

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	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 06/07/2021	Overall study status Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 06/08/2024	Condition category Mental and Behavioural Disorders	<input checked="" type="checkbox"/> 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
siri.store@kau.se

Study website
<https://www.kau.se/somnrobot>

Contact information

Type(s)
Public

Contact name
Mrs Siri Jakobsson Støre

ORCID ID
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Home

Study type(s)

Treatment

Participant information sheet

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

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 measure

Insomnia measured with the Insomnia Severity Index at baseline, 10, and 24 days

Secondary outcome measures

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

Overall study start date

01/12/2020

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

Age group

Adult

Sex

Both

Target number of participants

44

Total final enrolment

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

Sponsor details

Department of Social and Psychological Studies

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info@kau.se

Sponsor type

University/education

Website

<http://www.kau.se/>

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

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

01/12/2022

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?
Protocol article		01/11/2021	31/10/2022	Yes	No
Results article		25/10/2022	31/10/2022	Yes	No
Dataset	SPSS file		07/03/2023	No	No

Statistical Analysis Plan	Section 2.5	01/11/2021	07/03/2023	No	No
Results article		13/07/2023	06/08/2024	Yes	No