

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Investigating the effect of implementing the 5A self-management model on the understanding of the facts of heart diseases and adherence to the treatment regimen in patients with type 2 diabetes under the comprehensive health service centers of Isfahan 1402

Protocol summary

Study aim

Determining the effect of the implementation of A5 self-management model on the understanding of the facts of cardiovascular diseases and adherence to treatment regimen in type 2 diabetes patients.

Design

In a clinical trial with a control group, with parallel groups, without blinding, randomized, on 70 people with type 2 diabetes, a systematic method is used for randomization.

Settings and conduct

The research population is type 2 diabetes patients who will be selected systematically. The setting of the intervention is the comprehensive health service centres of Isfahan City. One centre is randomly selected and assigned to the intervention group, and then from among the centres If the social and economic conditions are Similar with the centre of the intervention group, one centre will be randomly selected and the subjects of the control group will be selected in it. The intervention group will receive the educational program based on the 5A self-management model in 5 stages. It includes review, guidance, agreement, assistance and follow-up. The control group will receive routine care.

Participants/Inclusion and exclusion criteria

The main inclusion criteria: suffering from type 2 diabetes, at least one year has passed since the diagnosis of type 2 diabetes. Major conditions for Exclusion criteria: unwillingness to participate in the study, cardiovascular disease, not suffering from cardiovascular disease, cognitive disorders, and mental retardation.

Intervention groups

The study has two groups. The intervention group receives the educational program based on the 5A self-management model, and the control group receives

heroin care.

Main outcome variables

Adherence to the treatment regimen, Understanding the facts of heart diseases

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130801014242N4**

Registration date: **2023-06-16, 1402/03/26**

Registration timing: **prospective**

Last update: **2023-06-16, 1402/03/26**

Update count: **0**

Registration date

2023-06-16, 1402/03/26

Registrant information

Name

Maryam Shirazi

Name of organization / entity

Isfahan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-20, 1402/03/30

Expected recruitment end date

2023-09-23, 1402/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of implementing the 5A self-management model on the understanding of the facts of heart diseases and adherence to the treatment regimen in patients with type 2 diabetes under the comprehensive health service centers of Isfahan 1402

Public title

The effect of the 5 A self-management model on the understanding of the facts of heart diseases and adherence to treatment regimen

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Be Persian speaking. At least one year has passed since the definitive diagnosis of type 2 diabetes Do not have any underlying disease that hinders speech and understanding, including cognitive, visual, and motor sensory diseases such as severe depression, mental retardation, and Parkinson's. Have minimum reading and writing literacy. Have an active file in comprehensive health service centers of Isfahan city. Be Iranian.

Exclusion criteria:

Aggravation of the disease from the time of the phone call to the time of attending the center to complete the questionnaires and perform the intervention that leads to hospitalization or death of the samples. Cardiovascular diseases The patient does not want to cooperate in the study.

Age

From **40 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done in three stages. In the first stage, between Isfahan health network one and Two, one of the centre's number one or two will be chosen randomly (tossing a coin) and then the list of comprehensive health service centres of this centre will be prepared. In the second stage, a centre will be selected by lottery as the intervention group, and the control group to be homogenous in terms of social and economic conditions with the subjects of the intervention centre, among the comprehensive health service centres

listed in the vicinity of the centre of the intervention group, A centre will be selected as a control group by drawing lots. In the third stage, in the centres selected by the researcher, through the Sib system, the head of the centre will prepare a list of all the people who meet the criteria for entering the study and will systematically select the subjects, in such a way that first, the total number of the population Divide the research by the required number of subjects to get the K number. Then randomly, the first number below ten is obtained, which is called n. Then the numbers N+K, N+2K, N+3K,... will be selected until the last subject.

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**

Ethics Committee of Isfahan University of Medical Sciences

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Faculty of Nursing and Midwifery, Isfahan University of Medical Sciences, Hazar Jarib Street

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8174673461

Approval date

2023-05-13, 1402/02/23

Ethics committee reference number

IR.MUI.NUREMA.REC.1402.028

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

Type 2 diabetes

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes

1

Description

Adherence to treatment regimen score in the Modanlo questionnaire/Score of understanding the facts of heart diseases in the Wegener heart disease facts questionnaire

Timepoint

At the beginning of the study, immediately and 2 months after the start of the intervention

Method of measurement

Questionnaires of the facts of Wegener's heart disease and adherence to Modanlo's treatment regimen

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Before starting the study, the intervention group completed demographic questionnaires, understanding the facts of heart diseases and adhering to the treatment regimen, and for them, a self-management program based on the 5A model is implemented in 5 stages. The 5 stages include examination, guidance, agreement, help and follow-up. The first 3 stages will be held individually and the 4th stage will be held in groups of 8 to 12 people for 1 to 2 hours in the form of peer group training. The follow-up stage will also be done by phone. At the end (immediately and two months after the intervention), the questionnaires on understanding the facts of cardiovascular diseases and adherence to the treatment regimen will be completed again in the intervention group.

Category

Treatment - Other

2

Description

Control group: Control group: Before starting the study, the control group will complete demographic questionnaires, understand the facts of heart diseases and adhere to the treatment regimen, and will receive the usual care. At the end (immediately and two months after the intervention), the questionnaires of understanding the facts of cardiovascular diseases and adherence to the treatment regimen will be completed again in the control group. After the intervention, at the end of the study, the educational content will be provided to the control group and a training session will be held for this group.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan comprehensive health service centers

Full name of responsible person

Maryam Shirazi

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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

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Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

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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

Not applicable

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

Not applicable

Data Dictionary

Not applicable