

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 2026

### The Effect of telephone counseling based on Orem model on adherence to treatment and resilience of patients with coronary angioplasty

#### Protocol summary

Registration timing: **prospective**

##### Study aim

The Effect of telephone counseling based on Orem model on adherence to treatment and resilience of patients with coronary angioplasty

Last update: **2021-06-18, 1400/03/28**

Update count: **0**

##### Registration date

2021-06-18, 1400/03/28

##### Design

Clinical trial with control group, with parallel groups, without blinding, randomized

##### Registrant information

###### Name

Mahsa Maryami

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

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##### Settings and conduct

80 patients with coronary angioplasty in hospitals affiliated to Shiraz University of Medical Sciences with CCU ward are divided into two groups of control and intervention by block randomization with size of 4 . The intervention includes telephone counseling related to adherence to treatment and resilience in the form of 3 telephone calls per week for 2 months. The control group receives only the usual hospital services. Two months after the intervention, both groups complete treatment adherence and resilience questionnaires.

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: no severe mental illness and have a mobile phone and the ability to use it and the ability to communicate; Exclusion criteria: not implementing the intervention program completely and participating in the same care program in the last 3 months

##### Expected recruitment start date

2021-07-13, 1400/04/22

##### Expected recruitment end date

2021-09-13, 1400/06/22

##### Intervention groups

People in the intervention group receive telephone counseling regarding treatment adherence and resilience. Control group members they do not receive any intervention.

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Main outcome variables

Adherence to treatment, resilience

##### Trial completion date

empty

#### General information

##### Scientific title

The Effect of telephone counseling based on Orem model on adherence to treatment and resilience of patients with coronary angioplasty

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210303050562N1**

Registration date: **2021-06-18, 1400/03/28**

##### Public title

The effect of telephone counseling on patients with coronary angioplasty

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

No known severe mental illness Ability to communicate and no hearing or speech problems Mobile or landline access and knowledge of its use Literacy for reading and writing Age 18 to 65 years

**Exclusion criteria:**

Incomplete completion of questionnaires Failure to implement the intervention program completely Participate in a similar care program in the last 3 months

**Age**

From **18 years** old to **65 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **80**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Initially, 80 patients with coronary angioplasty will be selected from among eligible individuals. Then, patients are divided into experimental and control groups based on a random quadruple block prepared using block generation software.

**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 Shiraz University of Medical Sciences

**Street address**

Vice Chancellor for Research, 7th floor, shiraz university of medical science, zand st.

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**Postal code**

7134814336

**Approval date**

2021-05-27, 1400/03/06

**Ethics committee reference number**

IR.SUMS.REC.1400.167

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

Acute myocardial infarction

**ICD-10 code**

I21.9

**ICD-10 code description**

Acute myocardial infarction

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

Adherence to treatment

**Timepoint**

Before the intervention and immediately after the intervention

**Method of measurement**

Questionnaire of adherence to treatment of chronic patients Madanloo 1392

**2****Description**

Resilience

**Timepoint**

Before the intervention and immediately after the intervention

**Method of measurement**

Resilience questionnaire for Ebadi heart and respiratory patients 2016

**Secondary outcomes**

empty

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

Intervention group: In the experimental group, in addition to educational pamphlets and routine hospital care, telephone counseling will be provided for 2 months after discharge. Each patient will receive a mobile and home number, as well as the mobile number of a family member, and the patient will be given the researcher's mobile number. They will be provided with a schedule of telephone calls, which includes 3 calls per week for 2 months. The average call time will be 30 minutes. The call time range is from 8 am to 9 pm Also, if you have a problem or have a question, contact the researcher within the same time frame. The patient will be referred to a physician to follow up on patients' questions and problems if needed In the first telephone call, the client's needs are assessed using the Orem Needs Assessment

Questionnaire, which includes three basic categories (general self-care needs, care needs for growth and development, self-care needs when deviating from health). To take. Then, based on the needs assessment, patients are evaluated and determined from three aspects in the field of nursing diagnosis, including: 1. Self-care treatment needs (which patient needs are met and which needs are not met, and what factors cause the needs to be met) , 2. Self-care agent (patient's potential self-care abilities) 3. Decreased self-care (where the patient is weak and unable to take care of himself).In the next stage, the care plan will be designed and developed based on the goals in the form of educational-supportive nursing system, which includes: a- meeting the patient's needs in self-care b- making the patient responsible for self-care c- increasing the patient's independence in His care and adaptation to the changes that have been made and ... is. In fact, the role of the nurse in the education-support system of Orem is more of a counseling mode. For example, a heart patient with high blood cholesterol, a nurse with training on a healthy diet, including: (reducing the consumption of saturated fats (animal fats) and replacing them with unsaturated fats (vegetable oils), consuming omega-3 oils, reducing consumption Salt, weight loss, more consumption of fruits and vegetables, etc.) helps the patient to achieve self-care by increasing awareness of their diet. Also, the heart patient who has undergone angioplasty and his self-confidence has decreased due to limitations, the nurse helps the patient to trust in his / her abilities against the disease by focusing on the patient's abilities, strengthening positive behaviors and improving the patient's behavioral and mental performance in order to adapt to the disease. Feel good despite the limitations. At this stage, the planned nursing measures will be implemented in the form of supportive counseling, and finally the evaluation will be done based on the goals of reducing needs and increasing abilities through telephone calls and repetition and practice. The content of telephone calls generally includes the following: 1. Introduce yourself and ask questions about the patient's general health status 2. Giving health advice and education related to nutrition and medicine 3. Patient adherence to diet, medication, activity and exercise 4. Enhancing patient health behaviors and agreed behavioral goals. Strengthen disease acceptance and patient adaptation to conditions 6. End the call using incentive sentences and determine the time of the next call.

**Category**  
Behavior

## 2

### **Description**

Control group: do not receive telephone counseling over the phone, and educational pamphlets and standard hospital care include: (education about diet, activity, medications, and presentation of educational pamphlets about illness and medication) as well as how to see a doctor at the time of discharge will be provided.

**Category**  
Behavior

## **Recruitment centers**

### 1

#### **Recruitment center**

**Name of recruitment center**

Namazi hospital in shiraz

**Full name of responsible person**

Mahsa maryami

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No.213, Alley42, Lashkari st., Rahmat Blvd., Shiraz Town

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### 2

#### **Recruitment center**

**Name of recruitment center**

Alzahra Heart Hospital, Shiraz

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### 3

#### **Recruitment center**

**Name of recruitment center**

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Younes Ghasemi

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

No

**Title of funding source**

Shiraz 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**

Shiraz University of Medical Sciences

**Full name of responsible person**

Khatereh Rostami

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Position**

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**Latest degree**

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**Other areas of specialty/work**

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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