

STUDY PROTOCOL

Effectiveness of a Telehealth Educational Intervention on Glycemic Control, Medication Adherence, and Quality of Life among Adults with Type 2 Diabetes in Oman: Study Protocol for a Two-Arm Parallel Randomized Controlled Trial

Samia Salim Al-Harrasi¹; Nahla Al Ali, PhD¹; Zakariya Yaqoob Al-Naamani, PhD¹; Huda Al-Noumani; Nasser Al Salmi, PhD¹

¹College of Nursing, Sultan Qaboos University, Muscat, Oman

Corresponding author: Dr. Nahla Al Ali, College of Nursing, Sultan Qaboos University, Muscat, Oman; n.alaali@squ.edu.om

Protocol version: 1.1 (25 July 2026)

Document date: 25 July 2026

Trial registration: ClinicalTrials.gov; NCT number: [TO BE ADDED AFTER REGISTRATION]

Ethics approval: Research and Ethics Committee, College of Nursing, Sultan Qaboos University (Ref. No. CON/IG/2025/15; 23 September 2025).

Additional ethics and site authorization: Sultan Qaboos University Medical Research Ethics Committee and Sultan Qaboos University Hospital authorization submitted/pending.

Funding: Sultan Qaboos University Internal Grant [Research Code: IG/--/CON/C&M/26/389; 5 February 2026].

Trial status: Recruitment has not commenced; additional ethics/site authorization, instrument permissions, telehealth platform approval, and prospective trial registration are pending.

Abstract

Introduction: Living with type 2 diabetes requires continuous self-management, while routine clinic visits provide only periodic opportunities for education and reinforcement. This study will assess a culturally tailored, nurse-led telehealth education program designed to support Omani adults whose glycemic control remains above target.

Methods and analysis: We will conduct a prospective, single-site, two-arm, parallel-group superiority randomized controlled trial involving 160 Omani adults with type 2 diabetes mellitus attending the diabetes outpatient clinics at Sultan Qaboos University Hospital. Eligible participants will be 18 years or older, taking at least one glucose-lowering medication, have glycated hemoglobin (HbA1c) $\geq 7.5\%$, and have access to an internet-enabled device. After written informed consent and baseline assessment, participants will be randomized 1:1 to usual care plus a weekly 20–30-minute synchronous telehealth education session for 24 weeks or to usual care alone. Randomization will use concealed variable blocks and will be stratified by sex and baseline HbA1c ($<9.0\%$ vs $\geq 9.0\%$). The primary outcome is the between-group difference in change in HbA1c from baseline to 6 months. The two principal secondary outcomes at month 6 are change in the Positive Attitudes towards Healthcare and Medication domain of the Medication Adherence Universal Questionnaire-Arabic Oman version (MAUQ-ar-OM) and change in the Diabetes Quality of Life Brief Clinical Inventory (DQOL-15) total score. Supportive outcomes include the remaining MAUQ-ar-OM domain scores and overall score, HbA1c change at 3 months, achievement of HbA1c $<7.0\%$, an HbA1c reduction of at least 0.5 percentage points, telehealth usability measured with the Arabic Telehealth Usability Questionnaire (TUQ-Arabic), intervention exposure, retention, and reported harms. The primary analysis will follow the intention-to-treat principle using linear mixed-effects models adjusted for baseline outcome and stratification variables. The first 30 randomized participants will form an internal feasibility pilot.

Ethics and dissemination: The telehealth program is educational and will not replace routine diabetes care or permit the research team to alter treatment. Ethical approval has been obtained from the Research and Ethics Committee, College of Nursing, Sultan Qaboos University (CON/IG/2025/15; 23 September 2025). Any additional required approvals from the SQU Medical Research Ethics Committee and Sultan Qaboos University Hospital will be obtained before recruitment. Written informed consent will be obtained from all participants. Study data will be coded and stored securely, and clinically concerning findings will be referred to the treating team. The trial will be registered prospectively before enrollment. Findings will be shared through peer-reviewed publication, conference presentations, stakeholder reports, and a lay summary for participants who request one.

Trial registration: ClinicalTrials.gov; NCT number: [TO BE ADDED AFTER REGISTRATION].

Keywords: type 2 diabetes; telehealth; patient education; medication adherence; glycated hemoglobin; quality of life; randomized controlled trial; Oman

Strengths and limitations of this study

- The randomized design, centralized allocation concealment, objective HbA1c assessment, and blinded outcome assessment and analysis where feasible will reduce selection and assessment bias.
- The intervention is a culturally tailored, nurse-led, synchronous program delivered weekly for 24 weeks, with prespecified provider training, fidelity monitoring, and an internal feasibility pilot.
- The trial evaluates both clinical and patient-reported outcomes and includes a prespecified intention-to-treat analysis with sensitivity analyses for missing data and intervention adherence.
- Participants and educators cannot be blinded, and medication adherence and quality of life are self-reported, which may introduce performance and reporting bias.
- The single-site design, restriction to Omani nationals, and requirement for digital access may limit generalizability and may under-represent people with digital exclusion.

Introduction

Type 2 diabetes mellitus (T2DM) is a major and growing cause of illness, disability, premature death, and healthcare expenditure. The burden is especially important in the Middle East and North Africa, where demographic change, obesity, physical inactivity, and urbanization continue to drive prevalence [1]. In Oman, diabetes remains a persistent public-health challenge and places sustained demands on outpatient follow-up and complication-prevention services [2].

Most diabetes self-management takes place outside the clinic. Day-to-day care may involve taking medicines as prescribed, making healthy food choices, remaining physically active, monitoring blood glucose when indicated, attending follow-up visits, and recognizing complications early. These tasks can be difficult to sustain. Treatment complexity, forgetfulness, limited health literacy, adverse effects, competing priorities, and gaps in patient-centered support may all contribute to poor medication adherence and suboptimal glycemic control. Studies from Oman have similarly highlighted adherence barriers, the importance of patient-centered care, and the effect of diabetes on quality of life [3–5].

Telehealth offers a way to extend structured education and behavioral support beyond periodic face-to-face appointments, while potentially reducing travel and allowing more frequent contact. Systematic reviews and meta-analyses suggest that telemedicine, mobile applications, telephone support, and other interactive digital interventions can improve glycemic control and medication adherence in some adults with T2DM, although the size of the benefit varies with intervention intensity, interactivity, engagement, and integration with routine care [6–10]. Regional evidence from Saudi Arabia also suggests potential benefits for glycemic control and treatment adherence [11]. Although remote health services expanded in Oman during the COVID-19 pandemic, randomized evidence on a culturally tailored, nurse-led telehealth education program remains limited [12,24].

The protocol follows the SPIRIT 2025 statement and its explanation and elaboration. The intervention is reported using the Template for Intervention Description and Replication (TIDieR) framework [17–19], and the final trial report will follow CONSORT 2025 [20].

Objectives and hypotheses

The primary objective is to determine whether adding a 6-month telehealth educational intervention to usual care leads to a greater reduction in HbA1c than usual care alone among Omani adults with T2DM and baseline HbA1c $\geq 7.5\%$.

Secondary objectives are to: (1) compare between-group changes from baseline to months 3 and 6 in positive attitudes towards healthcare and medication, measured using the corresponding MAUQ-ar-OM domain; (2) compare changes in diabetes-specific quality of life at months 3 and 6; (3)

explore changes in the MAUQ-ar-OM lack-of-discipline, aversion-towards-medication, and active-coping-with-health-problems domain scores and the overall score at months 3 and 6; (4) compare the proportions of participants achieving HbA1c <7.0% and a reduction in HbA1c of at least 0.5 percentage points at month 6; (5) assess perceived telehealth usability and satisfaction using the TUQ-Arabic at months 3 and 6 among intervention participants; (6) describe intervention attendance, exposure, fidelity, technical failures, clinical referrals, retention, protocol deviations, and harms; and (7) explore whether treatment effects differ by age, sex, diabetes duration, or baseline HbA1c. If the data and assumptions are adequate, an exploratory mediation analysis will assess whether early changes in positive attitudes towards healthcare and medication may partly explain the intervention effect on HbA1c.

We hypothesize that participants allocated to telehealth education will show a greater mean reduction in HbA1c from baseline to 6 months than those receiving usual care alone. The two principal secondary hypotheses are that the intervention group will show greater improvement by month 6 in (1) the Positive Attitudes towards Healthcare and Medication domain of the MAUQ-ar-OM and (2) the DQOL-15 total score. Month-3 contrasts, the remaining MAUQ-ar-OM domains and overall score, binary HbA1c outcomes, TUQ-Arabic outcomes, subgroup analyses, and mediation analyses will be treated as supportive or exploratory, as prespecified.

Methods and analysis

Trial design

This prospective, single-site, two-arm, parallel-group superiority randomized controlled trial will use 1:1 allocation. Participants will be assessed at baseline, 3 months, and 6 months. Those assigned to the intervention group will receive usual diabetes care plus weekly telehealth education, while the control group will receive usual care alone. The primary endpoint is the between-group difference in change in HbA1c from baseline to 6 months. Figure 1 summarizes the planned participant flow.

Figure 1. Planned participant flow through screening, randomization, intervention, follow-up, and analysis.

Internal feasibility pilot

The first 30 randomized participants will form an internal feasibility pilot. The team will review recruitment, consent, attendance, platform performance, data completeness, privacy incidents, and retention without conducting formal comparative efficacy testing. Minor operational refinements may be made and documented if they do not change the intervention objectives, eligibility criteria, outcomes, or randomization procedures. Any substantive change will require ethics approval and a decision on whether pilot data remain comparable with the main trial.

Study setting

The trial will take place in the diabetes outpatient clinics of Sultan Qaboos University Hospital (SQUH), Muscat, Oman. Screening, consent, and in-person assessments will be conducted in a private clinical or research space. HbA1c will be measured through the SQUH laboratory using routine standardized methods traceable to accepted glycohemoglobin reference procedures. Telehealth sessions will be delivered from a private institutional room using a platform that has received the required SQU/SQUH approval before use. Routine prescribing and all clinical treatment decisions will remain the responsibility of the participant's treating team.

Eligibility criteria

Participants must meet all of the following inclusion criteria:

- Omani national aged 18 years or older.
- Confirmed T2DM documented in the medical record.
- Prescribed at least one glucose-lowering medication and receiving treatment for at least 3 months before enrolment.
- Most recent clinically valid HbA1c, or screening HbA1c when appropriate, $\geq 7.5\%$.
- Access to an internet-enabled smartphone, tablet, or computer and ability to participate in video or audio-supported telehealth sessions.
- Able to understand Arabic or English sufficiently to provide informed consent and participate in study procedures and able to complete the validated Arabic Oman version of the medication-adherence questionnaire.
- Willingness to be randomized and availability for 6 months of follow-up.

Exclusion criteria are:

- Type 1 diabetes, gestational diabetes, or another diabetes type for which the intervention and outcome plan is not appropriate.
- Current pregnancy or planned pregnancy during follow-up.
- Severe cognitive impairment, active psychosis, or another condition preventing informed consent or meaningful participation.
- Acute medical instability or hospital admission at recruitment.
- Participation in another interventional study that could materially affect trial outcomes.
- Inability to use telehealth even with reasonable assistance or absence of a private and safe setting for sessions.
- Another clinical or ethical reason identified by the treating clinician or principal investigator that makes participation inappropriate.

