

A robot intervention for adults with ADHD and insomnia

Submission date 29/03/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input checked="" type="checkbox"/> Protocol
Registration date 29/03/2023	Overall study status Completed	<input checked="" type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 09/10/2023	Condition category Mental and Behavioural Disorders	<input checked="" type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

The study looks at individual effects and experiences of a sleep robot intervention in adults with ADHD and insomnia. Different methods to collect data were used such as sleep diaries, wrist actigraphy, questionnaires, and individual interviews.

Who can participate?

Adults aged over 18 years with ADHD and insomnia.

What does the study involve?

A three-week at-home intervention with the Somnox sleep robot.

What are the possible benefits and risks of participating?

The main possible benefit was reduced insomnia symptoms. Risks with participation included 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.

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 June 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)

Principal Investigator

Contact name

Mrs Siri Jakobsson Støre

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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

A robot intervention for adults with ADHD and insomnia - A mixed-method study

Study objectives

The aims are to assess whether a three-week sleep robot intervention have individual effects in adults with adhd and insomnia, and how initial results can be understood in light of participants' experiences with the robot.

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; +46 10-475 08 00; registrator@etikprovning.se), ref: DNR 2020-06975

Study design

Mixed-methods study with an explanatory sequential design

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Home

Study type(s)

Treatment

Participant information sheet

See study outputs table

Health condition(s) or problem(s) studied

Insomnia

Interventions

A three-week sleep robot intervention with the Somnox sleep robot. Assessments were conducted daily for six weeks (sleep diary and wrist actigraphy), and pre- and post-intervention (questionnaires).

Recruitment happened through the university webpage and social media. Screening was conducted via phone (60-90 minutes). Participants were individually trained in how to use the sleep robot for 10-15 minutes. The intervention lasted for 21 days in participants' homes. Participants were encouraged to use the robot each evening/night of the intervention phase. Daily subjective sleep measurements were obtained with a sleep diary for six consecutive weeks (two baseline weeks, three intervention weeks, and one post-intervention week) (approximately 5 minutes). The same sleep variables were also obtained objectively with wrist actigraphy for two weeks of the study: week 1 (baseline) and week 3 (intervention). Additionally, participants answered questionnaires at pre-intervention, mid-intervention, post-intervention, and 1-month follow-up (approximately 10 minutes).

Intervention Type

Device

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Somnox sleep robot

Primary outcome measure

Sleep onset latency and wake after sleep onset: the Consensus Sleep Diary (daily for weeks 1-6 of the study) and actigraphy (week 1 and week 3).

Secondary outcome measures

1. Total sleep time and sleep efficiency: the Consensus Sleep Diary (daily for weeks 1-6 of the study) and actigraphy (week 1 and week 3).
2. Insomnia severity was measured using the Insomnia Severity Index at baseline, mid-intervention (week 4), post-intervention (week 6), and at 1-month follow up (week 10).
3. Somatic arousal was measured using the Pre-Sleep Arousal Scale at baseline, post-intervention (week 6), and at 1-month follow up (week 10).
4. Anxiety and depression symptoms were measured using the Hospital Anxiety and Depression Scale at baseline, post-intervention (week 6), and at 1-month follow up (week 10).
5. ADHD symptoms were measured using the Adult ADHD Self-Report Scale at baseline, post-intervention (week 6), and at 1-month follow up (week 10).

Overall study start date

01/12/2020

Completion date

01/06/2023

Eligibility

Key inclusion criteria

1. Speak Swedish fluently
2. 18 years+ of age
3. Previously diagnosed with ADHD
4. Meet the diagnostic criteria of insomnia

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

6

Total final enrolment

6

Key exclusion criteria

1. Meet the diagnostic criteria of another untreated sleep disorder
2. Meet the diagnostic criteria of another current psychiatric disorder

Date of first enrolment

01/01/2022

Date of final enrolment

01/04/2022

Locations

Countries of recruitment

Sweden

Study participating centre**Karlstad University**

Department of Social and Psychological Studies

Karlstad

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Sponsor information

Organisation

Karlstad University

Sponsor details

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Sponsor type

University/education

Website

<https://www.kau.se/en>

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

01/01/2024

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Siri Jakobsson Støre, siri.store@kau.se

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	in Swedish		29/03/2023	No	Yes
Dataset			20/06/2023	No	No
Protocol file			20/06/2023	No	No
Protocol file			20/06/2023	No	No
Protocol file			20/06/2023	No	No
Statistical Analysis Plan			20/06/2023	No	No
Statistical Analysis Plan			20/06/2023	No	No
Results article		01/09/2023	09/10/2023	Yes	No