Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

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

Protocol summary

Study aim

To evaluate the effectiveness of a structured digital diabetes self-management education (DSME) program delivered through WhatsApp and the mySugr mobile application in improving glycemic control (HbA1c) compared with conventional counseling among adults with type 2 diabetes mellitus over 12 weeks. Secondary objectives are to assess changes in fasting blood glucose, diabetes self-efficacy, and self-care behaviors.

Design

Single-blind, parallel-group randomized controlled trial with 1:1 allocation using computer-generated block randomization. Outcome assessors will be blinded to treatment allocation.

Settings and conduct

The study will be conducted at the outpatient diabetes clinic of a tertiary care hospital in Jhelum, Pakistan. A total of 158 eligible participants will be randomized equally into intervention and control groups and followed for 12 weeks

Participants/Inclusion and exclusion criteria

Adults (≥18 years) with type 2 diabetes diagnosed for at least 3 months, having smartphone access with WhatsApp and mySugr, and providing informed consent will be included. Exclusion criteria include type 1 or gestational diabetes, severe diabetes complications, cognitive impairment, pregnancy, hospitalization during the study, or inability to use a smartphone

Intervention groups

Participants will receive structured digital DSME for 12 weeks, including WhatsApp-based educational and motivational messages 2–3 times weekly and fasting blood glucose logging using the mySugr application three times weekly, in addition to routine diabetes care.

Main outcome variables

The primary outcome is change in HbA1c from baseline to 12 weeks. Secondary outcomes include fasting blood glucose, Diabetes Self-Efficacy Scale (DSES) score, and Summary of Diabetes Self-Care Activities (SDSCA) score.

General information

Reason for update

Acronym

DiGEST Trial

IRCT registration information

IRCT registration number: **IRCT20260703070054N1**
Registration date: **2026-07-09, 1405/04/18**
Registration timing: **retrospective**

Last update: **2026-07-09, 1405/04/18**
Update count: **0**

Registration date

2026-07-09, 1405/04/18

Registrant information

Name

paaras suleman

Name of organization / entity

National University of Medical Sciences

Country

Pakistan

Phone

+92 334 3931815

Email address

sulemanpaaras@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-09-01, 1404/06/10

Expected recruitment end date

2025-09-30, 1404/07/08

Actual recruitment start date

2025-09-01, 1404/06/10

Actual recruitment end date

2025-09-30, 1404/07/08

Trial completion date

2026-08-31, 1405/06/09

Scientific title

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

Public title

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

Purpose

Treatment

Inclusion/Exclusion criteria

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 my Sugr app Willing to participate and provide informed consent

Exclusion criteria:

Type 1 diabetes or gestational diabetes. Severe complications (e.g., end-stage renal disease, severe retinopathy) Mental health conditions or cognitive impairments preventing participation Inability to use WhatsApp or lack of smartphone access. Pregnancy or hospitalisation during the study period.

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **158**

Actual sample size reached: **160**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be randomized in a 1:1 ratio to either the structured digital diabetes self-management education (DSME) intervention group or the conventional counseling control group. The unit of randomization is the individual participant. Computer-generated block randomization with variable block sizes of 4, 6, and 8 will be used to ensure balanced allocation between study arms while minimizing predictability. Randomization will be stratified according to baseline HbA1c (<7% vs. ≥7%) and literacy level to achieve balance in important prognostic factors. The random allocation sequence will be generated by an independent researcher using a computer-based random number generator (IBM SPSS Statistics version 26) before participant enrollment.

Blinding (investigator's opinion)

Single blinded

Blinding description

This is a single-blind randomized controlled trial. Due to the nature of the intervention, participants and the investigators delivering the intervention cannot be blinded to group allocation. However, outcome assessors, including laboratory personnel measuring HbA1c and researchers administering and scoring the Diabetes Self-Efficacy Scale (DSES) and Summary of Diabetes Self-Care Activities (SDSCA), will remain blinded to treatment allocation throughout the study. Statistical analyses will be performed using coded group assignments whenever feasible to minimize detection bias.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Review Committe-AFPGMI

Street address

CMH Rd, Rawalpindi,

City

Rawalpindi

Postal code

46000

Approval date

2025-08-25, 1404/06/03

Ethics committee reference number

605-AAA-ERC-AFPGMI

Health conditions studied

1

Description of health condition studied

Type 2 Diabetes Mellitus (T2DM)

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes

1

Description

Change in glycated haemoglobin (HbA1c) level from baseline to 12 weeks to assess glycaemic control.

