Study protocol

Official Study Title:

Effect of Nurse-Led Remote Monitoring and Patient Navigation on Psychological Distress and Self-Management among Patients with Diabetes Mellitus

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Protocol id: HUNURSERC2026/10/67/14

ClinicalTrials.gov Identifier (NCT): Not yet assigned

Document Date: 12/11/2026

Document Version: Version 1.0

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Introduction

Diabetes mellitus is a chronic metabolic disorder that requires continuous medical care, lifestyle modification, medication adherence, and ongoing self-management to prevent complications and maintain quality of life. Effective diabetes management extends beyond blood glucose control to include healthy eating, physical activity, medication adherence, foot care, regular follow-up, and the ability to recognize and respond to changes in health status. However, the continuous demands of managing diabetes may create psychological burdens and difficulties in maintaining recommended self-care behaviors. Therefore, comprehensive diabetes care should integrate clinical management, psychosocial support, health education, and accessible follow-up services **(Ahmad & Joshi, 2023).**

The American Diabetes Association recommends screening for Diabetes Distress using standardized instruments at the first appointment of a diabetic patient, at regular periods, and whenever there is a change in the complaint, medication, or life conditions. Additionally, the association advises physicians to assess DD, particularly in patients who have not reached their glycemic control targets despite receiving appropriate therapy and experiencing related chronic complications.6 DD can be efficiently addressed through behavioral procedures, making it a favorable focus for involvements aimed at improving both emotional well-being and diabetes-related health effects **(Hassan, Osman & Ali ,2025).**

Remote monitoring and patient navigation are promising approaches for improving continuity of care among people living with diabetes. Remote monitoring involves the regular collection and review of relevant health information through telephone communication, mobile applications, electronic messages, or other appropriate digital technologies. Patient navigation involves helping patients overcome barriers to healthcare access, understand care plans, attend appointments, obtain appropriate services, and communicate with healthcare professionals. When combined with community nurse assistance, these approaches may support timely

identification of health concerns, reinforce self-management practices, and facilitate access to clinical and psychosocial services **(Johnson & Miller, 2022).**

Psychological distress is an important concern in diabetes care because patients may experience diabetes-related emotional burden, anxiety, depressive symptoms, fear of complications, and frustration associated with daily self-management demands. These experiences are distinct from, although they may coexist with, clinically diagnosed mental disorders. Psychological distress may interfere with motivation, treatment adherence, and engagement in recommended self-care activities. Integrating psychological assessment and appropriate referral into community-based diabetes services may therefore help address the emotional and behavioral dimensions of the disease **(Ali, Raya, & Hussein, 2025).**

As stated by **Neenu and Sharma (2025)**; Community health nurses play a central role in diabetes prevention, health promotion, continuity of care, and the delivery of diabetes self-management education and support. Their responsibilities include assessing patients' health needs, providing individualized education regarding medication use and lifestyle modification, reinforcing blood glucose monitoring when clinically indicated, identifying barriers to treatment adherence, and facilitating referrals to appropriate healthcare services. Through telephone follow-up and other remote communication methods, community health nurses can monitor patients' progress, identify emerging concerns, and encourage active participation in their care. These activities should complement, rather than replace, scheduled clinical assessments and medical consultations. Within patient navigation, community health nurses can assist patients in arranging appointments, understanding referrals, accessing diabetes education, and communicating with healthcare providers. They can also assess social and practical barriers, such as transportation difficulties, limited digital literacy, financial constraints, and inadequate family support. **(Dailah, 2024).**

Psychiatric and mental health nursing contributes to diabetes care by assessing psychological distress, identifying emotional and behavioral difficulties, providing supportive communication and helping patients develop effective coping strategies. Mental health nurses can support patients experiencing diabetes-related emotional burden, anxiety, depressive

symptoms, or difficulties adapting to the demands of a chronic illness. They can also collaborate with community health nurses to identify patients who require further psychological assessment or referral to specialized mental health services. Psychological screening should be conducted using validated instruments, with appropriate follow-up for patients who report substantial distress **(da Silva, Lima& Saidel, 2023).**

