EFFECTIVENESS OF DIABETES SELF-MANAGEMENT EDUCATION ON GLYCAEMIC CONTROL IN PATIENTS WITH TYPE 2 DIABETES MELLITUS: A RANDOMISED CONTROLLED TRIAL

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LIST OF ACRONYMS

AADE- American Association of Diabetes Education

BMI- Body Mass Index

BP- Blood Pressure

DBP- Diastolic Blood Pressure

DM- Diabetes Mellitus

DSME- Diabetes Self- Management Education

FBG- Fasting Blood Glucose

HbA1c- Haemoglobin A1c

HDL-C- High Density Lipoprotein Cholesterol

KATH- Komfo Anokye Teaching Hospital

KNUST- Kwame Nkrumah University of Science and Technology

LDL-C- Low Density Lipoprotein Cholesterol

LMIC- Lower Middle-Income Country

M-health- Mobile health

MNT- Medical Nutrition Therapy

MODY- Maturity- Onset Diabetes of the Young

OPD- Outpatient Department

RCT- Randomised Control Trial

SBP- Systolic Blood Pressure

SGM- Self Glucose Monitoring

SPSS- Statistical Package for Social Sciences

SSA-Sub-Saharan Africa

T1DM- Type 1 Diabetes Mellitus

T2DM- Type 2 Diabetes Mellitus

TC- Total Cholesterol

TG- Triglycerides

WC- Waist circumference

WHO- World Health Organization

ABSTRACT

BACKGROUND: Diabetes mellitus prevalence has been rising rapidly in middle- and low-income countries. Diabetes self- management education (DSME) is a critical element of care for all people with diabetes and is necessary in order to improve patient outcomes. About 70% of patients with diabetes have poor glycaemic control in Ghana. This situation necessitates effective diabetes control measures including DSME, especially noting that a 1-point improvement of HbA1c is associated with a 20% and 30%-40% decrease in macrovascular and microvascular complications, respectively.

OBJECTIVES: To determine the effectiveness of diabetes self-management education on glycaemic control when combined with usual care vs usual care alone in patients with T2DM

METHODS: This is a parallel-group, 2-arm randomized controlled trial among sub-optimally controlled (HbA1c > 7.9%) T2DM patients to compare the effectiveness of a 6-month nurse led DSME intervention on glycaemic control in addition to usual diabetes care versus usual care alone.

ANALYSIS: Data will be analysed using the Statistical Package for Social Sciences (SPSS) Version 26 (SPSS Inc, Chicago, IL, USA) software program. Categorical variables will be displayed using frequencies and percentages. Continuous variables will be presented as means and standard deviations. Chi-square test of independence and student's t-test will be used to examine the association between any 2 categorical variables and 2 continuous variables respectively**.** The mean change in HbA1c after six months for all outcomes, will be calculated in both groups and the significance tested using the student's t-test for the mean difference between the intervention and control arm. Statistical significance for all tests will be set at the 0.05 level, and all analysis will be 2-tailed.

EXPECTED OUTCOME: Our study will evaluate the effectiveness of DSME in improving glycaemic control using a mixed delivery strategy. If DSME is shown to be effective it will enhance scaling up of this intervention in diabetes clinics and the adoption of this model in the

national diabetes management guidelines. This will lead to improved knowledge of diabetes, glycaemic control, reduced lost hours due to hospitalization from poorly controlled diabetes mellitus and improved patient outcomes.

BACKGROUND INFORMATION

2.1 INTRODUCTION

Diabetes mellitus (DM) prevalence has been rising rapidly in middle- and low-income countries. Africa is reported to have 24 million adults (20-79) living with DM in 2021, majority being Type 2 Diabetes Mellitus (T2DM). This figure is estimated to increase to 33 million by 2030 and 55 million by 2045. Diabetes was responsible for 416,000 deaths in 2021(1).

DM is a major cause of blindness, kidney failure, heart attacks, stroke and lower limb amputation(1). Almost half of all deaths attributable to high blood glucose occur before the age of 70 years. The World Health Organization (WHO) projects that diabetes will be the 7th leading cause of death in 2030 (1).

Healthcare in developing countries primarily focuses on acute disease, relying little on laboratory services, and offers limited patient follow-up. By contrast, chronic disease management requires sustainable laboratory services, training of the healthcare workforce, the availability of appropriate drugs, and patient education in nutrition and self-care (2).

Patients with T2DM need complex care to control acute complications and reduce their risk of long-term complications. Patients with T2DM require not only ongoing medical care, but also diabetes self-management, which patients must do themselves. Effective glycaemic control is a vital component of the management of patients with T2DM. A healthy lifestyle, appropriate diet, and medication adherence are essential factors for good glycaemic control (3).

The American Diabetes Association has recommended haemoglobin A1c (HbA1c) as the established standard measurement for assessing glycaemic control in individuals with diabetes. Following the guidelines, an HbA1c level of around 7% indicates good glycaemic control (4).

Recent studies have shown that a high proportion of patients attending the Diabetes Clinic in Ghana have poorly controlled diabetes and this has serious implications for the management of T2DM diabetes as it suggests that current hospital-based treatment measures are less effective(5). Hence, patients with diabetes need self-management education to assist them in comprehending and dealing with the disease.

Diabetes self-management education (DSME) is a critical element of care for all people with diabetes and is necessary in order to improve patient outcomes (6). DSME is the ongoing process of facilitating the knowledge, skill, and ability necessary for diabetes self-care. This process incorporates the needs, goals, and life experiences of the person with diabetes and is guided by evidence-based standards (6). The overall objectives of DSME are to support informed decision-making, self-care behaviours, problem-solving and active collaboration with the health care team and to improve clinical outcomes, health status, and quality of life (6). It improves glycaemic control which has been shown to reduce micro and macrovascular complications (7).

About 70% of patients with diabetes have poor glycaemic control in Ghana (8). This situation necessitates effective diabetes control measures including DSME, especially noting that a 1-point improvement of HbA1c is associated with a 20% and 30% – 40% decrease in macrovascular and microvascular complications, respectively (7). DSME has been shown to reduce HbA1c averagely by 0.76% immediately after follow-up, 0.26% after 1-3 months and 0.26% after 4 months and beyond (9). It has been shown by various studies that self-management in Sub-Saharan Africa (SSA) is poor and a serious threat to glycaemic control (10).

Diabetes care in lower middle-income countries (LMIC) is beset with gaps especially in the area of DSME leading to poor outcomes. A meta-analysis of DSME among African Americans showed that DSME leads to non-significant improvement in HbA1c (11). Systematic meta-analysis of DSME in SSA has shown that limited research has evaluated this practice with only two reported in Ghana using mobile phone intervention and structured group education respectively which showed reduction in mean HbA1c(5,12–14). The limited availability of evidence supporting the use of DSME in Ghana has led to difficulty in scaling up the use of this effective intervention across the country.

In Ghana, unstructured diabetes education is usually given on an ad hoc basis by nurses at hospital waiting areas and by physicians during consultation and we are yet to conduct a study that evaluates how DSME delivered via a mixed delivery strategy will improve glycaemic control.

Thus, the objective of this study is to evaluate the effectiveness of DSME when combined with usual care on glycaemic control as compared to usual care alone in patients with sub-optimal glycaemic control.

2.2 RESEARCH QUESTION

Does diabetes self-management education when combined with usual care improve glycaemic control when compared to usual care alone?

2.3 AIM AND OBJECTIVES

2.3.1 AIM

To determine the effectiveness of diabetes self-management education on glycaemic control when combined with usual care vs usual care alone in patients with T2DM.

2.3.2 SPECIFIC OBJECTIVES

1) To determine the effectiveness of the intervention on HbA1c
2) To determine the effectiveness of the intervention on Fasting blood glucose (FBG)
3) To determine the effectiveness of the intervention on Blood pressure (BP) control
4) To determine the effectiveness of the intervention on body weight
5) To determine the effectiveness of the intervention on Low density lipoprotein cholesterol (LDL-C)

2.4 HYPOTHESIS

Diabetes self-management education when combined with usual care vs usual care alone leads to reduction in HbA1c (improvement in glycaemic control) in patients with Type 2 DM.

