Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

1

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

1

Description of health condition studied
Myocardial infarction
ICD-10 code
I21.4
ICD-10 code description
Non-ST elevation (NSTEMI) myocardial infarction

Primary outcomes

1

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

2

Description
Subjective sleep quality
Timepoint
Before intervention, one month after intervention
Method of measurement
Pittsburgh Sleep Quality Questionnaire

3

Description
Sleep latency
Timepoint
Before intervention, one month after intervention
Method of measurement
Pittsburgh Sleep Quality Questionnaire

4

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
City
Tehran
Province
Tehran
Postal code
1417653761
Phone
+98 21 8163 3102
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

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 of Laleh Park

City

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Province

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Postal code

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Phone

+98 21 8163 3102

Email

noghanif@tums.ac.ir

Person responsible for scientific 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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Email

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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

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Tehran

Postal code

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Phone

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Email

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