

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

<b>Submission date</b> 04/07/2021	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 06/07/2021	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 06/08/2024	<b>Condition category</b> 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

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**Contact details**  
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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](mailto: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  
Karlstad  
Sweden  
SE-651 88  
+46547001000  
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](mailto: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?
<a href="#">Protocol article</a>		01/11/2021	31/10/2022	Yes	No
<a href="#">Results article</a>		25/10/2022	31/10/2022	Yes	No
<a href="#">Dataset</a>	SPSS file		07/03/2023	No	No

<a href="#">Statistical Analysis Plan</a>	Section 2.5	01/11/2021	07/03/2023	No	No
<a href="#">Results article</a>		13/07/2023	06/08/2024	Yes	No