2.5 OUTCOMES

2.5.1 PRIMARY OUTCOME

Mean change in HbA1c at 6 months

2.5.2 SECONDARY OUTCOMES

1) Mean change in FBG at 3 months
2) Mean change in blood pressure at 6 months
3) Mean change in body weight at 6 months
4) Mean change in LDL-C at 6 months

2.6 INCLUSION CRITERIA

1) Patients with T2DM who are at least 18 years old without any co-morbidities requiring immediate hospitalisation
2) HbA1c >7.9%
3) Have access to a personal mobile phone and able to answer calls
4) Mentally stable, with no vision, verbal, or hearing impairments
5) Must have access a glucometer
6) Consents to the study

2.7 EXCLUSION CRITERIA

1) Other forms of DM such as type 1 DM or gestational diabetes
2) End-stage renal disease(eGFR<15ml/min)
3) Anaemia
4) History of stroke with paresis

METHODOLOGY

3.1 STUDY SITE

The study will be conducted at the Diabetes Centre of Komfo Anokye Teaching Hospital (KATH) in Kumasi, the second largest urban area in Ghana. Kumasi has an estimated T2DM prevalence of 3.8% (15), which is higher than the national prevalence of 2% (16).

KATH is a 1200 bed capacity tertiary level health facility affiliated to KNUST and the most advanced healthcare facility in the city running an outpatient diabetes clinic. The clinic runs weekly with the exception of Thursdays and receives referrals for adults > 18 years with diabetes from 9 out of the 16 administrative regions of Ghana and serves an estimated population of 15 million (17). A quarter of referrals to the clinic are received from health centres located within the northern and middle belts of Ghana while the remainder are referred from within the teaching hospital particularly after patients have been discharged as inpatients. On average, 40 patients attend the clinic daily. The Diabetes Centre is manned by endocrinologists, diabetes specialist doctors and nurses, pharmacists and dieticians.

3.2 STUDY DESIGN

This is a parallel-group, 2-arm randomized controlled trial among sub-optimally controlled (HbA1c > 7.9%) T2DM patients to compare the effectiveness of a 6-month DSME intervention on glycaemic control in addition to usual diabetes care with usual care alone.

The minimum sample size of study participants will be determined using the formula (18)

$$n_i = 2\left(\frac{Z_{1-\alpha/2} + Z_{1-\beta})}{ES}\right)^2$$

$$ES = \frac{\mu 1 - \mu 2}{\sigma}$$

Where n_i is the sample size in each of the groups for a statistically significant study;

$\mu 1-\mu 2$ is the absolute value of the difference in means (HbA1c) between the two groups expected under the alternate hypothesis which is 1.5% for this study;

σ = standard deviation of the outcome of interest which is 2.25 based on study by Asante et al(14)

ES is effect size which is calculated to 0.7

$1-\beta$ is the power which is 80% for this study and $Z_{1-\beta}$ is the value from the standard normal deviation holding $1-\beta$ below it.

α is the selected level of significance which is 0.05 for this study, $Z_{1-\alpha/2}$ is the value from the standard normal deviation holding $1-\alpha/2$ below it. selected level of confidence set at 0.05 for this study

32 subjects in each group will be needed to ensure an adequate trial. An assumed 15% attrition and drop-out rate over the study period will be added to make a total sample size of 74 participants.

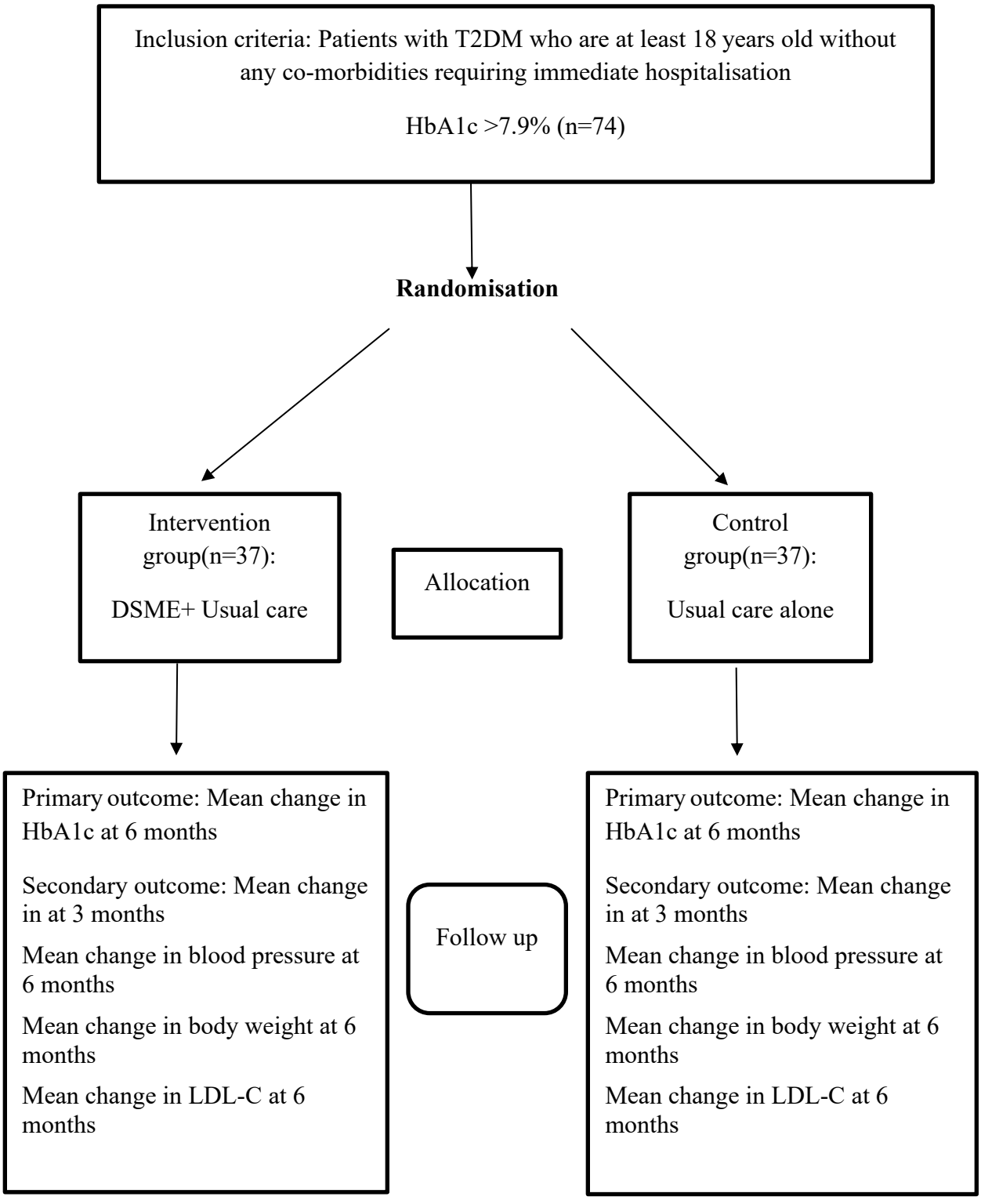
3.3 STUDY POPULATION

The study population comprises all patients with T2DM attending the Diabetes clinic at KATH. Participation in the study will be limited to individuals who meet the set criteria.

3.4 STUDY PERIOD

The study will take place from August 2023 to April 2024

3.5 STUDY FLOW DIAGRAM



3.6 SCREENING OF PARTICIPANTS

Individuals seeking care at the diabetes clinic will be approached by the principal investigator to introduce the study to them. They will be briefed on the study purpose and objectives and those who provide consent will be screened using the participant screening sheet (appendix A). Following the screening procedure, persons who meet the inclusion criteria and provide consent for inclusion will have blood sample collected for measurement of baseline HbA1c using semi-automated Quo-Lab HbA1c analyser. Individuals with T2DM and baseline HbA1c > 7.9% will then be recruited into the study.

3.7 STUDY ARMS

3.7.1 USUAL CARE

The current standard practice (the usual care) includes an outpatient specialist service with patients scheduled every 1 to 6 months, depending on their diabetes control and complications profile. The other services provided include dietician appointments, laboratory investigations, clinical examinations, group education on self-management practices, and medication refills.

Usual care by a doctor entails a 10–15 min standard doctors' consultation where the recent HbA1c level and medication compliance are reviewed, and a brief informal patient-tailored diabetes education is offered. This enables the individual an opportunity to learn about self-management in a flexible and informal way. There is no structure to it and the information is offered according to what the patient requests to know as well as what the doctor thinks would be important for the patient to know, during that consultation.

Phone calls will be made to remind them of their clinic appointment for data collection.

