Study Protocol and SAP

Official Title: **Effect of Peer Support Intervention on Medication Adherence, Self-care and Knowledge Among Patients with Diabetes**

ClinicalTrials.gov ID (NCT number): **NCT07145983**

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Scientific Background

Diabetes mellitus is a chronic condition that requires consistent adherence to treatment, regular self-care, and adequate knowledge of the disease to prevent complications and improve quality of life. However, many patients struggle to maintain optimal adherence and integrate self-care into their daily routines. Now a days, many diabetes self-management modalities have emerged as a promising approach to address these gaps. This randomized controlled study evaluated the effect of a structured peer support program on medication adherence, self-care practices, and diabetes-related knowledge among patients with diabetes who attended follow-up at a tertiary hospital.

Study Objectives

- To assess the effect of a peer support group intervention on Medication adherence among patients with diabetes on follow up at ACSH
- To assess the effect of peer support group intervention on self-care practice among patients with diabetes on follow up at ACSH
- To explore the effect of peer support group interventions on patients' knowledge among patients with diabetes on follow up at ACSH

Study Design & Methods

Study Setting

The study was conducted at Ayder Comprehensive Specialized Hospital (ACSH), the largest referral hospital in the Tigray region, situated in Mekelle city, about 780 kilometers north of Addis Ababa, Ethiopia's capital. ACSH serves an estimated 10 million people from Tigray and neighboring regions, including Amhara and Afar. With a capacity of 500 beds, the hospital manages approximately 10,000 inpatient admissions and 100,000 outpatient visits annually. The diabetic clinic at ACSH is a major center for diabetes management, providing follow-up care for around 5,000 patients. Outpatient services are delivered two days a week, serving more than 100 patients per visit. The clinic is operated by two senior physicians, residents and five nurses who provide a range of essential services, such as diabetes education, individualized counseling on diet, emergency care, medication adherence and insulin administration. Antidiabetic treatments are adjusted based on fasting blood glucose and HbA1C results. Newly diagnosed patients receive intensive follow-up during the first six months to help maintain optimal blood glucose levels.

Study Design and Period

A randomized controlled trial (RCT) design was employed from January to September 2025 to evaluate the effect of a peer support intervention among patients with diabetes attending ACSH. This trial has been registered and can be accessed at: *https://clinicaltrials.gov/study/NCT07145983* which initially released on August 21, 2025.

Sample Size Determination

The sample size for this study was determined separately for the peer support group and the two comparison groups. Five participants were purposively selected for the peer support group based on predefined eligibility criteria. Selection was done in collaboration with clinical service providers at the diabetic center to ensure the inclusion of experienced individuals, following guidance from validated studies on peer support interventions for diabetic patients(28). For the intervention and control groups, the sample size was calculated using the statistical superiority design formula for continuous variables: $n = [(Z_1 + Z_2)^2 \times (2S^2)] / d^2$. In this formula, Z_1 represents the z-score for a 95% confidence level (1.96), Z_2 corresponds to a power of 80% (0.84) (29). The standard deviation (S = 4) was estimated based on the range of scores from the Morisky Medication Adherence Scale with eight items (MMAS-8), which ranges from 0 (indicating poor adherence) to 8 (indicating high adherence). A minimum clinically meaningful difference of 2 points (d = 2) in adherence scores between the groups was considered for sample size calculation. This calculation provided the required sample size for the intervention and control groups to detect a meaningful difference in adherence outcomes (30). A total of 100 eligible patients with diabetes were recruited using a simple random sampling method with 50 participants assigned to the intervention group and 50 to the control group.

Standard Care

Scheduled consultations with a physician, laboratory investigations and medication refill were the standard care services delivered for patients with diabetes during the clinic's service days at the diabetic center of the hospital. Follow-up appointments are typically scheduled every two to three months. Newly diagnosed patients receive individualized counseling from the nurse on duty, addressing diabetes-related and patient-specific concerns. Additionally, patients collect their prescribed medications from the hospital pharmacy up on visiting the hospital for follow up in

which standard pharmacy care was also served. Thus, in this trial both groups received this standard health care service equally.

Peer Support Intervention and Procedures

The study was conducted in two phases. Phase I involved the recruitment and preparation of the peer support group (n = 5). These individuals were selected in advance and remained consistent throughout the intervention period. One registered nurse was recruited to serve as a facilitator for the peer support sessions. The recruited peer educator attended an initial 2-days training program on how to facilitate and structure the consecutive sessions which included role-playing exercises to prepare them for effective communication and engagement with intervention group members. They were primarily trained in their local language (Tigrigna) to educate and share their experience to peers on scheduled sessions focused on treatment adherence, self-care behaviors, and diabetes-related knowledges which was adopted from the Internation Diabetes Federation peer leader manual.

On Phase II, enrollment of the intervention and control group was continued during their regular appointments at the diabetic clinic. Both groups were matched in terms of sociodemographic characteristics and disease-related factors. While the control group received baseline assessments only and continued with standard care, members of the intervention group attended a one-hour orientation session to explain the study's objectives, potential risks of withdrawal, and the importance of sustained participation. Following this, each peer supporter was assigned to a group of 10 intervention participants and formed five peer-led support groups.

The peer support intervention was delivered through scheduled, one-hour group session during regular clinic appointments. These interventions were conducted in the 2^{nd}, 4^{th} and 6^{th} months, i.e., for three rounds over the study period for each group. Each group member was expected to participate in all the three sessions, which were structured around three core components: (a) sharing personal experiences and knowledge about diabetes and its complications, blood glucose triggering factors and providing psychosocial support focused on the self-management (disease-related component); (b) offering education and encouragement for medication adherence (medication adherence component); and (c) supporting the integration of dietary and physical activity recommendations into daily routines (behavioral component). The principal investigator conducted close follow-up of the intervention sessions to document the topics covered during each session and address any challenges encountered during the implementation. Monthly debriefing

sessions were conducted to discuss their experiences and challenges. Feedback on their performance was provided based on each group sessions.

Data collection Instruments and Measurements

Data were collected using participant interviews, review of medical records as well as adapted diabetes questionnaires for each outcome variable in the intervention and control groups. Four clinical pharmacists who were blinded as to the group assignments were recruited to collect the consecutive data. Medication adherence of each group was assessed through a mixed method using the Morisky Medication Adherence Scale (MMAS-8) and self-reported pill count. The MMAS-8 consisted of seven dichotomous items and one item rated on a five-point Likert scale. To minimize acquiescence bias ('yes-saying'), each 'no' response was assigned one point, except for item 5, which was reverse-coded. The eighth item provided five response options, scored from 0 to 1 in 0.25-point increments. Based on the total score, patients were classified as low adherers (score <6), medium adherers (score 6 to <8), or high adherers (score = 8).

Self-care practices were measured using the Summary of Diabetes Self-Care Activities (SDSCA) scale, which captures five key domains of diabetes management. General diet was measured as the mean of two items, while specific diet included two items, one of which was reverse-coded, Exercise, blood-glucose testing, and foot-care were each evaluated by averaging two respective items.

Diabetes-related knowledge was assessed using a structured questionnaire adapted from the Diabetes Knowledge Test (DKT) (34). The instrument included 14 core items administered to all participants, with an additional 9 items for insulin users, The DKT presents six dimensions, including: (i) food, with four items about the composition of food, its safety and which types of food should be avoid; (ii) ways to assess diabetes, with two items regarding methods to assess this disease; (iii) effect of external variables on diabetes control, with six items such as physical exercise or infection, on diabetes control; (35) signs and symptoms, containing three items concerning the symptoms associated with natural evolution of diabetes and failures on its monitoring; (v) control over medication and its effects, with six items measuring individual's response to adversities or forgetting to take insulin; and (vi) causes of glycemic deregulation, with two items aimed at understanding the individual's perception of possible causes that may change

blood glucose levels. Each correct response was scored as 1, and incorrect or "don't know" responses were scored as 0. Non-insulin users were scored out of 14 points, while insulin users were scored out of 23 points. Participants were classified as having **good knowledge** if their score exceeded the mean, and **poor knowledge** if their score was at or below the mean. All baseline pre-intervention data including surveys and clinical outcomes were collected in the first week, and follow-up data was collected in the 1st month of post-intervention.

Eligibility Criteria

Study Population and Eligibilities

The study involved diabetic patients aged 18 to 65 years who were receiving follow-up care at ACSH. Participants were divided into three groups whose were categorized as the peer support group, the intervention group and the control group. Eligible participants of the peer support group had a minimum of 10th grade educational background with more than three years of disease duration, stable glycemic control with HbA1C <7.5%), a documented history of regular follow-up at ACSH. Besides, the intervention group were those who received the peer-led educational sessions, which aimed to improve adherence to diabetes treatment, enhance self-care behaviors, and increase diabetes-related knowledge. Eligible participants of this group were those who had on at least one diabetes medication, most recent HbA1C value of ≥7.5% based on information collected by the research team at point of care HbA1C testing and those had regular follow-up visits at ACSH. The control group comprised patients with diabetes meeting similar eligibility criteria as the intervention group but received standard diabetes care during routine clinic visits without additional peer support.

Patients with diabetes who declined to participate in any of the groups, those diagnosed with other concurrent endocrine disorders (such as thyroid disease, obesity, or gestational diabetes) and chronic diseases like cardiac heart failure, hepatitis and cancer were excluded. Additionally, those enrolled in other educational programs during the study period and health professionals were excluded from this study.

Statistical Considerations

Data were entered into Epi-Data version 4.6 and exported to SPSS version 25 for analysis. Descriptive statistics such as frequencies, percentages, means, and standard deviations were used

to summarize sociodemographic, clinical, and behavioral characteristics of participants. Medication adherence, diabetes knowledge, and self-care practice scores were calculated according to their respective validated scales. The effect of the peer support group intervention within-group and between-group was assessed and comparisons were performed. Paired t-tests were used to determine changes in the outcome variables within each group (intervention and control) before and after the intervention. Independent sample t-tests were applied to compare mean differences between groups. Furthermore, a Difference-in-Differences (DiD) approach was employed to evaluate the net effect of the intervention by comparing the changes in outcomes from baseline to follow-up between the intervention and control groups.