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 educate 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)

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**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**

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

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

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

Primary outcomes

1. Description of health condition studied
- Coronary artery disease

ICD-10 code
- I25

ICD-10 code description
- Chronic ischemic heart disease

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

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Parastar Ave

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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

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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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