3.7.2 DIABETES SELF-MANAGEMENT EDUCATION

The intervention group will receive the usual consultation from their doctor and referral to a trained diabetes educator for individualised structured DSME training. An empowerment and

interactive teaching model will be used with focus on behavioural assessment, goal-setting and problem-solving to promote autonomous self-regulation for better health and quality of life. A clinical sheet will be used while delivering the education to ensure that all core topics are covered.

For this study, 3 trained diabetes educators will offer the individualised DSME sessions using the American Association of Diabetes Education (AADE) 7 self-care behaviour model which focuses on: being active, healthy eating, monitoring blood glucose, healthy coping, reducing risks, problem solving and adherence to medication (19).

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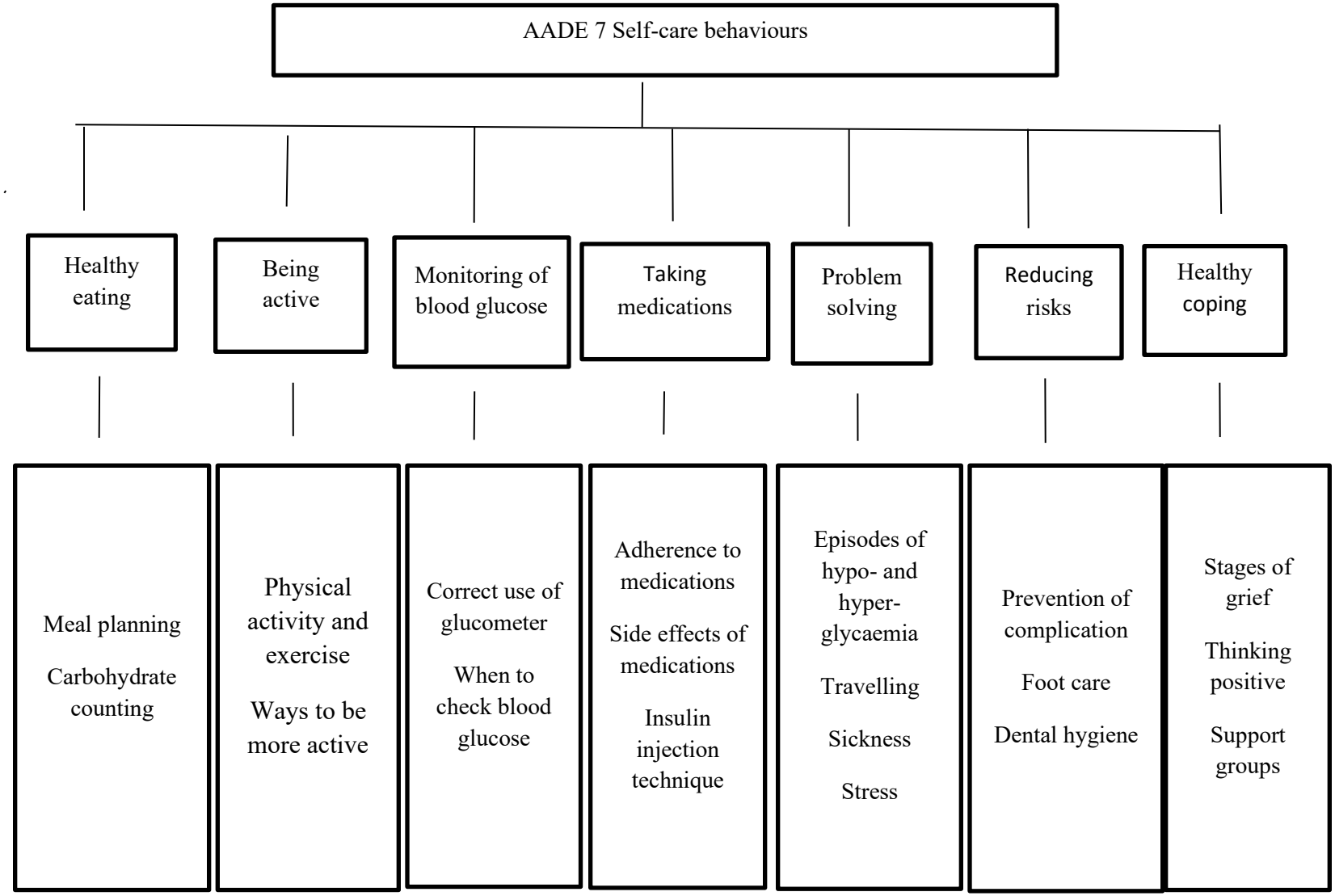
AADE 7 Self-care behaviours
Healthy eating
Being active
Monitoring of blood glucose
Taking medications
Problem solving
Reducing risks
Healthy coping
Meal planning
Carbohydrate counting
Physical activity and exercise
Ways to be more active
Correct use of glucometer
When to check blood glucose
Adherence to medications
Side effects of medications
Insulin injection technique
Episodes of hypo- and hyper-glycaemia
Travelling
Sickness
Stress
Prevention of complication
Foot care
Dental hygiene
Stages of grief
Thinking positive
Support groups

