

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Design, implementation and evaluation of family-centered intervention program on adherence to treatment in Type 2 Diabetic patients

Protocol summary

Study aim

Determining the effectiveness of a family-oriented intervention program on treatment adherence in patients with type 2 diabetes

Design

The clinical trial will have a control group, randomized, on 110 patients, and randomization will be done by a statistician using the Balanced Blocked randomization method.

Settings and conduct

The intervention group will receive the family-oriented intervention program under the application for 8 weeks, and the control group will receive the usual diabetes programs in the center.

Participants/Inclusion and exclusion criteria

Inclusion criteria: proven type 2 diabetes; HbA1c level equal to or greater than 7; age range of 18 to 60 years old; literate in reading and writing; have a mobile phone personally or in the family in order to participate in the program; do not have debilitating diseases (such as liver failure, psychological diseases, kidney failure, etc.).

Exclusion criteria: hospitalization during the study for any reason; suffering from serious diseases such as diabetic ketoacidosis or hyperglycemic non-ketogenic hyperosmolar syndrome.

Intervention groups

The intervention group: the group of diabetic patients under family-oriented intervention and the control group: the group of diabetic patients receiving the usual programs of the diabetes center

Main outcome variables

Adherence to treatment

General information

Reason for update

Due to illness and knee injury, my start of work was delayed for a while. Furthermore, since my place of study is in Isfahan, it was not agreed to start and conduct

research outside of Isfahan. On the other hand, my place of work and life is in Karaj, and my leave was not agreed to at work due to my previous sick leave and severe shortage of staff. Therefore, due to the problems that have arisen, the start of my research work and sampling has been delayed. Given the tacit agreement of my place of work to take leave, I will start my research work in Isfahan.

Acronym

IRCT registration information

IRCT registration number: **IRCT20220907055909N1**

Registration date: **2022-10-03, 1401/07/11**

Registration timing: **prospective**

Last update: **2025-12-23, 1404/10/02**

Update count: **1**

Registration date

2022-10-03, 1401/07/11

Registrant information

Name

Seyedeh Azemat Mousavifar

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-02-27, 1404/12/08

Expected recruitment end date

2027-03-11, 1405/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Design, implementation and evaluation of family-centered intervention program on adherence to treatment in Type 2 Diabetic patients

Public title
Investigating the effect of family-centered intervention on adherence to diabetes treatment

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Have type 2 diabetes and their diabetes has been diagnosed and confirmed by a doctor before registration
 Have diabetes for at least 6 months HbA1c level equal to or greater than 7 Be in the age range of 18 to 60 years old Be literate in reading and writing Have a phone at home Have a mobile phone personally or in the family in order to participate in the program Do not have disabling physical problems and diseases Are not pregnant and do not intend to become pregnant during the study period Do not suffer from known psychological diseases Do not suffer from serious diseases (such as liver failure, kidney failure, etc.) Willing to participate in the study and complete the informed consent form Do not currently participate in other research studies. Family member entry criteria: Be over 18 years old Do not have diabetes Be a First degree family member (wife, child, parent, sister or brother) Be literate in reading and writing Willing to participate in the study Can use a smartphone
Exclusion criteria:
 Being hospitalized during the study for any reason Suffering from diabetic ketoacidosis or hyperglycemic hyperosmolar Nonketotic syndrome Suffering from serious diseases such as advanced form of cardiovascular diseases, uncontrolled high blood pressure, psychological disorders, severe vision disorders, psychiatry diseases or suffering from physical or mental problems preventing participation in the research Unwillingness of the patient or family member to participate or continue cooperation

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **110**

Randomization (investigator's opinion)
Randomized

Randomization description

In this study, research samples are first selected based on the available criteria and then randomly (Block Randomization) are divided into intervention and control groups. In this method, block randomization is used; Blocking is used in order to balance the number of samples allocated to each of the studied groups, so that since we have two groups under study, we use equal blocks of 4 and create all possible states of 4. Then, the sequence of the blocks is determined with the simple randomization service software, and since the sample size in this study is 110 people (55 people in each group), 28 blocks of 4 are used. Blocked randomization method Balanced and using Sealed Envelope Ltd web software. It is 2020. The method of random allocation is using blocks of size 4. Randomization will be performed by a statistician, who will have no contact with the patients. Researchers and study participants are unaware of the randomization sequence. After confirming the patient's entry into the study, the clinical researcher places the patient in the intervention groups by registering the patient's code based on the determined random sequence.

