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A study protocol for a randomized controlled trial of digital vs conventional diabetes self-management education on glycemic control in a Pakistani tertiary care setting

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Effectiveness of Structured Digital Diabetes Self-Management Education (DSME) on Glycemic Control in Type 2 Diabetes in Jhelum, Pakistan: Study Protocol for a Randomized Controlled Trial

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ABSTRACT

Introduction

Effective management of Type 2 diabetes mellitus (T2DM) is critical for preventing complications and improving quality of life. Globally, over 584 million adults live with diabetes, with Pakistan reporting one of the highest prevalence rates at 30.8%. This study aims to evaluate the effectiveness of structured digital diabetes self-management and education (DSME) compared with conventional counselling on glycemic control (HbA1c) in T2DM patients.

Methods and analysis

A single-blind, concurrent, parallel-group randomised controlled trial will be conducted over one year (August 2025 – July 2026) among T2DM patients aged 18 years or above attending a tertiary care hospital in Jhelum, Pakistan. Participants will be randomly assigned in a 1:1 ratio to an intervention or control group. The intervention group will

receive twice-weekly WhatsApp-based DSME messages over 12 weeks, including text reminders and educational and motivational content, together with once-weekly fasting blood sugar (FBS) logging via the mySugr mobile application. The control group will receive standard in-person counselling during routine hospital visits. Quantitative data (HbA1c, Diabetes Self-Efficacy Scale, Summary of Diabetes Self-Care Activities Measure) will be collected at baseline and at 3 months and analysed using SPSS, applying descriptive statistics (mean, standard deviation) and inferential statistics (t-tests, ANCOVA and regression analysis) to compare outcomes, adjusting for baseline scores.

Ethics and dissemination

Ethical approval (605-AAA-ERC-AFPGMI) has been obtained from the Institutional Review Board of the Armed Forces Postgraduate Medical Institute (AFPGMI), Rawalpindi, Pakistan, to conduct this trial at a tertiary care hospital in Jhelum, Pakistan. Written informed consent will be obtained in the local language, with verbal explanation for low-literacy participants, and participation will be voluntary with the right to withdraw. Confidentiality of patient data will be ensured. Findings will be disseminated through methodology papers, conference presentations and peer-reviewed publications, and reported according to the Consolidated Standards of Reporting Trials (CONSORT) guidelines. Participation in national and international academic conferences will provide further opportunities for dissemination.

Trial registration number

ID20260703070054N1 (dated *[date]*).

Keywords

Conventional counselling; digital DSME interventions; glycemic control; self-management; self-efficacy; treatment adherence; type 2 diabetes.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This is a pioneer randomized controlled trial in a hospital-based setting in Jhelum, Pakistan, in a population with generally low digital literacy, addressing a critical gap in diabetes education research.

⇒ The trial delivers a cost-effective, smartphone-based digital DSME intervention within a gold-standard RCT design, including two stages stratified and simple randomization, allocation concealment and blinded outcome assessment.

⇒ The study is limited to a urban/semiurban population with low digital literacy, which may affect generalizability.

⇒ The 12-week follow-up period is short-term and cannot establish the long-term sustainability of glycemic control.

INTRODUCTION

Type 2 diabetes mellitus (T2DM) is a pressing global health challenge, with significant regional burdens in Asia, particularly in Pakistan (1). Globally, T2DM affected 537 million adults in 2021, with a projected rise to 783 million by 2045 (2). In Asia, South-East Asia

alone accounts for 90 million cases, with Pakistan ranking third globally, reporting 33 million adults living with diabetes in 2021 a prevalence rate of 30.8% among adults aged 20–79 years (3). Additionally, 11 million adults in Pakistan have impaired glucose tolerance (IGT), and 26.9% of diabetes cases remain undiagnosed, amplifying the public health crisis (4). T2DM prevalence is notably higher in urban areas (28.3%) compared with rural areas (25.3%), with regional variation showing Punjab at 16% and Khyber Pakhtunkhwa at 11% (5). This high prevalence driven by genetic predisposition, rapid urbanization, sedentary lifestyles and high-sugar diets underscores the need for effective interventions in resource-constrained settings such as secondary and tertiary care hospitals in Pakistan (6).

T2DM, characterized by insulin resistance and progressive beta-cell dysfunction, requires lifelong self-management to prevent complications such as cardiovascular disease, nephropathy, retinopathy and neuropathy. In tertiary care hospitals, where patients often present with advanced disease or comorbidities, achieving glycemic control (measured by HbA1c) is challenging (7). Conventional diabetes education, delivered through in person counselling, guides lifestyle modification, medication adherence and glucose monitoring, but is limited by time constraints, high patient volumes and logistical barriers particularly in Pakistan, where healthcare access is uneven and only 1% of GDP is allocated to health (8).

Digital health interventions, such as mobile applications and web-based platforms, offer scalable solutions for T2DM self-management. Effective T2DM management relies on self-care practices diet, exercise, medication adherence and glucose monitoring which are enhanced through diabetes self-management and education (9). Structured DSME programs have shown significant improvements in glycemic control (HbA1c reduction of 0.5–1.3%) and self-efficacy in high-resource settings (10). In low-resource settings like Pakistan, however, conventional counselling often lacks personalization and accessibility, resulting in poor glycemic control (HbA1c >7%) in 70% of T2DM patients (11).

Digital tools provide real-time education, medication reminders, dietary tracking and personalized feedback, enhancing patient engagement between clinic visits. A 2020 meta-analysis reported that digital interventions reduced HbA1c by 0.49% compared with usual care, with greater efficacy when paired with clinician support (12). In Asia, where smartphone penetration is high, digital interventions hold promise, but their efficacy in tertiary care settings in Pakistan — with its diverse population and varying digital literacy remains underexplored. Digital health technologies, including mobile health (mHealth) apps and WhatsApp-based interventions, offer scalable, cost-effective solutions for DSME delivery (13).

This randomized controlled trial aims to evaluate whether there is a significant difference in the efficacy of structured digital diabetes education compared with conventional counselling in improving glycemic control (HbA1c) and secondary outcomes — including fasting blood glucose, self-efficacy and self-care activities — among T2DM patients in Jhelum's hospital care setting.

OBJECTIVES

The specific objectives are to assess:

1. To evaluate the effectiveness of structured digital diabetes self-management and education compared with conventional counselling on glycemic control (HbA1c) in T2DM patients in a tertiary care hospital in Jhelum, Pakistan, over 3 months.
2. To assess changes in self-efficacy and diabetes-related self-care behaviors between the intervention and control groups.

HYPOTHESIS

We hypothesis that patients receiving the digital DSME intervention will show significantly better glycemic control than those receiving conventional counselling.

METHODS

Trial design

This is a single-blind, concurrent, parallel-group randomized controlled trial. The study duration is one year (August 2025 – July 2026). Participants will be randomly assigned in a 1:1 ratio to receive either structured digital DSME delivered by smartphone (intervention) or conventional in-person counselling / routine care (control).

Setting

The study will be conducted at a tertiary care hospital in Jhelum, in the outpatient diabetes clinics serving T2DM patients. The rural/semi-urban, mixed catchment population reflects Pakistan's broader healthcare challenges and is considered well suited to testing a scalable DSME intervention across diverse socioeconomic and literacy levels.

Participants

Adults aged 18 years and above with T2DM — including government personnel, retirees and civilians attending the outpatient diabetes clinics — will be eligible for inclusion.

Inclusion criteria:

- ► Age >18 years.
- ► Diagnosed with T2DM for >3 months (to ensure familiarity with self-care challenges).
- ► Access to a smartphone with WhatsApp and the mySugr app.

Exclusion criteria:

- ► Type 1 diabetes or gestational diabetes.
- ► severe complications (end-stage renal disease, severe retinopathy, cardiac complications).
- ► Mental health conditions or cognitive impairments preventing participation.
- ► Pregnancy or hospitalization during the study period.