The participants are scheduled to attend a 30 minutes individualised session at the hospital every 3 months as well as telephone consultations lasting up to 15 minutes every 2 weeks at the convenience of the participant to reinforce DSME for 6 months. The first session is arranged on the first day of consultation with the doctor. At the end of the sessions, the participants will receive a patient guide to diabetes booklet and graphic material illustrating several self-care activities such as foot care. Subsequent consultations will be mainly feedback sessions, aimed at reviewing previously discussed matters, reinforcing key messages, addressing challenges and providing additional information.

The patients will also receive telephone reminders, a week prior to their scheduled appointment with the doctors, to ensure confirmation of their visit. A hotline number will be made available to them to consult with the diabetic educator at any given time of the day. Participants will be counselled that if FBG is less than 4.0mmol/L upon self-monitoring, they should take 15g of glucose(250mls of Coke, Spirite or Fanta drink) and call the hotline number provided.

Monthly meetings will be held with educators and research assistant to provide feedback on study progress and ensure quality control in the administration of intervention.

3.8 RANDOMISATION

The principal investigator will invite all the eligible patients for participation, and randomise them equally into two groups based on computer-generated random numbers and inform them of the assigned group. The randomisation allocation sequence will remain concealed from the doctors to further eliminate conscious or unconscious selection bias. After recruitment, the patients will complete their demographic and medical history information on a standard data collection form.

3.9 STUDY INSTRUMENTS

The following materials, equipment, and reagents will be used to obtain the data.

1. Consent form
2. Participant screening sheet
3. Structured Questionnaire
4. Clinical sheet

5. EDTA bottle container
6. Serum Separating Tube
7. Accu Chek Glucometer
8. Blood pressure monitor, weight scale and stadiometer
9. Measuring tape

3.10 DATA COLLECTION METHODS AND MEASUREMENTS

3.10.1 RECRUITMENT AND DATA COLLECTION FOR MEDICAL HISTORY

Following the screening and measurement of baseline HbA1c, individuals with T2DM and HbA1c >7.9% will be eligible for recruitment. All patients who give informed consent (appendix D) will be then entered into the study.

A structured questionnaire will be used to collect data on demographics, medical history including presence of other co-morbidities, drug history.

3.9.2 PHYSICAL MEASUREMENTS

Measurements will follow the WHO guidelines for physical measurements (20)

Weight measurement will be done using the Omron HN286 electronic human weighing scale. The participants will take off their shoes, empty their pockets and stand erect on the scale which will be placed on a firm flat floor and set to zero display. The weight will be recorded to one decimal place (20).

The height measurements will be done using the Seca 213 mobile stadiometer. This will be placed on a firm flat surface against the wall. Participants will stand on the board with their feet together, heels against the backboard, and their knees straight. With the participants looking straight ahead and their eyes at the same level as the ears, the height measurements will be read to the nearest 0.1cm with the measuring arm placed gently on the head. BMI will be calculated from the weight and height measurement using the formula: BMI (kg/m^2) = weight (kg) /$height^2$ (m^2).

Waist circumference (WC) will be measured in the horizontal plane midpoint between the lower margin of the last palpable rib and the top of the iliac crest (hip bone) with a measuring tape with the participant's arms relaxed at the side and at the end of normal expiration. WC will be measured in a private room and recorded to the nearest 0.1cm. Blood pressure measurements will be done using a validated 'Omron M3 Intelli IT' Upper Arm Blood Pressure Monitor. Participants will sit quietly with their feet on the floor and their clothes loosened around the arm for at least five minutes before the blood pressure readings will be taken. A correct-sized cuff (bladder width being 80% of the arm circumference) will be placed on an exposed arm about 2 cm above the elbow, with the tube placed in front and at the centre of the arm. The blood pressure reading which will show some minutes after pressing the start button will be documented. Three measurements will be taken three minutes apart and the mean of the second and third readings will be used for the analysis.