Blinding (investigator's opinion)

Double blinded

Blinding description

Randomization will be performed by a statistician, who will have no contact with the patients. Researchers and study participants are unaware of the randomization sequence. After confirming the patient's entry into the study, the clinical researcher places the patient in the intervention groups by registering the patient's code based on the determined random sequence.

Placebo

Not used

Assignment

Parallel

Other design features

The studied patients will be examined and compared in 2 groups. A control group is diabetic patients who receive routine care. The family members are present with the patient and in this group the patient and the family member are considered as an intervention unit, the training is provided to the patient himself and the families do not participate in educating and informing the patient and play a passive role or They have a patio. In the intervention group, the family member will participate directly in the clinical care processes. Family members are considered as independent units and direct contributors. In this group, the intervention is done on the family members and the family member plays the main role. In this group, the application is installed on the family member's mobile phone or tablet, the family member is taught how to perform the intervention and how to use it (receiving training and compliance programs for family-oriented treatment through the application) and answers to the existing problems. It will be given. In this group, patients will receive the usual care and family members (not patients) as patient supporters, will receive the necessary training in the field of diabetes control through the installation of the designed application. All educational programs using the application with Various methods such as text, images,

videos, listening profile and multimedia are presented to the intervention group and the convenience of family members to receive information is also considered and patients and their family members are advised to Ask any questions or problems regarding how to use the application. In addition to that, training on how to use the application is sent in the form of video and text in the application, and one day after receiving the application, the training will be sent weekly in the application. Submissions will be based on the constructs of awareness, perceived threat, perceived benefits, perceived barriers, perceived self-efficacy, outcome expectations (positive outcomes), self-regulation, and perceived social support. For example, for the perceived threat regarding the complications caused by diabetes, an educational video on foot injury and diabetic foot ulcer will be shown, and the statistics related to leg amputation due to diabetes and lack of blood sugar control will be displayed as a message. Or for self-efficacy in the field of how to perform a daily foot examination by the person himself, it is taught step by step through the video so that the person is able to perform the foot examination alone. Data collection will be done at the beginning of the study and 3 months after the intervention.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committees of Medical University of Isfahan

Street address

Department of Health Education and Health Promotion, School of Health, Isfahan University of Medical Sciences, Hezar Jerib Street.

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Province

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Postal code

81746-73461

Approval date

2022-08-22, 1401/05/31

Ethics committee reference number

IR.MUI.RESEARCH.REC.1401.189

Health conditions studied

1

Description of health condition studied

Type 2 diabetes

ICD-10 code

E11.9

ICD-10 code description

Type 2 diabetes mellitus without complications

Primary outcomes

1

Description

Medication compliance score

Timepoint

Before the intervention and 3 months after the intervention

Method of measurement

Morisky Medication Adherence Scale

2

Description

Physical activity score

Timepoint

Before the intervention and 3 months after the intervention

Method of measurement

International Physical Activity Questionnaire (IPAQ)

3

Description

Self-Efficacy Scale

Timepoint

Before the intervention and 3 months after the intervention

Method of measurement

Diabetes Management Self-Efficacy Scale(DMSES)

4

Description

Self-care behaviors score

Timepoint

Before the intervention and 3 months after the intervention

Method of measurement

Summary of Diabetes Self Care Activities (SDSCA)

5

Description

Perceived family social support score

Timepoint

Before the intervention and 3 months after the intervention

Method of measurement

Diabetes Specific Family Support Scale

6

Description

Self-regulation score in treatment

Timepoint

Before the intervention and 3 months after the intervention

Method of measurement

Treatment Self-Regulation Questionnaire (TSRQ)

Secondary outcomes

1

Description

Glycosylated hemoglobin

Timepoint

Before the intervention and 3 months after the intervention

Method of measurement

Blood sample test

Intervention groups

1

Description

Intervention group: This group will receive the intervention under the application on the mobile phone for 8 weeks, and all educational programs will be presented to the intervention group using the application in various ways, including text, images, videos, audio profiles, and multimedia.

Category

Behavior

2

Description

Control group: This group will receive the usual programs at the diabetes center.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Sedigheh Tahereh Educational, Therapeutic and Research Complex

Full name of responsible person

Seyedeh Azemat Mousavifar

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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 code / Reference number

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

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Seyedeh Azemat Mousavifar

Position

PhD student

Latest degree

Master

Other areas of specialty/work

Health Promotion

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available