

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 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

Hope, lifestyle, adherence to treatment

##### 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

#### 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**

I21

**ICD-10 code description**

I21

**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

##### Street address

Ibn Sina Square. Fasa University of Medical Sciences

##### City

Fasa

##### Province

Fars

##### Postal code

7461686688

##### Phone

+98 21 5335 0994

##### Email

bizhani\_mostafa@yahoo.com

## 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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##### Phone

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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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## Person responsible for updating data

### Contact

**Name of organization / entity**  
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**Full name of responsible person**  
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**Position**  
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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**