

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

study the effect of one shot cognitive behavioral therapy on insomnia and heart rate variability of healthcare workers at the time of covid-19

Protocol summary

insomnia, heart rate variability

Study aim

Study the effect of one shot cognitive behavioral therapy on insomnia and heart rate variability of health care workers at the time of Covid-19 pandemic

Design

Clinical trial, with parallel groups, for 70 patients, randomized using a random string, double-blind, the outcome evaluator and data analyzer will be blinded,

Settings and conduct

This study is being performed on health care workers at Al-Zahra and Khorshid Hospitals in Isfahan. 70 healthcare workers will randomly divide into two groups and the intervention group underwent a one-shot cognitive behavioral therapy intervention. Blinding is done by assigning a unique code to patients and the outcome assessor and the data analyzer are unaware of the groups.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Healthcare workers who work in ALzahra hospital, insomnia score of 8 and higher based on Insomnia Severity Index, age 18 years old and above; Exclusion criteria: History of cardiovascular disease, history of seizure, manic depressive disorder, narcolepsy, and parasomnia, using beta-adrenergic blockade or antiarrhythmic medications

Intervention groups

Intervention group: The sleep diary sheets are given to participants to be completed by them within the next 2 weeks. Then participants are divided into groups of 2-3 people and each group will come for a group meeting (for one-shot cognitive behavioral therapy) at a specific time. An ECG will be recorded for 5 minutes before the start of the session to assess changes in basal heart rate. After a month, the consequences are reviewed. Control group: includes hospital health staff for whom no intervention is performed and only at similar times in the intervention group, heart rate changes and insomnia severity are evaluated for them.

Main outcome variables

General information

Reason for update

This study is carried on healthcare workers. During the recruitment, they were involved with the 4th wave of the Covid-19 pandemic. Hence, we had to change the protocol.

Acronym

IRCT registration information

IRCT registration number: **IRCT20171219037964N4**

Registration date: **2021-03-20, 1399/12/30**

Registration timing: **prospective**

Last update: **2021-12-18, 1400/09/27**

Update count: **1**

Registration date

2021-03-20, 1399/12/30

Registrant information

Name

Babak Amra

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3668 0048

Email address

amra@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-09, 1400/01/20

Expected recruitment end date

2021-07-22, 1400/04/31

Actual recruitment start date

2021-04-21, 1400/02/01
Actual recruitment end date
2021-07-22, 1400/04/31
Trial completion date
2021-09-22, 1400/06/31

Scientific title
study the effect of one shot cognitive behavioral therapy on insomnia and heart rate variability of healthcare workers at the time of covid-19

Public title
study the effect of cognitive therapy on insomnia and heart rate variability of health care workers

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Healthcare workers who work in ALzahra and Khorshid hospital Insomnia score of 8 and higher based on insomnia severity index age over 18 years old
Exclusion criteria:
History of cardiovascular disease History of seizure, manic depressive disorder, narcolepsy and parasomnia Using beta adrenergic blockade or anti arrhythmic medications

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **70**
Actual sample size reached: **57**

Randomization (investigator's opinion)
Randomized

Randomization description
A random sequence for 70 numbers is made using randomization.com and is available to the research assistant. Each person is given a code (from one to 70). The research assistant places the person in the relevant groups by matching the person's code with a random sequence.

Blinding (investigator's opinion)
Double blinded

Blinding description
Each person is given a unique code and these codes are given to the research assistant. The person in charge of data analysis and the person in charge of follow-up are unaware of their allocation to study groups and study codes.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

Hezarjerib St.

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2021-03-15, 1399/12/25

Ethics committee reference number

IR.MUI.MED.REC.1399.1153

Health conditions studied

1

Description of health condition studied

Insomnia

ICD-10 code

F51.01

ICD-10 code description

Primary insomnia

Primary outcomes

1

Description

insomnia

Timepoint

at baseline, after one month

Method of measurement

Insomnia Severity Index

2

Description

Heart rate variability

Timepoint

at baseline, after one month

Method of measurement

heart monitoring

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: This group first completes sleep diary for two weeks and then receives a group session (in groups of 2-3) of a one-session cognitive behavioral intervention based on their sleep status and sleep habits.

Category

Treatment - Other

2

Description

Control group: Routine treatments

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Babak Amra

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Soffe St.

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8174675731

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2

Recruitment center

Name of recruitment center

Khorshid Hospital

Full name of responsible person

Babak Amra

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Ostandari St.

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8145831451

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amra@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo

Street address

Chancellory of Research, Isfahan University of Medical Sciences, Hezarjerib St.

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Babak Amra

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Participants data will be Shared after being unidentified

When the data will become available and for how long

Six months after the publication of the results

To whom data/document is available

All researchers are allowed to have access to data

Under which criteria data/document could be used

In order to use in Meta-analysis studies

From where data/document is obtainable

A request should be sent to the Chancellery of Research of Isfahan University of Medical Sciences

What processes are involved for a request to access data/document

The request will be reviewed in the Chancellery of Research and the Ethics Committee of Isfahan University of Medical Sciences; Data will be delivered upon approval.

Comments