

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jun 2026

The effect of counseling based on Roy adaptation model on Multidimensional fatigue and adherence to treatment in patients with myocardial infarction

Protocol summary

Study aim

the effect of counseling based on Roy's adaptation model on fatigue and adherence to treatment in patients with MI.

Design

Controlled random clinical trials with parallel groups with a sample size of 50

Settings and conduct

Consultation sessions will be conducted based on the results of the Roy model evaluation at the heart clinic affiliated to Zanjan University of Medical Sciences.

Participants/Inclusion and exclusion criteria

Written consent to participate in the study Having a history of myocardial infarction for at least three months Inappropriate fatigue and adherence to inappropriate treatment Having a acute Myocardial Infarction Myocardial infarction complications such as heart failure, acute pulmonary edema and ...

Intervention groups

Demographic characteristics, fatigue and adherence to treatment of both groups were evaluated first. Then samples in the intervention group were identified based on ROY compatibility form, maladaptive behaviors, and major, underlying and residual maladaptive behaviors. The care program - counseling including 2-6 sessions of direct and individual intervention was implemented according to the needs of patients for 30-45 minutes at affiliated heart clinic of Zanjan University of Medical Sciences. Telephone follow-up was performed for two months and then post-test. In the control group, in order to control the impact of the presence of medical professional care givers as a confounder variable, during the sessions to complete the questionnaires, general questions of the samples were answered and then, the dependent variables were measured in both groups.

Main outcome variables

The fatigue variable; Adherence variable to treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130124012257N9**

Registration date: **2019-08-30, 1398/06/08**

Registration timing: **retrospective**

Last update: **2019-08-30, 1398/06/08**

Update count: **0**

Registration date

2019-08-30, 1398/06/08

Registrant information

Name

Farhad Ramezani-Badr

Name of organization / entity

Zanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 24 3527 9412

Email address

ramazanibadr@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-21, 1397/02/31

Expected recruitment end date

2018-12-21, 1397/09/30

Actual recruitment start date

2018-06-20, 1397/03/30

Actual recruitment end date

2018-12-21, 1397/09/30

Trial completion date

2019-05-21, 1398/02/31

Scientific title

The effect of counseling based on Roy adaptation model on Multidimensional fatigue and adherence to treatment in patients with myocardial infarction

Public title

The effect of Roy adaptation model on fatigue and adherence to treatment in patients with MI

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Having written consent to participate in the study and knowledge of the place and time ability to communicate and call in the research period History of myocardial infarction for at least three months Moderate and severe fatigue, as well as adherence to good to low treatment based on the questionnaires used Only one doctor is a cardiologist

Exclusion criteria:

There are known psychological disorders Acute myocardial infarction Having communication problems such as blindness, deafness and any cognitive impairment Complications of myocardial infarction, such as heart failure, myocardial rupture, acute pulmonary edema, pericarditis, cardiogenic shock The presence of any underlying illness that affects dependent variables.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **50**

Actual sample size reached: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the blocking method will be used. In the blocking technique, blocks are created with a pair size (usually four or six) blocks, in which randomly half the individuals of each block in one group and the other half in the other group. Then the block is chosen so as to reach the required sample size. In this study, to place 50 people in two groups of 25, first all four modes in which half of the subjects are group A and the other half are assigned to group B. These states are written below: 1 b b a a 2 b a b a 3- a b b a 4 a a b b 5- a b a b 6- b a a b We then assign each of these four combinations one of the digits 1 to 6. In the next step, we need to select 13 random blocks of four blocks and write their combinations in succession. To do this, we need to put 6 samplers in this community 13 times. In this way we will have two groups: 25 in the control group and 25 in the test group.

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants in the study did not know about belonging to the intervention and control group

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zanjan University of Medical Sciences

Street address

First of Jomhore Eslami Blvd, Azadi Square

City

Zanjan

Province

Zanjan

Postal code

4515613191

Approval date

2018-05-25, 1397/03/04

Ethics committee reference number

IR.ZUMS.REC.1397.91

Health conditions studied

1

Description of health condition studied

Fatigue

ICD-10 code

ICD-10 code description

2

Description of health condition studied

Adherence to treatment

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Fatigue and its dimensions in the studied patients

Timepoint

This variable will be measurement once before the intervention and again 2 month after the end of intervention.

