COVER PAGE

Official Study Title: Assessment of mobile application designed to support patients with type 1 diabetes in adjusting their insulin doses

NCT Number: [To be assigned by ClinicalTrials.gov]

Document Date: 23 September 2025

Document Type: Study Protocol (Randomized Controlled Trial)

Principal Investigator: Noor Kadhim Mohamed-Jawad

Affiliation: College of Pharmacy, University of Baghdad, Iraq

Brief Study Description: A randomized controlled trial to evaluate the effectiveness of a culturally adapted mobile application for insulin dose adjustment in Iraqi adults with poorly controlled type 1 diabetes compared to standard care alone.

PROTOCOL: RANDOMIZED CONTROLLED TRIAL

Official Title: A Randomized Controlled Trial of a Mobile Application for Insulin Dose Adjustment in Iraqi Adults with Type 1 Diabetes

NCT Number: [To be assigned by ClinicalTrials.gov]

Protocol Version: 2.0 Date: 23 September 2025

1.0 STUDY IDENTIFICATION

Principal Investigator: Noor Kadhim Mohamed-Jawad

Affiliation: College of Pharmacy, University of Basrah, A PhD candidate at college of pharmacy , University of Baghdad

Study Sites: Faiha Specialized Diabetes, Endocrine, and Metabolism Center in Basrah Endocrinology Center (FDMEC) , Basrah, Iraq.

Study Design: Parallel-group, randomized controlled trial

Allocation Ratio: 1:1

2.0 BACKGROUND AND RATIONALE

Type 1 diabetes mellitus (T1DM) requires complex insulin dose adjustments based on carbohydrate intake, blood glucose levels, and physical activity. Many patients in Iraq have poor glycemic control (HbA1c ≥8%) due to difficulties in performing these calculations. While numerous diabetes apps exist, few are culturally adapted for Arabic-speaking populations or designed for patients with low health literacy. This randomized controlled trial aims to rigorously evaluate a newly developed, evidence-based mobile application specifically designed for Iraqi T1DM patients.

3.0 STUDY OBJECTIVES

Primary Objective:

To evaluate the effect of the mobile application on glycemic control (change in HbA1c from baseline to 3 months) compared to standard care alone.

Secondary Objectives:

To assess differences in medication adherence between groups

To compare quality of life changes between groups

To evaluate the frequency of hypoglycemic events between groups

To assess user satisfaction and usability of the application (intervention group only)

4.0 STUDY DESIGN

Design: Prospective, parallel-group, randomized controlled trial

Allocation: Computer-generated randomization with block randomization (block size 4-6)

Blinding: Open non-blind study

Duration: 3-month intervention period

Follow-up: Baseline and 3-month assessments. In addition to monthly call and Whats-up communication as needed.

5.0 RANDOMIZATION AND MASKING

Randomization Procedure:

Computer-generated random sequence using statistical software

Blinding: Participants cannot be blinded due to nature of intervention.

6.0 STUDY POPULATION

Inclusion Criteria:

1. Adults ≥15 years with T1DM
2. HbA1c ≥7% at screening
3. On multiple daily insulin injections (MDI) for ≥3 months
4. Willing to perform self-monitoring of blood glucose ≥3 times daily
5. Smartphone ownership and basic proficiency
6. Provides informed consent

Exclusion Criteria:

1. Pregnancy, lactation, or planning pregnancy
2. High hypoglycemia risk (hypoglycemia unawareness, recent severe hypoglycemia)
3. Significant psychiatric disorders affecting adherence
4. Visual or motor impairment preventing app use
5. Participation in other diabetes intervention studies
6. Major insulin dose change (>20%) anticipated during study period

7.0 INTERVENTION

Intervention Group (n=26):

1. Training session on mobile application use (30-45 minutes)
2. Application features: insulin dose calculator, educational content, glucose logging, alerts
3. Monthly phone follow-up for adherence support (month 1,2, 3)

4. Continues standard diabetes care
5. Access to technical support hotline

Control Group (n=26):

1. Standard diabetes care only (no application access)
2. Equivalent attention time with general health check
3. Will receive application access after study completion if desire.

8.0 OUTCOME MEASURES

Primary Endpoint:

Absolute change in HbA1c from baseline to 3 months

Secondary Endpoints:

1. Change in medication adherence score
2. Change in quality of life score
3. Number of hypoglycemic events (<70 mg/dL) per patient-month
4. Severe hypoglycemia events requiring assistance
5. System Usability Scale score (intervention group only)

9.0 DATA COLLECTION SCHEDULE

Assessment	Baseline	Month 1	Month 2	Month 3
Informed Consent	X			
Demographic/clinical data	X			X
FBS measurement	X			X
HbA1c measurement				X
Adherence questionnaire	X			X
Quality of life questionnaire	X			X
Hypoglycemia event	X	X	X	X
System usability (intervention only)	X			X
Monthly call		X	X	X
Adverse events		X	X	X

10.0 STATISTICAL ANALYSIS

Analysis Principles: Intention-to-treat analysis for primary outcome

Primary Analysis: Linear mixed model for HbA1c change (group × time interaction)

Secondary Analyses:

Chi-square tests for categorical outcomes

T-tests or Mann-Whitney for continuous outcomes

Repeated measures ANOVA for longitudinal data

Subgroup analyses by baseline HbA1c, diabetes duration

Software: SPSS version 29, R version 4.3

Significance Level: $p<0.05$ (two-tailed)

11.0 ETHICAL CONSIDERATIONS

Approval: Required from University of Baghdad and Al-Faiha Endocrine Center ethics committees

Informed Consent: Written consent obtained from all participants after detailed explanation of randomization process

Confidentiality: Participant data de-identified, encrypted storage, access limited to research team

Right to Withdraw: Participants may withdraw at any time without affecting standard care

12.0 SAFETY MONITORING

Stopping Rules: Study suspension if ≥3 severe hypoglycemia events related to app use

13.0 DISSEMINATION PLAN

Publication in peer-reviewed journals regardless of outcome

Results shared with participants and local diabetes community