

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

The effects of discharge plan on stress, anxiety and depression in patients undergoing percutaneous transluminal coronary angioplasty in hospitals affiliated to shiraz university of medical science

Protocol summary

Summary

This is a randomized control trail which was planned to determine the effects of discharge planning on the stress, anxiety, and depression of those undergone the angioplasty of coronary artery. The inclusion criteria contain age limit of 30 to 70, lack of psychological disorders and psychological therapy on the basis of a psychologist advice, lack of any types of cognitive, speech and hearing disorders. Moreover, the exclusion criteria are the incidence of sharp deterioration or worsening ailment for each subject during the survey. Based on randomized control method, 80 candidates of angioplasty who had the inclusion criteria were classified into control and experimental groups. The instruments for data collection were a demographic questionnaire and a stress, anxiety and depression questionnaire (DASS-21). Participants of control group received the usual treatment while the patients in the experimental group took part in two training sessions before and after the procedure. They were also provided a follow-up on the phone once a week in two weeks time after their discharge. The questionnaires were completed by both the control and experimental subjects at admission, discharge and a month after their discharge.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201302182812N12**

Registration date: **2013-09-07, 1392/06/16**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-09-07, 1392/06/16

Registrant information

Name

Farkhondeh Sharif

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1212 2401

Email address

fsharif@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2012-12-21, 1391/10/01

Expected recruitment end date

2013-04-21, 1392/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of discharge plan on stress, anxiety and depression in patients undergoing percutaneous transluminal coronary angioplasty in hospitals affiliated to shiraz university of medical science

Public title

The effects of discharge plan on stress, anxiety and depression in patients undergoing percutaneous transluminal coronary angioplasty in hospitals affiliated to shiraz university of medical science

Purpose

Treatment

Inclusion/Exclusion criteria
inclusion criteria: Age limit of 30 to 70; Lack of psychological disorder and psychological therapy on the basis of a psychologist advice; Lack of previous angioplasty; Lack of any types of cognitive, speech and hearing disorders; Access to telephone; A complete consent to participate in the survey. Exclusion criteria: The incidence of sharp deterioration in the ailment.; The elimination of those who face critical conditions during the survey; The elimination of those who are not willing to keep taking part in the survey.

Age
From **30 years** old to **70 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

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

1

Registry name

Secondary trial Id

Registration date
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Shiraz University of Medical Sciences

Street address
Shiraz University of Medical Sciences, Central building, Zand St

City
Shiraz

Postal code
713451978

Approval date

2012-12-24, 1391/10/04

Ethics committee reference number
CT-91-6353

Health conditions studied

1

Description of health condition studied
coronary heart disease

ICD-10 code
125.1

ICD-10 code description
Atherosclerotic heart disease

Primary outcomes

1

Description
anxiety

Timepoint
time of the admission, discharge and a month after their discharge.

Method of measurement
stress,anxiety.depression questionnar DASS-21

2

Description
Stress

Timepoint
time of the admission, discharge and a month after their discharge.

Method of measurement
stress,anxiety.depression questionnar DASS-21

3

Description
Depression

Timepoint
time of the admission, discharge and a month after their discharge.

Method of measurement
stress,anxiety.depression questionnar DASS-21

Secondary outcomes

empty

Intervention groups

1

Description
participants of control group received routine oral instructions: to be NPO, to shave, and how to take the drugs. And after angioplasty, at discharge, they also received a pamphlet on diet, amount of activities, and incidence of pain and bleeding.

Category

Other

2

Description

Patients in the experimental group participated in a 30-minute training session about the reason of angioplasty, its procedures, and the required equipment for angioplasty, and the events occurring at angioplasty. At discharge, they received a booklet about the necessity of changes in the life style such as doing exercises, giving up smoking, stress and anxiety control and relaxation, amount of activities, diet, taken drugs and their side effects, when and how to have sexual activity, taking care of the incision and its pain, necessary actions in case of bleeding and/or hematoma, referral of symptoms, and also necessity of participation in cardiac rehabilitation program. These subjects were explained to the patients and a family member, face-to-face, in a forty-minute session. They also were followed up on the phone once a week in two weeks time immediately after discharge.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Namazi hospital

Full name of responsible person

Dr Farkhondeh Sharif

Street address

Namazi hospital, Namazi Square, Zand street,

City

shiraz

2

Recruitment center

Name of recruitment center

Shahid Dr. Faghihi Hospital

Full name of responsible person

Dr Farkhondeh Sharif

Street address

Zand Avenue, Shahid Dr. Faghihi Hospital

City

shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

DrGholamreza Hatam

Street address

Shiraz University of Medical Sciences, University

Central Building, Zand street, beside red cross

City

SHIRAZ

Grant name

Grant code / Reference number

CT-91-6353

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

Yes

Title of funding source

Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences,

Full name of responsible person

Farkhondeh Sharif

Position

ph.D

Other areas of specialty/work

Street address

Shiraz University of Medical Sciences, ZAND Street,

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Contact

Name of organization / entity

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Farkhondeh sharif

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Fax**Email**

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Web page address**Person responsible for updating data****Contact****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty