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A study to test whether a new website, Sleep Buddy, developed by doctors and psychologists, can help parents and carers of children aged 6-12 years with a diagnosis of ADHD who are experiencing sleep problems to improve their child's sleep

Submission date
11/04/2025

Recruitment status
Recruiting

Registration date
22/01/2026

Overall study status
Ongoing

Last Edited
22/01/2026

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Almost 75% of children with Attention Deficit Hyperactivity Disorder (ADHD) have sleep problems. Parents and carers tell us that poor sleep makes their children's daytime behaviour and schoolwork worse and affects the quality of life of the whole family.
The aim of this study is to see if our new website Sleep Buddy, can help parents/carers of children aged 6-12 years with a diagnosis of ADHD, to improve their child's sleep.
Sleep Buddy was developed by parents and carers of children with ADHD working with sleep experts. It has personalised information and advice on how primary caregivers can manage their child's sleep problems with videos and top tips from other parents. The website will help primary caregivers to create a sleep plan to help their child's sleep.

Who can participate?
Children aged 6 - 12 years who suffer from ADHD and chronic insomnia.

What does the study involve?
The study will last for 6 months, and over 300 people will take part. The study can be completed online.
Parents or carers taking part will be put into one of two groups. One group will have access to the Sleep Buddy website for 6 months. The other group will not, but will continue to receive the health care and support that they have always been given. This group will also get access to the website after 6 months, at the end of the research project.
At the start of the study, both groups will be asked to fill out a short sleep diary online every morning for 10 Days. They will also complete some questionnaires online and some with a study researcher on video chat. The child will be invited to complete some computer-based attention

and memory tasks, with the support of one of our researchers. All participants will complete the sleep diary, questionnaires and tasks at month 3 and month 6.

What are the possible benefits and risks of participating?
If you are allocated to the group asked to use the website, you will have the opportunity to use a website developed by experts. Participants in all groups will be helping to contribute to our understanding of how best to help children diagnosed with ADHD experiencing sleep problems and their carers.
If you and your child are in put in the group that does not have access to the website, you may not benefit during the study, but we hope that you will find it a positive experience. There is no financial benefit to participating, you may however benefit from the use of the study website that will be offered to you at the end of the study.
Whichever group you are randomised into, you will be helping to contribute to our understanding of how best to help sleep problems in this population.Children who complete all online tasks will be entered into a prize draw to win a £25 Love2Shop or Amazon gift voucher. There will be 20 prizes of this amount. Additionally, if you participate in the interviews, you will receive a £20 Love2Shop or Amazon gift voucher.
A possible disadvantage is the time taken to be a part of the study. Completing the 10-Day Diary, questionnaires and attention and memory tasks will take some time, as well as time associated with using the website.

Where is the study run from?
University Hospital Southampton NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
July 2025 to February 2028

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK).

Who is the main contact?
Alannah Morgan, sleepbuddy@soton.ac.uk

Contact information

Type(s)
Public

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Additional identifiers

Central Portfolio Management System (CPMS)
66477

National Institute for Health and Care Research (NIHR)
203684

Integrated Research Application System (IRAS)
349971

Study information

Scientific Title
Multicentre randomised controlled trial of digital parent guided sleep intervention (Sleep Buddy) versus usual care in children aged 6-12 years with ADHD and chronic insomnia

Acronym
DISCA (SleepBuddy)

Study objectives
Scientific:
To determine whether the addition, to Usual Care (UC), of a digital parent-guided sleep intervention reduces mean sleep onset latency at 3 months post-randomisation, in children with ADHD and chronic insomnia.

Public:
To see if an online parent-guided sleep intervention website helps improve sleep problems in 6-12 year old children with ADHD.

Ethics approval required
Ethics approval required

Ethics approval(s)

approved 24/03/2025, West of Scotland REC 5 (West of Scotland Research Ethics Service, Level 2, Administration Building Gartnavel Royal Hospital 1055 Great Western Road, GLASGOW, G12 0XH, United Kingdom; +44 141 314 0213; ggc.wosrec5@nhs.scot), ref: 25/WS/0007

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Insomnia and ADHD (attention deficit hyperactivity disorder)

Interventions
Randomisation process
Following informed consent, completion of screening, baseline measurements, and confirmation of eligibility by the Hub RA, participants will be randomised as part of the online platform 1:1 via the GI platform managed by Southampton CTU to the digital parent-guided sleep intervention (Sleep Buddy) or usual care. Stratification variables will include NHS region, age, sex, and ADHD medication status (stimulant/non-stimulant treatment). It will not be possible to blind participants to their allocation.

Intervention + Usual Care
Participants allocated to this arm will continue to receive usual care for their ADHD and chronic insomnia from Primary Care and Child and Adolescent Mental Health Services. In addition, they will receive access to Sleep Buddy for the 6-month study duration. Sleep Buddy is an interactive multi-session digital behavioural intervention that provides participants with accessible information, tools and support to effectively manage their child's chronic insomnia. total duration of treatment

Usual Care
Participants allocated to this arm will continue to receive usual care for their ADHD and chronic insomnia from Primary Care and Child and Adolescent Mental Health Services. At the end of the study, participants randomised to the usual care arm will receive access to the Sleep Buddy website.
For both Arms, Usual Care will be captured through the adapted Client Service Receipt Inventory at baseline, 3 months (brief version) and 6 months.

Follow Up
All participants will complete follow-up measures at Month 3 and Month 6.

Intervention Type
Behavioural

Primary outcome(s)
Sleep Onset Latency is measured using a parent-completed 10-day sleep diary at Baseline and month 3

Key secondary outcome(s))
1. Sleep Onset Latency is measured using a parent-completed 10-day sleep diary at Baseline and Month 6
2. Sleep Quality is measured using a parent-completed SASS-Y at Baseline, Month 3 and Month 6
3. Subjective report of child sleep is measured using SNAP-IV parent report at Baseline, Month 3 and Month 6
4. Irritability is measured using the Affective Reactivity Index (ARI) at Baseline, Month 3 and Month 6
5. Mental well-being is measured using the Warwick-Edinburgh Mental Well-being Scale (WEMWBS) at Baseline, Month 3 and Month 6
6. Sleep problem score (parent report) is measured using the Omnibus Sleep Questionnaire (OSQ) at Baseline and Month 6
7. Quality of life of parent is measured using EQ-5D-5L at Baseline, Month 3 and Month 6
8. Quality of life of child is measured using the Child Health Utility 9D index (CHU-9D) proxy for children aged 7 to 12 at Baseline, Month 3 and Month 6
9. Working memory is measured using a 2-back working memory task at Baseline, Month 3 and Month 6
10. Selective attention and motor response inhibition are measured using a Go/No-Go task at Baseline, Month 3 and Month 6
11. Sustained attention and vigilance on detection of rare signals are measured using the Mackworth Clock task at Baseline, Month 3 and Month 6
12. Continuous performance variables are measured using a CPT task at Baseline, Month 3 and Month 6

Process Evaluation
1. Parent enablement will be measured using the Patient Enablement Instrument (PEI) at Baseline, Month 3 and Month 6
2. Intervention acceptability will be measured using the Theoretical framework of acceptability (TFA) at Month 3
3. Engagement with the intervention will be measured by intervention usage over the 6-month intervention period

Qualitative Interviews
Qualitative process interviews will be carried out with 25-30 trial participants to provide in-depth understanding of participant experiences within the trial and provide a better understanding of factors that may influence engagement with the intervention behaviours.

Completion date
28/02/2028

Eligibility

Key inclusion criteria
1. Child aged 6-12 years inclusive
2. Diagnosis of ADHD (including ADD)
3. Child meets the criteria for chronic insomnia based on primary carer report (sleep onset latency > 30 minutes for > 3 nights/week for > 3 months)
4. Sufficient understanding of English by primary carer to allow access to the digital sleep intervention (our digital interventions are aimed at a reading age of 11y so will be accessible to adults with English as a second language)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 years

Upper age limit
12 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Child has sleep-related rhythmic movement disorder
2. Child has severe learning disabilities
3. Child with physical ill health or disability likely to require admission to hospital during the 6-month trial period
4. Child with long term health problems that affect their sleep. (e.g. severe eczema or epilepsy)
5. Primary carer has participated in the DISCA study ‘think aloud’ interviews during Sleep Buddy development

Date of first enrolment
04/07/2025

Date of final enrolment
30/04/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Hampshire and Isle of Wight Healthcare NHS Foundation Trust
Tatchbury Mount Hospital
Calmore

Southampton
England
SO40 2RZ

Study participating centre
Sheffield Children's NHS Foundation Trust
Western Bank
Sheffield
England
S10 2TH

Study participating centre
Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust
St Nicholas Hospital
Jubilee Road
Gosforth
Newcastle upon Tyne
England
NE3 3XT

Study participating centre
South London and Maudsley NHS Foundation Trust
Bethlem Royal Hospital
Monks Orchard Road
Beckenham
England
BR3 3BX

Sponsor information

Organisation
University Hospital Southampton NHS Foundation Trust

ROR
https://ror.org/0485axj58

Funder(s)

Funder type

Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are or will be available upon request following the process outlined at https://www.southampton.ac.uk/ctu/about/index.page, with requests made via ctu@soton.ac.uk. The type of data required will need to be specified in the request, but all datasets are available for request from three months after publication. All participants will have consented for their data and their child's data to be held securely on servers located in the UK, where they will be stored for up to ten years after the end of the study. Access to data will be strictly controlled and all relevant data laws will be followed. If participants take part in the attention and memory tasks, they consent to the research data from these tasks being held securely on a server located in the EU. The data are anonymous and will not identify the child or primary caregiver.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			21/01/2026	No	Yes