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The effects of a sleep robot intervention on sleep, depression, and anxiety in adults with insomnia

Submission date
04/07/2021

Recruitment status
No longer recruiting

Registration date
06/07/2021

Overall study status
Completed

Last Edited
06/08/2024

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Insomnia is a sleep disorder characterized by difficulties initiating sleep, maintaining sleep, and /or early-morning awakenings. Hyperarousal, increased activity of the brain, nervous system, heart rate, and metabolism, is thought to be a common cause of insomnia and in maintaining insomnia. Different techniques to decrease arousal have shown to be effective in treating insomnia. Calm breathing can be an approach to enhance sleep. The Somnox sleep robot gives physical and auditive guidance to calm down the users' breathing. There is currently no impartial empirical evidence of the sleep robot's effects on insomnia.

Who can participate?
Adults with insomnia

What does the study involve?
Participants will be allocated to one of two groups, with an equal chance of being in either group (like tossing a coin). One group (the active group) will use the sleep robot at home for three weeks, whereas the other group (the control group) will not. Assessments are conducted before, during, and after the treatment for both groups. The control group will receive the intervention after the active phase of the experiment is complete.

What are the possible benefits and risks of participating?
The main benefit of participation is the possibility of symptom relief.

Risks with participation include the individuals' experiences of invasion of privacy when sensitive questions about psychiatric symptoms and well-being are asked. However, the outcome measures of the current study have been used in many studies without any known complications concerning the character of the questions.

Concerning the risks of infection during the COVID-19 pandemic, the sleep robot has a cover that will be washed between different participants' use of the robots. The screening process is done by phone. Hand sanitizers are provided in physical meetings (e.g. when retrieving the

robot). In case of an infected participant, the research group will consult the security manager at Karlstad University, on how to manage the sleep robot. A sleep robot that has been with an infected participant will not be used until an expert explicitly states that it is safe to do so.

Where is the study run from?
Karlstad University (Sweden)

When is the study starting and how long is it expected to run for?
December 2020 to February 2022

Who is funding the study?
Karlstad University (Sweden)

Who is the main contact?
Mrs Siri Jakobsson Støre
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Contact information

Type(s)
Public

Contact name
Mrs Siri Jakobsson Støre

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
The effects of a sleep robot intervention on sleep, depression and anxiety in adults with insomnia - a randomized waitlist-controlled trial

Study objectives
The intervention group will report significantly greater improvements regarding symptoms of insomnia (total score on the Insomnia Severity Index), compared with the waitlist control group, post-treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/01/2021, Swedish Ethical Review Authority (Etikprövningsmyndigheten, Box 2110, 750 02 Uppsala, Sweden; +46104750800; registrator@etikprovning.se), ref: EPM DNR 2020-06975

Study design
Interventional randomized waitlist-controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Insomnia

Interventions
The active intervention group will use a sleep robot (Somnox) at home for three weeks. Assessments will be conducted at baseline, mid-treatment, and post-treatment for both the active intervention group and the waitlist control group. Participants will be sequentially randomized to one of the two treatment conditions using a 1:1 allocation ratio. The method used to generate the random allocation sequence will be block randomization with a block size of 6. A statistician outside the research group will prepare and record the randomization in advance, and check that the study coordinator abides by the randomization.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Not provided at time of registration

Primary outcome(s)
Insomnia measured with the Insomnia Severity Index at baseline, 10, and 24 days

Key secondary outcome(s))

1. Pre-sleep arousal measured with the total score of the Pre-Sleep Arousal Scale at baseline, and 24 days
2. Symptoms of anxiety and depression measured with the total scores from the anxiety and depression scales of the Hospital Anxiety and Depression Scale at baseline, and 24 days
3. Sleep parameters measured with sleep diaries and actigraphy where the values from both will be averaged over a week to compute single summary scores for each of the relevant variables, for the periods -7 to 0 days and 14 to 21 days

Completion date
01/02/2022

Eligibility

Key inclusion criteria
Meets the DSM-5 diagnostic criteria for insomnia disorder as measured by clinical evaluation by a licensed psychologist using the Insomnia severity index (ISI) and the Duke structured clinical interview for sleep disorders (DSISD)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
44

Key exclusion criteria
1. Does not speak Swedish
2. Aged <18 years
3. Meet the criteria for another sleep disorder which they are not adequately treated for
4. Meet the diagnostic criteria for a medical or psychiatric condition that may explain the symptoms of insomnia

Date of first enrolment
09/08/2021

Date of final enrolment
13/12/2021

Locations

Countries of recruitment
Sweden

Study participating centre
Karlstad University
Department of Social and Psychological Studies
Karlstad
Sweden
SE-651 88

Sponsor information

Organisation
Karlstad University

ROR
https://ror.org/05s754026

Funder(s)

Funder type
University/education

Funder Name
Karlstads universitet

Alternative Name(s)
Karlstad University, KAU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Sweden

Results and Publications

Individual participant data (IPD) sharing plan

The dataset analyzed in the current study will be available upon reasonable request from Siri Jakobsson Støre, siri.store@kau.se, from March 2022 and for 10 years. Informed consent was obtained from the participants, and the data will be anonymized.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		25/10/2022	31/10/2022	Yes	No
Results article		13/07/2023	06/08/2024	Yes	No
Protocol article		01/11/2021	31/10/2022	Yes	No
Dataset	SPSS file		07/03/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Statistical Analysis Plan	Section 2.5	01/11/2021	07/03/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes