and support on clinical outcomes of adults living with type 2 diabetes in Western Ethiopia: A Pilot Randomised Controlled Trial (Abstract and oral presentation). *33rd Ethiopian Public Health Association* Annual Conference (March 13-15, 2022), Addis Ababa, ETHIOPIA.
4. Diriba, D.C., Leung, D.Y.P., & Suen, L.K.P. (2022). Effects of culturally tailored self-management education and support on quality of life and family support among people with type 2 diabetes in Western Ethiopia: A Pilot Randomised Controlled Trial (Abstract and oral presentation). *National Research* Conference (May 20-21, 2022), Wollega University, Nekemte, ETHIOPIA.

Refereed journal articles arising from the thesis

1. Diriba, D.C., Leung, D.Y.P., & Suen, L.K.P. (2021a). The effects of diabetes self-management interventions on physiological outcomes in people living with diabetes in Africa: A systematic review and meta-analysis. *Diabetic Medicine*, *38*(5), e14501. https://doi.org/10.1111/dme.14501
2. Diriba, D.C., Leung, D.Y.P., & Suen, L.K.P. (2021b). Cultural adaptation and psychometric properties of the diabetes quality of life scale in Afaan Oromoo among people living with type 2 diabetes in Ethiopia. *International Journal of Environmental Research and Public Health*, *18*(14), Article 7435. https://doi.org/10.3390/ijerph18147435
3. Diriba, D.C., Leung, D.Y.P., & Suen, L. K.P. (2021c). A nurse-led, community-based self management program for people living with type 2 diabetes in Western Ethiopia: A feasibility and pilot study protocol. *Diabetic Medicine*, *38*(8), Article e14587. https://doi.org/10.1111/dme.14587

Institutional presentations

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2. Diriba, D.C. Translation and psychometric properties of diabetes quality of life measure in Afaan Oromoo among patients living with type 2 diabetes mellitus in Ethiopia. School research seminar (November 2020), School of Nursing, The Hong Kong Polytechnic University, Kowloon, HONG KONG.

3. Diriba, D.C. A community-based self-management program for people living with type 2 diabetes in western Ethiopia: Preliminary results of a pilot RCT study. School research seminar (November 2021), School of Nursing, The Hong Kong Polytechnic University, Kowloon, HONG KONG.

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CHAPTER ONE: INTRODUCTION

1.1 Introduction

This chapter presents the background information about diabetes, its prevalence, the multifaceted types of burden of diabetes, its pharmacologic and non-pharmacologic management and the particular challenges of managing diabetes in Ethiopia. The problem statement, which includes the research gaps and the significance of the research project, is also presented. Lastly, the aim and objectives of the research project and the organisation of the thesis are depicted.

This chapter is organised into seven sections. Section 1.1 introduces the chapter. Section 1.2 presents the definition and the background information about the prevalence of diabetes, burden of diabetes, the management of diabetes and the challenges of diabetes management in Ethiopia. Section 1.3 presents the problem statement. Section 1.4 discusses the significance of the study. Section 1.5 shows the summary of the chapter. Section 1.6 shows the organisation of the thesis. Section 1.7 presents the aim and the objectives of the research project.

1.2 Background

1.2.1 Definition of diabetes

The World Health Organisation (WHO, 2019) defines diabetes as a group of metabolic disorders characterised and identified by the presence of hyperglycaemia in the absence of treatment. Hyperglycaemia, a high level of blood glucose, may happen due to reduced insulin secretion, a decrease in glucose utilisation and an increase in glucose production, and it depends on the destruction and dysfunction of β-cells of the pancreas (Powers et al., 2018). The American Diabetes Association (2021a) classifies diabetes into four broad categories: type 1 diabetes (T1D), type 2 diabetes (T2D), specific types of diabetes and gestational diabetes. WHO (2019) further classifies diabetes into six specific types with a finer classification: T1D, T2D, hybrid forms of diabetes, other specific types of diabetes, unclassified diabetes and hyperglycaemia first detected during pregnancy. T2D is related to relative insulin deficiency and peripheral insulin resistance.

Diabetes develops due to several long-standing risk factors. T2D is attributable to the combination of genetics- and lifestyle-related factors. Individuals have high chance to develop the disease when they are overweight or obese (body mass index (BMI) of ≥25 kg/m^2), aged 45 or older, have a family history with diabetes, have an ethnicity/race prone to diabetes, have a high blood pressure (≥140/90 mmHg), have a history of cardiovascular diseases (CVDs), have a high-density lipoprotein (HDL) cholesterol level of ≤35 mg/dL (0.90 mmol/L) and/or a triglyceride level of ≥250 mg/dL (2.82 mmol/L), are physical inactive, are women with polycystic ovary syndrome and have other clinical conditions associated with insulin resistance, such as severe obesity. Although family history, age, and ethnicity are non-modifiable, the lifestyle factors, such as eating, physical activity and weight, are modifiable (American Diabetes Association, 2020; Powers et al., 2018). American Diabetes Association (2020) recommends that overweight or obese individuals or those with one or more risk factors be screened for prediabetes or T2D as soon as they reach 45 years old.

Type 1 diabetes is manifested by the clinical symptoms of excessive thirst, blurry vision, bedwetting, fatigue, constant hunger and sudden weight loss, but the onset of T2D is slow and usually symptomless (International Diabetes Federation, 2021). Symptoms of diabetes combined with either a fasting blood sugar level of ≥126 mg/dl (7.0 mmol/L) or glycosylated haemoglobin (HbA1c) of ≥6.5% or a random blood glucose of ≥200 mg/dl (11.1 mmol/L) or oral glucose tolerance test of ≥200 mg/dl (11.1 mmol/L) indicate diabetes (International Diabetes Federation, 2021; WHO, 2019). HbA1c is recommended as a gold standard diagnostic test for diabetes, and it is commonly used as an indicator for monitoring the blood glucose of people who have diabetes for over 8–12 weeks (WHO, 2011).

1.2.2 Prevalence of diabetes

The prevalence of diabetes is alarmingly increasing and has become the fastest-growing disease at the global level (International Diabetes Federation, 2021; WHO, 2019). More than a half-billion adults around the world have diabetes, with T2D as the most prevalent type (International Diabetes Federation, 2021). The distribution of diabetes varies based on age. Most T1D is common at a young age, whereas T2D is prevalent during adulthood (American Diabetes Association, 2020), although T1D may also exist during adulthood and T2D may also occur during a young age (Powers et al., 2018). According to International Diabetes Federation (2021), approximately half of the global population are undiagnosed, but 24 million adults are estimated to live with diabetes in the African Region, with 1.9 million cases estimated in Ethiopia. IDF (2021) also reports that Ethiopia is one of the countries with high cases of adult diabetes and it is even ranked fourth amongst countries in the African Region. In addition, more than half of people with diabetes live in urban areas (International Diabetes Federation, 2021). Observational studies have also reported that more people with diabetes live in urban areas than in rural areas (Abebe et al., 2017; Animaw & Seyoum, 2017; Bishu et al., 2019).

1.2.3 Burden of diabetes

Diabetes poses a significant burden on people with diabetes, families and healthcare systems (Jaffiol, 2011). In Africa, the burden of diabetes has increased due to multifaceted factors and problems. A few years back, sub-Saharan Africa (SSA) was challenged by communicable diseases. Currently, non-communicable diseases, including diabetes, have become the most challenging health problem in SSA. Diabetes causes direct or indirect mortality amongst people with diabetes. If diabetes is left untreated, then it may lead to an overabundance of acute and chronic complications with varying physiologic functions, causing premature death (Atun et al., 2017). According to the International Diabetes Federation (2021), approximately 6.7 million adults living with diabetes die due to the disease. Ethiopia shares this diabetes-related mortality, and the number is increasing (WHO, 2016).

Moreover, diabetes consumes the family caregiver's time, especially since people with diabetes require care and emotional support and help in self-management (Haugstvedt et al., 2011). Besides, the family may be involved in managing people with diabetes health and cover the drug costs when people with diabetes cannot afford management costs. Beyond the family, diabetes also imposes a considerable economic burden on the society with adverse effects (Elrayah-Eliadarous et al., 2017). The types of burden are comparatively higher amongst people receiving low social support (Kaya & Caydam, 2019).

Diabetes is one of the most burdensome chronic illnesses in health systems in Africa, posing a 'double burden of infectious and chronic diseases' (Atun et al., 2017; de-Graft Aikins et al., 2010; Naik R. & Kaneda T, 2015). Diabetes has also burdened the governance of the healthcare system because of its cost requirement, shortage of workforce, low access to health information systems and supply chains and poor service delivery (Mercer et al., 2019). The lack of clear policies and poor leadership commitment are the main burden besetting the healthcare system (Beran &

Yudkin, 2006). At the global level, the estimated annual cost for treating diabetes is nearly US$ 1 trillion (International Diabetes Federation, 2021); by contrast, for each African country, the cost is from US$ 3.5 to 4.5 billion (Mutyambizi et al., 2018), indicating an inadequate healthcare budget in the African Region. In Ethiopia, the direct cost of hospitalising adults with diabetes was US$ 154 in 2019; although much lower compared with the world average of US$ 1,641, this amount is already expensive for Ethiopians (Bishu et al., 2019), and majority of people with diabetes in the country could not afford spending for healthcare (Mercer et al., 2019). The situation is expected to even worsen for people with complicated diabetes, as the cost of its treatment is higher than those of the uncomplicated ones (Assefa et al., 2014; Erzse et al., 2019). Even though the government of Ethiopia has started providing health insurance to support people with diabetes, antidiabetic drugs are not consistently available due to limited budget and resources (Mebratie et al., 2014).

The aforementioned different types of burden indicate that the quality of diabetes care is poor in SSA (Mercer et al., 2019), further leading to the poor quality of life (QOL) of people with diabetes in the region (Atun et al., 2017). Poor diabetes care results in uncontrolled diabetes and complications, hence the worsening of QOL (Cannon et al., 2018). QOL is concerned with the psychological well-being, psychological care and the lived experience of people with diabetes. It is recognised as an essential health aspect of people with diabetes but is rarely assessed in diabetes research (Richard & Shea, 2011). Furthermore, QOL is a significant predictor of premature mortality (Powers, Bardsley, Cypress, et al., 2015)

1.2.4 Management of T2D

The management of diabetes is intended to bring three primary targets, including (i) eliminating hyperglycaemia-related symptoms, (ii) preventing or eliminating diabetes-related complications and iii) helping people with diabetes to attain a lifestyle as normal as possible (Powers et al., 2018). Pharmacologic management and lifestyle modification are the usual recommendations (American Diabetes Association, 2020; Powers et al., 2018).

1.2.4.1 Pharmacologic management

The initial therapy for type 2 diabetes depends on comorbidities, patient-centred treatment factors, and management needs. The use of metformin as first-line drug and comprehensive lifestyle management maximise the benefit of glucose control (American Diabetes Association, 2020). Taking metformin should be continued if it can be tolerated or not contraindicated. Insulin may be added to the drug if weight loss, signs of presence of hyperglycaemia (i.e. HbA1c of 10% or high blood glucose) or long-standing T2D are observed. The standard also recommends selection of pharmacologic agents based on the patient-centred factors like presence or increased risk of atherosclerotic cardiovascular disease, heart failure, and/or chronic kidney disease or renal complications, cost, individual preferences, impact on weight, risk of side effects and risk of hypoglycaemia should be considered. If the target treatment goals are not achieved, then treatment intensification is needed. Other glucose-lowering agents like sulfonylureas, a sodium–glucose cotransporter 2 inhibitor, glucagon-like peptide 1 receptor agonist and insulin are also available. If people with type 2 diabetes diagnosed with atherosclerotic cardiovascular disease or high risk to develop the cardiovascular disease, established kidney disease, or heart failure, a sodium–glucose cotransporter 2 inhibitor and/or glucagon-like peptide 1 receptor agonist is recommended by ADA (American Diabetes Association, 2020). The regimen of drug intake and self-medication behaviour of people with diabetes should be evaluated. Insulin therapy may be provided to individuals with diabetes to control their glucose level. Basal insulin is given with metformin or other oral hypoglycaemic agents if needed; this approach is the most convenient for people with diabetes. Many individuals with T2D may need prandial insulin before meals to achieve glycaemic targets (American Diabetes Association, 2020; Powers et al., 2018).

1.2.4.2 Lifestyle management

Lifestyle management is needed to synergise the effects of medicines (American Diabetes Association, 2020). ADA defines lifestyle management as ‘any aspect of diabetes care that includes DSM education and support (DSMES), nutrition therapy and psychosocial care’ (Powers et al., 2018). The American Association of Diabetes Educators (AADE) has categorised these measures into seven self-care behaviours: healthy eating, being active, monitoring blood glucose, taking medication, reducing risks, problem solving and healthy coping (Powers, Bardsley, & Cypress, 2015). Orem (2001) defines self-care as ‘deliberately performed actions to regulate human functioning and development’. Self-care includes an individual’s actions for healthy lifestyle behaviours needed for human development, functioning and managing acute and chronic health conditions that can be performed at home (Clark et al., 1991; Richard & Shea, 2011). Self-care activities include the monitoring of outcomes for achieving lifestyle modification (Kvam & Lyons, 1991) and they should be cost-effective (Ausili et al., 2017).

Individuals with chronic illnesses, including diabetes, must perform three main activities to reduce the impact of the disease on their daily life. Firstly, individuals must acquire adequate knowledge about their disease’s condition and its management; secondly, they must perform activities to manage the conditions; finally, they must apply the required skills to maintain sufficient psychosocial functioning (Clark et al., 1991). The details of the seven self-care behaviours for people with diabetes as recommended by ADA (2020) can be further described as follows.

a) Healthy eating

Food is essential in controlling blood glucose (American Diabetes Association, 2020). ADA recommends medical nutrition therapy (MNT) to improve weight and glycaemic control. MNT is a nutrition diagnosis and therapeutic and counselling service for managing diseases (Academy of Nutrition and Dietetics, 2022). Nutrition therapy delivered by comprehensive, knowledgeable and experienced professionals in diabetes care can reduce HbA1c by 0.3% to 2.0% for people with T2D (Franz et al., 2017). Besides, nutrition therapy can save costs, decrease cholesterol and reduce weight. Overweight and obese people with diabetes are encouraged to reduce weight by 5%. However, what and/or how much to eat is challenging for many people with diabetes. Glucose is obtained from carbohydrates, protein and fats. According to ADA recommendation, a variety of eating patterns can be considered for the management of T2D. Consumption of carbohydrate, protein, dietary fats, alcohol, non-nutritive sweeteners and sodium can be considered for the management of T2D. However, intakes of these food sources should be individualised. People with diabetes should bear in mind the metabolic targets during food intake. Since carbohydrate is the primary source of glucose, its intake should not only emphasise on the nutrient-dense carbohydrate sources that are high in fibre but also the food should be minimally processed. The food pyramid for diabetes includes non-starchy vegetables, fruits and whole grains, and dairy products at the base. Proteins can be recommended because protein appears to increase insulin response without increasing plasma glucose concentrations. It is strongly recommended that low fat food in general, in particular reducing intake of animal source fat. There is no clear evidence regarding the relationships between vitamins, minerals and herbs with glucose control and hence, their consumptions are generally not recommended for glycaemic control. Sodium consumption should be limited to less than 2,300 mg/day. An individual with diabetes can take a moderate level of alcohol but with a limit of one drink per day for adult women and two drinks per day for adult men (American Diabetes Association, 2020).

b) Being active

Physical activity, which is an integral part of lifestyle modification, refers to any movement that can increase energy use. (American Diabetes Association, 2020) recommends that people with T2D decrease their sedentary life by walking, standing, performing light activities and performing moderate aerobic physical activity for 30 minutes per day (i.e. 150 minutes per week). Physical activity enhances blood glucose control, reduces risks of CVDs, reduces weight and enhances a person’s well-being (Katzmarzyk et al., 2019). People with diabetes taking insulin and with underlying comorbidities should manage the risk of hypoglycaemia and undertake pre-exercise preparations (American Diabetes Association, 2020).

c) Self-monitoring of blood glucose

Self-monitoring of blood glucose (SMBG) is recommended for people with diabetes by taking intensive insulin therapy before meal and snack time, at bedtime, preceding exercise, at suspicion of low blood glucose and after treatment of hypoglycaemia until it becomes normal before and whilst performing some serious tasks for instance driving. People with diabetes are responsible for performing self-monitoring of their blood glucose. Healthcare providers should ensure that people with diabetes obtain instruction and evaluation of performing techniques and understand the results of SMBG and the value for controlling their blood glucose. Appropriate technology, such as the glucometer, is needed to monitor the blood level of glucose (American Diabetes Association, 2020). Recently, American Diabetes Association (2020) has suggested the use of continuous glucose monitoring (CGM) devices to assess glucose levels. Four types of CGM devices are available at present: (1) real-time CGM for continuously measuring glucose levels whilst providing users with automated alarms and alerts at specific glucose levels; (2) intermittently scanned CGM for continuously measuring glucose levels, but only the glucose values are displayed on the device; (3) blinded (professional) CGM that entail the measurement of glucose levels but the values are not known to the person with diabetes in real time combined with unblinded CGM for measuring glucose levels and the values are shown to the person with diabetes. However, in Ethiopia, only the glucometer is used to measure glucose levels at home.

d) Medication compliance

Self-medication is one of the activities that people with diabetes should perform by themselves. For people taking insulin, insulin syringes or insulin pens may be utilised based on their preferences, with the options extending to the type of insulin, dose and cost, but self-management capability should be considered. Subcutaneous injections are often preferred, but people with diabetes should be educated on their self-medication skills. People with T2D who are given oral hypoglycaemic agents should receive appropriate education (American Diabetes Association, 2020; Powers et al., 2018).

e) Reducing diabetes-related complications

People with diabetes may develop microvascular and macrovascular complications if the diabetes is poorly controlled. Dyslipidaemia and hypertension increase the risk of diabetes-related acute and chronic complications, which may then increase morbidity and mortality. Thus, routine atherosclerotic CVD prevention, screening and treatments are also needed.

Diabetic dyslipidaemia and hypertension are modifiable risk factors (Bhowmik et al., 2018; Jahangiri-Noudeh et al., 2014). Hypertension is a common CVD related to diabetes. ADA (2020) recommends measuring blood pressure at every clinical visit time, and the person with diabetes is expected to manage the blood pressure in their homes. The control target of blood pressure may vary based on the individual's risk for CVD. If a person with diabetes is at a higher risk for CVD, then a reduction of blood pressure to <130/80 mmHg is appropriate; however, if people with diabetes are at a lower risk, a blood pressure of <140/90 mmHg is acceptable (American Diabetes Association, 2020; Powers et al., 2018). Lipid management is also essential for people with diabetes. Lipid profiles are composed of four components: total cholesterol, low-density lipoprotein (LDL) cholesterol, HDL cholesterol and triglycerides. Lifestyle modification approaches, such as adopting the 'Dietary Approaches to Stop Hypertension' (DASH) eating habits, reducing trans-fat and saturated fat, boosting dietary n-3 fatty acids, fibres and plant source stanols/sterols and performing physical activity, can improve the lipid levels and halt the risk of atherosclerotic CVD amongst people with diabetes. The intensity of lifestyle modification may be increased based on the lipid profiles. In particular, lipid profiles should be assessed at the time of diagnosis, at the first medical evaluation and at least every five years for people with diabetes under 40 years old. The recommendations may be changed if the person with diabetes has started with statins or other lipid-lowering drugs (American Diabetes Association, 2020; Powers et al., 2018).

Diabetes-related microvascular complications can lead to various impairments. Chronic kidney disease, diabetes retinopathy and neuropathy are some of the diseases related to diabetes. The risk of complications is higher amongst people with diabetes compared with those without diabetes.

ADA (2020) has developed screening and treatment recommendations for these diseases. Chronic kidney disease screening is recommended to be assessed once a year, and urinary albumin and angiotensin-converting enzyme inhibitors are needed to halt the progress of kidney damage estimation of the glomerular filtration rate. Boosting glycaemic control, controlling blood pressure and continuing treatment are required to prevent diabetes-related complications (American Diabetes Association, 2020; Powers et al., 2018). Diabetic retinopathy is another form of vascular complication and the most frequent cause of blindness in adults with diabetes. The risk is increased amongst people with standing (long-term) diabetes and poor glucose control. ADA (2020) recommends that controlling the glucose levels and optimising the blood pressure and serum lipid levels are necessary to reduce the risk or slow the progress of diabetic retinopathy. A comprehensive eye examination is needed to mitigate diabetes-related blindness, and it should be routinely conducted upon the diagnosis of diabetes. If the finding of the eye examination shows macular oedema, then a treatment must be enacted to slow or prevent blindness (American Diabetes Association, 2020).

Another microvascular complication of diabetes is neuropathy and the damage or dysfunction of nerves manifested by tingling, unpleasant burning sensation and muscle weakness. Hypertension, high cholesterol, obesity, diabetes and heavy alcohol intake are the risks for peripheral neuropathy (Powers et al., 2018). People with T2D should be assessed for diabetic peripheral neuropathy at the time of diagnosis and must be treated; that is, a prompt history and careful sensation assessment are necessary. Glucose must be controlled to slow or reduce diabetic peripheral neuropathy (American Diabetes Association, 2020).

Foot ulcers and amputation are also prevalent amongst people with diabetes, and they are often attributable to poor glucose control, peripheral neuropathy, smoking, visual impairment and a history of foot ulcers (Powers et al., 2018). ADA (2020) recommends a comprehensive foot examination at least once annually to assess the risk factors, and people with diabetes who also have a loss of sensation or a history of a foot ulcer or amputation should be inspected every visit. People with diabetes and their families should be educated about the risk factors of foot ulcers, its implication and the recommended management (Bonner et al., 2016). People with diabetes should perform appropriate foot examinations, know the proper footwear and practise good footwear behaviour every day at home (American Diabetes Association, 2020). Care providers should perform diabetes-related foot examinations one to two times every year (Powers et al., 2018).

f) Healthy coping

People with diabetes may encounter enormous environmental, social, behavioural and emotional challenges. These factors affect the psychosocial aspects of people with diabetes, leading to depression, eating disorders, anxiety and severe mental illnesses (American Diabetes Association, 2020). People with diabetes should acquire individualised psychosocial support to improve their health outcomes and QOL. Screening for psychosocial aspects amongst people with diabetes should be practised by addressing their attitudes about diabetes, medication, outcomes, affect and diabetes-related QOL (DQOL) (American Diabetes Association, 2020).

The Association of Diabetes Care and Education Specialists (2020) defines healthy coping as ‘having a positive attitude towards managing your condition and positive relationships with others’. It is considered the road to achieving treatment targets and finding a healthy lifestyle in challenges. Poor coping may increase the risk of diabetes-related complications. Educators should focus on teaching healthy coping methods, such as seeking support by attending DSMEs, moving the body (e.g. having a walk when worried or stressed), thinking positively and being good to one's self (Association of Diabetes Care & Education Specialists, 2020).

g) Problem solving

In self-management theory, problem solving is defined as 'the process by which one translates techniques for self-management into actual self-managing' (Yates, 1985). Hill-Briggs (2003) classifies problem solving in chronic illness self-management into four components: (1) problem-solving skills, (2) problem-solving orientation, (3) disease-specific knowledge and (4) the transfer of experience. Problem-solving techniques undergo a series of steps, namely, (a) problem identification, (b) defining the problem, (c) looking for solutions, (d) acting on solutions in the context of daily living and (e) learning from the results. In these problem-solving strategies, diabetes-specific knowledge is needed to bring behavioural change and achieve diabetes management goals (Hill-Briggs, 2003). Given that diabetes is a chronic illness and causes enormous problems, AADE recommends that the person with diabetes should practise the ways to solve these problems. Identifying the problem, finding the solutions and taking action are needed (Association of Diabetes Care & Education Specialists, 2020). (American Diabetes Association, 2020) also recommends that the person with diabetes identify the problems, find solutions and implement the solutions as appropriate. The problem-solving strategies recommended by ADA and AADE include most aspects of self-management theory (Hill-Briggs, 2003). A problem-focused coping strategy is related to improved well-being (Kvam & Lyons, 1991).

1.2.5 DSMES

DSMES, which comprises lifestyle management components (Powers et al., 2018), is defined as 'the ongoing process of facilitating the knowledge, skills and ability necessary for prediabetes and diabetes self-care, as well as activities that assist a person in implementing and sustaining the behaviours needed to manage his or her condition on an ongoing basis, beyond or outside of formal self-management training' (Beck et al., 2018). Self-management refers to 'the ability of a patient to deal with chronic illnesses, including symptoms, treatment, physical and social consequences and lifestyle changes' (Glasgow et al., 2003). International guidelines, such as those by ADA, WHO, the Diabetic UK and the Australian Diabetes Educators Association, have recommended diabetes self-management (DSM) interventions to enhance the health of people with diabetes. DSMES provides education and support related to five domains, namely, nutrition education, physical activity, foot care, self-blood sugar monitoring and self-medication (American Association of Diabetes Educators, 2008), to control blood glucose (American Diabetes Association, 2020). Education and support in DSM interventions can be delivered by means of group education, one-on-one counselling, coaching and technology-assisted methods (Sherifali et al., 2013). Self-management intervention is effective when the following criteria are met: HbA1c of <7%, systolic blood pressure (SBP) of <140 mmHg and diastolic blood pressure (DBP) of <90 mmHg, total cholesterol of <200 mg/dL, LDL cholesterol of <100 mg/dL, HDL cholesterol of >35 mg/dL and triglycerides of <150 mg/dL (American Diabetes Association, 2020). The ultimate goal of DSM interventions is the control of HbA1c (WHO, 2011), a gold standard in glycaemic control. A reduction in HbA1c by 0.5% is considered clinically significant (Little et al., 2011).

Numerous systematic reviews and studies have been conducted to assess the effectiveness of DSM interventions on diabetes outcomes amongst persons with diabetes. Although many studies collectively support small to modest improvements in outcomes, these interventions have shown mixed results with substantial variations across the studies. The most commonly reported physiological outcome is HbA1c, and the reported reduction is in the range of 0.08% and 0.8%

(Almutairi et al., 2019; Carpenter et al., 2019; Chew et al., 2017; Cunningham et al., 2018; Duke et al., 2009; Steinsbekk et al., 2012).

Most of the reviews about the pooled DSM intervention effects concluded that the intervention effects are not clinically significant (Chew et al., 2017; Cunningham et al., 2018; Steinsbekk et al., 2012). At the same time, a systematic review of randomised controlled trials (RCTs) on African Americans with diabetes reported that DSM education is ineffective in HbA1c control (Cunningham et al., 2018). Previous studies also reported the reductions being from no effect to 1.8 mmHg in SBP and 0.3–1.5 mmHg in DBP (Chew et al., 2017; Pal et al., 2013). Nonetheless, other studies demonstrated improved lipid profiles amongst people with diabetes who received DSM interventions (Jack, 2003; Mikhael et al., 2020; Tang et al., 2015). Significant decrements were reported in BMI from 0.1 to 0.21 kg/m^2 (Duke et al., 2009) and waist circumference by 0.013 cm (Cai & Hu, 2016).

Previous research showed that DSM interventions cannot significantly improve all of the self-care behavioural components of African Americans (Lynch et al., 2019; Saxe-Custack & Weatherspoon, 2013). The systematic review and meta-analysis of studies involving African Americans with diabetes suggest that DSM education is effective in improving QOL (Cunningham et al., 2018). However, the self-care practises of persons with diabetes in SSA (Stephani et al., 2018) and Ethiopia (Habebo et al., 2020; Ketema et al., 2020) are poor, and education and support are needed to boost their knowledge, attitude and skills.

1.2.6 Management of T2D in Ethiopia

In Ethiopia, the management of diabetes only focuses on medical management with no structured diabetes education and self-management practise (Ketema et al., 2020). Ethiopia has developed two guidelines for the management of diabetes at healthcare tiers. At the national level, the guideline called 'Clinical and Programmatic Management of Major Non-Communicable Diseases' refers to non-communicable diseases and addressed the screening, diagnosis and glycaemic control methods, including evaluation of people with diabetes, non-pharmacologic and pharmacologic management and the management of diabetes complications (Federal Democratic Republic of Ethiopia Ministry of Health, 2016). At the hospital level, the guideline called 'Standard Treatment Guidelines for General Hospitals' is used to guide the clinical management of all common forms of diseases, in which diabetes management is also stated (Food Medicine Health Care Administration Control Authority of Ethiopia, 2014). On the basis of the national guideline, the screening recommendation for prediabetes and diabetes follows the ADA recommendations and fasting blood glucose, the most feasible diagnostic measurement in Ethiopia. The diagnosis criteria for diabetes are the same as those set by WHO. However, although HbA1c tests are available in tertiary hospitals in Ethiopia, they are not accessible in most primary hospitals because of the limited supply of devices and test kits.

The main treatment target of diabetes mellitus is controlling glycaemia. The evaluation of blood glucose includes history taking about the duration of diabetes onset, treatment history, adherence to treatment, level of exercise, dietary history, follow-up profile, level of glucose control, history of complications of diabetes, physical examination focusing on BMI, abdominal circumference, blood pressure, skin and foot examination and inspection of the insulin injection site and laboratory investigation of blood sugar, urine analysis and lipid profile (Federal Democratic Republic of Ethiopia Ministry of Health, 2016; Food Medicine Health Care Administration Control Authority of Ethiopia, 2014). In Ethiopia, although people with diabetes are commended for having monthly medical check-ups in hospitals, the recommended examinations are not consistently practised.

For T2D, the non-pharmacologic management of diabetes considers diabetes education as the cornerstone. The non-pharmacologic management for diabetes in Ethiopia covers healthy eating, physical exercise and SBGM, but diabetes education teaching materials are not available in the two aforementioned guidelines (Federal Democratic Republic of Ethiopia Ministry of Health, 2016; Food Medicine Health Care Administration Control Authority of Ethiopia, 2014). The situation has improved recently with the Ethiopian Diabetes Association crafting a general handbook on diabetes education, distributing it to certain hospitals in Ethiopia. However, the handbook lacks practical demonstrations of some techniques, such as glucometer use, and it does not comprehensively address all components of self-care activities, such as psychosocial aspects and diabetes complications.

Pharmacologic management includes oral hypoglycaemic agents and insulin therapy. Oral hypoglycaemic agents can be initiated at a health centre. Taking metformin 500 mg orally every day is the first-line drug, with a titrate dose every four weeks if the glucose level is high. However, if metformin does not control glucose or is contraindicated, then sulfonylurea will be added, such as glibenclamide and titrate. Insulin can be indicated if oral drugs cannot achieve the target. Physicians should initiate insulin, and follow-up and dose titration can be conducted at the primary health centre. Currently, medical check-ups are solely conducted in hospitals. The dose is adjusted based on the glycaemic level, and 10 units of neutral protamine Hagedorn insulin should be taken at bedtime initially and then increased by 2 to 4 units every week. If complications develop, then the treatment guideline for complicated cases is also included. People with diabetes should also collect drugs every month based on the prescription. If people with diabetes show evidence of chronic complications, then they are referred to a tertiary hospital one to two times per year for further diagnosis and treatment (Federal Democratic Republic of Ethiopia Ministry of Health, 2016; Food Medicine Health Care Administration Control Authority of Ethiopia, 2014), but this approach is not routinely practised.

1.3 Challenges of diabetes management in Ethiopia

Diabetes has become a public health problem at the global level, with a particularly high burden in low- and middle-income countries (Bommer et al., 2018; Zhang et al., 2010). The Lancet Diabetes and Endocrinology Commission 2017 report mentions five key challenges related to diabetes: lack of understanding of the actual burden of diabetes, high health costs, inability to cope with the challenges of the disease, scarce healthcare resources and low screening of diabetes (Atun et al., 2017). Similarly, other studies identified the lack of resources for managing the disease, including the lack of glucometers and other technologies (Whittemore et al., 2019), and the increasing daily-disability adjusted life in SSA was pinpointed as the main challenge of the disease (Gouda et al., 2019). IDF Africa pointed out that the chronic nature of the disease, progressive development of diabetes complications and poor economies are the main challenges of disease management (International Diabetes Association Africa region, 2006). Besides, studies reported inequalities in healthcare access in developing countries (Linard et al., 2012). Ethiopia's diabetes management is constrained by four main challenges in diabetes management: lack of knowledge about glucose-related local food, misconceptions about diabetes, gaps in family support and a poor healthcare system.

1.3.1 Food-related challenges

Lack of understanding about food intake remains the main challenge in the management of diabetes (Bekele et al., 2020). Misconception about food intake also contributes to the risk of diabetes and challenges its management. Most societies in Africa perceive obesity as a sign of wealth (International Diabetes Association Africa region, 2006). Diet in Ethiopia is composed mainly of cereals (sorghum, maise and teff, which is only found in Ethiopia and Eritrea), tubers and root crops (sweet potatoes, potatoes and ensete), pulses and oilseeds (Food and Agriculture Organization, 2020). ‘Injera’, which is made up of teff, is a staple food in Ethiopia and a native to the horn of Africa (Soumya, 2020); this food can raise blood sugar (Bekele et al., 2020). The ‘injera’ is consumed with different forms of ‘Wot.’ ‘Wot’ is prepared from diverse food sources and spices. Red chilli powder and butter are usually used for cooking as a spice. Perhaps due to the lack of knowledge about the source of nutrients and the economy with respect to buying various foods (Bekele et al., 2020; Dedefo et al., 2020; Demilew et al., 2018), people with diabetes in Ethiopia do not practise nutritional recommendations. The recommended daily allowance of nutrients for people with diabetes is unknown for most of the foods available in Ethiopia; thus, people with diabetes do not know the amount and type of food to consume for diabetes management.

Apart from the aforementioned issue, the traditional food of Wollega Oromoo (people living in western parts of Ethiopia) can be regarded as peculiar (Susan, 1994). Traditional foods of Wollega Oromoo are ‘cuukkoo’, ‘marqaa’, ‘cumboo’, ‘micciraa’, ‘foon waaddii’, ‘ancootee’, ‘buna qalaa’, ‘ukkaamsaa’ and local drinks, such as ‘araqee’, ‘farsoo’, ‘booka’ and ‘garbuu guggubaa’ (in Afaan Oromoo language). Even though the percentage of the population who consume these foods and drinks is not reported yet, their consumption is high during religious and cultural festivals, social and private events and holy days (McGuigan, 2010; Selinus, 1971). These foods are prepared from a mixture of corn, meat, tubers and a high amount of butter (Dereje et al., 2019; McGuigan, 2010); they can raise glucose and lipid levels in the blood and eventually cause diabetes and hypertension. Although the pooled nutritional content of these foods and drinks is not yet indicated, they are assumed to be rich in carbohydrates, protein and fat and have the potential to raise blood glucose, lipids and blood pressure. The rise in blood glucose, lipid profiles and blood pressure may lead to hypertension, diabetic ketoacidosis (another form of complication) and death (Powers et al., 2018).

In Ethiopia, the Western culture influences the translation of diet from traditional diet habits to the consumption of high carbohydrate and packed foods. The people’s dietary practise depends on their perception and is sometimes influenced by personal preferences and physical obstacles (Gebremariam et al., 2018). Most people who consume a traditional diet with high carbohydrates need a dietary change to control blood glucose and prevent diabetes complications. However, the people can hardly change their cultural diet and eating tradition (Belue et al., 2012). Hence, understanding the nutrient contents of the food to be obtained, particularly the cultural and traditional food, and consuming a healthy diet are necessary for people with diabetes in Ethiopia.

1.3.2 Misconception-related challenges

Similar to people in other countries in SSA, Ethiopians have plenty of myths, misconceptions and beliefs about diabetes. Misconceptions and beliefs about diabetes include considering diabetes as a communicable disease, taking honey on an empty stomach to treat diabetes and taking whiskey to cure diabetes and decrease the blood glucose. In addition, misconceptions abound regarding the methods for curing diabetes, including drinking urine, eating bitter food, eating plenty of table sugar that cause diabetes and taking holy water (‘tsebel’) on an empty stomach (International Diabetes Association Africa region, 2006). Furthermore, some people with diabetes discontinue their medication due to prophecy, believing they have been cured. A qualitative study in Ethiopia showed that religious healing beliefs and practises are barriers to diabetes management (Habte et al., 2017), and it causes discontinuation of medication, which may cause premature death.

1.3.3 Family-related challenges

Social support, which is the provision of assistance to other people to help them cope with a variety of problems, can be provided by family members (Pam, 2013). Family is important in social networking. Family relations are strong between families, relatives and community members (Susan, 1994). As most family members depend on each other, a family member is also responsible for supporting and attending health facilities for people with diabetes and seeking medical care. For people with diabetes, their family’s motivation to support self-care activities and family engagement in diabetes care are altogether essential (Adeniyi et al., 2015; Mayberry & Osborn, 2012). The family can provide the core or extended support, and family members can live together with people with diabetes. A previous study showed that family support is a predictor of self-care practise amongst people with diabetes in Western Ethiopia (Diriba et al., 2020).

Family can demonstrate supportive or non-supportive behaviour or both to the patient’s management of diabetes. Supportive family behaviours include giving praise for following the diet, suggesting approaches that may help people with diabetes, helping to decide if changes occur to blood glucose, as well as encouraging them to participate in sports activities and eating and exercising together with people with diabetes. Supportive behaviour of the family may encourage the self-care behaviours of people with diabetes and discourage the negative ones (August et al., 2011; Beanlands et al., 2005; Newton-John et al., 2017). By contrast, non-supportive family behaviours include nagging people with diabetes to perform self-care, criticising them for not exercising regularly, arguing about diabetes self-care activities and forcing them to eat foods that are not a part of a diabetic diet. Non-supportive family behaviour may lead to diabetes distress and negatively affect people with diabetes (Anderson et al., 1981; Pereira et al., 2008). Thus, family caregivers need to understand their role in supporting their relatives with diabetes, particularly the supportive and non-supportive behaviours.

A typical Ethiopian tradition, especially at lunch and dinner, to consume food with all family members from a communal plate. Eating together is an essential part of Ethiopian culture, and it is a sign of love (Soumya, 2020). Owing to this tradition, the chance is high for foods of family members to be mixed amongst those with and without diabetes. Thus, the dietary preference or needs of the person with diabetes may not be respected. The lack of dietary choice makes it difficult to change the behaviour of people with diabetes, leading them to abort their dietary practise. Educating the family can help to synergise dietary habits (Chlebowy et al., 2010; Sohal et al., 2015) and DSM activities (McEwen et al., 2017).

1.3.4 Healthcare system-related challenges

Similar to other low-income countries, Ethiopia experiences healthcare system-related challenges in diabetes control. According to the global health expenditure report and a review of healthcare costs, treating diabetes in Ethiopia entails a high cost (Bishu et al., 2019; Zhang et al., 2010).

Although the health insurance for people with diabetes with financial problems has commenced in Ethiopia, most of them are expected to cover healthcare costs by themselves (Workneh et al., 2016). Besides, observational studies found that unavailability and frequent stock outs of drugs, low diabetes knowledge, long duration of treatment, lack of social support in healthcare, low healthcare-seeking behaviour (Mebratie et al., 2014), lack of glucometer to self-monitor one's sugar (Ketema et al., 2020) and problems with adherence to recommendations (Demoz et al., 2019; Habte et al., 2017) altogether hinder diabetes treatment and monitoring. Furthermore, healthcare delivery systems are challenged by the lack of a system to continue care, the low number of staff, poor knowledge and skills of health workers, low government attention about diabetes and poor data management (Workneh et al., 2016). The findings from these studies revealed that multiple factors affect diabetes care, further hindering people with diabetes from visiting healthcare facilities.

In conclusion, the delivery and implementation of DSM interventions in Ethiopia are challenged by considerable factors, including limited access to a healthy diet, lack of awareness about healthy food (Gaskin et al., 2014), lack of glucometer to monitor blood glucose (Ketema et al., 2020), misconceptions about the disease, low quality of care, frequent stock out of drugs, inability to afford for health cost and lack of trained family about diabetes (Diriba et al., 2020). Hence, the effective components of DSMES for controlling diabetes amongst people with diabetes in Ethiopia should be investigated. Thus, this study aimed to identify effective DSM intervention, develop appropriate intervention and pilot the intervention on people with T2D living in Ethiopia.

1.4 Statement of the problem

In Africa, diabetes prevalence is alarmingly increasing. Approximately 3.2% of adults have diabetes, which puts Ethiopia fourth in rank in diabetes prevalence in the African Region, followed by South Africa, Nigeria and the United Republic of Tanzania (International Diabetes Federation, 2021). Regarded as a low-income country (US$ < 1,036 gross national income per capita) (The World Bank, 2020), similar to other developing countries, Ethiopia suffers from diabetes due to limited resources and a lack of awareness about the disease (International Diabetes Federation, 2021; Rodriguez-Saldana, 2019; WHO, 2019). Despite the increased prevalence and burden of diabetes, patient-related and healthcare system-related problems both challenge diabetes management. Patient-related factors, such as low diabetes knowledge, inability to afford medical care, inability to cope with diabetes burden, lack of social support, lack of culturally tailored self-management education and other many predictors, have continuously challenged the management of the disease (Atun et al., 2017; International Diabetes Association Africa region, 2006; Workneh et al., 2016). Furthermore, people with diabetes in Ethiopia have many misconceptions about the disease and its management (International Diabetes Association Africa region, 2006). As for the healthcare system-related factors, the inequalities and inaccessibility of healthcare, shortage of drug supply, frequent drug stock out, lack of leadership commitment, inadequate staffing for diabetes care, lack of separate diabetes clinics in hospitals, poor knowledge and skills of health workers, low government attention and poor data management have challenged diabetes management (Atun et al., 2017; International Diabetes Association Africa region, 2006; Workneh et al., 2016).

Due to the factors mentioned above, the morbidity and mortality attributable to diabetes-related complications remain high (Bishu et al., 2019). Amongst the different approaches for managing diabetes, DSMES is essential in improving the outcomes of people with diabetes (American Diabetes Association, 2020). The main aim of DSMES is to improve the knowledge, skills and ability of people with diabetes so they can perform self-management, and it should be cost-effective (Powers, Bardsley, & Cypress, 2015). As the pharmacologic management for diabetes is not optimal in Africa, enforcing DSM education is necessary (Stephani et al., 2018). In developed countries, DSMES is given by trained diabetes educators and other trained health professionals on diabetes education (Powers et al., 2017), but this is not the case in African countries, including Ethiopia. The practise of DSMES is overlooked in this region due to multifaceted problems (Bishu et al., 2019; Stephani et al., 2018). Several cross-sectional studies showed that poor self-management practises amongst people with diabetes are associated with lack of family support, occupation, education level, presence of comorbidities and poor knowledge about diabetes (Chali et al., 2018; Dedefo et al., 2019; Diriba et al., 2020). The systematic review and meta-analysis involving cross-sectional studies also showed that the overall diabetes self-care behaviours in Ethiopia are poor (Ketema et al., 2020). A systematic review about the barriers and strategies of lifestyle and dietary management of T2D in Africa highlights the lack of culturally specific dietary education and family support, and these factors act as the main barriers to diabetes management in Africa (Bekele et al., 2020). Therefore, the current best available evidence regarding DSMES interventions for treating people with diabetes in Africa should be reviewed, and a culturally specific DSMES intervention for people with diabetes in Ethiopia must be developed and pilot-tested.

1.5 Significance of the study

Developed based on the best available evidence regarding the effectiveness of DSM interventions on diabetic-related outcomes amongst people with diabetes in Africa, a pilot study was conducted to examine the feasibility, acceptability and preliminary effects of the DSMES programme pertaining to the clinical outcomes (SBP, DBP, BMI, total cholesterol, LDL cholesterol, HDL cholesterol and triglycerides), psychological outcomes (self-management behaviour and QOL) and perceived social support outcome of people with diabetes and the family caregiver's supportive behaviour outcome. The study aimed to examine the preliminary effects of a nurse-led, culturally specific dietary management, family caregiver-supported, community-based intervention on the outcomes.

This pilot study aimed to address two steps of the Medical Research Council (MRC) framework: the intervention's development and the testing for feasibility/pilot of the study methods (Craig P, 2019). The theoretical modelling of the intervention was developed effectively based on social cognitive theory (SCT) (Bandura, 1986) and the results of the systematic review and meta-analysis on the effectiveness of self-management programmes amongst adults with diabetes in Africa (Diriba et al., 2021b). The preliminary efficacies of the DSMES programme on the clinical outcomes (SBP, DBP, BMI, total cholesterol, LDL cholesterol, HDL cholesterol and triglycerides), psychological outcomes (self-management behaviour and QOL) and perceived social support outcome of people with diabetes and the family caregiver's supportive behaviour were examined. The preliminary efficacy of the developed intervention programme (i.e. the DSMES) and effect sizes of the pilot RCT would then be used as basis for the third step of the MRC framework, particularly the evaluation of the DSMES programme's effectiveness on a large sample size (i.e. full-scale RCT) in Ethiopia.

1.6 Chapter summary

Diabetes is a metabolic disorder characterised by hyperglycaemia (WHO, 2019). In the 21st century, diabetes has become one of the fastest-growing diseases, with more than a half-billion adults living with the disease at the global level. Ethiopia bears 1.9% of adult diabetes cases and is ranked fourth in Africa (International Diabetes Federation, 2021). T2D is the most prevalent type of diabetes both globally and in Ethiopia. According to (International Diabetes Federation, 2021) and WHO (WHO, 2016), the burden of diabetes is increasing from time to time. Ethiopia is suffering from the double burden of non-communicable disease with a high health cost, mortality and a poor healthcare system. Multiple DSM strategies, including pharmacologic and non-pharmacologic approaches, have been implemented to manage diabetes. Self-management activities are currently recommended because of their safety, cost-efficiency and effectiveness in controlling blood glucose. The management of diabetes is a problem in Ethiopia due to misconceptions, lack of knowledge about self-management and inaccessibility of healthcare. Thus, culturally tailored self-management by means of addressing the challenges of self-management interventions is needed. Hence, this research project aimed to study the feasibility, acceptability and preliminary effectiveness of the DSMES programme intervention.

1.7 Organisation of this thesis

This thesis consists of nine chapters. Chapter One presents the introduction of the doctoral research project, including the background information, statement of the problem and significance of the research project, and the aims and objectives of the study. Chapter Two presents a systematic review and meta-analysis conducted to review and synthesise the best available evidence on DSM interventions in Africa. Chapter Three presents the narrative review of dietary management and family support. Chapter Four gives the development of the DSMES programme, conceptual framework and details of the intervention programme. Chapter Five shows the details of cultural adaptation and psychometric properties of self-reported outcomes measures. Chapter Six presents the pilot RCT study methods and materials utilised to examine the feasibility, acceptability and preliminary effects of the DSMES programme on the selected outcomes. Chapter Seven depicts the results of a pilot RCT study, showing the feasibility, acceptability and preliminary effects of the DSMES programme on the outcomes. Chapter Eight discusses the pilot RCT results. Lastly, the study's implications, conclusion and recommendations are presented in Chapter Nine. The appendices and references are also attached in this thesis.

1.8 Aim and objectives of the research project

1.8.1 Aim of the research project

The overall aim of the doctoral study was to develop a DSMES programme for people with T2D–family caregiver dyads in Ethiopia and examine its feasibility, acceptability and preliminary effects on the blood pressure, BMI, HbA1c, total cholesterol, LDL cholesterol, HDL cholesterol, triglycerides, self-management practise, perceived support status and QOL of people with diabetes and the family caregiver's supportive behaviour in Western Ethiopia.

1.8.2 Objectives of the research project

In this doctoral study, three different phases were conducted, including a review of the effectiveness of the DSMES programme interventions, the development of the intervention protocol and the examination of the developed programme's feasibility, acceptability and preliminary efficacy on selected outcomes for dyads in Western Ethiopia.

Phase I. The objective of Phase I is to review and synthesise the best available evidence regarding the effectiveness of DSMES interventions on diabetic-related outcomes amongst Africans with diabetes by conducting a systematic review and meta-analysis and identifying the components of effective DSMES programmes in terms of content, dosage, provider type, duration of follow-up and delivery mode for this subpopulation. The findings are used to guide the programme development in Phase II.

Phase II. The objective of Phase II is to develop a DSMES programme that comprises effective components of DSMES identified in Phase I. New components targeting the knowledge of food, family support and misconception about DM for people with diabetes in Ethiopia are added based on SCT to address some of the challenges in diabetes management in Ethiopia.

Phase III. The objective of Phase III is to examine the feasibility and preliminary effects of the DSMES programme on the BP, BMI, HbA1c, total cholesterol, LDL cholesterol, HDL cholesterol, triglycerides, self-care behaviours, QOL and perceived social supportive behaviour of people with diabetes and the family caregiver's supportive behaviour. The main focus is the conduct of a two-arm parallel-group pilot RCT involving people with diabetes–family caregiver dyads.

CHAPTER TWO: A SYSTEMATIC REVIEW AND META-ANALYSIS

2.1 Introduction

This chapter presents a systematic review of the effectiveness of DSM interventions in African people with diabetes. The best available evidence produced from RCT studies conducted in Africa was reviewed and synthesised to generate evidence of the effectiveness of the intervention. This systematic review of the effectiveness of DSM interventions on physiological outcomes was previously published (Diriba et al., 2021b).

This chapter is organised into eight sections. Section 2.1 briefly introduces the chapter, and Section 2.2 gives the background information of the review. Section 2.3 presents the methods, Section 2.4 presents the results, and Section 2.5 elaborates the discussion. Section 2.6 presents the conclusions, Section 2.7 presents the implications of the findings for intervention development, and Section 2.8 summarises the chapter.

2.2 Background

Globally, the number of individuals with diabetes has increased alarmingly over time. According to (International Diabetes Federation, 2021), the number of people with diabetes in Africa is approximately 24 million, with the highest mortality in the world. Africa is being challenged by the management of diabetes, and healthcare systems can hardly manage the cases and achieve the common treatment goals (Naik R. & Kaneda T, 2015). Apart from these issues, the practise of DSM, which is the ability of people with diabetes to deal with DSM (symptoms, treatment, physical and social consequences) and lifestyle changes, remains poor (Stephani et al., 2018).

The curriculum of DSMES is flexible and can be based on up-to-date evidence. A curriculum for age, health literacy level, diabetes types, culture and existing comorbidities should be adapted (Cavanaugh et al., 2008; Glazier et al., 2006; Lindstrom et al., 2019; Magee et al., 2011; Schillinger et al., 2002). Several studies demonstrated that interventions may consider the AADE-7 self-care behaviours and knowledge for the pathophysiology of diabetes and treatment methods' improved outcomes (American Association of Diabetes Educators, 2008; Norris et al., 2002). DSMES may further cover eight curriculum content areas: diabetes pathophysiology and treatment options, healthy eating, physical activity, medication usage, monitoring and using patient-generated health data, preventing and treating diabetes complications, healthy coping and problem solving (International Diabetes Association Africa region, 2006). Although ongoing DSMES can help people with diabetes with effective self-management in producing better outcomes based on research findings (Tang et al., 2010), four critical times have been recommended for DSMES delivery: (1) when a person is newly diagnosed, (2) annually, (3) when new complicating factors influence self-management and (4) when transitions in care happened (American Diabetes Association, 2020; Childs et al., 2017).

Studies conducted in different parts of the world showed that DSM interventions support small to modest improvements in diabetes outcomes, and these interventions also showed mixed results with substantial variations across studies (Almutairi et al., 2019; Carpenter et al., 2019; Chew et al., 2017; Cunningham et al., 2018; Duke et al., 2009; Steinsbekk et al., 2012). A systematic review and meta-analysis reported that DSME is ineffective on HbA1c but effective on QOL amongst African Americans (Cunningham et al., 2018).

Several systematic reviews and meta-analyses were conducted to examine the pooled effects of different DSM interventions around the world (Almutairi et al., 2019; Carpenter et al., 2019; Chew et al., 2017; Cunningham et al., 2018; Duke et al., 2009; Steinsbekk et al., 2012). As an African study is lacking in these reviews, the findings' generalizability may be inappropriate to Africans with diabetes. Besides, Africa is being challenged by misconceptions about the disease, lack of self-management knowledge and poor healthcare system-related factors. As Africa has diversified cultures, languages, religions and misconceptions, the effective components of DSMES interventions should also be identified in terms of content, dosage, provider type, duration of follow-up and delivery mode for people with diabetes. Therefore, a systematic review and a meta-analysis are needed to examine the effect of DSM interventions on diabetes outcomes amongst people with diabetes in Africa. Consequently, the effectiveness of DSMES interventions on African people with diabetes was reviewed, and a meta-analysis and a subgroup analysis were conducted to identify the effective components of the DSMES in terms of content, dosage and delivery model, guided by the following research question: what is the effect of the DSM interventions on the diabetic-related outcomes amongst African with diabetes compared with those receiving usual care?

2.3 Methods

A review was guided and reported according to the preferred reporting systematic review and meta-analysis guidelines of (Moher et al., 2009).

2.3.1 Search strategy

The key search terms used were 'diabetes' or 'diabetes mellitus' or 'self-management' or 'self-care' or 'nutritional management' or 'DSM' or 'DSME' or 'diabetes education' and/or 'Africa'.

Five electronic databases, namely, PubMed, CINAHL Complete, Scopus, the Cochrane Library Central Register of Controlled Trials, and Google Scholar, were searched for studies published from inception until September 28, 2019. Two independent researchers (the doctoral student and the Chief Supervisor) performed the study selection. The reviewers screened the articles for eligibility and excluded the duplicates (**Figure 2.1**).

2.3.2 Study eligibility

Studies were included in the review and meta-analysis if they 1) were RCTs; 2) consisted of African people or included a subgroup analysis for Africans; 3) included participants aged 18 years and older with T1D or T2D; 4) focused on interventions covering at least one component of DSM; 5) included a comparison arm receiving usual care; 6) reported at least one diabetic-related outcome, such as HbA1c, SBP, DBP, BMI and total cholesterol either as primary or secondary outcomes, medication adherence or QOL; 7) conducted follow-up for at least three months; and 8) were original articles. Studies were excluded if 1) they were study protocols; 2) the participants had gestational diabetes; or 3) the outcomes were not reported. No restriction was applied regarding the year of publication.

2.3.3 Data extraction

After cross-checking the articles, the doctoral student prepared the data extraction table, and a consensus was reached with the Chief Supervisor. For the included studies, they comprised the study design, the study participants, the setting, the content of the interventions and the outcome measures, and then their results were extracted. The study authors of the included studies were contacted to retrieve missing data, but no responses were received.

2.3.4 Risk of bias assessment

The study-level risk of bias was assessed using the Cochrane collaboration's tool for RCTs (Higgins & Green, 2011), which includes seven domains aimed at detecting random and allocation concealment, selection bias, performance bias, detection bias, attrition bias, reporting bias and other biases (**Figure 2.2**). The two reviewers independently assessed, compared and reached a consensus in evaluating the risk of bias. The overall quality of the included studies was assessed by the 'Grading of Recommendations, Assessment, Development and Evaluations' criteria (Guyatt et al., 2008). Initially, the high grade rank was assigned for RCTs; however, the rank would be downgraded when clear allocation, concealment, blinding of participants, blinding of outcome assessments and exposure to other biases, such as a follow-up, were lacking.

2.3.5 Data analysis

The data were synthesised and statistically pooled using the Review Manager 5.3 software. Meta-analysis was conducted when two or more of the included studies reported the outcome by using the endpoint mean and standard deviation (SD) of that outcome. For missing values of the outcome of concern in the endpoint, the mean and SD were estimated based on Cochrane's recommendation (Higgins et al., 2019). For studies reporting a change in scores, the endpoint means were calculated by adding the change score to the baseline score of the outcome variable, and the corresponding SD was calculated using standard error and p-value. For studies that did not report any related information, the statistics were imputed by the average means and SDs of the other studies included in the meta-analysis. Two sets of sensitivity analyses were conducted for each outcome. The first set of analyses was performed by imputing the minimum and maximum values of the means and SDs of the other included studies. Then, the results were reported based on the imputed average means and SDs when similar results were obtained from sensitivity analyses. The second set was determined by means of the leave-one-out method. For n studies reporting the outcome, n-1 meta-analyses that ignore the result of one study were conducted (Viechtbauer & Cheung, 2010), and the value of variation from the overall mean difference of the outlier study was reported. The heterogeneity of the studies was assessed using I^2 and Cochran's Q, with an I^2 value of >50% and a p-value of <0.05 for Cochran's Q, indicating possible heterogeneity (Higgins et al., 2019). Random-effects models were used to estimate the pooled mean difference across studies. However, when the heterogeneity was low, the fixed-effects model was applied. The standard mean difference model was implemented when different measurement tools were used for assessing the outcome. Subgroup analyses were conducted for HbA1c based on intervention characteristics in terms of the number of DSME components used in the intervention, provider type, duration of follow-up, intervention intensity, application of theory to guide the intervention, type of diabetes, approach of delivery and mode of delivery. Egger's regression asymmetry and the rank correlation tests of (Begg & Mazumdar, 1994) were performed to test the publication bias by using the Comprehensive Meta-Analysis version 3.0 software. A p-value of <0.1 (two-tailed) indicates the presence of publication bias.

2.4 Results

2.4.1 Study selection

The search of the five electronic databases yielded 10,500 studies, amongst which 4,998 were retained after removing duplicates. After screening the 4,998 abstracts, 4,812 were excluded because they were not related to the research question. The full texts of the remaining 186 studies were screened for eligibility, and 11 studies reporting study outcomes were included in the review and meta-analysis (**Figure 2.1**).

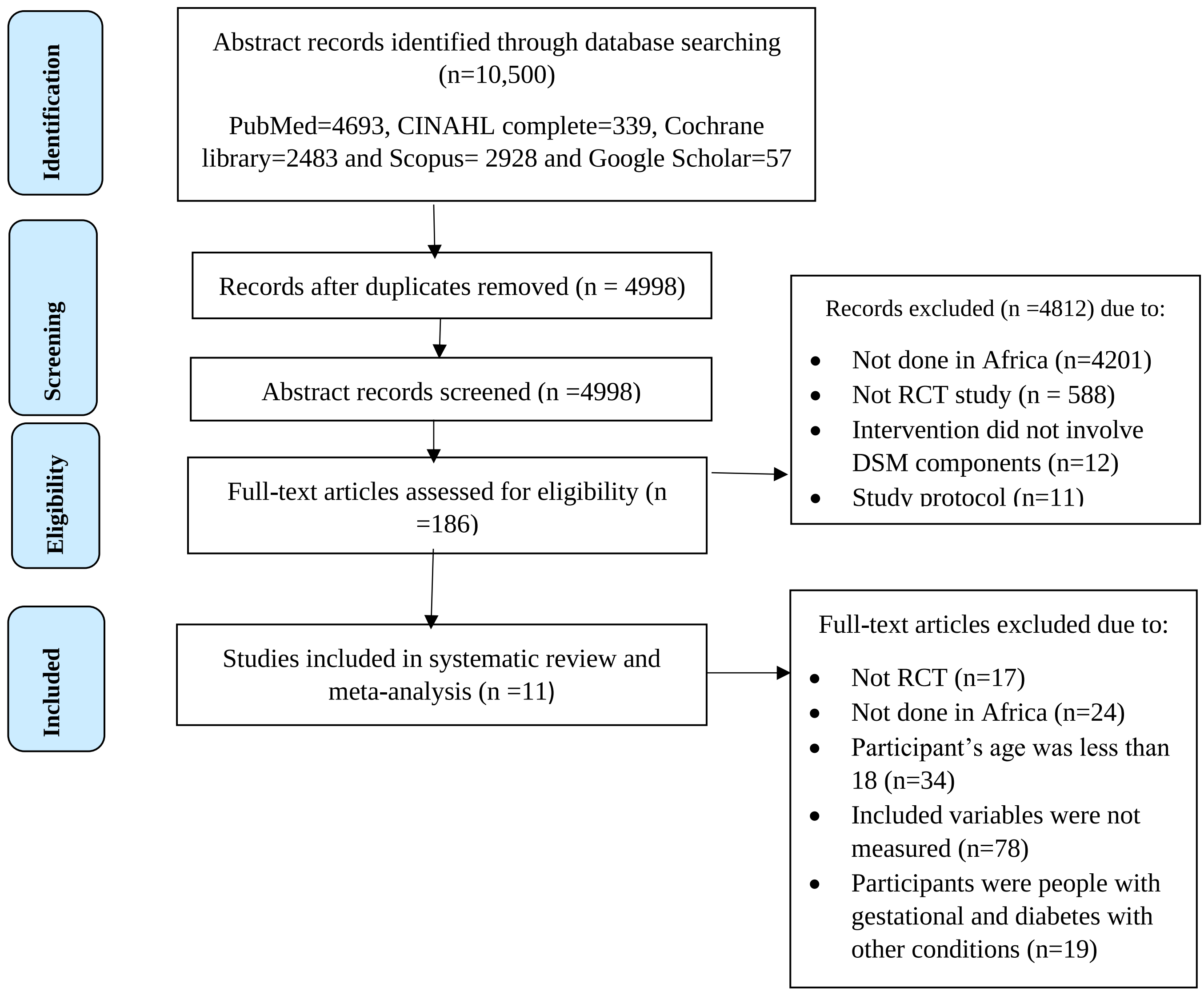

Figure 2.1 PRISMA flow diagram to select the studies

2.4.2 Subjects' characteristics

For the included studies, they were conducted in Egypt (n = 1), South Africa (n = 4), Ethiopia (n = 2), Kenya (n = 1), the Democratic Republic of Congo (n = 1), Mali (n = 1) and Nigeria (n = 1) and published between 2010 and 2018. Regarding the study design, nine were RCTs, and two of them were cluster RCTs (Fairall et al., 2016; Mash et al., 2014). The sample size ranged from 53 to 1795. Overall, 3,771 people with diabetes participated in the included studies, with 47.6% and

52.4% of participants assigned to intervention and control groups. In the intervention group, over half of the participants were females (61.5%), and the mean age was 54.5±3.2 years. In the control group, 66.3% of participants were females, and the mean age was 54.2±4.5 years. Three studies involved people with T1D and T2D (Abaza et al., 2017; Essien et al., 2017; Van Olmen et al., 2017), whereas the remaining eight studies involved people with T2D only (**Table 2.1**).

Table 2.1 Characteristics of the study participants and interventions

Author, year, country	Participants	Sample size IG	Sample size CG	Study design	Sex (%) and mean age (yrs.) IG	Sex (%) and mean age (yrs.) CG	Intervention characteristics: Intervention group	Intervention characteristics: Control group	Attrition rate (%) IG	Attrition rate (%) CG
Abaza and Marscholle k, 2017, Egypt	Diabetes patient	45	45	Pilot RCT	F:52.94 M: 47.06 51.24 yrs.	F:58.97 M: 41.03 51.77 yrs.	Intervention: SMS and weekly reminders on diabetic care based on ADA, booklet of diabetes care given Strategy: Phone-based SMS education Duration of follow-up: 12 weeks Frequency of intervention: Daily SMS and one diabetic care category every day throughout the week Total contact: 84 SMS educational and 12 SMS reminders were given Provider: Diabetic specialist, internists Setting: Hospital	Usual care and booklet of diabetes care given	24.4	13.3
Agatha et al., 2010, South Africa	T2 diabetic patients Age 40-65; for at least one year, HbA1c1 $\geq$ 8 – 9.5% and patients on dietary therapy and glucose-lowering agents. Exclusion: Illiterate Patients	27	24	RCT	F:52.2 M:47.8 53.74 yrs.	F: 75 M: 25 54 yrs.	Intervention: Usual care plus group education on nutritional self-management and physical activity supported by motivational SMS Topic covered: planning, purchasing, and preparing food and meals; food sources, including glycaemic index and load Strategy: face-to-face education Duration of follow-up: 1 year Frequency of intervention: four weekly educations, continued at home from Week 5 and received motivational text messages biweekly and ended at week 16 Total contacts: 4 weekly group sessions Provider: Podiatrist Setting: Hospital-based The model used: Learning Nests approach, empowerment-based approach	Usual care	14.8	16.7
Debussche et al., 2018, Mali	Poorly controlled Type 2 diabetes (HbA1c $\geq$8%); Age 30-80. With regular follow-up	76	75	RCT	F:75 M: 25 53.9 yrs.	F:77.3 M: 22.7 51.1 yrs.	Intervention: Conventional care plus culturally tailored structured group patient education and provided booklet Topic covered: 3 courses on CV risk management, food intake, exercise, BG and insulin management Strategy: Peer-led face-to-face Duration of follow-up: 1 year Freq. of intervention: Every three months for one year. Every session was given for 1.5-2 hrs.	Conventional care Strategy: Underwent conventional diabetes monitoring and regular follow-ups, including individual counselling sessions, blood glucose measurement, weight and blood pressure, data	7.9	6.6

							Total contact:8 hrs. Provider: Trained peer-educators Setting: Community-based, urban The model used: Learning Nests approach, empowerment-based approach	collection, clinical examination, and prescription or renewal of treatment. Duration of follow-up: 1 year		
Erku et al., 2017, Ethiopia	T2DM aged at least 18 years. Take at least one long-term antidiabetic medication for at least 3 months and have regular monthly follow-ups. Excluded Patients were mentally incapable and unable to communicate.	62	65	Parallel RCT	F: 44.5 M: 55.5 61.3 yrs.	F: 41.5 M:58.5 59.8 yrs.	Intervention: Medication therapy management (MTM) + usual care Topic covered: Education and training on diabetes medications, education on health-promoting behaviours Strategy: Face-to-face education and counselling via telephone call Duration of follow-up: 6 months Frequency of intervention: 45 min/session Total contacts: 45 minutes Provider; Pharmacist Setting: Diabetes clinic	The patient received usual care in the diabetes clinic. Brief discussion (3-4 min) on disease diagnosis and medication adherence given	12.9	20
Essien et al., 2017, Nigeria	T1DM or T2DM aged >18yrs, HbA1c $\geq$ 8.5%, able to engage in moderate exercise; free of eye disease	59	59	Parallel RCT	F: 52.5 M: 47.5 52.6 yrs.	F:67.8 M: 32.2 52.8 yrs.	Intervention: Intensive education Topic covered; IDF recommended COMDIS-HSD health educator Desk guide Strategy: Group face-to-face, mobile phone message to remind Duration of follow-up: 6 months Frequency of intervention: 12 structured teaching sessions. Total contact:24hrs. Provider: Doctors and nurses in separately. They trained certified diabetes educators by IDF Setting: Hospital	Conventional education (DSME) with usual care at the clinic. DSME is not mandatory. Frequency of intervention: Once every 3-4 weeks, Attended around 6 DMSE sessions	10.2	13.5
Fairall et al., 2016, South Africa	Self-report Diabetes patients, age 18 or older, taking diabetes medications (Cohort on DM)	851	963	Pragmatic cluster RCT	F:73 M: 27 51yrs.	F: 73 M: 27 53 yrs.	Intervention: Primary care 101 (PC101) management tool at PHC training was given to nurses, pharmacists, and doctors. Topic covered: PC101 management tool for NCDs Strategy: Group face-to-face education and expanded diabetes drugs prescription by nurses Duration of follow-up: 3-6 months Frequency of intervention: 8 sessions Total contact: 12 hrs. Provider: Nurses Setting: Primary health care	Continued to use the Practical Approach to Lung Health and HIV/AIDS in South Africa (PALSA PLUS), take drugs as usual care, and no new training was given	Not specified	

Gathu et al., 2018, Kenya	Sub-optimally controlled (HbA1c ≥8%) T2D. Age 18-65, Excluded those with diabetes complications.	70	70	RCT	F: 41 M: 59 50.2 yrs.	F: 47 M: 53 47.5 yrs.	Intervention: DSME and usual care Topic covered: American Association of Diabetes Educators (AADE) components Strategy: Individualized DSME, which is supported by the booklet. Weekly reminders were given by telephone Duration of follow-up: 3 months Freq. of intervention: 3 one hr. sessions every six-weeks Total contact: 3 hrs. Provider: Certified diabetes educators Setting: Clinic Model: Empowerment and interactive teaching model	Usual care offered by the family physician Duration of care: 20-30 min standard doctor's consultation. Informal patient-tailored diabetes education was given Follow-up: Quarterly	21	41
Hailu et al., 2018, Ethiopia	T2DM, aged >30 yrs. Excluded: T1DM or gestational DM, severe cognitive or physical impairment, pregnant women. Terminally ill people	116	104	Before and after RCT	F: 30 M: 70 55 yrs.	F: 36 M: 64 54 yrs.	Intervention: DSME Topic covered: International Diabetes Federation and AADE for sub-Saharan Africa inpatient handbook Strategy: Group DSME Duration of follow-up: 6 months Freq. of intervention: Six DSME sessions for 1.5 hr. Total contact: 9 hrs. Provider: PhD. Nurse student and one clinical nurse fluent in the local language Setting: Hospital	Continued usual follow-up care	32.8	38.5
Mash et al., 2014, South Africa	Type 2 diabetic patients. Excluded: T1D, unable to participate (acutely ill)	710	860	Pragmatic cluster RCT	F: 71.5 M:28.5 55.8 yrs.	F: 75.7 M: 24.3 56.4 yrs.	Intervention: DSME Topic covered: Diabetes, health style, understanding medication and avoiding complications Strategy: Group DSME Duration of follow-up: 12 months Freq. of intervention: Four DSME sessions for 60 min Total contact hrs.: 4 Provider: Health promoter Setting: Health centre	Received usual education at the health centre. Contains ad hoc educational talks in the waiting or club room	44.9	44.8
Muchiri et al., 2015, South Africa	T2DM aged 40-70 yrs.; HbA1c ≥8%; having diabetes at least 1 year; not on insulin therapy; regular diabetes follow-ups; not pregnant or in full-time employment;	41	41	Parallel RCT	F: 87.8 M: 12.2 59.4 yrs.	F: 85.4 M: 14.6 58.2 yrs.	Intervention: Nutrition education (NE) and received educational materials and usual care Topic covered: Received 3 components of NE (curriculum, follow-up and vegetable gardening Strategy: Group NE Duration of follow-up: 12 months Freq. of intervention: Follow-up lasts for four monthly meetings for 1.5 hrs. Total contact: 26.5 hrs. Provider: Dietitians Setting: Community health centre	Received educational materials (pamphlet and hall/fridge poster) and usual medical care	7.3	7.3

							Model: HBM, Social cognitive theory was used			
Olmen et al., 2016, Democratic Republic of Congo	T1or T2DM aged ≥18 yrs.; currently participating in DSME, had at least one session	254	252	RCT	F: 67 M: 33 59 yrs.	F: 67 M:33 63 yrs.	Intervention: DSME plus DSMS Topic covered: According to the nine dimensions of DSME Strategy: SMS-based DSMS Duration of follow-up: 2 years Frequency of intervention: Five times per week, 15.7 SMS per month Total SMS sent on averagely of 377 times Provider: Implementation manager Setting: Delivered by SMS at any elsewhere Model: Theory of planned behaviour was used	Received biomedical care and DSME, which contains periodic consultations with a doctor every two months Provided by nurses	37	38.5

Abbreviations: AADE: American Association of Diabetes Education, CV: Cardiovascular, DSME: Diabetes self-management education, DSMS: diabetes self-management support, F: Female, HBM: Health Belief Model, IDF: International Diabetes Federation, M: Male, NE: Nutrition Education, RCT: Randomised Controlled Trial, SMS: Short Message Services, T1D: Type 1 diabetes, T2D: Type 2 diabetes.

2.4.3 Intervention characteristics

Amongst the included studies, five of them covered all components of DSM, including diet, physical activity, medication compliance, blood glucose testing, foot care, smoking and diabetes complications (Abaza et al., 2017; Essien et al., 2017; Gathu et al., 2018; Hailu et al., 2018; Van Olmen et al., 2017); two of studies covered diet therapy, physical activity, medication and avoiding complications (Debussche et al., 2018; Mash et al., 2014); one study covered physical activity and dietary intake topics in education (Agatha et al., 2010); one study included only nutritional therapy education (Muchiri et al., 2016); and one study covered only medication therapy management in the intervention (Erku et al., 2017). One study delivered basic lifestyle activities, including diet and physical activity (Fairall et al., 2016). Seven studies were delivered using a group approach (Agatha et al., 2010; Debussche et al., 2018; Essien et al., 2017; Fairall et al., 2016; Hailu et al., 2018; Mash et al., 2014; Muchiri et al., 2016), whilst four studies were delivered individually (Abaza et al., 2017; Erku et al., 2017; Gathu et al., 2018; Van Olmen et al., 2017). The intervention follow-up period ranged from three months to two years. The follow-up covered six months or less in four studies (Abaza et al., 2017; Erku et al., 2017; Essien et al., 2017; Gathu et al., 2018), with the rest lasting for more than six months. The comparator group received usual care (routine intervention) in all studies. The overall attrition rate reached 23.4%, with 22.3% (7.3%–44.9%) in the intervention group and 24.5% (6.6%–44.8%) in the control group.

Face-to-face interventions were implemented in nine studies (Agatha et al., 2010; Debussche et al., 2018; Erku et al., 2017; Essien et al., 2017; Fairall et al., 2016; Gathu et al., 2018; Hailu et al., 2018; Mash et al., 2014; Muchiri et al., 2016). The intervention was delivered via short message services (SMS) in two studies (Abaza et al., 2017; Van Olmen et al., 2017). Additionally, a weekly

SMS was sent to remind the participants to undergo testing for blood glucose, and the readings were recorded (Abaza et al., 2017). In addition to the face-to-face intervention, telephone calls and sending of SMS were conducted to remind participants to attend the intervention session in three studies (Agatha et al., 2010; Erku et al., 2017; Essien et al., 2017). Only one study was conducted in a community setting (Debussche et al., 2018). The length of the interventions ranged from 3 to 26.5 hours for the face-to-face interventions, and 84–377 SMS were sent for the message interventions. The interventions were delivered by health professionals in nine studies, whereas trained health promoters and peer educators provided the education in two studies (Debussche et al., 2018). A multidiscipline approach was used to deliver the intervention in two studies (Abaza et al., 2017; Essien et al., 2017). Amongst the included studies, four applied theoretical models to guide the enquiry, including the empowerment-based ‘Learning Nests’ approach (Debussche et al., 2018), empowerment and interactive teaching model (Gathu et al., 2018), a health belief model and SCT (Muchiri et al., 2016) and the theory of planned behaviour (Van Olmen et al., 2017). Nine of the included studies measured HbA1c level as the primary outcome, followed by SBP (n = 6), DBP (n = 6), total cholesterol (n = 3), BMI (n = 6), waist circumference (n = 3), diabetes self-efficacy (n = 2), QOL (n = 1), medication adherence (n = 3), physical activity (n = 2) and diabetes knowledge level (n = 4) as the secondary outcomes. Two studies reported medication adherence (Erku et al., 2017; Fairall et al., 2016). The details are shown in **Table 2.2**.

Table 2.2 Primary outcomes, secondary outcomes, strengths, and limitations of the studies

Author, year, country	Outcomes measures	Results		Strengths and Limitations of the study
		Intervention group	Control group	
Abaza and Marschollek, 2017, Egypt	**Primary outcome** HbA1c **Secondary outcomes** Medication adherence Diabetes self-efficacy Diabetes knowledge Medication adherence	The mean at baseline was 9.78 (SD=2.53); the mean at three months was 8.73 (SD: 1.98); the level of significance was non-significant Mean at baseline: 2.74; Mean at 3-month= 3.76; level of significance was not significant Mean at baseline = 2.68; mean at 3-month = 3.51; level of significance was not significant Mean at baseline = 0.35; mean at 3-month = 0.73; level of significance was not significant at baseline Mean at baseline =3.94; mean at 3-month = 4.76; level of significance at baseline was not significant	The mean at baseline was 9.53 (SD=2.78); the mean at three months was 8.84 (SD: 2.4); the level of significance was non-significant Mean at baseline = 2.74; mean at 3-month = 2.74; level of significance was significant Mean at baseline = 2.82; mean at 3-month = 2.88; level of significance was significant Mean at baseline = 0.29; mean at 3-month = 0.34; level of significance was significant Mean at baseline = 3.9; mean at 3-month = 3.90 level of significance was significant	Strength Not indicated Limitations Short period Small sample size Delays during recruitment and overlaps between study phases
Agatha et al., 2010, South Africa	**Primary outcome** HbA1c **Secondary outcomes** Total cholesterol Body mass index Diabetes knowledge	The adjusted mean from baseline was increased by 1.95 with P-value of 0.523; the level of significance was non-significant Estimated mean: 8.89, SD=2.36 The adjusted mean was increased by 0.16 (P=0.047); the level of significance was significant The adjusted mean: was increased by 0.61(P=0.741); the level of significance was not significant The adjusted mean difference at 1-year = -4.27. level of significance was significant at 1-year	The adjusted mean was decreased by 0.01 with P=0.523; the level of significance was non-significant. Estimated mean: 9.37, SD=2.39 The adjusted mean was -0.39 (P=0.047); the level of significance was significant The adjusted mean was + 0.38; the level of significance was significant Adjusted mean difference = -2.00	Strengths Used appropriate statistical tests Measured the intended outcomes Limitations High attrition rate The results of outcomes were not indicated in mean
Debussche et al., 2018, Mali	**Primary outcome** HbA1c **Secondary outcomes** Body mass index	The mean at baseline was 10.6 (SD=1.8); at 12 months was 9.55 (SD: 2.33); the level of significance was significant The mean at baseline was 28.3 (SD=5.4); the mean at 12 months was 26.65 (SD: 2.5); the level of significance was significant	The mean at baseline was 10.8 (SD=1.9); the mean at 12 months was 10.65 (SD: 2.33); the level of significance was significant The mean at baseline was 28.8 (SD=5.5); the mean at 12 months was 28.85 (SD:3.2); the level of significance was significant	Strengths The study was culturally tailored High dosage of group education components Applied Learning Nests approach, which includes behavioural strategies

	Waist circumference (cm) Systolic Blood Pressure Diastolic Blood Pressure Diabetes knowledge	The mean at baseline was 93.5 (SD=12.1); waist circumference at 12 months was decreased by 3.34; the level of significance was significant The mean at baseline was 132.8 (SD=26.9); the mean at 12 months was 126.34; the level of significance was significant The mean at baseline was 82.9 (SD=10.5); the mean at 12 months was 83.3; the level of significance was non-significant Mean at baseline = 5.2; mean change from baseline at 12 months = 1.06, level of significance of the change was not significant	Mean at baseline was 94.1 (SD=11.6); waist circumference at 12 months was increased by 2.64; level of significance was significant The mean at baseline was 127.1 (SD=20.1); the mean at 12 months was 130.67; the level of significance was significant The mean at baseline was 80.3 (SD=10.6); the mean at 12 months was 82.3; the level of significance was non-significant Mean at baseline = 5.2; mean change from baseline at 12 months = 0.61; level of significant change was not significant	Limitations Randomization was conducted on an individual level which may have led to information contamination Conducted only in urban Not indicated the mean value at the endpoint
Erku et al., 2017, Ethiopia	**Primary outcome** Medication adherence scores at 3 and 6 months Assessed by Morisky Medication adherence scale (MMAS-8) Reported as a reliable tool **No secondary outcome reported**	MMAS-8$\geq$ 6 score Good adherence score (% of patients) Score at baseline: 9.2% Score at three months: 29.6% Score at six months: 61%	MMAS-8 $\geq$ 6 score Good adherence score (% of patients) Score at baseline: 13.2% Score at three months: 20.7% Score at six months: 30.2 %	Strengths Used appropriate statistical analysis Limitations Not using a standard tool to measure medication adherence Not measured HbA1c
Essien et al., 2017, Nigeria	**Primary outcome** HbA1c No secondary outcome reported	The mean at baseline was 10.9 (SD: 1.7); the mean at six months was 8.4; estimated SD: 1.63; the level of significance was significant; Cohen's d = -1.8 (-2.4 to -1.2)	The mean at baseline was 10.5 (SD: 1.5); the mean at six months was 10.2; Estimated SD:1.6; the level of significance was significant	Strength The education session is simple to run Limitations Different professionals delivered the intervention Short follow-up Intervention effectiveness is not explicitly investigated
Fairall et al., 2016, South Africa	**Primary outcome** Treatment intensification: defined as the addition or increase in the dose of metformin and/or the addition or increase in the dose of sulphonylurea and/or the addition or increase in the dose of an ACE inhibitor and/or addition of aspirin and/or the	57% of participants have intensively used the treatment with adjusted RR =1.11 (0.99 to 1.26)	50% of participants were intensively used the treatment with adjusted RR =1.11; the level of significance was non-significant	Strengths Pragmatic trial Involved large sample size Limitations The study did not put the outcome in mean Unanticipated change in usual care in the health districts under study: a shift in focus from communicable disease care to NCD care. The short duration of follow-up

	addition or increase in the dose of statin No secondary outcome reported			
Gathu et al., 2018, Kenya	**Primary outcome** HbA1c Secondary outcomes Systolic blood pressure Diastolic blood pressure Body mass index	The baseline mean was 9.8 (SD=1.9); the mean at six months was 8.8 (SD= 1.89); the level of significance level was not significant The mean at baseline was 134.3 (SD= 15.9); the mean at six months was 132.6 (SD=15.32); the level of significance was non-significant The mean at baseline was 80.8 (SD=10.32); the mean at six months was 78 (SD=9.04); the level of significance was non-significant The mean at baseline was 28.6 (SD=4.03); the mean at six months was 28.9 (SD=3.87); the level of significance was non-significant	The baseline mean was 9.9 (SD=1.45); the mean at six months: was 9.3 (SD=1.75); the level of significance level was not significant The mean at baseline was 134.1 (SD= 13.6); the mean at six months was 133.8 (SD=11.54; level of significance was non-significance Mean at baseline: 83.5 (SD=10.07); mean at 6 months: 82.6 (SD= 9.86); level of significance level non-significant The mean at baseline was 28.9 (SD=4.48); the mean at six months was 29.3 (SD=4.55); the level of significance was non-significant	Strength Put the value of the outcomes in mean Limitations Risk of cross-contamination The usual care group has a greater attrition rate than the intervention group (41% vs 21%) Short follow-up period Patients were long-standing diabetic patients
Hailu et al., 2018, Ethiopia	**Primary outcome** HbA1c **Secondary outcomes** Systolic blood pressure Diastolic blood pressure Body mass index Fasting blood sugar	The baseline mean was 11 (SD=4); the mean at nine months was 8.12; the level of significance level was not significant The estimated SD=3.24 The mean at baseline was 124(SD=20); the mean at nine months was 112; the difference in mean change in SBP was 12 ± 3; the level of significance was significant The mean at baseline was 79; the mean at nine months was 71(SD: 2); the difference in mean change in DBP was 8 ± 2; the level of significance was significant The mean at baseline was 25; the mean at nine months is not indicated; the level of significance was non-significant The mean at baseline was 154; the difference in mean change in FBS was 27 ± 10; the level of significance was non-significant	The baseline mean was 10 (SD=3); the mean at nine months was 7.43; level of significance level was not significant; the estimated SD=3.24 The mean at baseline was 125 (SD=19); the mean at nine months was 135; the level of significance was significant The mean at baseline was 78; the mean at nine months was 85(SD:11); the level of significance: significant The mean at baseline was 25; the mean at nine months is not indicated; the level of significance was non-significant The mean at baseline was 158; the mean at nine months is not indicated; the level of significance was non-significant	Strength Showed the results change over the period Limitations Risk for cross-contamination Didn't measure HbA1c in outcomes
Mash et al., 2014, South Africa	**Primary outcome** HbA1c **Secondary outcomes** Systolic blood pressure Diastolic blood pressure	The mean at baseline was 8.9 (SD=2.3); the mean at 12 months was 8.81 (SD= 3.5); the significance level was not significant. The mean is estimated from the mean difference and SD is the estimated value. The baseline mean was 140.2 (SD=22.4); the mean at 12 months was 143.1 (SD= 24.2); the level of significance was significant	The mean at baseline was 9.3 (SD=2.3); the mean at 12 months was 8.8 (SD= 3.5); the level of significance was non-significant The baseline mean was 137.2 (SD=24.3); the mean at 12 months was 146.1 (SD: 24.6); the level of significance was significant	Strengths Measured the outcomes Large sample Limitations High drop rate Subjected to social desirability bias

		The baseline mean was 85.9 (11.7); the mean at 12 months was 85.0 (=SD: 11.9); the level of significance was significant	The baseline score was 85.4 (SD=13.0); the mean at 12 months: was 88.2 (SD: 12.8); the level of significance was significant	
	Total cholesterol	The baseline mean was 5.0 (1.1); the score at 12 months was 4.8 (SD= 1.1); the level of significance was non-significant	The baseline score was 4.9 (SD=1.3); the score at 12 months was 4.9 (SD= 1.2); the level of significance was non-significant	
	Quality of life			
	Self-efficacy	No total score was indicated; however, the results of each domain indicated non-significant results	No total score was indicated; however, the results of each domain indicated non-significant results	
	Medication adherence	Endpoint mean = 3.7	Endpoint means =3.7. Between-group differences indicate -0.03, with no significant difference between groups.	
		Mean at endpoint = 6.8	Mean at endpoint = 6.9; between-group mean difference= 0.01	
Muchiri et al., 2015, South Africa	**Primary outcome** HbA1c	The mean at baseline was 10.8 (SD=1.80); mean at 12 months was 9.8 (SE=0.3); estimated SD: 1.92; mean difference = 0.63 (-0.26 to 1.50); level of significance was non-significant	The mean at baseline was 11.4 (SD=2.20); mean at 12 months was 10.4 (SE: 0.3); estimated SD: 1.92; mean difference = 0.63 (-0.26 to 1.50).	Strengths Low attrition rate The intervention was culturally tailored Limitations Low power and high SD Facilitators of education were not experienced
	Secondary outcomes Systolic blood pressure	The mean at baseline was 142.9 (SD=22.9); the mean at 12 months was 141.1 (SE: 2.90); the mean difference was 0.18 (-8.10 to 8.40); the level of significance was non-significant	The mean at baseline was 143.3 (SD=28.0); the mean at 12 months was 140.0 (SE= 2.9); the level of significance was non-significance	
	Diastolic blood pressure	The mean at baseline was 84.3 (SD=11.7); the mean at 12 months was 79.8 (SE: 1.6); the mean difference was 2.33 level of significance was non-significant	The mean at baseline was 84.5 (11.7); the mean at 12 months was 82.1 (SE= 1.6); the level of significance was non-significant	
	Body mass index	The mean at baseline was 31.5 (SD=7.00); the mean at 12 months was 30.6 (SE= 0.3); the mean difference was 0.49 (-0.40 to 1.10)	The mean at baseline was 30.4 (6.80); the mean at 12 months was 31.1 (SE=0.3)	
	Total cholesterol	The mean at baseline was 4.8 (SD=1.20); the mean at 12 months was 4.74 (SE: 0.1) The level of significance was not significant at the endpoint	The mean at baseline was 4.9 (0.90); the mean at 12 months was 4.9 (SE= 0.1) The level of significance was not significant at the endpoint	
Van Olmen et al., 2016, Democratic Republic of Congo	**Primary outcome** The proportion of people being controlled HbA1c (<7.0%) at two years	The proportion of people being controlled HbA1c (<7.0%) baseline was 23.2%; the proportion of people being controlled HbA1c (<7.0%) at two years was 29.4% with OR 0.80 (0.48-1.34) and level of significance was not significant Estimated mean=8.89, SD=2.36	The proportion of people being controlled HbA1c (<7.0%) baseline was 22.0%; the proportion of people being controlled HbA1c (<7.0%) at two years was 21.9%with OR 0.80 (0.48-1.34), and level of significance was not significant Estimated mean=9.37, SD=2.39	Strength Long follow-up duration Limitations Lack of intention-to-treat analysis High drop rate Information contamination
	Secondary outcomes Body mass index	BMI was increased by 0.3 $\pm$2.7 by two years; the level of significance was non-significant	BMI was increased by 0.3 $\pm$2.7 by two years; the level of significance was non-significant	

Systolic blood pressure	No change at two years 0±27; level of significance was non-significant	It was increased by 2±30 at two years; the level of significance was non-significant
Diastolic blood pressure	It was decreased by 4 ± 16 at two years; the level of significance was non-significant	It was decreased by 3 ± 15 at two years; the level of significance was non-significant
Diabetes knowledge	Mean change from baseline to end = +0.3; level of significance of the change was not significant	Mean change from baseline to endpoint = +0.43 level of significance of the change was not significant

Months or years indicated under the result in the above table indicate the endpoint of the follow-up.

2.4.4 Risk of bias in individual studies

Overall, the methodological rigour of the included studies was moderate. Three studies had a low risk of bias in most categories and a high risk of bias in at least two categories. The risk of bias attributable to the blinding of participants was high in nine studies, and unclear risk was observed in two studies. Nine studies were exposed to other biases. Performance bias existed in all of the studies. The outcome assessments could be blinded, although only 2 of the 11 studies clearly stated that they had blinded the outcome assessor. The details are shown in **Figure 2.2**.

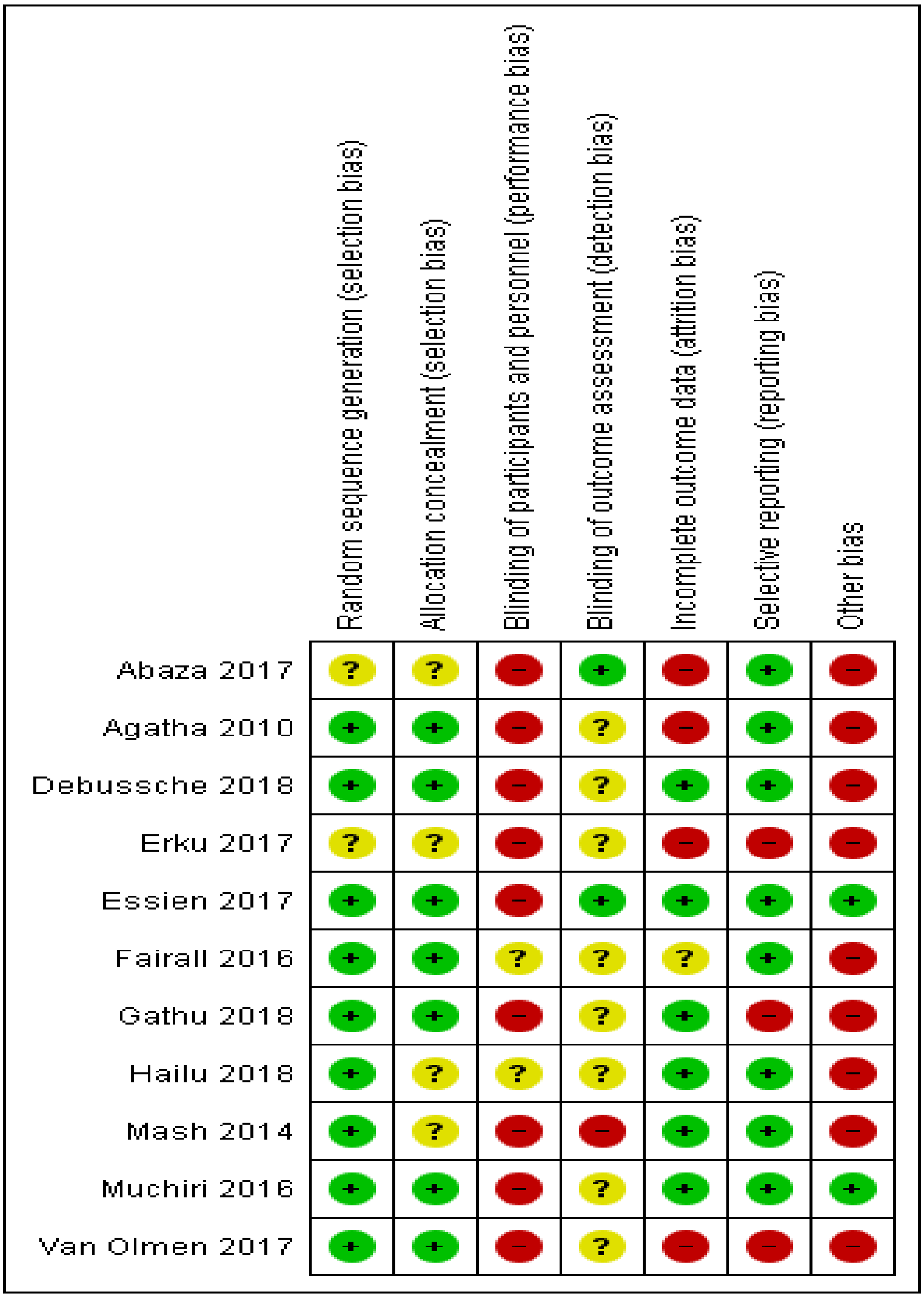

Figure 2.2 Risk of bias summary of the included studies

2.4.5 Results of individual studies

2.4.5.1 HbA1c

Amongst all of the included studies, two of them reported significant improvement in HbA1c (Debussche et al., 2018; Essien et al., 2017), with a large interventional effect found in one study (Essien et al., 2017), whereas the remaining seven studies reported a non-significant reduction. The pooled meta-analysis examining the effect of DSM interventions on HbA1c was not reported due to inconsistent results on sensitivity analyses. Sensitivity analysis 1 produced inconsistent results when different imputed values were used. Three meta-analyses were significant, whereas six were non-significant, ranging from −21 to −17 mmol/mol (0.2%–0.6%). The results of using the leave-one-out method showed that removing a study with an intervention covering extensive DSME (Essien et al., 2017) can yield a large variation of −21 mmol/mol (0.2%) from the pooled mean difference, with a range from −19 to 16 mmol/mol (−0.4% to −0.7 %). Clinical significance reduction in HbA1c was achieved in three studies (Debussche et al., 2018; Essien et al., 2017; Muchiri et al., 2016).

Subgroup Analyses Result

Subgroup analyses of HbA1c showed no significant difference in all of the performed subgroup analyses. Subgroup analyses showed non-significant findings in terms of the components of DSME [all: −18 mmol/mol (−0.5%) (95% confidence interval (CI): −1.3%, 0.3%) versus some: −18 mmol/mol (−0.5%) (95% CI: −1.1%, 0.2%); $p = 0.96$], the length of the intervention [≤6 months: −14 mmol/mol (−0.9%) (95% CI: −1.9%, 0.2%) versus >6 months: −19 mmol/mol (−0.4%) (95% CI: −0.8%, 0.1%); $p = 0.39$], the intensity of intervention [<10 hours: −20 mmol/mol (−0.3%) (95% CI:−0.9%, 0.4%) versus ≥10 hours: −15 mmol/mol (−0.8%) (95% CI: −1.8%, 0.2%); $p = 0.35$], types of diabetes [T2DM only: −20 mmol/mol (−0.3%) (95% CI: −0.7%, 0.1%) versus both: −12 mmol/mol (−1.1%) (95% CI: −2.4%, 0.2%); $p = 0.24$], intervention provider [health professionals: −18 mmol/mol (−0.5%) (95% CI: −1.1%, 0.1%) versus paraprofessionals: −18 mmol/mol (−0.5%) (95% CI: −1.6%, 0.6%); $p = 0.96$], the format of intervention [individual: −19 mmol/mol (−0.4%) (95% CI: −0.8%, −0.1%) versus group-based: −17 mmol/mol (−0.6%) (95% CI: 1.3%, 0.2%); $p = 0.72$], the application of the theory to guide the intervention [theory applied: −17 mmol/mol (−0.6%) (95% CI: −1.0%, −0.3%) versus theory not applied: −19 mmol/mol (−0.4%) (95% CI: −1.3%, 0.6%); $p = 0.61$]

and the mode of delivery [face-to-face alone: −20 mmol/mol (−0.3%) (95% CI: −1.0%, 0.4%) versus SMS alone: −19 mmol/mol (−0.4%) (95% CI: −0.9%, 0.1%) versus SMS-supported face-to-face intervention: −13 mmol/mol (−1.0%) (95% CI: −2.0%, −0.1%); p = 0.66].

2.4.5.1 Blood pressure

Six trials examined the effect of DSM interventions on SBP and DBP. Three studies reported a significant reduction in SBP (Debussche et al., 2018; Hailu et al., 2018; Mash et al., 2014), whereas another three studies reported non-significant results (Gathu et al., 2018; Muchiri et al., 2016; Van Olmen et al., 2017). A significant reduction (i.e. by 4.24 mm Hg) was observed in SBP (95% CI: −6.85, −1.62; p<0.010). Significant between-group differences in SBP were obtained when different imputed values were used, ranging between −4.24 and −4.70 mm Hg. The heterogeneity across studies was low, with a p-value of Cochran's Q = 0.17 and I^2 = 35%. The details are shown in **Figure 2.3**. The leave-one-out method showed variations in the pooled between-group mean difference, with a range of −3.61 to −4.82 mm Hg. The variations were largely attributed to nurse-led DSME (Hailu et al., 2018).

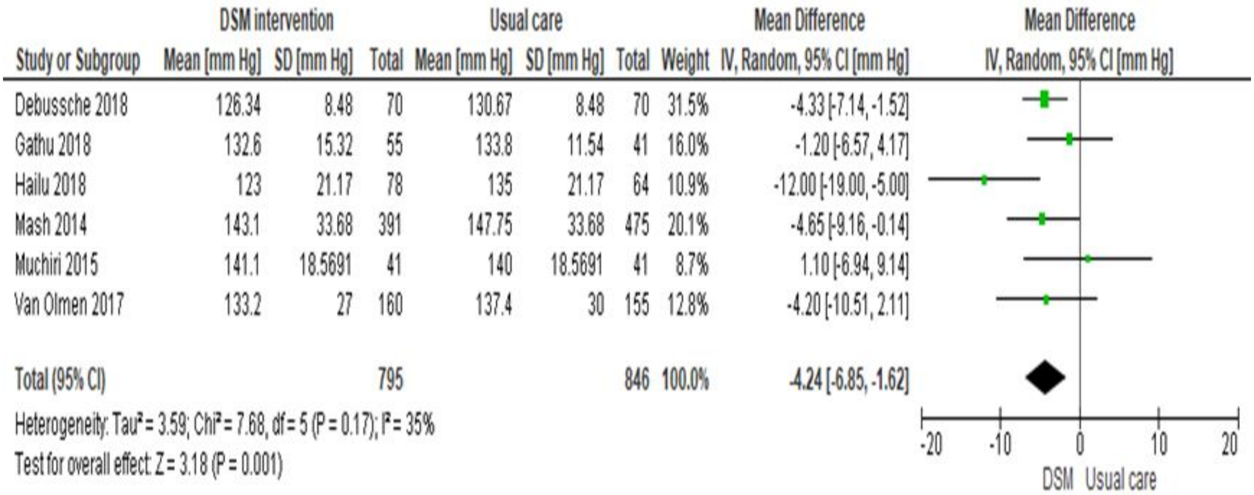

Figure 2.3 Forest plot showing the effect of diabetes self-management interventions on systolic blood pressure

Similar results were obtained for DBP, with three studies reporting significant reductions (Hailu et al., 2018; Mash et al., 2014; Van Olmen et al., 2017) and another three studies reporting non-significant results (Debussche et al., 2018; Gathu et al., 2018; Muchiri et al., 2016). According to the meta-analysis, the DSM interventions produced a significant reduction in DBP by 3.27 mmHg (95% CI: −0.62, −5.92; p = 0.020). The details are shown in **Figure 2.4**. Significant between-group mean differences in DBP were obtained when different imputed values were used, ranging between 2.47 and 3.27 mmHg. However, the studies may have moderate heterogeneity (p-value of Cochran's Q < 0.001 and I^2 = 82%). The leave-one-out method yielded substantial variations in the pooled mean differences, ranging from −2.36 to −4.14 mmHg. The study by Hailu et al. (2018) contributed substantially to the observed variations.

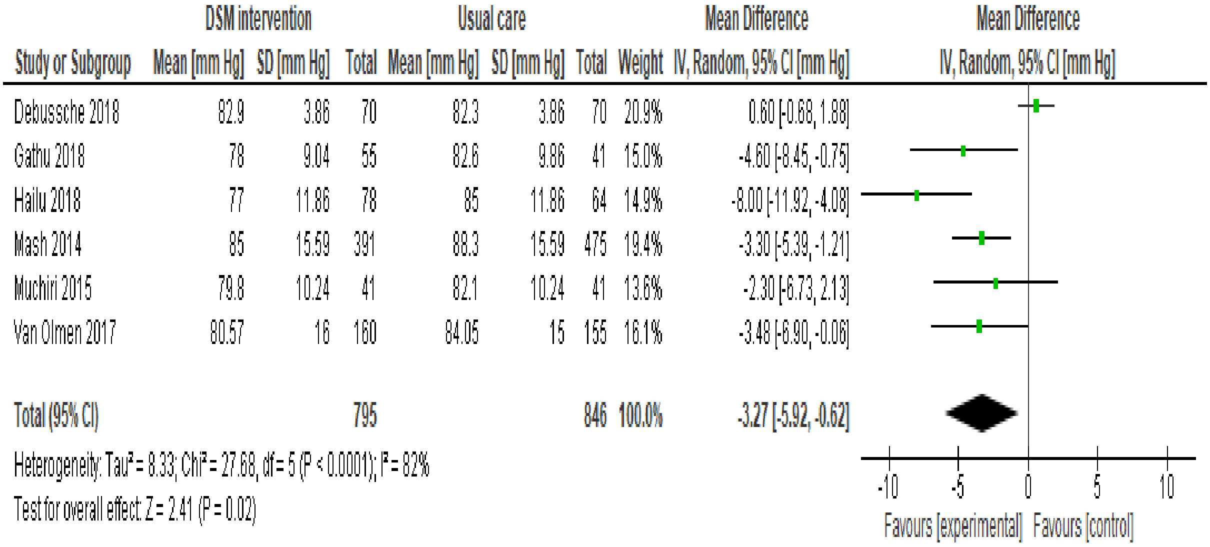

Figure 2.4 The effect of diabetes self-management interventions on diastolic blood pressure

2.4.5.2 Total cholesterol

Total cholesterol was reported in three studies, with non-significant results reported in two of them (Mash et al., 2014; Muchiri et al., 2016) and a significant finding in the remaining study (Agatha et al., 2010). According to the meta-analysis, the DSM interventions yielded a significant reduction in total cholesterol by 0.14 mmol/L (95% CI: −0.26, −0.02; p = 0.030). The details are shown in **Figure 2.5**. No heterogeneity was observed across studies (p-value of Cochran's Q = 0.980 and I^2 = 0%). All sensitivity analyses yielded similar results when different imputed values were used. The leave-one-out method also reported stable findings in the pooled mean difference, ranging from −0.13 to −0.15 mmol/L.

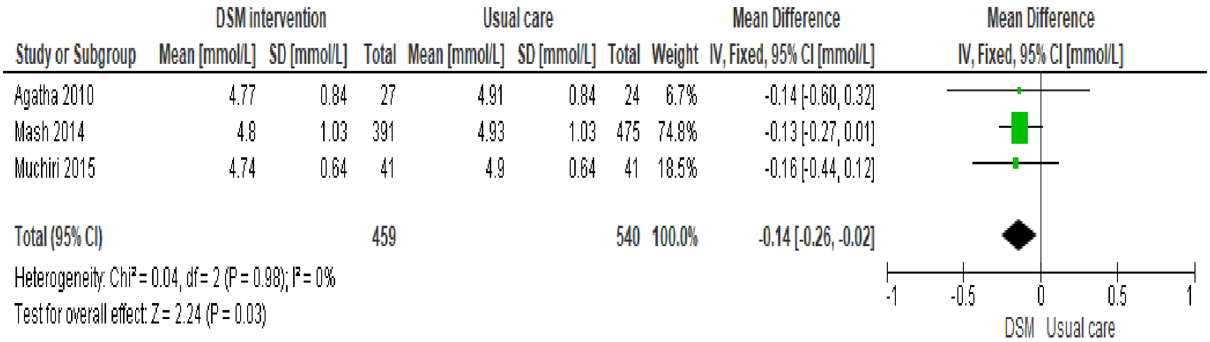

Figure 2.5 The effect of diabetes self-management interventions on total cholesterol

2.4.5.3 BMI

Six studies reported BMI, with five of them reporting non-significant results (Agatha et al., 2010; Gathu et al., 2018; Hailu et al., 2018; Muchiri et al., 2016; Van Olmen et al., 2017). The meta-analysis showed that DSM interventions significantly reduced BMI by 0.9 kg/m^2 (95% CI: −1.39, −0.45; p = 0.001). Significant between-group mean differences were obtained when different imputed values were used, ranging between 0.6 and 1.7 kg/m^2. No heterogeneity was recorded across studies (p-value of Cochran's Q = 0.570 and I^2 = 0%). The details are shown in **Figure 2.6**. The leave-one-out method showed variations in the pooled mean difference, ranging between −0.8 and −1.1 kg/m^2. The variations can be attributed to the study by Muchiri et al. (2016).

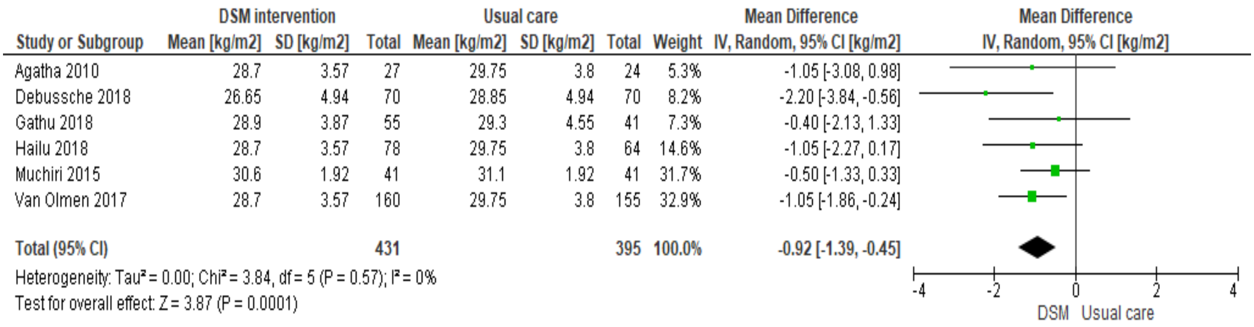

Figure 2.6 The effect of diabetes self-management interventions on body mass index

2.4.5.4 Waist circumference

Three studies reported waist circumference. Two of them reported non-significant findings (Hailu et al., 2018; Mash et al., 2014). On the basis of the average mean and SD imputed for missing data, the meta-analysis showed a non-significant reduction of 3.3 cm (95% CI: −6.82, 0.32; p = 0.070). The sensitivity analyses demonstrated a non-significant reduction, ranging between 2.39 and 4.23 cm. The heterogeneity across studies was substantial (p-value of Cochran's Q = 0.020 and I^2 = 76%). The details are shown in **Figure 2.7**. The leave-one-out sensitivity analysis also revealed substantial variations in the pooled mean difference in the range between −1.8 and −5.0 cm, which can be explained by the study of Mash et al. (2014).

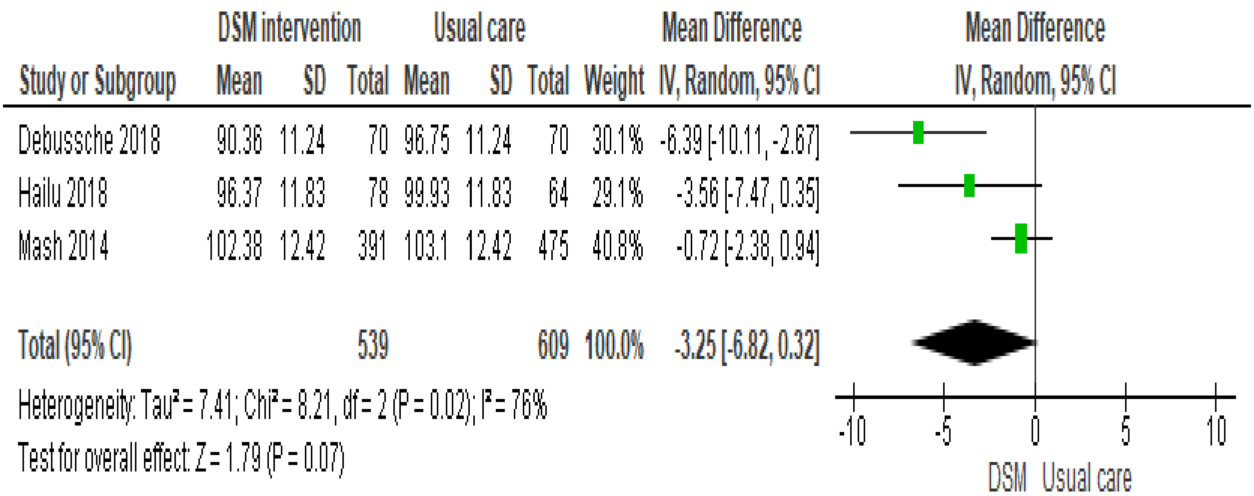

Figure 2.7 The forest plot showing the effect of diabetes self-management interventions on waist circumference

2.4.5.5 QOL

Only the study of Mash et al. (2014) reported QOL. Their findings showed a non-significant difference in the QOL between the intervention and control groups.

2.4.5.6 Diabetes knowledge

Diabetes knowledge was assessed using the 'Michigan Diabetes Knowledge Scale' (Abaza et al., 2017), but the '0–15 Diabetes Knowledge Questionnaire Form B' (Agatha et al., 2010), a locally adapted diabetes knowledge questionnaire in Mali (Debussche et al., 2018) and a scale used to measure diabetes knowledge in one study, was not indicated (Van Olmen et al., 2017). Abaza et al. (2017), who provided SMS-based DSME, and Agatha et al. (2010) delivered nutritional and physical activity education for the intervention group, and significant improvement in diabetes knowledge was attained. Except for the study conducted by Debussche et al. (2018), all included studies significantly improved diabetes knowledge. The standard mean differences in the meta-analysis showed that diabetes knowledge improved significantly by 0.79 (p = 0.01) with substantial heterogeneity. The details are shown in **Figure 2.8**.

	DSM intervention			Usual care				Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
Abaza 2017	0.73	0.18	39	0.34	0.21	34	22.9%	1.98 [1.42, 2.55]
Agatha 2010	4.27	4.48	27	2	1.82	24	23.0%	0.64 [0.07, 1.20]
Debussche 2018	6.26	2.65	70	5.81	2.65	70	26.4%	0.17 [-0.16, 0.50]
Van Olmen 2017	3.75	2.44	160	2.67	1.56	155	27.6%	0.52 [0.30, 0.75]
Total (95% CI)			**296**			**283**	**100.0%**	**0.79 [0.19, 1.40]**

Heterogeneity: Tau² = 0.33; Chi² = 29.75, df = 3 (P < 0.00001); I² = 90%

Test for overall effect: Z = 2.57 (P = 0.01)

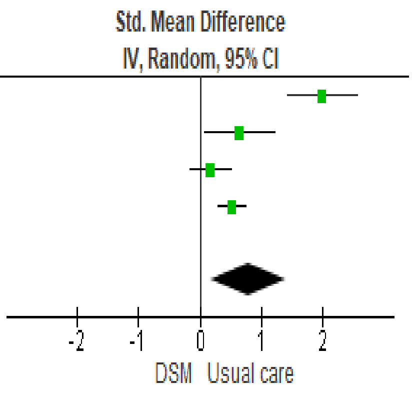

Figure 2.8 The forest plot showing the effect of diabetes self-management interventions on diabetes knowledge

2.4.5.7 Diabetes self-efficacy

Only two studies addressed diabetes self-efficacy (Abaza et al., 2017; Mash et al., 2014), and the results were assessed using the ‘Stanford Self-Efficacy for Diabetes’ and the ‘Michigan Diabetes Empowerment Scale’ separately. Mixed results were reported. Abaza et al. (2017) found that diabetes self-efficacy was significantly increased with weekly SMS delivery of DSME, but Mash et al. (2014) reported that the participants’ self-efficacy was not significantly improved. Improvement in self-efficacy ranged from 0.20 to 0.63. DSM interventions resulted in non-significant improvement by 0.43 (p = 0.29) with substantial heterogeneity. The details are shown in **Figure 2.9**.

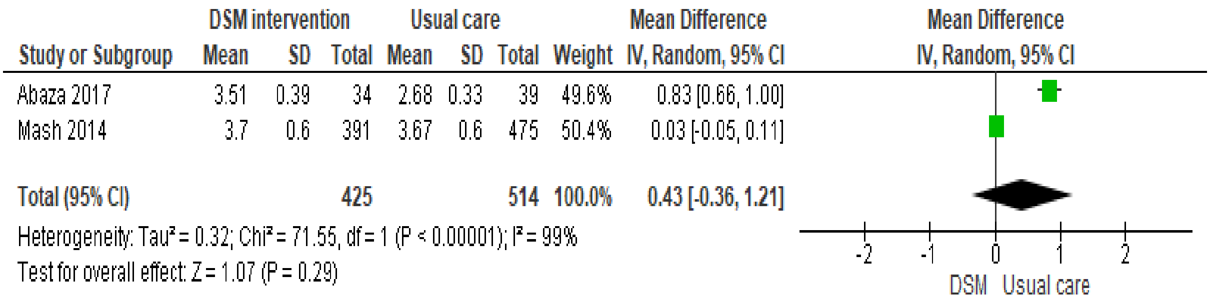

Figure 2.9 The forest plot showing the effect of diabetes self-management interventions on self-efficacy

2.4.5.8 Medication adherence

‘Morisky Medication Adherence Scale’ was used to assess medication adherence, and −4 and −8 were used to assess medication adherence in all studies reporting medication adherence. The studies that implemented DSME significantly increased between 2.74 and 3.76 (Abaza et al., 2017) for medication therapy management education (Erku et al., 2017). Group diabetes education demonstrated a non-significant effect on medication adherence (Mash et al., 2014).

Adherence to diabetes drugs slightly increased based on treatment intensification in the intervention group, but the difference between groups was not significant (Fairall et al., 2016). The result of the meta-analysis showed that the DSM interventions can significantly improve medication adherence by 0.72 (p = 0.05). The details are shown in **Figure 2.10**.

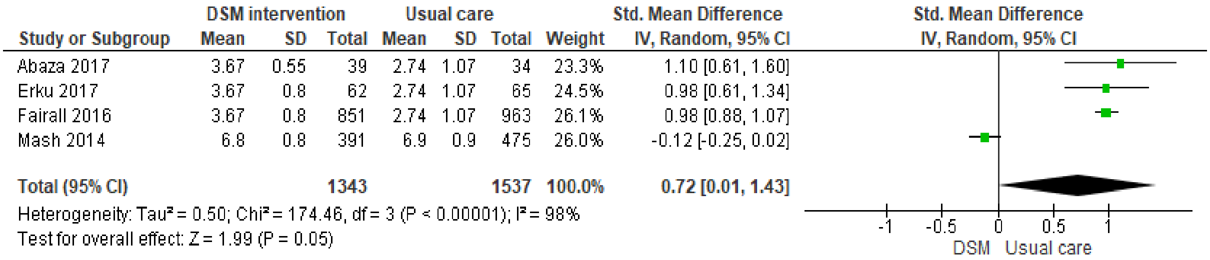

Figure 2.10 The forest plot showing the effect of diabetes self-management interventions on medication adherence

2.4.5.9 Physical activity

Two studies reported physical activity. A significant improvement was observed in the DSME group as opposed to that in the control group (Abaza et al., 2017). However, Mash et al. (2014) revealed that the participants who received usual care slightly improved their physical activity in contrast to that of the intervention group. A meta-analysis finding showed that the effect of DSM interventions on physical activity was not significant. The pooled mean difference improvement was 0.40 (p = 0.46). The details are shown in **Figure 2.11**.

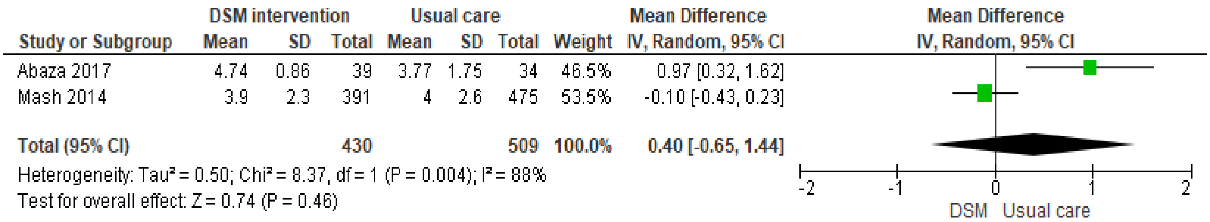

Figure 2.11 The forest plot showing the effect of diabetes self-management interventions on physical activity

2.4.6 Publication bias

The results of Egger's regression did not show any publication bias ($p > 0.10$) in four outcomes [HbA1c ($p = 0.177$), SBP ($p = 0.973$), total cholesterol ($p = 0.562$) and waist circumference ($p = 0.323$)], but it was observed in two outcomes [$p < 0.10$; DBP ($p = 0.033$) and BMI ($p = 0.072$)]. However, the rank correlation of Begg and Mazumdar did not show any publication bias for any of the studies ($p > 0.1$), with p-values ranging between 0.453 and 1.000.

2.5 Discussion

The systematic review and meta-analysis were conducted to synthesise the best available evidence regarding DSM interventions on physiological outcomes and other psychological outcomes amongst African people with diabetes. The meta-analysis revealed the inconclusive effects of DSM interventions on HbA1c for people with diabetes in Africa. More than three-fourths of the nine included studies reported non-significant results for HbA1c. Although this finding is inconsistent with those of previous studies reporting significant reductions in HbA1c (Chew et al., 2017; Cunningham et al., 2018; Duke et al., 2009; Little et al., 2011; Pal et al., 2013; Steinsbekk et al., 2012), the current finding is in line with the non-significant results reported amongst African Americans (Cunningham et al., 2018). Consistent non-significant findings regarding intervention intensity, length of follow-up, component of intervention and provider type were reported amongst African Americans with T2D (Cunningham et al., 2018; Norris et al., 2002), and a significant effect of individual intervention was inconsistent with a review involving Latino and African Americans with diabetes that reported non-significant reduction (Cunningham et al., 2018; Hildebrand et al., 2020). A reduction in HbA1c may be attributed to individual-based interventions that motivate each person to self-manage his or her disease condition (Odgers-Jewell et al., 2017).

As most of the interventions in the included studies were delivered in a health institution, the non-significant results may be explained by Africans with diabetes having limited access to diabetes management and the difficulties of continuing DSME in hospitals catering to low-income populations (Fraser et al., 2006). Community-based DSME may be a good alternative because it can improve glycaemic outcomes in rural settings (Paz-Pacheco et al., 2017). In addition, a previous study in Africa mentioned that most people with diabetes received support from their families (Adeniyi et al., 2015). Family members encourage, motivate and provide instrumental support when people with diabetes prepare food, take medication and perform physical activities. Family involvement may be a good option for boosting glucose control and monitoring other clinical parameters with respect to the cultural value of familyism (Pesantes et al., 2018; Withidpanyawong et al., 2019). However, none of the studies in this review included a family component in their intervention.

The meta-analyses showed that SBP and DBP were significantly reduced. The significant finding in SBP was in line with the studies conducted in Guatemala (Flood et al., 2017) but inconsistent with the results of nurse-led DSM education amongst Chinese people with diabetes (Liu et al., 2019). This inconsistency may be explained by Africa's multicultural societies, diversified religions, languages and foods. People in Africa consume high amounts of complex carbohydrates (Sheehy et al., 2019). Given the culture, language, religion and traditional foods that may serve as options for controlling blood pressure, the preparation and use of culturally sensitive national education guidelines and policies are important in improving blood pressure (Dube et al., 2015; Whittemore et al., 2019). The large variation in blood pressure may be explained by the participants in the included studies likely following the instructions of the intervention providers to be able to change their lifestyles, such as by being more active and taking medication, hence potentially leading to the better control of blood pressure, but it may not be intensive enough to change HbA1c. However, the included studies did not report behavioural changes in their studies, and thus, this assertion could not be explored.

Our meta-analysis detected a significant effect of DSMES on total cholesterol. This result is consistent with a review finding from countries in the Middle East (De la Fuente Coria et al., 2020; Mikhael et al., 2020). Most African people with diabetes have low literacy levels and need to receive education in their local language and through practical demonstrations, images and visual aids (Azami et al., 2018; Dube et al., 2015; Flood et al., 2017; Whittemore et al., 2019). However, only one study used images and flyers to deliver education (Hailu et al., 2018). Diabetes education adapted to the socio-economic context and literacy level of people with diabetes may be needed to control their cholesterol. Therefore, the DSMEs to be delivered by healthcare professionals, such as nurses, supplemented with visual aids and practical demonstrations, may be a good option to improve diabetes outcomes (Tshiananga et al., 2012).

In this meta-analysis, the DSM interventions effectively and significantly reduced BMI by 0.9 kg/m^2 amongst African people with diabetes. This result is higher than those in prior studies, which delivered individualised education and reported reductions of 0.2 kg/m^2 (Duke et al., 2009) and 0.1 kg/m^2 (Pal et al., 2013). The finding is also higher than a study that delivered empowerment and motivational diabetes education (Varming et al., 2019). This substantial effect may be explained by the integration of physical activity and nutrition education in most of the reported studies, as it has been reported that people knowledgeable in BMI are sensitive to change (Agatha et al., 2010; Muchiri et al., 2016; Van Olmen et al., 2017). Group-based DSME can improve self-perception and self-esteem and establish a strong social relationship, and empowerment and motivational education can focus on improving these modifiable variables to further enhance the clinical outcomes (Trento et al., 2004).

The effect of DSM interventions on waist circumference was not significant. This result is inconsistent with a study delivered via family-based DSME (Cai & Hu, 2016). Family support is a significant predictor of DSM amongst African people with diabetes (Diriba et al., 2020). The non-significant result amongst African people with diabetes may be due to the lack of family involvement in the intervention. A possible alternative solution may include the engagement of family members in the intervention. This recommendation can address the needs of people with diabetes, as the implementation of self-management needs is extended into the community setting, and it also engages the family of people with diabetes.

In the studies, DSM interventions improved diabetes knowledge. Nonetheless, previous studies from Australia and Norway (Bruce et al., 2003; Rygg et al., 2012) contrast the review's findings, and they are even comparable with the findings of a systematic review (Lepard et al., 2015). The differences may be attributed to the diabetes awareness of people with diabetes. The review also indicates that people who underwent DSM interventions seem to have increased self-efficacy, ranging from 0.2 to 0.63, with a varied significance level although the result is not significant. This finding is comparable with a study conducted in South Korea and a systematic review (Chew et al., 2017; Lee et al., 2019). The disparity across the reviews may be explained by the confidence of people with diabetes to control their diabetes. People with low income may bear low self-efficacy to perform self-management activities. This review showed no significant differences in QOL. This finding contrasts with a systematic review (Cunningham et al., 2018) and the RCT results from South Asia (Shah et al., 2019). Non-significant changes in QOL imply that QOL may need a much longer period to be improved, and holistic intervention components of DSM interventions are necessary.

In this review, self-management interventions improved medication adherence. Approximately 61% of the study participants had good medication adherence, and 57% of people with diabetes who took treatment intensification adhered to diabetes medication. These results are slightly lower than that of a systematic review from SSA (64%) (Stephani et al., 2018). Meanwhile, DSME significantly improved physical activity. This finding is similar to a systematic review and the result of a meta-analysis (Almutairi et al., 2019). The change in physical activity may need more practise prior to a change in behaviour.

2.5.1 Strengths and limitations

The systematic review and meta-analysis offer several strengths. Only RCTs were included in determining the effects of DSM interventions on physiological outcomes and psychological outcomes amongst Africans with diabetes. The methodological quality of the included studies was moderate. The outcome results were pooled together in a meta-analysis to determine the effectiveness of the interventions. Leave-one-out meta-analyses were conducted for each outcome.

The study's limitations centred on the small number of eligible studies included in this meta-analysis. As a result, the generalizability of the results across the African continent is limited. The high dropout rates and high heterogeneity amongst the included studies also affected the robustness of the pooled effects in the meta-analysis, and the missed values of HbA1c in some studies were imputed from other studies and these imputations caused difficulty in generalisation. Regardless, sensitivity analyses were performed to examine the influence of clinical heterogeneity and missing values on the pooled effects. Inconsistencies were found between the results reported in the individual studies and the current meta-analysis in terms of DBP (Gathu et al., 2018), total cholesterol (Agatha et al., 2010) and BMI (Van Olmen et al., 2017). The differences may be explained by the rounding errors in the study findings used in our meta-analysis calculation.

2.6 Conclusions

DSM interventions effectively improved most physiological outcomes, such as blood pressure, total cholesterol and BMI. However, their effects on HbA1c and waist circumference reduction were inconclusive, suggesting a need for modifications to the DSM interventions used for African people with diabetes. The intervention also improved diabetes knowledge, medication adherence and physical activity but not self-efficacy and QOL improvement.

2.7 Implications on programme development

This systematic review and meta-analysis of 11 RCT studies demonstrated that DSM interventions have differential impacts on physiological and behavioural outcomes. On the basis of the nine HbA1c studies, the pooled effect of DSM intervention on HbA1c was inconclusive amongst Africans with diabetes. The current finding highlights the need to modify the DSM interventions for Africans with diabetes. The following five directions may be considered:

Setting. As most of the interventions of the included studies were delivered in a health institution, the non-significant results may be explained by people with diabetes, limited resources in Africa for adequate diabetes management and difficulties in continuing DSME in hospitals catering to low-income populations (Fraser et al., 2006). In Africa, people with diabetes usually have no access to glucose monitoring devices, which adversely affects the patient's diabetes management. People with diabetes experienced difficulty in continuing diabetes education and diabetes care in healthcare facilities due to high transportation costs (Atun et al., 2017). Community-based DSME may be a good alternative because previous studies showed that better glycaemic outcomes could be obtained in rural settings where transportation is a challenge (Paz-Pacheco et al., 2017). As a recommendation, community-based management of diabetes should be scaled up in SSA (Atun et al., 2017).

Family involvement. None of the studies in this review included a family component in their intervention. A previous study in Africa reported that most people with diabetes received support from their families (Adeniyi et al., 2015). Family members encourage, motivate and provide instrumental support when people with diabetes prepare food, take medication and perform physical activities. Family involvement may be a good option to boost the control of glucose and monitor other clinical parameters for the cultural value of familyism (Pesantes et al., 2018; Withidpanyawong et al., 2019). However, the literature on the impact of interventions involving family members to support people with diabetes as a part of diabetes management had produced mixed results for HbA1c (Hemmati Maslakpak et al., 2017; Osuji et al., 2018; Withidpanyawong et al., 2019). Given the important role of the family in Ethiopian culture, particularly in preparing food for the family, family members should be involved in the intervention for people with diabetes in Ethiopia.

Dosage. The subgroup analysis of the length of intervention in this review showed that following the intervention of ≤6 months resulted in a better reduction in HbA1c. A systematic review of DSMES interventions amongst Latino adults with T2D and a multisession diabetes education programme targeting low-income minority people with diabetes showed that DSMES intervention with a length of less than six months could effectively improve glycaemic control and manifest readiness to improve dietary behaviours (Hildebrand et al., 2020). These two pieces of evidence suggest that DSMES interventions with a length of <6 months may effectively improve HbA1c in low-income countries. According to a subgroup analysis of this systematic review, providing interventions for ≥10 hours could produce greater reductions in the outcomes compared with the interventions delivered for <10 hours. This finding coincides with the results of a review of studies delivered culturally adapted and family model DSMES for people with T2D, which demonstrated that delivering education for ≥10 hours leads to significant and better reductions in HbA1c (Chrvala et al., 2016; Cunningham et al., 2018; McElfish et al., 2019). These findings imply that an intervention for 10 hours or more is more effective in improving HbA1c.

Delivery mode. The current systematic review and meta-analysis also found that delivering DSM interventions via SMS could support the face-to-face mode, and it could significantly affect HbA1c, SBP and DBP. In addition, either face-to-face mode or SMS mode did not bring a significant reduction. This review finding is similar to a study showing that a face-to-face delivery mode resulted in a non-significant reduction (Duke et al., 2009). The finding of this review is also in line with the meta-analysis results of studies that delivered the interventions via face-to-face and mobile-based SMS (Wong et al., 2020). In this review, DSM interventions provided by health professionals tended to reduce HbA1c better than that that involved paraprofessionals. This finding is inconsistent with the finding of self-management interventions provided by paraprofessionals for young adults with diabetes (Saxe-Custack & Weatherspoon, 2013; Spencer et al., 2018). This finding also implies that interventions provided by trained health professionals via face-to-face format supplemented with SMS reminders may improve the effect on HbA1c.

Theoretical framework. The SCT and health belief model were combined in the study as a means of delivering nutrition education for people with diabetes (Muchiri et al., 2016). The theory of planned behaviour was used to guide the intervention in the study delivered by DSME via SMS (Van Olmen et al., 2017). The effects of the interventions in these three studies on HbA1c, SBP, DBP, BMI and total cholesterol were not significant. A possible reason for the ineffectiveness of the interventions in improving the outcomes may be that these theories focus on the behaviour and cognitive functioning of a person without considering the disease condition (Ajzen, 1991), implying a need to address most theoretical constructs whilst applying behavioural change strategies.

In conclusion, this systematic review and meta-analysis reviewed and synthesised the effectiveness of DSMES interventions on diabetic-related outcomes amongst Africans with diabetes and identified the components of effective DSMES programmes in terms of content, dosage and delivery mode for this subpopulation. However, none of the studies included interventions adapted to the local context, such as the family setting, the misconceptions about diabetes and the frequent consumption of cultural food as part of the intervention, and only one study was conducted in the community context. Although the finding showed that DSM interventions can effectively improve blood pressure, total cholesterol and BMI, the effect was inconclusive in improving HbA1c. The subgroup analyses of HbA1c showed that interventions covering all components of DSME as provided by health professionals, followed by sessions of less than six months for 10 hours or more, tended to produce a larger reduction in HbA1c after the intervention. An intervention provided via SMS-supported face-to-face mode produced significant reductions in HbA1c. Most of the self-care behaviours were not changed by the DSM interventions. These findings suggest the need to modify the DSM interventions for African people with diabetes. No attention was paid to the barrier of local food and the facilitator of family support in the DSM interventions in the included studies for people with diabetes in Africa. Researchers may consider locally adapted, community-based interventions that engage families as an integral part of achieving management targets.

2.8 Chapter summary

A systematic review and a meta-analysis, including the 11 RCTs involving Africans with diabetes and those constituting a subgroup analysis of these populations, were conducted to examine the effects of DSM intervention on physiologic, QOL and other outcomes. The systematic review and meta-analysis findings were used to develop the intervention protocol for the pilot RCT. The corresponding results revealed that DSM interventions were effective in improving many physiologic outcomes, medication adherence and physical activity. However, the results were inconclusive in terms of improving HbA1c, and they were also ineffective in addressing the QOL and self-efficacy issues.

CHAPTER THREE: LITERATURE REVIEW OF DIETARY MANAGEMENT AND FAMILY-BASED INTERVENTIONS

3.1 Introduction

This chapter presents a narrative review of the effectiveness of dietary management and family-based interventions on the diabetes outcomes of people with diabetes as a means of addressing the implication of involving family members in food preparation. The discussion is based on the systematic review and meta-analysis presented in Chapter Two.

This chapter is organised into four sections. Section 3.1 presents the chapter's introduction. Section 3.2 shows the narrative review of dietary management for diabetes. Section 3.3 shows the family-based interventions. Section 3.4 summarises the chapter.

3.2 Dietary Management

3.2.1 Introduction

Food refers to 'any material consisting essentially of protein, carbohydrate, and fat used in the body of an organism to sustain growth, repair, and vital processes and to furnish energy' (Merriam-Webster dictionary, 2020). According to a proverb, 'You are what you eat'. This notion means that a person becomes healthy if he or she eats good food. The health of a person depends basically on the consumed food. Studies reported that food and T2D have positive associations. Diet is one of the modifiable risk factors for T2D (Powers et al., 2018). In most societies, eating excessive sugar is believed to cause diabetes. Even though excessive sugar intake does not directly cause diabetes, studies reported that excessive consumption of oil, flour and sugar is related to T2D (Khatib, 2004; Sami et al., 2017). In developing countries, diabetes is increasing due to the Western lifestyle and dietary patterns (Sami et al., 2017).

Dietary management is an integral aspect of diabetes management, and it reduces the risk of complications, ensuring that people with diabetes can monitor and manage the healthy intake of their diet in appropriate frequencies. According to a review conducted involving studies from Middle Eastern countries (Sami et al., 2017), dietary knowledge, attitude and practise are important parameters of dietary management amongst people with T2D. Dietary practise mediates the effect of insulin by 34% and enhances body weight reduction by 20%. The effects can be further boosted by physical activities (den Braver et al., 2017). In developing countries, dietary knowledge is generally poor, and a central component of diabetes care and attitude towards food remains negative and inconsistent with dietary practise. Nutrition education is needed to increase dietary knowledge, attitude and practise (Sami et al., 2017).

3.2.2 Factors affecting dietary practise

Several observational studies, qualitative studies and systematic reviews pointed out several facilitators and barriers to dietary behavioural change and practise amongst people with diabetes. A focus group discussion of people with T2D in Portugal reported that family interaction entails facilitating or hindering effects with respect to practising dietary recommendations (Laranjo et al., 2015). Another study conducted in the USA involving people with T2D reported that family, healthcare professionals and peers are facilitators in dietary practise through direct support, reinforcement and knowledge provision (Chlebowy et al., 2010). A systematic review of 20 studies, which included T2D management amongst South Asian countries, demonstrated that culturally appropriate dietary education and family involvement are facilitators of dietary practise. At the same time, language discordance, lack of cultural specific diet, lack of social responsibility to endure a traditional diet and misconceptions about diet collectively act as barriers to dietary practise (Sohal et al., 2015). A recent systematic review of 14 studies involving people with T2D in Africa showed that numerous factors affect dietary pattern changes (Bekele et al., 2020). People with diabetes who participate in health education, advocacy in the community and capacity building can strengthen the practise of dietary recommendations. According to the findings of this review, Western cultural influences, poor access to healthcare, population changes and low-quality healthcare are systemic barriers to a changing dietary behaviour. Poverty, cost, perception of the disease and educational status are patient-related barriers. Lack of knowledge and diabetes education, cost and lack of access to healthcare are pointed out as the most common barriers.

In Africa, the lack of educational guidelines, scarce human resources and time limitations hinder the increase in dietary knowledge from a healthcare system aspect. Apart from these issues, habits related to cultural diet, eating style and family support in the African region make it difficult to implement lifestyle modifications (Bekele et al., 2020; Muhabuura, 2014). Dietary management is related to the food habit of the family, personal preferences and nutritional recommendations. A qualitative study in Ghana found that dislike, confusion and changing the habitual diet of people with diabetes and diversion from dietary goals by the family are barriers to dietary practise (Hushie, 2019). Most people living in SSA participate in different social gatherings, and socio-cultural norms and values related to food impede glucose control. Residents crave cultural or traditional food and consume it without considering their dietary intake (Bekele et al., 2020; Tewahido & Berhane, 2017).

The recently conducted cross-sectional studies in Eastern Ethiopia (Mohammed et al., 2020) and Northern Ethiopia (Demilew et al., 2018) identified nutrition education, family support, created awareness about diabetes diet and secondary school level education as significant facilitators of dietary practise. However, the lack of dietary education and the inability to afford food are barriers to practising dietary recommendations. Other studies conducted in

Western Ethiopia found that unemployment, lack of dietary knowledge and lack of family support are the hindering factors to practise self-care and changing the dietary behaviour (Dedefo et al., 2020; Dedefo et al., 2019; Diriba et al., 2020).

In summary, three factors facilitate dietary practise: 1) culturally specific dietary education, 2) the presence of family, peers and healthcare professional support and 3) income. Five major factors negatively affect the dietary practise and hinder dietary behavioural changes: 1) lack of dietary knowledge, 2) misconceptions about the diet through the telling of facts and discussing the existing myths, 3) lack of dietary education, 4) lack of prompt support from family members and other stakeholders and 5) healthcare system-related limitations, such as the absence of educational guidelines, lack of cultural food norm considerations and inadequate healthcare professionals. The studies recommended addressing the barriers and maintaining the facilitators to increase the dietary practise and ensure glycaemic control (Bekele et al., 2020; Tewahido & Berhane, 2017).

3.2.3 Effectiveness of dietary interventions

Dietary interventions aim to improve dietary practise and change dietary behaviours. The Academy of Nutrition and Dietetics classifies dietary interventions into three groups: nutrition education, nutrition counselling and MNT (Academy of Nutrition and Dietetics, 2006). Nutrition education is defined as the 'reinforcement of basic or essential nutrition-related knowledge'. The Encyclopaedia of Food Sciences and Nutrition defines nutrition education as 'the process of teaching the science of nutrition to an individual or group' (Caballero et al., 2003). Nutrition education aims to promote individual, family and group participation in healthy eating. An effective nutrition education makes nutrition information understandable and usable in an individual's everyday life (Caballero et al., 2003). Nutrition counselling is 'a supportive process to set priorities, establish goals, and create individualised action plans that acknowledge and foster self-care responsibility'. MNT focuses on nutrition diagnosis and therapeutic and counselling services to manage diseases (Academy of Nutrition and Dietetics, 2022). MNT is applied in clinical settings with the aim of managing the diseases. ADA recommends that the MNT for people with diabetes be included in DSMES. MNT is a cornerstone of diabetes management and DSMES (American Diabetes Association, 2020), and it can prevent or slow down the onset of diabetes complications by controlling blood glucose and other clinical parameters (Muchiri et al., 2009; Sami et al., 2017).

According to the literature, MNT produces outcomes comparable to those of oral hypoglycaemic drugs (Muchiri et al., 2009), including HbA1c reduction by 0.5% to 2% (Bekele et al., 2020). Although not significant, the nutrition education intervention for people with T2D in South Africa yielded a greater reduction of 0.63% in HbA1c compared with the control group in an RCT with only 82 participants (Muchiri et al., 2016). These findings indicate that nutrition education is the main and the most important component of diabetes management for improving diabetes outcomes in non-clinical settings. Muchiri et al. (2009) stated that nutrition education entails the active involvement of learners and comprises theory-based intervention, face-to-face delivery, interventions considered to be at the literacy level, culturally tailored dietary intervention and social support. On the basis of the results of the systematic review, Bekele et al. (2020) argued that diabetes dietary education should be culturally tailored and given in the local language.

Several other systematic reviews were conducted on nutrition education in diabetes management. The systematic review and meta-analysis of different dietary approaches produced better reductions in HbA1c, SBP and DBP (Abbasnezhad et al., 2020). The effectiveness of nutrition education interventions depends on the duration of ≥5 months, limiting the study objectives to ≤3 and applying a theory-guided appropriate study design (Murimi et al., 2017). A systematic review finding reported that reinforcing nutrition education by stakeholders, such as health professionals, is appropriate in enhancing self-care practise and improving QOL (Sami et al., 2017). The methodological limitations of the previous studies include the lack of family support, individualised goal setting and skills training (Muchiri et al., 2016). The recent systematic review and meta-analysis results of 28 studies concluded that a combination of individualised and group-based interventions was the most effective approach in improving the outcomes of HbA1c and BMI (García-Molina et al., 2020). In these included studies, few studies were conducted by nurses.

Nutrition education should be targeted to improving the outcomes of people with diabetes. This study attempts to address the pertinent parameters in the intervention. The family is expected to be involved as a supporter. Furthermore, SCT would be used to guide the study, and other self-care components would be addressed in the intervention. The plate method and the nurses who delivered the intervention were considered in demonstrating the skills of estimating a healthy portion of food. There is a need for cultural adaptation of the intervention because the finding of the recent scoping review involved studies conducted in WHO Africa region reported DSME programmes resulted to a mixed effect on the outcomes. The majority of the studies reported a statistically significant positive effects on HbA1c; however, the intervention on people with diabetes outcomes like physical activity, SMBG, medication adherence and alcohol intake was not effective (Kumah et al., 2021).

3.3 Family-based intervention

Family support is a specific type of social support in which all four components of social support (emotional, tangible, informational and companionship support) are provided (Delamater & Marrero, 2020). Family support is central in the management of diabetes to ensure the well-being of people with diabetes, enhancing their achievement with utmost satisfaction (Ahmed & Yeasmeen, 2016). Family members also play a significant role in adopting relatives with diabetes and keeping lifestyles and behaviours that are crucial for attaining the clinical and behavioural outcomes (Mayberry & Osborn, 2012). In most societies, spouses provide support related to better adherence to the regimen. A family member usually has no clear role and responsibility (Ahmed & Yeasmeen, 2016); however, the family can be involved in emotional, informational, tangible and companionship support (Delamater & Marrero, 2020). Emotional support is provided to boost feelings of self-value and worth. Tangible support is given to satisfy the financial, subsistence and material needs of people with diabetes. Informational support is given to people with diabetes to help solve their problems, and companionship support is given to increase the sense of social acceptance. Family support roles and responsibilities vary from one society to another society based on the sociodemographic characteristics and culture of the population (Delamater & Marrero, 2020). Instrumental support, which is defined as the 'observable actions that make it possible or easier for individuals to perform healthy behaviours', is as powerful and impactful as family support (Mayberry & Osborn, 2012)

The family provides appraisal for people with diabetes, and it is taken as the best strategy to manage diabetes and other chronic diseases. A meta-analysis found that perceived and received social support has a very small to moderate burden on informal caregivers, commonly the family members (del-Pino-Casado et al., 2018). Contemplating family-oriented approaches to diabetes management can ensure the highest satisfaction and provide happiness (Ahmed & Yeasmeen, 2016). However, the family members' knowledge, attitude and beliefs about DSM strongly correlate with the adherence of people with diabetes. Family members who have better knowledge recommend and enact self-care activities and interventions for people with diabetes tend to provide better outcomes, and vice versa (Bekele et al., 2020; Mayberry & Osborn, 2012). Studies reported that family support plays an equivocal effect on supportive or non-supportive behaviours. Women are more likely to discuss and support people with diabetes than men (Bekele et al., 2020). The qualitative finding from families of American Indian with T2D indicates that involving family members in the education programme requires culturally tailored education (Scarton et al., 2019).

The effectiveness of family-involved DSMES on different outcomes varies (Baig et al., 2015). Whilst most studies reported a significant effect, a few of them reported a non-significant or equivocal one. An experimental study conducted in the USA amongst Mexican Americans with T2D and their family caregivers showed a significant improvement in diet, exercise, diabetes self-efficacy and total self-management score. However, the intervention is not effective in reducing HbA1c (McEwen et al., 2017). The finding from a systematic review that included 23 studies for synthesising the effect of family support on diabetes outcomes amongst people with T2D showed positive outcomes on self-care behaviours, including improved dietary practise, self-efficacy, psychosocial well-being and perceived support, but the effect on clinical outcomes, including HbA1c, triglycerides and BMI, was inconclusive (Pamungkas et al., 2017). Another RCT study conducted in Chile reported that family interventions effectively reduced HbAc1, but the improvements in dietary behaviour, medication and physical activities were ineffective (García-Huidobro et al., 2011). A study conducted in Brazil and Thailand showed that family intervention is not effective on HbA1c and all lipid profiles (Gomes et al., 2017; Kang et al., 2010). Family engagement in the intervention enhanced supportive behaviours of the family (Kang et al., 2010), and family-based education improved the QOL of people with T2D (Ebrahimi et al., 2018). A systematic review and meta-analysis finding showed that the family-based intervention’s impact on self-management activities was equivocal, that is, it was neither supportive nor non-supportive (Vongmany et al., 2018). However, family involvement in the intervention did not change the QOL and glycaemic level (Wichit et al., 2017).

Another important component of self-management is the availability of caregiver support. Numerous studies recommended family involvement as part of the receiver during intervention to improve glycaemic outcomes, self-care behaviours and QOL. The study recommended that the roles of the family should be clearly stated in the intervention (Baig et al., 2015) and implemented in the support process, and the sociodemographic characteristics and culture of the society should be considered (Delamater & Marrero, 2020). Particularly in Africa, diabetes is increasing due to population changes (Bekele et al., 2020), and this situation needs early intervention to decrease the risk of complications, allowing caregivers to engage in the interventions. Thus, family-based and culturally tailored interventions are needed to achieve the desired goals in diabetes management.

3.4 Chapter summary

Dietary management and family-based interventions are vital for enhancing diabetes control. Nutrition education is widely accepted in providing information about healthy diet in non-clinical settings. The effectiveness of nutrition education was mixed for HbA1c, blood pressure and BMI; however, better improvements were reported in the psychological outcomes, such as self-management behaviours and QOL. Dietary management is affected by family, healthcare professionals, peers, culture, misconceptions and beliefs. Therefore, culturally specific nutrition education, debunking misconceptions about a healthy diet for diabetes and family involvement should be considered in the intervention.

Family-based intervention synergises the self-management practises of people with diabetes. Families may provide technical, emotional and economic support for people with diabetes. Family-based DSM interventions can produce a mixed effect on HbA1c, triglycerides, BMI, dietary behaviour, medication and physical activity. Studies reported family behaviour as supportive (positive), non-supportive (negative) or both. These results may be explained by the lack of diabetes knowledge and the poor definition of the family's roles in the intervention. Hence, improving diabetes knowledge and delineating family roles should be included in the intervention.

CHAPTER FOUR: THEORETICAL FRAMEWORK AND DEVELOPMENT OF THE INTERVENTION

4.1 Introduction

This chapter presents the details of the theoretical modelling and conceptual framework used to guide the intervention and its development. SCT and the results of the systematic review and meta-analysis regarding the effectiveness of self-management programmes amongst adults with diabetes in Africa, as presented in Chapter Two, were used to guide the intervention development.

This chapter is organised into seven sections. Section 4.1 introduces the chapter. Section 4.2 presents SCT, including the introduction, theoretical constructs, and rationale for using the theory. Section 4.3 presents the conceptual framework for guiding the development of the DSMES programme to be tested in a pilot RCT study. The development of the DSMES programme is presented in Section 4.4. The details of the intervention programme are presented in Section 4.5. Section 4.6 shows the matching of behavioural change strategies to SCT. Section 4.7 summarises the chapter.

4.2 SCT

4.2.1 Theoretical overview

SCT is rooted in social learning theory, which was developed in the 1960s by Albert Bandura, a psychologist from Stanford. Thereafter, in 1986, SCT was developed from social learning theory, and the book 'Social Foundations of Thought and Actions: Social Cognitive Theory' was published (Bandura, 1986). The theory considers learning to 'occur in a social context in a dynamic and continuous interaction of the environment, the cognitive and person, and behaviour' (reciprocal determinism). The personal factors, environmental influences and behavioural determinants are constructed, and a reciprocal interdependence exists amongst these three determinants (triadic reciprocality). The interaction of these factors also manifests vice versa. The double arrow in **Figure 4.1** represents the bidirectional influence of one factor on another factor.

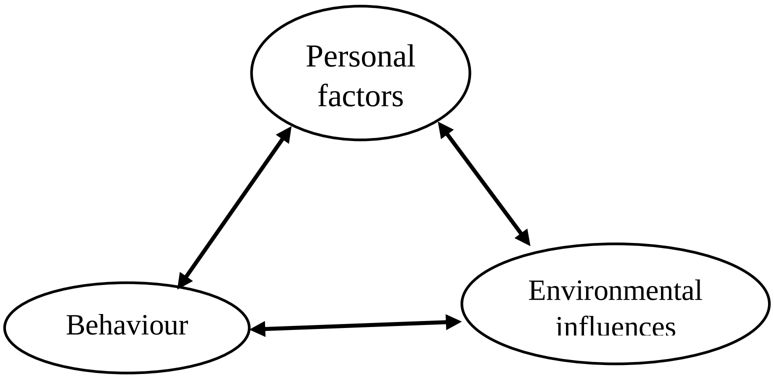

Figure 4.1 Triadic reciprocality of determinants in SCT

The unique feature of SCT is the special attention given to social effects and its internal and external social reinforcement. The theory proposes that learning occurs in a social environment. Social interaction determines the individual's capability to learn and sustain behaviour. The social effects represent any influences from a society that may affect the individual's behaviour. Internal and external reinforcements can influence the likelihood of continuing or discontinuing the behaviour, which can come from the self or its environment. With the application of SCT to diabetes management, the internal factors that can affect people with diabetes may include knowledge about diabetes and self-management interventions, misconceptions about diabetes and its management, perceived risks of diabetes, ability to learn from others and self-regulation on a sick day. The external factors may include the family influences on DSM, income of persons with diabetes, inaccessibility to healthcare facilities and external motivations, such as support from family, and awards. SCT considers the way through which individuals learn and maintain behaviour. The person's past experiences are essential for behavioural change and maintaining the change. The ultimate goal of SCT is to explain how the person regulates his or her behaviour by controlling and reinforcing one's actions to achieve a goal-directed behaviour that can be maintained over time (Bandura, 1986).

In SCT, five human capabilities are addressed as important foundations that enable individuals to acquire knowledge and skills for learning.

a. The symbolising capability, which provides the symbol for altering and adapting to the environment, is linked to the observational learning construct. The production processes of this construct deal with learning that occurs when the observer converts symbolic conceptions into appropriate actions.
b. Vicarious capability refers to learning from others through observation. It is linked to the observational learning construct, which believes that learning occurs by observing others, and learning facilitates people to expand their knowledge and skills.
c. Forethought capability refers to anticipating the likely consequences of perspective actions and setting goals to solve them. It is linked with the behavioural capability construct, which states that people acquire information from behaviour results.
d. Self-regulatory capability refers to the ability of a person to self-regulate, as motivated by internal standards and self-evaluative reactions. It is linked to the self-efficacy construct dealing with a person's confidence or generative capability that influences his or her ability to perform a behaviour.
e. Self-reflective capability is a form of self-reflection by analysing one's experiences and thought processes; in other words, it indicates the capability to reflect on oneself, and the adequacy of one's thoughts and actions is another distinctly human attribute. The four central thought processes of self-reflective capability are the cognitive, motivational, emotional and decisional processes. Furthermore, self-reflective capability is related to the self-efficacy constructs, which address the person's beliefs

and self-confidence to talk and deal with issues as a means of attaining behavioural change.

4.2.2 Theoretical constructs

SCT entails six theoretical components for explaining the learning process.

1. Reciprocal determinism can be regarded as the central concept of SCT. It refers to the dynamic and reciprocal interaction of the person, the environment and the behaviour. Moreover, reciprocal interaction refers to the mutual action between two causal factors. Behavioural, personal and environmental factors all operate interactively as determinants. The theory signifies that many factors are needed to reach the given effect. These domains are described by ‘determinism’, suggesting the production of an impact by certain factors. Three determinisms are core to this theory. i) Personal determinism refers to an individual with a set of learning experiences in the form of drive, traits and other motivational forces. Therefore, this factor is an individual-related factor that can affect the person’s learning, including cognition. ii) Environmental determinism is any factor that influences behavioural or personal factors, which can take the form of external factors (e.g. social, family or external stimuli). It also describes how environmental factors control behaviour. Apart from a person’s behavioural change, environmental influences can affect a person’s thoughts and feelings, which can be modified through modelling, tuition or social persuasion. iii) Behaviour is a response to stimuli to achieve goals (Bandura, 1986). It is the response a person acquires after they perform a behaviour, i.e. if the person conducts behaviour correctly, then he or she will learn and achieve the goals. If the goal is reached, then the person can celebrate the achievement of expected outcomes. Thus, this construct is linked with the person, environment and behaviour, and these determinants interact with each other. This construct also interacts with the behaviour capability construct via a personal

factor that depends on the actual ability of the person to implement a behaviour. The interaction between the three determinants may influence behavioural capacity.

The literature supports reciprocal determinism as a centre for learning. For example, the study used reciprocal determinism to guide drug addiction intervention and identified drug use as a critical behaviour, and all three factors would continually evolve as a functional relationship (Smith, 2021). Another review suggested that learning occurs through the continual contact of internal factors (cognitions and behaviour) and external factors (environment, social norms) (Little, 2018).

2. Behavioural capability refers to a person's actual ability to implement a behaviour through essential knowledge and skills. The person needs to know what to do and how to do it. People acquire knowledge from the consequences of their behaviour. The behavioural capacity is affected by their environment construct, and it focuses on the ability of the individual to perform to change their behaviour. The individual's knowledge and skills to perform a behaviour are essential. Essential knowledge and skills are central components for reinforcing behavioural change, increasing self-efficacy and enhancing outcomes. Behaviour is a determinant component that continuously and reciprocally interacts with the person and the environment. Hence, improved behavioural capability may influence observational learning.

3. In observational learning, people can witness and observe a behaviour conducted by other people and reproduce the observed behaviour. This component asserts that human behaviour is learnt by observation through modelling. The capacity to learn by observation facilitates people to expand their knowledge and skills based on the

obtained information and those authorised by others. This theory indicates that social learning is nurtured by observing the actual performance of others and the potential consequences. For example, learning occurs from social interaction by activating the neurons to directly learn from society in each context (Carcea & Froemke, 2019). Seeing other similar individuals perform successfully can increase self-perception of efficacy amongst the observers to maximise their capacity to perform comparative activities. The observer persuades themselves that 'if others can do it, I should achieve at least some improvements in performance'. Observational learning undergoes four processes: attention, retention, production and motivational techniques. <u>Attentional processes</u> establish what is selectively noted in the profusion of modelling inspirations and what information is extracted from ongoing modelled events. <u>Retention processes</u> are the retention of knowledge pertaining to activities that have been modelled. <u>Production processes</u> govern the organisation of constituent subskills into new response patterns, in which the observer converts symbolic conceptions into appropriate actions. <u>Motivational processes</u> determine whether the observationally acquired competencies will eventually be used (i.e. from acquisition to measurement).

Sociocultural diffusion is the construct by which society poses its traditional practise to improve QOL. Sociocultural diffusion is ensured by displacing the traditional view with new social organisations and technologies. Promulgating new ideas and practises from society eventually influence a person's behaviour. Thus, social support is necessary to enhance self-efficacy. Observational learning may influence reinforcement.

4. Reinforcements are the internal or external responses to a person's behaviour, and they affect the likelihood of continuing or discontinuing the behaviours. Reinforcements are

positive incentives that are affirmed for individuals ‘to do certain things as rewards and privileges’; if the individuals do not perform as desired, then negative sanctions and censurable conduct lead to punishment costs. This negative sanction may involve the withdrawal of rewarding events (Bandura, 1986). Reinforcements may influence the interaction between a person, environment and behaviour. For example, if a person obtains positive reinforcement, then he or she may have better self-efficacy. Hence, the behavioural change is solely influenced by the reinforcements.

Reinforcement is essential in facilitating learning. For example, a systematic review of studies of theoretical intervention frameworks identified that self-incentives and rewards are essential to facilitate and maintain one’s behaviour. A person can set a self-administered reward for achieving improvement or attaining goals, whereas external rewards can take the form of rewards for achieving progress or reaching goals (Tougas et al., 2015).

5. Outcome expectations are the consequences of an act, and they are usually set based on a set of criteria. Expected outcomes can take the form of health-related or not health-related outcomes. Most outcomes arise from actions and depend on a judgment of how well a person will be able to perform in each situation. Before engaging in any behaviour, people anticipate the consequence of their actions, which can influence the successful completion. The outcome expectations may be influenced by personal, environmental and behavioural factors. The outcome construct may be associated with all of the other constructs. The capacity to change a behaviour, the willingness to learn via observation, the motivation to change a behaviour and the confidence to change a

behaviour are the influences of the outcomes. Low levels of these constructs may result in negative outcomes or vice versa.

6. Self-efficacy, a core concept of SCT, is the level of a person's confidence or generative capability in which cognitive, social and behavioural subskills are organised into integrated courses of action when performing a behaviour. It is influenced by the individual's specific capabilities and environmental factors, including facilitators and barriers. Verbal persuasion is one of the widely used techniques to encourage people to perform actions and allow them to 'achieve what they seek' (Bandura, 1986). Self-efficacy is an important component of a person's capacity, affects responses to the environment and changes one's behaviour. Thus, self-efficacy may influence the outcomes via the willingness to learn.

This SCT pronounces learning as a reciprocal interaction amongst the cognitive, behavioural and environmental factors (reciprocal determinism). The application of SCT to diabetes management focuses on the environment around people with diabetes, cognition and other factors. In diabetes education, the elements of reinforcement, behavioural capacity and self-efficacy are commonly addressed (Muchiri et al., 2009). A meta-analysis in health-related intention and behaviour reported that self-efficacy-guided interventions can effectively promote a behavioural change (Sheeran et al., 2016).

Rationale for using SCT

Behaviour modification is an intricate process; thus, a theory is needed to guide the development of an interventional programme for behavioural change (Muchiri et al., 2009). The health belief model, SCT, trans-theoretical model, and theory of planned behaviour are commonly used theories to guide interventions for changing the self-care behaviours of people with diabetes. The theory most commonly used to design and employ DSMES interventions is SCT, in which most of the studies reported effective intervention (Murimi et al., 2017).

SCT was used to guide the intervention development and implement the DSMES programme for three main reasons.

1. The aim of the study was to change the self-management behaviours. SCT is appropriate for addressing behavioural changes and promoting health (Bandura, 1986, 1998). The theory addresses personal and environmental factors, models of learning and reinforcements, and it considers the learners' self-efficacy. The expected outcomes are also indicated as one of the theoretical constructs. Other behavioural theories may offer a best fit for the perception and intention to learn, but these aspects are not solely the concern of this study.
2. The theoretical constructs are a better fit with the intended behavioural change. SCT addresses both personal and environmental factors, and it also includes the incentives and capabilities of the person.
3. SCT addresses the issue of social impacts, asserting that behaviour is the product of the interaction between environmental influences and personal factors. In this study, family support is the active component of the intervention.

4.3 Conceptual framework of the pilot RCT

The DSMES programme was adapted as an intervention in the study. The intervention could further modify the two factors of SCT considered to be relevant to people with diabetes living in Western Ethiopia. (i) Personal factor – This aspect pertains to the diabetes-related knowledge of people with diabetes. Besides the elements of common self-management interventions, the intervention emphasises the nutritional knowledge specific to Western Ethiopia. (ii) Environmental factor – This aspect pertains to the support from family for providing suitable food and other support to people with diabetes. As depicted in **Figure 4.2**, the DSMES programme may directly influence the reciprocal determinism of personal factors, environmental determinants and behaviour. The intervention focuses on the persons' knowledge about diabetes, seven self-care behaviours, misconceptions about diabetes and diabetes complications. Focus is given to the cultural food and estimation of the recommended amount. The intervention also focuses on the environmental factor of family support with respect to food planning, purchase, preparation, intake and other self-care activities to be delivered to persons with diabetes. The behaviour includes identifying culturally specific food and its recommendations, attention to food portion estimation, physical activity, SMBG, foot care and medication. Furthermore, healthy coping, problem-solving skills, understanding of diabetes complications and management were included in the behavioural factors of people with diabetes. The family caregiver's supportive behaviour is another aspect of the behaviour.

The three SCT factors (person, environment, and behaviour) continuously interact with each other. Personal factors may influence the environmental determinants and behaviour, and the environmental factors may influence behaviour and vice versa. The influence and interactions amongst the three factors can improve the physiologic and behavioural outcomes of people with diabetes and the family caregiver's supportive behaviour. The expected outcomes include the physiological outcomes of people with diabetes, such as improved HbA1c, BP, BMI and lipid profiles. The behavioural outcomes entail self-management behaviour (diet, blood glucose testing and foot care), DQOL, improved QOL and perceived social support. The family caregiver's behaviour includes supportive behaviour. The changes in personal factors and environmental determinants are expected to improve the behaviours of people with diabetes and those of the family caregivers.

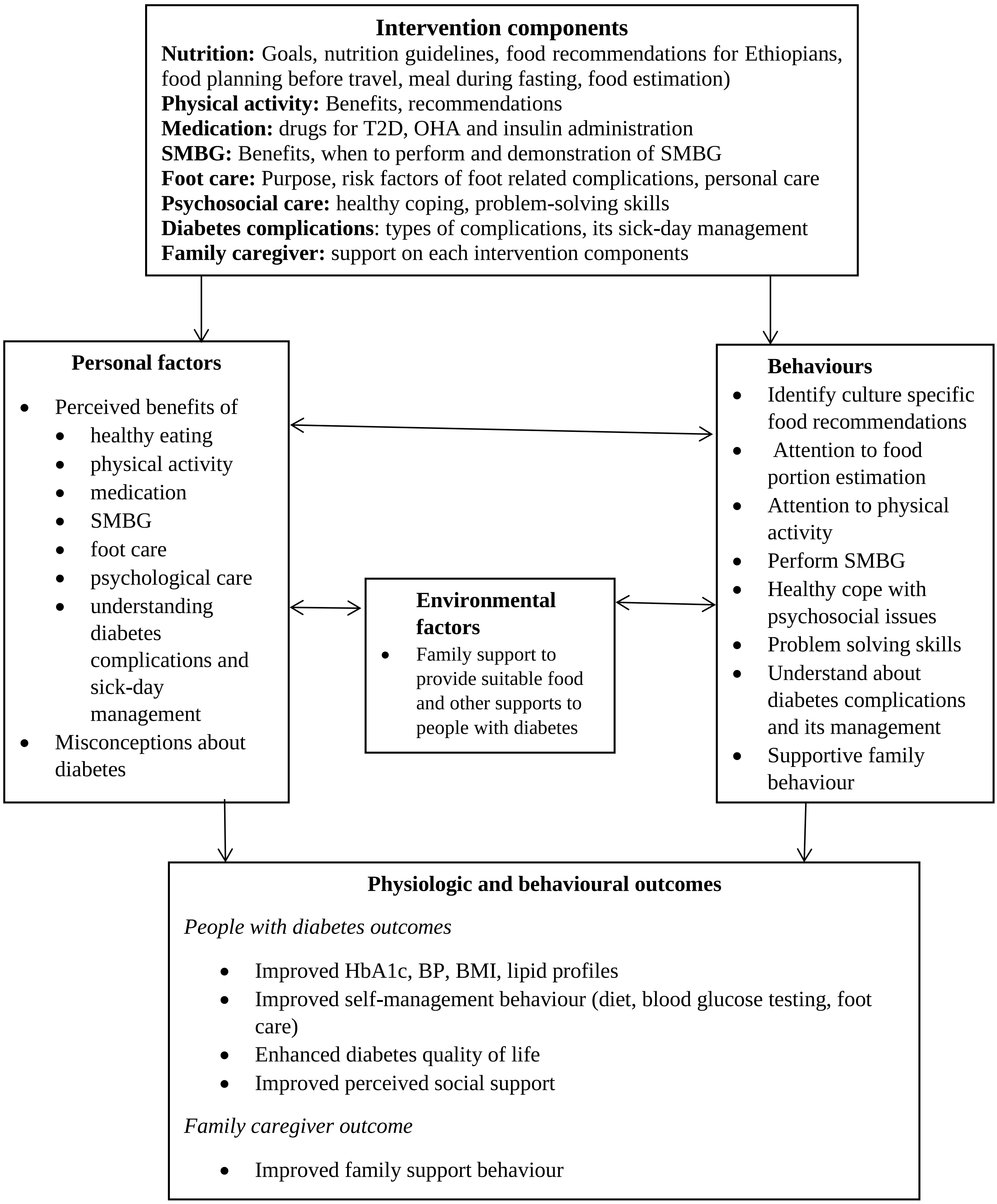

Figure 4.2 A conceptual framework to guide the intervention by using SCT

4.4 Development of the intervention programme

The intervention was a DSMES programme targeting people with diabetes and their family caregivers. The goal of the intervention was to enhance the self-care behaviours, clinical outcomes and QOL of people with T2D in Ethiopia through the DSMES education and home-based family caregiver's support. SCT and the systematic review and meta-analysis results pertaining to the effectiveness of self-management programmes amongst adults with diabetes in Africa (Chapter Two) were used to guide the intervention development. On the basis of the conceptual framework, the contents of the intervention were developed from three sources: i) a diabetes education training manual for SSA (International Diabetes Association Africa region, 2006), ii) lifestyle recommendations extracted from the ADA standards of medical care in diabetes (American Diabetes Association, 2020) and iii) an educational video produced on foods and drinks for Ethiopians and Eritreans with diabetes (Mei Yook Woo, 2020). Two videos regarding self-insulin injection and foot care were produced (Hinkle, 2018). The intervention materials were prepared in three forms: i) educational handbook, ii) videos and iii) flyers.

The DSMES programme intervention comprised two basic activities for supporting the self-management of people with diabetes in Western Ethiopia: 1) education and 2) support. On the basis of the systematic review and meta-analysis conducted to identify effective DSM interventions (Diriba et al., 2021b), all components of the DSM education were included in the DSMES programme. In addition, the engagement of family members and the delivery of the intervention in the community setting (Paz-Pacheco et al., 2017) were also recommended for improving the clinical outcomes. Family caregivers were involved in the intervention because previous studies suggested that family involvement positively improves the diabetes outcomes and even modified certain behaviours (Delamater & Marrero, 2020; Khosravizade Tabasi et al., 2014; La Greca & Bearman, 2002; McEwen et al., 2017). As presented in Chapter One, diabetes-specific constraints in Ethiopia include food-, misconception-, family-and healthcare system-related challenges. The DSMES programme was specifically designed to enhance the nutritional knowledge of cultural foods, ensure psychological care and improve family support, and it was conducted in the community setting.

The DSMES programme covered four content areas: (i) a brief introduction to diabetes, (ii) misconceptions about diabetes in Ethiopia, (iii) seven self-care behaviours (i.e. healthy eating, physical activity, self-blood glucose monitoring, medication usage, preventing and treating diabetes complications, healthy coping and problem-solving skills) and (iv) foot care over six sessions, with each session covering two hours (**Table 4.1**). The term 'nutrition education' was used to present education with respect to the utilisation of healthy eating. More attention was given to nutrition education, which is a vital component of DSM (Powers, Bardsley, & Cypress, 2015). Nutrition education can hinder or delay diabetes complications (Muchiri et al., 2009; Yancy Jr et al., 2014). Thus, nutrition education was provided based on the eating culture of Western Ethiopia. The local food and its preparation were considered to address the food-related misconceptions. The food portions were demonstrated via the plate model. The plate method is a helpful meal planning tool for healthy eating, and it gives a formula for promoting the consumption of more nutritious food and fewer unhealthy foods (American Diabetes Association, 2015). This approach is encouraged to be used for low-literate people with diabetes (McGuigan, 2010). Family caregivers participated in all sessions and received the DSMES programme. In addition to the DSMES programme, family caregivers received a separate brief orientation on their roles in supporting the self-management of people with diabetes.

4.5 Details of the intervention

Each of the two-hour six sessions of the DSEMS programme has two parts. In Part 1, people with diabetes and their family caregivers received an educational DSMES intervention in the first 1 hour and 40 minutes. In Part 2, the last 20 minutes were delivered to family caregivers only to orient their specific roles on home-based support to their relatives with diabetes.

4.5.1 Content development

Part 1: Intervention for people with diabetes–family caregiver dyads

Three teaching materials were produced to deliver the intervention: 1) an educational handbook, 2) videos and 3) flyers in the local language (Afaan Oromoo). **Table 4.1** presents the details of the educational handbook, including the contents, schedule of delivery and activities in each session. The intervention materials were developed by considering the participants' culture and were delivered in Afaan Oromoo.

1) Educational handbook: An educational handbook with the following DSMES contents:

   a) A brief introduction about diabetes and its management, including the definition, diagnostic criteria overview, risk factors, prevalence and management approaches, was addressed.

   b) Common diabetes-related myths and misconceptions in Ethiopia: The available myths and misconceptions include considering diabetes as a communicable disease, taking honey on an empty stomach to cure diabetes, drinking whiskey to cure diabetes and lower blood sugar, drinking urine to cure diabetes, eating bitter foodstuff, such as the bile of sheep and cows, and taking holy water on an empty stomach to cure diabetes were addressed in the intervention. The scientifically available evidence on these misconceptions was included, and the activities to reduce these myths and misconceptions were discussed.

c) The seven content areas of self-care behaviours (American Association of Diabetes Educators, 2008) included the following:

- Healthy eating is the consumption of medically recommended food on a recommended daily allowance for people with diabetes. Nutritional education included the general nutrition guidelines for diabetes, nutrition recommendation for Ethiopia and nutrient sources, including glycaemic index. In addition, the food estimation techniques, including the plate method, were included. For example, teff is a whole grain and staple food in Ethiopia. Choosing injera made with 100% teff is healthier because it has higher nutrients, but it will increase blood glucose. A half of injera is an appropriate portion for one meal, but full injera is excessive. Full injera is appropriate if the source of carbohydrates is a single injera. When a person makes ‘fitfit’ or ‘firfir’, half of injera should be used. The appropriate portion of ‘firfir’ or ‘fitfit’ is one cup (the size of a fist). Moreover, cultural foods, such as ‘cumbo’, ‘ancootee’, ‘miccirraa’, ‘ukkamsaa’ and ‘caccabsaa’ are usually consumed. These cultural foods are prepared with high butter, thus increasing the risk of metabolic syndromes like diabetes, hypertension and hyperlipidaemia. Hence, limiting the butter content should be practised. The foods are prepared from carbohydrate-rich foods, Ijera and bread; thus, a half cup for ‘miccirraa’, ‘ancootee’ and ‘caccabsaa’, and one-fourth of the whole ‘cumbo’ and ‘ukkamsaa’ are a healthy amount.
- Physical activity included the benefits of physical activity, recommendations of physical activity for people with diabetes and necessary cautions and how to use local facilities for physical activities.
- Self-blood glucose monitoring included the benefits and time to check blood glucose.

- Medication usage includes the drugs used to treat diabetes, self-medication of drugs (OHA and insulin) and the benefits of medication adherence. A video supporting the self-insulin injection was shown in the intervention session.
- Prevention and treatment of diabetes complications included an overview of acute and chronic complications of diabetes, prevention and actions to be taken when complications occur.
- Healthy coping included the sources of psychological issues and coping strategies specific to diabetes and the generic techniques, such as exercise, relaxation exercise, meditation, distraction and refraining from stressful factors.
  - Problem-solving skills included the problem-solving of persons with diabetes and the roles of families and society with respect to problem solving.

d) Foot care included the benefits of foot care, risk factors for foot ulcers and amputation in diabetes, activities in foot care and a guide on when to perform foot care. Another video on foot care supported the interactive lecture on this topic.

The educational handbook was first developed in English because most of the reference materials from the three main sources were published in English, including i) a diabetes education training manual for SSA (International Diabetes Association Africa region, 2006), ii) lifestyle recommendations from ADA standards of medical care in diabetes (American Diabetes Association, 2020) and iii) an educational video named 'How Foods Affect Blood Sugar: A Guide for Ethiopian & Eritrean with Diabetes' (in Oromo) pertaining to foods and drinks for Ethiopian and Eritrean people with diabetes, which was developed by the Department of Nutrition Science, School of Public Health, University of Washington (Mei Yook Woo, 2020); accessed from https://www.youtube.com/watch?v = XJsln4GRojQ&feature

= youtu.be). The permission to reproduce materials using the abovementioned three sources for the educational handbook was obtained from the authors/producers.

Culturally specific nutritional knowledge

The educational video on food and drinks for Ethiopian and Eritrean with diabetes, which was published by the University of Washington, was subsequently produced according to the culture of Ethiopia and was made available in the Afaan Oromoo language. The material was initially developed to teach Ethiopians and Eritreans living in the USA about food intake. This video covers the recommended amounts of foods, particularly food recommendations, during fasting time. Most people living in Ethiopia perform religious fasting that lasts at least two months a year. Hence, fasting time should be considered by people with diabetes. The contents of the educational video were transcribed. However, the education material only considers the food available in the USA but not all traditional foods and drinks in Ethiopia. Thus, the culturally specific food menu in Western Ethiopia was incorporated into the nutrition education content in the educational handbook in this doctoral study.

As cultural foods vary from one area to another, culturally dietary preferences must be integrated into nutrition education (Muchiri et al., 2009). The cultural component of foods and drinks amongst the Wollega Oromoo society (people widely reside in the western area) was addressed in the DSMES intervention. Focus was given on food sources with high sugar content and the recommended healthy portion of the foods and drinks. Furthermore, the effect of local traditional foods and drinks on blood glucose was addressed. Previous studies suggested that education should be delivered in a simple manner, in the local language and with colourful illustrations, with the aim of improving behavioural change (Dube et al., 2015; Muchiri et al., 2009). Thus, the handbook was prepared in Afaan Oromoo, and colourful images were used in the handbook. Fewer words were included in the slide presentation.

Diabetes-related misconceptions

Misconception as ‘a conclusion that is a wrong or inaccurate conception’ (Merriam-Webster, 1828). Diabetes is a communicable disease. Taking honey on an empty stomach to cure diabetes, drinking whiskey to cure diabetes and lower blood sugar, drinking urine to cure diabetes, eating bitter foodstuff, such as the bile of sheep and cows, and taking holy water on an empty stomach to cure diabetes are diabetes-related myths and misconceptions in Ethiopia (International Diabetes Association Africa region, 2006). These misconceptions should be debunked based on available evidence. Thus, discussions and explanations were broadly addressed in the intervention. For example, Ethiopian people have the misconception that taking honey on an empty stomach can cure diabetes, but studies demonstrated the inconclusive effect of honey. Some studies also reported that honey decreases glucose (Ramli et al., 2018), whilst another study reported honey as a novel oral hypoglycaemic agent (Bobiş et al., 2018). The studies did not indicate a clear strategy for the hypoglycaemic effect, and some of them even indicated that honey can increase insulin and enhance glucose uptake (Bobiş et al., 2018). Contrarily, a recent systematic review of the RCT studies concluded that consuming a high amount of honey increases the glucose level and should not be practised as a cure for diabetes (Akhbari et al., 2021). None of the studies concluded the curative effect of honey.

Foot care

Foot care is an essential component in diabetes care because diabetes is related to foot ulcers and amputation. Foot ulcers and amputation are caused by diabetic neuropathy and peripheral arterial disease, which is a common complication of diabetes. Early and appropriate foot care can reduce the risk of foot ulcers and amputation. Although the risk of foot ulcers and amputation is high due to foot deformities, peripheral arterial disease, poor glycaemic control, history of foot ulcers and peripheral neuropathy, it is preventable. Hence, ADA recommends performing comprehensive foot care at least once a year to identify the risk factors and inspect the condition of feet (American Diabetes Association, 2020).

Therefore, in this intervention, the rationale for foot care and the risk assessment for foot ulcer and amputation were introduced to the dyads. Knowledge of food care is needed for people with diabetes to practise appropriate foot care. In the intervention, people with diabetes obtained tips and skills to perform foot care. Interestingly, supportive family behaviour with respect to foot care is common in Ethiopia. For example, the children, spouse and other family members provide foot-washing facilities, wash legs and dry feet and provide appropriate shoes for people with diabetes. Hence, the family caregivers were introduced to the process of how to sustainably care for people with diabetes.

Diabetes-related complications

Diabetes-related complications can be classified into microvascular and macrovascular complications, which can cause morbidity and mortality (American Diabetes Association, 2020). Thus, knowing these complications and what to do on a sick day is necessary. In the intervention, the types, common clinical manifestations and sick-day management were introduced. The family caregivers were also advised on what they should do if a person with the disease experiences the manifestations.

2) **Video:** With the support from Wollega University, two videos on the self-injection of insulin and foot care were produced in Afaan Oromoo to enhance the learning during intervention. In the video on self-injection of insulin, a self-insulin injection is a self-administration of insulin into the subcutaneous tissue using special insulin syringes. The doll for injection, the insulin needle and the insulin were used to demonstrate the self-injection in the video. The video explained the equipment, type of insulin, storing, dosage of administration, syringes for injection and the technique of mixing insulin, if necessary.

The video on foot care showed how foot care can be performed on persons with diabetes. Ten-foot care tips adapted from the Medical-Surgical Nursing 14th Ed. textbook (Patient Education Chart 51-10) (Hinkle, 2018) and the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDKD, 2017) were considered. The foot care tips included taking care of one's diabetes, daily inspection and washing of feet, keeping the skin soft and smooth and gently smoothing corns and calluses. Moreover, trimming toenails each week or when needed, always wearing shoes and socks, protecting feet from hot and cold surfaces, keeping the blood flowing to your feet and checking the status of feet with the help of a primary caregiver were included.

3) **Flyers:** The flyers, which contained other essential tips on signs and symptoms of hyperglycaemia, the glycaemic index of common foods in Western Ethiopia, the side effects of metformin, common tips for foot care and sick-day management were distributed every session. The contents were taken from other literature (Atkinson et al., 2008; Hinkle, 2018; IDF African Region Task Force, 2006) and translated into Afaan Oromoo.

Part 2: Intervention to the family caregivers

Although previous studies showed the potential effect of involving family members in diabetes management (Pesantes et al., 2018; Withidpanyawong et al., 2019), previous results of the systematic review and meta-analysis of people with diabetes in Africa found that none of the studies included a family component in their intervention (Diriba et al., 2021b). In addition, given the important role of family cohesion and food preparation amongst Ethiopian families, this pilot RCT engaged one primary family caregiver to support their relative with diabetes in the study. The primary family caregiver, usually the spouse, nominated by people with diabetes, was recruited to participate in the intervention. A primary family caregiver is 'any relative, partner, friend, or neighbour who has a significant personal relationship with and provides a broad range of assistance for an older person or an adult with a chronic or disabling condition' (Family Caregiver Alliance).

The family caregivers attended the DSMES sessions (i.e. Part 1 of the intervention) together with the people with diabetes to obtain the necessary knowledge and skills about diabetes and its self-management. In Part 2 of the intervention, the support to family caregivers focused on the facilitation and encouragement of their relatives with diabetes on the change in self-management behaviours and providing decision support. In each session, the role of the family caregiver in supporting their relatives in performing self-management behaviours was discussed (**Table 4.1**). The family members were told to continue to support their relatives after completing the six sessions of the intervention.

Table 4.1 DSMES programme topics, contents and activities and delivery schedule for dyads

Week and session	Topic	Content and activities

1	Brief introduction about diabetes mellitus
	
	Diabetes-related misconceptions in Ethiopia
		The joint session for people with diabetes and family caregivers
		• Interactive lecture
		  ○ Definition, diagnosis criteria, classification, pathophysiology, and clinical features of diabetes
		  ○ Risk factors of T2D
		  ○ Prevalence of diabetes in Ethiopia
		  ○ Management of diabetes
		Activity: Group discussion on symptoms of diabetes and diagnostic criteria
		• Interactive lecture
		  ○ State common misconceptions related to diabetes
		  ○ Facts about misconceptions
		• Activities
		  ○ Experience sharing about the misconceptions held by people with diabetes and family members
		  ○ Group discussion on how to reduce or avoid such misconceptions
		• Goal setting
		  ○ Set goals and strategies for increasing awareness about misconceptions
		Role of the family caregiver
		• Hold an informal discussion with another family member on awareness creation on diabetes clinical features and misconceptions (information support)

2	Nutrition education	**The joint session for people with diabetes and family caregivers**
		• Interactive lecture
		  ○ Goals of nutrition therapy
		  ○ General nutrition guidelines for diabetes
		  ○ Nutrition recommendations for Ethiopia (focusing on the western part)
		  ○ Nutrient sources of foods (the foods that raise sugar levels and those that do not)
		• Activities
		  ○ Experience sharing of dietary habits and meal planning
		  ○ Group discussion on the food sources of sugar
		• Goal setting
		  ○ Set meal plan for the coming week
		Roles of the family caregiver
		  ▪ Support people with diabetes in the selection of healthy food

		▪ Purchase a healthy diet ▪ Cook the food
3	Nutrition education (continued)	**The joint session for people with diabetes and family caregivers** • Interactive lecture o Estimating food portions (using plate model) o Traditional food and drink intake (focusing on the Western Ethiopian culture) o Recommended drinks o Food planning tips before travelling o Meals during periods of fasting (Christian and Muslim fasting) *fasting in the Ethiopian context means going without meat or eggs or butter for Orthodox Christians (i.e. vegetarian +/- fish) rather than not eating. This is on certain days of the week and periods of the year, for example before Easter, and for Muslims, they do not eat for a half day, on the daytime like in Ramadan). • Activities o Experience sharing in estimating food portions o Group discussion on food intake whilst fasting • Goal setting o Meal planning and portion estimation for the coming week **Roles of the family caregiver** • Support people with diabetes by estimating healthy meal portion • Discuss with other family members a healthy portion of food • Promote people with diabetes to take a healthy portion of drinks, including alcohol
4	Physical activity and medication	**The joint session for people with diabetes and family caregivers** • Interactive lecture o Benefits of physical activity o Recommendations of physical activity for diabetes o Cautions on physical activity o How to use local facilities for physical activity • Activity o Experience sharing concerning the physical activity • Goal setting o Set goal to perform physical activity • Interactive lecture o Medication o Intake of oral hypoglycaemic agents o Insulin injection techniques (video watch) o Benefits of medication adherence • Activity

		○ Experience sharing on self-medication practise and strategies for medication adherence • Goal setting ○ Set goals to increase medication adherence and self-injection **Roles of family caregivers** • Encourage people with diabetes to perform physical activity for 30 minutes/day for at least five days/week • Walk with people with diabetes for at least 30 minutes two days/a week • Remind people with diabetes to receive medication
5	SMBG and foot care	**The joint session for people with diabetes and family caregivers** • Interactive lecture ○ Benefits of SMBG ○ When to check blood glucose ○ How SMBG improves diabetes outcomes ○ Benefits of foot care ○ Risk factors for foot ulcer and amputation in diabetes ○ What and when to perform foot care ○ Personal care in foot care (Video watch) • Activity ○ Experience sharing on SMBG and foot care • Goal setting ○ Set goals to monitor blood glucose and perform foot care for one week **Roles of family caregivers** • Assist blood glucose testing • Help people with diabetes decide if the change has been made on the blood level. • Encourage people with diabetes to record their blood test results • Support people with diabetes in choosing shoes • Assist in performing personal foot care
6	Coping with psychosocial issues and problem-solving skills Diabetes complications and sick-day management	**The joint session for people with diabetes and family caregivers** • Interactive lecture ○ Sources of psychosocial issues and their features ○ Effective coping strategies ○ Problem-solving skills • Activity ○ Experience sharing on psychosocial issues encountered and coping strategies used ○ Group discussion on steps of problem-solving skills ○ Testimonies from the success story • Goal setting ○ Take one coping strategy and set an action plan • Overview of diabetes complications

		○ Acute and chronic complications ○ Why complications develop ○ Sick-day management • Activities ○ Experience sharing on the sick-day management ○ Group discussion on strategies to reduce complications • Goal setting ○ Set a goal to prevent complications and take action if complications develop **Roles of family caregivers** • Provide emotional support • Assist in the implementation of relaxation techniques • Establish survival skills and develop an action plan with all family members. • Congratulate people with diabetes for sticking to diabetes self-care activities • Establish companionship with people with diabetes • Assist in the sick-day management • Encourage to seek medical care if a complication happens Conclusion of all sessions

4.5.2 Validation of intervention materials

1) Educational handbook

The content validity of the DSMES educational handbook, an intervention protocol, was assessed by four experts in the subject area and four people with diabetes in two stages. In Stage One, the English version of the educational handbook was evaluated by a panel of four subject area experts who are Ethiopians and understand the culture of Western Ethiopia. The team was composed of one nutritionist, one physician with an internal medicine specialty (internist), one nurse experienced in diabetes care and one experienced clinical pharmacist. Using a four-point Likert scale, the experts evaluated the handbook against the content's relevance, appropriateness and feasibility. The experts rated the relevance of the content ('not relevant' to 'very relevant'), appropriateness ('not appropriate' to 'very appropriate') and feasibility ('not feasible' to 'very feasible') (Appendix II). Then, the experts independently scored and summarised their comments. The topic-level content validity index (CVI) was computed for relevance, appropriateness and feasibility. The CVI score of the educational handbook was 1.0, indicating the relevance, appropriateness and feasibility of the content (Rodrigues et al., 2017; Shi et al., 2012). The experts' comments were to 1) address more content in a culturally acceptable manner and 2) add more pictures. After their comments were addressed, the handbook was sent to the experts for further evaluation, and they subsequently approved it for future use.

Then, the validated English version of the educational handbook was translated into Afaan Oromoo. In Stage Two, four people with diabetes were asked to evaluate the Afaan Oromoo version of the educational handbook via a group discussion by focusing on the interpretation of the contents, relevance of the contents and clarity of the words and by providing comments that may need revision. They commented on changing some words; hence, the terms were changed. At this time, it was inconvenient to include the family caregivers in the discussion because of COVID-19 restrictions. Subsequently, a PhD holder in Afaan Oromoo edited the educational handbook, and the version was finally used for the intervention.

2) Videos

A physician working in the diabetes centre of the participating hospital and another internist validated the contents of the two videos. The video content was adapted from textbooks. Only one comment reflected the missed explanation of the procedure step about self-insulin injection. Therefore, the video was re-recorded, including the missed procedure step used for the intervention.

3) Flyers

The contents of the flyers were not validated, as they were merely used to support the learning and boost participants' motivation to join the intervention sessions.

4.5.3 Format

The intervention was delivered in a group. Although the SMS-supported face-to-face delivery mode favoured the diabetes outcomes improvements in the systematic review and meta-analysis on Africans with diabetes (Diriba et al., 2021b), this delivery mode was not adopted in this pilot RCT study. SMS could be delivered by mobile phones, but smart mobile phone coverage is limited in Ethiopia, which was only 11.2% in 2018 (Wikipedia, 2019). In addition, the elderly participants may not be able to read the message due to low literacy levels, which is common in Ethiopia (51.8% in 2017) (Macrotrends, 2017). Hence, the face-to-face delivery format was adopted in this pilot study because it was deemed to be more appropriate. Therefore, the nurses delivered the intervention through face-to-face sessions.

4.5.4 Intervention setting

As most of the interventions of the included studies in the systematic review and meta-analysis involving people with diabetes in Africa (Diriba et al., 2021b) were delivered in health institutions, the non-significant results may be explained by the limited resources of people with diabetes in Africa to adequate diabetes management and their difficulties in continuing their DSM education in hospitals accommodating low-income populations (Fraser et al., 2006). Low income reduces access to transport, and socioeconomic status impedes access to continuous quality care (Glazier et al., 2006; Lu et al., 2018). Previous studies showed that people with diabetes in Africa had difficulty in continuing diabetes education and diabetes care in healthcare facilities due to their inability to afford transport (Atun et al., 2017). Community-based DSM education should be a good alternative because it could result in better glycaemic outcomes in rural settings where access to hospitals is a challenge (Paz-Pacheco et al., 2017). It has been recommended that community-based management of diabetes should be scaled up in SSA (Atun et al., 2017). Thus, the community-based intervention was adopted in this pilot RCT. Temporary intervention centres were formed for intervention delivery in the community (see Section 6.8 in Chapter Six). After the dyads received the DSEMS programme intervention in the community, the participating family members were expected to provide home-based support and encourage people with diabetes to have a healthy diet, perform physical activity, encourage people with diabetes to undergo self-medication and foot care and identify diabetes-related complications.

4.5.5 Intervention dosage

The result of the systematic review and meta-analysis in Chapter Two reported that the length of intervention delivered for ≤6 months resulted in a better reduction in HbA1c (Diriba et al., 2021b). Another systematic review of DSMES interventions amongst Latino adults with T2D and a multisession diabetes education programme targeting low-income minority people with diabetes also showed that intervention with a length of fewer than six months was effective in improving glycaemic control and their readiness to improve dietary behaviours (Hildebrand et al., 2020; Ryan et al., 2013). These findings suggest that DSMES interventions less than 6 months may effectively improve diabetic outcomes in low-income countries. According to the subgroup analysis in the systematic review and meta-analysis presented in Chapter Two (Diriba et al., 2021b), the difference was not significant between providing interventions for ≥10 and <10 hours. Other systematic review and meta-analysis studies attempted to deliver culturally adapted and family model-based DSMES for people with T2D, and they showed that an intervention for ≥10 hours could lead to significant and better reductions in HbA1c (Chrvala et al., 2016; Cunningham et al., 2018; McElfish et al., 2019). The results from these previous systematic reviews and studies suggest that intervention given for 10 hours or more may be more effective in improving HbA1c. Hence, in consideration of the topics to be covered in the intervention and the findings from previous studies, the length of the DSMES programme of 12 hours was adopted for the current pilot RCT.

4.6 Matching to SCT: Behavioural change strategies

Behaviour is the response to stimuli/factors (personal or environmental) to achieve expected outcomes. Diabetes self-care behaviours, including a healthy diet, physical activity, SMBG, medication, reducing complications, healthy coping and problem-solving, are core elements of diabetes management (Powers, Bardsley, & Cypress, 2015). The positive change in these behaviours may improve the clinical outcomes (HbA1c, BP, BMI and lipid profiles), diabetes self-care behaviours (diet, physical activity, SMBG, medication and foot care) and DQOL and improve family supportive behaviour. Various behavioural change strategies were implemented to change the behaviour of the dyads. **Table 4.2** presents the behavioural change strategies, the SCT constructs addressed and the related learning activities in the DSMES programme. Goal setting is widely recommended in interventional studies related to DSM (Locke & Latham, 2002), and it is even an effective strategy for ensuring behavioural change (Fredrix et al., 2018; O'Donnell et al., 2018). Thus, goal setting, experience sharing and group discussions were implemented in each session because learning occurs when the person develops and achieves a goal. Furthermore, goal setting encourages individuals to perform and achieve the goal in their daily life. The sharing of experiences by other individuals, focusing on their diabetes and taking part in group discussions on the raised points, enable the affected persons to learn. Moreover, verbal appraisal was implemented in each session, and appraisal feedback was shown to increase participation and change their behaviour. The plate method was implemented via a nutrition education session, demonstration in SMBG and medication and foot care video sessions. The SCT supports the pursuit of symbolising enhancing and sustaining behaviour. Healthy coping and problem-solving skills were also implemented. The coping mechanisms and problem-solving skills may reduce the anticipated risks of the behaviour. The plate method, demonstration and videos were linked to the symbolising capability and observation learning construct. The experience sharing and group discussion were related to vicarious capacity and observational learning construct. Motivators, such as verbal persuasion and rewards for best performers, were linked to the self-regulatory ability and reinforcement construct. Goal setting, healthy coping and problem-solving skills were related to forethought capacity and behavioural capability. The family support technique was implemented in each session, and it was related to self-efficacy and reciprocal determinism.

Table 4.2 Behavioural change strategies and SCT constructs addressed in the DSMES programme

Behavioural change techniques	SCT construct addressed	Learning activities
Goal setting and developing an action plan	Self-efficacy	• Participants shared their experiences of performing self-care behaviours in all sessions • Set the goal and action plan to achieve the goal • The goal was set by dyads together and was facilitated by intervention facilitators • The action plan was developed for a week and implemented in the corresponding week
Verbal persuasion and awarding glucometer	Reinforcement	• The verbal appraisal was given after the dyads presented their achievements at the recap session • Awarded to best performers to sustain their behaviour
Using the plate model	Observational learning	• A plate model was used to visualise the meal portions
Group discussion and experience sharing	Observational learning	• Group discussion and experience sharing on managing diabetes were discussed in all sessions • Participants were asked about the lessons they had learnt
Healthy coping and problem-solving skills	Behavioural capability	• Healthy coping and problem-solving strategies to overcome diabetes-related challenges were delivered • Testimonies from the success stories were shared
Provide family support	Self-efficacy Reciprocal determinism	• The family was involved in all sessions of the DSMES • The family provided home-based support • The roles of the family were communicated and evaluated by educators
Video display and demonstration of skills to encourage mastery in learning	Observational learning	• An educational video was displayed at the end of every session to demonstrate the desired skills, such as foot care and self-injection of insulin • Demonstration of meal estimation (portion estimation)

4.7 Chapter summary

The SCT and results of the systematic review and meta-analysis pertaining to the effectiveness of self-management programmes amongst adults with diabetes in Africa were used to guide the intervention development. Previous studies guided by SCT showed promising effects on the outcomes. SCT focuses on personal, environmental and behavioural factors. Reciprocal determinism, behavioural capacity, observational learning, reinforcements, outcomes expectations and self-efficacy comprise the key constructs of the theory. Goal setting, modelling (via videos and demonstration), verbal persuasion, experience sharing and group discussions, aimed to enhance behavioural change, were implemented in the entire session. Different international guidelines and pertinent videos and textbooks were used to develop the intervention materials. A 12-hour DSMES programme divided into six sessions was delivered to the group in a face-to-face manner. The intervention contents were indicated separately for people with diabetes–family caregiver dyads and the family caregivers. The methods used to conduct the pilot RCT study are presented in Chapter Six.

CHAPTER FIVE: THE TRANSLATION AND PSYCHOMETRIC PROPERTIES OF OUTCOME MEASURES

5.1 Introduction

This chapter presents the translation, cultural adaptation and psychometric properties evaluation of four scales for measuring the outcomes, namely, the summary diabetes self-care activities (SDSCA) (expanded), DQOL measure, the diabetes care profile (DCP) questionnaire–support scale amongst people with T2D and the diabetes family behaviour checklist (DFBC) amongst their family caregivers. Except for DFBC, the same translation, cultural adaptation and methods were used to evaluate psychometric properties for all scales. The psychometric properties of the DQOL–Afaan Oromoo finding were published elsewhere (Diriba et al., 2021a).

This chapter is broadly organised into five sections. Section 5.1 introduces the chapter. Section 5.2 shows the translation procedures of all of the four scales. Section 5.3 shows the psychometric properties of all scales used to measure outcomes reported by people with diabetes. Section 5.4 presents the psychometric properties of the scale used to measure the outcome reported by family caregivers. Lastly, Section 5.5 summarises the chapter.

5.2 Translation of the scales

Permission to translate and adapt the scales was obtained from the scale developers. The translation and cultural adaptation were conducted according to the six-stage recommendation of cross-cultural adaptation developed by the Institute for Work and Health in 2007 (Beaton et al., 2007). In stage 1, two versions of the forward translation of the original version of the scales were prepared by two translators (a health professional and a naïve translator who is a PhD holder in Afaan Oromoo). In stage 2, the doctoral student synthesised the translations obtained in stage 1 and a reconciled translation of the scales separately after an agreement on any discrepancies was reached. In stage 3, two separate versions of the back-translation of the scales were prepared by another two excellent translators, who were PhD holders in English and native speakers of Afaan Oromoo. In stage 4, an expert panel consisting of seven professionals (one public health expert, one nurse, one Afaan Oromoo language expert and two forward and two backward translators) was formed, and they evaluated the conceptual, semantic and idiomatic equivalences of the translated versions of the scales using five-point Likert scale items to calculate the CVI. Disparities were reported amongst the experts on the wording of some items and the correctness of others. For example, one expert commented concerning item 10 of the DQOL regarding the impact on the individual's sexual life, 'complications related to T2D, like impotence, is gradual and permanent. It is not something that comes and goes'. It was explained that the 'always' response is an option. Thus, if the individual has a sexual-related problem, he/she may respond 'always.' Varying opinions on other items were solved through discussion amongst the translators and subject experts. The CVI of the Afaan Oromoo version of the scales ranged between 0.91 and 0.97. The content validity of the translated version was evaluated by experts and demonstrated acceptable CVI (Yusoff, 2019). Similarly, the experts suggested replacing the term 'insulin' with 'diabetic medication' in two items (items 3 and 14) of the DFBC scale. As all experts agreed to replace this term, it was incorporated into the scale.

In stage 5, 30 people with T2D were asked to assess the applicability, readability and clarity of the item content of the expert-evaluated version of the scales (Beaton et al., 2000). The cultural adaptation was made using locally spoken and acceptable words. The people with diabetes were requested to suggest the appropriate terms, and amendments were made to the local culture. In stage 6, an amendment was made based on feedback from the participants, using proper words and restructuring some sentences in a culturally appropriate way. The final version of the scales in Afaan Oromoo was developed and subjected to psychometric testing.

5.3 Part One: Psychometric Properties of Scales used to Measure People with T2D Outcomes

5.3.1 Objectives of the study

To test the psychometric properties of three scales, the summary of diabetes self-care activities, DQOL and DCP support scales for people with T2D in Western Ethiopia.

5.3.2 Study design

The institution-based cross-sectional study design was conducted to evaluate the psychometric properties of the Afaan Oromoo version of the scales.

5.3.3 Participants

People with T2D were included if (1) they had been treated at the diabetes centre in the hospital for six months or more; (2) they were in a stable medical condition; (3) they were aged 18 or above; (4) they were cognitively intact (from the medical record); and (5) they could speak and understand Afaan Oromoo. Participants were excluded if they had a hearing problem.

5.3.4 Sample size

For psychometric testing, the required sample size was determined based on exploratory factor analysis (EFA) using a widely used case-to-variable (rule of thumb) ratio of 10:1 (Nunnally, 1994; Schreiber et al., 2006). EFA is used because many previous validation studies have reported variations in the factor structure of the scale in populations with different languages (Jin et al., 2018; Tang et al., 2020); hence it is better to use EFA to explore the factor structure of the scales in the current target population, which uses a different language. As the same population was used to evaluate psychometric properties, the scale with maximum items, the

DQOL, was used for sample size calculation; therefore, the planned sample size for subject recruitment was set to 460.

5.3.5 Data collection techniques

Trained eight data collectors collected the data. People with diabetes were approached when they were waiting for monthly medical follow-ups in the diabetes centre of Nekemte Specialised Hospital. The eligible subjects were asked for informed written consent, and the questionnaire was administered via face-to-face interview.

5.3.6 Statistical analysis

The factor structure of the scales was examined in two steps. In step 1, item reduction was performed based on the item–total correlation or Pearson product-moment correlation. Any item with an item–total correlation coefficient below 0.3 was removed (Cristobal et al., 2007; Nunnally, 1994). The Pearson product-moment correlation (r) applied for the SDSCA scale was calculated as low correlations were demonstrated between items in previous versions (Adarmouch et al., 2016; Mogre et al., 2019). Items with the Pearson's r less than 0.2 were deleted.

In step 2, EFAs were conducted on the items remaining after step 1. As a low correlation was demonstrated between the unrotated factors of the SDSCA, Varimax rotation was applied in EFA. The Kaiser–Meyer–Olkin (KMO) and Barlett's tests checked for the appropriateness of conducting EFA. The factor retention was based on four criteria: (i) eigenvalues of >1; (ii) scree plot; (iii) interpretability of the retained factors; and (iv) factor loadings of >0.4. For items cross-loaded on factors, the item's retention to the factor was determined by two criteria: (1) a higher loading effect of the item onto the factor and (2) the interpretability of the result. Cronbach's alpha was then calculated to assess the reliability of the scales and the subscales. Ceiling and floor effect analysis was performed for the scales and the subscales to distinguish the proportion of respondents with the highest and lowest scales scores, respectively (Garin, 2014). Ceiling or floor effects were judged if more than 15% of subjects reached the highest or lowest score, respectively (Terwee et al., 2007).

The known group and correlation analysis assessed the construct validity of the scales—Pearson-product moment correlation was used for continuous demographic variables, and an independent t-test or ANOVA was used for categorical variables. If the data is not normally distributed, the Mann-Whitney test was applied. In all of the analyses, a p-value of <0.05 was statistically significant.

5.3.7 Ethical approval

Ethical approval for the study was obtained from the School of Nursing Human Subjects Ethics subcommittee, The Hong Kong Polytechnic University (Reference number: HSEARS20200317007). Permission to collect data was obtained from the participating hospital administrator and informed written consent was obtained from the subjects. The anonymity of the data was ensured through coding.

5.3.8 Scales

5.3.8.1 SDSCA (expanded)

5.3.8.1.1 Introduction

The SDSCA scale was developed to measure DSM behaviours by Toobert and Glasgow (1994). Later, the SDSCA was expanded to 15 items to have a broader coverage of DSM behaviours, including diet, exercise, blood glucose testing, foot care and medication. The scale had been translated and psychometrically tested in different languages. A review of seven studies that used SDSCA showed the tool was valid and reliable, with a low level of correlation between subscales (D. J. Toobert et al., 2000). This scale is available in the Korean, Indonesian, Chinese, Spanish, Germany, Arabian, Moroccan, Urdu and Ghanaian versions (Adarmouch et al., 2016; AlJohani et al., 2016; Ansari et al., 2020; Caro-Bautista et al., 2016; Kamradt et al., 2014; Mogre et al., 2019; Schmitt et al., 2013; Vincent et al., 2008; Xu et al., 2008). An acceptable validity and reliability were obtained except for two versions (Adarmouch et al., 2016; Mogre et al., 2019). The study involving Moroccans reported low reliability of 0.20 in the diet subscale in a sample of 75 people with T2D (Adarmouch et al., 2016), whilst another study reported that construct validity of the SMBG and foot care subscales was not supported in a sample of adults with T2D in Ghana (Mogre et al., 2019). Various studies reported that sociodemographic characteristics, such as gender, marital status, educational level, employment status, age and diabetes-specific factors, including years since diagnosis and presence of diabetes complications, were found to be significant predictors of self-management practise (Alodhayani et al., 2021; Degefa et al., 2020; Demoz et al., 2020; Diriba et al., 2020; Oluma et al., 2020). In particular, female gender (Alodhayani et al., 2021), merchant (Diriba et al., 2020), having diabetes for ≥5 years (Degefa et al., 2020), presence of diabetes complications, those who attended primary, secondary and tertiary education (Demoz et al., 2020) were associated with self-management. The SDSCA is the most common and widely used scale to assess the level of DSM, yet the scale was not available in the Afaan Oromoo language. Therefore, we aimed to translate the SDSCA into Afaan Oromoo and psychometrically evaluate this translated version of the scale.

5.3.8.1.2 Instrument

The SDSCA (expanded) contains five domains with 15 items. The domains include diet (items 1-5), physical activity and exercise (items 6 and 7), blood glucose testing (items 8 and 9), foot care (items 10–14) and medication (item 15). The items address people with diabetes last seven days of practise of diet intake, physical activity, SMBG, foot care and medication. All items were rated on a seven-point Likert scale, ranging from 0 (no practise) to 7 (daily practise in a week), with item 4 in the reverse direction. The mean score for a number of days practised diet, physical activity and exercise, SMBG, foot care and medication was calculated, with a higher score indicating more practise.

5.8.3.1.3 Results

i. Sociodemographic characteristics

Amongst 460 approached for the study, 456 (99.1%) of the participants responded to the interview. After removing the cases with missing data, the final sample of 452 was used for analysis. The mean age of the participants was 50.0 ±10.8, more than half (51.5%) were females, and more than a third quarter (77.4%) were married. Most of the participants (88.9%) were Oromoo, and more than half (57.7%) were Protestant Christians. A third (33.6%) attended elementary school, and a fifth (20.1%) were retired and disabled. The majority (83.4%) had a history of diabetes for ≤10 years since diabetes diagnosis; more than half (54.9%) had at least one comorbid disease, with 83.5% having hypertension. Nearly two-thirds (60.2%) received support primarily from their spouses (**Table 5.1**).

Table 5.1 Sociodemographic characteristics of the participants

Variables with categories	Frequency (%)
Age in years (mean ± SD)	50.0 ± 10.8
Gender	
Female	233 (51.5%)
Male	219 (48.5%)
Marital status	
Married	350 (77.4%)
Never married	102 (22.6%)
Ethnicity	
Oromoo	402 (88.9%)
Amhara	50 (11.1%)
Religion	
Protestant Christian	261 (57.7%)
Orthodox Christian	141 (31.2%)
Muslim	50 (11.1%)
Primary caregiver (support provider)	
Spouse	272 (60.2%)
Child	180 (39.8%)
Educational status	
No formal education	81 (17.9%)
Elementary school (≤ grade 8)	152 (33.6%)
Secondary school (grade 9-12)	113 (25.0%)
Tertiary education	106 (23.5%)
Employment status	
Retired/disabled	91 (20.1%)
Government employee	81 (18.4%)
Farmer	74 (16.4%)
Merchant	72 (16.2%)
Homemaker	64 (14.2%)
NGO/private organization employee	42 (9.3%)
Status of diabetes-related complication	
Present	248 (54.9%)
Absent	204 (45.1%)
Type of diabetes-related complication	
Hypertension	207 (83.5%)
Other diseases	28 (11.3%)
Cardiac disease	13 (5.2%)
Years since diabetes diagnosis	
≤ 10	377 (83.4%)
>10	74 16.4%)

ii. Factor Structure

Pearson-moment product correlation

The Pearson's r was calculated to examine the correlation between individual items. Items with Pearson's r less than 0.2 were deleted from the scale. The bold figure in **Table 5.2** indicates a Pearson correlation of less than 0.2. Accordingly, five items (items 4, 6, 7, 8 and 15) were deleted from the scale. Hence, 10 items (items 1–3, 5 and 9–14) were retained in the scale, labelled as the SDSCA–Afaan Oromoo and finally subjected to EFA.

Table 5.2 Pearson product-moment correlation of the summary of diabetes self-care activities-expanded scale

Correlations (Pearson's r)																
		Days followed eating plan (Item 1)	Days per week average (Item 2)	Eat five or more fruits and veg (Item 3)	Eat high fat foods (Item 4)	Evenly CHO consumption (Item 5)	Exercise for 30 minutes (Item 6)	Performs specific exercise (Item 7)	Days of BG testing (Item 8)	Number of recommendations (Item 9)	Check feet (Item 10)	Inspect shoes (Item 11)	Wash foot (Item 12)	Soak foot (Item 13)	Dry after washing (Item 14)	Medication usage (Item 15)
Days followed eating plan (Item 1)	Pearson Correlation	1														
	Sig. (2-tailed)		.000													
Days per week average (Item 2)	Pearson Correlation	.921**	1													
	Sig. (2-tailed)	.000														
Eat five or more fruits and veg (Item 3)	Pearson Correlation	.251**	0.207*	1												
	Sig. (2-tailed)	.001	0.023													
Eat high fat foods (Item 4)	Pearson Correlation	**-.014**	**.017**	-.258**	1											
	Sig. (2-tailed)	.765	0.722	0.000												
Evenly CHO consumption (Item 5)	Pearson Correlation	.226**	.256**	.201**	-.320**	1										
	Sig. (2-tailed)	.000	.000	.000	.000		.185									
Exercise for 30 minutes (Item 6)	Pearson Correlation	**.096***	**-.129****	.290**	**.077**	**.062**	1									
	Sig. (2-tailed)	.042	.006	.000	.101	.185		.000								
Performs specific	Pearson Correlation	**-.103***	**-.081**	**.002**	**-.099***	**-.147****	.262**	1								

exercise (Item 7)	Sig. (2-tailed)	.028	.086	.959	.035	.002	.000		.390							
Days of BG testing (Item 8)	Pearson Correlation	**.027**	**.041**	**-.046**	**-.025**	**-.050**	**-.068**	**.040**	1							
	Sig. (2-tailed)	.567	.383	.325	.601	.293	.147	.390								
Number of recommendation (Item 9)	Pearson Correlation	.281**	.299**	**-.051**	**-.127****	**.042**	-.218**	.218**	**.039**	1						
	Sig. (2-tailed)	.000	.000	.279	.007	.375	.000	.000	.403		.613					
Check feet (Item 10)	Pearson Correlation	.368**	.351**	.245**	**.054**	.200**	**.078**	-.257**	**-.031**	**.024**	1					
	Sig. (2-tailed)	.000	.000	.002	.255	.000	.099	.001	.514	.613		.000				
Inspect shoes (Item 11)	Pearson Correlation	.260**	.252**	.212*	**.013**	.213*	**.139****	**-.103***	**.112***	**.042**	**.724****	1				
	Sig. (2-tailed)	.000	.000	.017	.786	.016	.003	.028	.017	.376	.000					
Wash foot (Item 12)	Pearson Correlation	.232**	-.207**	.203**	**.139****	**-.067**	.325**	**-.025**	**.028**	-.224**	.295**	.242**	1			
	Sig. (2-tailed)	.005	.000	.000	.003	.152	.000	.600	.556	.000	.000	.000				
Soak foot (Item 13)	Pearson Correlation	.243**	**.149****	.243**	-.227**	.242**	**.072**	-.202*	**.064**	**.070**	.208**	.292**	**.115***	1		
	Sig. (2-tailed)	.002	.001	.000	.007	.000	.126	.030	.176	.135	.000	.000	.014			
	Pearson Correlation	.255**	.251**	.298**	**.047**	.268**	.366**	**-.079**	**.090**	**-.019**	.371**	.449**	.352**	.323**	1	

Dry after washing (Item 14)	Sig. (2-tailed)	.001	.001	.000	.320	.000	.000	.094	.057	.685	.000	.000	.000	.000		
Medication usage (Item 15)	Pearson Correlation	**.047**	**-.009**	**-.031**	.266**	**-.162****	**.136****	**-.072**	**-.019**	-.218**	**.106***	**.050**	.212**	**-.189****	-.009	1
	Sig. (2-tailed)	.315	.844	.516	.000	.001	.004	.127	.682	.000	.025	.287	.000	.000	.847	

**. Correlation is significant at the 0.01 level (2-tailed).

*. Correlation is significant at the 0.05 level (2-tailed).

Exploratory Factor Analysis

An EFA was conducted to examine the factor structure of the remaining 10 items of the SDSCA–Afaan Oromoo. The KMO statistic was 0.668, and Bartlett's test statistic was 1734.496 ($p < 0.001$), indicating sampling adequacy and appropriateness for factor analysis. The scree plot and eigenvalues suggested three-factor solutions, comprising 61.6% of the total variance retained. All items loaded on the factor greater than 0.4; hence, all 10 items in the SDSCA–Afaan Oromoo were included.

The items were examined with their factor loadings. Any item that loaded on other subscales in addition to its original subscale was retained in its original subscale only to enhance the interpretability. The label of the subscale is based on the highest loading of the item on the factor. As indicated in **Table 5.3,** three items were cross loaded on the factors. Initially, four items were loaded on factor 1, four items were loaded on factor 2 and four items were loaded on factor 3. As the highest loading of the items on factor 1 was from foot care-related items, factor 1 is labelled as foot care; factor 2 is labelled as general diet and blood glucose testing; factor 3 is labelled as a specific diet. For easy interpretation of the items, item 8 was retained under factor 1, and items 3 and 4 were retained under factor 2.

Moreover, item 5 related to blood glucose testing was moved to factor 3 for easy interpretation. The SDSCA–Afaan Oromoo version comprises 10 items with three domains, namely, general diet and blood glucose testing (items 1 to 3), specific diet (items 3 and 4) and foot care (items 6 to 10). The version was subjected to psychometric properties evaluation of reliability and construct validity.

Table 5.3 Rotated exploratory factor analysis results of the SDSCA-AO scale

	Items	Fact or 1	Factor 2		Fact or 3
	General diet and blood glucose testing				
1	How many days of the last SEVEN DAYS have you followed your eating plan?		.856		
2	On average, how many DAYS PER WEEK have you followed your eating plan over the past month?		.879		
3	How many of the last SEVEN DAYS did you test your blood sugar the number of times your health care provider recommended?		.565		0.454
	Specific diet				
4	On how many of the last SEVEN DAYS did you eat five or more servings of fruits and vegetables?				.714
5	How many of the last SEVEN DAYS did you space carbohydrates evenly through the day?				.626
	Foot care				
6	On how many of the last SEVEN DAYS did you check your feet?	.841			
7	On how many of the last SEVEN DAYS did you inspect the inside of your shoes?	.854			
8	On how many of the last SEVEN DAYS did you wash your feet?	.573	-.489		
9	On how many of the last SEVEN DAYS did you soak your feet?	0.54			.672
10	How many of the last SEVEN DAYS did you dry between your toes after washing?	.597			.453

iii. Reliability of the scale

Table 5.4 shows the internal consistency, ceiling and floor effects of the SDSCA–Afaan Oromoo. The internal consistency of the SDSCA–Afaan Oromoo scale was 0.73. The internal consistency of the subscales ranged between 0.70 and 0.77, showing acceptable reliability. There was no evidence of any ceiling or floor effects in the SDSCA–Afaan Oromoo version and subscales (Terwee et al., 2007).

Table 5.4 The internal consistency, ceiling, and floor effects of the SDSCA-AO version

Scale/subscale	**Number of Items**	**Cronbach's Alpha**	**Ceiling effect n (%)**	**Floor effect n (%)**
General diet and blood glucose testing	3	0.77	67 (14.7)	1 (0.2)
Specific diet	2	0.71	28 (6.1)	1 (0.2)
Foot care	5	0.70	1 (0.2)	6 (1.3)
Total SDSCA-AO	10	0.73	1 (0.2)	1 (0.2)

iv. Construct validity

Table 5.5 indicates the construct validity results and the direction of relationships, with the bold figure indicating better self-care behaviour. The results of ANOVA showed that education level ($F = 5.527$, $p = 0.001$), employment status ($F = 2.597$, $p = 0.017$) and diabetes-related comorbid ($F = 6.521$, $p = 0.002$) demonstrated a significant difference in the SDSCA–Afaan Oromoo scores. There was a significant difference between participants who attended tertiary education (3.29±1.02, $p < 0.001$) and elementary school (2.94±1.02, $p < 0.001$). However, those who attended tertiary education had better self-management practise. There was a significant difference between the government employee (3.28±0.95, $p = 0.003$) and the farmer (2.64±1.10, $p = 0.003$). There was also a significant difference between those who had hypertension (3.09±1.10, $p = 0.002$) and those who had any cardiac diseases (3.62±0.98, p =

0.035) with better self-management practise observed amongst people with diabetes living with cardiac diseases.

By contrast, status of diabetes-related comorbid ($t = -0.252$, $p = 0.801$), family caregivers ($t = 0.137$, $p = 0.891$), marital status ($t = -0.480$, $p = 0.631$) and gender ($Z = -1.370$, $p = 0.171$) showed non-significant results. In addition, a non-significant but positive correlation was obtained between age and SDSCA–Afaan Oromoo ($r = 0.040$, $p = 0.402$).

Table 5.5 Relationships between the SDSCA-AO scores and demographic variables and pairwise comparison

Variables with categories	Frequency (n)	Mean score	SD	Between-group p-value	Pairwise comparison
Gender					
Female	233	**3.05**	0.99	0.171[a]	
Male	219	2.93	1.12		
Age	452	r=0.040		0.402	
Diabetes-specific complication(s) status					
Absent	204	2.98	1.03	0.801	
Present	248	**3.00**	1.08		
Marital status					
Married	350	**3.00**	1.05	0.631	
Never married	102	2.95	1.07		
Education level					
No formal education	81	2.94	1.02	0.001	Tertiary education < elementary school
Elementary school (≤ grade 8)	152	2.77	1.04		
Secondary school (grade 9-12)	113	3.06	1.07		
Tertiary education	106	**3.29**	1.02		
Employment status					
Government employees	83	**3.28**	0.95	0.017	Government employee < farmer
Private employees	42	3.04	1.08		
Merchant	73	3.08	1.05		
Homemaker	64	2.97	0.89		
Retired	91	2.94	1.17		
Farmer	74	2.64	1.10		
Others	25	3.00	0.99		
Primary care provider					
Spouse	272	**3.00**	1.06	0.891	
Children	180	2.98	1.04		
Type of diabetes-related complication					
Hypertension	207	3.09	1.10	0.002	Hypertension < cardiac diseases
Cardiac disease	13	3.38	1.13		
Other diseases	28	2.36	0.61		

[a]Mann Whitney test; r=Pearson correlation coefficient.

5.8.3.1.3 Discussion

The psychometric properties evaluation of the SDSCA (expanded) scale, which measures DSM behaviours, was performed for adults with T2D in Western Ethiopia. Five items showing the

Pearson's r less than 0.2 were dropped from the scale to achieve the desired internal consistency. The number of items dropped in this scale is consistent with a summary finding of 7 studies (Toobert et al., 2000) and an Urdu version (Ansari et al., 2020). The items that showed low correlation were also problematic in other versions (Kamradt et al., 2014; Mogre et al., 2019). The deleted item 4 in this study showed the lowest correlation consistent with the Moroccan (Adarmouch et al., 2016) and German (Kamradt et al., 2014) versions. Dropped items from the scale were items 4, 6–8 and 15. The items that were dropped are possibly due to two reasons. Firstly, item 4 measures the frequency of fat and high-fat food intake. The possible reason for deleting item 4 is that the item is less important for people with diabetes as they may be aware of fatty food and its health risks already. Secondly, items 6 and 7 measure physical activity. Due to low economic status and shortage of transportation facilities, people with diabetes usually walk on their feet. Deleting item 8 is appropriate because self-blood glucose testing is frequently recommended for people with T1D and taking insulin therapy (American Diabetes Association, 2020). For people with T2D, an item that measures the SMBG practise according to the recommendation from health professionals is essential to assess the SMBG. The lack of a glucose monitoring device, such as a glucometer, may have hindered the SMBG. Hence, SMBG practise could have been addressed in item 9. Item 15 measures medication practise, and the item may be less important because medication adherence is high amongst people with diabetes in Ethiopia, which was 75.35% (Habebo et al., 2020). In total, 10 items were retained in the scale. Although the included items are different, the number of retained items is consistent with previous versions (Kamradt et al., 2014; Mogre et al., 2019).

The SDSCA–Afaan Oromoo internal consistency was demonstrated as acceptable reliability. This finding is consistent with the Arabic (AlJohani et al., 2016) and the original (Toobert & Glasgow, 1994) versions. However, the finding is incongruent with the Ghanaian (Mogre et al., 2019), Moroccan (Adarmouch et al., 2016), German (Kamradt et al., 2014), Spanish (Caro-Bautista et al., 2016) and Urdu (Ansari et al., 2018) and the Chinese (Xu et al., 2008) versions. The variation in internal consistency of the whole scale may be due to socioeconomic variation. Ethiopia is one of the low-income countries in the world. The people with diabetes may not be able to purchase the required food and lack infrastructure for physical activities and a glucometer for self-blood glucose testing, whilst the populations included in previous studies of the SDSCA versions had medium to high income to access the food and infrastructure to perform the self-management recommendations. On the hand, a three-factor structure, namely, general diet and blood glucose testing, specific diet and foot care, was formed in the Afaan Oromoo version of the scale, which is incongruent with the German (Kamradt et al., 2014) and Moroccan (Adarmouch et al., 2016) versions but consistent with the Spanish version (Caro-Bautista et al., 2016). The items to measure the exercise domain were deleted in this EFA factor structure; however, the exercise factor was produced in Germany (Kamradt et al., 2014) and Moroccan (Adarmouch et al., 2016) versions. The variation between versions may be due to low economic status and shortage of transportation facilities; people in Ethiopia usually prefer walking. Hence, measuring exercise amongst these populations may be less important. The foot care factor was not formed in the Spanish version, which is inconsistent with this study (Caro-Bautista et al., 2016). Reports about foot care in relation to diabetes-related complications are soaring (American Diabetes Association, 2020). This finding may be due to the importance of assessing foot care practise. The internal consistency of the subscales showed acceptable reliability, which is consistent with previous studies in testing the Ghanaian (Mogre et al., 2019), German (Kamradt et al., 2014) and Arabic versions (AlJohani et al., 2016). In construct validation, the education level, government-employed, and the type of diabetes-related comorbid were found as associated factors with self-management behaviour. This finding is congruent with previous studies conducted in Saudi Arabia (Alodhayani et al., 2021) and Ethiopia (Demoz et al., 2020). However, it is inconsistent with other studies conducted in Ethiopia (Diriba et al., 2020; Oluma et al., 2020). The inconsistency may be due to different scales used to measure DSM activities, such as the non-standardised scale (Diriba et al., 2020) and the unvalidated SDSCA scale (Oluma et al., 2020) were used. Individuals who attended tertiary education were a significant determinant of the self-management practise; this study is consistent with the study conducted in Southern Ethiopia (Demoz et al., 2020). This finding can be explained by better education and government-employed approaches increasing their awareness, hence the better self-management. Overall, these findings suggest that the SDSCA–Afaan Oromoo is suitable to measure the summary of DSM activities amongst people with T2D who understand Afaan Oromoo.

The strengths of this study include the involvement of a large sample size to test the psychometric properties of the scales. The limitations of this study include that the recruitment of the subjects was by convenience and thus may not be representative of all adults with T2D who understand Afaan Oromoo in Ethiopia. However, the demographic characteristics of the participants in terms of gender, education level and employment status are almost similar. Nevertheless, the hospital is one of the largest hospitals in Western Ethiopia, and many people with diabetes attend medical check-ups there. Another limitation of this study was that test–retest reliability was not examined due to the COVID-19 pandemic, and the medical follow-up visits for diabetes in the centre were delayed beyond the subject recruitment period. To the SDSCA scale, low missing data and low correlation were observed in most items.

5.8.3.1.3 Conclusions

The summary of diabetes self-care activities (Afaan Oromoo version) demonstrated acceptable reliability and factorial and construct validity. It provided preliminary evidence to use the SDSCA–Afaan Oromoo to measure self-management activities amongst adults with T2D.

Further study is needed to address the test–retest reliability and predictive validity of the SDSCA–Afaan Oromoo.

5.8.3.2 DQOL

5.8.3.2.1 Introduction

QOL amongst people with diabetes becomes a daily goal and is considered an important treatment outcome (Walker & Bradley, 2002). QOL assesses people with diabetes physiological well-being, physical and psychosocial aspects and lived experience. Several studies have reported that diabetes negatively affects a person's QOL. Diabetes poses social, physical, sexual and physiological impacts, and these impacts are worse if complications of diabetes develop. Although QOL is an important patient-reported outcome, it is rarely assessed in diabetes research (Jones et al., 2015). A recent study of 25 years of experience on the impact of diabetes assessment study pointed out that the QOL needs to be addressed by researchers as a priority (Speight et al., 2020).

Measuring QOL in people with diabetes is imperative (Rubin & Peyrot, 1999). Even though various forms of diabetes specific QOL measures are available, the DQOL scale provides a comprehensive assessment of the components of QOL amongst people with diabetes. It has been widely used in different studies to measure QOL amongst people with diabetes and is sensitive to disease severity and lifestyle changes (Jacobson et al., 1994).

The DQOL scale was initially developed in 1988 by the diabetes control and complications trial (DCCT) research group in English in a study aimed to evaluate the effects of two different diabetes treatment regimens on QOL. The DQOL has 46 items measuring four domains: satisfaction, impact, social/vocational worry and diabetes-related worry, with a Cronbach's alpha of 0.92 for the whole scale (The DCCT Research Group, 1988). Subsequently, numerous shortened versions of the DQOL were produced in different languages. A 24-item Chinese version (Jin et al., 2018), a 44-item Brazilian DQOL version (Brasil et al., 2014), an eight-item Brazilian brief version (Brasil et al., 2015), a 45-item Turkish version (Yildirim et al., 2007), a 46-item Iranian version (Pakpour et al., 2012) and a 13-item Malay revised version were developed (Bujang et al., 2018); all showed acceptable validity and reliability. Consistent with the original version of the DQOL, all of the shortened versions of the DQOL have four domains, with one exception: the 13-item Malay revised version (Bujang et al., 2018) measures three domains, namely, satisfaction, impact and worry. Some studies have also reported that some items of the DQOL had a low correlation with items in the same domain, thus it is deemed necessary to establish the correlation matrix amongst items in the domain. The DQOL scale Cronbach's alpha of these versions ranged from 0.702 to 0.92.

The construct validity of the various DQOL studies demonstrated that educational status, employment status, age and comorbidity status were significantly related to QOL amongst adults with diabetes. In particular, people with diabetes who were female and married scored significantly higher than their male counterparts. In contrast, people with diabetes who had not attended formal education, were older, were separated/widowed, were unemployed and those with diabetes complications scored significantly lower in QOL.

Though the DQOL scale is available in different language versions, there is no translated, culturally adapted, and psychometrically validated version in Afaan Oromoo, which is the most widely spoken language in Ethiopia (33.8%) and is the fourth most widely spoken language in Africa (Wikipedia, 2021). Hence, this study aimed to translate the original English version of the DQOL into Afaan Oromoo and culturally adapt and evaluate its factor structure, reliability and construct validity amongst adults with T2D in Ethiopia.

5.8.3.2.2 Instrument

The 46-item DQOL has four major domains: satisfaction (15 items), impact (20 items), social/vocational worry (7 items) and diabetes-related worry (4 items). Items in the satisfaction domain are scored on a five-point scale ranging from 1 (very satisfied) to 5 (very dissatisfied), and the items in the impact and the two worry domains are scored on a five-point scale, ranging from 1 (no impact and never worried) to 5 (always impacted and always worried). If an item is not relevant to the respondent, the 'Does not apply' option is provided for the social/vocational worry and diabetes-related worry subscales and will not be scored. A lower score in DQOL indicates a better QOL (Jacobson et al., 1994).

Sociodemographic variables, such as gender, marital status, ethnicity, religion, education level, a family member usually providing support, employment status and people with diabetes-related factors, such as the diabetes-specific complication(s), and the year since diabetes diagnosis were collected.

5.8.3.2.3 Results

Sociodemographic characteristics of the participants

Table 5.6 shows the sociodemographic characteristics of the participants. The response rate of the participants was 90.6% (417/460), and cases with missing data were excluded from the analysis. The mean age of the subjects was 50.2±11.7 years; 51.3% were female, 77.5% were married and 88.2% were Oromoo. More than half (56.8%) were Protestant Christians, and the majority (61.6%) received support from their spouse. A third (33.1%) of the participants had attended elementary school, and 27.2% were private organisation employees. More than half (55.4%) of the people with diabetes had comorbid diseases, and nearly half (45.6%) had hypertension. More than three quarters (82.7%) had less than 10 years of history of diabetes.

Table 5.6 Sociodemographic characteristics of the participants

Variables with Categories	Frequency (%)
Age in years	Mean 50.2 (SD ± 11.7)
Gender	
Female	214 (51.3%)
Male	203 (48.7%)
Marital status	
Married	323 (77.5%)
Never married	30 (7.2%)
Separated/widowed	64 (15.3%)
Ethnicity	
Oromoo	368 (88.2%)
Amhara	43 (10.3%)
Other	6 (1.4%)
Religion	
Protestant Christian	237 (56.8%)
Orthodox Christian	138 (33.1%)
Muslim	34 (8.2%)
Other	8 (1.9%)
Primary caregiver (support provider)	
Spouse	257 (61.6%)
Children	123 (29.5%)
Mother or father	37 (8.9%)
Educational status	
No formal education	76 (18.2%)
Elementary school	138 (33.1%)
Secondary school	101 (24.2%)
College and above	102 (24.5%)
Employment status	
Government employee	76 (18.2%)
Private organization employee	113 (27.2%)
Unemployed	73 (17.5%)
Retired/disabled	86 (20.6%)
Farmer	69 (16.5%)
Presence of disease-related complication	
Yes	231 (55.4%)
No	186 (44.6%)
Type of diabetes-related complication	
Hypertension	190 (82.3%)
Other diseases	41 (17.7%)
Years since diabetes diagnosis	
≤ 10	345 (82.7%)
>10	72 (17.3%)

Factor structure

(i) Item–total correlation

Table 5.7 shows the item–total correlation statistics of all items, 12 of which had item–total correlations <0.3, indicated in bold. These included two items (items 7 and 15) from the satisfaction subscale; seven items (items 3, 8 and 16–20) from the impact subscale; two items (items 4 and 5) from the social/vocational worry subscale; and one item (item 4) from the diabetes-related worry subscale. Satisfaction Item No. 7, which talks about satisfaction with the knowledge of diabetes, may not be removed due to their belief that they know about diabetes. Impact items 3, 8 and 17 were removed in this version, possibly because this population knows about low glucose levels, self-esteem, and respect. Similarly, Impact Item No. 20 was deleted, possibly as most people with T2D do not receive insulin; hence an insulin reaction is not expected and is not a relevant item (American Diabetes Association, 2021b). The items were removed from the Afaan Oromoo version of the DQOL. A total of 34 items were retained in the scale: satisfaction (13 items), impact (13 items), social/vocational worry (6 items) and diabetes-related worry (3 items). These items were subjected to EFA.

Table 5.7 Item–total statistics of the DQOL-AO version

Item Number	Domain and Items	Item–total Correlation
Satisfaction		
1.	How satisfied are you with the time it takes to manage your diabetes?	0.581
2.	How satisfied are you with the amount of time you spend getting check-ups?	0.543
3.	How satisfied are you with the time it takes to determine your sugar level?	0.352
4.	How satisfied are you with your current treatment?	0.461
5.	How satisfied are you with the flexibility you have in your diet?	0.326
6.	How satisfied are you with your diabetes burden on your family?	0.365
7.	How satisfied are you with your knowledge about your diabetes?	0.207
8.	How satisfied are you with your sleep?	0.351
9.	How satisfied are you with your social relationships and friendships?	0.626
10.	How satisfied are you with your sex life?	0.481
11.	How satisfied are you with your work, school, and household activities?	0.543
12.	How satisfied are you with the appearance of your body?	0.596
13.	How satisfied are you with the time you spend exercising?	0.537
14.	How satisfied are you with your leisure time?	0.496
15.	How satisfied are you with life in general?	**0.223**
Impact		
1.	How often do you feel the pain associated with the treatment of your diabetes?	0.363
2.	How often are you embarrassed by having to deal with your diabetes in public?	0.303
3.	How often do you have low blood sugar?	**0.181**
4.	How often do you feel physically ill?	0.473
5.	How often does your diabetes interfere with your family life?	0.518
6.	How often do you have a bad night's sleep?	0.412
7.	How often do you find your diabetes limiting your social relationships and friendships?	0.486

8.	How often do you feel good about yourself?	**−0.151**
9.	How often do you feel restricted by your diet?	0.339
10.	How often does your diabetes interfere with your sex life?	0.523
11.	How often does your diabetes keep you from driving a car or using a machine (e.g., a typewriter)?	0.522
12.	How often does your diabetes interfere with your exercising?	0.468
13.	How often do you miss work, school, or household duties because of your diabetes?	0.554
14.	How often do you find yourself explaining what it means to have diabetes?	0.359
15.	How often do you find that your diabetes interrupts your leisure-time activities?	0.557
16.	How often do you tell others about your diabetes?	**0.284**
17.	How often are you teased because you have diabetes?	**0.245**
18.	How often do you feel that because of your diabetes you go to the bathroom more than others?	**0.273**
19.	How often do you find that you eat something you shouldn't rather than tell someone that you have diabetes?	**−0.291**
20.	How often do you hide from others the fact that you are having an insulin reaction?	**0.167**
Social/Vocational Worry		
1.	How often do you worry about whether you will get married?	0.387
2.	How often do you worry about whether you will have children?	0.429
3.	How often do you worry about whether you will not get a job you want?	0.433
4.	How often do you worry about whether you will be denied insurance?	**0.019**
5.	How often do you worry about whether you will be able to complete your education?	**0.292**
6.	How often do you worry about whether you will miss work?	0.404
7.	How often do you worry about whether you will be able to take a vacation or a trip?	0.358
Diabetes-Related Worry		
1.	How often do you worry about whether you will pass out?	0.496
2.	How often do you worry that your body looks different because you have diabetes?	0.574
3.	How often do you worry that you will get complications from your diabetes?	0.407
4.	How often do you worry about whether someone will not go out with you because you have diabetes?	**0.116**

(ii) Exploratory Factor Analysis

An EFA was conducted to examine the factor structure of the remaining 34 items of the DQOL–Afaan Oromoo. The KMO statistic was 0.865, and Bartlett's test statistic was 5739.562 ($p < 0.001$), implying sampling adequacy and appropriateness for factor analysis. The scree plot and eigenvalues suggested four possible factor solutions, namely, the four-, five-, six- and seven-solutions. On the basis of the interpretability of the factors, the four-factor solution was selected because it produced four explicit factors that resembled the original DQOL. The findings of EFA showed a four-factor solution comprising 45.12% of the total variance retained. All the factor loadings of the four-factor solution were greater than 0.4, and all 34 items in the DQOL–Afaan Oromoo were retained.

The items were examined with their factor loadings. Any item that loaded on (an) other subscale(s) in addition to its original subscale was retained in its original subscale only to enhance the interpretability. As indicated in **Table 5.8**, 13 items were retained under the impact subscale, 13 items in the satisfaction subscale, five in the social/vocational worry subscale and 3 items three in the diabetes-related worry subscale. All 34 items were retained as the DQOL–Afaan Oromoo version by EFA.

