Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 2026

Improving diabetes health symptoms by using a specialized VR gamification self-care method: A parallel-group randomized controlled trial

Protocol summary

Study aim

To develop a self-care system using gamification in a virtual reality (VR) environment and to evaluate its effects on diabetic patients' metabolic symptoms, including fasting blood sugar (FBS), HbA1c, and BMI, as well as health-related behaviors, including physical activity and food intake.

Design

A randomized clinical trial with four parallel groups (VR gamification, monitoring application, traditional counseling, and control group) was conducted. Sampling was performed using a closed, offline recruitment method at a clinic. The total sample size was 78 participants, of whom 60 were included in the final analysis. Randomization was performed using stratified block randomization based on age and gender.

Settings and conduct

Study setting: Children's Medical Center in Tehran; Study population: children and adolescents aged 7–15 years with diabetes; Type of blinding: blinded data analyst; Blinding method: data analysis was conducted using coded labels for the groups so that the data analyst was unaware of the actual group identities.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Formal diagnosis of Diabetes,; Age between 7 and 15 years; Willingness and ability to participate in a six-week VR-based program. Exclusion criteria: Physical or medical conditions that would prevent safe use of VR headsets (e.g., severe motion sickness or nausea).

Intervention groups

VR gamified group: Participants received the VR gamified intervention specifically developed for this study. MySugr application group: Participants were instructed to use the MySugr diabetes self-care. Traditional counseling group: Participants received routine face-to-face diabetes counseling, aligned with the clinic's standard educational protocol. Control group: Participants received standard clinic care only, with no additional training.

Main outcome variables

Fasting blood glucose (FBS); Weekly sum of daily calculated physical activity (PA); Weekly average daily calculated food intake (daily calories); Weekly BMI; HbA1c

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260317068997N1**
Registration date: **2026-04-11, 1405/01/22**
Registration timing: **retrospective**

Last update: **2026-04-11, 1405/01/22**
Update count: **0**

Registration date

2026-04-11, 1405/01/22

Registrant information

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Name of organization / entity

Tehran university

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-11-21, 1403/09/01

Expected recruitment end date

2025-03-20, 1403/12/30

Actual recruitment start date

2025-01-04, 1403/10/15

Actual recruitment end date

2025-04-04, 1404/01/15

Trial completion date

2025-06-20, 1404/03/30

Scientific title

Improving diabetes health symptoms by using a specialized VR gamification self-care method: A parallel-group randomized controlled trial

Public title

Studying a modern Gamified Study for diabetes self-care

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Formal Diagnosis of Diabetes Willingness to participate in a six week self-care program Age Range between 7-15

Exclusion criteria:

Medical conditions that prevent VR headset use

Age

From **7 years** old to **15 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **52**

Actual sample size reached: **78**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization in this study was performed using computer-generated stratified block randomization. After confirming eligibility and obtaining informed consent, participants were enrolled in the study. To ensure balance between study groups with respect to important baseline characteristics, randomization was stratified by age and gender. Within each stratum, participants were assigned to one of the four study groups (VR gamification intervention, MySugr application, traditional counseling, and control group) using random block allocation. The allocation sequence was generated using a computer-based random number generator. Specifically, the website Randomization.com (https://www.randomization.com) was used to generate the block randomization sequence. The random allocation list was prepared before the start of participant recruitment by a technical assistant who was not involved in participant recruitment, intervention delivery, or outcome assessment. To ensure allocation concealment, the randomization sequence was placed in sequentially numbered, opaque, sealed envelopes. After a participant was confirmed eligible and formally enrolled, the next envelope in sequence was opened to reveal the assigned group. The principal investigator and the healthcare provider delivering the intervention were unaware of the allocation sequence prior to assignment. Due to the nature of the interventions (VR game intervention, mobile application use, or face-to-face counseling), blinding of participants and intervention providers was not feasible. However, to minimize potential bias, data analysis was conducted using anonymized group labels, so that the data analyst remained blinded to the actual group identities during statistical analysis.

Blinding (investigator's opinion)

Single blinded

Blinding description

Due to the nature of the intervention, blinding of participants and intervention providers was not feasible. However, data analysts were blinded to group allocation; all datasets were anonymized and provided with coded labels that contained no information about the intervention type. The analyst received only de-identified data files and had no knowledge of the participants' assigned groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Psychology Department, Tehran University

Street address

Faculty of Psychology and Education, University of Tehran, Dr. Kardan Street, Jalal Al-Ahmad Street, Shahid Chamran Expressway.

City

Tehran

Province

Tehran

Postal code

1445983861

Approval date

2025-11-19, 1404/08/28

Ethics committee reference number

IR.UT.PSYEDU.REC.1404.106

Health conditions studied

1

Description of health condition studied

Diabetes

ICD-10 code
E10
ICD-10 code description
Type 1 diabetes mellitus

Primary outcomes

1

Description
Weekly average daily monitored fast blood sugar (FBS)
Timepoint
Monitoring was conducted at baseline and then weekly for five weeks after the start of the study.
Method of measurement
Participants measured their fasting blood sugar levels every morning using a personal glucometer and self reported the values. The recorded daily FBS values were then used by the experimenters to calculate a weekly average for each participant.

