Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Nov 2026

Effect of Sleep Intervention Programs on the Quality of Sleep of Patients in Cardiac Rehabilitation Center

Protocol summary

Study aim
Effect of Sleep Intervention Programs on the Quality of Sleep of Patients in Cardiac Rehabilitation Center

Design
The study was a quasi-experimental research with control and test groups

Settings and conduct
Demographic and clinical profile and the Pittsburgh sleep quality questionnaire. Conducted in Afshar Heart Rehabilitation Center of Yazd

Participants/Inclusion and exclusion criteria
Inclusion criteria: cardiovascular diseases requiring cardiac rehabilitation, age of 18 years and older, familiarity with Persian language, and consent to participate in the study. Exclusion criteria: sleep disorder requiring medication before the rehabilitation, history of hypnotic drug use for more than 6 months, history of depression and anxiety according to psychiatrist, cognitive impairment (vision or hearing problem),

Intervention groups
Patients who participated in the rehabilitation program were considered as the experimental group, and patients who did not participate in the rehabilitation program or left the program despite being taught the need for rehabilitation, were assigned to the control group. . Based on a complete test and results of the initial exercise test of patients, having a companion, and other factors such as a history of heart surgery and myocardial infarction and patients' risk levels, the clinician specified the length and speed of exercise with treadmill and exercise program for any patient in the experimental group to perform the rehabilitation program. Accordingly, the intensity of training in the initial sessions started from 20% to 40% of the reserve heart rate and gradually increased to 60% in the last sessions. The cardiac rehabilitation program included 12 weeks of exercise, 3 sessions per week, and 3 sessions of training programs each for 45 minutes.

Main outcome variables
Cardiac rehabilitation; sleep quality; cardiovascular patients

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140307016870N6**
Registration date: **2020-09-14, 1399/06/24**
Registration timing: **retrospective**

Last update: **2020-09-14, 1399/06/24**
Update count: **0**

Registration date
2020-09-14, 1399/06/24

Registrant information

Name
Khadije Nasiriani

Name of organization / entity
Yazd Shahid Sadoughi University Of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 35 1824 1755

Email address
nasiriani@ssu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-01-15, 1398/10/25

Expected recruitment end date
2020-04-13, 1399/01/25

Actual recruitment start date
2020-01-16, 1398/10/26

Actual recruitment end date

2020-04-21, 1399/02/02

Trial completion date

2020-04-21, 1399/02/02

Scientific title

Effect of Sleep Intervention Programs on the Quality of Sleep of Patients in Cardiac Rehabilitation Center

Public title

Effect of Sleep Intervention Programs on the Quality of Sleep

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

cardiovascular diseases requiring cardiac rehabilitation consent to participate in the study familiarity with Persian language age of 18 years and older

Exclusion criteria:

sleep disorder requiring medication before the rehabilitation history of hypnotic drug use for more than 6 months cognitive impairment (vision or hearing problem)

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Actual sample size reached: **35**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Patients who participated in the rehabilitation program were considered as the experimental group, and patients who did not participate in the rehabilitation program or left the program despite being taught the need for rehabilitation, were assigned to the control group. In both groups, the selection of samples continued until a sample size of 35 was achieved

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Sadoghi University of Medical Sciences

Street address

Shahid Sadoughi University of Medical Sciences, Bahonar Square, Yazd

City

Yazd

Province

Yazd

Postal code

8916978477

Approval date

2020-01-14, 1398/10/24

Ethics committee reference number

IR.SSU.REC.1398.200

Health conditions studied

1

Description of health condition studied

sleep disorder

ICD-10 code

G47.2

ICD-10 code description

Circadian rhythm sleep disorders

Primary outcomes

1

Description

The overall quality of sleep

Timepoint

Before and one week after the intervention

Method of measurement

The Pittsburgh Sleep Quality Index

2

Description

Sleep duration

Timepoint

Before intervention and one week after the intervention

Method of measurement

The Pittsburgh Sleep Quality Index

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Based on a complete examination and results of the initial exercise test of patients, having a companion, and other factors such as a history of heart surgery and myocardial infarction and patients' risk levels, the clinician specified the length and speed of

exercise with treadmill and exercise program for any patient in the experimental group to perform the rehabilitation program. Accordingly, the intensity of training in the initial sessions started from 20% to 40% of the reserve heart rate and gradually increased to 60% in the last sessions. The cardiac rehabilitation program included 12 weeks of exercise, 3 sessions per week, and 3 sessions of training programs each for 45 minutes

Category

Treatment - Devices

2

Description

Control group: patients who did not participate in the rehabilitation program or left the program despite being taught the need for rehabilitation, were assigned to the control group

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Afshar Heart Rehabilitation Center of Yazd

Full name of responsible person

Fatemeh Ghaneh

Street address

Afshar Hospital،Jomhori Blvd

City

yazd

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8916877443

Phone

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Email

nasiriani@ssu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Dr.Masud.Mirezaee

Street address

Research Council of Yazd University of Medical Sciences

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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

Yazd University of Medical Sciences

Proportion provided by this source

50

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

Yazd University of Medical Sciences

Full name of responsible person

Khadijeh Nasiriani

Position

ph.D of nursing

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

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Position

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Other areas of specialty/work

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Person responsible for updating data

Contact

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

Analytic Code
Not applicable

Data Dictionary
Not applicable