

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

The Effectiveness of Cognitive-Behavioral Intervention on Sleep Quality in Patients Rescued from Acute Myocardial Infarction

Protocol summary

Study aim

Determining the effectiveness of cognitive-behavioral intervention on sleep quality in patients rescued from acute myocardial infarction

Design

Patients were randomly assigned to experimental (cognitive-behavioral internalization according to Beck instructions) and control (routine appointments) by block allocation. The required sample size was 68 people and 34 people were considered in each group. The method of assigning patients to the experimental group and the control group was randomized based on the names of patients discharged from the hospital.

Settings and conduct

The research environment of Fatemeh Al-Zahra Hospital in Sari (Mazandaran Heart Center) is in Sari. First, the questionnaires were completed by both groups one week after discharge (before the intervention). Cognitive-behavioral intervention was performed individually in 12 sessions of 45 minutes according to Beck instructions. After a month of rest (because it is a psychotherapy intervention and its effects should be evaluated), the questionnaires were completed again by both groups.

Participants/Inclusion and exclusion criteria

Age 30 to 55 years old; discharge with diagnosis of myocardial infarction from the hospital; stable condition of the patient; having the ability to communicate effectively for learning (having a sufficient level of literacy and not having a language barrier and no hearing problems); absence of diagnosed psychological disorder; absence of underlying factors and diseases affecting sleep (COPD)

Intervention groups

Intervention group: cognitive-behavioral intervention based on Beck instructions. Control group: has received routine care.

Main outcome variables

cognitive behavioral therapy; sleep quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220208053973N1**

Registration date: **2022-02-27, 1400/12/08**

Registration timing: **registered_while_recruiting**

Last update: **2022-02-27, 1400/12/08**

Update count: **0**

Registration date

2022-02-27, 1400/12/08

Registrant information

Name

maryam ziyari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8889 6696

Email address

maryamziyari20@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-23, 1400/12/04

Expected recruitment end date

2022-03-29, 1401/01/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effectiveness of Cognitive-Behavioral Intervention on Sleep Quality in Patients Rescued from Acute Myocardial Infarction	
Public title	The Effectiveness of Cognitive-Behavioral Intervention on Sleep Quality
Purpose	Supportive
Inclusion/Exclusion criteria	Inclusion criteria: Discharge with diagnosis of myocardial infarction from the hospital Stable condition of the patient Having the ability to communicate effectively for learning (having a sufficient level of literacy and not having a language barrier and no hearing problems) Exclusion criteria: The presence of a diagnosed psychological disorder Existence of underlying factors and diseases affecting sleep (COPD)
Age	From 30 years old to 55 years old
Gender	Both
Phase	N/A
Groups that have been masked	No information
Sample size	Target sample size: 68
Randomization (investigator's opinion)	Randomized
Randomization description	The method of assigning patients to the experimental group and the control group is randomized based on the names of patients discharged from the hospital. In this way, the names of all selected patients are written on 68 different cards without any special order and the cards are placed in a box, then the cards are mixed, the cards are selected one after the other, the individual cards in the test group And even cards are in the control group.
Blinding (investigator's opinion)	Not blinded
Blinding description	
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	
<u>1</u>	
Ethics committee	
Name of ethics committee	Ethics Committee of the School of Nursing and Midwifery and the School of Rehabilitation
Street address	Keshavarz Boulevard, corner of Quds Street, in front of Laleh Park
City	Tehran
Province	Tehran
Postal code	1417653761
Approval date	2020-08-22, 1399/06/01
Ethics committee reference number	IR.TUMS.FNM.REC.1399.087
Health conditions studied	
<u>1</u>	
Description of health condition studied	Myocardial infarction
ICD-10 code	I21.4
ICD-10 code description	Non-ST elevation (NSTEMI) myocardial infarction
Primary outcomes	
<u>1</u>	
Description	Sleep quality
Timepoint	Before intervention, one month after intervention
Method of measurement	Pittsburgh Sleep Quality Questionnaire
<u>2</u>	
Description	Subjective sleep quality
Timepoint	Before intervention, one month after intervention
Method of measurement	Pittsburgh Sleep Quality Questionnaire
<u>3</u>	
Description	Sleep latency
Timepoint	Before intervention, one month after intervention
Method of measurement	Pittsburgh Sleep Quality Questionnaire
<u>4</u>	
Description	Sleep duration
Timepoint	Before intervention, one month after intervention
Method of measurement	Pittsburgh Sleep Quality Questionnaire

5

Description

Habitual sleep efficiency

Timepoint

Before intervention, one month after intervention

Method of measurement

Pittsburgh Sleep Quality Questionnaire

6

Description

Sleep disturbances

Timepoint

Before intervention, one month after intervention

Method of measurement

Pittsburgh Sleep Quality Questionnaire

7

Description

Use of sleeping medication

Timepoint

Before intervention, one month after intervention

Method of measurement

Pittsburgh Sleep Quality Questionnaire

8

Description

Day time dysfunction

Timepoint

Before intervention, one month after intervention

Method of measurement

Pittsburgh Sleep Quality Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: first, the sleep quality questionnaire was completed by patients one week after discharge (before the intervention). Cognitive-behavioral intervention was performed individually in 12 sessions of 45 minutes according to Beck instructions. The first intervention session was done one week after the patients were discharged from the hospital, two sessions per week for 6 weeks online (due to the prevalence of Covid-19 epidemic) by the researcher and with the favorable opinion of the supervisor. After a month of rest (because it is a psychotherapy intervention and its effects should be evaluated), the mid-patient sleep quality questionnaire was completed again.

Category

Behavior

2

Description

Control group: did not receive any intervention and received routine care.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemeh Al-Zahra Hospital in Sari (Mazandaran Heart Center) in Sari

Full name of responsible person

Maryam ziyari

Street address

Hazrat Fatemeh Al-Zahra Hospital in Sari (Mazandaran Heart Center), Imam Square

City

Sari

Province

Mazandaran

Postal code

4818813371

Phone

+98 11 3332 3023

Email

maryamziyari20@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Seyed Ahmad Rezaei

Street address

Keshavarz Boulevard, corner of Quds Street, in front of Laleh Park

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Province

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Email

rezaii@sina.tums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran 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

City
Tehran
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Tehran
Postal code
1417653761
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noghanif@tums.ac.ir

Person responsible for general inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Fatemeh Noghani
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
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Keshavarz Boulevard, corner of Quds Street, in front
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Maryam Ziyari
Position
Masters student
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
Keshavarz Boulevard, corner of Quds Street, in front
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Tehran
Province
Tehran
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1417653761
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+98 21 8163 3102
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maryamziyari20@gmail.com

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

There is no more information

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