

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

The effect of home based nurse- led cardiac rehabilitation on adherence to therapeutic regiments in patients with myocardial infarction

Protocol summary

Study aim

Determining the effect of cardiac rehabilitation of home-based guidance nurse on adherence to treatment in patients with myocardial infarction

Design

Randomized clinical trial, Parallel, one-way blind, with control group, eligible individuals (78 people) and in each group randomly block with four blocks of random allocation will be performed using Excel software

Settings and conduct

Patients are selected from the heart ward of Shariati Hospital based on the inclusion criteria and the rehabilitation of the supervising nurse is performed with the necessary coordination in the patient's home and using the means of communication. All participants believe they were involved in the intervention, even though some did not. We send a written consent and an online questionnaire to all participants with a description of the research. Then the necessary coordination is done with the test group Placed.

Participants/Inclusion and exclusion criteria

Patients between 40-65 years 6-12 months with myocardial infarction - Has not participated in the training program - Apart from the underlying diseases, the cause of myocardial infarction is not a disease or a cognitive problem. Failure to respond to a home visit more than once Acute disease with the need for hospitalization and surgery

Intervention groups

For the test group (39 people) 4 sessions once a week, and for questions and answers until the post-test, continuous communication will be used using communication tools. The control group will receive routine care in the hospital and then, they will be provided with an educational booklet on the topic of following treatment for myocardial infarction.

Main outcome variables

Adherence to treatment, diligence in treatment, willingness to participate in treatment, ability to adapt,

integration of treatment with life, clinging to treatment, commitment to treatment, tact in implementing treatment

General information

Reason for update

Acronym

HBCR

IRCT registration information

IRCT registration number: **IRCT20201006048953N1**

Registration date: **2020-12-24, 1399/10/04**

Registration timing: **prospective**

Last update: **2020-12-24, 1399/10/04**

Update count: **0**

Registration date

2020-12-24, 1399/10/04

Registrant information

Name

Zohreh Parsaeian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2201 6435

Email address

zohrehparsaeian@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-04, 1399/10/15

Expected recruitment end date

2021-02-19, 1399/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of home based nurse- led cardiac rehabilitation on adherence to therapeutic regiments in patients with myocardial infarction

Public title

The effect of home based nurse- led cardiac rehabilitation on patients with myocardial infarction

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

The definitive diagnosis of myocardial infarction is based on the opinion of a cardiologist for 6-12 months. Literacy Speaking Persian Lack of communication and cognitive problems No other underlying diseases (except diseases that lead to myocardial infarction), Resides in Tehran Age between 40-65 years

Exclusion criteria:

Failure to respond to a home visit more than once Acute disease with the need for hospitalization and surgery

AgeFrom **40 years** old to **65 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Participant

Sample sizeTarget sample size: **78****Randomization (investigator's opinion)**

Randomized

Randomization description

Given the four classes (women under 50, women equal to or older than 50, men under 50 and men equal to or older than 50) each class will use a quadruple random block (in each The following four states may occur: (I = Intervention & C = control) 1- (IICC) 2- (ICIC), 3- (ICCI), 4- (CICI), 5- (CCII), 6- (CIIC) The order in which each of the above blocks is placed will be determined by the software, then the cards will be sorted according to the specified order and the entry row (according to the order of entry) and the type of assigned group will be covered. Each person's entry into the study of the assigned group will be determined by removing the cover from each intervention or control group card. It should be noted that on the cover of each card, a row of cards is written (meaning that this is the second person in the desired category to enter the study) and before opening the cover, another researcher checks the entry row of the person in the floor with the check tables. And then the cover of the card will be opened and the type of individual group (intervention group or control group) will be specified.

Blinding (investigator's opinion)

Single blinded

Blinding description

All participants thought they were involved in the intervention, even though some did not. The researcher sends a written consent and an online questionnaire to all participants and it is explained to them that they participate in the research. After random allocation and selection of the test group, the necessary coordination is done with the test group Placed.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Tehran University of Medical Sciences

Street address

Floor 5, Number 30, Zeinab Alley, Mohry Alley, Valiasr Street, Tehran

City

Tehran

Province

Tehran

Postal code

1966765664

Approval date

2020-08-24, 1399/06/03

Ethics committee reference number

IR.TUMS.FNM.REC.1399.092

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

Myocardial Infraction

ICD-10 code

I21

ICD-10 code description

ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction

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

Adherence to therapeutic regiments

Timepoint

Beginning of research and after 3 months from the start of research

Method of measurement

Madanlu Treatment Adherence Questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Cardiac rehabilitation of a guiding nurse at home in 4 sessions with lifestyle modification topics in the field of stress management, healthy nutrition and exercise that is done by the researcher and patients are followed for 3 months and patients' weight and blood pressure control is done and educational pamphlet in It is at the disposal of the patients. Patients in 4 sessions of one and a half hours at home and through virtual educational topics on heart function, blood pressure and heart attack, the effects of exercise and walking on weight control and better heart function, healthy and unhealthy stress management, DASH diet (including vegetables , Sausages, sprouts, whole grain breads and white meat protein) and instructional videos. Patients walk 30 minutes a day and do health meditation, are followed up electronically within two months of training, and patients' questions are answered during this time. Weight and blood pressure are controlled. At the beginning and end of this course, patients take an online questionnaire of demographic information and adherence to Madanlu treatment.

Category

Rehabilitation

2**Description**

Control group: They receive only the usual care (Includes medication, doctor visits and tests) after discharge from the hospital and at the end, an educational pamphlet is provided to the patients.

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shariatee Hospital

Full name of responsible person

Dr. Mehrpour Mohammadabadi

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Tehran, North Kargar Street, Jalal Al-Ahmad Three Ways

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shariatihosp@tums.ac.ir

Web page address

http://shariati.tums.ac.ir/

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mehrnaz Granmayeh

Street address

Tehran, Tohid Square, Tehran School of Nursing and Midwifery

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Tehran

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Email

pajoheshyar@sina.tums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Zohreh Parsaeian

Position

Nurse, Bedside Instructor, Technical Assistant

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Zohreh Parsaeian

Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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Latest degree

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Other areas of specialty/work

Nursery

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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 more information

Study Protocol

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

Statistical Analysis Plan

No - There is not 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

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

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