Significance of the Study

Diabetes management requires sustained patient engagement and access to appropriate healthcare services. Nevertheless, some patients experience difficulties maintaining self-management practices, attending appointments, and accessing timely guidance between clinic visits. Nurse-assisted remote monitoring and patient navigation may provide an accessible, structured approach to identifying emerging concerns, reinforcing self-care behaviors, and facilitating communication with healthcare providers. Evaluating this approach may generate useful evidence for strengthening community-based diabetes services and improving continuity of care. **(Hassan , Osman, & Ali , 2025).**

A study conducted by **Ali, Raya, & Hussein, 2026;** At zagazig university **;** the study highlighted a bidirectional relationship between diabetes and psychological health highlights the need for integrated care approaches that address both physical and mental health, ensuring better outcomes and improved quality of life for diabetic individuals.

This study is significant because it examines psychological distress alongside diabetes self-management rather than focusing exclusively on clinical indicators. Its findings may help clarify whether participation in a structured nurse-assisted monitoring and navigation program is associated with changes in patients' psychological distress and self-management behaviors. The results may inform the development of integrated community nursing interventions that recognize the relationship between emotional well-being, treatment demands, and daily diabetes care.

Problem Statement:

Despite advances in diabetes treatment and healthcare delivery, effective diabetes management continues to depend on patients' ability to maintain recommended self-management behaviors and access appropriate follow-up services. The ongoing demands of diabetes may contribute to psychological distress, while difficulties navigating healthcare services and obtaining support between appointments may create additional barriers to effective self-care. Remote monitoring and patient navigation are potential strategies for addressing these challenges, but their value should be evaluated within the specific healthcare setting and patient population in which they are implemented.

Accordingly, the proposed study will investigate community nurse-assisted remote monitoring and patient navigation in relation to psychological distress and self-management among diabetic patients. It will assess changes in these outcomes following the intervention and explore whether improvements in patients' experiences are accompanied by better engagement in recommended diabetes self-management practices.

Aim of the Study

To evaluate the Effect of Nurse-Led Remote Monitoring and Patient Navigation on Psychological Distress and Self-Management among Patients with Diabetes Mellitus. **Through the following objectives:**

1) To assess the baseline levels of psychological distress among diabetic patients.
2) To assess the baseline levels of diabetes self-management behaviors among diabetic patients.
3) To implement a structured nurse-led remote monitoring and patient navigation intervention for diabetic patients.
4) To evaluate changes in psychological distress among diabetic patients following the intervention.

5) To evaluate changes in diabetes self-management behaviors among diabetic patients following the intervention.
6) To examine the relationship between psychological distress and diabetes self-management among diabetic patients before and after the intervention.
7) To identify the sociodemographic and clinical factors associated with psychological distress and diabetes self-management among diabetic patients.

Research Hypotheses:

H1: Diabetic patients will demonstrate a statistically significant reduction in psychological distress scores after implementation of the nurse-led remote monitoring and patient navigation intervention compared with their baseline scores.

H2: Diabetic patients will demonstrate a statistically significant improvement in diabetes self-management scores after implementation of the intervention compared with their baseline scores.

H3: There will be a statistically significant relationship between psychological distress and diabetes self-management among diabetic patients before and after the intervention.

H4: Selected sociodemographic and clinical characteristics will be significantly associated with psychological distress and diabetes self-management outcomes among diabetic patients.

Operational definitions:

Nurse-led remote monitoring and patient navigation: refers to a structured, eight-week intervention delivered by a trained community health nurse through scheduled telephone calls or other agreed remote communication methods. It includes reviewing patients' reported health status, reinforcing diabetes self-management education, identifying barriers to healthcare access, facilitating appointments and referrals, and coordinating follow-up with healthcare providers.

Psychological distress: refers to the severity of depressive symptoms, anxiety symptoms, and stress experienced by diabetic patients during the preceding week, as measured using the

Patient Health Questionnaire-9 (PHQ-9). Higher scores indicate greater psychological symptom severity.

Diabetes self-management: refers to the frequency with which diabetic patients perform recommended diabetes-related self-care activities, including healthy eating, physical activity, blood glucose monitoring when indicated, medication adherence, and foot care, as measured using the Summary of Diabetes Self-Care Activities (SDSCA) questionnaire. Higher scores indicate more frequent performance of the corresponding self-care behaviors.

