

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparative investigating the effect of relaxation and meditation techniques on quality of life in patients with coronary artery disease referred to the outpatient clinic

Protocol summary

Study aim

Comparison the effect of relaxation and meditation techniques on quality of life in patients with coronary artery disease

Design

Randomized, parallel group clinical trial

Settings and conduct

Study population are patients with coronary artery disease referred to outpatient clinics of Rafsanjan University of Medical Sciences. Sample size estimated 100 based on previous studies. Samples will allocated two groups of relaxation and meditation using random number table. Exercises will educated to patients by researcher. In relaxation group, patients undergo relaxation exercises twice a day (morning and night), each time for 15 minutes. In meditation group, patients undergo meditation exercises twice a day (morning and night), each time for 15 minutes.

Participants/Inclusion and exclusion criteria

Diagnosis of coronary artery disease (based on angiography), complete consciousness, history of admission to the CCU, ability to understand and speak persian and informed consent for participate in the study are inclusion criteria. History of mental illness, using of psychiatric drugs and heart failure in the last 6 weeks are exclusion criteria.

Intervention groups

Relaxation group: In this group, patients undergo relaxation exercises twice a day (morning and night), each time for 15 minutes. Meditation group: In this group, patients undergo meditation exercises twice a day (morning and night), each time for 15 minutes.

Main outcome variables

Quality of Life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150519022320N14**

Registration date: **2018-10-28, 1397/08/06**

Registration timing: **registered_while_recruiting**

Last update: **2018-10-28, 1397/08/06**

Update count: **0**

Registration date

2018-10-28, 1397/08/06

Registrant information

Name

Tayebeh Mirzaei

Name of organization / entity

Rafsanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 34 3425 5900

Email address

t.mirzaei@rums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-23, 1397/08/01

Expected recruitment end date

2019-01-20, 1397/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparative investigating the effect of relaxation and meditation techniques on quality of life in patients with coronary artery disease referred to the outpatient clinic

Public title
Comparative investigating the effect of relaxation and meditation techniques on quality of life in patients with coronary artery disease

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of coronary artery disease (based on angiography) Complete consciousness History of admission to the CCU. Ability to understand and speak Persian Informed consent for participate in study
Exclusion criteria:
History of mental illness History of using psychiatric drugs Heart failure in the last 6 weeks

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization based on random number table: In this method, first a list of patients will provide based on inclusion and exclusion criteria, then patients are divided into two groups of relaxation and meditation using random number table.

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 Rafsanjan University of Medical Sciences
Street address

Imam Ali Blvd
City
Rafsanjan
Province
Kerman
Postal code
7717933777
Approval date
2018-06-27, 1397/04/06
Ethics committee reference number
IR.RUMS.REC.1397.071

Health conditions studied

1

Description of health condition studied
Coronary artery disease
ICD-10 code
I25
ICD-10 code description
Chronic ischemic heart disease

Primary outcomes

1

Description
Mean score of quality of life
Timepoint
Before the intervention, one month after the intervention, two months after the intervention
Method of measurement
Minnesota quality of life questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Relaxation : In this group, patients undergo relaxation exercises twice a day (morning and night), each time for 15 minutes.
Category
Lifestyle

2

Description
Meditation: In this group, patients undergo meditation exercises twice a day (morning and night), each time for 15 minutes.
Category
Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Heart clinic

Full name of responsible person

Mahboobeh Kafizadeh

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Parastar Ave

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7718796755

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

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

Yes

Title of funding source

Rafsanjan 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

Rafsanjan University of Medical Sciences

Full name of responsible person

Ali Ravari

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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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

Not applicable

Informed Consent Form

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

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable