Sheffield Children's NHS
NHS Foundation Trust

Can the SleepCogni device (a handheld device that treats insomnia using biofeedback) improve sleep in children with chronic insomnia?

SHORT STUDY TITLE: SleepCogni

4/12/25 Version 4

LAY SUMMARY

Around 30% children in mainstream and 80% of children with neurodevelopmental disorders such as Attention Deficit Hyperactivity Disorder (ADHD) and autism are reported to have significant difficulties with sleep. This may be a problem with settling off to sleep, waking repeatedly in the night, or both.

Often these children will be prescribed a medication called melatonin to help them sleep, but there is no strong evidence of its effectiveness in most children, the long-term side effects are not known and prescriptions for this drug cost millions of pounds a year for the NHS. Many children continue to have persistent sleep problems despite taking melatonin.

Sleep support programmes delivered by nurses and sleep practitioners are known to be effective and to give parents and young people long-term strategies for promoting sleep without the use of medication. However, sleep support services are not universally funded. Sleep apps have been designed, but their efficacy is lacking and none has been designed for children or young people. A solution is needed to help children to resolve sleep problems and to prevent them from escalating to the extent that they require specialist input.

SleepCogni is a CE marked device that uses biofeedback to aid sleep and is effective for adults with insomnia. Users' comments included *"I felt in control of my sleep", "Shifts attention away from worry", "I found it easier to relax my thinking".* We therefore believe that the device will be helpful for children, especially those with autism, anxiety and ADHD who have difficulty calming their thoughts around bedtime. The Adaptive Music for Sleep (AdMuS) is a new technology developed by The University of Sheffield that employs fading music to help sleep onset and quality that will be included in the SleepCogni platform.

In this observational study, we will recruit children and young people with chronic insomnia, as defined by the International Classification of Sleep Disorders (ICSD III) as difficulty getting to sleep or staying asleep at least 3 nights a week for at least 3 months. We will test whether SleepCogni is helpful in improving sleep and wellbeing parameters for these children and their caregivers. AdMuS

will be used in a small subsample of children to test its effectiveness. We will also investigate the cost benefits of using SleepCogni in the NHS.

GENERAL INFORMATION

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BACKGROUND

Sleep is a restorative process, fundamental to physical and psychological health[1]. Sleep disturbances including bedtime resistance and night-time awakening occur in 30% children attending mainstream schools and around 80% children with neurodisability, the most common associations being with Attention Deficit Hyperactivity Disorder (ADHD) and Autism Spectrum Disorder (ASD)[2-4].

The impact of sleep disturbance on children's health is wide-ranging with sleep deprivation leading to difficulties with mood, psychosocial problems and a detrimental impact on the child's cognitive ability and learning[5,6]. Parents of children with sleep difficulties can suffer high levels of stress and anxiety, decreased ability to work or to drive safely, relationship and financial problems[7-9]. These stresses lead to an increased demand on NHS primary care services and to prescriptions of drugs such as antidepressants.

Children with significant sleep difficulties in the UK are often treated with melatonin, a hormone playing a key role in the timing of sleep-wake cycle, despite the findings of a recent systematic review that suggest that evidence does not strongly support its use[10]. The drug is costly to the health service, with individual Integrated Care Boards (ICBs) spending up to £500k per year on prescription charges for this drug alone. An alternative approach is an intensive sleep support intervention that can be delivered in the local authority, NHS and voluntary sectors. This approach can be highly effective[11,12] but is time-intensive and provision across the UK is patchy and under-resourced. A solution is still needed for milder cases to resolve them quickly and prevent them from escalating to cases that require specialist input. A technological solution is an attractive option but current digital health-solutions for insomnia do not provide personalised treatment.

The SleepCogni is a device that is used at home and is unique in that it both monitors and treats insomnia using biofeedback from physiological, behavioural and environmental data. Treatment is personalised by applying state-of-the-art artificial intelligence. Trials in adults have confirmed that SleepCogni's system can accurately predict sleep onset. It can also deliver a treatment for insomnia using light, sound and tactile cues personalised through a biofeedback system. SleepCogni is a specially moulded and patented handheld trigger device that harbours multiple sensors measuring eleven different aspects of physiology (Figure 1). Users engage actively with SleepCogni (active-biofeedback), during a continuous reaction time task, which measures grip strength and how much force is exerted on the reaction time task button. As the user becomes more sleepy, they relax the grip on the trigger, respond more slowly to the cues, and press more lightly on the reaction time button. Intuitively, an active disengagement from the reaction time task and relaxing grip and pressure on the trigger will result in a feeling of security, control and active relaxation all of which are sleep promoting.

Device Images



Figure 1.

Research at Sheffield Hallam University has shown that there was a statistically significant improvement by comparing the sleep quality of the participants, following the use of the SleepCogni prototype ($p<0.005$). Further studies together with the Department of Music at The University of Sheffield have shown that SleepCogni's auditory stimulation statistically significantly reduced sleep onset latency ($p=0.029$) and significantly increased sleep quality ($p=0.037$).

A clinical trial of 80 adults with insomnia (40 using SleepCogni and 40 using a similar placebo device) showed that compared with placebo, users perceived the device to be useful in helping them to fall asleep more quickly ($p=0.006$), would recommend it to a friend ($p=0.003$) and found it more effective than other approaches they had tried in the past ($p=0.001$). The vast majority found the device easy to use. Comments included *"I felt in control of my sleep." "Shifts attention away from worry.", "I found it easier to relax my thinking".* Insomnia severity index reduced significantly in the intervention group ($p=0.002$)[13].

Sleep trials with music indicate that music offers a promising tool for sleep facilitation[14]. Purpose-designed music technology for sleep enables the optimisation of the effectiveness of music on sleep onset and quality, taking into account subjective and objective characteristics of the music[15] and an application of music that is adaptable to users' preferences and sleep circumstances. The Adaptive Music for Sleep (AdMuS) refers to music that changes in phases in characteristics from relaxed-active to sleep-ready, supporting a change in arousal and mood, and guiding a user towards sleep. AdMuS is used in combination with the SleepCogni bedside hub.

In this evaluation study, we will recruit children and young people with chronic insomnia, as defined by the International Classification of Sleep Disorders (ICSD III) as difficulty getting to sleep or staying asleep at least 3 nights a week for at least 3 months. We will test whether SleepCogni is helpful in

improving sleep and wellbeing parameters for these children and their caregivers and will include AdMuS in a subset of the participants. We will also investigate the cost benefits of using SleepCogni in the NHS.

STUDY OBJECTIVES AND PURPOSE

Hypothesis

1. Use of SleepCogni will significantly improve bedtime settling, sleep duration, sleep continuity and sleep efficiency in children with insomnia and in turn improve the health and well-being of the child and caregivers.
2. SleepCogni will provide a cost beneficial step in the pathway for the treatment of insomnia in children in the NHS.

The objectives of this study are:
To test the device with children recruited from the sleep clinic at SCH:

- To measure sleep and wellbeing parameters before and after use of the device for children with insomnia and for their caregivers;
- To explore potential cost benefits in terms of staff time, medication costs
- To collect biofeedback data using the SleepCogni to inform future device development;
- To explore acceptability and utility of the device in further cohorts of children with more severe sleep, anxiety and/or neurodevelopmental disorders.
- To test the efficacy and tolerability of AdMuS in association with the SleepCogni platform in a subset of participants.

STUDY DESIGN

The study will be an observational "real world" study which will both help us to understand the needs and potential benefits to children and young people as well as inform the algorithms within the device.

Study 1: 2-week trial period of SleepCogni.

We will recruit cohorts of children and young people with chronic insomnia, as defined by the International Classification of Sleep Disorders (ICSD III) as difficulty getting to sleep or staying asleep at least 3 nights a week for at least 3 months. Baseline and follow-up assessments will be completed using validated and self-written questionnaires and sleep diaries; the intervention period will involve use of the SleepCogni device for 2 weeks, following which user feedback will be collected. Usual treatment in the sleep clinic involves a 2 week period of sleep data collection with a diary; Study 1 will take place during this period.

Ten children in each of the following cohorts will be recruited:

a. Children with insomnia, as defined using the ICSD III criteria but with no other comorbidity
b. Children with insomnia, as defined using the ICSD III criteria but also with ADHD and/or ASD

c. Children with insomnia, as defined using the ICSD III criteria but also on a waiting list to be assessed for possible ADHD and/or ASD

d. Children with insomnia, as defined using the ICSD III criteria but also with anxiety and/or depression

e. Children with insomnia, as defined using the ICSD III criteria who have already been prescribed melatonin and/or other medication for their sleep difficulty

The end of the two-week period, participants will be given a choice to either:

- stop the study and stay on the clinic waiting list (usual care)
- continue to use SleepCogni and stay on the waiting list (use of SleepCogni with no clinical interaction)
- continue to use SleepCogni and come off the waiting list, if use of SleepCogni is successful and the parent deems the child to no longer require clinical advice
- progress to study 2 (use of SleepCogni alongside clinical feedback and advice)

<u>Study 2: 12-week treatment programme (use of SleepCogni alongside clinical feedback and advice)</u>

After the initial trial period of SleepCogni use, if the participant chooses, they will progress to Study 2. This will involve:

- Sleep nurse assessment (usually face to face) with a sleep nurse and practitioner. At this appointment, a goal will be set by the parent/child/young person and sleep nurse and a sleep programme will be developed with the sleep practitioner.
- Follow up appointments (usually virtual) with a sleep practitioner for as long as is required to reach the goal set at the baseline assessment or for 3 months, whichever is sooner.
- 12-week follow-up assessment with the sleep nurse to assess whether the child can be discharged or will require continued support in the sleep clinic.
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<u>Study 3: 15-day trial of SleepCogni with AdMuS</u>

This is a separate study from studies 1 and 2. A different cohort of 20 children with insomnia will be recruited to trial three different music conditions via the SleepCogni hub for five days each. The three conditions are:

1. AdMuS music technology,
2. Static music (ie not fading towards sleep onset) or white noise (as preferred),
3. No music/noise

Evaluation will take place at baseline and the end of each of the three conditions.

Study 4: 8-week programme with use of Sleep Cogni at home with 3 community nurse-led assessments (n= 30 participants)

This will involve:

- Sleep nurse assessment (usually face to face) with a community sleep nurse. At this appointment, a goal will be set by the parent/child/young person and sleep nurse and a sleep programme will be developed.
- One follow-up appointment (usually virtual) at 4 weeks with the sleep nurse.
- 8-week follow-up assessment with the sleep nurse to assess whether the child can be discharged or will require continued support in the sleep clinic.

Use of SleepCogni

Each participant will be asked to use the SleepCogni device after getting settled into bed. Instructions will be given to hold and respond to the cues from the device both at bedtime and if the child wakes and needs to resettle to sleep in the night.

Members of the sleep nursing/practitioner staff will be trained by Dr van de Werken in the use of the SleepCogni device and platform in order for the information generated to be used to assist with the support of the participant.

Three video links will be given to participants to support the use of SleepCogni:

- How to set up SleepCogni: https://www.youtube.com/watch?v=tpMTD8OgB_I
- How to use SleepCogni: https://www.youtube.com/watch?v=SEzJcEBdz0A
- Explainer video: https://www.youtube.com/watch?v=8a8F56E7b9I

Data collection:

Sleep diary evaluation:

Sleep and activity diaries will be completed via the SleepCogni platform at the following timepoints:

1. At baseline (for 1 week before the baseline questionnaires)
2. For the duration of the two-week trial period of use of SleepCogni
3. At weeks 4, 8 and 12 of the 12-week treatment programme (if relevant)
4. For the duration of the AdMuS trial (if relevant)

Actiwatch evaluation:

Actigraphy will be used as a surrogate measure of sleep quality in patients at the same time as the sleep diaries at the following timepoints:

1. At baseline (for 1 week before the baseline questionnaires)
2. For the duration of the two-week trial period of use of SleepCogni
3. At weeks 4, 8 and 12 of the 12-week treatment programme (if relevant)
4. For the duration of the AdMuS trial (if relevant)

Questionnaire evaluation:

Evaluations will be completed at three timepoints:

1. At baseline,

2. On completion of the 2-week trial period of SleepCogni,
3. On completion of the study at 8 or 12 weeks (if relevant).
4. On completion of each of the music conditions (if relevant)

Data will be collected by the research team using the on-line SleepCogni platform and paper questionnaires. The evaluations will be facilitated by home visits, video-link, phonecalls and/or questionnaires will be posted to be completed at home and returned via email or post.

Questionnaires:

- Child Sleep Disturbance Index
- Sleep questionnaires:
    - Child Sleep Habits Questionnaire (for parents to complete for children aged 6-16 years)
    - Sleep Self Report (for children aged 6-11 years to complete themselves)
    - Cleveland Adolescent Sleepiness Questionnaire (for young people aged 12-16 years to fill in themselves)
- Wellbeing and Quality of Life questionnaires:
    - Impact on Wellbeing questionnaires - child (parent to complete on behalf of children aged 6-11 years), parent (parent to complete for themselves) and YP (YP aged 12-16 years to complete for themselves)
    - Warwick and Edinburgh wellbeing questionnaire (parent to complete for themselves)
    - Quality of Life questionnaires for parent to complete about themselves (EQ-5D-5L) and their child (EQ-5D-Y-5L)
    - Carer burden scale (parents to complete)
- Health utilisation questionnaire (parent to complete) - baseline only

An additional questionnaire for the AdMuS study (3) will also be used:

- Evening and morning questionnaire

User feedback:

A feedback questionnaire and a structured feedback interview will be carried out by telephone after the device has been used. This will explore the perceived tolerability and utility of SleepCogni in the home environment after the 2-week trial period and the 3-month study period (if relevant).

Cost benefit analysis (see Healthcare utilisation questionnaire above):

- Number, duration and type (face-to-face, video, telephone) of appointments attended and type of professional consulted (nurse, practitioner, consultant)
- Medication use

Biofeedback:

The device will automatically collect biofeedback with regards to reaction speeds and patterns of use while the child is using the device. The physiological and behavioural responses collected by the device during its of use will provide the high-quality data necessary to optimise the internal AI algorithm for the paediatric population, thereby improving the cues delivered by the device to ensure that they are suitable for children. This information will be pivotal to the final development of the device software for a future effectiveness trial.

END OF STUDY

The end of study date will be the date of the last contact from the research team for feedback on the device and study design.

SELECTION OF PARTICIPANTS

Potential participants will be recruited from the sleep or neurodisability clinic waiting lists, CAMHS or the wards (AdMus only), at Sheffield Children's NHS Foundation Trust.

Inclusion Criteria

- Children and young people aged 6-16 years (11-16 years for AdMuS)
- Chronic Insomnia, as defined by ICSD III
- Willingness to engage with the SleepCogni device by both parent and child/young person
- Inclusion criteria for study 4 are direct GP referrals with no previous sleep practitioner support.

Exclusion Criteria

- Primary sleep problem is physiological, eg sleep disordered breathing
- Insufficient understanding of English language,
- Severe presentation, eg non-verbal, learning difficulties which mean child is unable to understand the purpose of the device.
- Children/parents already known to be unable to engage with behavioural strategies

PARTICIPANT RECRUITMENT

Patients fulfilling the inclusion criteria will be approached by members of the sleep team at SCH in clinic or by telephone and, if in agreement, will be screened in detail for eligibility to check formally that they meet all of the inclusion criteria and do not meet any of the exclusion criteria. Parent/patient information sheets and consent/assent forms will then be sent in the post or by email. A follow-up phone call will be made approximately 4 days later to check whether there are any queries. If the participant is willing to consent, this will be done on the phone using Docusign or the signed consent/assent forms will be returned in the post.

BURDEN TO PARTICIPANTS

After the initial approach, if a family decides to take part in the study, this will involve:

Study 1: 2-week trial period of SleepCogni.

- Use of SleepCogni for two weeks
- Completion of sleep diaries every day during the week before the trial and two-week study period.
- Use of actiwatch every day during the week before the trial and two- week study period.
- 2 sets of questionnaires – one at baseline and one after the two-week trial period. Each set of questionnaires will take around 30- minutes to complete.
- 3 phone calls – one to check for eligibility, one to complete consent and one to complete the final evaluation.

Study 2: 12-week treatment programme (use of SleepCogni alongside standard clinical treatment)
In addition to Study 1:

- Use of SleepCogni for further 12 weeks
- Completion of sleep diaries every day during weeks 4, 8 and 12 of the 12- week study period.
- Use of actiwatch every day during weeks 4, 8 and 12 of the 12- week study period.
- 1 set of questionnaires at the end of the 12-week treatment period.
- 1 further phone call to complete the final evaluation.

Study 3: 15-day trial of SleepCogni with AdMuS

- Use of SleepCogni for 15 days
- Completion of sleep diaries every day during the 15-day study period.
- Use of actiwatch every day during the 15-day study period.
- 4 sets of questionnaires – one at baseline and one after each of the three music conditions. Each set of questionnaires will take around 15 minutes to complete.
- 2 phone calls – one to check for eligibility, one to complete consent.

Study 4: 8-week use of Sleep Cogni at home with 3 community nurse-led reviews

- Use of SleepCogni for 8 weeks
- Completion of sleep diaries every day during weeks 4 and 8 of the 8- week study period.
- Use of actiwatch every day during weeks 4 and 8 of the 8- week study period.
- 1 set of questionnaires at the end of the 8-week treatment period.
- 1 further phone call to complete the final evaluation.

This study burden will be made clear in the parent/patient information sheets and again prior to consent.

Participants will not be offered payment but will receive a thankyou voucher on completion of the project.

DATA HANDLING AND RECORD KEEPING

The SCH project team will be responsible for collecting and recording all questionnaire data under the guidance of Heather Elphick as project lead. The data will be anonymized using project-specific patient identifiers.

The participating children will be assigned a unique study number to link their results to their identifiable hospital information. A spreadsheet linking the patient data to the unique study number will be kept securely on an encrypted NHS computer. The anonymous evaluation questionnaires and anonymous data collection sheets will be electronically scanned. The original paper copies will be kept with the research files at Sheffield Children's Hospital in a secure location. The data collection will take place at Sheffield Children's Hospital and will only be shared with the research team after anonymisation. The consent forms will be stored at Sheffield Children's Hospital in the research site file and a copy in the patient's medical notes.

Data will be collected and retained in accordance with the Data Protection Act 2018. Trial documents (paper and electronic) will be retained in locked filing cabinet drawers and encrypted electronic files stored on secured NHS Trust servers during and after the trial has finished. All source documents will be retained for a period of 10 years following the end of the trial. Where trial related information is documented in the medical records – those records will be retained for 10 years after the last patient last visit.

Data collected via the SleepCogni platform will be anonymised by the following process: each participant is assigned a unique ID number and a unique email account. Email accounts will be pre-made so that the research team can provide participants with their ready-made account and log in details when they consent to the study.

Data will not be shared outside of the research team. No identifiable data will be used for the purposes of presentations, publications, and further development.

ACCESS TO SOURCE DATA

The sponsor will permit monitoring and audits by the relevant authorities, including the Health Research Authority and Research Ethics Committee. The investigator will also allow monitoring and audits by these bodies and the sponsor, and they will provide direct access to source data and documents.

STATISTICAL ANALYSIS

As this is an observational study, there is no sample size calculation. The purpose is to test the process, to identify positive and negative outcomes explore cost/benefit ratio and to inform the paediatric AI algorithm.

Data will be entered in an appropriate statistical software package (e.g., Excel) and analysed by the study team. In the analyses we will determine the longitudinal relationship between the SleepCogni intervention and the outcomes measures as well as an inter-group analysis.

SAFETY ASSESSMENTS

New clinical equipment to Sheffield Children's Hospital is reviewed by the medical equipment management group (MEMG) and the study will only proceed if the device is given approval.

The study will be monitored and audited in accordance with the Monitoring Standard Operating Procedures of the Directorate of Research & Innovation at Sheffield Children's NHS Foundation Trust. All study related documents will be made available on request for monitoring and audits by the Sponsor, the Health Research Authority and the relevant Research Ethics Committee.

ETHICAL CONSIDERATIONS

The study will be conducted in compliance with the NHS Research Ethics Committee favourable opinion, Health Research Authority approval and Confirmation of Capacity & Capability at all participating sites.

The study will also be conducted in accordance with the International Conference for Harmonisation of Good Clinical Practice (ICH GCP), and the Research Governance Framework for Health and Social Care (2nd Edition).

No clinical decisions will be made on the basis of data collection during this study. Clinical management will continue as usual and any changes in management will be made by the clinical team as a result of direct clinical review.

FINANCE AND INDEMNITY

The study will be funded by Innovate UK. Study 4 is funded by NIHR i4i FAST.

The study sponsor will be BrainTrain 2020, the manufacturer of SleepCogni. If there is negligent harm during the study when the NHS body owes a duty of care to the person harmed, NHS Indemnity will

cover NHS staff, medical academic staff with honorary contracts and those conducting the study. NHS Indemnity does not offer no-fault compensation and is unable to agree in advance to pay compensation for non-negligent harm. Ex-gratia payments may be considered in the case of a claim.

REPORTING AND DISSEMINATION

The findings of this project will be of interest and benefit to researchers, practitioners and parents of children who have sleep disorders. Intended dissemination opportunities include: The Sleep Charity conference, British Sleep Society (BSS) conference; social media dissemination.

IMPACT

The primary aim of the study is to test whether SleepCogni can deliver an improvement in children's sleep patterns, thereby reducing the pressure on sleep services which are widely under-resourced. We will also look at cost benefit measures to assess whether the device may reduce the need for NHS resources. Prof Elphick is well-connected, with links to NIHR CYP MedTech and the BPSS in terms of widening the scope for NHS adoption if this trial is successful.

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