ISRCTN11007746 https://doi.org/10.1186/ISRCTN11007746

A robot intervention for adults with ADHD and insomnia

Submission date	Recruitment status
29/03/2023	No longer recruiting
Registration date	**Overall study status**
29/03/2023	Completed
Last Edited	**Condition category**
09/10/2023	Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[X] 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

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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
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

Study type(s)
Treatment

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(s)
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).

Key secondary outcome(s))
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).

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
Sweden
65188

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 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?
Results article		01/09/2023	09/10/2023	Yes	No
Dataset			20/06/2023	No	No
Participant information sheet	in Swedish		29/03/2023	No	Yes
Protocol file			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