Study Protocol and SAP

Official Title: **Effect of a Peer Support Intervention on Glycemic Control and Economic Burden Among Patients with Diabetes (PSI)**

ClinicalTrials.gov ID (NCT number): **NCT07499375**

Protocol Date: **January 1/ 2025**

Scientific Background

Diabetes imposes a growing global burden due to rising care costs and reduced quality of life from its complications. There is increasing interest in the role that peers may play to support positive health behaviors in diabetes. However, studies which evaluating both clinical effectiveness and economic feasibility of peer support interventions remain limited to date. Thus, this study aimed to evaluated the effect of a group-based peer support intervention on glycemic control and its implementation cost 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 Glycemic control among patients with diabetes on follow up at ACSH
- To determine the implementation cost of peer support group intervention among patients with diabetes on follow up at ACSH

Study Design & Methods

Study Setting

This study was conducted as part of a randomized controlled trial (RCT) under evaluating the effectiveness of a peer support intervention among patients with diabetes attending Ayder Comprehensive Specialized Hospital (ACSH), a tertiary referral hospital in Northern Ethiopia. The trial employed a parallel-group design with a 1:1 allocation ratio to intervention and control arms. The study followed the Consolidated Standards of Reporting Trials (CONSORT) guidelines, and participant flow was reported using a CONSORT flow diagram. The detailed trial protocol and overall methodology have been described elsewhere.

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/NCT07499375* which initially released on March 24, 2026.

Study participants and Sample size Determination

This study has involved three group of study participants whose were categorized as the peer support group, the intervention group and the control group who were on regular follow-up at the ACSH diabetic clinic. All participants were required to have a confirmed diagnosis of diabetes and to be willing to provide informed consent. The sample size for this study was derived from the main randomized controlled trial, which was powered to detect differences in medication adherence between groups. 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). 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. Thus, considering the lost to follow up 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. Besides, 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 chronic diseases.

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-intervention subgroups.

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.

Outcome measures

Glycemic control was evaluated using glycated hemoglobin (HbA1c) levels measured at baseline and at the end of the six-month follow-up period. All measurements were performed in the hospital laboratory following standard clinical procedures. HbA1c values were used to assess changes over time within and between the intervention and control groups. The economic evaluation focused on the implementation cost of the peer-support intervention from the program/provider perspective. Cost components included peer supporter recruitment, intervention group recruitment, peer supporter training, peer-support session delivery, and general program implementation activities. Resource utilization data were documented prospectively using a structured costing tool developed for this study. All costs were valued in United States Dollars ($) for the 2025 costing year. Where applicable, estimates were standardized and inflation-adjusted to the reference currency year to ensure comparability

Data collection procedures

Data were collected by trained data collectors using interviewer-administered questionnaires and medical record reviews. Baseline data included sociodemographic characteristics, clinical information, glycemic measures, and cost-related variables. endline assessments were conducted after three consecutive follow ups using the same tools and procedures to ensure consistency. Because of the behavioral nature of the intervention, participants and peer supporters were not blinded. However, trained data collectors who conducted baseline and endline assessments were blinded to treatment allocation. Laboratory personnel performing biochemical measurements were also not informed of group assignment to reduce detection bias

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. The effect of the peer support intervention on glycemic control and economic burden was estimated using a difference-in-differences (DiD) approach, comparing changes from baseline to endline between the intervention and control groups.