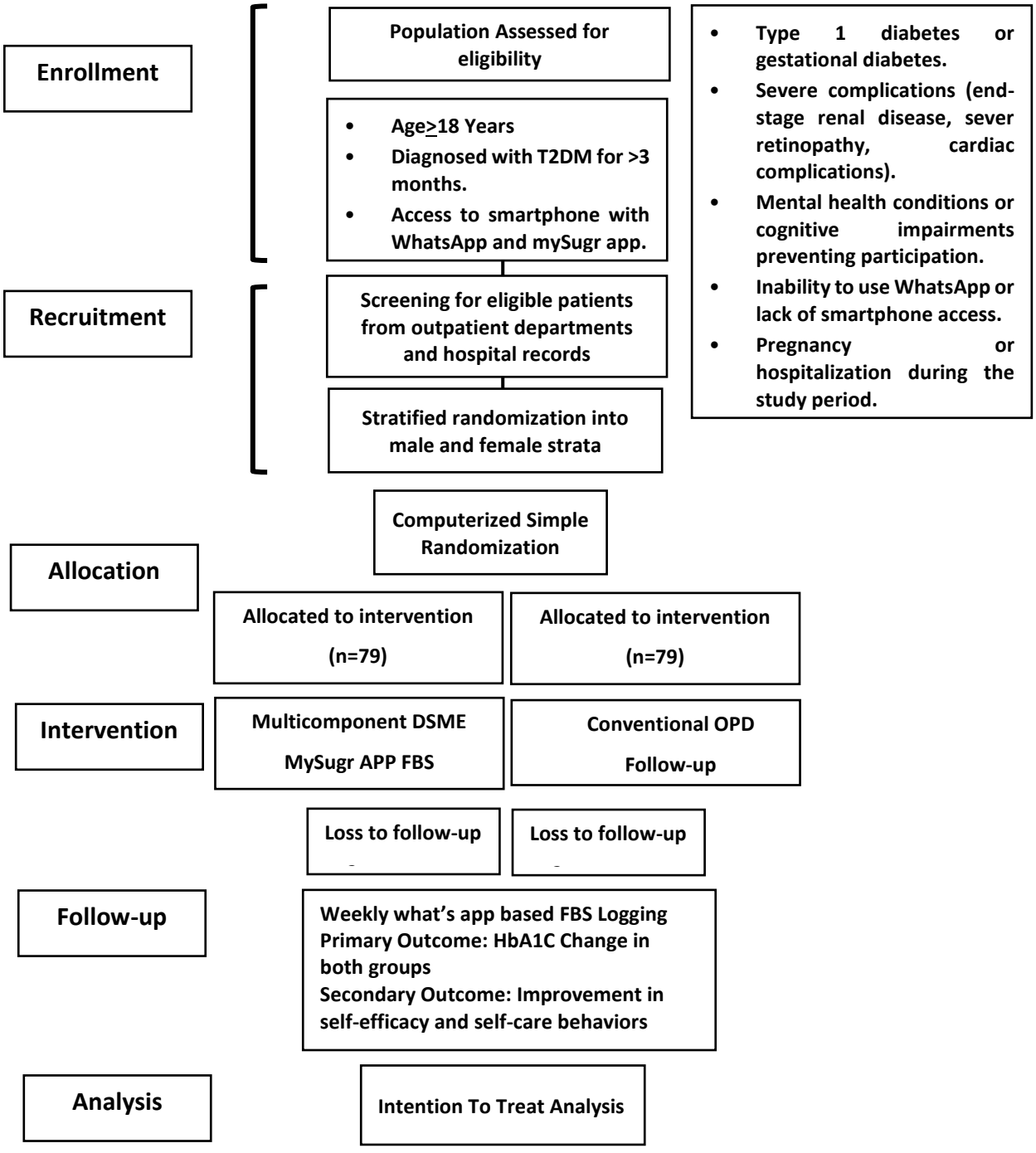

Enrollment
Population Assessed for eligibility
Age≥18 Years
Diagnosed with T2DM for >3 months.
Access to smartphone with WhatsApp and mySugr app.
Type 1 diabetes or gestational diabetes.
Severe complications (end-stage renal disease, sever retinopathy, cardiac complications).
Mental health conditions or cognitive impairments preventing participation.
Inability to use WhatsApp or lack of smartphone access.
Pregnancy or hospitalization during the study period.
Recruitment
Screening for eligible patients from outpatient departments and hospital records
Stratified randomization into male and female strata
Allocation
Computerized Simple Randomization
Allocated to intervention (n=79)
Allocated to intervention (n=79)
Intervention
Multicomponent DSME MySugr APP FBS
Conventional OPD Follow-up
Loss to follow-up
Loss to follow-up
Follow-up
Weekly what's app based FBS Logging
Primary Outcome: HbA1C Change in both groups
Secondary Outcome: Improvement in self-efficacy and self-care behaviors
Analysis
Intention To Treat Analysis

Figure 1 Flow diagram of the trial algorithm showing participant enrolment, randomization, intervention allocation, follow- up and analysis. Tertiary Care Hospital Jhelum, Pakistan

Recruitment

Eligible patients will be identified through screening of patients registered in the hospital's continuous-treatment (CT) clinics via Health Management System (HMS) records, as well as those attending the outpatient department (OPD). Patients will be assigned unique IDs, stratified into male and female strata, and allocated by simple random sampling (IBM SPSS V.27) to the intervention or control group in blocks of 4, 6 or 8 to ensure balanced distribution between arms.