People who have an acute illness, an immediate clinical concern, or insufficient time to consider participation may be temporarily deferred and approached again at a later routine visit when clinically appropriate.

Identification, recruitment, and informed consent

Authorized clinical or research personnel will identify potential participants from clinic schedules or medical records. Before any research approach, the treating team or designated clinic staff will confirm that contact is appropriate and ask whether the individual is willing to hear about the study. Those who are interested will receive an ethics-approved participant information sheet in Arabic or English and will have enough time to ask questions, discuss participation with family if they wish, and make a voluntary decision. Written informed consent will be obtained before any research-specific data are collected. Declining participation will not affect clinical care, and individuals will not be asked to provide a reason.

Consent will be obtained by the principal investigator or a trained team member with formal delegated authority. Understanding will be checked using open questions. Participants will be reminded that they may skip questionnaire items, stop intervention sessions, or withdraw from follow-up without affecting their usual care. Re-consent will be sought if an approved amendment materially changes study procedures, risks, benefits, or data use.

Randomization and allocation concealment

An independent statistician or randomization officer who is not involved in recruitment, consent, intervention delivery, or outcome assessment will generate the allocation sequence using computer software. Participants will be allocated 1:1 using randomly varied block sizes of 4 and 6, with stratification by sex and baseline HbA1c ($<9.0\%$ vs $\geq 9.0\%$). Recruiters will not have access to block sizes or future assignments.

Once consent and the baseline assessment are complete, the recruiter will send the participant's study identification number and stratification variables to the independent officer through a secure institutional channel. Only the current assignment will be released. The full sequence will be kept in a restricted randomization log so that allocation remains concealed until the participant has been irreversibly enrolled.

Blinding

Participants and telehealth educators cannot be blinded because the intervention involves direct, interactive education. Laboratory personnel will process HbA1c samples without access to the allocation list. Where staffing permits, follow-up questionnaires will be administered by outcome assessors who are blinded to group assignment, and participants will be asked not to reveal their group. The analysis dataset will use coded group labels, and the statistician will remain unaware of

what those labels represent until the primary model and interpretation framework have been finalized. Any accidental unblinding will be documented.

Interventions

Intervention group: usual care plus telehealth education

Participants assigned to the intervention group will continue their routine diabetes care and will also receive one individual synchronous telehealth education session each week for 24 weeks. Sessions will usually last 20–30 minutes and will be delivered in Arabic or English by a trained diabetes nurse educator or research nurse through an institutionally approved secure platform. Video will be encouraged when acceptable and technically feasible; secure audio may be used when connectivity is insufficient. Sessions will not be recorded.

During the first 12 weeks, participants will work through a standardized curriculum. Weeks 13–24 will focus on reinforcement, review of personal goals, discussion of barriers, and revisiting modules when needed, while keeping the intervention's educational objectives unchanged. Table 1 summarizes the curriculum.

Table 1. Telehealth educational intervention curriculum

Module	Core content
1	Orientation, personal goals, understanding T2DM, and the role of HbA1c
2	Medicines: purpose, dosing routines, safe use, and questions for the clinical team
3	Remembering medicines: habit formation, cues, pill organizers, and planning
4	Healthy eating: balanced meals, portions, local foods, and label reading
5	Physical activity and safe reduction of sedentary time
6	Blood glucose monitoring and interpretation according to the clinical care plan
7	Recognition and response to hypoglycemia and hyperglycemia
8	Prevention of complications: foot care, eye care, kidney health, and cardiovascular risk
9	Problem-solving during illness, travel, fasting, and schedule changes; clinical decisions remain with the treating team
10	Stress, sleep, diabetes distress, and social support
11	Communication with healthcare professionals and preparation for clinic visits
12	Review, maintenance planning, relapse prevention, and participant priorities

Providers will be trained in the curriculum, role boundaries, privacy, telehealth etiquette, cultural and health-literacy adaptation, documentation, safety escalation, and management of technical difficulties. Competency will be checked through a simulated session and completion of a training checklist. The core sequence, learning objectives, and safety messages will remain standardized, while examples, pace, repetition, language level, and goal-setting may be adapted to the

participant's treatment regimen, literacy, culture, and prior knowledge. Research staff will not start, stop, or adjust medication; clinical questions will be referred to the treating team.

Each session will be documented using a checklist that records the topics covered, session duration and mode, technical issues, participant questions, goals, and referrals. The intervention coordinator will review these logs monthly. When feasible and acceptable to the participant, at least 10% of sessions will undergo contemporaneous fidelity observation; sessions will not be recorded. For the per-protocol sensitivity analysis, intervention adherence will be defined as completion of at least 18 of the 24 sessions (75%).

Missed sessions may be rescheduled within 7 days when feasible. The team will make up to three reasonable contact attempts using the participant's approved method. If video fails, the session may continue by secure audio provided privacy can be maintained. Participants who stop attending telehealth sessions will remain in outcome follow-up unless they withdraw consent.

Comparator: usual care

Participants in the control group will continue usual diabetes care according to SQUH clinical practice, including routine clinic review, medication management, laboratory testing, and education normally provided by the clinical service. No established service will be withheld. To minimize contamination, the study curriculum and materials will not be provided to control participants before the 6-month assessment. Participants in either group may receive any clinically indicated treatment changes, referrals, hospitalization, or emergency care; major co-interventions will be recorded.

Outcomes

The primary outcome is the between-group difference in change in HbA1c from baseline to 6 months. HbA1c provides an objective measure of average glycemic exposure and is routinely used to evaluate longer-term glycemic control [16]. Table 2 summarizes the secondary, process, feasibility, and safety outcomes.

Table 2. Outcomes, measurement, and assessment time points

Classification	Outcome	Definition/measurement	Time point(s)
Primary	HbA1c	HbA1c measured as continuous percentage points. The prespecified treatment effect is the adjusted between-group difference in change from baseline to month 6.	Baseline, month 3, month 6

Classification	Outcome	Definition/measurement	Time point(s)
Key secondary	Positive attitudes towards healthcare and medication	The four-item Positive Attitudes towards Healthcare and Medication domain of the validated Medication Adherence Universal Questionnaire–Arabic Oman version (MAUQ-ar-OM) will be scored according to the official instructions. Items use a seven-point response scale, producing a domain score from 4 to 28; higher scores indicate more favorable attitudes towards healthcare and medication. The principal comparison is change from baseline to month 6; the month-3 comparison is supportive [14,15].	Baseline, month 3, month 6
Key secondary	Diabetes-specific quality of life	Diabetes Quality of Life Brief Clinical Inventory (15 items; DQOL-15), scored according to the official instrument guidance. The principal comparison is change from baseline to month 6; the month-3 comparison is supportive [13].	Baseline, month 3, month 6
Supportive secondary/exp loratory	Other medication-adherence beliefs and behaviors	The MAUQ-ar-OM lack-of-discipline, aversion-towards-medication, and active-coping-with-health-problems domains (four items each; score range 4–28 per domain) and the 16-item overall score (range 16–112) will be calculated according to the official instructions. After required reverse coding, higher scores indicate more favorable adherence-related beliefs and behaviors. Scores will be analyzed continuously; domain-level interpretation will be emphasized, the overall score will be interpreted cautiously, and no adherence-category cutoffs will be applied [14,15].	Baseline, month 3, month 6
Supportive secondary	Glycemic target attainment	Proportion of participants achieving HbA1c <7.0% at month 6. This fixed threshold is a standardized research outcome and will not replace individualized glycemic targets determined by the treating clinical team.	Month 6
Supportive secondary	Clinically meaningful HbA1c reduction	Proportion of participants achieving a reduction in HbA1c of at least 0.5 percentage points from baseline to month 6.	Month 6
Secondary	Telehealth usability and satisfaction	The Arabic Telehealth Usability Questionnaire (TUQ-Arabic) contains 21 items across six domains: usefulness, ease of use and learnability, interface quality, interaction quality, reliability, and satisfaction and future use. Items are rated on a seven-point scale, producing a total score from 21 to 147. Higher total and domain scores indicate more favorable perceptions of telehealth usability. Total and domain scores will be calculated according to the official instrument instructions [26,27].	Month 3 and month 6; intervention group only
Process	Intervention exposure, utilization, and fidelity	Number and proportion of scheduled sessions completed; session duration and delivery mode; missed or rescheduled sessions; technical failures; clinical referrals; intervention discontinuation; and fidelity indicators.	Throughout intervention
Safety	Harms and incidents	Participant-reported distress, adverse events occurring during or in close temporal association with study procedures, privacy incidents, and urgent clinical referrals.	Throughout study
Feasibility	Recruitment and retention	Numbers screened, eligible, consented, randomized, retained, and completing each assessment, together with voluntarily provided reasons for non-participation, discontinuation, withdrawal, or loss to follow-up.	Throughout study

241 Where available, the study will record clinical conditions that may affect interpretation of HbA1c,
242 including anemia, hemoglobinopathy, recent blood loss or transfusion, advanced kidney disease,

243 and dialysis. Results that are clinically discordant or concerning will be referred to the treating
244 team. The MAUQ-ar-OM will be administered in Arabic without modification and scored
245 according to the official instructions; written permission or confirmation of authorized use will be
246 obtained before recruitment. The exact authorized language version and scoring instructions for the
247 DQOL-15 will be confirmed before use. The TUQ-Arabic will also be administered and scored
248 according to the official instrument instructions and any applicable permission requirements.
249 Questionnaire items will not be reproduced in the public protocol or supplementary materials
250 without authorization.

Participant timeline

Each participant will be followed for approximately 24 weeks. The schedule of enrollment, intervention delivery, and assessments is shown in Table 3 using the SPIRIT format.

Table 3. Schedule of enrolment, interventions, and assessments

Study activity	Pre-screen	Baseline/week 0	Weeks 1–12	Month 3 / week 12	Weeks 13–24	Month 6 / week 24	Close-out
Eligibility screening	X	X					
Participant information and consent		X					
Baseline demographic and clinical data		X					
Randomization		X					
Usual diabetes care		X	Ongoing	Ongoing	Ongoing	Ongoing	
Telehealth education (intervention only)			Weekly		Weekly		
HbA1c		X		X		X	
MAUQ-ar-OM		X		X		X	
DQOL-15		X		X		X	
TUQ-Arabic (intervention only)				X		X	
Concomitant care and medication changes		X	Continuous	X	Continuous	X	
Adverse events, privacy incidents, and technical incidents			Continuous	X	Continuous	X	
Retention and contact verification		X	As needed	X	As needed	X	
End-of-study or withdrawal form						X	X

Sample size

The sample size is based on the primary endpoint. A between-group difference of 0.5 percentage points in HbA1c, assuming a standard deviation of 1.0 percentage point, was selected as a clinically relevant target and is consistent with effects considered plausible in previous telehealth studies and the original grant assumptions [6–10]. With a two-sided alpha of 0.05 and 80% power, 64 participants are required per group. Allowing for 20% attrition increases the target to 80 participants per group, giving a total sample of 160. The calculation was performed in G*Power using a two-group comparison. Because HbA1c at 6 months is the single primary endpoint, no adjustment is made for multiple primary outcomes.

Data collection and retention

At baseline, the study will collect age, sex, education, employment, marital status, governorate of residence, diabetes duration, glucose-lowering treatment, major comorbidities, relevant clinical history, height and weight or recent clinically recorded values, HbA1c, MAUQ-ar-OM, DQOL-15, digital access, prior telehealth experience, language preference, and accessibility needs. Only variables needed for the scientific objectives, safety, and equity analyses will be collected.

