

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Oct 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)

Phone

+98 71 3753 1745

Email address

mahsamyami93@gmail.com

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.

City

Shiraz

Province

Fars

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

Street address

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

City

Shiraz

Province

Fars

Postal code

7166714458

Phone

+98 71 3753 1745

Email

mahsamyami93@gmail.com

2

Recruitment center

Name of recruitment center

Alzahra Heart Hospital, Shiraz

Full name of responsible person

Mahsa maryami

Street address

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

City

Shiraz

Province

Fars

Postal code

7166714458

Phone

+98 71 3753 1745

Email

mahsamyami93@gmail.com

3

Recruitment center

Name of recruitment center

Shahid Faghihi Hospital

Full name of responsible person

Mahsa maryami

Street address

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

City

Shiraz

Province

Fars

Postal code

7166714458

Phone

+98 71 3753 1745

Email

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Younes Ghasemi

Street address

Deputy of Research and technology, 7th floor, Central building of Shiraz University of Medical Science, Zand street

City

Shiraz

Province

Fars

Postal code

7131811336

Phone

+98 71 3728 3235

Fax**Email**

vcrdep@sums.ac.ir

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

Street address

School of Nursing and Midwifery, Namazi Square, Zand st.

City

Shiraz

Province

Fars

Postal code

7193613119

Phone

+98 71 3647 4254

Email

khaterehrostami61@yahoo.com

Person responsible for scientific 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

Street address

School of Nursing and Midwifery, Namazi Square, Zand st.

City

Shiraz

Province

Fars

Postal code

7193613119

Phone

+98 71 3647 4254

Email

khaterehrostami61@yahoo.com

Person responsible for updating data

Contact**Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Mahsa maryami

Position

MSc Nursing student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

No.213, Alley42, Lashkari Ave., Rahmat Blvd., Shiraz town

City

Shiraz

Province

Fars

Postal code

7166714458

Phone

+98 71 3753 1745

Email

mahsamaryami93@gmail.com

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