Table 5.8 Initial exploratory factor analysis results of the DQOL-AO version

Item Number	Item	Factor Loading			
		Factor 1	Factor 2	Factor 3	Factor 4
Satisfaction					
1.	How satisfied are you with the time it takes to manage your diabetes?		−0.742	0.503	
2.	How satisfied are you with the amount of time you spend getting check-ups?		−0.705	0.569	
3.	How satisfied are you with the time it takes to determine your sugar level?		−0.342	0.510	
4.	How satisfied are you with your current treatment?		−0.536		
5.	How satisfied are you with the flexibility you have in your diet?		−0.352		0.321
6.	How satisfied are you with your diabetes burden on your family?	0.374			
7.	How satisfied are you with your sleep?		−0.546		
8.	How satisfied are you with your social relationships and friendships?	0.423	−0.448		
9.	How satisfied are you with your sex life?		−0.497		
10.	How satisfied are you with your work, school, and household activities?	0.726			
11.	How satisfied are you with the appearance of your body?	0.567			
12.	How satisfied are you with the time you spend exercising?	0.611			
13.	How satisfied are you with your leisure time?	0.500			
Impact					
1.	How often do you feel the pain associated with the treatment of your diabetes?	0.453			
2.	How often are you embarrassed by having to deal with your diabetes in public?			0.391	
3.	How often do you feel physically ill?	0.600			
4.	How often does your diabetes interfere with your family life?	0.682			
5.	How often do you have a bad night's sleep?		−0.560		
6.	How often do you find your diabetes limiting your social relationships and friendships?	0.431			
7.	How often do you feel restricted by your diet?	0.401			
8.	How often does your diabetes interfere with your sex life?	0.502	−0.308		

9.	How often does your diabetes keep you from driving a car or using a machine (e.g., a typewriter)?	0.775			
10.	How often does your diabetes interfere with your exercising?	0.709			
11.	How often do you miss work, school, or household duties because of your diabetes?	0.614			
12.	How often do you find yourself explaining what it means to have diabetes?	0.478			
13.	How often do you find that your diabetes interrupts your leisure-time activities?	0.555		0.359	
	Social/Vocational Worry				
1.	How often do you worry about whether you will get married?		0.587	0.306	
2.	How often do you worry about whether you will have children?		0.475	0.500	
3.	How often do you worry about whether you will not get a job you want?			0.760	
4.	How often do you worry about whether you will miss work?			0.673	
5.	How often do you worry about whether you will be able to take a vacation or a trip?			0.389	
	Diabetes-Related Worry				
1.	How often do you worry about whether you will pass out?				0.765
2.	How often do you worry that your body looks different because you have diabetes?				0.745
3.	How often do you worry that you will get complications from your diabetes?				0.725

Reliability Estimate

Table 5.9 below presents the internal consistency, ceiling and floor effects of the DQOL–Afaan Oromoo. The finding of the DQOL–Afaan Oromoo showed good internal consistency (>0.7) in three subscales (impact, satisfaction and diabetes-related worry), but the social/vocation worry subscale has questionable internal consistency (α = 0.654).

The ceiling and floor effects of the items were calculated for the scale and subscales of the DQOL–Afaan Oromoo version. A very small proportion of the people with diabetes (≤1.0%) attained the highest QOL score, and ≤6.2% of the study participants achieved the lowest QOL score in all four subscales. For the overall DQOL–Afaan Oromoo scale, there was also no evidence of any ceiling or floor effect (0.2%).

Table 5.9 The internal consistency, ceiling, and floor effects of the DQOL-AO version

Scale/Subscale	**Number of Items**	**Cronbach's Alpha**	**Mean Score (±SD)**	**Ceiling Effect n (%)**	**Floor Effect n (%)**
Impact	13	0.827	2.43 (0.49)	2 (0.5)	1 (0.2)
Satisfaction	13	0.846	2.46 (0.56)	1 (0.2)	1 (0.2)
Social/vocational worry	5	0.654	1.53 (0.93)	26 (6.2)	2 (0.5)
Diabetes-related worry	3	0.727	3.20 (0.65)	2 (0.5)	4 (1.0)
Total DQOL-AO	34	0.867	2.38 (0.43)	1 (0.2)	1 (0.2)

Construct Validity

Table 5.10 shows the construct validity results and its direction, with bold figures indicating better QOL. The results of ANOVA showed that education status (F = 7.164, p < 0.001) and employment status (F = 4.211, p = 0.02) demonstrated a significant difference in the DQOL–Afaan Oromoo scores of the participants. There was a significant difference between participants who attended college and above (2.23±0.40) and those who had not attended formal education (2.43±0.43, $p = 0.008$) or attended only elementary school (2.47±0.42, $p < 0.001$). However, those who attended college and above had better QOL. There was also a significant difference between government employees (2.23±0.39) and those who were retired/disabled (2.44±0.39, $p = 0.014$) or farmers (2.39±0.44, $p = 0.002$): better QOL was revealed amongst government employees. There was no statistically significant difference in QOL with other variables.

By contrast, diabetes-related complication(s) ($t = -1.397$, $p = 0.163$), marital status ($F = 1.047$, $p = 0.352$), and gender ($t = -1.064$, $p = 0.288$) showed non-significant results. In addition, a non-significant but positive correlation between age and DQOL–Afaan Oromoo ($r = 0.057$, $p = 0.242$) was obtained.

Table 5.10 Relationships between DQOL–Afaan Oromoo scores and demographic variables and pairwise comparison

Variables with Categories	**Frequency (n)**	**Mean Score**	**SD**	**Between-Group p-Value**	**Pairwise Comparison**
Age	217	r = 0.057		0.247	
Gender					
Female	214	2.40	0.42	0.288	
Male	203	**2.36**	0.42		
Diabetes-specific complication(s) status					
No	186	**2.35**	0.43	0.163	
Yes	231	2.41	0.42		
Marital status					
Married	323	**2.36**	0.42	0.352	
Never married	30	2.43	0.47		
Separated/widowed	64	2.44	0.43		
Education level					
No formal education	76	2.43	0.43	<0.001	College and above < elementary school, no formal education
Elementary school (≤ grade 8)	138	2.47	0.42		
Secondary school (grades 9–12)	101	2.37	0.42		
College and above	102	**2.23**	0.40		
Employment status					
Government employees	76	**2.23**	0.39	0.02	Government employees < retired/disabled, farmer
Private organisation employees	113	2.35	0.45		
Unemployed	73	2.39	0.41		
Retired/disabled	86	2.44	0.39		
Farmer	69	2.39	0.44		

r = Pearson correlation coefficient.

5.8.3.2.1 Discussion

According to cross-cultural adaptation guidelines, the original version of the DQOL scale was translated to Afaan Oromoo. The DQOL–Afaan Oromoo version was reliable and valid to measure diabetic-related QOL amongst adults with T2D who speak Afaan Oromoo. A 34-item DQOL–Afaan Oromoo organised into a four-factor solution was retained in the scale. These four factors were consistent with the original (The DCCT Research Group, 1988), Brazilian (Brasil et al., 2014), Brazilian brief (Brasil et al., 2015), Chinese (Jin et al., 2018), and Turkish (Yildirim et al., 2007) versions of the scale but inconsistent with the Malay versions (Bujang et al., 2018; Bujang et al., 2017).

A total of 15 items, six items from satisfaction, six items from impact, two items from social/vocational worry and one item from the diabetes-related worry scale, were deleted from the original scale. The dropping of these items can be attributed to two main reasons. Firstly, some of the deleted items may be less relevant for measuring the QOL of adults with diabetes. Amongst the 15 removed items in the DQOL–Afaan Oromoo version, seven items (Impact Item Nos. 3, 16, 19 and 20; Social/Vocational Worry Item Nos. 4 and 5; and Diabetes-Related Worry Item No. 4) were also removed in the revised Malay version (Bujang et al., 2018). Furthermore, the deleted Satisfaction Item No. 7; Impact Item Nos. 8, 16, 17, 19 and 20; and Social/Vocational Worry Item No. 5 harmonise with the items deleted in the Chinese version (Jin et al., 2018). Four items (Satisfaction Item No. 7 and Impact Item Nos. 3, 8 and 17) were dropped in this version, such as items deleted in the Chinese and brief DQOL-Brazil-8 versions. Second, these items are redundant in depicting QOL amongst adults with diabetes. For instance, the satisfaction items 7 and 15 and impact items 4 and 16 are consistent with the Malay version (Bujang et al., 2018). The social/vocational worry items 4 and 5 were dropped from the subscale. Perhaps most participants were employed or retired and may not be concerned about employment. The removal of these items indicates that they are less relevant to measuring the satisfaction and impact amongst people with diabetes who comprehend Afaan Oromoo. The DQOL–Afaan Oromoo is a relatively short scale obtained with good psychometric properties; hence it is potentially suitable for assessing QOL amongst Oromoo people with T2D, especially in busy clinical settings.

The overall DQOL–Afaan Oromoo showed a good internal consistency, such as the Turkish and Chinese versions (Jin et al., 2018; Yildirim et al., 2007). The impact subscale revealed better internal consistency compared with the original and a revised Malay version (Bujang et al., 2018) and was consistent with the Chinese (Jin et al., 2018) and Turkish versions (Yildirim et al., 2007). The satisfaction subscale's internal consistency revealed good reliability consistent with the original version (The DCCT Research Group, 1988) and different from the revised 13-item Chinese, Malay, revised Malay and Turkish versions (Bujang et al., 2018; Bujang et al., 2017; Jin et al., 2018; Yildirim et al., 2007). Whilst the diabetes-related worry subscale demonstrated good internal consistency in this study, the social/vocational worry subscale was questionable. These findings were inconsistent with the Chinese, Turkish, Malay and revised Malay versions (Bujang et al., 2018; Bujang et al., 2017; Jin et al., 2018; Yildirim et al., 2007), but the low level of internal consistency compared with the original version (The DCCT Research Group, 1988). The possible difference in internal consistency in the social/vocational worry subscale is perhaps because they rate all of the items on the scale with low scores. Another justification for the low internal consistency amid worry items could be that few items were in the domain (Schrepp, 2020). In addition, this scale addresses the more specific apprehension of people with diabetes having insights into diabetes-related psychological distress (The DCCT Research Group, 1988).

The known-group analyses revealed that education level and employment status were associated with QOL amongst people with T2D. Attending tertiary education and being government employees were associated with better QOL. These results were in accord with the study done in Botswana and Gondar, Ethiopia, amongst people with diabetes, which reported that educated and employed patients had better QOL (Aschalew et al., 2020; Rwegerera et al., 2018). No significant association was obtained between people with diabetes in terms of age and overall QOL, which is different from the finding of (Jacobson et al., 1994). Females are likely to demonstrate a lower QOL, which was consistent with the results from the Chinese population (Cheng et al., 1999).

Nevertheless, being comorbid with diabetes-related disease(s), marital status and gender of participants showed non-significant results that were unlike those from an earlier study done in Botswana (Rwegerera et al., 2018). Previous studies reported that those married had better QOL than those separated/widowed (Imayama et al., 2011; Jacobson et al., 1994; Rwegerera et al., 2018), which is similar to this study's result. The better QOL, perhaps owing to the marriage status, may obtain support from their families/partners, thus enhancing their QOL (Diriba et al., 2020; Imayama et al., 2011). This result demonstrated a significant worry because of diabetes and is comparable with research conducted in Spain (Rodríguez-Almagro et al., 2018).

5.8.3.2.2 Conclusions

The 34-item DQOL–Afaan Oromoo provided preliminary evidence as a reliable and valid tool to measure QOL amongst adults with T2D who speak Afaan Oromoo. Future research should assess the psychometric properties, such as test–retest reliability and the predictive validity of the 34-item DQOL–Afaan Oromoo before it can be widely used amongst adults with T2D who understand Afaan Oromoo.

5.8.3.3 DCP support scale

5.8.3.3.1 Introduction

Social support helps people with diabetes with different self-management activities and can protect the risk of getting stress. Some studies have pointed out that social support improved self-management capacity of people with diabetes and decreased the risk of negative impact of people with T2D (Kadirvelu et al., 2012; Koetsenruijter et al., 2016), whilst one study has reported the negative impact of family on adherence to self-management (Gherman et al., 2011). The Michigan Diabetes Research Centre developed the DCP questionnaire to measure the social and psychosocial factors of diabetes and its treatment. The scale has three subscales: support needs, support received and support attitudes (The Michigan Diabetes research center, 1998). Validation of DCP was done in Chinese and English language versions involving Chinese (Li et al., 2015) and African Americans (Fitzgerald et al., 1998) with T2D, respectively. The internal consistency of the support needs was 0.61, support received was 0.73, and support attitude was 0.77 in the Chinese version (Li et al., 2015); however, the internal consistency amongst African Americans was high for support needs (0.94), support received (0.93) and support attitudes (0.72). Similarly, the consistency of the scale for Caucasians for support needs, support and support attitudes were 0.94, 0.92, and 0.68, respectively. The DCP-support scale seems to be useful in measuring diabetes-related social support, yet it is not available in the Afaan Oromoo language for its use in Western Ethiopia.

5.8.3.3.2 Instrument

The DCP-support scale contains three domains, support needs (six items), support received (six items) and support attitudes (six items). Items 3(b), (d) and (f) were scored reversely. The mean score of the subscales was separately computed, with a higher score indicating better support (The Michigan Diabetes research center, 1998).

5.8.3.3.3 Results

Sociodemographic characteristics of the participants

Amongst 460 people with T2D who consented to participate in the study, 452 gave complete data. The same study population participated with participants in the psychometric evaluation of the SDSCA. Hence, details of the participants' sociodemographic characteristics have been reported in **Table 5.1**.

Factor Structure

(i) Item–total Correlation

An item–total correlation was performed to examine the correlation between individual items and each subscale's total items. As indicated in **Table 5.11**, all items had a greater than 0.3 correlation; hence, all items were subject to EFA.

Table 5.11 Item–total correlation of the DCP support scales

Items	Item–total Correlation
Support needed	
Q1. I want plenty of help and support from my family or friends in:	
a) following my meal plan.	0.602
b) taking my medicine.	0.632
c) taking care of my feet.	0.656
d) getting enough physical activity.	0.548
e) testing my sugar.	0.519
f) handling my feelings about diabetes.	0.619
Support received	
Q2.My family or friends help and support me a lot to:	
a) follow my meal plan.	0.450
b) take my medicine.	0.306
c) take care of my feet.	0.675
d) get enough physical activity.	0.730
e) test my sugar.	0.474
f) handle my feelings about diabetes.	0.353
Support attitudes	
Q3.My family or friends:	
a) accept me and my diabetes.	0.475
b) feel uncomfortable about me because of my diabetes.	0.384
c) encourage or reassure me about my diabetes.	0.511
d) discourage or upset me about my diabetes.	0.461
e) listen to me when I want to talk about my diabetes.	0.455
f) nag me about diabetes.	0.491

(ii) Exploratory factor analysis

An EFA was conducted to examine the factor structure of the support scale. The KMO statistic was 0.786, and Bartlett's test statistic was 3031.936 ($p < 0.001$), implying sampling adequacy and appropriateness for factor analysis. Results from the eigenvalues suggest a four-factor solution, whereas the scree plot suggests a three-factor solution. On the basis of the interpretability of the factors and the result of the scree plot, a three-factor solution was selected—the factor solutions comprising 51.59% of the total variance. **Table 5.12** shows the factor structure and item loading on the factors., such as the original version, the pattern matrix with oblimin rotation of the items provided three factors, and the items were explicitly loaded on the entire factors with the more interpretative pattern. The naming of the factors resembles the original version.

Table 5.12 Factor structure and items loading on the factors of DCP Support-Afaan Oromoo scale

Items		Factor 1	Factor 2	Factor 3
Support needed				
Q1.	I want a lot of help and support from my family or friends in:			
a)	following my meal plan.	0.770		
b)	taking my medicine.	0.785		
c)	taking care of my feet.	0.781		
d)	getting enough physical activity.	0.665		
e)	testing my sugar.	0.627		
f)	handling my feelings about diabetes.	0.734		
Support received				
Q2.	My family or friends help and support me a lot to:			
a)	follow my meal plan.		0.564	
b)	take my medicine.		0.412	
c)	take care of my feet.		0.837	
d)	get enough physical activity.		0.881	
e)	test my sugar.		0.736	
f)	handle my feelings about diabetes.		0.439	
Support attitudes				
Q3.	My family or friends:			
a)	accept me and my diabetes.			0.528
b)	feel uncomfortable about me because of my diabetes.			0.495
c)	encourage or reassure me about my diabetes.			0.652
d)	discourage or upset me about my diabetes.			0.771
e)	listen to me when I want to talk about my diabetes.			0.619
f)	nag me about diabetes.			0.773

Reliability estimates

Table 5.13 shows the internal consistency, ceiling and floor effects of the DCP support–Afaan Oromoo scale and its subscales. Acceptable reliability was demonstrated in the overall DCP support–Afaan Oromoo scale with an internal consistency of 0.75. Whilst the support needed scale showed good reliability (0.81), the support received (0.75) and support attitudes (0.71) scales showed acceptable reliability. There was no evidence of any ceiling and floor effects in the scale and subscales.

Table 5.13 The internal consistency, ceiling, and floor effects of the DCP support–Afaan Oromoo version

Scale/subscale	Number of items	Cronbach's Alpha	Ceiling effect n (%)	Floor effect n (%)
Support needed	6	0.81	1 (0.2)	2 (0.4)
Support received	6	0.75	1 (0.2)	8 (1.7)
Support attitudes	6	0.71	1 (0.2)	1 (0.2)
DCP Support–Afaan Oromoo	18	0.75	1 (0.2)	1 (0.2)

Construct validity

Table 5.14 presents the construct validity results and the direction of the relationship of the support scales with the sociodemographic and diabetic-specific variables. The result of the Pearson correlation showed that age ($r = 0.111$, $p = 0.019$) demonstrated a statistically significant difference in the support needs. The independent sample t-test showed whether having a family care provider ($t = 2.130$, $p = 0.034$) had a statistically significant difference in the support needs. There were statistically significant differences between those who needed support from the spouse and child. Those married had better support needs than those who were unmarried. The results of ANOVA showed that education level ($F = 16.813$, $p<0.001$) and employment status ($F = 5.365$, $p<0.001$) had statistically significant differences in the support received. Those who have attended tertiary education had better support (4.66±0.42) from their family caregivers than those who have attended secondary school (4.61± 0.40). There was a statistical difference between those who were government employees, merchants and farmers in support received. There was a significant difference in family care providers ($t = 2.997$, $p = 0.03$) and support attitudes.

By contrast, age ($r = 0.043$, $p = 0.374$), gender ($t = 0.193$, $p = 0.847$), marital status ($Z = -1.122$, $p = 0.262$), ethnicity ($t = -0.315$, $p = 0.753$), education level ($F = 2.366$, $p = 0.070$) and employment status (F = 1.217, p = 0.296) were found as non-significant associated factors of support needs. Similarly, age (r = 0.043, p = 0.374), gender (t = 0.957, p = 0.339), marital status (t = −0.833, p = 0.405), ethnicity (t = −0.556, p = 0.579), care provider (t = 0.808, p = 0.419) and employment status (F = 1.315, p = 0.249) demonstrated non-significant difference in support received. Besides, age (r = 0.040, p = 0.391), gender (t = 1.401, p = 0.162), marital status (t = −0.724, p = 0.469), ethnicity (t = 0.867, p = 0.386), care provider (t = 2.997, p = 0.03), education level (F = 1.481, p = 0.219) and employment status (F = 1.315, p = 0.249) were non-significantly associated with support attitudes.

Table 5.14 Construct validity of the DCP support–Afaan Oromoo scale

Support subscales	Categories with frequency	Mean score	SD	Between-group P-value	Pairwise comparison
Support needs	Male: 216	4.71	0.44	0.847	
	Female: 231	4.70	0.47		
Support received	Male: 212	3.76	0.83	0.339	
	Female: 226	3.69	0.77		
Support attitudes	Male: 219	4.63	0.48	0.162	
	Female: 232	4.57	0.50		
Support needed	Never married: 101 Married: 346	4.39 4.72	0.77 0.41	<0.001*	Married < never married
Support received	Never married: 101 Married: 336	3.74 3.72	1.09 0.77	0.889*	
Support attitudes	Never married:102 Married: 349	4.53 4.62	0.53 0.48	0.099	
Support needs	Oromo: 397 Amhara: 50	4.70 4.72	0.47 0.29	0.753	
Support received	Oromo: 391 Amhara: 47	3.72 3.78	0.80 0.77	0.579	
Support attitudes	Oromo: 401 Amhara: 50	4.60 4.54	0.48 0.57	0.386	
Support needed	Spouse: 269 Child:179	4.74 4.65	0.36 0.56	0.034*	Spouse < child
Support received	Spouse: 260 Child:178	3.75 3.69	0.74 0.87	0.419	
Support attitudes	Spouse: 272 Child:179	4.65 4.51	0.42 0.57	0.003*	Spouse < child
Support needs	No formal education: 81 Elementary education:151 Secondary education: 113 Tertiary education:106	4.82 4.70 4.66 4.66	0.30 0.53 0.43 0.45	0.070	

Support received	No formal education: 81 Elementary education:151 Secondary education: 113 Tertiary education:106	4.51 4.58 4.61 4.66	0.69 0.47 0.40 0.42	0.001*	Tertiary education < secondary education
Support attitudes	No formal education: 81 Elementary education:151 Secondary education: 113 Tertiary education:106	4.51 4.58 4.61 4.66	0.69 0.47 0.40 0.42	0.219	
Support needs	Employment status Government employees:81 Private employees: 42 Merchant:72 Homemaker:63 Retired:90 Farmer:74 Others:25	 4.62 4.73 4.77 4.66 4.77 4.68 4.64	 0.63 0.29 0.31 0.47 0.32 0.53 0.44	0.296	
Support received	Employment status Government employees:80 Private employees: 42 Merchant:68 Homemaker:63 Retired:87 Farmer:73 Others:25	 3.97 4.05 3.54 3.76 3.75 3.41 3.56	 0.92 0.79 0.69 0.91 0.70 0.62 0.69	0.001*	Government employee <merchant <farmer
Support attitudes	Employment status Government employees:83 Private employees: 42 Merchant:72 Homemaker:64 Retired:91 Farmer:74 Others:25	 4.67 4.58 4.66 4.49 4.61 4.52 4.61	 0.42 0.59 0.43 0.46 0.44 0.64 0.43	0.249	

*Statistically significant

5.8.3.3.3 Discussion

The psychometric properties testing of the DCP-support scale to measure the perception of social support from the person with diabetes perspective was performed. The results showed that the original three-factor structure of the DCP-support scale was reproduced in the Afaan Oromoo version of the scale with the current sample of people with diabetes in Ethiopia, showing the factorial validity of the DCP support–Afaan Oromoo scale. The scale also showed an acceptable correlation between each item and the total items in the scale. All three subscales showed acceptable reliability. The acceptable internal consistency of support needed is consistent with most of the other language versions except the Chinese version (Li et al., 2015), which showed questionable reliability, and the studies involved the African Americans and Caucasian versions (Fitzgerald et al., 1998), which showed excellent reliability. The possible explanation in this study is that items in the support needed scale address the support needed issues in the Ethiopian population. The support received scale reliability showed an acceptable consistency. This finding is consistent with the Chinese version (Li et al., 2015) and inconsistent with studies that involved African Americans and Caucasian people versions (Fitzgerald et al., 1998). The variation in the finding from African Americans and Caucasian versions may be because people with diabetes in Ethiopia have more economic and emotional support needed. The support attitudes' internal consistency is found to be acceptable. This result aligns with the study conducted amongst the Chinese population (Li et al., 2015) and African Americans but is inconsistent with the Caucasian population (Fitzgerald et al., 1998). The disparities could be due to the culture of social interaction amongst the population (Baig et al., 2015).

The construct validity results showed that age, education level and employment status were significantly associated with the three support subscales. These findings are consistent with the Chinese version (Li et al., 2015), demonstrating that age significantly affected the support needs. The spouse was one of the typical support providers for people with diabetes; this finding is congruent with the review finding, which reported that the spouse had an influential role in dietary adherence (Albanese et al., 2019). Individuals who attended higher education had better support from their family or friends. The educated person can convince and lobby the families and friends to receive support. Those government-employed showed a significant influence in support, which may be due to being more trusted in government institutions; hence, more attention from friends and families. Marital status was not significantly correlated with any of the support scales. This finding was inconsistent with a study done in the United States (Idalski Carcone et al., 2011). Ethnicity was not considerably influencing the support; this finding is congruent with the Chinese version (Li et al., 2015). The result implies that race or ethnicity may not relate with support in diabetes management.

5.8.3.3.4 Conclusions

The support needed, support received and support attitudes scale in the Afaan Oromoo language amongst adults with T2D showed acceptable reliability, factorial and construct validity. Thus, the results provided promising evidence to support the DCP support–Afaan Oromoo scale to measure the support status of people with T2D who understand Afaan Oromoo.

5.4 Part Two: Psychometric Property Testing of the Scale used to Measure the Family Caregiver's Outcome

5.4.1 DFBC

5.4.1.1 Introduction

Family behaviour is a pattern of behaviour that a family uses for dealing with family situations (Epstein et al., 2003). The DFBC measures the family's status of support and non-supportive behaviour related to diabetes-specific self-care, including diet, blood glucose, medication and exercise. The DFBC is a short and comprehensive scale to assess the family support related to self-care activities provided for people with diabetes. The scale was selected based on its appropriateness to measure the support level, and it is a specific tool to measure diabetes family support. Previous studies reported acceptable internal consistency of the supportive behaviour subscale, ranging between 0.71 (Glasgow & Toobert, 1988; Lewin et al., 2005) and 0.73 (Schafer et al., 1986), whereas a wide range for the non-supportive behaviour scale amongst adult families, from 0.43 (Schafer et al., 1986), 0.64 (Glasgow &

Toobert, 1988), to 0.71 (Lewin et al., 2005). The test–retest value of the original version showed reliability over time with a correlation of 0.95 for supportive (positive) and 0.77 for non-supportive (negative) subscales (Schafer et al., 1986). The Japanese version's Cronbach's alpha of the DFBC for those taking insulin was 0.950 for supportive, and 0.928 for non-supportive domain, and the Cronbach's alpha for the oral hypoglycaemic agent user was 0.946 for supportive and 0.938 for non-supportive behaviour. The scale's validity shows a positive correlation with self-management dietary and exercise behaviours. The study reported that the scale is satisfactory for measuring the family support level for people with diabetes. In the Japanese version, three items were deleted, including item 8 ('Encourage you to participate in sports activities'), item 12 ('Eat at the same time that you do') and item 16 ('Eat food that is not part of your diabetic diet') (Hara et al., 2013). There was no psychometrically tested Afaan Oromoo version of the DFBC; thus, the stability and psychometric properties of the scale were evaluated.

5.4.1.2 Objective of the study

To test the psychometric properties of the DFBC.

5.4.1.3 Methods

5.4.1.3.1 Study design

The longitudinal study design with a one-month follow-up was conducted to assess the internal consistency and test–retest reliability of the DFBC scale. The test-retest reliability was conducted due to the difficulty of involving the larger family members due to COVID-19 cases surge and difficulty to access them during the study period.

5.4.1.3.2 Participants

Subject recruitment using the convenience sampling method was conducted between November and December 2020 by approaching people with T2D attending Nekemte Specialised Hospital and asking them to nominate one primary caregiver from their family members. Then, the telephone number of the nominated family caregiver was obtained, and the family was approached for eligibility via telephone. The family members were included if they 1) were the primary caregiver of the individual with T2D, 2) were aged 18 or over, 3) lived in the same home with people with T2D, 4) provided consent to participate in the study. The families were excluded if they were potentially unavailable during the retest.

5.4.1.3.3 Instrument

The scale comprises16 items and was organised into two subscales. Nine items (items 1, 3, 5, 8–10, 12, 13 and 15) measure the supportive, and seven items (items 2, 4, 6, 7, 11, 14 and 16) measure the non-supportive behaviour of the family. Each item was rated with a scale ranging from 1 (never) to 5 (at least once a day), which shows the frequency of family support (Schafer et al., 1986). The mean score of the supportive and non-supportive items was obtained separately, and higher scores indicated stronger family perception to support people with diabetes (Glasgow & Toobert, 1988).

Besides the items in the scale, the family caregiver's sociodemographic variables, including age, gender, marital status, ethnicity, religion, education level and employment status, were collected.

5.4.1.3.4 Sample size

The required sample size was estimated assuming an 80% power, and a 95% confidence level to detect the significance of an intraclass correlation coefficient (ICC) of 0.4, and the minimum sample size is 36 (Bujang & Baharum, 2017). Adding 10% of the dropout rate, the required sample size was 40.

5.4.1.3.5 Data collection procedure

Two data collectors who have experience in data collection were oriented on the scale and the recruitment process. Firstly, the data collectors approached the people with T2D when they were waiting to get medical care in the diabetes centre of Nekemte Specialised Hospital. Data collectors contacted an eligible family member via telephone and obtained verbal consent to participate in the study. The interview was conducted via telephone. The retest was conducted a month after the first test via telephone.

5.4.1.3.6 Statistical analysis

The descriptive statistics to examine the frequency, percentage, mean and SD of the variables were computed. The item–total correlation, Cronbach's alpha to estimate the internal consistency, and the two-way mixed-effects model with an average ICC were calculated. ICC is widely used to measure test–retest reliability with values <0.5 indicates poor, 0.5−0.75 reveals the moderate, 0.75−0.9 shows good, and >0.90 indicates excellent reliability (Koo & Li, 2016). EFA was not computed because the sample was inadequate for exploratory factor analysis (KMO = 0.203). On the basis of the recommendation of the item developer, analysis for subscales was performed separately, and a higher score indicates a more frequent family supportive/non-supportive behaviour (Glasgow & Toobert, 1988). A p-value of <0.05 was considered statistically significant. The construct validity was not done for this scale because the sample size is small, so the chance of getting statistically non-significant is likely.

5.4.1.3.7 Ethical consideration

Ethical approval was obtained from the Institutional Review Board of Wollega University to conduct the study (Reference Number: WU 165,429/D1-21). The study was conducted following the declaration of Helsinki. Permission to collect data was obtained from the Nekemte Specialised Hospital administrator. The voice of the respondents was not recorded.

5.4.1.4 Results

5.4.1.4.1 Sociodemographic characteristics of the participants

A total of 40 primary family caregivers of randomly selected people with diabetes attending Nekemte Specialised Hospital were recruited via telephone in November 2021. **Table 5.15** presents the sociodemographic characteristics of the family caregivers. The mean age of the participants was 36.75 (SD±12.01). More than half (57.5%) of the participants were male, and nearly a third quarter (72.5%) were married. The majority (90.0%) of the participants were Oromoo, and nearly two-thirds (60.0%) were protestant Christians. Half of them (50.0%) attended tertiary education, and nearly half (45.0%) were government, NGO and private organisation employees.

Table 5.15 Sociodemographic characteristics of family caregivers

Variables with categories	Frequency (%)
Age in years (mean ± SD)	36.75±12.01
Gender	
Male	23 (57.5%)
Female	17 (42.5%)
Marital status	
Never married	11 (27.5%)
Married	29 (72.5%)
Ethnicity	
Oromoo	36 (90.0%)
Amhara	4 (10.0%)
Religion	
Protestant Christian	24 (60.0%)
Orthodox Christian	14 (40.0%)
Educational status	
No formal education	4 (10.0%)
Elementary school (≤grade 8)	4 (10.0%)
Secondary school (grades 9–12)	12 (30.0%)
Tertiary education	20 (50.0%)
Employment status	
Government/private/NGO/employee	18 (45%)
Merchant	6 (17.5%)
Unemployed	16 (40.0%)

5.4.1.4.2 Item–total correlation

The item–total correlation of the scale was computed for supportive and non-supportive items separately. The test–retest items were pooled together to determine their correlation. **Table 5.16** indicates the item–total correlation of the items in entire subscales. The items with item–total correlation below 0.3 were deleted, i.e. items 4, 5, 9 and 10. Items 4 and 11 were negatively correlated with other items. Reliability estimates were calculated for the remaining 12 items.

Table 5.16 Item-Total correlation of the diabetes family behaviour checklist -Afaan Oromoo scale

Item number	Questions	Item-Total Correlation
Supportive items		
1	Praise the patient for following his/her diet	0.362
3	Suggest things that might help the patient take insulin on time	0.472
5	Help the patient decide if changes should be made based on blood testing results	**0.186**
8	Encourage the patient to participate in sports activities	0.368
9	Plan family activities so that they will fit in with his/her diabetes self-care schedule	**0.186**
10	Congratulate the patient for sticking to his/her diabetes self-care schedule	**0.090**
12	Eat at the same time that the patient does	0.313
13	Exercise with the patient	0.358
15	Buy the patient things containing sugar to carry in case of an insulin reaction	0.454
Non-supportive items		
2	Nag the patient about testing his/her blood	0.665
4	Criticize the patient for not exercising regularly	**-0.136**
6	Nag the patient about not following his/her diet	0.762
7	Argue with the patient about his/her diabetes self-care activities	0.531
11	Criticize the patient for not recording the results of blood tests	-0.485
14	Let the patient sleep late rather than getting him/her up to take his/her insulin	0.562
16	Eat foods that are not part of the patient's diabetic diet	0.304

Reliability estimates

The Cronbach's alpha values of the DFBC–Afaan Oromoo were 0.725 and 0.761 for supportive and non-supportive subscales, respectively. The Cronbach's alpha of the total scale was not computed because the items are not correlated as they measure two different dimensions: positive and negative. A two-way mixed model with mean ratings at 95% CI ICC was computed to assess the agreement of the DFBC at a one-month interval. The ICC of the overall DFBC was 0.593, which shows moderate consistency (Koo & Li, 2016). The ICC of the non-supportive DFBC subscale was 0.725, which shows moderate, whereas the supportive DFBC's ICC was 0.761, which reveals good test–retest reliability.

5.4.1.5 Discussion

The DFBC was tested using ICC amongst family members of people with T2D. Twelve items (six in supportive and six in non-supportive) were retained after the item–total correlation test. Most people in Ethiopia prefer to walk due to inaccessibility to transport; hence, the deleted item 4 is less important to measure family support given to people with diabetes in Ethiopia. Item 5 may be deleted due to the unavailability of a glucometer to perform blood glucose testing frequently; thus, the family members may not ask them to record their blood glucose level. Items 9 and 10 were deleted because of the lack of regular self-care schedules amongst people with diabetes in Ethiopia (Habebo et al., 2020). The deleted items were not congruent with the Japanese version (Hara et al., 2013), in which three items (items 8, 12 and 16) were omitted. The variation in the number of items deleted may be due to variations in the gender of the study population. The study suggests that females are actively involved in family support (Horikawa et al., 2020), and 42.5% of females participated in this study whilst 56.3% participated in the Japanese version (Hara et al., 2013).

The test–retest ICC values for the DFBC were 0.725 for supportive and 0.761 for non-supportive behaviours. These findings show moderate reliability for supportive and good reliability for non-supportive domains (Koo & Li, 2016). The supportive domain reliability result is inconsistent with the original version (Schafer et al., 1986); however, the reliability of the non-supportive domain is consistent. This inconsistency in the supportive domain may be due to the items in this domain focused on people with T2D. The negative items in non-supportive items showed similar behaviour of the families.

In addition, the reliability of supportive domain items was inconsistent with the study involving Japanese with diabetes (Hara et al., 2013). This variation from the Japanese version may be because of variation in sample size and deleted items. Whilst 327 people with diabetes and their family caregivers were involved in the Japanese version study (Hara et al., 2013), only 40 family caregivers were involved. The strength of this study was that the scale was tested for test–retest reliability with a follow-up assessment at 1-month. However, it lacks the generalisation of the results because of the small sample size. Another limitation was that the factor structure of the scale was not tested. Hence, the DFBC–Afaan Oromoo is reliable for measuring the family behaviour of those with diabetes. Future psychometric studies on the DFBC–Afaan Oromoo should focus on factorial and construct validity by including a large sample.

5.4.1.6 Conclusions

The DFBC Afaan Oromoo version is a short and quick scale with acceptable reliability to assess people with diabetes support received from their families. Further study is needed to assess the psychometric properties of this tool in Afaan Oromoo.

5.5 Chapter summary

A translation was conducted, and the psychometric characteristics of four scales were determined. The 10 items of the SDSCA–Afaan Oromoo scale, 34 items of the DQOL–Afaan Oromoo scale and 18 items of the support–Afaan Oromoo scale demonstrated acceptable reliability and good construct validity amongst people with T2D in Western Ethiopia. The DFBC–Afaan Oromoo provides preliminary evidence to measure the family support status. However, further studies are needed to evaluate other psychometric properties of these scales.

CHAPTER SIX: METHODS AND MATERIALS

6.1 Introduction

This chapter presents the methods and materials to conduct the feasibility and pilot RCT. This chapter is organised into 16 sections. Section 6.1 presents the introduction of the chapter. Section 6.2 presents the study's aim and objectives. Section 6.4 to Section 6.15 present the methodological rigour applied to conduct the study. The methodological rigour of this trial was conducted and reported according to the Consolidated Standards of Reporting Trials (CONSORT) 2010 statement, an extension to a randomised pilot and feasibility trials (Eldridge et al., 2016). Lastly, the summary of the chapter is presented in Section 6.16. The trial protocol was registered prospectively by the Chinese clinical registry with the registration number ChiCTR2000040292, and a brief version of the protocol has been published (Diriba et al., 2021c).

6.2 Aim and objectives of the pilot RCT

Aim: To examine the feasibility, acceptability and preliminary effects of a nurse-led community-based DSMES programme on people with diabetes on SBP, DBP, BMI, HbA1c, total cholesterol, LDL cholesterol, HDL cholesterol, triglycerides, self-management practise, DQOL, perceived support status and family caregiver's supportive behaviour in Western Ethiopia through a pilot RCT.

Objectives

1. To determine the eligibility rate, recruitment rate, retention rate and item-level missing rate for people with diabetes and family caregivers in Western Ethiopia.
2. To examine the preliminary effects of a nurse-led community-based DSMES programme on people with diabetes SBP, DBP, BMI, HbA1c, total cholesterol, LDL cholesterol, HDL

cholesterol, triglycerides, self-management practises, DQOL, perceived support status and family caregiver's supportive behaviour in Western Ethiopia.

3. To estimate the effect sizes for a nurse-led community-based DSMES programme for people with diabetes SBP, DBP, BMI, HbA1c, total cholesterol, LDL cholesterol, HDL cholesterol, triglycerides, self-management practise, DQOL, perceived support status and family caregiver's supportive behaviours in Western Ethiopia.
4. To identify the acceptability of the DSMES programme for dyads in the intervention group in Western Ethiopia.

6.3 Study design

A two-arm, parallel-group pilot RCT with a 1:1 allocation ratio of the intervention to the control group and a post-intervention and a follow-up in the second month was conducted. **Figure 6.1** delineates the flow diagram for enrolment of the participants, outcome assessments and acceptability assessment at each time-point of the pilot RCT.

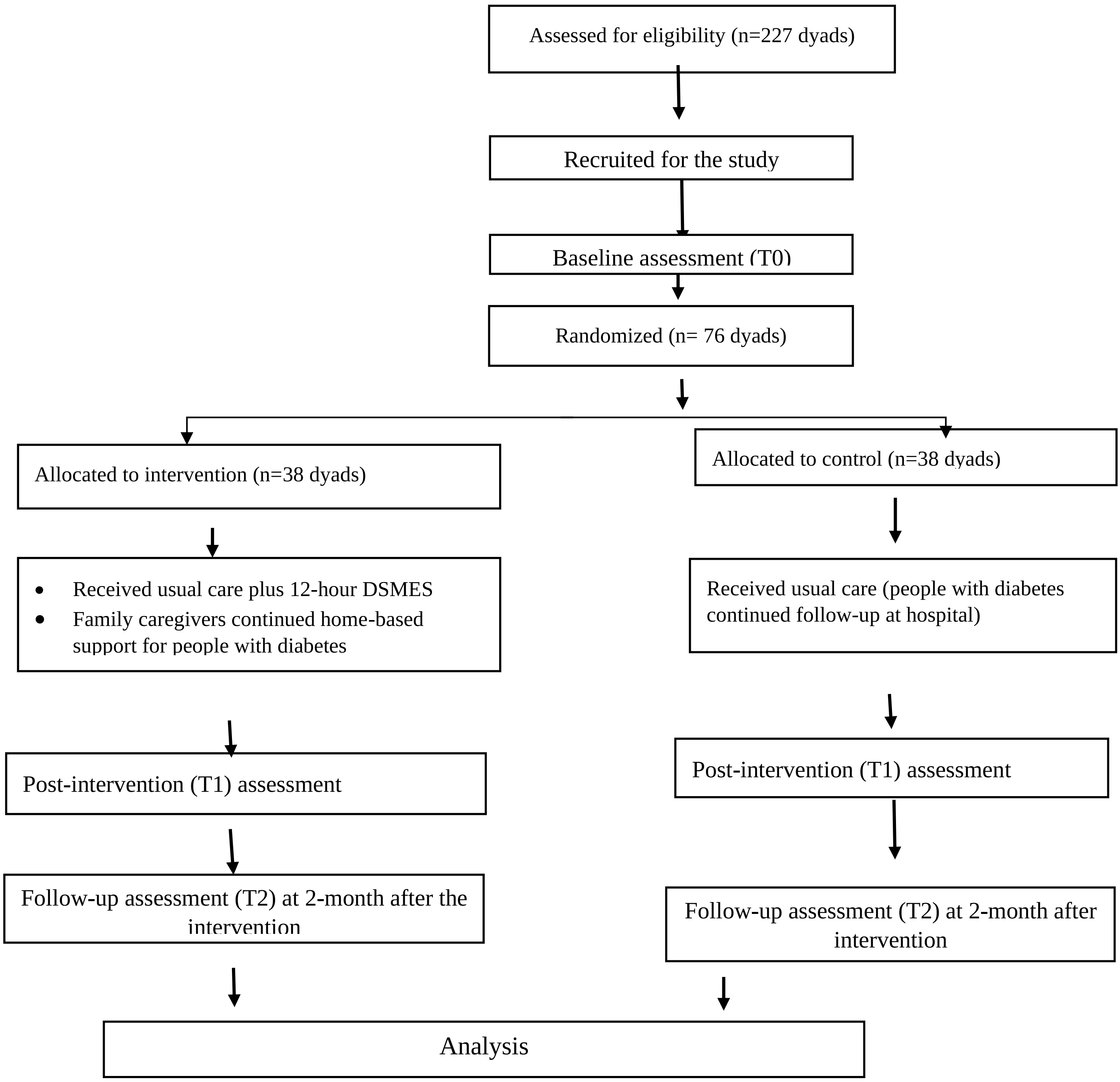

Figure 6.1 Flow diagram for enrolment of the participants, outcomes and acceptability assessments

6.3.1 Rationale for conducting a pilot RCT

According to the British MRC framework, four key elements (the development of the intervention, testing for feasibility/pilot of the study methods, evaluation of treatment effectiveness and intervention implementation) can be conducted. The MRC framework is a cyclical process (Craig P, 2019). Availability of the evidence, identifying appropriate theory to guide the intervention, and the intervention outcomes are needed to be considered to develop an intervention. A feasibility/pilot study can be conducted using a developed intervention protocol to estimate recruitment rate, retention rate, test procedures of intervention and determine sample size. An evaluation of the intervention regarding its effectiveness can be assessed. On the basis of the effectiveness of the intervention, implementation of the intervention will be scaled up for a large population and practised in a natural setting.

A National Institute for Health Research of the UK defined the terms of feasibility studies and pilot studies separately. A feasibility study is 'a piece of research done before the main study' to answer the question "Can this study be done?" A pilot study is defined as 'a smaller version of the main study used to test whether the components of the main study can all work together. It is focused on the processes of the main study to ensure that recruitment, randomisation, treatment and follow-up assessments all run smoothly' (National Institute for Health Research, 2020). Feasibility studies can be done to understand the willingness of participants to participate in randomisation, the willingness of the clinicians to recruit subjects, to know the eligibility rate, follow-up rates, rates of response to the questionnaire and compliance rate. However, pilot studies ensure that recruitment, randomisation, treatment and follow-up assessments are done together (National Institute for Health Research, 2020). Another framework developed to define feasibility and pilot studies demonstrated that a pilot study includes a feasibility study; however, a feasibility study precedes the pilot study (Eldridge et al., 2016). Thus, the term pilot study is broadly used in this study. Under the umbrella of the pilot study, the feasibility of the study was addressed.

There are several reasons for conducting pilot studies in randomised controlled studies. The MRC suggests testing the feasibility and piloting on a small scale to know the acceptability of the intervention and prepare for full-scale study, intervention delivery and compliance with the intervention (Craig P, 2019). A pilot study may be conducted because of the unknown recruitment rate, retention rate, refusal rate, intervention adherence rate, eligibility criteria, assess the time and resources needed, know the problems related to participation, assess the intervention safety and doses (Thabane et al., 2010). In this doctoral study, a pilot study was conducted for four main reasons: 1) a community based DSMES was not tested in Ethiopia, 2) the feasibility and acceptability of the trial are unknown, 3) the effect size of the intervention outcome is unknown and 4) time constraint. This doctoral study conducted intervention development and feasibility/piloting of the intervention. Full-scale RCT will be conducted in the future based on the finding of feasibility and pilot RCT results. The developed intervention was tested for its feasibility to estimate the rates of eligibility, recruitment, retention and item-level missing data; and the pilot study was conducted to examine the preliminary effects of the intervention on the outcomes. Between-group differences effect sizes were computed.

6.4 Study setting

Participants were recruited in Nekemte Specialised Hospital, and the intervention was conducted in the community of two selected Kebeles in Nekemte, Western Ethiopia. Two tertiary hospitals, namely, Nekemte Specialised Hospital and Wollega University Referral Hospital, are situated in the city. These two hospitals provide diabetes care. However, due to the COVID-19 pandemic, the government has designated Wollega University Referral Hospital as one of the COVID-19 care centres, and Nekemte Referral Hospital was the only hospital to provide diabetes care in the community during the study period. This hospital serves 1,562 people with diabetes for monthly follow-up after the recruitment for the pilot RCT (Nekemte Specialised Hospital, 2020). The city has six Kebeles. Kebele is a small administrative unit with at least 500 families (Wikipedia, 2022). The territory of each Kebele is not wide and, on average, two kilometres. The two selected Kebeles had high numbers of people with diabetes and were easily accessible for the intervention. It was impossible to include participants from all of the six Kebeles due to the distance between the Kebeles and the availability of intervention centres. The number of people with diabetes in the two selected Kebeles was 92 and 108.

6.5 Participants

Study participants were dyads (people with T2D and one of their nominated family caregivers) living in Nekemte, Western Ethiopia. People with diabetes were included if 1) they were with T2D (from their medical records); 2) they were aged 18 or over; and 3) they came from the two selected Kebeles in Nekemte and (4) were taking insulin and/or oral hypoglycaemic agents (Appendix III). Those were excluded if 1) they were unable to nominate primary family caregivers who can support them in diabetes management (usually, a spouse, mother, father, child or siblings will provide care for people with diabetes in Ethiopian society) at home; 2) they did not fulfil the inclusion criterion of 'having primary caregiver'; 3) they were a pregnant woman with T2D; 4) they had a physical limitation; 5) they did not live in the two selected Kebeles; 6) they do not have T2D; 7) they were aged below 18 years; 8) they were not taking anti-diabetic medicine; and 9) they could not understand Afaan Oromoo. In a situation where people with diabetes came with more than one family caregiver to attend the intervention, all of the family caregivers could receive the assigned intervention; however, only one primary family caregiver was selected to join the study and participate in the outcome assessments.

Family caregivers were included if 1) they were the primary family caregiver; 2) they were aged 18 or over; 3) they were willing to provide support; and 4) they were living with the people with diabetes. They were excluded if 1) they had physical limitations preventing them from performing the caregiver responsibilities and 2) they could not understand Afaan Oromoo.

6.6 Interventions

The participants were randomly allocated into two arms. The control arm received the usual care from the participating hospital, and the intervention arm received the usual care and the DSMES programme.

a) Control group

Usual care in the hospital includes pharmacological management approaches to diabetes. According to the participating hospital schedule, people with diabetes attend the diabetes centre every month. Nurses and physicians take a health history and conduct a physical examination. Medical laboratory professionals routinely perform the laboratory evaluation of blood glucose via fasting blood glucose (Walelgne et al., 2016). On the basis of the indication(s), oral hypoglycaemic agents or/and insulin can be prescribed. They are also treated for any available diabetes comorbid disease. Every month, the people with diabetes would collect the prescribed drugs and take the drugs by themselves in their homes (Food Medicine Health Care Administration Control Authority of Ethiopia, 2014).

The standard treatment guidelines for general hospitals in Ethiopia indicate that usual care for people with T2D entails non-pharmacologic and pharmacologic management approaches (Food Medicine Health Care Administration Control Authority of Ethiopia, 2014). Non-pharmacologic management includes nutrition therapy, exercise, self-blood glucose monitoring, screening and treating microvascular and macrovascular complications. Nurses or physicians provide a brief explanation about diabetes and required lifestyle modifications only to newly diagnosed people with diabetes. Diabetes education is not routinely practised due to the low attendance rate of the people with diabetes (Bahru & Abdulkadir, 1993) and the inadequate health workforce (Habebo et al., 2020).

b) Intervention group

On top of the usual care, the intervention group received a DSMES programme. The details of the intervention development are presented in Sections 4.4 and 4.5 in Chapter Four. Briefly, the programme consisted of an educational package and six two-hour face-to-face sessions that address seven self-care behaviours for diabetes management (healthy diet, physical activity, medication, SMBG, diabetes complications, healthy coping and problem-solving), diabetes-related misconceptions and foot care, followed by home-based family support. The contents for the family caregivers include the roles and responsibilities of family caregivers (**Table 4.1**).

The intervention was delivered by three experienced clinical nurses in diabetes care who have a nursing Bachelor of Science degree and work in the participating hospital. The doctoral student gave a two-day training workshop on the intervention contents and facilitation skills. The pre-test and post-test were conducted to evaluate knowledge of DSMES and training facilitation skills. The knowledge tests addressed the types of diabetes and its prevalence, management of diabetes focusing on the non-pharmacologic approach, psychosocial aspects in diabetes care and diabetes-related complications. The knowledge test also included some important points for training facilitation skills. The test contained 20 questions at both pre-test and post-test and was scored out of 100%. The trainees scored above 80% on both tests. The checklist was used to ensure the consistent delivery of the educational content. The research supervisors supervised the delivery of the sessions and filled the checklist in every session (Appendix IX).

A group based face-to-face DSMES programme was delivered. Six groups containing six to seven dyads per group were formed. The participants were assigned to the intervention delivery group based mainly on the proximity to their homes and taking into account other considerations, such as time or schedule conflict. People with diabetes and their family caregivers were assigned to the same group as far as possible. Subjects who wanted to change their group were allowed to do so.

The 12-hour DSMES programme consists of six weekly two-hour sessions. Intervention facilitators made an interactive presentation in each session. Each session had an introduction (warm-up and recap session for 10 minutes), body (illustrative presentation on topic/s for 60 minutes), group discussion and experience sharing for 20 minutes and conclusion and goal setting for 20 minutes. There was a break of 10 minutes in between presentations. The DSEMS sessions were delivered on Saturday, and family home-based support to people with diabetes was expected to be continued. The intervention delivery's detailed topics, contents and schedules are presented in Section 4.4 and **Table 4.1** (Chapter Four). Dyads in the intervention group were requested not to share or discuss the intervention content with other people with diabetes during their monthly follow-up visits to the hospital.

The DSMES educational handbook was distributed in the first education session, whereas flyers were distributed every session. Other contents were delivered according to the session plan. The DSMES programme was delivered using visual aids (LCD projector and demonstration equipment), and active learning methods were implemented at each session. The doctoral student prepared the common PowerPoint in Afaan Oromoo and used it in all sessions. The PowerPoint encompassed the pictures and a few words to enhance understanding. Group discussion and experience sharing was conducted during the sessions. Dyads set the goals on the selected intervention contents to be implemented in that week. The action plan table was distributed in every session, and the intervention facilitators supported them on goal setting. In the 20-minute recap time in each session, each dyad was invited to present their achievements in the past week, and the intervention facilitators evaluated their performance regarding the goal set in the previous session accordingly. In particular, participants asked questions for clarification, and the improvement points were forwarded. Then, their performance was rated out of 100% for each goal by the intervention facilitator. Best-performed dyads (model successors) were rewarded with a glucometer with its test strips.

The intervention facilitators collected the intervention attendance at each session. One of the nurse intervention facilitators gave a phone call to boost attendance if the participants did not show up at the scheduled time. A coffee break for 10 minutes was offered, and a snack suitable for diabetes was provided in all sessions. Participants also received 60 Ethiopian Birr for transportation after attending the intervention session. No incentive was provided for the control group.

6.7 Formation of intervention centres in the community

Seven organisations (four government bodies and three private organisations) were contacted to discuss the possibility of setting up temporary centres in their organisations in the two selected Kebeles. Three of them agreed to allow the research team to use their space to deliver the intervention, whilst four declined the request due to a lack of required facilities or without any reason. Lastly, the intervention was delivered in three temporary established centres in the community. The centres were set up in the two purposely selected Kebeles of Nekemte City. The establishment of the centres was based on five considerations: 1) the willingness of the institution's administrator to offer the room; 2) the proximity of the dyads' home to each other; 3) conducive to being a centre for education; 4) the availability of essential services, such as electric supply with socket; and 5) availability of transportation services. There were facilitators and barriers encountered in the process of centre formation. The facilitators for centre formation were 1) availability of cooperation from the local Diabetes Association, in which the chairperson of the association gave a phone call to the government institution's administrator for their cooperation and 2) the creation of awareness about the project for the local community leaders, local health authorities and institution's administrator. It was understood that a thorough awareness of the aim and the benefits of the DSMES programme intervention and strong cooperation from other stakeholders is needed. On the other hand, the barriers faced in the process of centre formation were as follows: 1) some institutions requested a hall rent and 2) although some institutions initially permitted the use of the hall, they refused to offer the place later. The first challenge was solved through discussion and explanation with the administrators; since the second challenge was encountered before the first session, it was solved by arranging another centre.

Community resources, such as health extension workers (HEW), health authorities, local diabetes association and local administrative structure leaders (Gott leader and Kebele chairperson) were co-operated in the intervention process. The HEW, community health workers in Ethiopia employed by the government to provide family health by means of reproductive health, performed a door-to-door visit a day before every session to remind the participants of the upcoming education session. In addition, they were involved in making proactive visits to the intervention dyads one day before the scheduled interventional sessions to boost the participation rate. At the same time, local administrative leaders arranged the hall for education delivery.

6.8 Sample size

The sample size was determined according to the recommendation by Hertzog (2008) for a pilot interventional study. Accordingly, 30 dyads per group were needed to estimate the variance between-group differences and add 20% of an attrition rate; 76 dyads were involved in the study; 38 dyads were recruited per group.

6.9 Subject recruitment and baseline data collection

Participants were recruited using convenience sampling during their monthly follow-ups at the participating hospital. The participating hospital provides routine monthly medical follow-up services for people with diabetes on every Wednesday and Friday. Data collectors approached the people with diabetes when they were waiting to visit a doctor in the waiting area of the participating hospital. The data collectors first screened for medical records (i.e. the people with diabetes folder) in the diabetes centre and identified eligible people with diabetes. Eligible people with diabetes were asked to nominate one primary family caregiver. Their eligibility was first screened for those family members who attended the hospital with the eligible people with diabetes. Data collectors explained the study purpose and procedure if both people with diabetes and their family members were eligible. Eligible dyads providing written consent were then included in the study. For those nominated primary family caregivers who were not with people with diabetes during recruitment, the data collector obtained the phone number of the nominated family member from people with diabetes and contacted the nominated family member immediately. If a family caregiver did not respond to the phone call two times, the family caregiver was classified as unreachable, and the dyad was excluded from the study. After explaining the purpose and aim of the project, the data collectors obtained written consent from eligible dyads. During recruitment, written consent was obtained in the hospital for family caregivers and people with diabetes.

The baseline assessment was then conducted in the hospital. The subject's participation was further confirmed before they left the hospital after completing their monthly visit for diabetes at the hospital. If people with diabetes or family members want to consult another family member to participate in the study or need more time to decide, they were offered the morning of the recruitment day for consideration and made their final decision in the afternoon of the recruitment day. If the family caregiver was recruited via telephone, oral consent was initially obtained, and the baseline assessment was conducted via telephone after obtaining verbal consent. The HEW obtained written consent during the proactive visit before the first session of the DSMES programme for those in the intervention group. For the control group, a HEW made a planned home visit to the family caregivers to obtain written consent as soon as possible after recruiting their respective people with diabetes.

6.10 Randomisation and blinding of the participants

After baseline assessment, dyads were randomly allocated to either the control group to continue usual care or the intervention group to continue usual care and receive the DSMES programme. A 1:1 allocation ratio with a block size of four was employed. An independent research team member who was not be involved in participant recruitment and who had no contact with potential participants generated a randomisation list using an online research randomiser software (https://www.randomizer.org/) and prepared a separate sequence of the group identified based on the computer-generated random codes and placed the codes in serially numbered opaque sealed envelopes. Data collectors opened the sealed envelope and passed the dyads' information to the intervention facilitator if they were assigned to the intervention group. Participants assigned to the intervention group were informed of the date of the first educational session after randomisation, and the HEW reminded them one day before the session. People with diabetes in the intervention and control groups were scheduled to attend the hospital for monthly follow-up visits on different dates by the physician working in the diabetes centre to minimise contamination across the group. Due to the nature of the intervention, participants and intervention providers could not be blinded. However, the outcomes assessors and the data analyst blinded the group allocation through coding.

6.11 Outcomes

Two sets of outcomes were assessed in this pilot RCT. Feasibility outcomes that include eligibility, recruitment, retention, item-level missing data rates, the intervention's acceptability and the pilot study outcomes, including clinical, behavioural and psychological and environmental variables of the dyads, were assessed.