2

Description
Weekly sum of daily calculated physical activity (PA)
Timepoint
Monitoring was conducted at baseline and then weekly for five weeks after the start of the study.
Method of measurement
Physical activity was quantified using a bar metric: one bar equaled either 30 minutes of vigorous activity (e.g., gym workouts or swimming) or 60 minutes of moderate activity (e.g., jogging). The weekly sum was calculated based on this definition.

3

Description
Weekly average daily calculated food intake (daily calories)
Timepoint
Monitoring was conducted at baseline and then weekly for five weeks after the start of the study.
Method of measurement
Participants either reported their total daily caloric intake directly or reported their food descriptions, from which caloric values were estimated. A weekly average of daily caloric intake was then computed.

4

Description
Weekly calculated BMI
Timepoint
Monitoring was conducted at baseline and then weekly for five weeks after the start of the study.
Method of measurement
Participants self-reported their weight on a weekly basis. BMI was calculated using the standard formula: weight (kg) divided by height squared (m^2), which had been reported at first.

5

Description
HbA1c pre-test and post-test
Timepoint
Monitoring was done, once before the beginning of the trial, and once, after the end of the trial.
Method of measurement
HbA1c levels were measured twice via laboratory blood tests: once before the intervention (pre-test) and once at the conclusion of the study (post-test), serving as a long-term indicator of blood glucose control.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1 (VR gamified group): A virtual reality–based gamification intervention designed to enhance diabetes self-care behaviors (physical activity, dietary adherence, and blood glucose monitoring). Participants in this group used the VR game “KallehGhandi,” which was specifically developed for this study. Number of sessions: 6 sessions. Duration of each session: approximately 30–45 minutes (in the clinic using a VR headset). Overall duration: 6 weeks (one weekly session after the start of the study).Session content: In each session, participants engaged in interactive, story-driven scenarios within the VR environment, where key diabetes self-care concepts (e.g., healthy food choices, appropriate physical activity, and blood glucose management) were presented as game-like challenges and missions. Immediate feedback, scoring, and level progression were used to strengthen intrinsic motivation and adherence to healthy behaviors. Initial orientation and guidance were provided by the healthcare team, and the VR sessions were delivered face-to-face under supervision.
Category
Behavior

2

Description
Intervention group 2 (Monitoring App group): Use of the commercial diabetes management application MySugr as a gamified self-care tool for logging and monitoring blood glucose and daily diabetes-related behaviors. Number of sessions: 6 training/follow-up sessions. Duration of each session: approximately 10-15 minutes. Overall duration: 6 weeks (one weekly session after the start of the study).Session content: During the first session, participants (and parents, when applicable) received face-to-face training on installing, setting up, and using the MySugr application, including logging FBS, physical activity, and food intake, viewing graphs and scores, and using reminder features. In the subsequent weekly sessions, app usage was reviewed, technical or practical

issues were addressed, and participants were encouraged to maintain regular daily logging. Guidance and recommendations were provided by the healthcare team, while the core intervention focused on daily self-directed use of the app.

Category

Behavior

3

Description

Intervention group 3 (Traditional counseling group): standard diabetes self-care education consistent with routine practice in specialized diabetes clinics in Iran. Number of sessions: 6 counseling sessions. Duration of each session: approximately 10-15 minutes. Overall duration: 6 weeks (one weekly session after the start of the study).Session content: Sessions were delivered by diabetes educators or trained nurses and included structured education on the nature of diabetes, the importance of regular blood glucose monitoring, dietary principles for children and adolescents with diabetes, practical recommendations for engaging in regular physical activity, and strategies for dealing with everyday challenges (e.g., parties, school, and sports activities). Each session included a brief review of the previous week's behaviors and individualized recommendations to improve adherence.

Category

Behavior

4

Description

Control group: Routine care without any additional structured self-care intervention. Number of sessions: 6 follow-up visits in line with routine clinical visits or brief assessment sessions. Duration of each session: approximately 10–20 minutes. Overall duration: 6 weeks (one weekly visit/assessment after the start of the study).Session content: Participants in this group received their usual medical care from the diabetes clinic, including physician visits, medication adjustments when needed, and general advice according to the standard protocol of the center. No extra structured program involving gamification, mobile applications, or specific educational counseling was provided, beyond the basic education normally offered as part of routine care for all patients at the clinic.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Children's Medical Care Center

Full name of responsible person

Dr. Arya Sotudeh

Street address

Children's Medical Center, Dr. Gharib Street, Keshavarz Boulevard, Tehran, Iran

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Grant for selected academic theses

Grant code / Reference number

-

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

Yes

Title of funding source

Psychology Department, Tehran University

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

Psychology Department, Tehran University

Full name of responsible person

Javad Hatami
Position
Professor
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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
Yes - There is 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
SPSS file named Diabetes Gamification
When the data will become available and for how long
Data is available upon reasonable request
To whom data/document is available
Practitioniers / Spacialists in health / psychology expertise
Under which criteria data/document could be used
Research Criteria in Health Interventions
From where data/document is obtainable
SPSS file located in google drive
What processes are involved for a request to access data/document
Formal request to first author/ Ruhollah Solat via email
Comments