

Brief internet-delivered intervention for insomnia among health care workers and nursing staff

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| Submission date 22/05/2022 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered |
| Registration date 24/05/2022 | Overall study status Completed | <input checked="" type="checkbox"/> Protocol |
| Last Edited 25/06/2024 | Condition category Mental and Behavioural Disorders | <input type="checkbox"/> Statistical analysis plan |
| | | <input type="checkbox"/> Results |
| | | <input type="checkbox"/> Individual participant data |
| | | <input type="checkbox"/> Record updated in last year |

Plain English summary of protocol

Background and study aims

Insomnia means you regularly have problems sleeping. It is particularly common among healthcare workers. Cognitive Behavioral Therapy for Insomnia (CBT-I) is established as the best available treatment. However, very few patients with insomnia receive this treatment. One potential way of improving the dissemination of CBT-I is by using online adaptations of CBT-I. This is a new method for delivering CBT-I and it is not known how effective online treatment is compared to face-to-face CBT-I. This trial's purpose is to compare internet-delivered Mindfulness-based stress reduction with online CBT-I. Because of the great advantage of online treatment in both availability and cost, the trial is designed as a noninferiority trial.

Who can participate?

Nurses who actively worked during the pandemic are targeted in the study.

What does the study involve?

Participants will be randomly allocated to receive 6 sessions of mindfulness training or an online CBT-I course for approximately 6 weeks. Participants will be followed up after 3 months.

What are the possible benefits and risks of participating?

The improvement in sleep quality is the most important benefit in this study. Nurses who learn the skills related to insomnia treatment will also be able to reduce the patients' insomnia and sleep problems. The interventions are classified as safe.

Where is the study run from?

Lorestan University (Iran)

When is the study starting and how long is it expected to run for?

January 2021 to September 2022

Who is funding the study?

Investigator initiated and funded

Who is the main contact?
Dr Nabi Nazari, nnpilotiriaf@gmail.com

Contact information

Type(s)
Scientific

Contact name
Dr Nabi Nazari

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IR.LUMS.REC.1399.269

Study information

Scientific Title
Mindfulness-based therapy for insomnia in nursing staff: a non-inferiority internet-delivered, randomized controlled trial

Acronym
iMBSR

Study objectives
An internet-delivered, two-arm, assessor-blinded, parallel group randomized controlled trial design will be used to examine the impact of CBT-I compared to MBSR among a sample

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 12/01/2021, Lorestan Research Ethics Committee (Lorestan University of Medical Sciences, Anooshirvan Rezaei Square, Khorramabad, Lorestan, Iran, 6813833946; +98 6633302033; publicrelation@lums.ac.ir), ref:

Study design

An internet-delivered two-arm assessor-blinded parallel-group randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Internet/virtual

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied

Insomnia

Interventions

The study will be a randomized, controlled trial of internet-based cognitive behavioral therapy (iCBT) vs Mindfulness based stress reduction for insomnia

Mindfulness group:

Session 1:

Physiological and psychological response to stress

What is mindfulness?

Mindfulness history, application and science research

Session 2: Brain's mode of action and existence

Session 3: Interpretation of insomnia

Session 4: Interpretation of thoughts Interpretation of emotions

Session 5: Avoidance response Allow emotions

Session 6: How to balance our life Seven attitude of mindfulness practices

Homework:

Meditation practice

Mindful breathing meditation

Mindful body scan Homework

Mindful breathing meditation

Bringing mindfulness to daily life

Control Group:

Participants in the CBT-I group will receive internet-based CBT-I intervention The core contents are designed based on CBT-I:
Sleep hygiene education,
Individualized sleep restriction,
Stimulus control,
Relaxation audios (muscle relaxation, breathing exercise, guided imagery, and mindfulness),
Cognitive components, information about sleeping pills, and
A brief overview.

Intervention Type

Behavioural

Primary outcome measure

Insomnia Severity Index (Total) at pre-intervention, intervention completion (expected average of 6 weeks), 3 months follow up

Secondary outcome measures

1. Self-reported beliefs and attitudes about sleep measured using the Dysfunctional Beliefs and Attitudes About Sleep Scale from Baseline to Post-Treatment and 3 month follow-up
2. Self-reported depression symptoms measured using the Beck Depression Inventory II from Baseline to Post-Treatment and 3 month follow-up

Overall study start date

12/01/2021

Completion date

01/09/2022

Eligibility**Key inclusion criteria**

1. Aged 18 years or older with no prior experience with CBT-I
2. Willing to participate and were randomly assigned to the control condition
3. Access to the Internet and had an e-mail address

Participant type(s)

Health professional

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

100

Key exclusion criteria

1. Pregnancy or breastfeeding
2. Clear and current or history of substance dependence disorder or alcohol, and suicide
3. Receive psychotherapy during the period of this study

Date of first enrolment

01/06/2022

Date of final enrolment

01/07/2022

Locations**Countries of recruitment**

Iran

Study participating centre

Lorestan University

5km highway tehran

Khorrarnabad

Iran

65055

Sponsor information**Organisation**

Lorestan University

Sponsor details

5Km Teharn Highway

Khorrarnabad

Iran

6505

+98 66566576

lu@ac.com

Sponsor type

University/education

Website

<http://www.lu.ac.ir/>

ROR

<https://ror.org/051bats05>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

The results will be submitted to high reputation Journals (e.g. BMC Psychiatry) for publication

Intention to publish date

01/09/2023

Individual participant data (IPD) sharing plan

Raw data, after it is depersonalized, will be submitted to ISRCTN.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|----------------------------------|---------|--------------|------------|----------------|-----------------|
| Protocol article | | 16/12/2022 | 25/06/2024 | Yes | No |