Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

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
insomnia, heart rate variability

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

Isfehan

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 dairy 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
Street address
Soffe St.
City
Isfahan
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Isfehan
Postal code
8174675731
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2

Recruitment center
Name of recruitment center
Khorshid Hospital
Full name of responsible person
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Ostandari St.
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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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Email
sh_haghjoo@med.mui.ac.ir
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
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Person responsible for updating data

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Amra@med.mui.ac.ir

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