Method of measurement

Multidimensional fatigue inventory

2**Description**

Adherence to treatment

Timepoint

This variable will be measurement once before the intervention and again 2 month after the end of intervention.

Method of measurement

The scale of adherence to treatment questionnaire of Medical Outcomes Study

Secondary outcomes

empty

Intervention groups1**Description**

Intervention group: For the samples in the intervention group based on the form of exploring and recognizing the pattern of zinc adaptation, incompatible behaviors and the main, underlying and residual impulsive behaviors were identified in each of the four physiological dimensions, self-understanding, role play, autonomy, and dependence . A care program called counseling sessions consisting of 2 to 6 sessions of direct and individual intervention as variables according to patients' needs each time for a period of 45 to 30 minutes by the researcher and other members of the research team at the heart clinic affiliated to the Ayatollah Mousavi Hospital. was planned and implemented. Phone follow up for two months and then post-test.

Category

Behavior

2**Description**

Control group: In the control group, in order to control the effect of the professional medical sciences as an interventional variable, during the holding of the sessions to complete the questionnaires, the general questions of the samples, which had no relation to the main intervention of the researcher, were answered. Follow up for two Month and then post-test.

Category

Behavior

Recruitment centers1**Recruitment center****Name of recruitment center**

Heart clinic affiliated to Ayatollah Mousavi Hospital

Full name of responsible person

Seyedeh Maryam Hosseini-zhad

Street address

Zanjan Province, Zanjan, Gavazang Boulevard, Ayatollah mousavi Hospital

City

Zanjan

Province

Zanjan

Postal code

4187697461

Phone

+98 24 3313 0000

Fax

+98 24 3313 1203

Email

Mousavihospital@zums.ac.ir

Web page address<http://www.zums.ac.ir>**Sponsors / Funding sources**1**Sponsor****Name of organization / entity**

Zanjan University of Medical Sciences

Full name of responsible person

Alireza Shoghli

Street address

First of Jomhore Eslami Blvd, Azadi Square

City

Zanjan

Province

Zanjan

Postal code

4515613191

Phone

+98 24 3342 0677

Fax

+98 24 3342 4770

Email

shoghli@zums.ac.ir

Web page address<http://www.zums.ac.ir>**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Zanjan 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

Zanjan University of Medical Sciences

Full name of responsible person

Seyede Maryam Hosseininezhad

Position

Master student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

No. 57, Behruz Sharifian Ave., Felestin street, Rasht city

City

Rasht

Province

Guilan

Postal code

4187697461

Phone

+98 13 3382 2166

Email

seyedehmaryam.hsn@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Farhad Ramezani-Badr

Position

Nursing PhD, associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Faculty of Nursing and Midwifery , Zanjan, Iran

City

Zanjan

Province

Zanjan

Postal code

4515789589

Phone

+98 24 3377 2513

Fax**Email**

ramazanibadr@zums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Seyyede Maryam Hosseininezhad

Position

دانشجو کارشناسی ارشد داخلی - جراحی

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

School of Nursing and Midwifery, Zanjan University of Medical Sciences, Haj Mahdavi Blv. Zanjan, Iran

City

Zanjan

Province

Zanjan

Postal code

4515613113

Phone

+98 24 4433 1004

Email

Seyedehmaryam.hsn@gmail.com

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

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The data file and report of the study method and results of this study will be published in a peer-reviewed journal. The data file in SPSS software can be presented on request by the relevant journal.

When the data will become available and for how long

2019-2020

To whom data/document is available

Officials, administrators, and supervisors associated with this study at Zanjan University of Medical Sciences have access to the data and documentation of this study while maintaining the confidentiality of the participants and observing ethical considerations.

Under which criteria data/document could be used

The data of this study can be used for decision making by senior managers of Zanjan University of Medical Sciences, while protecting the confidentiality of participants and ethical considerations.

From where data/document is obtainable

Farhad Ramezani Badr- Zanjan University of Medical Sciences

What processes are involved for a request to access

data/document

Contact with the author responsible for this study-

Farhad Ramezani Badr

Comments