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
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

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
Recruitment center
Name of recruitment center
Heart clinic
Full name of responsible person
Mahboobeh Kafizadeh
Street address
Parastar Ave
City
Rafsanjan
Province
Kerman
Postal code
7718796755
Phone
+98 34 3425 5900
Email
kafizadehm@yahoo.com

Sponsors / Funding sources

1
Sponsor
Name of organization / entity
Rafsanjan University of Medical Sciences
Full name of responsible person
Ali Shamsizadeh
Street address
Imam Ali Blvd
City
Rafsanjan
Province
Kerman
Postal code
7717933777
Phone
+98 34 3428 0097
Email
vcrt@rums.ac.ir
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
Street address
Parastar Ave
City
Rafsanjan
Province
Kerman
Postal code
7718796755
Phone
+98 34 3425 5900
Email
Ravary4776@yahoo.com

Person responsible for scientific 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
Street address
Parastar Ave
City
Rafsanjan
Province
Kerman
Postal code
7718796755
Phone
+98 34 3425 5900
Email
Ravary4776@yahoo.com

Person responsible for updating data
Contact
Name of organization / entity
Rafsanjan University of Medical Sciences
Full name of responsible person
Tayebeh Mirzaei
Position
Associate Professor
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