At months 3 and 6, participants will complete the outcome questionnaires and undergo HbA1c testing. The study will also record medication changes, major healthcare use, technical issues, protocol deviations, and adverse events. Participants in the intervention group will complete the TUQ-Arabic. Whenever possible, assessments will be coordinated with routine visits, and questionnaires may be completed in person or through an approved secure method that is consistent with the authorized administration mode.

To support retention, the team will confirm participants' preferred contact methods and suitable times, send neutral appointment reminders, offer flexible assessment windows, and coordinate assessments with routine visits where possible. Up to three contact attempts may be made after a missed assessment. Outcome follow-up will continue even if a participant stops the intervention, unless consent is withdrawn. Reasons for loss to follow-up will be recorded only when participants provide them voluntarily.

Data management and confidentiality

Each participant will be assigned a unique study identification number. Names, civil identification numbers, and medical record numbers will not appear in the analysis database. A separate encrypted linkage file connecting study identifiers with contact and medical record information will be stored separately and will be accessible only to the principal investigator and an authorized data manager. Electronic study data will be kept in an institutionally approved, password-protected database on a secure network with role-based access, encryption, and backup. Identifiable study

data will not be stored on personal devices, unencrypted removable media, personal email, or consumer messaging applications.

Signed consent forms and paper source documents will be stored in locked cabinets in a restricted-access institutional office, with consent forms kept separately from coded research forms. Data quality procedures will include range and logic checks, second-person verification of consent status, verification of randomization and primary-outcome assessment, sampling of key variables, documented resolution of data queries, programmed scoring checks, and database lock once all prespecified checks are complete.

Essential records and de-identified research data will be retained for at least 5 years after study completion or publication, or longer if required by institutional, funder, or ethics policy. At the end of the authorized retention period, identifiable paper records will be confidentially shredded and identifiable electronic files will be securely deleted. After publication, a de-identified dataset and analysis code may be shared on reasonable request, subject to approval by the principal investigator, institution, and ethics authorities and to an appropriate data-use agreement.

Telehealth privacy and security

- Only an SQU/SQUH-approved platform and institutional accounts will be used for research communication.
- Participant identity will be confirmed at the start of each session using two non-sensitive identifiers.
- The educator will confirm that both parties are in a private and safe location and are comfortable proceeding.
- Sessions will not be audio- or video-recorded; appointment reminders will use neutral wording.
- If privacy is interrupted, the session will pause or be rescheduled.
- Clinical emergencies will not be managed solely through the research platform; participants will be directed to emergency or routine clinical services as appropriate.
- Suspected privacy or security incidents will be contained, documented, assessed, and reported through institutional information-security and ethics procedures.

Statistical analysis

A detailed statistical analysis plan will be finalized and dated before group codes are revealed and before the primary analysis begins. Analyses will use SPSS version 29 or a later validated institutional version, with other validated software used if needed. All tests will be two-sided with $\alpha=0.05$, and effect estimates will be presented with 95% confidence intervals. Interpretation will consider the size and precision of effects rather than relying on p values alone.

Analysis populations

- Intention-to-treat population: all randomized participants analyzed according to allocated group, regardless of intervention attendance or treatment changes. This is the primary analysis population.
- Per-protocol population: participants with a valid primary outcome and no major eligibility or randomization violation; intervention participants must have attended at least 75% of sessions. This analysis is supportive.
- Safety population: all participants who complete any study procedure after randomization, summarized according to the intervention actually received when relevant.

Baseline characteristics, recruitment, retention, attendance, fidelity, protocol deviations, adverse events, and missing data will be summarized descriptively. Continuous variables will be reported as mean and standard deviation or median and interquartile range, as appropriate, and categorical variables as frequencies and percentages. Decisions about covariate adjustment will not be based on significance testing of baseline differences.

Primary analysis

The primary endpoint will be analyzed with a linear mixed-effects model using post-baseline HbA1c measurements at 3 and 6 months. Fixed effects will include group, time, the group-by-time interaction, baseline HbA1c, sex, and baseline HbA1c stratum, with a participant-level random intercept to account for repeated measurements within individuals. The prespecified treatment effect is the adjusted between-group difference in mean change from baseline to 6 months, obtained from the group-by-time contrast. Model estimates will be reported with 95% confidence intervals and p values.

Secondary and exploratory analyses

The MAUQ-ar-OM Positive Attitudes towards Healthcare and Medication domain score and the DQOL-15 total score are the two principal secondary outcomes. They will be analyzed using linear mixed-effects models aligned with the primary analysis. Each model will include treatment group, time, the group-by-time interaction, the relevant baseline outcome score, and the prespecified stratification variables, together with a participant-level random intercept. The main contrasts will be the adjusted between-group differences in change from baseline to month 6; month-3 contrasts will be supportive. Effect estimates will be reported with 95% confidence intervals.

The MAUQ-ar-OM lack-of-discipline, aversion-towards-medication, and active-coping-with-health-problems domain scores, together with the overall MAUQ-ar-OM score, will be examined using comparable models as supportive or exploratory outcomes. Scores will be analyzed as continuous variables because validated cutoffs for classifying low, moderate, or high adherence

have not been established. Interpretation will emphasize domain-level findings, while the overall score will be treated cautiously as a descriptive summary of medication-adherence beliefs and behaviors.

At month 6, HbA1c target attainment (HbA1c <7.0%) will be analyzed using logistic regression adjusted for baseline HbA1c and the prespecified stratification variables. A comparable model will assess the proportion of participants whose HbA1c falls by at least 0.5 percentage points from baseline to month 6. Treatment effects will be reported as adjusted odds ratios with 95% confidence intervals. These binary outcomes are supportive secondary outcomes; continuous change in HbA1c remains the primary efficacy outcome.

TUQ-Arabic total and domain scores will be summarized at months 3 and 6 using means and standard deviations or medians and interquartile ranges, as appropriate. Change in perceived telehealth usability between months 3 and 6 will be assessed with a linear mixed-effects model that includes time as a fixed effect and participant as a random intercept. The estimated mean change and its 95% confidence interval will be reported. Because the TUQ-Arabic is administered only to the intervention group, these analyses describe within-group changes in usability and satisfaction and are not randomized between-group comparisons.

Intervention attendance, session duration and mode, missed or rescheduled sessions, technical failures, clinical referrals, intervention discontinuation, and fidelity indicators will be summarized descriptively. Open-ended feedback about participants' telehealth experiences will be analyzed using concise content analysis.

The prespecified principal secondary-outcome family consists of two month-6 outcomes: the MAUQ-ar-OM Positive Attitudes towards Healthcare and Medication domain score and the DQOL-15 total score. Holm-adjusted p values will be calculated across these two outcomes to control the family-wise type I error rate. Results will include unadjusted and Holm-adjusted p values, adjusted between-group differences, and 95% confidence intervals. Month-3 analyses will be supportive. The remaining MAUQ-ar-OM domains, the overall MAUQ-ar-OM score, TUQ-Arabic analyses, and binary HbA1c outcomes will not be included in this multiplicity adjustment and will be interpreted as supportive or exploratory.

Exploratory subgroup analyses will examine treatment-by-subgroup interactions for age, sex, diabetes duration, and baseline HbA1c. These analyses are intended to generate hypotheses rather

than confirm subgroup effects. Interpretation will focus on the estimated interaction effects and their 95% confidence intervals rather than on separate significance tests within subgroups.

An exploratory mediation analysis will examine whether change from baseline to month 3 in the MAUQ-ar-OM Positive Attitudes towards Healthcare and Medication domain may partly mediate the effect of treatment allocation on HbA1c at month 6. The analysis will adjust for baseline domain score, baseline HbA1c, and the prespecified stratification variables. It will be undertaken only if temporal ordering, measurement quality, sample size, missing-data patterns, and model assumptions are adequate. Where feasible, direct and indirect effects will be reported with bootstrap 95% confidence intervals.

Missing data and sensitivity analyses

The amount, pattern, and reasons for missing data will be described. Mixed-effects models will use available repeated measurements under a missing-at-random assumption. If more than 5% of participants are missing the 6-month primary outcome, or if missingness differs materially between groups, multiple imputation by chained equations will be used as a sensitivity analysis. The imputation model will include allocation, baseline and follow-up outcomes, stratification variables, and predictors of missingness. At least 20 imputations will be used, with more added if the fraction of missing information is high. Complete-case and per-protocol results will be compared with the primary analysis. Last observation carried forward will not be used.

Model assumptions and influential observations will be examined. If assumptions are seriously violated, the analysis may use transformation, robust standard errors, an alternative covariance structure, or an appropriate generalized model. Any departure from the prespecified primary method will be documented and, where possible, justified before unblinding.

No interim efficacy analysis or early stopping for benefit is planned. The internal pilot will focus on feasibility and safety and will not include formal comparative efficacy testing.

Harms, safety monitoring, and trial oversight

The trial is considered minimal risk because the intervention is educational, non-pharmacological, and does not authorize treatment changes. Potential burdens include the time required to participate, emotional discomfort, technical difficulties, privacy concerns, and the possibility that educational information could be misunderstood as prescriptive advice. These risks will be

addressed through flexible scheduling, respectful communication, secure systems, clear role boundaries, practical technical support, and established clinical referral pathways.

An adverse event is any unfavorable medical, psychological, privacy, or technical occurrence during participation, whether or not it is related to the research. Serious adverse events include death, life-threatening events, hospitalization or prolonged hospitalization, persistent disability, or another medically important event. Unexpected problems and privacy incidents will be documented and escalated in accordance with institutional and ethics requirements. Immediate clinical concerns will be referred to the treating team or emergency services. Serious adverse events and unexpected problems will be reported to the principal investigator within 24 hours of awareness and to the ethics committee and institutional authorities within the required timelines.

A separate data monitoring committee is not planned because this is a minimal-risk, single-site, short-duration study with no interim efficacy testing. Trial oversight will be provided by the principal investigator, co-principal investigator, clinical site collaborator, and a trial management group that will meet at least monthly. Quality will be supported by a delegation log, staff training records, a trial master file, internal quality checks, corrective and preventive actions, and access for authorized ethics or institutional monitors.

Participant withdrawal and protocol amendments

Participants may withdraw consent at any time without giving a reason and without affecting their clinical care. They may also stop the telehealth sessions while continuing outcome follow-up. The investigator may discontinue the intervention if there are safety concerns, privacy cannot be maintained, abusive behavior persists, or continued participation is clinically inappropriate, while seeking permission to retain outcome follow-up. Data collected before withdrawal will normally be retained to preserve research integrity unless deletion is requested before anonymization and is permitted by ethics and institutional requirements.

Protocol deviations will be documented, assessed for their impact, corrected where possible, and reviewed to prevent recurrence. Substantive amendments will be submitted for ethics approval before implementation. Urgent changes needed to remove an immediate hazard may be implemented before approval but will be reported promptly with justification. The protocol, participant documents, registry record, and manuscript will be maintained under version control.

Patient and public involvement

Patients were not formally involved in developing the original grant proposal. During the internal pilot, participants in the intervention group will be invited to comment on the clarity and burden of the program, scheduling, technical usability, cultural relevance, and privacy. Their feedback may inform minor operational refinements. Any change that could affect risk or scientific validity will

require ethics approval. The final report will describe how participant feedback influenced implementation.

Ethics and dissemination

The trial will be conducted in accordance with the 2024 World Medical Association Declaration of Helsinki, the SQU General Research Ethics Procedure, applicable institutional policies, and proportionate Good Clinical Practice principles [21–23]. Ethical approval has been obtained from the Research and Ethics Committee, College of Nursing, Sultan Qaboos University (Ref. No. CON/IG/2025/15; 23 September 2025). Any additional approval required from the SQU Medical Research Ethics Committee and authorization from SQUH will be obtained before recruitment or collection of research-specific data. The trial will be prospectively registered in a publicly accessible registry before the first participant is enrolled, in line with international registration expectations [25].

Participation will be voluntary and based on adequate information and understanding. Clinical dependency, academic authority, or financial inducement will not be used to influence the decision to participate. Participants will not be paid, and they will not be charged for research-specific procedures. The control group will continue to receive usual care, and no participant will be denied established treatment. Any clinically concerning finding will be referred to the treating team according to urgency.

Results will be reported regardless of their direction or statistical significance. Dissemination will include peer-reviewed publications, conference presentations, academic and clinical seminars, trial registry updates, and reports to SQU/SQUH and relevant health-system stakeholders. Participants may request a brief lay summary after the study is complete. Publications will present aggregate findings or carefully anonymized quotations and will not include identifiable information. Authorship will follow accepted scholarly criteria, and other contributors will be acknowledged with permission.

Discussion

This trial will examine whether a structured, culturally tailored, nurse-led telehealth education program can improve glycemic control and patient-reported outcomes among adults with T2DM in Oman. The study addresses a practical gap in diabetes care: clinic visits are intermittent, but self-management is continuous. Regular synchronous contact may allow participants to revisit information, work through barriers, review goals, and receive reinforcement while clinical decision-making remains with their usual treating team.

Several features strengthen the design, including concealed randomization, an objective primary endpoint, prespecified blinding of outcome assessment and analysis where feasible, intervention fidelity monitoring, an internal feasibility pilot, and an intention-to-treat analysis. The 6-month follow-up is sufficient to assess change in HbA1c and medium-term engagement, while measurements at more than one follow-up point will provide information on how outcomes change over time.

The study also has limitations that should be considered when interpreting the findings. Participants and educators cannot be blinded, and self-reported medication-related outcomes and quality of life may be affected by recall or social-desirability bias. The weekly intervention also provides more contact to the intervention group than to the control group. Because the trial is conducted at a single site, includes Omani nationals only, and requires access to an internet-enabled device, the findings may not generalize to all people with T2DM, particularly those affected by digital exclusion. Changes in routine clinical treatment during follow-up may also influence outcomes; these changes will therefore be recorded and considered in sensitivity or exploratory analyses where appropriate.

If the intervention is effective and acceptable, it could offer a practical model for extending diabetes education beyond routine clinic visits and may help inform nursing practice and digital-health policy in Oman. Even if no clinically important benefit is found, the trial will provide useful information about feasibility, engagement, privacy, acceptability, and the practical requirements of delivering an intensive telehealth education program in a tertiary outpatient setting.

Trial status

Protocol version 1.1 is dated 25 July 2026. At the time this protocol was prepared, approval had been obtained from the Research and Ethics Committee, College of Nursing, Sultan Qaboos University (CON/IG/2025/15; 23 September 2025). Additional SQU Medical Research Ethics Committee review and SQUH site authorization, instrument permissions, telehealth platform approval, and prospective trial registration were still pending, and recruitment had not started. Recruitment is planned to begin once all required approvals are in place. It is expected to continue for approximately 9 months, with each participant followed for 6 months.

Declarations

Ethics approval and consent to participate

Ethical approval was obtained from the Research and Ethics Committee, College of Nursing, Sultan Qaboos University (Ref. No. CON/IG/2025/15; 23 September 2025). Any additional

required SQU Medical Research Ethics Committee approval and SQUH site authorization will be obtained before recruitment. All participants will provide written informed consent.

Consent for publication

Not applicable. This protocol does not include identifiable participant information.

Trial registration

Registry and registration number: ClinicalTrials.gov; NCT number: [TO BE ADDED AFTER REGISTRATION].

Funding

This study is supported by a Sultan Qaboos University Internal Grant (grant number IG/--/CON/C&M/26/389). The funder will have no role in recruitment, data collection, data analysis, interpretation of findings, manuscript preparation, or the decision to publish.

Competing interests

The authors declare no financial or commercial competing interests. Any actual, potential, or perceived conflict that arises before submission will be disclosed.

Author contributions

NAA conceived the study, led protocol development, and is responsible for scientific and ethical oversight, funding acquisition, supervision, data-access authorization, analysis oversight, and dissemination. SSAH contributed to the study design and protocol development and will lead operational oversight, recruitment supervision, intervention quality assurance, and participant retention. ZYA and NAS reviewed and refined the protocol, provided contextual and methodological input, and critically revised the manuscript for important intellectual content. All authors reviewed and approved the final manuscript and accept accountability for their respective contributions.

Data availability

No participant data have yet been generated. After publication of the primary findings, a de-identified dataset and analysis code may be shared on reasonable request, subject to approval by the principal investigator, institution, and ethics authorities and to an appropriate data-use agreement.

Acknowledgements

The authors will acknowledge additional contributors, if any, once their roles are confirmed.

