

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Application carbohydrate counting application on daily blood sugar control and glycosylated hemoglobin level in children with diabetes type 1

Protocol summary

Study aim

Application carbohydrate counting application on daily blood sugar control and glycosylated hemoglobin level in children with diabetes type 1

Design

A randomized clinical trial with a control group, parallel groups, and a blind strain, on 100 patients with type 2 diabetes. The rand function of Excel software was used for randomization.

Settings and conduct

This study will be conducted in Akbar Hospital in Mashhad. A sugar counting app will be installed for caregivers of control group patients. Before and three months after the intervention in both groups, FBG, 2hpp, and Hb A1C will be taken. The study analyst will be blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Parents who have a child with type 1 diabetes, Patients with type 2 diabetes for at least three months, The age of a child with diabetes is 1 to 18 years, Literacy for reading and writing, Having a Android smartphone and internet access exclusion criteria: Having other chronic underlying diseases in children

Intervention groups

Intervention group: In this group, an Android app will be installed for parents of children with type 1 diabetes. Parents will record the food consumed by the child during the day in the app. The app will automatically calculate the consumed carbohydrates and the insulin dose of the child (based on the doctor's prescription). Before and three months after installing and using the app, fasting blood glucose (FBG), Two-Hour Postprandial Glucose (2hpp), and Hg A1C will be measured. Control group: There will be no intervention in this group. Only a notebook will be given to parents of children with diabetes to record insulin, FBG, 2hpp, and Hg A1C. In this group, before and three months after

receiving the notebook, fasting FBG, 2hpp, and Hg A1C will be measured.

Main outcome variables

fasting blood Glucose, Two-Hour Post Prandial blood Glucose, Glycated hemoglobin

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191026045251N3**

Registration date: **2023-03-04, 1401/12/13**

Registration timing: **registered_while_recruiting**

Last update: **2023-03-04, 1401/12/13**

Update count: **0**

Registration date

2023-03-04, 1401/12/13

Registrant information

Name

Mohamad hossein Mafi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3377 2208

Email address

mafimh971@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-21, 1401/09/30

Expected recruitment end date

2023-12-21, 1402/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Application carbohydrate counting application on daily blood sugar control and glycosylated hemoglobin level in children with diabetes type 1

Public title

Application carbohydrate counting application

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Parents who have a child with type 1 diabetes Children with at least 3 months history of diabetes The age of a child with diabetes is 1 to 18 years Literacy for reading and writing Having a smart phone and internet access The age of mothers of children with diabetes is between 18 and 60 Consent to participate in the study

Exclusion criteria:

Having other chronic underlying diseases in children with diabetes

Age

From **1 year** old to **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the participants are allocated to the intervention and control groups with Simple Blocked Randomization. The randomized unit is individual. First, blocks of four consisting of control group (2 people) and intervention group (2 people) will be formed. Based on this, 6 different sequences will be formed. After counting the blocks, the blocks will be randomly selected. The random selection continues forever until the sequence is determined for 100 people. The created sequence will be kept in a sealed envelope.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committee of School of Nursing and Midwifery, Mashhad University of Medical Sciences

Street address

School of Nursing and Midwifery, Gholestan Ave, Doctora Blvd, Mashhad Town

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Approval date

2022-07-05, 1401/04/14

Ethics committee reference number

IR.MUMS.NURSE.REC.1401.033

Health conditions studied**1****Description of health condition studied**

Type 1 diabetes mellitus

ICD-10 code

E10

ICD-10 code description

Type 1 diabetes mellitus

Primary outcomes**1****Description**

Fasting blood Glucose

Timepoint

Before and three months after the intervention

Method of measurement

glucometer (Glucose meter)

2**Description**

Two-Hour Postprandial Glucose

Timepoint

Before and three months after the intervention

Method of measurement

glucometer (Glucose meter)

3**Description**

Glycated hemoglobin

Timepoint

Before and three months after the intervention

Method of measurement

blood test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: In this group, an Android app will be installed for parents of children with type 1 diabetes. In this app, it is possible to determine the carbohydrate content of the child's food. Parents will record the food consumed by the child during the day in the app. The app automatically calculates the carbohydrates of the food consumed and the dose of insulin the child needs. The calculation formula will be based on the doctor's prescription. Also, the app has a notebook to record insulin and blood glucose fasting and two hours after a meal. In this group, before and three months after installing and using the app, fasting blood glucose levels, two-hour postprandial glucose, and Hg A1C will be measured.

Category

N/A

2

Description

Control group: In this group, parents of children with type 1 diabetes will be given a notebook. In this notebook, parents will record the amount of prescribed insulin, fasting blood glucose levels, two-hour postprandial glucose, and Hg A1C according to the table. The recording of the mentioned markers is based on the doctor's order. In this group, before and three months after receiving the booklet, fasting blood glucose levels, two-hour postprandial glucose, and Hg A1C will be measured..

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Akbar Hospital

Full name of responsible person

Dr. Hossein Mohsenzadeh

Street address

Knowledge and Health City-Shahid Fakouri Blvd-
Fakouri #94

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Mashhad

Province

Razavi Khorasan

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9177897157

Phone

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Email

ak.pr@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Majid Ghayoor Moarhan

Street address

Deputy of Research and Technology, Ghorashi
Building, next to Hoveyzeh Cinema, University Street

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Mashhad

Province

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9138813944

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vcresraech@mums.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Mashhad University of Medical Sciences

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

Mashhad University of Medical Sciences

Full name of responsible person

Tahereh Sadeghi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

School of Nursing and Midwifery, Ibn Sina Ave,
doctora Crossroads, university Blve

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Tahereh Sadeghi
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Ph.D.
Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Mohamad Hossein Mafi
Position
MSc
Latest degree
Master

Other areas of specialty/work

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Email
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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

Information about main outcome variables is shared.

When the data will become available and for how long

One year after the results are published

To whom data/document is available

Researchers of medical sciences of reputable scientific institutions

Under which criteria data/document could be used

Analysis of the main variable - if there is a need to publish, permission must be obtained from the researchers of the present project.

From where data/document is obtainable

Person responsible for general inquiries email

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

A maximum of one month after the applicant's email

Comments