3.9.3 BIOCHEMICAL ASSAY

Fasting blood glucose will be measured using Accu Chek Instant glucometer at the DM Clinic on every hospital visit.

Blood samples will be taken by trained laboratory technicians adhering to standard procedures including infection prevention and control practices. 10mls of venous blood will be obtained from each patient with 5ml each in an EDTA tube for HbA1c and serum separation test tube for lipid profile respectively taken at baseline and 6 months after recruitment. Each tube will be properly marked with unique identifiers and codes to de-personify the participants. All samples for lipid profile measurements will be kept in sample bags and sent to the biochemistry lab of the Komfo Anokye Teaching Hospital for processing. The samples will be processed and analysed with the Vitros® 5600 integrated immunochemistry analyser and a semi-automated Quo-Lab HbA1C analyser to determine the lipid profile and the HbA1c respectively.

3.9.4 DSME

A clinical sheet will be used by the diabetes educators while delivering the education to ensure that all core topics are covered

3.10 FOLLOW UP

Each study participant will be followed up for 6 months starting from the first encounter which is the first day of recruitment and ending at the last encounter which is the day of blood collection for 6-month HbA1c and lipid profile testing.

3.11 PLAN FOR DATA MANAGEMENT

3.11.1 STATISTICAL ANALYSIS

Data will be analysed using the Statistical Package for Social Sciences (SPSS) Version 26 (SPSS Inc, Chicago, IL, USA) software program. Categorical variables will be displayed using frequencies and percentages. Continuous variables will be presented as means and standard deviations. Chi-square test of independence and student's t-test will be used to examine the association between any 2 categorical variables and 2 continuous variables respectively**.**

The mean change in HbA1c after six months for all outcomes, will be calculated in both groups and the significance tested using the student's t-test for the mean difference between the intervention and control arm.

Statistical significance for all tests will be set at the 0.05 level, and all analysis will be 2-tailed.

3.12.2 ETHICAL CONSIDERATION

Ethical consideration will be sought from the Komfo Anokye Teaching Hospital Institutional review board. Voluntary participation and written informed consent will be obtained from all participants. Confidentiality of all participants will be assured. Data obtained will be analysed solely for the purpose of this study and utmost discretion will be exercised in the handling of personal information provided.

3.12.3 LIMITATIONS OF STUDY

The research is being conducted at a single tertiary hospital centre which may not reflect fully what is happening at the regional and district hospitals. Also, there is a high level of expertise in the tertiary hospital setting hence usual care of patients with T2DM may be comparable to a structured DSME.

Furthermore, this study has only a 6 month follow up period and it is therefore not clear how sustainable participant adherence and improvements in glycaemic control will be maintained over longer time period. Only individuals who have access to glucometers will be enrolled in the DSME intervention arm; this may lead to some degree of selection bias.

RELEVANCE OF STUDY

Diabetes mellitus is associated with significant morbidity, mortality and healthcare resource utilisation if poorly controlled. Patients with T2DM need complex care to control acute complications and reduce their risk of long-term complications. Patients with T2DM require not only ongoing medical care, but also diabetes self-management, which patients must do themselves. Effective glycaemic control is a vital component of the management of patients with T2DM.

The Ghana Standard Treatment Guideline recommends a glycaemic target of 7% which indicates good glycaemic control. However, about 70% of Ghanaian patients with Type 2 DM fail to reach glycaemic control targets due to the complex nature of type 2 diabetes self-management. Hence, patients with diabetes need self-management education to assist them in comprehending and dealing with the disease. Diabetes education about health behaviours, including diet, medication adherence, blood glucose self-monitoring, and physical activity, is essential for successful diabetes management.

Mixed delivery strategy structured DSME has not been adequately studied in Ghana considering the peculiarities of a resource poor healthcare system, availability of trained personnel and cultural set up.

