Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Investigating the effect of medication self-management intervention based on the 5A model on medication adherence and quality of life of myocardial infarction patients hospitalized in Jahrom medical sciences hospitals

Protocol summary

Study aim
Determining the effect of medication self-management intervention based on the 5A model on medication adherence and quality of life of heart attack patients hospitalized in Jahrom Medical Sciences affiliated hospitals in 2024

Design
A clinical trial with a control group, with a parallel group, a blind strain, randomized, will be used on 66 patients

Settings and conduct
In this way, the letters A and B will be written on small cards, and kept in a closed envelope. At the beginning of each week, the door of one of the envelopes is randomly opened and based on the writing on the card, it will be determined that during that week, the samples will be placed in the intervention or control group.

Participants/Inclusion and exclusion criteria
Inclusion criteria include: being literate, age range between 30 and 65 years old, diagnosis of myocardial infarction by a doctor, not having a history of previous myocardial infarction, hospitalized patients for at least three days, having one of blood pressure diseases, diabetes or Blood lipids that have taken medicine for at least six months are the ability to perform self-care, especially the consumption and adherence to the drug regimen, the ability to prepare and buy prescribed drugs, and the patient's non-participation in other educational plans for self-care methods. Exclusion criteria include: death of the patient during the study, non-participation of the patient in telephone follow-up and completion of the questionnaire.

Intervention groups
Medication self-management intervention will be done for patients in the intervention group, which will use face-to-face training and question and answer, and the control group will only receive the usual care in their care and treatment process.

Main outcome variables
Medication Adherence quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20231227060543N1**
Registration date: **2024-01-17, 1402/10/27**
Registration timing: **prospective**

Last update: **2024-01-17, 1402/10/27**
Update count: **0**

Registration date
2024-01-17, 1402/10/27

Registrant information

Name
Mahsa Heydari aghcheghlo

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-01-21, 1402/11/01

Expected recruitment end date
2024-05-04, 1403/02/15

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of medication self-management intervention based on the 5A model on medication adherence and quality of life of myocardial infarction patients hospitalized in Jahrom medical sciences hospitals

Public title
effect of medication self-management intervention based on the 5A model on medication adherence and quality of life of myocardial infarction patients
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Literacy Age range between 30 and 65 years Diagnosis of myocardial infarction by a doctor Have no previous history of myocardial infarction Hospitalized patients for at least three days Having one of the diseases of blood pressure diabetes or hyperlipidemia that they have taken for at least six months The ability to perform self-care, especially the consumption and adherence to the medication regimen Ability to prepare and buy prescribed drugs The patient's non-participation in other educational plans of self-care methods
Exclusion criteria:
Patient death during the study Non-participation of the patient in telephone follow-up and questionnaire completion
Age
From **30 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **66**
Randomization (investigator's opinion)
Randomized
Randomization description
The samples will be randomly assigned to two intervention and control groups in such a way that the letters A and B will be written on small cards, and kept in a closed envelope. At the beginning of each week, the door of one of the envelopes is randomly opened and based on the writing on the card, it will be determined that during that week, the samples will be placed in the intervention or control group.
Blinding (investigator's opinion)
Single blinded
Blinding description
The samples will be assigned to two intervention and control groups in such a way that the letters A and B will be written on small cards, and kept in a closed envelope. At the beginning of each week, the door of one of the envelopes is randomly opened and based on the writing on the card, it will be determined that during that week, the samples will be placed in the intervention or control group. Patients do not know about the interventions performed for the other group, and which group they belong to. This intervention is performed by the researcher himself, so the researcher is not blinded.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Jahrom university of Medical Sciences
Street address
Jahrom University of Medical Sciences - campus site, Ostad Motahari St., Jahrom town
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Jahrom
Province
Fars
Postal code
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Approval date
2023-12-23, 1402/10/02
Ethics committee reference number
IR.JUMS.REC.1402.103

Health conditions studied

1

Description of health condition studied
Myocardial infarction
ICD-10 code
I21
ICD-10 code description
ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction

Primary outcomes

1

Description
Medication adherence score in Morisky questionnaire
Timepoint

Measurement of medication adherence at the beginning of the study (before the start of the intervention) and six weeks after the start of the intervention

Method of measurement

Moriski medication adherence questionnaire

Secondary outcomes

1

Description

Quality of life score

Timepoint

At the beginning of the study (before the start of the intervention) and six weeks after the start of the intervention

Method of measurement

Mac New Quality of Life Questionnaire

Intervention groups

1

Description

"Intervention group" After each patient is randomly assigned in two Test and control groups, the demographic information questionnaire, the morrisky drug compliance questionnaire, the quality of life questionnaire, will be completed by each patient before the intervention is performed. Then the drug self-management intervention will begin for patients of the intervention group, which will use face-to-face training and Q & A.The planned educational content for the intervention group includes a program to promote drug self-management (information related to medications taken, long-term drug regimen compliance, drug complications, and disease management). The intervention follows the following steps in five face-to-face sessions on the second and third days of hospitalization in two shifts in the morning and evening and in the shift when discharging patients for each participant of the intervention group, which will be presented for 20 minutes in the patient's clinic in the hospital by creating a private environment. But this period can be extended based on the needs of patients. After discharge, 8 phone calls will also be made to follow up on patients. In the first two weeks, the phone call will be made three days in between(twice a week) and after two weeks, for four weeks, once a week until the end of the intervention period. The intervention will be implemented on the following basis(self-management model 5A).Review stage: at this stage, the patient will be examined in person in terms of the history of the disease, the underlying disease, the recognition of previous medications, the use of medications, the occurrence of drug complications.Guidance stage: at this stage, based on the results of previous stage studies, the risks of drug non-compliance diagnosed will be communicated to the patient and the benefits of behavior change will be emphasized. The importance of controlling the disease, the importance of taking medicines and the diet, and the consequences of not taking medicines are discussed, and the patient is encouraged to express his experiences of taking medicines and build trust. The benefits and importance of drug compliance in preventing disease complications will be explained.Agreement stage: a written agreement on the patient's performance will be made to set goals between the patient and the researcher. According to the diagnosed problems, appropriate and agreed goals will be set with the patient and an action plan will be drawn up for each of the goals.(For example, in patients who arbitrarily discontinue the drug by observing signs of recovery, the risks of not taking the drug and its importance to health will be explained, and a written agreement will be made between the patient and the researcher regarding the timely use of the drug and the time of its use.)Assistance phase: this phase involves cooperation in the development of the action plan(compliance with drug therapy). At this stage, which will be done during the shift during discharge, the patient will be given face-to-face training to teach about the medication regimen during discharge and control of his vital signs, and will be practiced. At this stage, training will be held with the aim of promoting patient awareness of medicines and providing patient and researcher experience, in which previous training materials will be reviewed. Care for medications and possible complications will also be expressed again.Performance follow-up: at this stage, patients ' performance will be followed up for 6 weeks. To ensure the implementation of action plans by patients, the first two weeks will be followed up by phone calls three days in between and after two weeks, for four weeks, once a week until the end of the intervention period. The calls will review the agreed action plan and objectives, and if necessary if changes are needed to the objectives and / or action plan will be made by re-agreement. Then at the end of the intervention, the variables of drug compliance and quality of life will be measured in two groups, and if necessary, if changes are needed in the objectives or action plan, the necessary changes will be applied by re-agreement. Then at the end of the intervention(at the end of the sixth week), the questionnaire on drug compliance and quality of life will be asked again by telephone and completed.

Category

Lifestyle

2

Description

Control group: "Patients in the control group" will fill in the medication compliance and quality of life questionnaire in the hospital and will only receive the usual care in their care and treatment process. Then, at the end of the intervention (at the end of the sixth week), the medication compliance and quality of life questionnaire will be administered by telephone again. will be asked and completed.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Seyyed al-Shohada Hospital
Full name of responsible person
Mahsa Heydari Aghchghlo
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2

Recruitment center

Name of recruitment center
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Jahrom 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
Jahrom University of Medical Sciences
Full name of responsible person
Mahsa Heydari Aghcheghlo
Position
Master's student in internal and surgery medicine
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Person responsible for updating data

Contact
Name of organization / entity
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Mahsa Heydari aghcheghlo
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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