Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of discharge plan training based on Orem self-care model on hope and adherence to treatment in patients undergoing coronary angioplasty

Protocol summary

Study aim

Determining the effect of Orem self-care model discharge training on hope, lifestyle and adherence to treatment in patients undergoing coronary angioplasty

Design

The present study is a randomized clinical trial without blinding performed on 90 patients undergoing coronary angioplasty. Sampling by sampling method will be available. The allocation of the sample in the intervention and control group is simple randomly, so that in a 90-card envelope, the letters A are written on 45 cards and the letters B are written on the other 45 cards. Patients who meet the intervention criteria are asked to pick up a card, if they pick up card A they will be in the intervention group and if they pick up card B they will be in the control group.

Settings and conduct

The present study is a randomized clinical trial study without blinding that is performed on 90 patients undergoing angioplasty referred to Vali Asr Hospital in Fasa, south of Fars province.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Literacy, no mental problems, minimum age 40 and maximum age 55 and willingness to participate in the study voluntarily. Exclusion criteria: Being illiterate, Having heart, kidney, lung and liver failure, Suffering from acute and chronic psychological disorder and intellectual disability

Intervention groups

For the intervention group, a training program based on the Orem self-care model will be designed and implemented in the form of 6 sessions. One-hour classes will be held in the form of group discussions and lectures with educational pamphlets. The control group will not receive training intervention, but will be provided with a training package

Main outcome variables

Hope, lifestyle, adherence to treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190917044802N5**
Registration date: **2022-07-17, 1401/04/26**
Registration timing: **prospective**

Last update: **2022-07-17, 1401/04/26**
Update count: **0**

Registration date

2022-07-17, 1401/04/26

Registrant information

Name

Mostafa Bijani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 5331 5012

Email address

bizhani_mostafa@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-23, 1401/05/01

Expected recruitment end date

2022-10-23, 1401/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of discharge plan training based on Orem self-care model on hope and adherence to treatment in patients undergoing coronary angioplasty

Public title
The effect of discharge plan training based on Orem self-care model on hope and adherence to treatment in patients undergoing coronary angioplasty

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Be literate No mental problem Minimum age 40 years and maximum age 55 years Willingness to participate in the study voluntarily

Exclusion criteria:
being illiterate Having heart, kidney, lung and liver failure Suffering from acute and chronic psychological disorder and intellectual disability

Age
From **40 years** old to **55 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
The allocation of the sample in the intervention and control group is randomly simple, as in a 90-card envelope with the letters A written on 45 cards and the letters B on the other 45 cards. Patients who meet the inclusion criteria are asked to pick up a card, if they pick up card A they will be in the intervention group and if they pick up card B they will be in the control group and this process will continue until the sample size is completed.

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 Fasa University of Medical Sciences

Street address
Ibn Sina Square. Fasa University of Medical Sciences

City
Fasa

Province
Fars

Postal code
7461686688

Approval date
2022-06-26, 1401/04/05

Ethics committee reference number
IR.FUMS.REC.1401.035

Health conditions studied

1

Description of health condition studied
Acute myocardial infarction

ICD-10 code
121

ICD-10 code description
121

Primary outcomes

1

Description
Hope

Timepoint
Before, immediately and three months after the educational intervention

Method of measurement
Snyder Hope Questionnaire

2

Description
life Style

Timepoint
Before, immediately and three months after the educational intervention

Method of measurement
Walker Health Promoting Lifestyle Questionnaire

3

Description
Adherence to treatment

Timepoint
Before, immediately and three months after the educational intervention

Method of measurement
Treatment Adherence Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The training program based on Orem's self-care model will be designed and implemented in 6 sessions. One-hour classes will be held in the form of group discussions and lectures with educational pamphlets. It is worth mentioning that all phone calls to follow up on the condition of the patients will be made by the researcher and phone follow-up will be done for 3 months. In each session, in addition to teaching, the patient's medications will also be checked and the status of the patients' compliance with the treatment will be checked and the patients They will be encouraged to cooperate more. Also, the factors that prevent adherence and adherence to the treatment of patients are identified and measures are taken to eliminate them. In the first session, the structure of the sessions and the goals of the educational program will be introduced, and hope will be defined based on Schneider's theory, and necessary explanations will be given about the complications and prognosis of the disease to improve lifestyle. Its impact on health is discussed. In addition, in these two sessions, we try to establish the necessary therapeutic relationship with each of the clients, and the processes and dynamics of the group are taken into consideration. The use of proper nutrition is recommended to improve the lifestyle. In the third session, each client is asked to tell his life story in his own language to the group, and these stories are explained based on the three main components of Schneider's theory: the goal, the agent, and the passages. and will be formatted. In this meeting, we try to identify and pay attention to the issues of hope in the life of each member, and in order to improve the lifestyle of the patients, we inform them about the drugs, how to take them, and the possible side effects of the drugs. In the fourth session, the members are asked to provide a list of current events and important aspects of their lives and to determine the importance of each of them. And we encourage patients to exercise, physical activity and appropriate physical activities to improve their lifestyle. In the fifth session, the characteristics of appropriate goals are presented, then people are encouraged to set goals in each of the areas of life, and patients In order to improve the lifestyle, we introduce risk factors such as obesity, smoking, inactivity, stress, anxiety and tension and any other factors that are harmful for patients. In the sixth and last session, people are asked to achieve the set goals. Find suitable solutions. In order to improve the patients' lifestyle, they are explained to visit their doctor every 1 to 3 months for re-examination and paraclinical procedures.

Category

Lifestyle

2

Description

Control group: The control group will not receive training intervention, but will be provided with a training package

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Vali Asr Hospital affiliated to Fasa University of Medical Sciences

Full name of responsible person
Mostafa Bizhani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Fasa University of Medical Sciences

Full name of responsible person
Yasser Mansouri

Street address
Ibn Sina Square. Fasa University of Medical Sciences

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Email
Mansouri@yahoo.com

Grant name

Grant code / Reference number

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

Title of funding source
Fasa 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

Fasa University of Medical Sciences

Full name of responsible person

Mostafa Bizhani

Position

Assistant Professor. Faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

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Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Mostafa Bizhani

Position

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

After completing the study and publishing the results, by requesting the use of the study process and the use of questionnaires, as well as the content of the training program, the author in charge of the documentation will be shared.

When the data will become available and for how long

It has no time limit

To whom data/document is available

For researchers working in academic and scientific institutions

Under which criteria data/document could be used

After completing the study and publishing the results, by requesting the use of the study process and the use of questionnaires, as well as the content of the training program, the author in charge of the documentation will be shared.

From where data/document is obtainable

Request to the responsible author via email

What processes are involved for a request to access data/document

Send a request to use the documents to the responsible author via email and send the documents requested by the responsible author to the applicant

Comments