This study will help fill the knowledge gap in assessing the effectiveness of a structured DSME in which a mixed delivery strategy is deployed to improve glycaemic control. Also, the results of this study will serve as a foundation for implementation studies to be conducted to assess the feasibility of a DSME in our healthcare system leading to improved glycaemic control and outcomes in patients with T2DM. The findings of the study will also be shared with relevant health agencies to formulate relevant policies aimed at improving management of T2DM in Ghana.

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STUDY BUDGET

ITEMS	QUANTITY	UNIT COST(GHS)	TOTAL COST(GHS)
Material purchases			
Stationary	4	80	320
Printing cost	100	2	200
Photocopying	200	6	1200
		Subtotal	**1720**
Ethics and Data management			
Ethics Application fees	1	250	250
database management	1	1000	1000
		Subtotal	**1250**
Equipment			
Weighing scale	1	500	300
Stadiometer	1	500	500
Blood pressure monitor	1	800	600
		Subtotal	**1400**
Lab Investigations			

Lipid profile	148	120	17760
HbA1c	300	60	18000
Glucometer	1	250	250
Glucose strips	5 boxes	250	1250
		Subtotal	**37260**
Study meetings and training workshops			
Secretarial services and communication	1	700	700
Quality assurance meetings	6	150	900
		Subtotal	**1600**
Personnel			
Diabetes Educators	3	2400	7200
Transport for participants	37	120	4440
		Subtotal	**13140**
Project dissemination			**1400**
Grand total			**57770**

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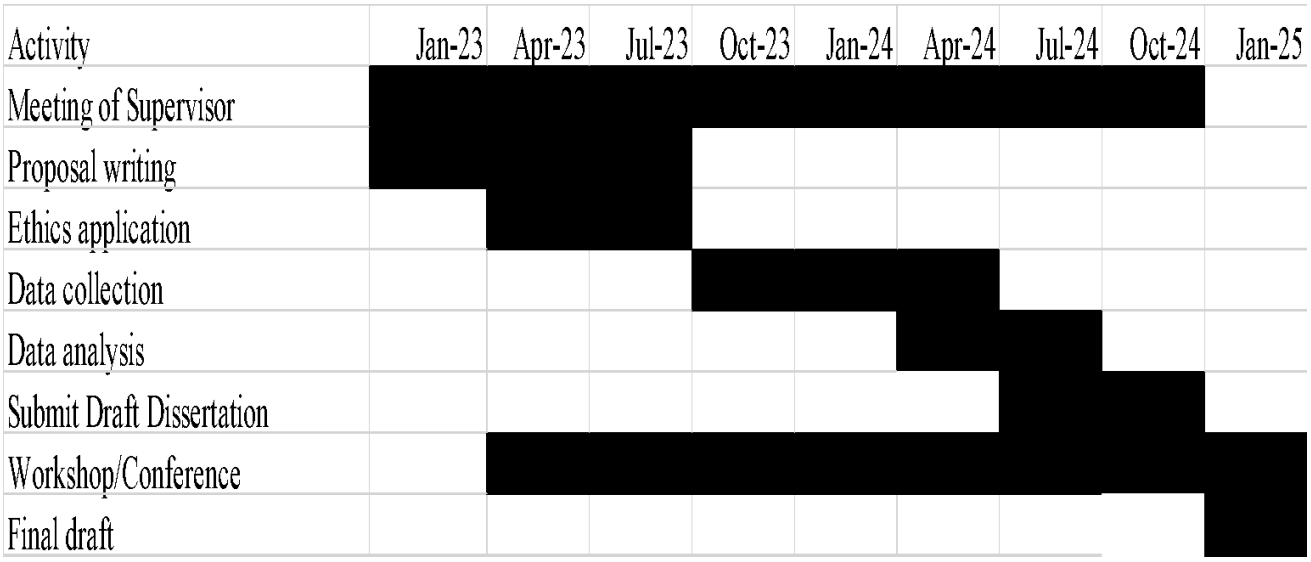
Activity
Jan-23
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Jul-24
Oct-24
Jan-25
Meeting of Supervisor
Proposal writing
Ethics application
Data collection
Data analysis
Submit Draft Dissertation
Workshop/Conference
Final draft

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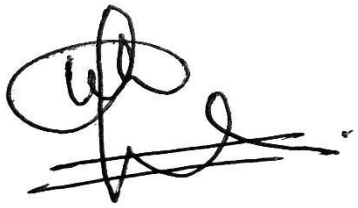

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