Subjects and Methods

Research Design

A Randomized Controlled Trial (RCT) will be conducted to evaluate the effect of smart watch monitoring on stress levels and coping strategies among nursing students during older adult clinical training.

Participants will be randomly assigned into two groups

1-Intervention group (APPLY nurse led monitoring and patient navigation)

2- Control group (Routine care group)

Randomization will be carried out using a simple randomization technique (e.g., computer-generated random numbers or sealed envelopes) to ensure equal distribution and minimize selection bias.

Sample and Sampling Techniques:

The target population comprises adult patients diagnosed with diabetes mellitus who meet the study's predefined eligibility criteria.

Sample Size Calculation:

The sample size was determined using Statistical Power Analysis (G*Power software, version 3.1.9.7) to ensure adequate statistical power for evaluating the intervention's effect on the primary outcomes (psychological distress and self-management).

Although the accessible population over a 3-month recruitment window (with the researcher available 3 days per week, totaling 39 working days, and an average daily flow of 25 cases) is estimated to be 975 patients, a finite descriptive sample size is methodologically inappropriate for this quasi-experimental (pre-test/post-test) design. Instead, the sample size calculation was based on a paired-samples t-test (or a Repeated Measures ANOVA, depending on the follow-up intervals) utilizing the following conservative standard parameters: Effect size (f or d): Set at a medium effect size of 0.50 (derived from comparable international literature on remote monitoring and patient navigation interventions). Alpha (α) error probability: Set at 0.05 (two-tailed, 95% confidence interval). Statistical Power (1 - β): Set at 0.80 (80% power to detect a true intervention effect).

Based on a statistical power analysis (using G*Power software) with a significance level (α) of 0.05, a statistical power (1-β) of 80%, and an anticipated medium-to-large effect size—accounting for potential participant dropout—a minimum total sample size of 80 diabetus patient were determined to be sufficient to detect clinically meaningful differences between groups. Eligible participants who meet the inclusion criteria will be recruited and randomly assigned in a 1:1 allocation ratio into two equal groups: the intervention group (n = 40), which will receive nurse led intervention and patient navigation in addition to routine care, and the control group (n = 40), which will receive routine care only.

Inclusion Criteria

Participants will be included in the study if they meet the following criteria:

1) Adults aged 18 years or older.
2) Patients with a confirmed diagnosis of type 1 or type 2 diabetes mellitus.
3) Patients receiving routine diabetes care at the selected study setting.
4) Patients who have access to a telephone or another suitable remote communication method.
5) Patients who are willing to participate in the study and provide written informed consent.
6) Patients who are able to understand and complete the study questionnaires in the selected validated language.

7) Patients who are expected to be available throughout the intervention and follow-up period.

Exclusion Criteria:

1) Patients experiencing an acute medical condition requiring emergency treatment or hospitalization at the time of recruitment.
2) Patients with severe cognitive impairment or communication difficulties that prevent meaningful participation in the intervention and completion of the assessment tools.
3) Patients experiencing an acute psychiatric crisis requiring immediate specialized mental health intervention.
4) Patients enrolled in another intensive remote diabetes-management program that could substantially overlap with the proposed intervention.
5) Patients who decline participation or withdraw their informed consent.

Note: A previous diagnosis of depression or anxiety should not automatically be an exclusion criterion unless justified by the study protocol. Including patients with stable mental health conditions may improve the applicability of the findings concerning psychological distress among diabetic patients.

Setting of the Study

The study will be conducted at the Diabetes and Endocrinology Outpatient Clinics of Helwan General Hospital, a major secondary-level governmental healthcare facility operating under the Ministry of Health and Population in Cairo, Egypt. Helwan General Hospital serves as a vital healthcare hub for a dense, socio-demographically diverse industrial and residential catchment area. This setting is optimal for the current study due to its high volume of patients with diabetes mellitus seeking subsidized, specialized medical care and routine follow-ups. The clinic provides an ideal environment to test a community nurse-assisted remote monitoring and patient navigation model, as it represents a vulnerable public healthcare sector that stands to benefit significantly from structured self-management support and psychological distress mitigation.

Procedure

Based on a statistical power analysis ($\alpha = 0.05$, power = 80%), a total sample size of 80 diabetic patient who meet the inclusion and exclusion criteria will be consecutively recruited from the out patient clinic. Written informed consent will be obtained from all participants after explaining the purpose and nature of the study. Following baseline assessment (pre-test), eligible participants will be randomly assigned in a 1:1 allocation ratio into two equal parallel groups using a computer-generated randomization sequence (or sealed opaque envelopes): the intervention group (n = 40), which will receive nurse led intervention and navigation program alongside routine care, and the control group (n = 40), which will receive routine care only. The execution of this quasi-experimental study will be carried out sequentially across four consecutive phases over the 3-month data collection period:

Phase I: The Preparatory Phase:

Upon obtaining formal ethical and administrative approvals, the researcher will coordinate with the medical and administrative staff at the Diabetes Outpatient Clinic of Helwan General Hospital. The researcher will establish a secure data tracking system and structure the educational materials (booklets/digital flyers) focusing on diabetes self-management behaviors, coping mechanisms for psychological distress, and navigation of hospital resources.

Phase II: Assessment phase (Pre-test):

During the three days of weekly attendance, the researcher will screen patients for eligibility. Eligible patients will be introduced to the study, and informed consent will be obtained. The researcher will then administer Part I, II, and III of the data collection tool via face-to-face interviews to gather baseline socio-demographic, clinical data (including baseline HbA1c), depressive symptoms (PHQ-9), and self-care activities (SDSCA).

Phase III: The Intervention and Remote Navigation Phase:

In this phase, the researchers will assume the dual role of a Community Nurse and a Patient Navigator for a designated period (e.g., 4 to 8 weeks per patient):

Patient Navigation: The researcher will facilitate the patients' healthcare journey within the hospital by addressing structural barriers. This includes assisting in rescheduling clinic appointments, optimizing the process of refilling subsidized diabetes medications/insulin, and bridging communication gaps between patients and medical staff.

Nurse-led Remote Monitoring: The researcher will conduct structured weekly follow-ups via telephone calls and/or a dedicated WhatsApp messaging protocol. During these remote contacts, the nurse will monitor home blood glucose logs, reinforce adherence to prescribed regimens, provide psychological support, and answer patient queries. Every successful contact and resolved barrier will be systematically documented in Part IV (Remote Monitoring and Patient Navigation Log).

Phase IV: Post-intervention Assessment (Post-test)

Following the completion of the intervention period, patients will be reassessed during their routine follow-up visit to the clinic. The researcher will re-administer the PHQ-9 and SDSCA scales (Post-test) to measure alterations in psychological distress and self-management behaviors. Additionally, recent Glycated Hemoglobin (HbA1c) levels will be recorded from the patient files to evaluate clinical outcomes.

Tools for data collection:

Data will be collected using a structured, **multi-part questionnaire** composed of four main instruments. **Part I comprises the Socio-demographic and Clinical Characteristics Questionnaire,** developed by the researcher to gather baseline data including age, gender, educational level, employment status, duration of diabetes, treatment modality, and Glycated Hemoglobin (HbA1c) levels at base line and post intervention. **Part II utilizes the Patient Health Questionnaire-9 (PHQ-9),** a gold-standard, 9-item tool to screen for the presence and severity of depressive symptoms and psychological distress over the past two weeks. Each item is scored on a 4-point Likert scale ranging from 0 (Not at all) to 3 (Nearly every day). The scoring system for the PHQ-9 yields a total score range of 0 to 27, where higher scores reflect greater severity of depression. The clinical severity thresholds are categorized as follows: scores of 0–4 indicate minimal or no depression, 5–9 indicates mild depression, 10–14 indicate

moderate depression, 15–19 indicate moderately severe depression, and 20–27 indicate severe depression. A cut-off score of (ge 10) is utilized to identify clinically significant depressive symptoms. **Part III consists of the Summary of Diabetes Self-Care Activities (SDSCA) Scale,** a widely validated instrument designed to evaluate diabetes self-management behaviors across key regimens including diet, exercise, blood glucose testing, foot care, and medication adherence. The tool contains 9 core items, and its scoring system records the frequency of performing each self-care behavior as the number of days per week, ranging from 0 to 7 days. For data analysis, an average score (ranging from 0 to 7) is calculated for each independent subscale or domain by summing the days and dividing by the number of items in that domain. Higher mean scores indicate a higher frequency of performing self-care behaviors and better overall diabetes self-management. **Part IV includes the Remote Monitoring and Patient Navigation record,** a researcher-designed tracker to document intervention fidelity. The scoring system for this log is purely quantitative and descriptive, recording the total frequency of successful monthly remote contacts (calls/messages) achieved per patient and calculating the percentage of distinct structural healthcare barriers (e.g., appointment rescheduling, medication refills) successfully navigated and resolved by the community nurse. Arabic-validated versions of the standard scales will be administered to ensure linguistic appropriateness and clarity for all participants.

Validity and Reliability: To ensure the scientific integrity and psychometric robustness of the research instruments, both validity and reliability assessments were verified: Content and Face Validity: the final compiled questionnaire (comprising socio-demographic data, clinical sheets, and the intervention log) was submitted to a panel of five academic experts in the fields of Community Health Nursing, Psychiatric Nursing, and Endocrinology. The experts evaluated the items for clarity, relevance, comprehensiveness, and clinical appropriateness. Minor modifications and linguistic refinements were implemented based on their consensus to ensure face and content validity. Construct Validity of Standard Scales: For the evaluation of primary

outcomes, well-established, standardized scales with pre-proven international validity were selected. The Arabic-validated version of the PHQ-9 was utilized, which has been rigorously tested in Arab and Egyptian clinical populations, demonstrating strong construct validity and high diagnostic accuracy for depressive symptoms in medical outpatients. Similarly, the Arabic version of the SDSCA scale was adopted, which has been previously validated in Middle Eastern contexts and demonstrated excellent structural validity for assessing diabetes self-care regimens. The internal consistency of the standardized scales will be statistically evaluated using Cronbach's alpha coefficient computed from the pilot study data. Based on extensive literature, the Arabic PHQ-9 is highly reliable, historically yielding a Cronbach's alpha value of ≥ 0.85. The Arabic SDSCA subscales also exhibit acceptable to strong internal consistency, with alpha coefficients typically ranging between 0.70 and 0.88 across different self-care domains (diet, exercise, glucose monitoring, and foot care). Any alpha value of 0.70 or higher will be considered acceptable for this study.

Ethical considerations: Formal administrative approvals will be obtained from the administration of Helwan General Hospital before data collection. The study protocol will be approved by the institutional research ethics committee. Prior to recruitment, the researcher will provide a clear explanation of the study's nature, purpose, and longitudinal tracking to each eligible patient. Informed written or verbal consent will be secured from all participants. Patients will be explicitly informed that participation is entirely voluntary and that they retain the right to withdraw from the study at any point without any consequence to their routine medical care. To ensure strict confidentiality and anonymity, no personal identifiers will be used on the questionnaires, and all collected data will be securely stored and utilized solely for research purposes.

Statistical Analysis

Data will be entered, cleaned, and analyzed using the Statistical Package for the Social Sciences (SPSS, version 26.0). Descriptive statistics will be calculated, including frequencies and percentages for categorical variables (e.g., gender, educational level, treatment type), as well as means and standard deviations (Mean / SD) for continuous variables (e.g., age, duration of diabetes, total depression scores, and self-care days).

The normality of the data distribution will be verified using the Shapiro-Wilk test. To evaluate the effectiveness of the community nurse-assisted remote monitoring and patient navigation program, inferential statistical tests will be applied: The Paired-samples t-test (or the non-parametric Wilcoxon signed-rank test if data deviate from normality) will be utilized to compare the mean scores of psychological distress (PHQ-9), diabetes self-management behaviors (SDSCA domains), and glycemic control levels (HbA1c) between the pre-intervention (baseline) and post-intervention phases. Chi-square test (\(\chi ^{2}\)) or Fisher's exact test will be used to compare categorical variables and evaluate the distribution shifts in depression severity categories before and after the program. The internal consistency of the standardized scales will be computed using Cronbach's alpha coefficient. For all statistical tests, a two-tailed p-value of (<0.05) will be considered statistically significant, and a p-value of (<0.01) will be considered highly significant.

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