Randomization and blinding

A two-stage probability sampling approach will be used: stratified random sampling by sex, followed by computer-generated simple randomization in a 1:1 ratio. A digital allocation number will be assigned to each group, and the research team will distribute sealed cards among participants at the time of registration for baseline diagnostic testing. The principal investigator will maintain a centralized record of all allocation numbers to prevent subversion of the randomization process.

Blinding of participants and intervention staff is not feasible given the nature of the intervention (digital versus in-person); however, outcome assessors (e.g. laboratory technicians, questionnaire administrators) and the data analyst will remain blinded to group allocation, with the data analyst receiving a de-identified dataset with the intervention arm masked to permit unbiased analysis. Allocation concealment will be maintained using sequentially numbered, opaque, sealed envelopes prepared by an independent collaborator and opened only at the point of assignment.

Intervention and comparator

Trial intervention

Participants in the intervention group will receive structured digital DSME delivered via WhatsApp on a smartphone, twice weekly, over 12 weeks, together with once-weekly fasting blood sugar (FBS) logging using the mySugr mobile application. Messages will include text reminders, educational content, self-monitoring prompts, lifestyle-modification tips and motivational messages, delivered in Urdu for accessibility. Message content was developed with input from a public health expert and an endocrinologist, drawing on related published literature, the WHO diabetes education toolkit, and International Diabetes Federation guidelines. Delivery comprises two components: (a) a DSME component supporting continuous patient engagement. (b) FBS logging once weekly through mySugr app, shared in csv format to the researcher through what's app. The intervention will be delivered under the supervision of the principal investigator, with oversight from the research supervisor.

Comparator group

Participants in the control group will receive standard, in-person counselling during routine OPD visits, consisting of printed educational material covering general dietary

advice, physical activity recommendations, and oral hypoglycaemic/medication adherence guidance. Using conventional counselling as the comparator allows evaluation of the added value of digital DSME against standard practice.

Adherence monitoring and concomitant care

Adherence in the intervention group will be monitored via delivery and usage reports generated by the mySugr application, exported weekly. Adherence in the comparator group will be assumed under standard practice, without additional monitoring. Undelivered reminders or incomplete app-usage records will be documented and addressed in intention to analyses. No additional restrictions will be placed on concomitant care during the trial.

Follow-up

Participants will be followed for 12 weeks. The intervention group will be followed via mobile contact to monitor glycemic control, weekly FBS logging and adherence to the intervention; the control group will be followed via mobile contact for study-inclusion purposes only, without DSME messaging or glucose logging. The intervention will be discontinued for participants who withdraw consent; a record will be maintained of participants who decline consent to follow-up, and their data will be considered withdrawn.

Public and patient involvement

Key stakeholders, including patients and physicians, will be engaged throughout the research process, from study design through to implementation, to ensure the intervention remains community-appropriate and accessible. Participant feedback will inform the development of DSME message content. Hospital staff will receive a brief training session to ensure implementation is sensitive to local dynamics. Dissemination approaches will be co-developed with hospital administration and patient representatives.

OUTCOMES

Primary outcome measure

The primary outcome of interest is the change in glycemic control, measured as the mean reduction/maintenance in HbA1c levels at 12 weeks post-enrolment, compared between the intervention and control groups. HbA1c will be assessed at baseline and follow-up, with outcome ascertainment performed by independent researchers masked to group allocation.

Secondary outcome measures

- Association of glycemic control with sociodemographic characteristics (age, gender, education, income level).
- Changes in self-care behaviours (dietary adherence, physical activity, medication compliance), assessed via the Summary of Diabetes Self-Care Activities (SDSCA) questionnaire.

- Improvement in self-efficacy towards diabetes management, assessed via the Diabetes Self-Efficacy Scale (DSES).

Data collection

Eligibility screening will assess inclusion and exclusion criteria (e.g. severe comorbidities, absence of smartphone access). Eligible adults with T2DM will be enrolled from outpatient clinics or identified via medical records, with informed consent obtained in Urdu or English using simplified materials suitable for low-literacy participants.