Timepoint

Measured at baseline (before randomisation) and at 12

weeks (end of the intervention).

Method of measurement

HbA1c will be measured using high-performance liquid chromatography (HPLC) (Bio-Rad D-10 analyser) on venous blood samples collected at baseline and at 12 weeks. Glycaemic control will be assessed by comparing the change in HbA1c between the two study groups.

Secondary outcomes

1

Description

Change in fasting blood glucose (FBG) level from baseline to 12 weeks.

Timepoint

Measured at baseline (before randomization) and at 12 weeks (end of the intervention).

Method of measurement

Fasting blood glucose will be measured after an overnight fast using standardized laboratory methods or a calibrated glucometer according to hospital protocol. The change in FBG between baseline and 12 weeks will be compared between study groups.

2

Description

Change in diabetes self-efficacy from baseline to 12 weeks.

Timepoint

Measured at baseline (before randomization) and at 12 weeks (end of the intervention).

Method of measurement

Self-efficacy will be assessed using the validated 8-item Diabetes Self-Efficacy Scale (DSES). The mean score will be calculated and changes from baseline to 12 weeks will be compared between the intervention and control groups.

3

Description

Change in diabetes self-care behaviors from baseline to 12 weeks.

Timepoint

Measured at baseline (before randomization) and at 12 weeks (end of the intervention).

Method of measurement

Self-care behaviors will be assessed using the validated Summary of Diabetes Self-Care Activities (SDSCA) questionnaire. Total and domain scores will be calculated, and changes from baseline to 12 weeks will be compared between study groups.

Intervention groups

1

Description

Intervention group: Participants randomized to the intervention arm will receive a structured Digital Diabetes Self-Management Education (DSME) program in addition to routine diabetes care for 12 weeks. The intervention comprises WhatsApp-based educational and motivational messages delivered 2–3 times per week covering healthy diet, physical activity, medication adherence, blood glucose monitoring, and prevention of diabetes-related complications. Participants will also use the mySugr mobile application to record fasting blood glucose (FBG) at least three times weekly and share glucose logs with the research team through WhatsApp. Routine diabetes care and prescribed medications will continue unchanged throughout the study.

Category

Behavior

2

Description

Control group: Participants randomized to the control arm will receive conventional diabetes care consisting of standard face-to-face counseling during routine outpatient visits for 12 weeks. Counseling will include advice on healthy diet, physical activity, medication adherence, blood glucose monitoring, and prevention of diabetes-related complications, according to routine clinical practice. Participants will continue their usual prescribed antidiabetic treatment and follow-up. They will not receive the structured digital DSME intervention, WhatsApp educational messages, or mySugr-supported glucose logging provided to the intervention group.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Combined Military Hospital, Jhelum

Full name of responsible person

Sumaira Riaz

Street address

CMH Jehlum Cantt, Pind Dadan Khan - Jhelum

City

Jhelum

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49600

Phone

+92 306 9578847

Email

sumairariaz1984@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Office of Research, Innovation & Commercialization-NUMS

Full name of responsible person

Dr Shahid Waseem (Director ORIC)

Street address
CMH Rd, Rawalpindi,

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Rawalpindi

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46000

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+92 51 9270677

Email
oric@numspak.edu.pk

Web page address
https://numspak.edu.pk/oric

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Office of Research, Innovation & Commercialization-NUMS

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Armed Forces Post Graduate Medical Institute

Full name of responsible person
Sumaira Riaz

Position
Medical Officer

Latest degree
Medical doctor

Other areas of specialty/work
Public Health

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Person responsible for updating data

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Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to

make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

De-identified individual participant data (IPD), study protocol, statistical analysis plan, and informed consent form.

When the data will become available and for how long

Available 6 months after publication of the primary results and for up to 5 years.

To whom data/document is available

Qualified researchers upon reasonable request and approval by the principal investigator.

Under which criteria data/document could be used

For scientifically sound research after approval of a research proposal and signing a data-sharing agreement.

From where data/document is obtainable

Available from the principal investigator via email upon reasonable request. (sumairariaz1984@gmail.com)

What processes are involved for a request to access data/document

Researchers should submit a written request by email to the principal investigator. Requests will be reviewed for scientific merit and ethical compliance. Approved requests will require a signed data-sharing agreement before de-identified data are provided.

Comments