

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Effectiveness of health literacy intervention on awareness, medication adherence and blood pressure levels in rural patients with cardiac ischemia

Protocol summary

Study aim

Determining the effectiveness of health literacy intervention on awareness, medication adherence and blood pressure in patients with ischemic heart

Design

A randomized, single-blinding clinical trial, with the parallel groups, Phase 3 on 100 patients

Settings and conduct

In this randomized, single-blind clinical trial study, 100 eligible patients will be included in the study under the coverage of Isfahan health and treatment centers and will be randomly divided into two groups. The patients in the first group will be under health literacy educational intervention and the patients in the second group will be without education. Then the level of acknowledgement, medication adherence and blood pressure levels of the patients will be evaluated and compared between the two groups.

Participants/Inclusion and exclusion criteria

The inclusion criteria in the study include patients with cardiac ischemia, in the age group of 30 to 65 years, and who are willing to participate in the study. Exclusion criteria include lack of literacy and less than one year of disease onset.

Intervention groups

Control group: patients in this group will not undergo any educational intervention. Intervention group: Patients in this group will undergo health literacy training during five 60-minute training sessions.

Main outcome variables

Acknowledgement, Medication adherence; Blood pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200825048515N64**

Registration date: **2023-02-11, 1401/11/22**

Registration timing: **registered_while_recruiting**

Last update: **2023-02-11, 1401/11/22**

Update count: **0**

Registration date

2023-02-11, 1401/11/22

Registrant information

Name

Asieh Maghami Mehr

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 0000 0000

Email address

asimaghami@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-22, 1401/06/31

Expected recruitment end date

2023-03-21, 1402/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of health literacy intervention on awareness, medication adherence and blood pressure

levels in rural patients with cardiac ischemia

Public title

Effectiveness of health literacy intervention on awareness, medication adherence and blood pressure in patients with cardiac ischemia

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with cardiac ischemia Age category 30 to 65 years Consent to participate in the study

Exclusion criteria:

Lack of literacy Less than one year of disease onset

Age

From **30 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, 100 eligible patients are randomly selected. For this, the letter A is written on 50 sheets, the letter B is written on 50 sheets, and each of them is placed in an envelope. Each patient is then asked to choose one of the envelopes. Depending on the selected envelope, the patient is assigned to one of two groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

According to the nature of the present study and conducting the educational intervention in only one group, the interventionist and the patient are aware of the type of intervention in each group, but the investigator and the statistical analyst will not be aware of the type of intervention in each group.

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

Street address

Street address Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq

City

Isfahan

Province

Isfahan

Postal code

8179964167

Approval date

2019-07-28, 1398/05/06

Ethics committee reference number

IR.MUI.MED.REC.1398.260

Health conditions studied

1

Description of health condition studied

Ischemic heart

ICD-10 code

I24.9

ICD-10 code description

Acute ischemic heart disease, unspecified

Primary outcomes

1

Description

Drug knowledge

Timepoint

Before and 1 month after the educational intervention

Method of measurement

Questionnaire

2

Description

Adherence to treatment

Timepoint

Before and 1 month after the educational intervention

Method of measurement

Questionnaire

3

Description

Blood pressure

Timepoint

Before and 1 month after the educational intervention

Method of measurement

Sphygmomanometer

Secondary outcomes

empty

Intervention groups

1

Description

Control group: patients in this group will not undergo any educational intervention

Category

N/A

2

Description

Intervention group: Patients in this group will undergo health literacy training during five 60-minute training sessions. In this way, in the first session, the patient is introduced. In the second session, after a brief review of the previous session and encouraging the patients; There will be a discussion about the disease and their medicines and the effect of the medicine for them. In the third session, after a short review of the previous session using questions and answers from the patients; The patients are requested to explain how to take their medicines and express their experiences regarding how to take the medicine and the feedback they have had in this regard in the meeting. In the fourth session, after a brief review of the previous session and the importance of correct drug use, the serious side effects of these drugs are discussed and an attempt is made to familiarize the patients with the symptoms of these side effects. In the fifth session, after a short review of the previous session and a discussion about the questions that have arisen for the patients and solving their needs and solving their stress and uncertainties; Finally, the therapeutic purpose of using these drugs will be stated.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan Health Center

Full name of responsible person

Arash Najimi

Street address

Faiz Street, Sheikh Mofid Street

City

Isfahan

Province

Isfahan

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8164969459

Phone

+98 31 3661 7371

Email

najimiarash@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mansour Siavash Dastjerdi

Street address

Vice Chancellor for Research, School of Medicine,
Hezar Jarib Street, Isfahan.

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 8597

Email

dean@med.mui.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Isfahan 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

Soheila Amini

Position

Non-faculty specialist doctor

Latest degree

Specialist

Other areas of specialty/work

Family Physician

Street address

Faculty of Medicine, Department of Family Medicine

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3792 8092

Email

soheila.amini120@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Soheila Amini

Position

Non-faculty specialist doctor

Latest degree

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available