

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jul 2026

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

#### Protocol summary

Percutaneous Coronary Intervention

##### 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

#### 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)

##### Phone

+98 34 3251 6766

##### Email address

salim.mp97@gmail.com

##### 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

**Street address**

Kosar Blvd, Kerman

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**Province**

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7618751151

**Phone**

+98 34 3211 5780

**Email**

shafahospital@kmu.ac.ir

**Web page address**

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Abbas pardakhty

**Street address**

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

**City**

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**Province**

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**Postal code**

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**Fax**

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abpardakhty@kmu.ac.ir

**Web page address**

http://vcrt.kmu.ac.ir

**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

**Street address**

Shafa hospital, end of the Shafa street, Jomhori  
boulevard

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Kerman University of Medical Sciences

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Marziyeh Salimpour

**Position**

Senior Student

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Bachelor

**Other areas of specialty/work**

Nursery

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Parvin Mangolian Shahrbabaki

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

Faculty of Nursing and Midwifery, Kerman University  
of Medical Sciences,

**City**

Kerman

**Province**

Kerman

**Postal code**

7616913555

**Phone**

## 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