6.11.1 Outcomes assessed from both people with diabetes and family caregivers

6.11.1.1 Feasibility outcomes

Eligibility, recruitment, retention and item-level missing data rates were calculated. In addition, the acceptability and intervention fidelity were assessed.

a) Eligibility rate indicates the rate of the participants eligible for the study from those screened for eligibility.

b) Recruitment rate indicates the rate of the participants recruited from those eligible. A rate of 80% or above was considered successful (Sosnowski et al., 2018).

c) Retention rate indicates the rate of the participants enrolled in the study who completed a two-month follow-up. The attendance of the participants who participated in the follow-up assessment was tracked. The retention rate was calculated, and the reasons for loss to follow-up were recorded. 70% or greater attendance shows effective intervention (Amico, 2009).

d) Item-level missing data rate indicates the rate of item-level missing data per each scale's total number of possible responses. The item-level missing data for each scale were calculated by dividing the number of subjects who missed the items by the total number of possible answers. The total number of possible responses was calculated by the total number of items on the scale X number of subjects in each group.

e) The acceptability of the intervention indicates the acceptability level of the intervention held by dyads in the intervention group. It was measured using a validated six-item credibility and expectancy questionnaire (Devilly & Borkovec, 2000). The scale has two sets of questions that address the thinking and feeling about what will happen after receiving therapy (Appendix IX).

f) Intervention fidelity: Intervention fidelity is the extent to which the intervention is delivered as intended (Gearing et al., 2011). Intervention fidelity is essential in RCT and is one method to ensure the validity and reliability of the intervention (Bellg et al., 2004). Intervention fidelity includes five essential components: an intervention design, training of providers, intervention delivery, receipt of intervention and enactment of skills gained from the interventions (Murphy & Gutman, 2012). Intervention fidelity was assessed using a 13-item self-developed checklist addressing the establishment of community-based intervention centres, training of the intervention facilitators, distribution of educational materials, utilisation of educational materials, duration of intervention delivery, delivery of all contents in each session according to the session plan, mode of delivery and implementation of active learning methods (Appendix VIII). Three possible responses were given (Yes/No/Not applicable). A PhD holder in Public Health and a doctoral student filled the checklist at each of the 36 DSMES sessions (=6 groups × 6 sessions). The percentage of accomplishment was calculated. The reasons for the gaps in implementation, if any, were recorded. Comments from participants from the intervention group were also collected during the intervention period.

6.11.2 Preliminary outcomes

Three sets of people with diabetes outcomes were collected: 1) clinical outcomes, including HbA1c, lipid profiles (total cholesterol, LDL cholesterol, HDL cholesterol and triglycerides), SBP, DBP and BMI; 2) psychological and behavioural outcomes (self-management practise, DQOL); and 3) one environmental outcome, namely, perceived support status (support needed, support received and support attitudes) (Appendix VI). Only one family caregiver outcome was assessed in this pilot RCT, the family caregiver's supportive behaviour, which assesses the support provided to the people with diabetes by the family caregiver (Appendix VII). The translated, culturally adapted and psychometrically tested the Afaan Oromoo versions of all scales were used to measure these self-reported outcomes in the study (Appendices X to XIII).

6.11.2.1 Primary outcomes and their measurement

There were two primary outcomes of this pilot RCT, the HbA1c of people with diabetes and the family caregiver's supportive behaviours reported by family caregivers.

a) The HbA1c of people with diabetes is a gold standard measure of blood glucose, measured after obtaining a blood sample and analysed using a COBAS C311 fully automated clinical chemistry machine reported in %. The machine is one of the most stable clinical chemistry analysers with high reliability (Medex World Wide, 2015).

b) The family caregiver's supportive behaviour: Family behaviour is a pattern of behaviour that a family uses for dealing with family situations (Epstein et al., 2003). It was measured using the DFBC–Afaan Oromoo scale (Appendix VII, Section II). The original version of the DFBC scale consists of nine items in supportive and seven items in non-supportive subscales (Schafer et al., 1986). The DFBC showed an acceptable internal consistency between 0.71 and 0.86 (Lewin et al., 2005; McKelvey et al., 1993; Schafer et al., 1986), and it was used to measure family behaviour in previous studies (Kang et al., 2010; Tang et al., 2008). The validated DFBC–Afaan Oromoo scale was used with 12-item (six in supportive and six in non-supportive subscales). Each item is rated with a five-point Likert scale ranging from 1 (never) to 5 (at least once a day). The mean score was computed to assess the pooled family behaviour.

6.11.2.2 Secondary outcomes and their measurements

The following secondary outcomes were collected from the people with diabetes in the pilot RCT.

a) SBP: The pressure exerted on the wall of arteries when the heart contracts. It was measured using an aneroid sphygmomanometer on the left upper arm and reported in mm Hg.

b) DBP: A pressure exerted on the wall of arteries when the heart refills, and it was measured using an aneroid sphygmomanometer on the left upper arm and reported in mm Hg.

c) BMI: An index of weight in kg to height in metre, measured using the TCS-200LP stadiometer. It is an indicator of body fat (kg/m^2).

d) Lipid profiles: The level of lipids circulating in the blood and composed of total cholesterol, LDL cholesterol, HDL cholesterol and triglycerides, which were measured after obtaining a venous serum sample; they were analysed using the COBAS C311 fully automated clinical chemistry machine and reported in mg/dl.

   - Total cholesterol is a waxy, fat-like substance our body needs.
   - LDL is a ‘bad’ lipoprotein that increases the serum fatty level, mobilising the liver's fats.
   - HDL is a ‘good’ lipoprotein because it decreases the serum level of fat via transporting it from blood to the liver and muscle for storage.
   - Triglycerides are fats we obtain from the food we consume and are carried in the blood.

e) The self-management practise: People with diabetes-reported outcome measure for diet, physical activity, medication, foot care and blood glucose testing behaviours and rated the number of days the people with diabetes practised these components in the past seven days. These domains were measured using the Summary of Diabetes Self-care Activities-Expanded (SDSCA) (Toobert & Glasgow, 1994). An article that analysed seven studies using the SDSCA showed that the scale is valid and reliable (Toobert et al., 2000). Numerous SDSCA versions involving people with T2D showed that the scale is valid and reliable self-management behaviour with overall internal consistency between 0.618 and 0.84 (Caro-Bautista et al., 2016; Kamradt et al., 2014; Mogre et al., 2019; Schmitt et al., 2013; Vincent et al., 2008).

- Diet: The mean number of days for people with diabetes practise diet in the last seven days (the mean score of 1 to 5 for diet items, and the score of item 4 was reversed on the score).
- Physical activity: The mean number of days for people with diabetes performed physical activity and exercise in the last seven days and measured using a two-item physical activity and exercise subscale.
- Blood sugar testing: The mean number of days for people with diabetes tested blood glucose levels in the last seven days and was measured using a two-item blood glucose testing subscale.
- Foot care: The mean number of days for people with diabetes performed foot care in the last seven days was measured using a five-item foot care subscale.
- Medication: The mean number of days for people with diabetes took the prescribed diabetes medication in the last seven days and measured using a 1-item medication subscale.

The translated and psychometrically tested 10-item SDSCA–Afaan Oromoo scale was used (Appendix VI, Section II). The overall Cronbach alpha of the items of the pilot RCT at baseline was 0.705, with 0.734 for the general diet and blood glucose testing, 0.678 for specific diet and 0.701 for the foot care subscales.

f) DQOL: It is an individual's perception of their position in life with diabetes. This outcome was measured using the DQOL scale. This tool has four major domains: Satisfaction (15 items), Impact (20 items), Social/Vocational Worry (7 items) and Diabetes-Related Worry (4 items), with each item scored with a five-point scale, and the lower scores indicating better QOL (The DCCT Research Group, 1988). Previous studies found that the DQOL scale had excellent reliability (Cronbach's α ranged between 0.90 and 0.92 (Jin et al., 2018; Pakpour et al., 2012; Reviriego et al., 1996; The DCCT Research Group, 1988). The mean score was calculated to obtain an overall DQOL and its domain score. The validated 34-item DQOL–Afaan Oromoo scale was used (Diriba et al., 2021a) (Appendix VI, Section III). The overall Cronbach's alpha of the items of the pilot RCT at baseline was 0.860, with 0.760 for satisfaction, 0.738 for impact, 0.720 for the social/vocational worry and 0.710 for diabetes-related worry subscales. The mean score was calculated for overall DQOL and its domains.

g) Perceived support status (support needed, support received and support attitude): The perceived or received support held by people with diabetes from their family or friends. The DCP support scale developed by the Michigan Diabetes Research Centre to measure the social and psychosocial factors of diabetes and its treatment (The Michigan Diabetes research center, 1998) was used. The scale has 18 items (six items in each subscale) (Appendix VI, Section IV). Internal consistency of the support scale showed an acceptable to excellent range from 0.73 to 0.93 (Fitzgerald et al., 1998; Li et al., 2015). The overall DCP support scale of the pilot RCT at baseline was 0.886, with 0.817 for support needed, 0.861 for the support received and 0.737 for support attitude subscales. The mean score of the scales was calculated.

6.11.3 Sociodemographic characteristics of the dyads

The sociodemographic characteristics of gender, age, marital status, ethnicity, religion, education level, employment status, monthly income, years since diagnosis of diabetes, type of medicine received, family caregiver, the relationship between family caregiver and people with diabetes, and the status of comorbidity and type of diabetes comorbid disease were obtained from people with diabetes. Gender, age, marital status, ethnicity, religion, education level and employment status were obtained from the family caregiver.

6.12 Data collection procedure

Outcome measurement was conducted at three time-points: baseline (T0: after recruitment), immediately after the DSMES programme intervention (T1: post-intervention), and two months after the intervention (T2) (**Table 6.1**). Except for HbA1c and DQOL, data for all of the dyads was collected at all three time-points. The HbA1c was assessed at T0 and T2 because it indicates the blood glucose level of people with diabetes over the last 8 to 12 weeks. Similarly, the DQOL was assessed at two time-points because previous studies reported that QOL may take a long time to change (Mulcahy et al., 2003), and significant improvement may be obtained after the second month follow-up or thereafter (Cheng et al., 2019; Sindhu & Jayakumar, 2018). Data collection from people with T2D and their family caregivers was conducted on the same day.

Table 6.1 Flow of the collection of outcome measures by time-point

Outcomes	Source of information	Time-point outcomes collected
Primary outcomes		
HbA1c	People with diabetes	T0 and T2
Family caregiver supportive behaviour	Family caregivers	T0, T1 and T2
Secondary outcomes		
Lipid profiles (total cholesterol, LDL cholesterol, HDL cholesterol and triglyceride)	People with diabetes	T0, T1 and T2
Blood pressure (SBP and DBP)	People with diabetes	T0, T1 and T2
BMI (was calculated from height and weight)	People with diabetes	
Self-management practise	People with diabetes	T0, T1 and T2
DQOL	People with diabetes	T0 and T2
Support needed, support received and support attitudes	People with diabetes	T0, T1 and T2
Acceptability of the intervention	People with diabetes–family caregiver dyads in the intervention group	T2

Note: T0: Baseline (T0): at the time of recruitment; T1: Post-intervention (T1): immediately after the intervention; T2: two-month follow-up (T2) post-intervention

Except for the SBP and DBP, no clinical outcomes were retrieved from medical records. Nurses of the hospital working in the diabetes centre measured the body weight and height. A medical laboratory technologist, a staff of the participating hospital, and recruited as a part-time staff of the study were collected whole blood samples for HbA1c and serum blood samples for lipid profiles. Most laboratory tests were done at the participating hospital. Due to the unavailability of reagents, some of the samples were transported to another hospital. The data collector took the subjects to a laboratory sample collection centre to hand over the person with diabetes to this research project's designated laboratory sample collector. A separate counter was used to collect blood samples. According to Ethiopia's national laboratory management standards and standard operating procedure, the medical laboratory technologist monitored the blood sample collection, transportation and testing. The HbA1c and lipid profile tests were performed using COBAS 311 fully automated clinical chemistry machine. The hospital's quality officer performed the machine's calibration and quality control every morning. The result of the tests was printed and collected by data collectors, and the results were communicated to the duty physician, and the duty physician communicated the results to those who were the source of the blood samples, people with diabetes.

Three experienced outcome assessors collected self-reported outcomes via face-to-face interviews in a private room in the hospital. One-day workshop was given by a doctoral student focusing on data collection and questionnaires. An extended data collection period was provided to avoid data collector fatigue. The data collectors at baseline were not blinded for group assignment because they conducted the randomisation after baseline questionnaire completion but were blinded at post-intervention and follow-up assessments. all of the research staff were blinded for the dyads' group assignment. Three supervisors, the Master of Science degree holders working for Wollega University and a doctoral student, have performed continuous supervision. The supervisors daily checked for completeness of the collected data and passed it to a doctoral student for the record. Data entry was conducted progressively.

6.13 Statistical analysis

Data were analysed by the IBM SPSS version 26 software package. The intention-to-treat principle was applied whenever applicable. A p-value of <0.05 was considered statistically significant. Descriptive statistics summarised the sociodemographic variables of the dyads; the clinical outcomes, self-management practise, DQOL and perceived caregiver's support of people with diabetes; family caregiver's support behaviours; and the acceptability level of the intervention. Independent sample t-tests for continuous variables and Chi-square tests for categorical variables examined the comparability of groups in terms of demographics produced by randomisation. Feasibility outcomes using rates/percentages were computed. Generalised estimating equations (GEEs) models were computed to estimate the between-group differences in the effectiveness of the DSMES programme intervention on the 13 outcomes amongst people with diabetes and family caregiver's support over the study period. The GEE model is an extension of generalised linear models, widely used to analyse longitudinal data (Twisk, 2004). The model was reported as a consistent and efficient estimator of linear data (Goetgeluk & Vansteelandt, 2008). GEE can be used to analyse the continuous, ordinal and dichotomous data; however, the study suggests a cautious use for nonlinear data analysis (Goetgeluk & Vansteelandt, 2008). In healthcare studies, the GEE model was used as an estimator of group and time interactions, and the model can handle the missing at random (McPherson et al., 2013; Nguyen et al., 2019). Apart from its consistent and efficient estimator, this study selected the GEE model because of longitudinal study and continuous data of this study. In the GEEs, Time (time-points) and Group (the intervention group versus control group) and their interaction term 'Time × Group' were computed. The beta coefficient (β) and p-value of the 'Time × Group' interaction was computed. A p-value of <0.05 indicates statistical significance. The means and standard error (SE) for each group were estimated in the GEE model. The effect sizes of the DSMES programme on the outcomes were estimated using between-group Cohen's d. The value of Cohen's d of 0.2, 0.5 and 0.8 indicate small, medium and large effect sizes, respectively (Cohen, 1988).

6.14 Quality control

The quality of the pilot RCT study was ensured through five aspects as follows: 1) intervention protocol was developed on the evidence obtained by systematic review and meta-analysis (Chapter Two) and other literature (Chapter Four), and the intervention protocol was validated; 2) the quality assurance of laboratory tests was ensured; 3) the self-reported outcomes were measured using the translated, culturally adapted, and scales with acceptable psychometric properties (the detail is presented in Chapter Five); 4) the close supervision of data collection was made by three research supervisors who were a general practitioner working in the diabetes centre of participating hospital and two Masters of Science degree holders of Wollega University. In addition, the doctoral student of this study consistently supervised all activities; and 5) the intervention fidelity was also assessed.

6.15 Ethical considerations

Ethical approval for the study was obtained from the Human Subjects Research Ethics subcommittee of The Hong Kong Polytechnic University (Reference number: HSEARS20201019003) (Appendix I). The trial was prospectively registered by the Chinese Clinical Trial Registry (registration no. ChiCTR2000040292). Permission to recruit subjects and collect data was obtained from the Nekemte Specialised Hospital medical director, and consent to gather the intervention group in the community was obtained from two selected Kebeles' chairpersons. The study follows the Declarations of Helsinki (World Medical Association, 2013). Information about the study was given in the information sheet at recruitment time (Appendix IV) and written informed consent was obtained from each participant (Appendix V). Participants were ensured that their participation was voluntary, and they could withdraw from the study at any time without any penalty and could continue to receive the usual care at the hospital. The confidentiality of the participants' data was maintained by coding. All blood samples were coded, and the subjects' anonymity was maintained. All laboratory samples were handled and discarded according to the standard operating procedures. The family caregivers were requested to consent after people with diabetes invited them to participate in the study.

6.16 Chapter summary

A two-arm parallel pilot RCT involving 76 people with diabetes–family caregiver dyads was designed for implementation. The intervention group received the DSMES programme and continued the usual care, whilst the control group continued the usual care. Nurses delivered the two-hour intervention for six consecutive weeks. A face-to-face delivery format was implemented in the community. The clinical, self-management practise, DQOL and perceived support status of people with diabetes and the family caregiver's supportive behaviour outcomes were assessed at two time-points (post-intervention) or three time-points (at two-month follow-up). The GEE models were computed to examine between-group differences over time-points. The quality of the study was ensured via different strategies, and ethical approval of the pilot RCT was obtained from The Hong Kong Polytechnic University.

CHAPTER SEVEN: RESULTS OF THE PILOT RCT

7.1 Introduction

This chapter shows the results of the pilot RCT study, a smaller version of the definitive RCT aimed to test the preliminary efficacy of an intervention (National Institute for Health Research, 2020). The pilot RCT aimed to examine the feasibility, acceptability, preliminary efficacy and effect sizes of the DSMES programme intervention on people with diabetes, the clinical, self-management practise, DQOL, support needed, support received and support attitudes and the family caregiver's supportive behaviour in Western Ethiopia. The study feasibility was assessed via recruitment, retention and item-level missing rates. The preliminary efficacy of the DSMES programme on the HbA1c and DQOL was assessed at two time-points (T0 and T2), and the assessments of the remaining outcomes were conducted at three time-points (T0, T1 and T2). In addition, the acceptability of the intervention was assessed for the participants in the intervention group.

This chapter is organised into six main sections. Section 7.1 introduces the chapter, Section 7.2 shows the formation of the intervention centres, Section 7.3 shows the feasibility of the participants, and Section 7.4 shows the sociodemographic characteristics of the participants at baseline (T0). Section 7.5 presents the results of the outcomes. Lastly, Section 7.6 summarises the chapter.

7.2 Formation of the intervention centres

All planned sessions were delivered in the community of two purposively selected Kebeles of the Nekemte City, Western Ethiopia. Three intervention centres were temporarily established in the community. Seven organisations (four government bodies and three private organisations) were contacted. The organisations were contacted twice, a month before commencing the intervention and another a few days before the first session to ensure the permission. Whilst three governments and two private organisations first offered their consensus to participate, one government was excluded due to a lack of required facilities, and one private organisation declined to offer the room. Amongst organisations agreed and included two governments and one private organisation declined to participate before the first intervention session. Then, one government organisation was later contacted to replace the declined organisation. Finally, two centres located in two governmental and one in private organisations were used for the intervention. The distance between the centres is approximately 1.5 kilometres. Although this distance may be still extremely far for some participants, such distance can cover most of the areas in the two Kebeles; in addition, the participants in the intervention group may get a chance to walk to reach the intervention centre to receive the DSMES programme.

7.3 Feasibility of the study

7.3.1 Subject recruitment

Subject recruitment was conducted at Nekemte Specialised Hospital between January and March 2021. In line with the participating hospital's schedule for medical follow-up of people with diabetes, the data was collected on every Wednesday and Friday, and hence subjects were recruited for 24 days (=two days/week * 4 weeks/month *3 months) in this pilot RCT. **Figure 7.1** presents the study procedure in a CONSORT flowchart. An average of nine dyads per day (227 dyads/24 days ≈ 9) were screened for eligibility. Amongst the 227 screened dyads, 89 dyads fulfilled the inclusion criteria, showing a 39.2% (89/227) eligibility rate. Amongst the 89 eligible dyads, 76 dyads consented to participate and 16 dyads declined to participate, resulting in a recruitment rate of 85.4% (76/89). Whilst the recruitment of all people with diabetes was performed at Nekemte Specialised Hospital, 23 family caregivers were recruited at the participating hospital and 53 were recruited by phone. The reasons for ineligibility of the

135 dyads included the following: 1) they were unable to nominate family caregiver who can support them in diabetes management (n = 31); 2) they did not fulfil the inclusion criterion of 'having family caregiver' (n = 14); 3) they were pregnant (n = 3); 4) they had a physical limitation (n = 3); 5) they did not live in the two selected Kebeles (n = 46); 6) they were not with T2D (n = 21); 7) they were aged below 18 (n = 12); 8) and not taking anti-diabetic medicine (n = 1); and 9) they were unable to understand Afaan Oromoo (n = 4).

7.3.2 Retention

After obtaining baseline assessment, the 76 eligible dyads were randomly assigned to the intervention group (n = 38) or the control group (n = 38). Six intervention groups were formed with sizes ranging from five to seven dyads, and the nurses delivered the intervention weekly for six weeks. Sixty Ethiopian Birr (equivalent to 1.3 USD) transportation fee was paid for every session they attended. No participants refused to receive the transportation fee. No incentives were offered to the control group.

Out of the 38 dyads allocated to the intervention group, 37 people with diabetes (97.4%) and 37 family caregivers (97.4%) completed the intervention sessions. One dyad did not attend the intervention due to a social event (mourning a family member's death). In the sixth session, the reward was offered for the best-performed dyads. On the other hand, amongst the 38 dyads allocated to the control group, 37 people with diabetes (97.4%) and 36 family caregivers (94.7%) completed the control treatment. One person with diabetes in the control group died, whereas two family caregivers discontinued due to health problems. The between-group differences in the intervention attrition for people with diabetes (p = 1.000) and the family caregivers (p = 0.244) were not statistically significant.

The attrition of the outcome assessment at T1 and T2 was computed. Low attrition rates were obtained for people with diabetes, and slightly higher attrition rates were observed for family caregivers. For people with diabetes, the attrition rate at T1 was 5.3% (2/38) for both groups, and the attrition rate at T2 was 5.3% (2/38) for the intervention group and 7.9% (3/38) for the control group. These people with diabetes could not be contacted during the follow-up(s). No statistically significant differences between groups in the attrition of persons with diabetes at T1 ($p = 1.000$) and T2 ($p = 0.361$).

For family caregivers, the attrition rate at T1 was 7.9% (3/38) for both groups, and they were not followed up because of social events. At T2, the attrition rate was 7.9% (3/38) for the intervention group and 10.5% (4/38) for the control group. The reason for the loss of follow-up was hospitalisation. There were no statistically significant between-group differences in family caregiver's attrition rate at T1 ($p = 1.000$) and T2 ($p = 0.344$).

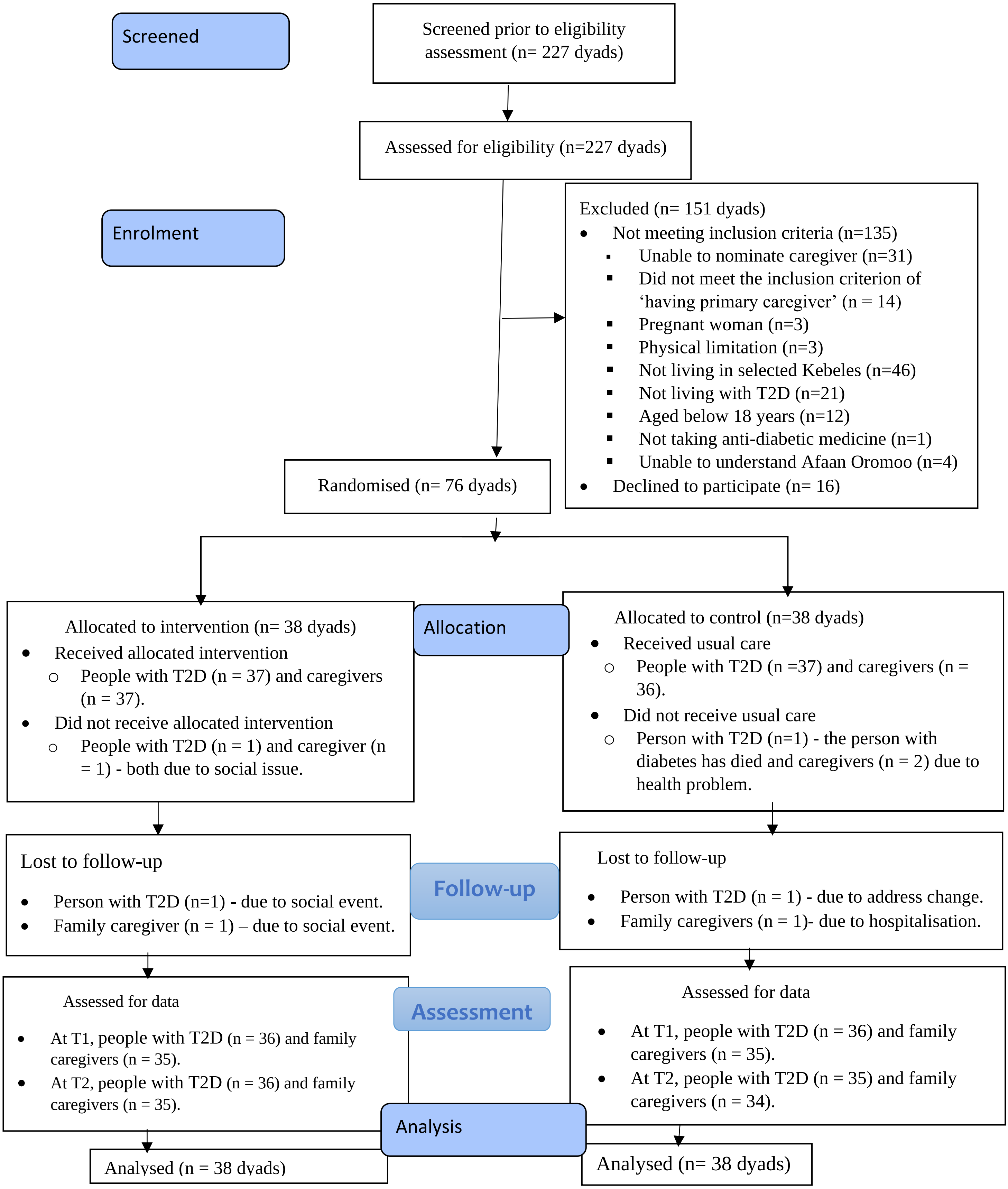

Figure 7.1 CONSORT flow diagram for study procedure

7.3.3 Missing rate at item-level

Table 7.1 shows the overall item-level missing values of the outcome measures for people with diabetes and the family caregivers. The item-level missing rates for people with diabetes and family caregivers were computed from the total number of possible responses for each scale. The results showed a low item-level missing rate, ranging from 0 to 3.5%. The between-group differences in the item-level missing values were not statistically significant. The detail of the item-level missing rate for the five outcome measures with missing data is presented in the following sections.

Table 7.1 Item-level missing values for people with diabetes and family caregivers

Source of data	**Scales**	**Intervention group (n=38)**		**Control group (n=38)**		**Statistics**	
		Missed items	Number of missed Participant	Missed items	Number of missed Participants	Test statistics	p-value
People with diabetes	SDSCA-AO (10 items)	Item 2 Item 9	1 1	Item 9 Item 3	1 1		
		Total	0.5% (2/380)	Total	0.5% (2/380)	0.000[a]	1.000
	Support received-Afaan Oromoo (six items)	Item Q2e	4	Item Q2e	5		
		Total	1.7% (4/228)	Total	2.2% (5/228)	23.916[b]	1.000
	Support attitudes-Afaan Oromoo (six items)	Item Q3d	5	Item Q3d Item Q3e	6 2		
		Total	2.2% (5/228)	Total	3.5% (8/228)	0.713[a]	0.399
	DQOL-AO (34 items)	Satisfaction Item 13 Impact Item 5	22 6	Satisfaction Item 13 Impact Item 5 Impact Item 12 Social/vocational worry Item 4	4 11 15 3		
		Total	2.2% (28/1,292)	Total	2.5% (33/1,292)	0.420[a]	0.517
Family caregivers	DFBC-AO (12 items)	-	-	Item 12	3		
		Total	0.0% (0/456)	Total	0.6% (3/456)	36.010[b]	0.083

Note: SDSCA-AO: The summary of diabetes self-care activities-Afaan Oromoo, DQOL-AO: Diabetes quality of life-Afaan Oromoo, DFBC-AO: Diabetes family behaviour checklist-Afaan Oromoo, a: Chi-squared test, b: Fisher exact test

7.3.3.1 Self-management practise (SDSCA–Afaan Oromoo)

The total number of possible responses for SDSCA–Afaan Oromoo for each group is 380 (=38 people with diabetes × 10 items). The item-level missing rate for SDSCA–Afaan Oromoo for the intervention group was 0.5% (2/380), and one person with diabetes did not respond to item 2 and one person with diabetes did not respond to item 9. Similarly, the item-level missing rate for SDSCA–Afaan Oromoo for the control group was also 0.5% (2/380), and one person with diabetes did not answer item 3, and one person with diabetes did not respond to item 9. The between-group difference was $X^2 = 0.000$, p = 1.000.

7.3.3.2 Support received

The total number of possible responses for the support received for each group is 228 (=38 people with diabetes × 6 items). The item-level missing items rate for the support received–Afaan Oromoo for the intervention group was 1.7% (4/228) and 2.2% (5/228) for the control group, and four people with diabetes in the intervention group and five in the control group did not respond to item Q2e. The between-group difference was $F = 23.916$, p = 1.000.

7.3.3.3 Support attitudes

The total number of possible responses for support attitudes–Afaan Oromoo for each group is 228 (=38 people with diabetes × 6 items). The item-level missing rate for support attitudes–Afaan Oromoo for the intervention group was 2.2% (5/228), and five people with diabetes did not respond to item Q3d. For the control group, the item-level missing rate was 3.5% (8/228), and six people with diabetes did not answer item Q3d and two people with diabetes did not respond to item Q3e. The between-group difference was $X^2 = 0.713$, p = 0.399.

7.3.3.4 DQOL–Afaan Oromoo

The total number of possible responses for DQOL–Afaan Oromoo for each group is 1,292 (=38 people with diabetes × 34 items). The item-level missing rate for DQOL–Afaan Oromoo for the intervention group was 2.2% (28/1,292), and 22 people with diabetes did not respond to Satisfaction Item No. 13 and six people with diabetes did not answer Impact Item No. 5. The item-level missing rate for the control group was 2.6% (33/1,292), and four people with diabetes did not respond to Satisfaction Item No. 13, 11 people with diabetes did not answer Impact Item No. 5, 15 people with diabetes did not respond to Impact Item No. 12, and three people with diabetes did not answer Social/Vocational Worry No. Item 4. The between-group difference was X^2 = 0.420, p = 0.517.

7.3.3.5 DFBC–Afaan Oromoo

For this outcome from the family caregivers, the item-level missing rate was also low. The between-group differences in the item-level missing data were not statistically significant. The total number of possible responses for DFBC–Afaan Oromoo for each group is 456 (=38 family caregivers × 12 items). The intervention group's item-level missing rate for DFBC–Afaan Oromoo was 0.0% (0/456), whereas 0.6% (3/456) for the control group, and all family caregivers did not respond to item 12. The between-group difference was F = 36.010, p = 0.083.

7.4 Sociodemographic characteristics of the participants at baseline

7.4.1 People with diabetes

Table 7.2 shows the sociodemographic characteristics of people with diabetes. No statistically significant between-group differences were obtained amongst people with diabetes characteristics at baseline. The mean age of all people with diabetes was 49.4±10.2 years, with older participants in the control group (49.9±10.6 years) than in the intervention group (48.8±9.8 years). More than half (55.3%) were females, with an equal proportion in each group.

Most of the participants (89.5%) were married, with a larger proportion (92.1%) in the control group than in the intervention group (86.8%). Most of the participants (97.4%) were Oromoo ethnic group, with a larger proportion in the intervention group (100.0%) than the control group (94.7%). Nearly two-thirds (64.5%) were Protestant Christians, with a slightly higher number (68.4%) in the intervention group than in the control group (60.5%). More than a quarter (27.6%) had attended elementary school, 27.6% had attended secondary school, and a quarter (25.0%) had attended tertiary education. More than a third of the participants (34.2%) were homemakers, 21.1% were government employees and 19.7% were unemployed. The mean monthly income of the participants was 2,815.3±2905.4 ETB, with a higher income (3161.0±3591.0 ETB) in the intervention group than in the control group (2469.6±1992.4 ETB). More than half (52.6%) had diabetes comorbid diseases, with slightly more people with diabetes (55.3%) in the control group. Hypertension is the most common diabetes comorbid disease (48.7%), with a higher proportion (52.6%) in the control group than in the intervention group (44.7%). The mean year since diagnosis of diabetes was 5.0±4.6 years, with equal average duration in both groups. Most of people with diabetes (88.2%) were taking only oral hypoglycaemic agents (Metformin and/or Glibenclamide), with slightly more people with diabetes (89.5%) in the intervention group than the control group (86.8%). Nearly two-thirds of people with diabetes (64.5%) received support from their spouse, with a larger proportion (71.1%) in the control group than in the intervention group (57.9%).

Table 7.2 Sociodemographic characteristics of people with diabetes

Variables	Total (n = 76) Frequency (%)	Intervention group (n = 38) Frequency (%)	Control group (n = 38) Frequency (%)	Statistics	
				Value	p-value
Age in years (Mean ± SD, range)	49.4 ± 10.2 [30-69]	48.8 ± 9.8 [30 – 69]	49.9 ± 10.6 [30 – 69]	-0.482[a]	0.631
Gender					1.000[c]
Female	42 (55.3%)	21 (55.3%)	21 (55.3%)		
Male	34 (44.7%)	17 (44.7%)	17 (44.7%)		
Marital status					0.711[c]
Married	68 (89.5%)	33 (86.8%)	35 (92.1%)		
Single	8 (10.5 %)	5 (13.2%)	3 (7.9%)		
Ethnicity					0.493[c]
Oromoo	74 (97.4 %)	38 (100.0%)	36 (94.7%)		
Amhara	2 (2.6 %)	0 (0.0%)	2 (5.3%)		
Religion					0.632[c]
Protestant Christian	49 (64.5 %)	26 (68.4%)	23 (60.5%)		
Orthodox Christian	27 (35.5%)	12 (31.6%)	15 (39.5%)		
Educational status				0.595[b]	0.897
No formal education	15 (19.7 %)	8 (21.1%)	7 (18.4%)		
Elementary school	21 (27.6 %)	9 (23.7%)	12 (31.6%)		
Secondary school	21 (27.6 %)	11 (28.9%)	10 (26.3%)		
Tertiary education	19 (25.0 %)	10 (26.3%)	9 (23.7%)		
Employment status				4.909[b]	0.297
Government employee	16 (21.1%)	7 (18.4%)	9 (23.7%)		
Private organization employee	12 (15.8%)	5 (13.2%)	7 (18.4%)		
NGO employee	7 (9.2 %)	6 (15.8%)	1 (2.6%)		
Unemployed	15 (19.7 %)	6 (15.8%)	9 (23.7%)		
Homemaker	26 (34.2%)	14 (36.8%)	12 (31.6%)		
Monthly income in ETB (Mean ± SD, range)	2815.3 ± 2905.4 [300 – 13,000]	3161.0 ± 3591.0 [300 – 13000]	2469.6 ± 1992.4 [500 – 8500]	1.038[a]	0.303
Presence of comorbidity					0.819[c]
Yes					
No	40 (52.6%)	19 (50.0%)	21 (55.3%)		
	36 (47.4%)	19 (50.0%)	17 (44.7%)		
Type of comorbid disease				0.688[b]	0.709
No comorbid disease	36 (47.4%)	19 (50.0%)	17 (44.7%)		
Hypertension	37 (48.7%)	17 (44.7%)	20 (52.6%)		
Other diseases	3 (3.9%)	2 (5.3%)	1 (2.6%)		
Years since diagnosis of diabetes (Mean ± SD, range)	5.0 ± 4.6 [0.3 – 19.0]	5.0 ± 4.6 [0.3 – 19.0]	5.0 ± 4.6 [0.3 – 19.0]	0.000[a]	1.000
Types of medicine					1.000[c]

OHA	67 (88.2%)	34 (89.5%)	33 (86.8%)	
Both OHA and insulin	9 (11.8%)	4 (10.5%)	5 (13.2%)	
Primary caregiver				1.000[c]
Spouse	49 (64.5%)	22 (57.9%)	27 (71.1%)	
Child	27 (35.5%)	16 (42.1%)	11 (28.9%)	

Note: SD: Standard Deviation, NGO: Non-governmental Organisation, OHA: Oral Hypoglycaemic Agents, a: Independent samples t-test statistics, b: Chi-square test statistics, c: Fisher's exact test, ETB: Ethiopian Birr, USD: United States dollar, 1ETB = 0.022 USD.

Baseline characteristics of the outcomes

Table 7.3 presents the baseline comparison of people with diabetes outcomes. Except for HbA1c, no statistically significant between-group differences were obtained amongst people with diabetes outcomes at baseline.

Table 7.3 Baseline characteristics of people with diabetes outcomes.

Variables	Total (n = 76) Mean (SD)	Intervention group (n = 38) (Mean (SD)	Control group (n = 38) (Mean (SD)	Statistics	
				Value	p-value
HbA1c	8.53 (1.65)	8.91 (1.74)	8.16 (1.48)	2.012	0.048
SBP	143.78 (19.80)	141.66 (22.32)	145.87 (16.95)	−0.932	0.354
DBP	83.88 (10.00)	83.42 (8.80)	84.34 (11.17)	−0.399	0.691
BMI	22.90 (5.58)	23.70 (5.48)	22.11 (5.64)	1.243	0.218
Total cholesterol	213.60 (78.81)	201.96 (70.08)	225.24 (86.02)	−1.294	0.200
LDL-cholesterol	171.80 (74.54)	162.73 (76.15)	180.86 (72.77)	−1.061	0.292
HDL-cholesterol	52.77 (19.96)	50.48 (20.98)	55.06 (18.88)	−1.000	0.320
Triglycerides	247.83 (174.24)	275.66 (191.84)	220.01(152.12)	1.401	0.165
DSM	3.47 (0.85)	3.36 (0.98)	3.57 (0.70)	−1.038	0.303
DQOL	1.91 (0.44)	1.84 (0.42)	1.99 (0.46)	−1.507	0.136
Support needed	4.24 (0.99)	4.04 (1.04)	4.44 (0.91)	−1.844	0.069
Support received	4.27 (1.01)	4.17 (1.08)	4.37 (0.94)	−0.851	0.398
Support attitudes	4.77 (0.41)	4.78 (0.42)	4.75 (0.41)	0.231	0.818

7.4.2 Family caregivers

Table 7.4 presents the sociodemographic characteristics of the family caregivers. No statistically significant between-group differences were observed in the family caregiver's characteristics at baseline. The mean age of family caregivers was 36.0±12.2 years, with older family caregivers in the control group (37.2±13.6 years) than in the intervention group (34.9±10.8 years). More than two-thirds (69.7%) were females, with a higher proportion (71.1%) in the intervention group than the control group (68.4%). More than two-thirds (68.4%) of the family caregivers were married, with a larger proportion (71.1%) in the control group than in the intervention group (65.8%). Most of the family caregivers (98.7%) were Oromoo ethnic group, with a larger proportion (100.0%) in the control group than in the intervention group (97.4%). Nearly a third quarter (72.4%) were Protestant Christians. Nearly a third of the family caregivers (31.6 %) had attended secondary school, 26.3% did not attend any formal education, and 26.3% had attended elementary school. Nearly a third (30.3%) were government/private employees, and 26.3% were unemployed.

Table 7.4 Sociodemographic characteristics of family caregivers

Variables	Total (n = 76) Frequency (%)	Intervention group (n = 38) Frequency (%)	Control group (n = 38) Frequency (%)	Statistics	
				Value	p-value
Age in years (Mean ± SD, range)	36.0 ±12.2 [18 – 64]	34.9 ± 10.8 [18 – 62]	37.2 ± 13.6 [18 – 64]	-0.813[a]	0.419
Gender					1.000[c]
Female	53 (69.7%)	27 (71.1%)	26 (68.4%)		
Male	23 (30.3%)	11 (28.9 %)	12 (31.6%)		
Marital status					0.805[c]
Married	52 (68.4%)	25 (65.8%)	27 (71.1%)		
Single	24 (31.6 %)	13 (34.2%)	11 (28.9%)		
Ethnicity					1.000[c]
Oromoo	75 (98.7 %)	37 (97.4%)	38 (100.0%)		
Amhara	1 (1.3 %)	1 (2.6%)	0 (0.0%)		
Religion				0.595[b]	0.867
Protestant Christian	55 (72.4 %)	27 (71.1%)	28 (73.7%)		
Orthodox Christian	13 (17.1%)	6 (15.8%)	7 (18.4%)		
Muslim	8 (10.5 %)	5 (13.2%)	3 (7.9%)		
Educational status				2.500[b]	0.517
No formal education	20 (26.3 %)	12 (31.6%)	8 (21.1%)		
Elementary school	20 (26.3 %)	9 (23.7%)	11 (28.9%)		
Secondary school	24 (31.6 %)	13 (34.2%)	11 (28.9%)		
Tertiary education	12 (15.8 %)	4 (10.5%)	8 (21.1%)		
Employment status				2.969[b]	0.595
Government/private employee	23 (30.3%)	12 (31.6%)	11 (28.9%)		
Merchant	13 (17.1%)	4 (10.5%)	9 (23.7%)		
Student	11 (14.5%)	5 (13.2%)	6 (15.8%)		
Unemployed	20 (26.3%)	12 (31.6%)	8 (21.1%)		
Homemaker	9 (11.8%)	5 (13.2%)	4 (10.5%)		

Note: SD: Standard Deviation, a: Independent samples t-test statistics, b: Chi-square test statistics, c: Fisher's exact test.

Baseline characteristics of family caregiver's outcomes

Table 7.5 indicates the baseline characteristics of the outcome from family caregivers. No statistically significant between-group differences were observed in the family caregiver's outcomes at baseline.

Table 7.5 Baseline characteristics of family caregivers' outcomes.

Variables	**Total (n = 76) Mean (SD)**	**Intervention group (n = 38) (Mean (SD)**	**Control group (n = 38) (Mean (SD)**	**Statistics**	
				Value	**p-value**
Supportive behaviour	16.61 (5.47)	17.66 (6.36)	15.55 (4.25)	1.697	0.094
Nonsupportive behaviour	15.82 (5.09)	16.89 (6.18)	14.73 (3.44)	1.881	0.064

7.5 Results of outcomes

The results of the outcomes are organised into two sections: the primary and secondary outcomes.

7.5.1 Primary outcomes

Primary outcomes include the HbA1c and family caregiver supportive behaviour.

i. HbA1c

The results for HbA1c were presented in **Table 7.6** and **Table 7.7**. The overall mean score of HbA1c dropped slightly in the whole sample in the study period from 8.53±1.65% at T0 to 8.27±1.99% at T2. The HbA1c level dropped substantially from 8.91% at T0 to 7.81% at T2 in the intervention group, showing a 1.10% reduction. On the other hand, an HbA1c slightly increased from 8.16% at T0 to 8.73% at T2 in the control group, indicating a 0.57% increase. American Diabetes Association (2020) recommends that the HbA1c amongst people with diabetes should be <7%, and a reduction of more than 0.5% is clinically significant (Little et al., 2011). Nearly half (43.4%) of all participants achieved a clinical significance target; however, majority of participants (72.7%) those achieved this target were in the intervention group. Accordingly, the results showed uncontrolled glycaemia in both groups at both time-points. The reduction in the intervention group was clinically significant but not in the control group.

Table 7.6 Means and SDs of HbA1c (%) of people with diabetes by the group over the study period

Time	Total (n = 76) Mean (SD)	Intervention group (n = 38) Mean (SD)	Control group (n = 38) Mean (SD)
T0	8.53 (1.65)	8.91 (1.74)	8.16 (1.48)
T2	8.27 (1.99)	7.81 (1.71)	8.73 (2.17)

The GEE result shows a statistically significant difference in the changes in HbA1c over the study period between the two groups, and the DSMES programme has outperformed usual care with a large effect size at T2 on HbA1c (**Table 7.7**).

Table 7.7 GEE results of HbA1c (%) of people with diabetes by the group over the study period

Time	Intervention group (n = 38) Estimated Mean (SE)	Control group (n = 38) Estimated Mean (SE)	Group * time interaction effect				Cohen's d
			β	95% CI		p-value	
T0	8.91 (0.28)	8.16 (0.24)					
T2	7.81 (0.27)	8.73 (0.35)	−1.667	−2.584	−0.751	<0.001	0.81

Note: SE: Standard Error; CI: Confidence Interval; β: Beta coefficient.

ii. Family caregiver's supportive behaviour

Two caregiver behaviour outcomes were examined in the study, and they were supportive or non-supportive behaviours. The family caregiver's supportive behaviour results were presented in **Table 7.8** and **Table 7.9**.

The overall mean scores of family caregiver's supportive behaviour in the whole sample were gradually increased: 16.61±5.47 at T0, 20.19±5.00 at T1 and 20.57±6.37 at T2. The family caregiver's supportive behaviour increased in the intervention group but gradually increased at T1 and then decreased at T2 in the control group.

On the other hand, the family caregiver's non-supportive behaviour means scores increased over the study period, with 15.82±5.09 at T0, 17.33±4.70 at T1 and 19.05±6.07 at T2. The family caregiver's non-supportive behaviour gradually increased in the intervention group but slightly increased at T1 and then slightly dropped at T2 in the control group.

Table 7.8 Means and SDs of supportive behaviour of family caregivers by the group over the study period

Time	**Total (n = 76) Mean (SD)**	**Intervention group (n = 38) Mean (SD)**	**Control group (n = 38) Mean (SD)**
Supportive behaviour			
T0	16.61 (5.47)	17.66 (6.36)	15.55 (4.25)
T1	20.19 (5.00)	22.55 (4.97)	17.76 (3.74)
T2	20.57 (6.37)	25.17 (3.28)	15.97 (5.30)
Non-supportive behaviour			
T0	15.82 (5.09)	16.89 (6.18)	14.73 (3.44)
T1	17.33 (4.70)	19.58 (4.46)	15.08 (3.82)
T2	19.05 (6.07)	23.31 (3.29)	14.79 (5.15)

As shown in **Table 7.9**, the GEE result shows a statistically significant difference in family caregiver's supportive behavioural changes over the study period between the two groups. The DSMES programme has outperformed usual care with a medium effect size at T1 and a large effect size at T2 on supportive behaviour. A statistically significant difference in the changes in family caregiver's non-supportive behaviour at T2 but not statistically significant at T1 between the two groups, with the DSMES programme has outweighed usual care, with medium effect size at T1 and large effect size at T2.

Table 7.9 GEE results of supportive behaviour of family caregivers by the group over the study period

Time	Intervention group (n = 38)	Control group (n = 38)	Group * time interaction effect				Cohen's d
	Estimated Mean (SE)	Estimated Mean (SE)	β	95% CI		p-value	
Supportive behaviour							
T0	17.65 (1.02)	15.55 (0.68)					
T1	22.55 (0.79)	17.70 (0.61)	2.743	0.435	5.050	0.020	0.54
T2	25.16 (0.52)	15.97 (0.85)	7.087	3.861	10.313	<0.001	0.97
Non-supportive behaviour							
T0	16.89 (0.99)	14.74 (0.55)					
T1	19.58 (0.71)	15.08 (0.61)	2.342	−0.060	4.744	0.056	0.43
T2	23.31 (0.53)	14.79 (0.82)	6.361	3.263	9.460	<0.001	0.91

Note: SE: Standard Error; CI: Confidence Interval; β: Beta coefficient.

7.5.2 Secondary outcomes

This section presents the secondary outcomes, including clinical, behavioural and psychological and environmental outcomes.

7.5.2.1 Clinical outcomes

i. SBP

The results for SBP were presented in **Table 7.10** and **Table 7.11**. The overall mean values of SBP in the whole sample were in decreasing trend, with 143.78±19.80 mm Hg at T0, 135.04±21.00 mm Hg at T1 and 136.51±20.97 mm Hg at T2. The SBP mean scores in the intervention group dropped substantially from T0 to T1 and then increased slightly at T2. A comparable pattern was observed in the control group, except the magnitude of the changes was smaller. According to the American Society of Hypertension and the International Society of Hypertension (Weber et al., 2014) classification, people with diabetes had stage 1 hypertension at T0 in both groups and prehypertension at T1 and T2 in the intervention and stage 1 hypertension at T2 in the control groups. Effective management in people with T2D should keep SBP below 140 mm Hg (American Diabetes Association, 2020). The SBP target levels were achieved at T1 and T2 in the intervention group; however, it was marginally reached at T1 in the control group.

Table 7.10 Means and SDs of SBP (mm Hg) of people with diabetes by the group over the study period

Time	Total (n = 76) Mean (SD)	Intervention group (n = 38) Mean (SD)	Control group (n = 38) Mean (SD)
T0	143.78 (19.80)	141.66 (22.32)	145.87 (16.95)
T1	135.04 (21.00)	130.18 (16.89)	139.89 (23.67)
T2	136.51 (20.97)	132.97 (20.56)	140.05 (21.04)

As shown in **Table 7.11**, although the GEE result indicates that there was no statistically significant difference in the changes in SBP over the study period between the two groups, the DSMES programme has outperformed usual care with small effect sizes at T1 and T2 on SBP.

Table 7.11 GEE results of SBP (mm Hg) of people with diabetes by the group over the study period

Time	Intervention group (n = 38) Estimated Mean (SE)	Control group (n = 38) Estimated Mean (SE)	Group * time interaction effect				Cohen's d
			β	95% CI		p-value	
T0	141.66 (3.57)	145.89 (2.71)					
T1	130.18 (2.70)	139.89 (3.79)	−5.474	-16.007	5.060	0.308	0.23
T2	132.97 (3.29)	140.05 (3.37)	−2.842	-13.023	7.339	0.584	0.12

Note: SE: Standard Error; CI: Confidence Interval; β: Beta coefficient.

ii. DBP

The results for DBP were presented in **Table 7.12** and **Table 7.13**. The observed overall mean DBP levels in the whole sample were also in decreasing trend, with 83.88±10.00 mm Hg at T0, 80.70±9.67 mm Hg at T1, and 80.51±11.62 mm Hg at T2. The mean DBP level dropped gradually in the intervention group, whereas the mean DBP level decreased at T1 then increased at T2 in the control group. Prehypertension was observed amongst participants in the control group at all time-points, and normal levels were observed amongst participants in the intervention group at both T1 and T2 (Weber et al., 2014). Effective management amongst people with T2D should reduce DBP to below 90 mm Hg (American Diabetes Association, 2020); hence, the target levels were achieved at all time-points.

Table 7.12 Means and SDs of DBP (mm Hg) of people with diabetes by the group over the study period

Time	Total (n = 76) Mean (SD)	Intervention group (n = 38) Mean (SD)	Control group (n = 38) Mean (SD)
T0	83.88 (10.00)	83.42 (8.80)	84.34 (11.17)
T1	80.70 (9.67)	79.47 (6.61)	81.92 (11.95)
T2	80.51 (11.62)	78.74 (10.80)	82.29 (12.28)

As shown in **Table 7.13**, although the GEE result indicates that there was no statistically significant difference in the changes in DBP over the study period between the two groups, the DSMES programme has outperformed usual care with small effect sizes at T1 and T2 on DBP.

Table 7.13 GEE results of DBP (mm Hg) of people with diabetes by the group over the study period

Time	Intervention group (n = 38) Estimated Mean (SE)	Control group (n = 38) Estimated Mean (SE)	Group * time interaction effect				Cohen's d
			β	95% CI		p-value	
T0	83.42 (1.41)	84.34 (1.79)					
T1	79.47 (1.06)	81.92 (1.91)	−1.526	−5.977	2.925	0.502	0.15
T2	78.74 (1.73)	82.29 (1.96)	−2.632	−8.091	2.827	0.345	0.21

Note: SE: Standard Error; CI: Confidence Interval; β: Beta coefficient.

iii. BMI

The results for BMI were presented in **Table 7.14 and Table 7.15**. The overall mean BMI levels remained stable over the study period, with 22.90±5.58 kg/m^2 at T0, 23.24±5.80 kg/m^2 at T1 and 23.69±8.44 kg/m^2 at T2. The mean levels of BMI remained stable over the study period in both groups. The literature indicated that BMI should be kept in the normal range between 18.00 and 24.99 kg/m^2 (WHO Expert consultation, 2004). Normal BMI levels were obtained at all three time-points in both groups.

Table 7.14 Means and SDs of DBP (mm Hg) of people with diabetes by the group over the study period

Time	Total (n = 76) Mean (SD)	Intervention group (n = 38) Mean (SD)	Control group (n = 38) Mean (SD)
T0	22.90 (5.58)	23.70 (5.48)	22.11 (5.64)
T1	23.24 (5.80)	24.14 (5.75)	22.34 (5.78)
T2	23.69 (8.44)	23.67 (6.33)	23.69 (10.21)

As shown in **Table 7.15**, the GEE result shows no statistically significant difference in the changes in BMI over the study period between the two groups. Again, the DSMES programme has outperformed usual care with a small effect size at T2, although the usual care has outperformed the DSMES programme with a small effect size at T1 on BMI.

Table 7.15 GEE results of BMI (kg/m^2) of people with diabetes by the group over the study period

Time	Intervention group (n = 38) Estimated Mean (SE)	Control group (n = 38) Estimated Mean (SE)	Group * time interaction effect				Cohen's d
			β	95% CI		p-value	
T0	23.70 (0.88)	22.11 (0.90)					
T1	24.14 (0.92)	22.34 (0.93)	0.214	−1.291	1.720	0.780	0.06
T2	23.67 (1.01)	23.69 (1.63)	−1.608	−4.673	1.457	0.304	0.23

Note: SE: Standard Error; CI: Confidence Interval; β: Beta coefficient.

iv. Total cholesterol

Table 7.16 shows the means and SDs, and **Table 7.17** presents the total cholesterol GEE results. The overall mean total cholesterol score in the whole sample was also decreasing: 213.60±78.81 mg/dL at T0, 196.49±56.56 mg/dL at T1, 194.60±50.53 mg/dL at T2. The mean total cholesterol level in the intervention group dropped gradually over the study period whilst it dropped at T1 and then bounded back at T2 in the control group. American Diabetes Association (2020) recommends that the total cholesterol amongst people with diabetes should be less than 200 mg/dL. The normal levels were observed at T1 and T2 in the intervention group and T1 in the control group.

Table 7.16 Means and SDs of total cholesterol (mg/dL) of people with diabetes by the group over the study period

Time	Total (n = 76) Mean (SD)	Intervention group (n = 38) Mean (SD)	Control group (n = 38) Mean (SD)
T0	213.60 (78.81)	201.96 (70.08)	225.24 (86.02)
T1	196.49 (56.56)	197.16 (62.24)	195.82 (51.08)
T2	194.60 (50.53)	185.08 (53.95)	204.11 (45.59)

As shown in **Table 7.17**, although the GEE result shows that there was no statistically significant difference in the changes in total cholesterol over the study period between the two groups, the usual care has outperformed the DSMES programme with small sizes at T1 and T2 on total cholesterol.

Table 7.17 GEE results of total cholesterol (mg/dL) of people with diabetes by group over the study period

Time	Intervention group (n = 38) Estimated Mean (SE)	Control group (n = 38) Estimated Mean (SE)	Group * time interaction effect				Cohen's d
			β	95% CI		p-value	
T0	201.96 (11.22)	225.24 (13.77)					
T1	197.16 (9.96)	195.82 (8.18)	24.623	−12.783	62.030	0.197	0.29
T2	185.08 (8.64)	204.11 (7.30)	4.261	−35.773	44.295	0.835	0.05

Note: SE: Standard Error; CI: Confidence Interval; β: Beta coefficient.

v. LDL cholesterol

Table 7.18 shows the means and SDs, and **Table 7.19** presents the GEE results of LDL cholesterol. The overall mean of the LDL cholesterol level dropped and then remained stable, with 171.80±74.54 mg/dL at T0, 114.39±49.11 mg/dL at T1 and 117.95±47.46 mg/dL at T2. Lower mean levels in LDL cholesterol at T0 and T2 were obtained in the intervention group compared with the control group, although the mean LDL levels in both groups were similar at T1. American Diabetes Association (2020) recommends that the LDL cholesterol level amongst people with diabetes should be below 100 mg/dL. The LDL cholesterol levels remained above the recommended level for all of the participants with diabetes in the pilot study.

Table 7.18 Means and SDs of LDL cholesterol (mg/dL) of people with diabetes by the group over the study period

Time	Total (n = 76) Mean (SD)	Intervention group (n = 38) Mean (SD)	Control group (n = 38) Mean (SD)
T0	171.80 (74.54)	162.73 (76.15)	180.86 (72.77)
T1	114.39 (49.11)	114.83 (50.06)	113.96 (48.80)
T2	117.95 (47.46)	115.63 (51.64)	120.27 (43.46)

It shown from **Table 7.19**, that although the GEE result shows that there was no statistically significant difference in the changes in LDL cholesterol over the study period between the two groups, the usual care has outperformed the DSMES programme with small effect sizes at T1 and T2 on LDL cholesterol.

Table 7.19 GEE results of LDL cholesterol (mg/dL) of people with diabetes by the group over the study period

Time	Intervention group (n = 38) Estimated Mean (SE)	Control group (n = 38) Estimated Mean (SE)	Group * time interaction effect				Cohen's d
			β	95% CI		p-value	
T0	162.73 (12.19)	180.86 (11.65)					
T1	114.83 (8.01)	113.96 (7.81)	19.000	-18.544	56.544	0.321	0.22
T2	115.63 (8.27)	120.27 (6.96)	13.487	-20.441	47.415	0.436	0.18

Note: SE: Standard Error; CI: Confidence Interval; β: Beta coefficient.

vi. HDL cholesterol

The results for HDL cholesterol were presented in **Table 7.20** and **Table 7.21**. The mean HDL cholesterol levels dropped substantially in the whole sample, with 52.77±19.96 mg/dL at T0, 37.58±18.96 mg/dL at T1 and 34.13±19.29 mg/dL at T2. It was observed that the mean levels of HDL cholesterol were in a decreasing trend in both groups, but the patterns were different. The mean level dropped gradually in the intervention group, but it dropped at T1 and remained stable at T2 in the control group. According to the ADA recommendation, the management should keep the HDL cholesterol level above 35 mg/dL (American Diabetes Association, 2020). The intervention group did not reach the recommended level at T2, but it was marginally achieved at T2 in the control group.

Table 7.20 Means and SDs of HDL cholesterol (mg/dL) of people with diabetes by the group over the study period

Time	Total (n = 76) Mean (SD)	Intervention group (n = 38) Mean (SD)	Control group (n = 38) Mean (SD)
T0	52.77 (19.96)	50.48 (20.98)	55.06 (18.88)
T1	37.58 (18.96)	40.19 (24.74)	34.96 (10.11)
T2	34.13 (19.29)	32.65 (13.64)	35.62 (23.74)

As shown in **Table 7.21**, although the GEE result shows that there was no statistically significant difference in the changes in HDL cholesterol over the study period between the two groups, the usual care has outperformed the DSMES programme with a medium effect size at T1 and a small effect size at T2 on HDL cholesterol.

Table 7.21 GEE results of HDL cholesterol (mg/dL) of people with diabetes by the group over the study period

Time	Intervention group (n = 38) Estimated Mean (SE)	Control group (n = 38) Estimated Mean (SE)	Group * time interaction effect				Cohen's d
			β	95% CI		p-value	
T0	50.48 (3.36)	55.06 (3.02)					
T1	40.19 (3.96)	34.96 (1.62)	9.799	−3.180	22.779	0.139	0.34
T2	32.65 (2.18)	35.62 (3.80)	1.616	−9.019	12.251	0.766	0.07

Note: SE: Standard Error; CI: Confidence Interval; β: Beta coefficient.

vii. Triglycerides

The results for triglycerides were presented in **Table 7.22** and **Table 7.23**. The overall mean triglycerides level in the whole sample was in decreasing pattern, with 247.83±174.24 mg/dL at T0 and 216.40±113.07 mg/dL at T1 and 201.13±98.42 mg/dL at T2. The mean level of triglycerides decreased substantially in the intervention group, whereas it substantially decreased at T1 and then increased again at T2 in the control group. The ADA recommends that the triglycerides level amongst people with diabetes should be <150 mg/dL (American

Diabetes Association, 2020). The recommended level of triglycerides remained above the target level at all time-points in both groups.

Table 7.22 Means and SDs of triglycerides (mg/dL) of people with diabetes by the group over the study period

Time	Total (n = 76) Mean (SD)	Intervention group (n = 38) Mean (SD)	Control group (n = 38) Mean (SD)
T0	247.83 (174.24)	275.66 (191.84)	220.01(152.12)
T1	216.40 (113.07)	231.91 (139.92)	200.90 (76.44)
T2	201.13 (98.42)	183.16 (79.93)	219.10 (112.17)

The GEE result shows a statistically significant difference at T2. However, no statistically significant difference at T1 in the changes in triglycerides between the two groups, with the DSMES programme has outperformed usual care with a small effect size at T1 and a medium effect size at T2 on triglycerides.

Table 7.23 GEE results of triglycerides (mg/dL) of people with diabetes by the group over the study period

Time	Intervention group (n = 38) Estimated Mean (SE)	Control group (n = 38) Estimated Mean (SE)	Group * time interaction effect				Cohen's d
			β	95% CI		p-value	
T0	275.66 (30.71)	220.01 (24.35)					
T1	231.91 (22.40)	200.90 (12.24)	-24.639	-114.641	65.363	0.592	0.12
T2	183.16 (12.79)	219.10 (17.95)	-91.590	172.964	10.217	0.027	0.50

Note: SE: Standard Error; CI: Confidence Interval; β: Beta coefficient.

7.5.2.2 Behavioural and psychological outcomes

i. Self-management practise

The self-management practise results and its domains are presented in **Table 7.24** and **Table 7.25**. The overall mean scores of self-management practise were in an increasing trend, with 3.47±0.85 days per week at T0, 4.34±1.11 days per week at T1 and 4.68±1.47 days per week at T2. The mean scores of overall self-management practise in the intervention group increased substantially whilst remained quite stable in the control group. The overall practise means increased scores of the three subscales, general diet and blood glucose testing, specific diet and foot care self-management practise. The mean scores in all subscales improved considerably in the intervention group, whilst different trends were observed in the control group, which is a gradually increasing trend in the first two self-management practise subscales but remained stable for foot care.

Table 7.24 Means and SDs of self-management practise and its domains of people with diabetes by the group over the study period

Time	Total (n = 76) Mean (SD)	Intervention group (n = 38) Mean (SD)	Control group (n = 38) Mean (SD)
Overall score			
T0	3.47 (0.85)	3.36 (0.98)	3.57 (0.70)
T1	4.34 (1.11)	4.95 (1.02)	3.72 (0.82)
T2	4.68 (1.47)	5.68 (0.95)	3.67 (1.17)
Subscales scores			
General diet and blood glucose testing			
T0	2.94 (1.54)	2.99 (1.65)	2.89 (1.43)
T1	3.74 (1.64)	4.60 (1.24)	2.88 (1.55)
T2	4.04 (1.66)	5.04 (1.12)	3.04 (1.52)
Specific diet			
T0	2.26 (1.38)	2.38 (1.46)	2.14 (1.30)
T1	3.53 (1.92)	4.18 (2.08)	2.87 (1.50)
T2	4.43 (1.95)	5.59 (1.64)	3.28 (1.49)
Foot care			
T0	4.43 (2.22)	4.31 (2.85)	4.55 (1.37)
T1	5.04 (1.42)	5.52 (1.40)	4.57 (1.30)
T2	5.16 (1.76)	6.12 (1.13)	4.21 (1.64)

As shown in **Table 7.25**, the GEE result shows that statistically significant difference in the changes in overall self-management practise over the study period between the two groups, with the DSMES programme, has outperformed usual care with large effect sizes both at T1 and T2. The GEE results show statistically significant differences in the changes in all self-management practise subdomains over the study period between the two groups, with the DSMES programme having outweighed usual care with medium to large effect sizes at both T1 and T2.

Table 7.25 GEE results of self-management practise and its domains of people with diabetes by the group over the study period

Time	Intervention group (n = 38) Estimated Mean (SE)	Control group (n = 38) Estimated Mean (SE)	Group * time interaction effect β	95% CI		p-value	Cohen's d
			Overall score				
T0	3.36 (0.16)	3.57 (0.11)					
T1	4.95 (0.16)	3.72 (0.13)	1.429	0.994	1.869	< 0.001	1.47
T2	5.68 (0.15)	3.67 (0.19)	2.216	1.671	2. 760	< 0.001	1.81
			Subscales scores				
			General diet and blood glucose testing				
T0	2.99 (0.26)	2.89 (0.23)					
T1	4.60 (0.20)	2.88 (0.25)	1.614	0.787	2.441	<0.001	0.86
T2	5.03 (0.18)	3.03 (0.24)	1.886	1.048	2.724	<0.001	1.00
			Specific diet				
T0	2.38 (0.23)	2.14 (0.21)					
T1	4.18 (0.33)	2.87 (0.24)	1.079	0.126	2.032	0.027	0.50
T2	5.59 (0.26)	3.28 (0.24)	2.079	1.235	2.923	<0.001	1.09
			Foot care				
T0	4.31 (0.46)	4.55 (0.22)					
T1	5.49 (0.23)	4.57 (0.21)	1.154	0.193	2.114	0.019	0.50
T2	6.11 (0.18)	4.21 (0.26)	2.137	1.095	3.178	<0.001	0.62

Note: SE: Standard Error; CI: Confidence Interval; β: Beta coefficient.

ii. DQOL

The results for DQOL and its domains were presented in **Table 7.26** and **Table 7.27**. The overall mean score of DQOL was 1.91±0.44 at T0 and 1.66±0.71 at T2, which suggests an improvement in DQOL in the whole sample during the study period as lower scores showed better QOL (Jacobson et al., 1994). The DQOL considerably improved in the intervention group; however, it was worse in the control group. The four domains of DQOL, satisfaction, impact, social/vocational worry and diabetes-related worry, improved substantially in the whole sample and the intervention group, but the only diabetes-related worry was slightly enhanced in the control group.

Table 7.26 Means and SDs of DQOL and its domains of people with diabetes by the group over the study period

Time	Total (n = 76) Mean (SD)	Intervention group (n = 38) Mean (SD)	Control group (n = 38) Mean (SD)
		Overall score	
T0	1.91 (0.44)	1.84 (0.42)	1.99 (0.46)
T2	1.66 (0.71)	1.17 (0.33)	2.16 (0.66)
		Subscale's score	
		Satisfaction	
T0	1.92 (0.53)	1.83 (0.53)	2.01 (0.52)
T2	1.79 (0.79)	1.22 (0.34)	2.36 (0.69)
		Impact	
T0	2.07 (0.52)	1.97 (0.49)	2.18 (0.53)
T2	1.76 (0.75)	1.25 (0.32)	2.28 (0.70)
		Social/vocational worry	
T0	1.30 (0.60)	1.32 (0.62)	1.28 (0.59)
T2	1.03 (0.65)	0.73 (0.34)	1.33 (0.74)
		Diabetes-related worry	
T0	2.18 (0.84)	2.12 (0.85)	2.24 (0.84)
T2	1.73 (0.97)	1.35 (0.60)	2.11 (1.12)

As shown in **Table 7.27**, the GEE result shows a statistically significant difference in the changes in overall DQOL over the study period between the two groups, with the DSMES programme, has outperformed the usual care approach with large effect sizes. The GEE results show that statistically significant differences in the changes in all DQOL subdomains over the study period between the two groups with the DSMES programme have outweighed usual care with medium to large effect sizes.

Table 7.27 GEE results of self-management practise and its domains of people with diabetes by the group over the study period

Time	Intervention group (n = 38) Estimated Mean (SE)	Control group (n = 38) Estimated Mean (SE)	Group * time interaction effect				Cohen's d
			β	95% CI		p-value	
			Overall score				
T0	1.83 (0.07)	1.99 (0.07)					
T2	1.17 (0.05)	2.16 (0.11)	−0.833	−1.083	−0.583	< 0.001	1.48
			Subscales scores				
			Satisfaction				
T0	1.83 (0.08)	2.01 (0.08)					
T2	1.22 (0.05)	2.36 (0.11)	−0.960	−1.227	−0.692	<0.001	1.58
			Impact				
T0	1.97 (0.08)	2.18 (0.08)					
T2	1.25 (0.05)	2.28 (0.11)	−0.927	−1.120	−0.734	<0.001	1.25
			Social/vocational worry				
T0	1.31 (0.10)	1.28 (0.09)					
T2	0.73 (0.05)	1.33 (0.12)	−0.637	−0.941	−0.333	<0.001	0.92
			Diabetes-related worry				
T0	2.12 (0.14)	2.24 (0.13)					
T2	1.35 (0.10)	2.11 (0.18)	−0.640	−1.151	−0.130	0.014	0.56

Note: SE: Standard Error; CI: Confidence Interval; β: Beta coefficient.

7.5.2.3 Environmental outcome

Perceived support status

Perceived support status entails three self-reported outcomes: support needed, support received and support attitudes. The results for perceived support status were presented in **Table 7.28** and **Table 7.29**. The overall mean score of support needed was decreased slightly at T1 and then bounded back at T2, with 4.24±0.99 at T0, 3.93±1.06 at T1 and 4.07±1.07 at T2. Support needed from family or friends steadily increased in the intervention group whilst gradually reduced in the control group. The overall mean score of people with diabetes support received from family or friends in the whole sample gradually decreased at T1 and then slightly increased at T2, with 4.27±1.01 at T0, 3.84±1.11 at T1 and 4.04±1.01 at T2. The support received score was progressively increased in the intervention group, but it was substantially decreased in the control group. The overall support attitudes mean scores decreased but with a different trend, with 4.77±0.41 at T0, 3.17±0.66 at T1 and 3.08±0.53 at T2. The support attitude was substantially reduced at T1 and gradually decreased at T2 in both groups.

Table 7.28 Means and SDs of perceived support status by people with diabetes by the group over the study period

Time	Total (n = 76) Mean (SD)	Intervention group (n = 38) Mean (SD)	Control group (n = 38) Mean (SD)
		Support needed	
T0	4.24 (0.99)	4.04 (1.04)	4.44 (0.91)
T1	3.93 (1.06)	4.31 (0.99)	3.55 (1.01)
T2	4.07 (1.07)	4.68 (0.63)	3.46 (1.07)
		Support received	
T0	4.27 (1.01)	4.17 (1.08)	4.37 (0.94)
T1	3.84 (1.11)	4.30 (0.99)	3.37 (1.04)
T2	4.04 (1.01)	4.81 (0.43)	3.26 (1.20)
		Support attitudes	
T0	4.77 (0.41)	4.78 (0.42)	4.75 (0.41)
T1	3.17 (0.66)	3.21 (0.60)	3.13 (0.72)
T2	3.08 (0.53)	3.11 (0.46)	3.05 (0.60)

As shown in **Table 7.29**, the GEE results show a statistically significant difference in the changes in support needed and support received over the study period between the two groups, with the DSMES programme has outperformed usual care with large effect sizes both at T1 and T2. However, no statistically significant difference in the changes in support attitudes over the study period between the two groups, and the DSMES programme has outweighed the usual care approach with a small effect size both at T1 and T2.

Table 7.29 GEE results of support status of people with diabetes by the group over the study period

Time	Intervention group (n = 38) Estimated Mean (SE)	Control group (n = 38) Estimated Mean (SE)	Group * time interaction effect β	95% CI		p-value	Cohen's d
			Support needed				
T0	4.04 (0.17)	4.44 (0.14)					
T1	4.31 (0.16)	3.55 (0.16)	1.175	0.591	1.760	< 0.001	0.88
T2	4.68 (0.10)	3.46 (0.17)	1.636	1.106	2.166	< 0.001	1.35
			Support received				
T0	4.17 (0.17)	4.37 (0.15)					
T1	4.30 (0.16)	3.37 (0.17)	1.123	0.558	1.688	< 0.001	0.88
T2	4.81 (0.07)	3.26 (0.19)	1.750	1.210	2.290	< 0.001	1.44
			Support attitudes				
T0	4.78 (0.07)	4.75 (0.06)					
T1	3.21 (0.10)	3.13 (0.12)	0.061	−0.293	0.416	0.735	0.06
T2	3.11 (0.07)	3.05 (0.09)	0.044	−0.268	0.356	0.783	0.07

Note: SE: Standard Error; CI: Confidence Interval; β: Beta coefficient.

7.5.3 Intervention fidelity

Intervention fidelity refers to how the intervention is manipulated as intended (Gearing et al., 2011). The intervention fidelity was evaluated using a self-developed 13-item checklist covering the intervention delivery areas according to the intervention protocol to assess and monitor its implementation. **Table 7.30** shows the results of intervention fidelity. The checklist was used to monitor the performance of the intervention as per the intervention protocol. A PhD holder in Public Health and a doctoral student evaluated its manipulation. The fidelity of intervention was achieved in most delivery areas; however, keeping the strengths and addressing the limitations in planning and execution of the intervention in full-powered RCT is needed.

The results showed that all of the dyads in the intervention group had obtained the DSMES educational handbook. Teaching aids, such as LCD projectors and demonstration equipment, were used in 33 of the 36 sessions (91.7%). The three sessions without teaching aids were due to technical error and the absence of electric supply. The two-hour intervention was delivered in all of the sessions. The intervention was delivered face-to-face, and the active learning methods, including group discussion, were implemented in all 36 sessions. The intervention facilitators demonstrated how to perform self-blood glucose testing using a glucometer instrument to increase participants' understanding. The participants watched the videos on self-injection of insulin and foot care. all of the intervention participants (people with diabetes and the family caregivers) had watched the videos. After the joint session for both people with diabetes and family caregivers, a 20-minute brief discussion was conducted with family caregivers on their roles and responsibilities. People with diabetes separately watched other videos of the food estimation (with permission from Christine Wilson Owens (EthnoMed Programme Supervisor) dated June 9, 2020, and accessible on https://www.youtube.com/watch?v=XJsln4GRojQ&feature=youtu.be).

The intervention delivery process poses strengths and limitations. Comments and feedback regarding the intervention content and delivery were obtained from participants receiving the DSMES programme. The strengths of the intervention delivery were as follows: 1) the educational handbook is informative about DSM; 2) the intervention facilitators had adequate knowledge, skills and experience about diabetes; 3) audio/visual materials supported the education; 4) engaging family caregivers with us (people with diabetes) was so important to boost our (people with diabetes) self-management practise; 5) practised weekly goal setting; and 6) enabled to practise DSM. In addition, the raised limitations were as follows: 1) more group discussions are needed; 2) it is challenging to plan a diet according to this education due to low income (amongst some participants); 3) the allotted time for sessions is short; 4) more participants should be included; 5) inadequate transportation fee; and 6) a long-lasting education centre should be established. Experience sharing and group discussions were implemented in the subsequent sessions. In response to the participants' comments and feedback, clarifications were given on the allotted time, and the number of participants, diet plan, and justification for transportation fee were provided in a brief session of the next session. However, the comment about establishing a long-lasting education centre was explained as these centres are temporarily established for only research purposes, perhaps considered in the full-powered RCT if the situation permits.

Table 7.30 Utilisation of the intervention fidelity over six sessions of all six groups (n = 36 sessions)

S/N	Checklist	Total number of sessions involved, N	The number of sessions has achieved the goal n (%)	Remark
1.	Was the intervention delivered in the community?	36	36 (100.0%)	
2.	Did the DSMES handbook distribute the first session of the DSMES - session?	6	6 (100%)	The educational handbook was planned to be distributed in session one.
3.	Did the trainers use teaching aids like LCD and demonstration equipment?	36	33 (91.7%)	LCD was not used due to technical and electric supply problems.
4.	Was one session of the DSMEs given for two hours?	36	36 (100.0%)	
5.	Did the trainer cover the session's topics according to the session plan?	36	36 (100.0%)	
6.	Was the intervention delivered face-to-face?	36	36 (100.0%)	
7.	Did the trainer implement active learning methods like experience sharing and group discussion?	36	36 (100.0%)	
8.	Did the trainer show a video on self-medication?	6	6 (100.0%)	The video show was planned once for each group.
9.	Did the trainer show a video on foot care?	6	6 (100.0%)	The video show was planned once for each group.
10.	Did the family obtain 20 minutes briefing session at each session?	36	36 (100.0%)	
11.	Did the patient watch the video while the families were in the briefing session?	36	36 (100.0%)	
12.	Did the roles of the family indicated and communicated?	36	36 (100.0%)	
13.	Did written feedback be obtained from the participants at the end of all sessions?	36	36 100.0%)	

7.5.4 Acceptability of the intervention

The acceptability of the intervention was assessed using the credibility/expectancy questionnaire at T2 from dyads in the intervention group. A score of 9 shows the highest acceptability, whereas a score of 1 shows the lowest acceptability. **Table 7.31** shows the response to the six acceptability and credibility questions.

The overall acceptability of the DSMES programme intervention amongst people with diabetes in the intervention group was 8.32±0.45, showing the highest acceptability. The intervention was offered in a very logical manner (mean score = 8.45), they thought the intervention was beneficial to improving the outcomes (mean score = 8.42), and they were very confident in suggesting the intervention for other people with diabetes (mean score = 8.63). They believed that the intervention improved their diabetes-related outcomes (mean score = 7.87). They felt strongly that the intervention would improve their diabetes outcomes (mean score = 8.50) and lead to many improvements in their clinical and other outcomes (mean score = 8.03).

Like amongst people with diabetes, the family caregivers in the intervention group were asked about the intervention's acceptability. The overall acceptability of the family caregiver of the DSMES programme intervention was 8.26±0.45, showing the highest acceptability. The intervention was delivered logically (mean score = 8.45), successfully improved their supportive behaviour (mean score = 8.26), and they were confident to suggest the interventions for others (mean score = 8.53). As the intervention improved their supportive behaviour (mean score = 7.96). They strongly felt that the educational intervention would help improve their supportive behaviour (mean score = 8.42) and lead to many improvements in their supportive behaviour (mean score = 8.03).

Table 7.31 Dyads acceptability of DSMES intervention among the intervention group

Number	Item	People with diabetes (n = 36)		Family caregivers (n = 35)	
		Mean	SD	Mean	SD
1	How logical does the DSME offered to you seem?	8.45	0.98	8.45	0.86
2	How successfully do you think this education will be in your self-management behaviour, support status, and quality of life?	8.42	0.79	8.26	0.98
3	How confident you recommend this training to a friend who experiences similar problems?	8.63	0.59	8.53	0.60
4	By the end of the DSME period, how much improvement in your diabetes symptoms and support level do you think will occur?	7.87	0.78	7.96	0.68
5	How much do you feel that education will help you improve your self-care behaviours and your diabetes symptoms?	8.50	0.69	8.42	0.68
6	By the end of the education period, how much improvement in your diabetes symptoms and support level do you feel will occur?	8.03	0.64	8.03	0.57
	Total	8.32	0.45	8.26	0.45

7.6 Chapter summary

Seventy-six people with diabetes–family caregiver dyads participated in the pilot RCT with a two-month follow-up. The results showed that it was feasible to recruit and retain the participants in the intervention. The item-level missing data was low in both people with diabetes and family caregivers. The completion rate of the intervention was high. The DSMES programme was acceptable amongst the participating dyads. Although the pilot study is of limited power, the study found that the DSMES programme produced some promising preliminary results in improving HbA1c, triglycerides, self-management practise, DQOL, support needed and support received amongst adults with T2D in Western Ethiopia, with medium to very large effect sizes. In addition, the findings of this study showed that the DSMES programme produced a positive effect in improving the caregiver’s supportive behaviours but inducing the family caregiver’s non-supportive behaviours, with large effect sizes.

CHAPTER EIGHT: DISCUSSION OF FINDINGS FROM THE PILOT RCT

8.1 Introduction

This study aimed to examine the preliminary effects of the DSMES programme on the clinical, behavioural, psychological and environmental outcomes of people with diabetes and the family caregiver's supportive behaviour. The clinical outcomes were assessed using the appropriate apparatus, whereas the self-reported outcome measures were adopted from the original developer and tested for psychometric properties of the target population (Chapter Six). This chapter discusses the feasibility and preliminary effects of the DSMES programme on the clinical, behavioural, psychological and perceived support status outcomes of people with diabetes and the family caregiver's supportive behaviour.

This chapter is organised into five sections. Section 8.1 introduces the chapter. Section 8.2 discusses the feasibility outcomes, and Section 8.3 discusses the preliminary pilot RCT outcomes. The strengths and limitations of the doctoral study are discussed in Section 8.4, and the chapter summary is presented in Section 8.5.

8.2 Discussion of the feasibility of the pilot RCT

Three feasibility outcomes (recruitment rate, retention rate and item-level missing data) and acceptability of the intervention were used to assess whether the pilot RCT was feasible in delivering the DSMES programme. A discussion of these results is presented in the next sections.

8.2.1 Eligibility screening

The subjects were screened for eligibility at Nekemte Specialised Hospital when they were waiting for their monthly medical follow-up at the diabetes centre. The eligibility rate of the pilot RCT was low (39.2%) compared with RCTs conducted in different parts of Africa, namely, 78.0% for Kenyans (Gathu et al., 2018), 80.0% for Nigerians (Essien et al., 2017) and 49.3% for Egyptians (Abaza et al., 2017). The possible reason for the lower eligibility rate in the current study could be the involvement of the nine criteria for eligibility. Amongst these nine criteria, the subjects were excluded from the pilot RCT mainly because of these two exclusion criteria: 1) not living in selected Kebeles (20.3%) and 2) being unable to nominate a family caregiver (13.6%). The two Kebeles were selected based on their higher number of T2D cases and the proximity of these Kebeles to each other, and only two Kebeles were involved because of the time and resource constraints of this pilot RCT. As the sociodemographic characteristics of the target population in the city are similar, the chosen Kebeles can likely represent people with diabetes in the city. For future studies targeting people with diabetes in Western Ethiopia, the recruitment rate can be boosted through the following strategies: (1) for the recruitment issue due to the participant's residency, it can be solved by including more Kebeles, if not all Kebeles, in the accessible city for recruitment, and (2) taking more time and seeking more resources for recruitment may be the solution in accessing all of the potential subjects from all Kebeles of Nekemte City. Some people with diabetes could not nominate a family caregiver for two reasons: i) they were not living in the same home and (ii) they came from prison custody. In the future, the nomination of family caregivers can be expanded to any primary caregiver regardless of their residence.

8.2.2 Formation of the intervention centres

Three intervention centres were established in the community setting for the two selected Kebeles of Nekemte City. The distance between each intervention centre is approximately 1.5 kilometres, covering most of the areas in the two Kebeles and providing a chance for participants to take a walk.

Although setting up the temporary centres for intervention delivery was tedious, a valuable lesson was learnt about the facilitators and barriers to the centre establishment in Kebeles in Western Ethiopia. The major two facilitators were (1) the availability of cooperation from the East Wollega Zone Diabetes Association (the zone is the second subdivision of Ethiopia under the region encompassing many districts, and Woreda, Nekemte is the capital city of the zone) and (2) the creation of awareness about the research project to the local leaders, local health authorities and the institution's administrator. The major challenge was related to the use of the hall in these organisations, and it was solved through discussions and explanations with the organisation's administrators. Establishing centres in a conducive place, as well as the availability of essential training facilities, is necessary. Thus, future researchers should identify more conducive areas and sign a memorandum of understanding with the organisation's administrator in the planning stage. A good suggestion is to focus on the government's organisations because they are more likely to offer the use of halls without rent, and the research project should arrange for transportation and fulfil the lacking intervention facilities.

In the setting-up process in the pilot RCT, the stakeholder's involvement seemed to be helpful in ensuring the interventions are acceptable to people with diabetes in a feasible and maintainable real-world practical manner (Kwan et al., 2016). Two strategies in the stakeholders' approach were implemented in the study. 1) Prior discussion: The discussion was held with important service departments (diabetes centre, laboratory service and pharmacy service) and the chief executive officer and medical director of the participating hospital and the identified administrators of the organisation. Three separate meetings were conducted. The aim and procedure of the study were communicated in each meeting. The issues of reagent supply and agreement covering the laboratory costs from the research project were also signed before the study commenced. 2) Shared responsibilities: The list of responsibilities was given separately to the stakeholders. For example, the diabetes association leader gave a phone call to the Kebele leaders to seek their cooperation in the intervention delivery. The diabetes centre offered the six glucometers to support the award given to the model successors. The HEWs encouraged the intervention participants to attend the upcoming session. The Wollega University Referral Hospital supported reagents for laboratory tests when the reagents were stocked out at the participating hospital. In general, more awareness creation on the benefits of the intervention and engagement of other stakeholders, such as participating hospitals, diabetes associations and health authorities, were needed to ensure the smooth establishment of the centres. The group size for each centre was limited to fewer than 14 subjects because of the COVID-19 restrictions. The COVID-19 restrictions also forced us to establish more centres, and the intervention was delivered by complying to the COVID-19 restrictions. The subjects were informed to wear masks and keep their distance between their intervention room seats to prevent COVID-19 transmission. Undeniably, COVID-19 had a substantial impact on the effectiveness of the intervention.

8.2.3 Subject recruitment

The recruitment rate in this study was high (85.4%) and achieved the set target of 80%, indicating the feasibility of subject recruitment for future similar studies in Ethiopia. In most previous studies involving people with diabetes, the recruitment target was not achieved. For instance, a review of 151 RCTs in the UK showed that the recruitment rate ranged from 21% to 92%, and only 56% of the studies achieved the recruitment target (Walters et al., 2017). In addition, the recruitment rate in the current pilot RCT was much higher than the recruitment rates of 41.6% to 63.6% in the RCTs conducted in African countries, including Kenya (Gathu et al., 2018), Nigeria (Essien et al., 2017) and Egypt (Abaza et al., 2017). The high recruitment rate in the current study may be explained by the small targeted sample size for a pilot study. It may also be attributed to the proactive strategies used in subject recruitment of the present study, including a welcoming approach from data collectors, support from staff working in the diabetes centre and the need to obtain education on diabetes. Data collectors approached the participants in person at the waiting area of the participating hospital. After the subject provided consent, an interview was performed in a separate room. The whole process did not affect their monthly follow-up visit to the hospital as they could see a doctor immediately after completing the interview. Furthermore, as the intervention was education, they believed it could improve their behaviour, and hence, they may have been motivated to join the study. However, the COVID-19 pandemic impacted the subjects' recruitment because individuals feared to stay long in hospitals.

8.2.4 Intervention compliance

Intervention compliance is crucial for ensuring the validity of RCTs (Valentine & McHugh, 2007). This study obtained a high intervention compliance (97.4%) amongst people with diabetes and their family caregivers. The overall reasons for non-compliance in the intervention were social events (mourning for the death of a family member), one person died or health problems. These reasons are unavoidable. In Ethiopian culture, families who lose their family members mourn for more than a month. Hence, the family caregivers did not attend the intervention sessions. Family caregivers who faced acute illnesses also hindered their attendance at the sessions. Several strategies can be considered to solve these challenges in future studies, including asking a participating dyad to join another group as a means of completing the session and video recording the lecture. In this manner, participants can listen to the video by themselves afterwards.

A study conducted in Kenya reported that loss of interest in diabetes education is the main reason for intervention non-compliance (Gathu et al., 2018). In contrast to this study conducted in Kenya, the acceptability of the DSMES programme in this pilot RCT was high. Nevertheless, the dyads should be encouraged to attend the programme, as the participants' expectations of the intervention programme are linked with the intervention compliance amongst people with diabetes (Gathu et al., 2018). Although a better attendance rate was obtained in this study, a prior need assessment of the programme's content and setting the expected programme outcomes may be needed for the diabetes population in culturally diverse African countries to ensure that the contents are relevant and culturally specific.

Regarding the acceptable level of non-compliance in experimental studies, numerous studies and meta-analyses reported diverse acceptable intervention non-compliance rates. Most of the experimental studies reported that a non-compliance of less than 20% is acceptable. For example, Valentine and McHugh (2007) suggested that 16% of non-compliance is acceptable. However, Amico (2009) indicated that the completion of 70% of participants qualifies for effective intervention in each study arm. In contrast to these suggestions, the non-compliance rate in this study's intervention was low but acceptable. The high intervention compliance in this study may be attributed to the intervention delivered in the community centre near the participant's home. Moreover, the transportation fee was covered by the project, and the co-engagement of dyads from the same home may have helped encourage the participants. Besides, rewards would be given to the best performers in the intervention. In addition, the involvement of HEW to remind the participants of the upcoming session, the satisfaction of the intervention from participants in the intervention group, the intervention delivered on a weekend to fit the schedule of those who have full-time jobs and the coverage of laboratory tests fee were other possible factors. Given the low income, most participants could not afford fees for the laboratory tests. Community-based intervention may be regarded as a good strategy to boost intervention compliance in low-income countries.

The location of the community centre and covering the transportation fee may have lessened the participants' worry about the accessibility of the transportation service; that is, even if transportation service is not available, they can walk to the community centre. Transportation is a barrier to attending health institutions in low-income countries because of the high transportation fees. However, paying transportation fees may not be feasible in all research projects; thus, the centres for intervention delivery in the community should be conveniently accessed by participants.

Another possible reason to boost intervention compliance is using motivators, which are a key element in SCT. Motivators can be internal or external. Satisfaction with the intervention and rewards for best performers may encourage them to attend the interventions. Interventions delivered by healthcare professionals and HEWs reminding them about the upcoming session may also influence the intervention attendance.

Furthermore, the usual care of diabetes in Ethiopia includes a laboratory evaluation of blood glucose via fasting blood glucose, which medical laboratory professionals are supposed routinely conduct. People with diabetes were reportedly need to aware of their HbA1c levels. The cost of the HbA1c test is quite expensive, and most participants said they could not afford it. This research project covered the laboratory costs and the payment of laboratory tests with the hope that knowing their HbA1c readings may encourage them to comply with the intervention. Furthermore, the involvement of family members in the intervention may have also boosted the participation of people with diabetes. The family caregivers may have enabled the participants with diabetes to join the intervention group.

The delivery mode and material of intervention may have also contributed to the high compliance rate. The intervention was delivered in a group face-to-face format. Selecting a group format for delivery was a good choice because 19.7% of the subjects with diabetes and 26.3% of the family caregivers did not have any formal education, which is highly similar to the national education level of individuals who could not attend formal education (Ethiopian Public Health Institute (EPHI) [Ethiopia] and ICF, 2019). By using a specific group format, the participants in the intervention group could support each other during the sessions. In addition, the content of the DSMES programme educational handbook was understandable and straightforward, although some participants commented that the font size should be larger, especially for aged people, and more pictures should be included. Intervention facilitators met with assigned supervisors before the scheduled session to practise and subsequently ensure they were familiar with the content, and good facilitation skills were implemented in most of the intervention sessions. The intervention fidelity results showed that most criteria were achieved except for the teaching aid aspect. However, multiple sessions are difficult to organise and delivered in a short period, and a prior organisation of the teaching aids and other facilities in the intervention centres should have been conducted.

8.2.5 Attrition

The attrition rates of the assessments for people with diabetes and their family members at both T1 and T2 were low, but the results were statistically non-significant between the two study groups. The attrition rates were low compared with the suggested acceptable attrition rates in the literature (Amico, 2009; Valentine & McHugh, 2007). The low attrition in this study can be explained by the assessments conducted during the participants' monthly follow-up visits in the hospital. Another possible explanation for the low attrition rate may be the length of follow-up time. This study implemented the follow-ups in the second month, and a low attrition rate ranging from 5.3% to 10.5% was obtained. These attrition rates are lower than the reported attrition rates of RCT with a follow-up of six months, ranging from 21% to 41% (Gathu et al., 2018). The attrition rate of the institution-based RCTs in Ethiopia with a six-month follow-up ranged from 12.9% to 37.5% (Erku et al., 2017; Hailu et al., 2018). In this pilot RCT, the attrition was due to social events, changes in addresses and hospitalisations. Although these reasons for attrition were imminent, strategies may be necessary to reach the non-attending participants as a follow-up measure, including contact tracing via phone or in person.

8.2.6 Item-level missing data

The problem about missing data should be emphasised due to its impact on the generalizability of the RCT results and the bias between groups. Data were collected in longitudinal time-points. The study's item-level missing rate was low, ranging from 0 to 3.5%. The lowest rate of the item-level missing score was for SDSCA–Afaan Oromoo, whereas the highest level was obtained for the support attitudes–Afaan Oromoo scale. Most of the scales' missing data were similar between the intervention and control groups.

The low rates in the obtained missing item data can be explained by several reasons. Firstly, the scales were translated and culturally adapted, and psychometric properties were tested for the same target population before implementing the pilot RCT. Secondly, except for DQOL, all of the scales used were short, with the number of items ranging from 10 to 34. Moreover, all items were closed-ended questions so that they were not time-consuming and easy to answer. Thirdly, the data were collected at a conducive place via a face-to-face interview technique in a separate room near the diabetes centre in the hospital. A conducive place is necessary to grasp the attention of participants whilst interviewing them. Besides the effective interviewing skills, an appropriate place of interview is essential because people in Ethiopia need hospitality and a conducive place to share their feelings. Thus, experienced data collectors and conducive interview places can help to gather more information, thus minimising the instances of incomplete questionnaires. Fourthly, regarding the adequate time needed for the interview, people with diabetes usually arrive at the hospital early in the morning because they are required to have a fasting blood sugar test. After taking the laboratory results, the participants could stay in the waiting area. The data collectors could easily approach and interview them. In the future, the low missing data of the items may be ensured by using scales during interviews.

In conclusion, low eligibility rate, high recruitment rate, intervention compliance and retention rate were obtained from the pilot RCT. On the basis of the experience from the pilot RCT, future studies in diabetes research to be conducted in Ethiopia may consider the following aspects: (i) providing hospitality and a conducive place for participants to share their feelings; (ii) using experienced data collectors and (iii) conducting face-to-face interview in a conducive room in a similar cultural setting. To increase the eligibility rate, researchers may involve participants from all Kebeles of Nekemte City and their family caregivers regardless of the home of residency. Extending the screening period may also be an option to increase the eligibility rate. The recruitment rate can be boosted by applying proactive strategies, such as a welcoming approach by data collectors, support from staff working at the diabetes centre of the participating hospital and improving the perceived benefits of the intervention. Intervention compliance can be enhanced by establishing more intervention centres, involving healthcare workers, arranging conducive times and areas for intervention and increasing the satisfaction of intervention receivers. Retention can be improved by designing a programme that would engage more dyads, thus achieving the expectations in the intervention, and conducting a prior need assessment of the programme. Future studies involving this target population in Ethiopia need to consider the aforementioned strategies to increase the eligibility, recruitment, retention and intervention compliance.

8.3 Discussion of the preliminary efficacy of the intervention

The study found that the DSMES programme intervention had favourable effects on reducing HbA1c, lowering triglycerides, improving self-management behaviour, enhancing DQOL and improving the support needed and the support received, with medium to large effect sizes amongst people with diabetes in Western Ethiopia. Similarly, the family caregiver's supportive behaviour was enhanced over the study periods, but non-supportive behaviour was improved only during the follow-up. Whilst blood pressure and BMI were reduced to a similar extent in both groups, the decrease in total cholesterol, LDL cholesterol and HDL cholesterol over time was more apparent in the intervention group than in the control group. Regarding the aspects of support needed and support received, they increased but eventually decreased with respect to support attitudes in the intervention group compared with those in the control group. The following sections discuss the primary and secondary outcomes of dyads.

8.3.1 Primary outcomes

8.3.1.1 HbA1c

A reduction of 1.10% in HbA1c in the intervention group in contrast to an increase of 0.57% in the control group led to a large effect size of 0.81. American Diabetes Association (2020) recommends MNT to improve weight and glycaemic control. Nutrition therapy delivered by comprehensive, knowledgeable and experienced professionals in diabetes care can reduce HbA1c by 0.3% to 2.0% for people with T2D (Franz et al., 2017). The intervention implemented two techniques to improve HbA1c: 1) nutrition education, in which food is considered an essential feature in controlling blood glucose and 2) family support during food preparation. For the first technique on nutrition education, Western Ethiopia-specific food was delivered, and food portion estimation was considered. The intervention participants were asked to partake in setting a weekly goal for consuming a healthy diet. Observational learning techniques, such as the plate method, cup-for-food estimation, demonstrations and videos were delivered to the intervention group. Considering that the level of education of most participants was low, such instrumental education may have led to behavioural change. For the second technique on family support during food preparation, an Ethiopian tradition, especially at lunch and dinner, is to consume food with all family members from a communal plate. Eating together is an essential part of Ethiopian culture, and it is a sign of love (Soumya, 2020). Given this tradition, a family will likely prepare the meals to suit all family members instead of only the family member with diabetes, who incidentally needs to follow a diet for diabetes control. Thus, the dietary preference or needs of the person with diabetes may not be respected. In this regard, the intervention in the pilot RCT involved the family as a crucial stakeholder in improving nutritional habits (Pesantes et al., 2018; Withidpanyawong et al., 2019). The dietary intake directly relates to glycaemic control and is one of the major factors for modification.

Moreover, the family members were asked to actively participate in the self-management activities of their relatives with diabetes. For instance, the dyads were instructed to take part in purchasing and preparing food and performing physical activity together with the person with diabetes, and the family member should remind him or her of blood glucose testing and medication intake. The participation of the family members in the self-management of persons with diabetes can help to improve their HbA1c level.

A reduction of 1.10% in HbA1c in the intervention group entailed numerous health benefits. According to the observational study conducted by the UK Prospective Diabetes Study (UKPDS) Group, a reduction of 1% in HbA1c can decrease the risk for microvascular complications by 37%, myocardial infarction by 14%, and diabetes-related deaths by 21% (UKPDS Group, 1998). Such reduction in the intervention group was also considered clinically significant (>0.5%) (Little et al., 2011). A decrease in 1.10% in HbA1c in the intervention group can potentially halt the risk of microvascular complications by 37%, myocardial infarction by 14% and diabetes-related mortality by 21%. American Diabetes Association (2020) also recommends the HbA1c of people with diabetes to be maintained at <7%. However, the HbA1c levels for both groups remained uncontrolled. The meta-analysis of studies involving African Americans (Cunningham et al., 2018) and DSM interventions amongst African people with diabetes (Diriba et al., 2021b) also showed ineffective results in terms of reducing HbA1c. The DSMES programme intervention with diet modification and social support in this pilot RCT may provide promising results, thus curbing these challenges in African countries. The large effect size of the DSMES programme intervention in this study compared with the usual care approach suggests that culturally specific dietary intake and family involvement in planning and implementing DSM activities is an option for controlling HbA1c in countries with dietary challenges. Subsequently, a full-scale main RCT based on the findings from the current pilot study is needed to generate evidence regarding the implementation of the DSMES programme in light of the diabetes education efforts in hospitals in Ethiopia.

8.3.1.2 Family caregiver’s support behaviour

The DSMES programme produced positive results in terms of the family caregiver’s supportive behaviour over the study period between the two groups. The DSMES programme outperformed the usual care approach with a medium effect size for T1 and a large effect size for T2 in terms of supportive behaviour. The positive change in the family caregiver’s supportive behaviours could be related to the DSMES programme providing a specific component to clarify the role of the family caregivers in diabetes management, further encouraging family caregivers to provide continuous support to their relatives with diabetes. The supportive behaviour of the family may encourage the self-care behaviours of the person with diabetes and discourage the negative ones (August et al., 2011; Beanlands et al., 2005; Newton-John et al., 2017). The family members obtained education on diabetes, its management, their roles in DSM and the misconceptions about diabetes in Ethiopia. Although most previous studies supporting family involvement in the intervention produced positive outcomes, some researchers argued that the roles of the family should be clearly stated in the intervention (Baig et al., 2015). This study clearly defined the family’s roles in each session. Defining the family roles may have been the reason for the effective supportive behaviour.

The RCT conducted in Jimma University Medical Centre, Ethiopia, reported that DSM education was successful in increasing diabetes knowledge (Hailu et al., 2019). Diabetes-related knowledge may be one reason affecting the supportive behaviour of family members. Education on diabetes and self-management was given, as these elements could change their knowledge and behaviour to support relatives with diabetes. Weekly goal setting was set to provide support, further increasing their supportive behaviour. Another possible reason for the enhanced family caregiver's supportive behaviour may be the increased self-efficacy owing to the intervention. Local diabetes-related misconceptions and myths were also addressed in the intervention. Group discussions and experience sharing on family support from participants were raised in the intervention sessions. Observational learning could help them develop the positive supportive behaviour of families who attended the intervention. Hence, a good recommendation is to include education on local diabetes misconceptions and myths, sharing positive experiences, clearly defining the roles of family in DSM, and arranging discussions on unclear issues.

The family caregivers held non-supportive behaviours at T2 but not at T1. Presumably, the family members may have been overwhelmed by behaviours, such as the non-compliance to DSM, of persons with diabetes, leading them to feel annoyed and manifest non-supportive behaviours. Family members were not non-supportive at post-intervention. This might be due to the intervention effect, as they might be aware of what to do and don't. However, they might become reluctant to provide support and show supportive behaviour in a longer period due to the chronic nature of the disease and low family income. Hence, the dosage for family members in the intervention should be strengthened to reduce or halt the non-supportive behaviour of the family caregivers. Another possible reason for non-supportive behaviour could be that family members might consider the support related to medication, dietary management and self-monitoring of blood glucose as primarily the responsibility of the healthcare workers. Nevertheless, further support to family caregivers in the intervention and the corresponding time requirement may be considered, such as seeking the help of healthcare workers in the community to help with the awareness creation about DSM activities. In this study, only 11.8% of the participants received insulin and metformin as prescribed in BID (twice a day), usually taking them in the morning and at night. Thus, families may not consider the person's sleeping time because they usually sleep after taking a drug; hence, it may not be regarded as a non-supportive behaviour. Encouraging family supportive behaviour is necessary to positively affect most diabetes outcomes.

8.3.2 Secondary outcomes

8.3.2.1 DSM behaviours

The DSMES programme effectively improved the DSM behaviours, and the effect sizes were large. Behavioural change strategies, such as symbolising, family support, goal setting, giving awards and experience sharing were implemented in the intervention, leading to the retention of knowledge applicable to the practise of DSM. Goal setting is widely recommended in interventional studies related to DSM (Locke & Latham, 2002), and it was reported as an effective strategy for behavioural change (Fredrix et al., 2018; O'Donnell et al., 2018). This finding is consistent with the results of the nurse-led DSM education and community-based interventional studies (Azami et al., 2018; Ing et al., 2016). Socially supportive group-led DSM education increases self-management practise (Ing et al., 2016), and it is especially effective amongst the low-income population (Vest et al., 2013). Hence, socially supportive (including the families' support), community-based and nurse-delivered DSM education is obligatory to improve and sustain self-management behaviour. Family-based DSM education was reported to improve self-care behaviour (Felix et al., 2019; Pamungkas et al., 2017).

Family influences may include nagging on dining, preparation, purchasing of food and disease-related misconceptions, which affect people with diabetes. However, positive family support was obtained by participants in the intervention group. The strong self-efficacy of the families may be associated with the enhanced DSM behaviour. Hence, family involvement in diabetes education may be needed to improve DSM behaviour. The plate method was used to estimate the healthy food proportion, and demonstration on SMBG and videos on foot care and self-insulin injection were also used. These techniques may influence the behaviour because SCT states that learning is enhanced if it is learnt via observation (observational learning). Reinforcements are also a necessary aspect of learning (Bandura, 1986). Here, best performers in the intervention were awarded, which could be a good strategy to motivate behavioural change. Therefore, reinforcement, goal setting, consistent family support, giving an award and experience sharing about successes should be practised.

The DSMES programme focused on the modification of the diet component by adding more nutritional education specific to Ethiopian culture to address the most challenging part, namely, dietary change. Observational learning via modelling of food estimation using the plate method may be one factor for gaining the positive effects on the DSM behaviours pertaining to diet and blood glucose testing. Goal setting boosts self-efficacy, and those persons with diabetes with higher self-efficacy are more likely to perform self-management behaviours (Oluma et al., 2020). Misconceptions about food in Ethiopian society may contribute to the dietary and blood glucose testing behaviour. Misconceptions were also addressed in the intervention.

Furthermore, fasting-related food intake was also discussed in the intervention. Orthodox Christian followers usually practise religion-based withholding of fatty foods, meat, milk and milk products every Wednesday and Friday. More than one-third (35.5%) of people with diabetes were Orthodox followers. In the Muslim religion, there is a time for fasting food in the daytime for a month. Similarly, Protestant Christians frequently practise fasting and prayer. The nutritional education component of the intervention addressed the fasting-related food intake, which may increase their nutritional knowledge during fasting and enhance their dietary intake practise according to the recommendation. Providing plates appropriate for food estimation, cups and glucometers may also improve the DSM behaviour pertaining to diet and blood glucose testing. However, the participants in this study had a low monthly income, and together with the existing economic inflation, following the general and specific dietary intake recommendations may be challenging. Hence, looking at the diverse sources of foods from local sources and, if possible, people with diabetes to consider setting a farm in their compound may increase the availability of vegetables and fruits (Muchiri et al., 2016).

8.3.2.2 DQOL

The preliminary result showed that the DSMES programme effectively enhanced the DQOL in contrast to the usual care approach. The possible reasons for the promising effect of the DSMES programme on DQOL may be attributed to family support, increased self-management behaviours, possibly due to self-efficacy, healthy coping and problem-solving skills. Family support is central in improving QOL because they are involved in all aspects of the life of a person with diabetes. Family support is prominent in the management of diabetes, and it can ensure the well-being of persons with diabetes and help them achieve utmost satisfaction (Ahmed & Yeasmeen, 2016). Social support is found to positively influence QOL (Azami et al., 2018). Family members can also play a significant role in adopting the relatives and in keeping lifestyles and behaviours crucial for attaining behavioural outcomes (Mayberry & Osborn, 2012). The family can be involved in emotional, informational, tangible and companionship support (Delamater & Marrero, 2020). Family may support the person with diabetes in terms of the satisfaction, impact and social/vocational aspects of having diabetes.

The diabetes family behaviour was a predictor of diabetes satisfaction and impact (Trief et al., 1998). For example, diabetes may interrupt the leisure time of persons with diabetes. The family can give them the time to share their leisure time; hence, they may not feel the impact of the disease. In addition, the intervention addressed the complications of diabetes; therefore, the chance to worry about diabetes-related complications may be reduced amongst participants in the intervention group. Diabetes-related worry was unrelated to family supportive behaviours (Trief et al., 1998); hence, intervention should focus on diabetes complications and what to do when the complication occurs.

Healthy coping and problem-solving skills were also delivered in the intervention. Healthy coping intervention may improve diabetes life satisfaction and its impact. Problem-solving skills may improve the social/vocational worrying problem because they introduce the practical skills to solve social and vocational challenges. The meta-analysis of RCTs involving African Americans showed that DSM education effectively improved QOL (Cunningham et al., 2018). A nurse-led and group-based family-supported DSM education intervention effectively increased QOL (Azami et al., 2018). The reviews of RCTs found that family support positively impacted the QOL and is one of the emotional coping mechanisms (Azami et al., 2018; Pamungkas et al., 2017). It is supported by a finding from a systematic review that included 23 studies to see the effect of family support on diabetes outcomes amongst people with T2D that showed positive outcomes on psychosocial well-being (Pamungkas et al., 2017). Family support may have enhanced the self-efficacy of people with diabetes. These findings are consistent with the result of this study. It can be suggested that family support, coping strategies, problem-solving skills, and enhancing self-efficacy are needed to improve the QOL amongst people with diabetes. However, this assertion has to be tested in future studies that collect data on participants' coping strategies, problem-solving skills, and self-efficacy.

Another possible reason for enhanced QOL was the use of diabetes-specific measures. The DQOL scale was used to measure QOL in this study. Unlike a previous study that used a generic health-related QOL scale showing that the intervention was not effective in all components of QOL (Mash et al., 2014), the DQOL is a more accurate measure of QOL and hence should be more sensitive to the change in DQOL. Therefore, we can observe a change in QOL in a shorter time compared with previous studies, which usually claimed that a follow-up time of six months is needed to observe a change in DQOL (Azami et al., 2018; Mash et al., 2014).

8.3.2.3 Support status

The preliminary DSMES programme significantly improved the support needed and received outcomes compared with the usual care. The main possible reason for better support needed and received from friends or families was the involvement of family caregivers in the intervention. According to SCT, family support is an environmental factor that influences personal behaviours. The support seeking behaviour of people with diabetes may be increased because the family caregivers co-attended the intervention and set a goal together, which may give them intimacy about diabetes and its management. A finding from a systematic review that included 23 studies to see the effect of family support on diabetes outcomes amongst people with T2D showed a positive outcome on perceived support (Pamungkas et al., 2017). In this study, nearly two-thirds (64.5%) of people with diabetes received support from spouses. The support needed from their friend or family may be enhanced because of frequent interaction between their spouse and people with diabetes. Most spouses live in the same home in Ethiopia and decide on most issues together. Hence, the chance to seek and receive support from their spouse is more likely compared with friends and other family members. More than two-thirds (69.7%) of family caregivers were females. In Ethiopia, females provide home-based support for a sick and diseased person; in contrast, males are responsible for most outdoor activities. Females provide better informal care for people with chronic illnesses (Sharma et al., 2016). Females are more likely to discuss and support purchasing and preparing foods, delivering drugs, foot washing equipment, assisting in blood glucose testing, and supporting on sick days (Bekele et al., 2020).

The females obtained a healthy diet for a person with diabetes and the technique of food estimation. Their diabetes knowledge may be increased by observation and experience sharing on DSM. A previous study reported that DSM education improved social support status (Azami et al., 2018). These findings are consistent with the result of this study, perhaps due to family involvement because their involvement will promote healthy behaviour and well-being (Schiøtz et al., 2012). Hence, it can be recommended that family involvement in the intervention, increased interaction between people with diabetes and family or friends and awareness creation for people with diabetes on the importance of social support in DSM is needed.

In contrast, the DSMES programme has not effectively improved the support attitudes in the intervention group compared with the usual care. Verbal persuasion and increased behavioural capacity were designed to boost the support attitudes. A community-based study implementing DSM education intervention found that intervention was ineffective compared with usual care (Sugiyama et al., 2015). The study reported that empowerment was ineffective in increasing social support, implying support attitudes may not be related to verbal persuasion, behavioural capacity, and empowerment, indicating that support attitudes may take intensive intervention and lower intervention duration.

8.3.2.4 Blood pressure

The DSMES programme did not produce a promising effect on blood pressure compared with the usual care, although greater reductions in both SBP and DBP were observed in the intervention group. The DSMES intervention programme did not achieve the target treatment level of SBP but DBP (American Diabetes Association, 2020). Nutrition therapy aims to attain and maintain normal blood pressure (Powers, Bardsley, & Cypress, 2015). The dietary approach and physical activity were intended to control blood pressure in the intervention group. However, the intervention was ineffective in controlling blood pressure.

Given that 48.7% of the participants with diabetes had hypertension and the blood pressure results remain above normal, special dietary education and more demonstration on physical activity may be needed. ADA-2020 recommended, 'a DASH eating pattern, including reducing sodium and increasing potassium intake, moderation of alcohol intake, and increased physical activity' (American Diabetes Association, 2020). However, this study did not focus on this dietary approach targeting hypertension recommended for intervention. The meta-analysis of RCTs from Africa showed effective reductions in SBP and DBP (Diriba et al., 2021b). The disparity between the findings may be due to two factors. Firstly, the longer duration of the intervention, and Secondly, most of the included studies were done in clinical settings. Therefore, a longer period may be needed, including the DASH component in the intervention.

8.3.2.5 BMI

BMI is calculated to determine whether overweight or obese. In this study, BMI was in the normal range (<25 kg/m^2) (WHO Expert consultation, 2004), but a slightly better reduction was obtained in the control group than in the intervention group. Dietary therapy, physical activity and self-management behavioural change were implemented in the study. The cumulative effect of these self-management activities and pharmacologic interventions are needed to control weight (American Diabetes Association, 2020). The observed small effect size in BMI may be that the change in weight takes longer than changes in lifestyle habits. Another possible explanation for ineffective BMI may be the inaccessibility of foods for diabetes control in Ethiopia (American Diabetes Association, 2020). Thus, accessing a healthy diet and more extended DSMES intervention may be needed to change BMI.

8.3.2.6 Lipid profiles (total cholesterol, LDL, HDL and triglycerides)

In the present study, except for triglycerides, lipid profiles were not effectively improved by the DSMES programme. The dietary approach, weight loss, family support and physical activity were delivered. The nutrition education in the intervention focused on glucose sources. The family involvement did not show an effective reduction in most lipid profiles. It is supported by the studies conducted in Brazil and Thailand showing that family intervention is not effective on all lipid profiles (Gomes et al., 2017; Kang et al., 2010). The meta-analysis of RCTs in Africa showed a slight reduction in total cholesterol (Diriba et al., 2021b). However, one reason for the difference may be the dietary practise, as the recommended dietary intake was low. On the other hand, triglycerides were effectively reduced, which may be due to medical nutrition education being sensitive to triglyceride reduction.

In future studies, food sources for lipids should be focused chiefly on 'good fat' food sources. Behavioural changing strategies are also necessary to change lipid profiles (Powers, Bardsley, & Cypress, 2015). However, a low income hinders the consumption of recommended foods. Practical estimation tools should be practised rather than focusing on macronutrients and micronutrients.

8.4 Strengths and limitations of the doctoral study

The study had some strengths and limitations. The SCT and results of the systematic review and meta-analysis on the effectiveness of self-management programmes amongst adults with diabetes in Africa (the details were provided in Chapter Two) were used to guide the intervention development. The constructs of SCT were addressed, including reciprocal determinism, observational capacity, observational learning, reinforcements, and self-efficacy.

Various behavioural strategies supported with theoretical constructs were used to enhance learning. The intervention materials were developed based on international guidelines and culturally specific materials. The intervention addressed self-care activities focusing on nutritional education. Misconceptions about diabetes were also discussed in the intervention. Culturally tailored intervention that addressed the misconceptions amongst the study population was delivered. The educational handbook was developed and validated by experts and people with diabetes. Disease-specific and psychometrically evaluated scales measured the self-reported outcome. The Cronbach's alpha of the scales ranged from acceptable to good reliability. Though the COVID-19 pandemic influenced the data collection for psychometric properties testing, all scales used for self-reported outcomes were translated, culturally adapted, and tested for psychometric properties. Large sample sizes were involved in these psychometric properties testing. High recruitment, retention, and response rates were obtained in the pilot RCT, and the intervention was acceptable. The intervention was delivered in the community setting, with closer intervention centres.

Apart from these strengths, the study possessed some limitations. The use of two Kebeles restricted subject recruitment. The intervention is a resource-intensive, and the establishment of an intervention centre and the use of healthcare workers may not be possible in other settings or countries, hence may restrict its applicability. Hence, the future study should include non-healthcare workers like HEWs or religious leaders as intervention facilitators.

Convenience sampling was used to recruit subjects in the scale validation and pilot RCT, making generalisation difficult. As the study was a pilot RCT, it presented limited power to conclude the efficacy of the intervention on the outcomes. The future trial could employ the probability sampling techniques to recruit subjects. Although the recruited subjects' attendance for follow-up was scheduled on different days for the participants in each arm, it could not be free from information contamination. Availability of information contamination may affect between-group differences in terms of efficacy of the intervention programme. The recruitment of subjects from different centres may be a solution for future study. The study did not address the exit interview or qualitative issues to examine the acceptability and effectiveness of the DSMES programme. Hence, future studies need to conduct exit interviews or qualitative studies to supplement the RCT results.

8.5 Chapter summary

The feasibility outcomes, including the subject recruitment, retention, acceptability and missing data, were comprehensively discussed. A welcoming approach by data collectors and health professionals in the diabetes centre and the perceived importance of the planned intervention favoured the higher recruitment rate. Retention in the intervention was encouraged by a continuous reminder from HEWs, intervention facilitators, the establishment of nearby intervention centres and the coverage of the transportation fee. Only a few data were missed from the scales because of the closed-ended questions, prior cultural adaptation and the use of psychometrically evaluated scales amongst similar target populations.