References

1. International Diabetes Federation. IDF Diabetes Atlas. 11th ed. Brussels: International Diabetes Federation; 2025.
2. Al-Lawati JA, Panduranga P, Al-Shaikh HA, et al. Epidemiology of diabetes mellitus in Oman: results from two decades of research. *Sultan Qaboos Univ Med J*. 2015;15(2):e226–e233.
3. Jimmy B, Jose J, Al-Hinai ZA, Wadair IK, Al-Amri GH. Adherence to medications among type 2 diabetes mellitus patients in three districts of Al Dakhliyah Governorate, Oman: a cross-sectional pilot study. *Sultan Qaboos Univ Med J*. 2014;14(2):e231–e235.
4. Al Mahrouqi AS, Mallinson RK, Oh KM, Weinstein AA. Patient-centred care, diabetes self-management and glycaemic control among Omani patients with type 2 diabetes. *Int J Nurs Pract*. 2023;29(1):e13103.
5. Al-Maskari MY, Al-Shookri AO, Al-Adawi SH, Lin KG. Assessment of quality of life in patients with type 2 diabetes mellitus in Oman. *Saudi Med J*. 2011;32(12):1285–1290.
6. De Groot J, Wu D, Flynn D, Robertson D, Grant G, Sun J. Efficacy of telemedicine on glycaemic control in patients with type 2 diabetes: a meta-analysis. *World J Diabetes*. 2021;12(2):170–197.
7. Al Ibrahim A, Al Omran AM, Alaithan DT, et al. Effectiveness of telemedicine in controlling hyperglycemia among diabetic patients on insulin therapy in primary care: a systematic review and meta-analysis. *Cureus*. 2023;15(12):e50045.
8. Bingham JM, Black M, Anderson EJ, et al. Impact of telehealth interventions on medication adherence for patients with type 2 diabetes, hypertension, and/or dyslipidemia: a systematic review. *Ann Pharmacother*. 2021;55(5):637–649.
9. Gurcay B, Yilmaz FT, Bilgin A. The effectiveness of telehealth interventions on medication adherence among patients with type 2 diabetes: a meta-analysis. *Telemed J E Health*. 2024;30(1):3–20.
10. Chong CJ, Bakry MM, Hatah E, Mohd Tahir NA, Mustafa N. Effects of mobile apps intervention on medication adherence and type 2 diabetes mellitus control: a systematic review and meta-analysis. *J Telemed Telecare*. 2025;31(2):157–173. doi:10.1177/1357633X231174933.
11. Almalki ZS, Imam MT, Ahmed NJ, et al. The influence of telemedicine in primary healthcare on diabetes mellitus control and treatment adherence in Riyadh region. *Saudi Pharm J*. 2024;32(1):101920.
12. Al Harthi T, Anwar H, Al Lawati A, et al. The impact of COVID-19 on diabetes care in Muscat Governorate: a retrospective cohort study in primary care. *J Prim Care Community Health*. 2021;12:21501327211051930.
13. Burroughs TE, Desikan R, Waterman BM, Gilin D, McGill J. Development and validation of the Diabetes Quality of Life Brief Clinical Inventory. *Diabetes Spectr*. 2004;17(1):41–49.
14. Asrawi I, Al-Maqbali JS, Cabral AC, Castel-Branco M, Figueiredo IV, Fernandez-Llimos F, et al. Translation, cultural adaptation, and validation of the Arabic version of the Medication Adherence Universal Questionnaire among Omani patients with type 2 diabetes mellitus. *Saudi Pharm J*. 2026;34(3):27. doi:10.1007/s44446-026-00083-1.
15. Cabral AC, Lavrador M, Castel-Branco M, Figueiredo IV, Fernandez-Llimos F. Development and validation of a Medication Adherence Universal Questionnaire: the MAUQ. *Int J Clin Pharm*. 2023;45(4):999–1006. doi:10.1007/s11096-023-01612-x.
16. American Diabetes Association Professional Practice Committee for Diabetes. Introduction and methodology: Standards of Care in Diabetes—2026. *Diabetes Care*. 2026;49(Suppl 1):S1–S5.
17. Chan AW, Boutron I, Hopewell S, et al. SPIRIT 2025 statement: updated guideline for protocols of randomized trials. *BMJ*. 2025;389:e081477.

18. Hróbjartsson A, Chan AW, Boutron I, et al. SPIRIT 2025 explanation and elaboration: updated guideline for protocols of randomized trials. *BMJ*. 2025;389:e081660.
19. Hoffmann TC, Glasziou PP, Boutron I, et al. Better reporting of interventions: Template for Intervention Description and Replication (TIDieR) checklist and guide. *BMJ*. 2014;348:g1687.
20. Hopewell S, Chan AW, Collins GS, et al. CONSORT 2025 statement: updated guideline for reporting randomized trials. *BMJ*. 2025;389:e081123.
21. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. ICH Harmonised Guideline E6(R3): Guideline for Good Clinical Practice. Final consolidated guideline. Geneva: ICH; 2026.
22. World Medical Association. Declaration of Helsinki: ethical principles for medical research involving human participants. Ferney-Voltaire: World Medical Association; 2024.
23. Sultan Qaboos University. General Research Ethics Procedure. Muscat: Sultan Qaboos University; 2023.
24. World Health Organization Regional Office for the Eastern Mediterranean. Oman: remote health services provision during the COVID-19 pandemic. Cairo: WHO Regional Office for the Eastern Mediterranean; 2021.
25. World Health Organization. International Clinical Trials Registry Platform: trial registration. Geneva: World Health Organization; accessed 20 July 2026.
26. Parmanto B, Lewis AN Jr, Graham KM, Bertolet MH. Development of the Telehealth Usability Questionnaire (TUQ). *Int J Telerehabil*. 2016;8(1):3–10. doi:10.5195/ijt.2016.6196.
27. Shebli KH, Alshehri FH, Alshehri YS, et al. Cross-cultural adaptation and psychometric properties of the Arabic version of the Telerehabilitation Usability Questionnaire. *Ann Med*. 2025;57(1):2525396. doi:10.1080/07853890.2025.2525396.