Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

The Effect of Cognitive-Behavioral Therapy on Perceived Stress and Sleep Quality among Patients undergoing Percutaneous Coronary Intervention

Protocol summary

Study aim
The Effect of Cognitive-Behavioral Therapy on Perceived stress and Sleep Quality among Patients undergoing Percutaneous Coronary Intervention referring to Shafa Hospital 2019

Design
Clinical trial study with control group with parallel, randomized, non-blinded groups،The sample size is 40 patients.

Settings and conduct
After obtaining written informed consent from the patient and providing the necessary information about the goals of the study, basic information about perceived stress and quality of sleep is taken from patients in both groups. Intervention after the first visit to the clinic and receiving the authorization from the trained physician under the supervision of a clinical psychologist in the rehabilitation clinic of Shafa hospital in groups of 5 to 6 persons. Control group patients received only routine medical intervention during this period. .

Participants/Inclusion and exclusion criteria
Inclusion criteria: patients undergoing percutaneous coronary intervention; Ability to speak Persian;Aged 18 years and up Exit criteria:Cognitive problems such as Alzheimer's disease, stroke;Hearing and visual impairment that prevents communication;Presence of psychiatric disorder;Taking antidepressants and anti-anxiety drugs;Taking sleeping pills and sedative medications;The presence of mental disorders which requiring immediate treatment (symptoms of psychiatry, substance dependency, suicide)

Intervention groups
Patients in the intervention group are receiving cognitive-behavioral intervention in addition to receiving the usual medical care, but the patients in the control group receive only the usual medical intervention during this period.

Main outcome variables
Perceived stress and Sleep Quality of patients with Percutaneous Coronary Intervention

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190725044329N1**
Registration date: **2019-09-07, 1398/06/16**
Registration timing: **registered_while_recruiting**

Last update: **2019-09-07, 1398/06/16**
Update count: **0**

Registration date
2019-09-07, 1398/06/16

Registrant information

Name
Marziyeh Salimpour

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 34 3251 6766

Email address
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-08-22, 1398/05/31

Expected recruitment end date
2019-11-20, 1398/08/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The Effect of Cognitive-Behavioral Therapy on Perceived Stress and Sleep Quality among Patients undergoing Percutaneous Coronary Intervention

Public title
The Effect of Cognitive-Behavioral Therapy on Perceived Stress and Sleep Quality
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Patients undergoing Percutaneous Coronary Intervention Aged 18 years and up Ability to speak Persian
Exclusion criteria:
Cognitive problems such as Alzheimer's disease, stroke Hearing and visual impairment that prevents communication Presence of psychiatric disorders Taking antidepressants and anti-anxiety drugs Taking sleeping pills and sedative medications Having psychiatric disorders requiring immediate treatment (symptoms of psychiatry, drug dependence, suicide)
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization which the patient was the randomization unit. Assignment of patients to the intervention and control group is carried out by a statistical expert by using blocks of 4 with the help of statistical software Minitab and using random numbers.
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 Kerman University of Medical Sciences
Street address
Beginning of the axis of Haft Bagh Alavi, Campus of Medical Sciences
City
Kerman
Province
Kerman
Postal code
7616913555
Approval date
2019-06-25, 1398/04/04
Ethics committee reference number
IR.KMU.REC.1398.173

Health conditions studied

1

Description of health condition studied
Patients undergoing Percutaneous Coronary Intervention
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Perceived Stress
Timepoint
Before, immediately and one month after the intervention
Method of measurement
Cohen Perceived Stress Questionnaire

2

Description
Sleep quality
Timepoint
Before, immediately and one month after the intervention
Method of measurement
Pittsburgh Sleep Quality Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients in the intervention group receive cognitive-behavioral intervention along with routine medical care for 4 weeks and 2 sessions per week. Intervention is performed by trained researcher based on packages prepared by clinical psychologist in rehabilitation clinic of Shafa hospital in groups of 5-6 persons.Session One: References and brief explanations

about stress management and its impact on coronary artery disease and treatment modalities, especially coronary interventions through the skin. Session 2: Understanding the Importance, Awareness of the Physical and Psychological Impacts of Stress, and the Importance of Managing and Monitoring Stress Levels and Creating a List of Stressors(Resting exercises). Session 3: Understanding the Relationship between Thoughts, Emotions, and the Evaluation Learning Process) Diaphragmatic Respiratory Exercise) Identifying Different Types of Negative Thoughts, Understanding Negative Impact on Behavior) Imaging Exercises as Imaging (, Identifying Logical and Irrelevant Self-talk, Learning Steps) Replacing Logical Thoughts (Calming Exercises as Imaging with Diaphragmatic Breathing.Session 4: Learn Coping Types Identify your own coping style, effective coping or ineffective) Relaxation exercises as visualized with diaphragmatic breathing (, learning and practicing effective coping steps, softening exercises for overwhelming stressors) As a positive self-induction visualization (, learn anger management. Session 5: Learn Interpersonal Styles, Expressive Communication Practice, and Use Problem Solving Skills) Perform Breathing Counting Meditation Exercises (and Understand the Benefits of Social Support Identify Barriers to Social Support Learn stress management techniques for social support and coping (coping exercises) Imaging face with diaphragmatic breathing). Session 6: Assessing Sleep Problem, Understanding Sleep and Insomnia, Thought Assessment, Calm Training and Homework (Sleep Calendar and Constructive Concerns Worksheet). New sleep hygiene and timing, sleep restriction, daily snooze, food hygiene and homework (sleep calendar and constructive worries). Session Seven: Problem Solving Skills, Summarizing Thoughts, Reality of Sleep, Brainstorming, Emotional Training, Mental Imagery, Tranquility, and Unnecessary Trying to Sleep (Antonyms Intention) Pre-assignments (Sleep Calendar and Constructive Concerns Worksheet) and outline the entire Cognitive-Behavioral Therapy Plan, Sleep Health, Behavioral and Cognitive Interventions.Eighth Session: The Three Sides of Past Meetings

Category

Behavior

2

Description

Control group: Patients in the control group receive only the usual medical intervention during this period.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Shafa hospital

Full name of responsible person

Marzieh Salimpour

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Kosar Blvd, Kerman

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Abbas pardakhty

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Research and Technology Dept. - Research Manager, Ibn Sina Ave.Tahmasebad Crossroad,

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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

Kerman 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
Kerman University of Medical Sciences

Full name of responsible person
Marziyeh Salimpour

Position
MSc student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Person responsible for updating data

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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
Failure to complete the plan

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available