The pilot RCT successfully measured the outcomes. The results showed that the DSMES programme can produce a promising positive effect on controlling blood glucose, improving self-management behaviours, enhancing QOL and perceived support from family/friends and improving family supportive behaviour. These findings are consistent with most previous RCTs; thus, a future full-scale RCT should be conducted using the outcomes' efficacy results and effect sizes to estimate sample sizes, and the full-scale RCT results can inform whether the programme can be used in clinical practise and diabetes education.

CHAPTER NINE: CONCLUSION AND RECOMMENDATIONS

9.1 Introduction

This chapter presents the implication, conclusion and recommendations of the whole thesis. The findings of the study have implications for research and practise. A psychometric testing of four self-reported scales was conducted, and the findings verified the acceptable to good reliability and construct validity. The pilot study's findings suggested the possibility of adequately recruiting subjects with good intervention compliance. Furthermore, the intervention materials can be used in future research and clinical practise. This study is a pilot RCT, and the aim was to examine the feasibility and preliminary effects of the DSMES programme on the clinical, psychological and social support for persons with diabetes and the family caregiver's supportive behaviour. The DSMES programmes produced promising effects on HbA1c, triglycerides and psychosocial outcomes but not on other clinical outcomes, such as SBP, organised total cholesterol, LDL cholesterol and HDL cholesterol.

The chapter is organised into four sections. Section 9.1 introduces the implications of the doctoral study. Section 9.2 delineates the implications of the pilot RCT. The conclusion of the doctoral study is presented in Section 9.3. Lastly, Section 9.4 highlights the recommendations of the pilot RCT study.

9.2 Implications of the pilot RCT

The results of the doctoral study may have positive implications for future research and practise. Section 9.2.1 delineates the implication of the study for future research, and Section 9.2.2 presents the practical implication.

9.2.1 Implications for future research

This study is the first RCT conducted to examine the effect of a community-based, culturally specific and SCT-guided DSMES programme on the clinical, psychological outcomes and support status of persons with diabetes. The study also involved family caregivers in the DSMES programme, and the specific family caregiver's roles were delivered in the intervention for dyads of people with T2D in Western Ethiopia. This study addressed two steps of the MRC framework: the intervention development and the testing for feasibility/pilot of the study methods (Craig P, 2019). The intervention was developed effectively based on SCT (Bandura, 1986) and the results of the systematic review and meta-analysis regarding the effectiveness of self-management programmes amongst adults with diabetes in Africa (Diriba et al., 2021b). The developed intervention was prepared in the form of educational handbooks, videos and flyers, which were validated by experts and people with diabetes. In the future, the intervention may be supported by more practical tools and strategies in food estimation, but a longer duration may be needed to ensure improvements in the clinical outcomes and the family's supportive behaviour. Then, the pilot RCT involving 76 dyads living in Western Ethiopia was conducted. The feasibility outcomes showed promising feasibility of the intervention. However, the intervention centre formation was a tedious process because it was dependent on the willingness of the organisation's owners and required cooperation from several stakeholders, such as hospitals, local health authorities and local diabetes associations. The intervention was also costly because of the need to coordinate with HEWs, transportation fees and laboratory fees. In this regard, future RCTs should consider the time requirement and the need to coordinate with community-based centres through a formal agreement with the organisation owner.

Moreover, if adequate funds are available, then establishing long-lasting training/DSMES centres in the community may be obligatory. Another implication of the study is the scope of the study area. Due to resource constraints and the largely unknown feasibility of the study, the subject recruitment was limited to two selected Kebeles. Hence, the future study needs to include participants from all Kebeles. Furthermore, other feasibility outcomes showed adequate recruitment, high retention rates and high programme acceptance.

The pilot RCT findings showed that the DSMES programme can produce promising results in most measured outcomes compared with the usual care approach. The intervention positively affected the HbA1c, self-management behaviours, DQOL and perceived social supportive behaviour of people with diabetes and the family caregiver's supportive behaviour. In addition, the effect sizes of between-group differences were identified. The next step is the evaluation of the DSMES programme's effectiveness on a large sample size. The effect sizes can be used to determine the sample size in future RCTs. In summary, an evaluation of the DSMES programme may be conducted by improving the available limitations and continuing the strengths involving people with T2D–family caregiver dyads in Ethiopia.

Using DQOL as a tool for measuring the outcome of people with diabetes may provide a more accurate measure of QOL in the target group than by using studies that require generic measures (Bradley, 2001; Nair & Kachan, 2017). Further validation studies for other scales are needed, particularly the one on family caregivers, as only test–retest reliability and internal consistency were assessed.

9.2.2 Implications for practise

The DSMES programme can be recommended in clinical practise. However, blood tests should be routinely performed; it was not carried out in Western Ethiopia. The developed educational handbook, videos and flyers can be used in diabetes education by healthcare institutions for people with T2D–family caregiver dyads. The intervention programme produced a clinically significant reduction in HbA1c in the intervention group. Furthermore, the decrease in HbA1c can reduce microvascular and macrovascular complications, as the reduction in the intervention group was 1.1%. The observational study conducted by the UKPDS Group showed a 1% reduction in HbA1c, attributing it to a decrease in 37% risk of microvascular complications, a decrease in 14% risk of myocardial infarction, and a decrease in 21% risk of diabetes-related deaths.

Moreover, the DSMES programme positively affected the psychological and perceived social support outcomes. Hence, clinicians may consider this intervention programme for sustainable self-management behaviour and QOL enhancement. The programme also boosted the behaviour to seek and receive social support. Furthermore, the intervention was facilitated by nurses. The nurses can deliver all components of DSMES without seeking other professionals to obtain better outcomes. Hospital-based diabetes education can be conducted during the morning session, and it offers an option for establishing community-based diabetes education centres and delivering outreach education.

9.3 Conclusion

The pilot RCT involved 76 people with diabetes–family caregiver dyads who were attending the Nekemte Specialised Hospital. The DSMES programme was delivered for six weeks in the community setting, and it was led by nurses. The recruitment rate, retention rate, item response rate and acceptability of the intervention were high. The intervention was delivered as intended in most of the sessions. Although the limited power of the pilot study made it difficult to reach a conclusion, the SCT-guided, nurse-led and community-based DSMES programme produced a promising positive effect on controlling glucose, improving self-management behaviours and enhancing the QOL and perceived support from their family/friends, and it also improved the family’s supportive behaviour. However, the programme seems weak in terms of reducing other clinical outcomes amongst adults with T2D in Western Ethiopia. Finally, the intervention boosted the family's supportive behaviour. Thus, family support should be incorporated into DSM programmes.

9.4 Recommendations

1) Community-based interventions should be encouraged in low-income countries to obtain better clinical and psychosocial outcomes.
2) Nurse-led, community-based DSMES programme showed promising effects on most diabetes-related outcomes. Therefore, nurses should deliver DSM education.
3) The DASH eating approach and lipid food sources should be incorporated into the DSMES programme in the future.
4) Future research should involve people with diabetes–family caregiver dyads from all Kebeles of Nekemte City, perhaps those in multicentres involving a large population depicting similar study characteristics.
5) A full-scale RCT is needed to evaluate the effectiveness of the DSMES programme on the clinical, psychological and support status outcomes amongst people with diabetes–family caregiver dyads.
6) Further psychometric testing of the outcome measures should be conducted, as only internal consistency and construct validity were assessed.

APPENDICES

Appendix I Pilot RCT ethical approval letter

THE HONG KONG POLYTECHNIC UNIVERSITY
香港理工大學

To	Leung Yin Ping (School of Nursing)		
From	Choi Kup Sze, Chair, Departmental Research Committee		
Email	thomasks.choi@	Date	09-Nov-2020

Application for Ethical Review for Teaching/Research Involving Human Subjects

I write to inform you that approval has been given to your application for human subjects ethics review of the following project for a period from 01-Dec-2020 to 30-Sep-2021:

Project Title:	Effectiveness of a nurse-led community-based self-management program for patients with type 2 diabetes mellitus in Western Ethiopia: A pilot study
Department:	School of Nursing
Principal Investigator:	Leung Yin Ping
Project Start Date:	01-Dec-2020
Reference Number:	HSEARS20201019003

You will be held responsible for the ethical approval granted for the project and the ethical conduct of the personnel involved in the project. In case the Co-PI, if any, has also obtained ethical approval for the project, the Co-PI will also assume the responsibility in respect of the ethical approval (in relation to the areas of expertise of respective Co-PI in accordance with the stipulations given by the approving authority).

You are responsible for informing the Human Subjects Ethics Sub-committee in advance of any changes in the proposal or procedures which may affect the validity of this ethical approval.

Choi Kup Sze

Chair

Departmental Research Committee (on behalf of Human Subjects Ethics Sub-Committee)

Appendix II DSMES programme expert validation form

The Hong Kong Polytechnic University

School of Nursing

Expert committee feedback

Instruction for the experts

You are invited as a member of an expert panel to judge the content of the intervention protocol. You are selected based on your expertise related to diabetes mellitus and clinical experience. The main purpose of this work is to validate the content of the intervention protocol titled 'Diabetes self-management education and support handbook.' This intervention protocol is developed to provide education and support for people living with type 2 diabetes and the primary family caregivers in Nekemte city. The main aim of the intervention is to deliver brief information and recommendations on the definition and pathology of diabetes, seven content areas of self-care behaviours developed by the Association of American diabetes educators, and misconceptions related to diabetes in Ethiopia. These contents are arranged into six sessions in the handbook.

Before we use this protocol, we would like to receive your kind feedback on whether the content matches the best available evidence, is appropriate, and is culturally acceptable. You can add or remove the statement or section if needed. However, we kindly request you give your feedback using 'track change' or write it down on the hard copy.

Please take your time and decide by specifying your comment whether it is appropriate to use, appropriate with modification, or not appropriate. Also, provide an overall suggestion about the handbook. Please submit the written report through my email address: 1904 @ .

Please read the ‘Diabetes self-management education and support’ handbook and rate all sessions of this educational handbook in terms of relevance to diabetes management, appropriateness of the content and feasibility to the target subjects. Encircle your response to the number indicating the rate.

Session	**Response**			
	Relevance to diabetes management			
	Not relevant	Somewhat relevant	Quite relevant	Very relevant
Session 1. Introduction about diabetes mellitus and misconceptions in Ethiopia	1	2	3	4
Session 2. Self-management: Medical nutrition therapy	1	2	3	4
Session 3. Physical activity and medication	1	2	3	4
Session 4. Self-monitoring of blood glucose and foot care	1	2	3	4
Session 5. Coping with psychosocial issues and problem-solving skills	1	2	3	4
Session 6. Diabetes mellitus complications and conclusion	1	2	3	4
	Appropriateness of the content			
Session	Not appropriate	Somewhat appropriate	Quite appropriate	Very appropriate
Session 1. Introduction about diabetes mellitus and misconceptions in Ethiopia	1	2	3	4
Session 2. Self-management: Medical nutrition therapy	1	2	3	4
Session 3. Physical activity and medication	1	2	3	4
Session 4. Self-monitoring of blood glucose and foot care	1	2	3	4
Session 5. Coping with psychosocial issues and problem-solving skills	1	2	3	4

Session 6. Diabetes mellitus complications and conclusion	1	2	3	4
	Feasibility to the target subjects			
Session	Not feasible	Somewhat feasible	Quite feasible	Very feasible
Session 1. Introduction about diabetes mellitus and misconceptions in Ethiopia	1	2	3	4
Session 2. Self-management: Medical nutrition therapy	1	2	3	4
Session 3. Physical activity and medication	1	2	3	4
Session 4. Self-monitoring of blood glucose and foot care	1	2	3	4
Session 5. Coping with psychosocial issues and problem-solving skills	1	2	3	4
Session 6. Diabetes mellitus complications and conclusion	1	2	3	4

Overall suggestion (very important)

Please put your genuine feedback, whether positive or negative, here below regarding the intervention protocol.

Appendix III Eligibility screening criteria for pilot RCT

Eligibility criteria (for the person with diabetes)

S/N	Criteria	Status		Remark
		No	Yes	
1.	Diagnosed with type 2 diabetes			Verify from the patient's medical record.
2.	Aged 18 years or above			
3.	Came from two selected Kebeles of Nekemte city			
4.	Taking medication treatments (insulin and/or oral hypoglycaemic agents)			
	Exclude if			
1.	Has cognitive impairment			Verify from people with diabetes medical record.
2.	Able to nominate one family caregiver			
3.	She is a pregnant woman			
4.	People with diabetes has physical impairments like blindness, paralysis, etc.			
5.	He/she unable to speak and understand the Afaan Oromoo language.			

Decision: Included/ excluded in the study (please encircle one)

Eligibility criteria (family caregiver)

S/N	Criteria	Status		Remark
	Include if	No	Yes	
1.	Is she/he a primary caregiver of people with diabetes?			Verify from the family member
2.	Aged 18 years or above			
3.	Do you have a willingness to provide support to people with diabetes?			
4.	Are you living in the same home with people with diabetes?			
	Exclude if			
1.	He/she unable to speak and understand the Afaan Oromo language.			
2.	Do you have any physical limitations to perform the caregiver responsibilities?			

Decision: Included/ excluded in the study (please encircle one)

Appendix IV Information sheet for pilot RCT - English Version

The Hong Polytechnic University

School of Nursing

Study title: Effectiveness of a nurse-led community-based self-management programme for people with type 2 diabetes in Western Ethiopia: A pilot randomised controlled trial.

Dear Sir/Madam, you are kindly invited to participate in the above research project conducted by Dereje Chala Diriba (a PhD fellow) under the supervision of Dr Doris Y.P. Leung and Dr. Lorna K.P. Suen, staff of the School of Nursing in The Hong Kong Polytechnic University. The project has been approved by the Human Subjects Ethics Sub-committee (HSESC) of The Hong Kong Polytechnic University (Reference Number: **______________________).**

Study aim: The study aims to examine the feasibility, acceptability, and preliminarily effect of a nurse-led community-based diabetes self-management education and support on clinical outcomes, self-care behaviours, quality of life, and family support through a pilot randomised controlled trial among adult patients with type 2 diabetes, Western Ethiopia.

What will be done? Two groups will be formed randomly.

Usual care

Participants in the control group will continue the usual care in the hospital. There will be no intervention for you.

Intervention

You will be provided with an intervention, ‘Diabetes self-management education and support for 12 hours over six consecutive weeks in your community. You will take part in six educational sessions, lasting for 2 hours every Saturday. This intervention aims to boost your knowledge and skills in the self-management of diabetes.

What is expected of you? Attend the intervention if you are requested to attend. Data collectors will approach you face-to-face to collect the data. If the results of glucose level (HbA1c), lipid profiles, blood pressure, weight, and height are available on your medical records, the result will be retrieved from the record. But if these records are not available, our research assistant, a medical laboratory technologist, will collect the blood sample and perform tests in this hospital. The results will be recorded in your medical record. Nurses will measure other parameters like weight, height, and blood pressure records. Additionally, you will be approached face-to-face by data collectors to complete a questionnaire at three time points (at baseline, immediately after completion of the intervention, and at 4-month of randomization). At one time point, the data collection will take about 50 minutes.

Benefits: You will get 60 Ethiopian Birr for transportation for each session you attend the intervention. You will be beneficial from education to boost your knowledge and skills in diabetes management.

Risks: There will be no obvious risk for your participation.

How will your information handle?

All information related to you will remain confidential and identifiable by codes that are only known to the researchers. The information collected will be kept for one year. The Hong Kong Polytechnic University takes reasonable precautions to prevent the loss, misappropriation, unauthorized access, or destruction of the information you provide.

Right for refusal: You have every right to withdraw from the study without penalty of any kind.

Inquiry: If you have any questions, you may ask Mr. Dereje Chala Diriba (tel. no.: +25191334 / email: kakudere@) of The Hong Kong Polytechnic University under the following situations:

a. if you have any other questions about the study.

b. If you become injured because you participate in a study; or

c. if you want to get access to/or change your data before (the expiry date).

Thank you for your interest in participating in this study.

Dr. Doris Y.P. Leung
Principal Investigator

Appendix V Consent form to participate in pilot RCT - English version

CONSENT TO PARTICIPATE IN RESEARCH

I ______________________________ hereby consent to participate in the captioned research titled '**Effectiveness of a nurse-led community-based self-management programme for people with type 2 diabetes in Western Ethiopia: A pilot randomised controlled trial'** supervised by Dr. Doris Y.P. Leung and Dr. Lorna K.P. Suen and conducted by Dereje Chala Diriba.

I understand that information obtained from this research may be used in future research and published. However, my right to privacy will be retained, i.e. my details will not be revealed. The procedure as set out in the attached information sheet has been fully explained. I understand the benefit and risks involved. My participation in the project is voluntary.

I acknowledge that I have the right to question any part of the procedure and can withdraw at any time without penalty of any kind.

Name of participant: ____________________________

Signature: ____________ Date: __________________

Name of researcher: _________________________

Signature: _________________________ Date: ___________

Appendix VI Questionnaire for pilot RCT, Afaan Oromoo - to be responded by people living diabetes - English version

Section I. Sociodemographic and person living with diabetes-related characteristics of the respondents

Instruction. Please give your appropriate response to the following questions. Circle the proper response.

Code	**Characteristics**	**Response**	**Remark**
1.	Age	____ years old	
2.	Gender	1. Male 2. Female	
3.	Marital status	1. Never married 2. Married 3. Separated/divorced 4. Widowed	
4.	Ethnicity	1. Oromo 2. Amhara 3. Tigre 4. Gurage	
5.	Religion	1. Protestant 2. Orthodox 3. Muslim 4. Catholic 5. Waaqefata 6. Others (specify)	
6.	Education level	1. Not attended formal education 2. 8 grade or less 3. Grade 9-12 4. College or degree graduate	
7.	Employment status	1. Government employee 2. Private organization /NGO employee 3. Merchant 4. Student 5. Retired 6. Others (specify)-------------	
8.	Do you have confirmed comorbid disease?	0. No 1. Yes	
9.	Type of comorbid disease?	1. Hypertension 2. Nephropathy 3. Retinopathy 4. Neuropathy 5. Foot ulcer/amputation 6. Other diseases(specify)__________________	
10.	Year since diagnosis	______ years.	

11.	Monthly income of your family (only those living with you) (please estimate in ETB)	____________________ ETB	
12.	Household size	___________	
13.	Do you have family support for your disease management?	0. No 1. Yes	If no, skip to section 2.
14.	From your family member, who usually provides support for you?	1. Spouse 2. Son/daughter 3. Servant 4. Mother or father 5. Other family members	

Section II. The Summary of Diabetes Self-Care Activities Questionnaire (expanded)-Afaan Oromoo version

The questions below ask you about your diabetes self-care activities during the past 7 days. If you were sick during the past 7 days, please think back to the last 7 days that you were not sick.

Instruction. Tick (✓) under appropriate response**.**

General diet and blood glucose testing **Number of days**

	0	1	2	3	4	5	6	7
1. How many days of the last SEVEN DAYS have you followed your eating plan?								
2. On average, how many DAYS PER WEEK have you followed your eating plan over the past month?								
3. How many of the last SEVEN DAYS did you test your blood sugar the number of times your health care provider recommended?								

Specific diet **Number of days**

4. On how many of the last SEVEN DAYS did you eat five or more servings of fruits and vegetables?								
5. On how many of the last SEVEN DAYS did you space carbohydrates evenly through the day?								

Foot Care **Number of days**

	0	1	2	3	4	5	6	7
6. On how many of the last SEVEN DAYS did you check your feet?								
7. On how many of the last SEVEN DAYS did you inspect the inside of your shoes?								
8. On how many of the last SEVEN DAYS did you wash your feet?								

9. On how many of the last SEVEN DAYS did you soak your feet?								
10. How many of the last SEVEN DAYS did you dry between your toes after washing?								

Section III. Diabetes Quality of Life-Afaan Oromoo measure

Instruction. Please read each statement carefully. Please indicate how satisfied or dissatisfied you currently are with the aspect of your life described in the statement. Circle the number that best describes how you feel. There are no right or wrong answers to these questions. We are interested in your opinion.

Code	Core items	Response rate				
	Satisfaction	Very satisfied	Moderately satisfied	Neither	Moderately dissatisfied	Very dissatisfied
1.	How satisfied are you with the time it takes to manage your diabetes?	1	2	3	4	5
2.	How satisfied are you with the amount of time you spend getting check-ups?	1	2	3	4	5
3.	How satisfied are you with your current treatment?	1	2	3	4	5
4.	How satisfied are you with the flexibility you have in your diet?	1	2	3	4	5
5.	How satisfied are you with your diabetes burden on your family?	1	2	3	4	5
6.	How satisfied are you with your knowledge about your diabetes?	1	2	3	4	5
7.	How satisfied are you with your sleep?	1	2	3	4	5
8.	How satisfied are you with your social relationships and friendships?	1	2	3	4	5
9.	How satisfied are you with your sex life?	1	2	3	4	5
10.	How satisfied are you with your work, school, and household activities?	1	2	3	4	5
11.	How satisfied are you with the appearance of your body?	1	2	3	4	5
12.	How satisfied are you with the time you spend exercising?	1	2	3	4	5
13.	How satisfied are you with your leisure time?	1	2	3	4	5

Instruction. Please indicate how often the following events happen to you. Circle the appropriate number.

Impact- core items		Never	Very seldom	Sometimes	Often	All the time
1.	How often do you feel the pain associated with the treatment of your diabetes?	1	2	3	4	5
2.	How often are you embarrassed by having to deal with your diabetes in public?	1	2	3	4	5
3.	How often do you feel physically ill?	1	2	3	4	5
4.	How often does your diabetes interfere with your family life?	1	2	3	4	5
5.	How often do you have a bad night's sleep?	1	2	3	4	5
6.	How often do you find your diabetes limiting your social relationships and friendships?	1	2	3	4	5
7.	How often do you feel restricted by your diet?	1	2	3	4	5
8.	How often does your diabetes interfere with your sex life?	1	2	3	4	5
9.	How often does your diabetes keep you from driving a car or using a machine (e.g., a typewriter)?	1	2	3	4	5
10.	How often does your diabetes interfere with your exercising?	1	2	3	4	5
11.	How often do you miss work, school, or household duties because of your diabetes?	1	2	3	4	5
12.	How often do you find yourself explaining what it means to have diabetes?	1	2	3	4	5
13.	How often do you find that your diabetes interrupts your leisure-time activities?	1	2	3	4	5

Instruction. Please indicate how often the following events happen to you. Please circle the number that best describes your feelings. If the question is not relevant to you, circle non-applicable.

	Social/vocational Worry Core items	Never	Very seldom	Sometimes	Often	All the time	Does not apply
1.	How often do you worry about whether you will get married?	1	2	3	4	5	0
2.	How often do you worry about whether you will have children?	1	2	3	4	5	0
3.	How often do you worry about whether you will not get a job you want?	1	2	3	4	5	0
4.	How often do you worry about whether you will miss work?	1	2	3	4	5	0

5.	How often do you worry about whether you will be able to take a vacation or a trip?	1	2	3	4	5	0
Diabetes-related Worry core items		**Responses**					
1.	How often do you worry about whether you will pass out?	1	2	3	4	5	0
2.	How often do you worry that your body looks different because you have diabetes?	1	2	3	4	5	0
3.	How often do you worry that you will get complications from your diabetes?	1	2	3	4	5	0

Section IV Diabetes care profile-Support scale- Afaan Oromoo

Instruction. Please circle the number that best describes the support you obtain from your family or friend. If the question is not relevant to you, circle non-applicable.

Q1. I want a lot of help and support from my family or friends in:

Question	**Strongly Disagree**	**Somewhat Disagree**	**Neutral**	**Somewhat Agree**	**Strongly Agree**	**Does Not Apply**
a) following my meal plan.	1	2	3	4	5	N/A
b) taking my medicine.	1	2	3	4	5	N/A
c) taking care of my feet.	1	2	3	4	5	N/A
d) getting enough physical activity.	1	2	3	4	5	N/A
e) testing my sugar.	1	2	3	4	5	N/A
f) handling my feelings about diabetes.	1	2	3	4	5	N/A

Q2.My family or friends help and support me a lot to:

Question	**Strongly Disagree**	**Somewhat Disagree**	**Neutral**	**Somewhat Agree**	**Strongly Agree**	**Does Not Apply**
a) follow my meal plan.	1	2	3	4	5	N/A
b) take my medicine.	1	2	3	4	5	N/A
c) take care of my feet.	1	2	3	4	5	N/A
d) get enough physical activity.	1	2	3	4	5	N/A
e) test my sugar.	1	2	3	4	5	N/A
f) handle my feelings about diabetes.	1	2	3	4	5	N/A

Q3.My family or friends:

Question	**Strongly Disagree**	**Somewhat Disagree**	**Neutral**	**Somewhat Agree**	**Strongly Agree**
a) accept me and my diabetes.	1	2	3	4	5
b) feel uncomfortable about me because of my diabetes.	1	2	3	4	5
c) encourage or reassure me about my diabetes.	1	2	3	4	5

d)	discourage or upset me about my diabetes.	1	2	3	4	5
e)	listen to me when I want to talk about my diabetes.	1	2	3	4	5
f)	nag me about diabetes.	1	2	3	4	5

Q4. Who helps you the **most** in caring for your diabetes? (select only one)

1. Spouse
2. Other family members
3. Friends
4. Paid helper
5. Doctor
6. Nurse
7. Case manager
8. Other health care professional
9. No one

Appendix VII Questionnaire for pilot RCT-Afaan Oromoo- to be responded to the family caregiver - English version

Section I. Sociodemographic and people with diabetes -related characteristics of the respondents

Instruction. Please give your appropriate response to the following questions. Circle the appropriate response.

Code	Characteristics	Response	Remark
1.	Age	____ years old	
2.	Gender	1. Male 2. Female	
3.	Marital status	1. Never married 2. Married 3. Separated/divorced 4. Widowed	
4.	Ethnicity	1. Oromo 2. Amhara 3. Tigre 4. Gurage 5. Others	
5.	Religion	1. Protestant 2. Orthodox 3. Muslim 4. Catholic 5. Waaqefata 6. Others (specify)	
6.	Educational level	1. Not attended formal education 2. 8 grade or less 3. Grade 9-12 4. College/degree graduate	
7.	Your current employment status	1. Government employee 2. Private organization /NGO employee 3. Merchant 4. Student 5. Retired 6. Other _____________	
8.	Your relationship with people with diabetes	1. Spouse 2. Mother/father 3. Son/daughter 4. Servant/home worker 5. Other relationship (specify): _____________________	

Section 2. Diabetes Family Behaviour Checklist-Family form- Afaan Oromoo measure

Instruction. We want to know how often family members do each of the following things. Just put down what usually happens at home. There are no right or wrong answers. Write downtick (✓) under the scale below that best shows how often the person being rated does each of the following things.

S/N	**Questions**	**Responses**				
		Never	Twice a month	Once a week	Several times a week	At least once a day
1.	Praise the patient for following his/her diet					
2.	Nag the patient about testing his/her blood					
3.	Suggest things that might help the patient take insulin on time					
4.	Nag the patient about not following his/her diet					
5.	Argue with the patient about his/her diabetes self-care activities					
6.	Encourage the patient to participate in sports activities					
7.	Criticize the patient for not recording the results of blood tests					
8.	Eat at the same time that the patient does					
9.	Exercise with the patient					
10.	Let the patient sleep late rather than getting him/her up to take his/her insulin					
11.	Buy the patient things containing sugar to carry in case of an insulin reaction					
12.	Eat foods that are not part of the patient's diabetic diet					

Appendix VIII Intervention fidelity assessment checklist (to be completed by the research supervisor)

S/N	Checklist	Response			Remark
		Yes	No	Not applicable	
1.	Did the DSMES handbook distribute before the commencement of the DSMES - sessions?				
2.	Did the trainers use teaching aids like LCD and demonstration equipment?				
3.	Was one session of the DSMEs given for two hours?				
4.	Did the trainer cover the session's topics according to the session plan?				
5.	Was the intervention delivered in the community?				
6.	Was the intervention delivered face-to-face?				
7.	Did the trainer implement active learning methods like experience sharing, group discussion, etc?				
8.	Did the trainer show a video on self-medication?				
9.	Did the trainer show a video on foot care?				
10.	Did written feedback obtain from the participants at the end of all sessions?				
11.	Did the family obtain 20 minutes briefing session at each session?				
12.	Did the patient watch the video while the families were in the briefing session?				
13.	Did the roles of the family indicated and communicated?				
	Total score				

Appendix IX Credibility and Expectancy Questionnaire

We would like you to indicate below how much you believe, right now, that the therapy you are receiving will help to improve your knowledge and increase your self-management practise. Belief usually has two aspects: (1) what one thinks will happen and (2) what one feels will happen. Sometimes these are similar; sometimes, they are different. Please answer the questions below. In the first set, answer in terms of what you think. In the second set, answer in terms of what you really and truly feel. We do not want your therapist ever to see these ratings, so please keep the sheet covered when you are done.

Set I

1. At this point, how logical does the therapy offered to you seem?

   1 2 3 4 5 6 7 8 9

   not at all logical somewhat logical very logical

2. At this point, how successfully do you think this treatment will be in your self-management behaviour and quality of life?

   1 2 3 4 5 6 7 8 9

   not at all useful somewhat useful very useful

3. How confident would you be in recommending this training to a friend who experiences similar problems?

   1 2 3 4 5 6 7 8 9

   not at all confident somewhat confident very confident

4. By the end of the therapy period, how much improvement in your diabetes symptoms do you think will occur?

   0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

Set II

For this set, close your eyes for a few moments, and try to identify what you really feel about the education given and its likely success. Then answer the following questions.

1. At this point, how much do you really feel that education will help you to improve your self-care behaviours to improve your diabetes symptoms?

1	2	3	4	5	6	7	8	9

not at all somewhat Very much

2. By the end of the education period, how much improvement in your diabetes symptoms do you really feel will occur?

0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%

Appendix X Information sheet for pilot RCT - Afaan Oromoo version

YUUNIVARSIITII POOLIITEEKINIKII HOONG KOONG

MANA BARNOOTAA NARSIINGII

Unka odeeffannoo Koodii hirmaataa: ______

Mata duree: Bu'aa barumsaa fi gargaarsa dhuunfaan of yaaluu dhukkuba sukkaaraa hawaasa keessatti kan narsiin dhukkubsattoota sukkaaraa gosa 2^ffaa Lixa Itiyoophiyaatti gaggeefamu: Qorannoo duraa.

Kabajamoo,

Isin akka qorannoo armaan olitti caqasame irratti akka hirmaattaniif kabajaan affeeramtaniittu. Qorannoon kunis kan adeemsifamu obbo Darajjee Caalaa Dirribaa (barataa digirii 3^ffaa) fi to'annaa Dr. Dooris Liyuung, Dr. Loornaa Suheen kanneen hojjettoota Yuunivarsiitii Pooliiteekinikii Hoong Koong dhaani. Qorannichi koree dhimma naamuusaa qorannoo nama irratti adeemsifamu kan Yuunivaarsiitii Pooliiteekinikii Hoong Koong'tti argamu irraa eeyyama qorannaa kan argateedha (Lakkoofsa xalayaa ittiin eeyyamame: **HSEARS20201019003).**

Kaayyoo qorannichaa: Kaayyoon qorannoo kanaas bu'aa barumsaa fi gargaarsa dhuunfaan of yaaluu dhukkuba sukkaaraa hawaasa keessatti kan narsiin dhukkubsattoota sukkaaraa gosa 2^ffaa kennamu bu'aa mallattoolee dhibee, gocha ofiin of yaaluu, sadarkaa qulqullina jireenyaa, fi gargaarsa maatii irraa argamu karaa qorannoo yaalii jalqabaa garee dhukkubsattootaa sukkaaraa gosa 2^ffaa fi maatii isaanii Lixa Itiyoophiyaa irraa carraan hundeeffaman qorachuu ta'a.

Maaltu raawwata?

Namoota fedhiidhaan qorannoo kana irratti hirmaachuuf filataman kun garee lamatti carraadhaan ni hiramtu.

Garee yaalii akka duraatti itti fufan

Yaalii duraan isinii kennamaa ture otoo addaan hin kutiin itti fuftu. Barumsi addaa isiniif dabalataan kennamu hin jiru.

Garee yaalii

Yoo garee yaalii keessatti ramadamtan, barumsii fi gargaarsi kitaabaan, vidiyoo fi waraqaa balaliituu adda addaatiin kan deeggarame sa'aa kudha lamaaf torbee torbeen yeroo jahaaf isiniif naannoo jiraattan keessatti ni kennamu. Tokkoon tokkoo waayitiin barumsaa sa'aa lamaaf kennamu. Akka isiniif mijaawuuf jedhamee barumsi Sanbata duraa (Qidaamee) isiniif kennama. Waanti isiniif kennamu kun waa'ee dhukkuba sukkaaraa fi yaalii dhuunfaa isaa irratti beekumsaa fi ogummaa akka guddifattan gargaara jedhamee yaadama.

Maaltu isin irra eegama?

Yoo garee yaalii keessatti ramadamtan, yeroo barumsi isiniif kennamu keessatti hirmaachuu qabdu. Bu'aa barumsaa fi gargaarsa kanaa beekuuf yeroo ji'a ja'a keessatti si'a sadii (leenjii dura, akka leenjii kana xumurtanii fi ji'a arfaffaa) irratti saamuda dhiigaa, ulfaatina qaamaa, hojjaa fi gaaffiiwwan adda addaa ni gaafatamtu. Ragaan nuuf laattan kun yaali keessan keessatti akka odeeffannoo yaalii keessanii irra ooluuf ni gargaara. Hojiiwwan kana xumuruuf gara giddu-galeessaan daqiiqaa 50 fudhaachuu danda'a. Ogeessi laaboratoorii saamuda dhiigaa kan fudhuu yoo ta'u, narsiin ulfaatinaa fi hojjaa keessan ni safara/ti akkasumas namootni gaaffii isin gaafatan ni jiru. Gaaffilee gaafatamtan kana keessatti kan isinitti hin tolle hin jiran jennee yaadna.

Bu'aa hirmaachuu

Namootni garee yaalii keessatti hirmaattan kan taaksiif isiniif ta'u qarshii 60 yeroo barumsa irratti hirmaattanitti isiniif ni kanfalama. Gama biraatiin beekumsaa fi ogummaa dhukkuba kana ittiin of yaaltan ni dabala jennee abdanna. Miidhaan biraa isin irra gahu hin jiru.

Icciitii eeguu

Odeeffannoon isin irraa argannu icciitiin eegama, koodiin gaggeessaan qorannichaa qofti beekuu isiniif ni laatama. Odeeffannoon nuuf laattan wagga tokkoof ni tura. Argannoon qorannoo kanaas maxxanfamuu ni mala. Odeeffannoon kun akka hin badneef, dogoggoraan akka hin hiikamneef, qaamni isa ilaallatu akka hin arganneef, akkasumas akka hin dhabamsiifamneef Yuunivarsiitiin Pooliitekinikii Hoong Koong of eegannoo barbaachisaa ni godha.

Mirga qorannoo addaan kutuu

Yoo hirmaannaa keessan addaan kutuu barbaaddan, adabbii tokko malee yeroo barbaaddanitti addaan kutuu ni dandeessu.

Gaaffii fi yaadaa

Gaaffii yoo qabaattan dursaa qorannoo kanaa kan ta'an obbo Darajjee Caalaa Dirribaa lakkoofsa bilbilaa +25191334 ykn i-meelii kakudere@ gaafachuu ni dandeessu.

a) Gaaffii qorannoon wal qabatan biroo yoo qabaattan
b) Hirmaannaa qorannoo kanaan kan walqabate miidhamni yoo isin mudate
c) Osoo guyyaan odeeffannoosaa hin darbin odeeffannoo waa'ee dhuunfaa keessanii argachuu ykn jijjiiruu yoo barbaaddan

Qorannoo kanaan wal-qabatee komii kamiyyuu yoo qabaattan, koree naamuusaa qorannoo nama irratti raawwatuuf kan Yuunivarsiitii Pooliiteekinikii Hoong Koongitiif (garagalcha biiroo qorannoo yuunivarsiitichaaf) gochuudhaan waan komii uume kana sirriitti caqasuun eenyu akka itti gaafatamuu fi muummee qorannaa kana geggeessu akkasumas lakkoofsa xalayaa ittiin eeyyamame caqasuun eeruu ni dandeessu.

Fedhii horattanii qorannoo kanarratti sababa hirmaattaniif guddaa galatoomaa!

Doktor Dooris Liyuung
Dursaa qorannoo

Appendix XI Consent for pilot RCT-Afaan Oromoo version

Unka walii galtee qorannoo keessatti hirmaachuu

Ani maqaan koo ______________________________qorannoo “Qorannoo yaalii bu’aa barumsaa fi gargaarsa dhuunfaan of yaaluu dhukkuba sukkaaraa hawaasa keessatti kan narsiin dhukkubsattoota dhukkuba sukkaaraa gosa 2^{ffaa} Lixa Itiyoophiyaa jiraataniif’ kan Dr. Dooris Liyuungii fi Dr. Lornaa Suyeenii fi kan obboo Darajjee Caalaa Dirribaatiin gaggeefamu keessatti fedhii kootiin hirmaachuuf walii galeera.

Odeeffannoon qorannoo kanaaf ani kennu gara fuulduraatti qorannoof akka ooluu fi akkasumas maxxanfamuu akka danda’u hubadheera.

Akkaataan adeemsa qorannichaa unka odeeffannoo irratti sirriitti naaf kennameera. Bu’aalee fi miidhaa isaas hubadheera. Qorannicha keessatti hirmaannaan koo fedhiidhaani.

Akkan gaaffii fedhe haala adeemsa qorannichaa fi yeroon barbaadeti adabbii tokko malee addaan kutuu akkan danda’u adda baafadheera.

Maqaa hirmaataa/ttu____________________________________
Mallattoo____
Guyyaa____
Maqaa dursaa qorannoo: Dr. Dooris Liyuung
Mallattoo____
Guyyaa____

Appendix XII Questionnaire for pilot RCT-Afaan Oromoo version- to be responded by people with diabetes

Kutaa 1[ffaa]: Odeeffannoo waa'ee hawaasummaa fi dhukkubsataa waliin wal-qabatan kan hirmaataan deebisu.

Qajeelfama: Maaloo gaaffilee armaan gadiif deebii sirriidha jettan kennaa. Deebii sirriidha jettanitti maraa.

Koodii	Amaloota	Deebii	Yaada
1.	Umurii	________ (waggaadhaan)	
2.	Saala	1. Dhiira 2. Dhalaa	
3.	Haala gaa'elaa	1. Takkaayyuu hin fuune/heerumne 2. Fuudheera/heerumeera 3. Nan hiike/addaan ba'e 4. Na duraa boqote/tte	
4.	Sabummaa (qomoo)	1. Oromoo 2. Amaara 3. Tigiree 4. Guraagee 5. Kan biroo (maaloo ibsaa)__________________	
5.	Amantii	1. Pirootestaantii 2. Ortodoksii 3. Musiliima 4. Kaatolikii 5. Waaqeffataa 6. Kan biroo (maaloo ibsaa)___________________	
6.	Sadarkaa barnootaa keessan	1. Barnoota idilee hin baranne 2. Kutaa 8 ykn isaa gadi 3. Kutaa 9-12 4. Kolleejjii ykn digiriin eebbifameera	
7.	Haala hojii amma irra jirtan	1. Hojjetaa/ttuu mootummaa 2. Hojjetaa/ttuu dhaabbata dhuunfaa/miti-mootummaa 3. Daldalaa/tuu 4. Barataa/ttuu 5. Soorama baheera 6. Kan biroo (maaloo ibsaa)__________________	
8.	Dhukkuba biroo ogeessaan mirkanaa'e kan kana faana dhukkubsattan qabduu?	1. Lakki 2. Eeyyee	Yoo deebiin keessan lakki ta'u gara gaaffii 10'tti cehaa
9.	Yoo deebiin gaaffii 8 eeyyee ta'e, dhukkuba maalii qabdu?	1. Dhibaa dhiigaa 2. Dhukkuba kalee 3. Dhukkuba ijaa	

		4. Dhukkuba narvii 5. Madaa'uu miilaa 6. Kan biro (maaloo ibsaa)________________	
10.	Dhukkuba sukkaaraa kana akka qabdan kan isinitti himame waggaa meeqa ta'a?	_______ (waggaadhaan)	
11.	Yaalii dhibee keetiif qoricha gosa kam fudhachaa jirta?	1. Insuliinii 2. Qorichoota hamma gilukosii gadi buusaan 3. Lamaanuu	
12.	Galii ji'aa kan dhuunfaa keetii meeqa? (Qarshiidhaan tilmaami)	______________ ETB	
13.	Waa'ee dhibee kee irratti maatiin ke si gargaaruu?	0. Lakki 1. Eeyyeen	Deebbiin kee lakki yoo ta'e gara kutaa 2[ffaatti] darbi
14.	Miseensa maatii kee keessaa yeroo baay'ee kan si gargaaru eenyu?	1. Gargaaraa/ttuu gaa'elaa 2. Haadha manaa/abbaa manaa 3. Haadha/Abbaa 4. Ilma ykn intala 5. Hojjettuu manaa 6. Miseensota maatii kan biroo (caqasaa)____________________	

Kutaa 2[ffaa]: Cuunfaa gaaffilee waa'ee gochaalee yaalii dhuunfaa dhukkuba sukkaaraaf godhamu (bal'inaan).

Gaaffileen armaan gadii kun gochaalee yaalii dhuunfaa dhukkuba sukkaaraa keessaniif guyyoota 7n darbaniif ofiif gootan ilaallatu. Guyyoota 7n darbaniif yoo isin dhukkubeera ta'e, maaloo guyyoota 7n darban kan isin hin dhukkubne of-duubatti deebi'aa yaada.

Qajeelfama: Iddoo deebii sirrii ta'etti mallattoo kana itti maraa.

Soorata waliigalaa fi qorannaa gilukosii **Baay'ina guyyootaa**

1	GUYYOOTA TOORBA darban keessaa guyyaa meeqa karoora nyaataa keessan hordoftaniittu?	0	1	2	3	4	5	6	7
2	Giddugaleessaan, ji'a darbe keessatti, torbanitti GUYYAA meeqa karoora nyaataa keessan hordoftaniittu?	0	1	2	3	4	5	6	7
3	GUYYOOTA TOORBA darban keessaa guyyaa meeqa hamma sukkaara dhiiga keessanii, akka ajaja ogeessaatti ilaallattan/safarattan?	0	1	2	3	4	5	6	7

Soorata adda bahan **Baay'ina guyyootaa**

4	GUYYOOTA TOORBA darban keessaa, guyyaa meeqa maaddii kuduraa fi muduraa si'a shanii fi isaa ol dhiyeeffattanii nyaattan?	0	1	2	3	4	5	6	7

5 GUYYOOTA TOORBA darban keessaa, guyyaa meeqa nyaata kaarboohaaydireetii guyyaa keessatti yeroo walfakkaataan addaan fageessitanii nyaattan?	0	1	2	3	4	5	6	7

Kunuunsa miillaa **Baay'ina guyyootaa**

6 GUYYOOTA TOORBA darban keessaa guyyaa meeqa miilla keessan ilaallattanii beektu?	0	1	2	3	4	5	6	7
7 GUYYOOTA TOORBA darban keessaa guyyaa meeqa keessa kophee keessanii to'attanii/ilaallattanii beektu?	0	1	2	3	4	5	6	7
8 GUYYOOTA TOORBA darban keessaa guyyaa meeqa miilla keessan dhiqattan?	0	1	2	3	4	5	6	7
9 GUYYOOTA TOORBA darban keessaa guyyaa meeqa miilla keessan bishaan keessa cuubdanii tursitanii beektu?	0	1	2	3	4	5	6	7
10 GUYYOOTA TOORBA darban keessaa guyyaa meeqa erga miilla dhiqattanii booda gidduu quba miilla keessanii qoorsitanii beektu?	0	1	2	3	4	5	6	7

Kutaa 3ffaa: Madaallii qulqullina jireenyaa namoota dhukkuba sukkaaraa qabanii-maxansa Afaan Oromoo

Qajeelfama: Maaloo tokkoon tokkoon hima armaan gadii sirriitti dubbisaa. Hagam akka haala jireenya keessan yeroo ammaa kan gaaffilee keessatti ibsaman itti quuftan ykn hin quufiin agarsiisaa. Lakkoofsa sirriitti miira keessan ibsu itti maraa. Nuti yaada keessan qofa baruu barbaanneeti malee gaaffilee kanaaf deebiin sirrii ykn dogoggoraa hin jiru.

Koo dii	**Gaaffiilee ijoo**	**Deebii**				
	Itti quufinsa	Baa y'ee itti quuf eera	Giddu-galeess aan itti quufeer a	Giddu galeessa	Giddug aleessa an itti hin quufne	Baay'een itti hin quufnee
1.	Dhukkuba sukkaaraa keessan yaalamuuf yeroo isinitti fudhatu ilaalchisee hagam itti quufiinsa qabdu?	1	2	3	4	5
2.	Dhukkuba sukkaaraa keessan ilaalamuuf yeroo isinitti fudhatu ilaalchisee hagam itti quufiinsa qabdu?	1	2	**3**	4	5
3.	Hanga sukkaara keessan baruuf yeroo isinitti fudhatu ilaalchisee hagam itti quufiinsa qabdu?	1	2	3	4	5
4.	Yaalii amma isiniif godhamaa jirutti hagam quufiinsa qabdu?	1	2	3	4	5

5.	Jijjiirama haala soorata keessan keessatti qabdanitti hagam quufiinsa qabdu?	1	2	3	4	5
6.	Ba’aa/dhiibbaa dhukkubni sukkaaraa keessan maatii keessan irraan ga’aa jirutti hagam quufiinsa qabdu?	1	2	3	4	5
7.	Haala hirriba keessanitti hagam quufiinsa qabdu?	1	2	3	4	5
8.	Walitti-dhufeenya hawaasummaa fi hiriyummaa qabdanitti hagam quufiinsa qabdu?	1	2	3	4	5
9.	Haala wal-quunnamtii saalaa qabdanitti hagam quufiinsa qabdu?	1	2	3	4	5
10.	Gochaalee bakka hojiitti, mana-barumsaatti, akkasumas mana keessan keessatti raawwattanitti hagam quufiinsa qabdu?	1	2	3	4	5
11.	Dhaabbii/bifa qaama keessanitti hagam quufiinsa qabdu?	1	2	3	4	5
12.	Sochii ga’uumsa qaamaa gochuuf yeroo fudhattanitti hagam quufiinsa qabdu?	1	2	3	4	5
13.	Yeroo bashannanaa qabdanitti hagam quufiinsa qabdu?	1	2	3	4	5
Qajeelfama: Maaloo wantootni armaan gadii hagam deddeebi’anii akka isin mudatan argisiisaa. Lakkoofsa sirriidha jettanitti maraa.						
Gaaffiilee ijoo		Deebii				
Dhiibbaa dhukkubichi isin irraan gahu		Tasa nah in mud anne	Baay’e e turee	Darbee darbee	Deddee bi’ee	Yeroo mara
1.	Dhukkubbiin (miidhaan) yaalii dhukkuba sukkaaraa keessan waliin walqabatu hagam deddeebi’ee isinitti dhaga’ama?	1	2	3	4	5
2.	Waa’ee dhibee sukkaaraa keessaniin wal-qabateen hawaasa gidduutti	1	2	3	4	5

	hagam deddeebitanii qaanoftanii/yeelloftanii/ beektu?					
3.	Dhukkubbiin qaamaa hagam deddeebi’ee isinitti dhaga’ama?	1	2	3	4	5
4.	Dhukkubni sukkaaraa keessan jireenya maatii keessan keessa hagam deddeebi’ee isin duraa seena/jeeqa?	1	2	3	4	5
5.	Hirriba halkanii badaa hagam deddeebitanii qabaattu?	1	2	3	4	5
6.	Dhukkubni sukkaaraa keessan walitti-dhufeenya hawaasummaafi hiriyummaa keessan hagam deddeebi’ee utuu daangessuu argitu?	1	2	3	4	5
7.	Haala soorannaa keessaniin daangeffamuun hagam deddeebi’ee isinitti dhaga’ama?	1	2	3	4	5
8.	Dhukkubni sukkaaraa keessan haala quunnamtii saalaa keessan keessa hagam deddeebi’ee isin duraa seena?	1	2	3	4	5
9.	Dhukkubni sukkaaraa keessan konkolaataa oofuurraa ykn maashinii fayyadamuu (fkn maashinii barreeffamaa) ykn hojii guyyaa guyyaan hojjattan irraa hagam deddeebi’ee isin dhorka?	1	2	3	4	5
10.	Dhukkubni sukkaaraa keessan sochii ga’uumsa qaamaa isin gootan keessa hagam deddeebi’ee isin duraa seena?	1	2	3	4	5
11.	Sababa dhukkuba sukkaaraa keessaniin bakka hojii, mana barumsaa ykn hojii mana keessaa hagam deddeebitanii irraa haftu?	1	2	3	4	5
12.	Dhukkuba sukkaaraa qabaachuu jechuun maal akka ta’e utuu ibsitanii hagam deddeebitanii of agartu?	1	2	3	4	5
13.	Dhukkubni sukkaaraa keessan kun yeroo bashannanaa keessan utuu	1	2	3	4	5

	addaan-kutuu hagam deddeebitanii argitu?						
Qajeelfama: Maaloo taateewwan armaan gadii hagam deddeebi’anii akka isin quunnaman argisiisaa. Lakkoofsa sirriitti miira keessan isiniif ibsutti maraa. Gaaffichi isin hin ilaallatu yoo ta’emmoo, ‘na hin ilaallatu’ kan jedhutti maraa.							
	Gaaffiilee ijoo waa’ee yaaddoo hawaasummaa/hojii ogummaa	Tasuma	Baay’ee turee	Darbee darbee	Deddeebi’ee	Yeroo mara	Na hin ilaallatu
1.	Gara fuulduraatti waa’ee gaa’ela dhaabbachuu keessan hagam deddeebitanii yaaddoftu?	1	2	3	4	5	0
2.	Gara fuulduraatti waa’ee ijoollee argachuu keessan hagam deddeebitanii yaaddoftu?	1	2	3	4	5	0
3.	Gara fuulduratti dhibee kana irraan kan ka’e waa’ee hojii barbaaddan argachuu dhabuu keessan hagam deddeebitanii yaaddoftu?	1	2	3	4	5	0
4.	Hojiikoo irraan hafaa laata jettanii hagam deddeebitanii yaaddoftu?	1	2	3	4	5	0
5.	Boqonnaaf ykn bashannanaaf bakka biraa deemuu danda’uu keessan hagam deddeebitanii yaaddoftu?	1	2	3	4	5	0
Dubbii ijoo yaaddoo dhukkuba-sukkaaraan wal qabatan Deebii							
1.	Dhukkubni kun na of-wallaalchisaa laata jettanii hagam deddeebitanii yaadoftu?	1	2	3	4	5	0
2.	Sababa dhukkuba sukkaaraa kanaaf qaamnikoo ni jijjiirame jettanii hagam deddeebitanii yaaddoftu?	1	2	3	4	5	0
3.	Sababa dhukkuba-sukkaaraa keessaniin kan ka’e dhibeen walxaxaan natti dhufa jettanii hagam deddeebitanii yaaddoftu?	1	2	3	4	5	0

Kutaa 4^{ffaa}: Deeggersa yaalii dhukkuba-sukkaaraaf taasifamu-maxxansa Afaan Oromoo

Qajeelfama: Maaloo lakkoofsa isa deeggarsa isin maatii fi hiriyaa keessan irraa argattan sirriitti ibsutti maraa. Yoo gaaffichi isin hin ilaallatu ta'emmoo 'hin ilaallatu (HI)' kan jedhutti maraa.

Gaaffii 1: Maatiikoofi hiriyootakoo irraa gargaarsaa fi deeggarsa kanneen armaan gadiif nan barbaada:

Gaaffii	Cimseen itti walii hin galu	Hamma tokko itti walii hin galu	Giddu-galeessa	Hamma tokko ittin walii gala	Cimseen itti walii gala	Na hin ilaallatu (HI)
a) karoora nyaataakoo akkan hordofuuf	1	2	3	4	5	HI
b) dawaakoo fudhachuuf	1	2	3	4	5	HI
c) miilla koof kunuunsa gochuuf	1	2	3	4	5	HI
d) sochii qaamaa ga'aa argachuuf	1	2	3	4	5	HI
e) hamma sukkaaraa dhiiga koo safaruuf	1	2	3	4	5	HI
f) waa'ee dhukkuba-sukkaaraakoof miira natti dhaga'amu to'achuuf	1	2	3	4	5	HI

Gaaffii 2: Maatiifi hiriyoonnikoo kanneen armaan gadii raawwachuuf gargaarsaafi deeggarsa hedduu naaf godhu:

Gaaffii	Cimseen itti walii hin galu	Hamma tokko itti walii hin galu	Giddu-galeessa	Hamma tokko itti walii gala	Cimseen itti walii gala	Na hin ilaallatu (HI)
a) karoora nyaataakoo akkan hordofuuf	1	2	3	4	5	HI
b) dawaakoo fudhachuuf	1	2	3	4	5	HI
c) miilla koof kunuunsa gochuuf	1	2	3	4	5	HI
d) sochii jabeenya qaamaa ga'aa argachuuf	1	2	3	4	5	HI
e) hamma sukkaaraa dhiiga koo safaruuf	1	2	3	4	5	HI
f) waa'ee dhukkuba-sukkaaraakoof miira natti dhaga'amu to'achuuf	1	2	3	4	5	HI

Gaaffii 3: Maatii ykn hiriyootni koo:

Gaaffii	Cimseen itti walii hin galu	Hamma tokko itti walii hin galu	Giddu-galeessa	Hamma tokko ittin walii gala	Cimseen itti walii gala
a) anaafi dhukkuba-sukkaaraakoo ni fudhatu	1	2	3	4	5

b)	sababa dhukkuba-sukkaaraakoof miira hin-tolletu itti dhaga’ama	1	2	3	4	5
c)	waa’ee dhukkuba-sukkaaraakoof na jajjabeessu, na faana jiraachuusaaniis naaf mirkaneessu	1	2	3	4	5
d)	waa’ee dhukkuba-sukkaaraakoof hamilee na buusu, na aarsu	1	2	3	4	5
e)	yeroo ani waa’ee dhukkuba-sukkaaraakoo haasa’uu barbaadu na dhaggeefatu	1	2	3	4	5
f)	waa’ee dhukkuba-sukkaaraakoof na qeequ	1	2	3	4	5

Gaaffii 4: Dhukkuba-sukkaaraa keessaniif yaalii gochuu keessatti eenyutu hunda caalaa isin gargaara? (tokko qofa filadhaa).

1 Hiriyyaa gaa’elaa
2 Miseensota maatii warra biroo (warra mana tokko keessa waliin jiraattan keessaa)
3 Hiriyyoota
4 Kaffaltiidhaan kan isin gargaaru
5 Doctora
6 Narsii
7 Hogganaa dhimma fayyaa
8 Ogeessa farmaasii
9 Ogeessa fayyaa kan biroo
10 Namni na gargaaru hin jiru

Appendix XIII Questionnaire to be responded by family caregiver- Afaan Oromoo

Kutaa 2. **Unka kan Amala Gargaarsa Maatiin Dhukkubsattoota Sukkaaraaf godhan**

Qajeelfama. Miseensotni maatii hangam deddeebi'anii tokko tokkoon wantoota armaan gadii miseensa maatii dhukkuba sukkaaraa dhukkubsatuuf/ttuuf akka raawwatan beekuu barbaanna. Wanta yeroo hunda mana keessatti raawwattan kaa'aa. Deebii sirrii yookaan dogoggoraa hin jiru. Namni madaalamaa jiru/tu hangam deddeebi'ee/tee waantoota armaan gadii akka raawwatu/ttu sirriitti kan ibsu madaallii armaan gadii jalatti mallattoo (✓) barreessaa.

T. Lakk.	Gaaffilee	Deebii				
		Gonkuma	Ji'atti si'a lama	Torbanittisi'a tokko	Torbanitti si'a baayyee	Yoo xiqqaate guyyaatti si'a tokko
1.	Dhukkubsataan qajeelfama soorata isaa hordofuu isaatiif nan jaja.					
2.	Dhukkubsataan/ttuun akka qorannoo dhiigaa isaa/ishee godhu/gootu irra deddeebiin itti nan qeeqa/nufisiisa					
3.	Qoricha yeroo fudhatan waantoota dhukkubsataa/ttu gargaaruu danda'an ittin hima/yaadan hiraafi.					
4.	Qajeelfama soorataa isaa/ishee hordofuu dhiisuuf dhukkubsaticha/ttii irra deddeebiin nan qeeqa/nufisiisa.					
5.	Waa'ee gochaalee kunuunsa dhuunfaa dhukkuba sukkaaraa isaa/ishee ilaalchisee dhukkubsaticha/ttii waliin falmii nan godha.					
6.	Gochaalee ispoortii adda addaa keessatti akka hirmaatuuf/ttuuf dhukkubsaticha/ttii nan jajjabeessa.					
7.	Firii qorannoolee dhiigaa galmeessuu dhiisuuf dhukkubsaticha/ttii nan qeeqa.					
8.	Anis yeroo dhukkubsatichi/ttiin nyaatun/ttun nyaadha.					
9.	Dhukkubsaticha/ttii waliin sochii jabeenya qaamaa nan godha.					
10.	Dhukkubsatichi/ttiin qoricha isaa/ishee turee/turtee fudhatee/ttee akka rafu/tu nan godha.					

11.	Rakkoowwan sababa qorichaan mudachuu danda'an to'achuuf, waantoota sukkaara of-keessaa qaban baadhatee/ttee akka deemuuf/tuuf nan bitaafi.					
12.	Nyaatawwan qaama soorata dhukkuba sukkaaraa dhukkubsatichaa/ttii hin taane akka nyaatu nan godha.					

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