Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effect of Benson relaxation method and routine treatment on anxiety in patients with myocardial infarction.

Protocol summary

Study aim
Determining the effect of Benson relaxation method on anxiety of patients with myocardial infarction, hospitalized in CCU wards.

Design
Comparison of Benson relaxation technique with routine treatment method in patient with myocardial infarction admitted to Urmia Seyyed Shohada Hospital who were non-randomly allocated to intervention and control groups with parallel-group design. Non of these groups were blind. The sample size was 60.

Settings and conduct
Every admitted patient with myocardial infarction in intensive care unit of Urmia Seyyedol Shohada Hospital was identified by the researcher and non-randomly was allocated to one of the groups. After obtaining consent and stabilizing the patient's condition and also the approval of the physician, a pre-test based on the demographic form and the Spielberger questionnaire was performed. In control group there was no intervention. These patients were put under the routine care only. In intervention group, pretest was done after explaining about the steps on the first day. In this group, Benson relaxation was performed for each patient, two 15-minute sessions a day for 2 consecutive days. Post-test was done on second.

Participants/Inclusion and exclusion criteria
Inclusion criteria: heart attack based on doctor's approval; Complete patient awareness; hospitalization; No history of mental illness; absence of work experience in health centers; absence of relaxation methods; Willingness to cooperate Non-inclusion criteria: History of anti-anxiety drugs; consciousness level change; Complications of disease; non cooperation or death of the patient; Cardiopulmonary resuscitation.

Intervention groups
In the intervention group, Benson's relaxation was performed during 2 days and in the morning and evening, and the control group received routine care only.

Main outcome variables
Anxiety

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160220026662N6**
Registration date: **2019-01-07, 1397/10/17**
Registration timing: **retrospective**

Last update: **2019-01-07, 1397/10/17**
Update count: **0**

Registration date
2019-01-07, 1397/10/17

Registrant information

Name
Nader Aghakhani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 44 3275 4816

Email address
nader1453@umsu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-05-20, 1396/02/30

Expected recruitment end date
2017-07-21, 1396/04/30

Actual recruitment start date
2017-06-02, 1396/03/12

Actual recruitment end date

2017-09-01, 1396/06/10

Trial completion date

2017-09-01, 1396/06/10

Scientific title

Comparison of the effect of Benson relaxation method and routine treatment on anxiety in patients with myocardial infarction.

Public title

The effect of Benson relaxation method on anxiety

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Having a heart attack approved by a medical practitioner Complete patient consciousness hospitalization in the ward No history of mental illness Not having work experience in the health centers Not receiving relaxation methods Willingness to cooperate

Exclusion criteria:

History of consuming anti-anxiety drugs Changing the level of consciousness Occurrence of disease complications Lack of cooperation or death of the patient Cardio-pulmonary resuscitation

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Not randomized

Randomization description

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 Urmia University of Medical Sciences

Street address

Orjhans Street, Resalat Blvd

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Approval date

2017-05-06, 1396/02/16

Ethics committee reference number

IR.UMSU.IRC.1396.31

Health conditions studied

1

Description of health condition studied

Myocardial infarction

ICD-10 code

I21

ICD-10 code description

Acute myocardial infarction

Primary outcomes

1

Description

Anxiety

Timepoint

Before the intervention and after the end of the intervention on the second day

Method of measurement

The Spielberger state-trait anxiety inventory

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Benson's relaxation technique for each patient for 2 consecutive days and 2 times a day in the morning and at night between 10-11 am and 6-5 pm, and each times for 15 minutes (4 sessions) was performed. On the second day after the implementation of the fourth session of the relaxation technique, the Spielberger Anxiety Scale Questionnaire for the intervention group was completed. This technique for patients in the intervention group in the intensive care unit on the patient's bed was placed in a semi-sitting position (45 degrees) was performed. As much as possible, light above the head of the patient and monitor's voice are reduced and, if the patient is beaten up, the alarms of the devices are used by the headphones or by any means in the ear to prevent disturbing sounds. Then it was asked from the patient to perform the Benson's relaxation as follows: the patient should be in a comfortable position and slowly close his eyes while relaxing his muscles from the soles of feets,

he consciously breathes out of his nose and exhales out of his mouth while murmuring a word or a number that make him calm after repeating this task for 15 minutes, he should try to relax his muscles. Then he can open his eyes, however, for a few minutes he should not get up.

Category
Other

2

Description
Control group: No intervention was done in the control group and this group only received routine care.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Seyedolshohada educational and treatment center in Urmia

Full name of responsible person
Nader Aghakhani

Street address
17 Shahrivar Boulevard

City
Urmia

Province
West Azarbaijan

Postal code
571478334

Phone
+98 44 3237 5909

Email
nader1453@umsu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Oroumia University of Medical Sciences

Full name of responsible person
Nader Aghakhani

Street address
Nazloo street

City
Urmia

Province
West Azarbaijan

Postal code
571478334

Phone
+98 44 3275 4961

Email
nader1453@umsu.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Oroumia 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
Oroumia University of Medical Sciences

Full name of responsible person
Nader Aghakhani

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
Nazloo street

City
Urmia

Province
West Azarbaijan

Postal code
571478334

Phone
+98 44 3275 4916

Fax
+98 44 3275 4916

Email
nader1453@umsu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Oroumia University of Medical Sciences

Full name of responsible person
Nader Aghakhani

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
Nazloo Street

City

Urmia

Province

West Azarbaijan

Postal code

571478334

Phone

+98 443275496

Email

nader1453@umsu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Nader Aghakhani

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Nazloo Street

City

Urmia

Province

West Azarbaijan

Postal code

571478334

Phone

+98 443275496

Email

nader1453@umsu.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Maintaining the principle of privacy

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

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

Not applicable

Data Dictionary

Not applicable