Randomization sequence generation will use a computer-generated random number table with 1:1 allocation, stratified by baseline HbA1c (<7% vs ≥7%) and literacy level to ensure balance between arms.

The study comprises a 12-week period with baseline and follow-up study visits. At visit 1, participants will be allocated to groups following informed consent. Participants in the intervention group will download the mySugr application (mySugr GmbH, Austria) and use it via a pseudonymised study account. Baseline assessment will include blood glucose data collection and completion of the DSES and SDSCA questionnaires. During the 12-week period, intervention participants will use the mySugr app for glucose logging and receive DSME messages via WhatsApp, while control participants will continue their usual self-management; intervention participants will additionally report glucose logs in CSV format to the researcher weekly. HbA1c and self-administered questionnaires will be collected from all participants at the end of 3 months for baseline and between-group comparison.

Sample size calculation

Sample size was calculated using G*Power software, with a significance level (α) of 0.05 and statistical power of 80%. Reference effect-size values for DSME (50% versus 25%) were derived from a previous study.

Pilot testing was conducted on 10% of the intended sample size, comprising fifteen participants. The purpose was to evaluate the smooth implementation of the intervention and to identify any systematic errors. These participants were not included in the final analysis. The pilot sample was in addition to the 158 participants who were ultimately enrolled in the main study

Statistical analysis

Data will be analyzed using IBM SPSS Statistics for Windows, V.27.0 (IBM Corp, Armonk, New York, USA). Descriptive statistics will be presented as means and standard deviations (SD) for continuous variables (HbA1c, fasting blood glucose) and as frequencies and percentages for categorical variables (demographic characteristics), to confirm randomization balance.

The primary outcome (change in HbA1c from baseline to 3 months) will be compared between groups using independent-samples t-tests. Analysis of covariance (ANCOVA)

will be performed to account for baseline differences and potential confounders, adjusting for baseline HbA1c and covariates including age and education. Secondary outcomes will be analyzed similarly, using t-tests and ANCOVA with the same covariate adjustments.

Bivariate analyses (t-tests for continuous outcomes; chi-square tests for categorical outcomes, e.g. proportion achieving HbA1c <7%) will explore associations of HbA1c change with age, gender, education and duration of T2DM, calculating odds ratios (ORs) with 95% confidence intervals. Multivariate regression linear regression for continuous outcomes and logistic regression for binary outcomes will adjust for confounders (age, literacy, baseline HbA1c, smartphone use) to quantify the intervention's independent effect.

All statistical tests will be two-tailed, with significance set at $p<0.05$. Intention-to-treat analysis will address anticipated attrition (approximately 20%) using multiple imputation for missing data. Results will be reported in accordance with CONSORT guidelines, including baseline characteristics, outcome comparisons, adjusted analyses and a participant flow diagram, consistent with SPIRIT 2013 recommendations.

Data monitoring

A formal Data Monitoring Committee will not be established for this trial, as it is a minimal-risk, hospital-based intervention conducted at Jhelum without investigational drugs or high-risk procedures. Oversight of trial conduct including data quality, participant safety and protocol adherence will be managed internally by the principal investigator and research team. No interim analyses or formal stopping guidelines are planned, given the short study duration, limited sample size and minimal risk involved. Final close-out will occur at 12 weeks, when end-of-study assessments are completed for all participants.

ADVERSE EVENT REPORTING AND HARMS

Previous studies have reported no adverse events associated with the use of digital diabetes self-management education (DSME) applications. Nevertheless, any signs or incidents of adverse events, including technical issues or participant distress related to the intervention, will be addressed promptly and reported immediately to the Ethics Review Board of AFPGMI, which will determine the appropriate course of action.

ETHICS AND DISSEMINATION

Ethical approval (605-AAA-ERC-AFPGMI) has been obtained from the Institutional Review Board (IRB) of the Armed Forces Postgraduate Medical Institute (AFPGMI), Rawalpindi, Pakistan, to conduct this trial at a tertiary care hospital in Jhelum. Permission to conduct the study was granted by the hospital administration of Jhelum. All participants will be required to provide written informed consent before enrolment; consent will be obtained in the local language (written, with verbal explanation for low-literacy participants), and participation will be voluntary with the right to withdraw at any time.

Special consideration will be given to message timing to avoid inconvenience (e.g. late-night notifications), and messages will not include personally identifiable information. The

DSME application and data management system will be securely maintained at a single site with restricted access; a dedicated contact number will be provided for participants to raise questions or concerns. Personal information will be collected using participant codes to ensure anonymity; identifiable data such as consent forms will be stored separately from clinical data and will not be entered into the electronic database. The electronic database will be securely stored with access restricted to investigators and data managers, and only de-identified data will be used for analysis and reporting, with records retained per ethical requirements.

No ancillary or post-trial care is anticipated, given the minimal risk of the intervention. In the unlikely event of harm, participants will be referred to appropriate healthcare services, with any compensation following institutional ethics policies. Protocol modifications will be approved by the ethics review board, updated on ClinicalTrials.gov, and communicated to participants with revised information sheets prior to re-consent.

Findings will be disseminated through methodology papers, conference presentations and peer-reviewed publications. Results will be reported according to the Consolidated Standards of Reporting Trials (CONSORT) guidelines. Participation in national and international academic conferences will provide further opportunities for dissemination.

TIMELINE FOR ENROLMENT, INTERVENTION, CONVENTIONAL FOLLOWUP and OUTCOMES IN RCT

TIME POINT	MEASUREMENT TOOL	ENROLMENT	ALLOCATION	POST-RANDOMISATION						CLOSE-OUT
		-ti to 0		t 1+2	t 3+4	t 5+6	t 7+8	t 9+10	t 11+12	tx
ENROLMENT										
Eligibility Screen	OPD Visits	X								**t1**
Informed Consent	Informed consent form		X							**t1**
Randomization	Computerized randomization		X							**t1**
INTERVENTION / CONTROL										
Intervention	Multi-component What's app DSME/FBS logging mySugr app		X							**t1**
Control	Routine OPD visits		X							**t1**
ASSESSMENT										
Sociodemographic Variables	Sociodemographic questionnaire		X							**t1**
Selfcare	SDSCA questionnaire		X							**t1**
Self-Efficacy	DSES questionnaire		X							**t1**
OUTCOMES										
Primary Outcome	mySugr app/What`s app	Follow-up over WhatsApp Improvement /maintenance of HBA1C/FBS		X	X	X	X	X	X	**t12**
Secondary Outcome	SDSCA/DSES questionnaires	Improvement in self-care activities and self-efficacy								**t12**

DISCUSSION

This study will provide evidence for the effectiveness of structured digital diabetes self-management education (DSME) compared with conventional counselling in improving glycemic control among patients with type 2 diabetes mellitus (T2DM) in a low-resource setting. By reporting the frequency of suboptimal glycemic control and evaluating the impact of digital DSME, it will contribute valuable data on diabetes management in low- and middle-income countries, extending beyond the scope of previous regional studies. The anticipated improvement in HbA1c reduction/maintenance would highlight the potential of digital health interventions to bridge healthcare gaps and facilitate timely, continuous support for patients at risk of diabetes-related complications. To the best of our knowledge, this will be the first randomized controlled trial in Pakistan to evaluate the effectiveness of a digital DSME intervention in a hospital setting.

The methodological strengths of this study include its gold-standard randomized controlled trial design with allocation concealment, objective outcome ascertainment, measures to minimize attrition, and a robust statistical approach, all of which enhance internal validity and the credibility of the findings. The incorporation of a multicomponent digital intervention adds methodological rigor and represents a distinctive feature of this trial.

A number of methodological limitations need to be taken into account when evaluating this protocol. The follow-up period of 12 weeks may not fully capture the long-term impact of digital DSME on sustained glycemic control. Although smartphone penetration is high in urban Pakistan, reliance solely on digital modules could limit effectiveness in settings with low digital literacy, as some patients may not fully engage with the application. Variations in internet access, smartphone ownership and health literacy may also restrict the generalizability of the findings to rural or underserved populations.

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Contributors

SR conceived the study design, developed the intervention, planned data collection and monitoring, and wrote the manuscript draft. SM contributed to review at all stages, critical revision, and reviewed the study for overall quality, design robustness and final approval of the manuscript. MA contributed to statistical analysis planning and critical review of the methods and analysis sections. HI assisted with data collection, database design and follow-up issues, and contributed to manuscript revision. SR is the guarantor. Corresponding authors are SR (*sumairariaz1984@gmail.com*) and SM (*sm104177@hotmail.com*)

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Competing interests

The authors declare that the research will be conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Patient and public involvement

Patients and/or the public were involved in the design, conduct, reporting and dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication

Not applicable.

Provenance and peer review

Not commissioned; externally peer reviewed.

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