ISRCTN36198096 https://doi.org/10.1186/ISRCTN36198096

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

Submission date
22/05/2022

Recruitment status
No longer recruiting

Registration date
24/05/2022

Overall study status
Completed

Last Edited
25/06/2024

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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

ORCID ID
https://orcid.org/0000-0003-3771-3699

Contact details
Lorestan University
Khorramabad
Iran
65065
+98 66986756
Nnpilotiriaf@gmail.com

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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, accessor-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

Study type(s)
Treatment

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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
Khorramabad
Iran
65055

Sponsor information

Organisation
Lorestan University

ROR
https://ror.org/051bats05

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes