SleepBuddy

Parent/ Carer Information Sheet

We are inviting you and your child to take part in a research study that is being run by the University Hospital Southampton NHS Foundation Trust and the University of Southampton Clinical Trials Unit (SCTU). Before you make a decision, it may help to understand why the research is being done and what it would involve for you and your child.

1. I have a question about the study, who can I speak to?

Please contact the study Research Team by emailing sleepbuddysupport@soton.ac.uk or calling 0330 1334 689.

You may also wish to take some time to speak to your family and friends or your GP before you make a decision.

2. What is the study about?

This study is trying to see if our new website, developed by medics and psychologists, can help parents/carers of children aged 6-12 years with a diagnosis of ADHD, to improve their child's sleep.

The Sleep Buddy website has information and advice on how to manage your child's sleep problems. It has videos and top tips from other parents/carers of children with ADHD and sleep problems. It will also help you to create a sleep plan that will support you to use a variety of sleep strategies designed specifically for children with ADHD. You can also answer a few short questions to get advice that is personalised to you.

The study will last 6 months, around 330 people will take part. The whole study can be completed online, using a tablet or computer. If you do not have access to either of these, the research team can help you.

3. Why have I been invited?

You may have been invited to take part in the study by your child's hospital because you are a parent/ carer of a child aged 6-12 with an ADHD (including ADD) diagnosis, or you may have seen this study advertised through CAMHS, your GP, social media or elsewhere.

To be eligible to take part, your child must also be experiencing sleep problems. If you would like to take part, we will ask you some questions about your child's sleep problems to check if they would be suitable for the study.

You must be a UK resident at the time of registering your interest in the study and you must intend to live in the UK for the 6-month study duration. Only one child in each household will be able to take part.

4. Do I have to take part?

No. It is up to you whether to take part in the study. Whether or not you choose to take part will not affect you or your child's medical care or legal rights in any way.

If you do not want to take part, we would be very grateful if you could let us know the reason. You can do this by clicking https://southampton.qualtrics.com/jfe/form/SV_1KQ647qEpFpGknQ. This is optional and anything that you say will not affect your medical care or legal rights in any way.

5. I'd like to take part, what happens next?

Once you have read this information sheet and you have decided that you would like to take part, you can let us know by clicking the 'Sign up for this trial' button.

You will be asked to register on the website and will be asked to provide your email address and mobile number so that we can contact and remind you about your study questionnaires and calls booked in with the study researchers.

We will then ask you to complete some **questions on the study website,** to check that this study is suitable for you and your child. If you and your child are suitable, we will ask you to complete a consent form to say that you are happy to take part.

Once you have completed your consent form, we will ask you to complete the following, on the study website:

- **Screening video call with the study Researcher (30 minutes)**
  We will ask you to book a slot to complete your screening video call with the study researcher. The call will happen in about 1-14 days from today. The researcher will confirm you and your child's suitability to take part in the study, they will ask for you to show documentary evidence of your child's ADHD diagnosis and will ask if your child is taking medication for their ADHD or sleep. They will ask to see the medication box and will note down the prescription dose and schedule. It does not matter if your child does not take medication for their ADHD or sleep, they can still take part.

  If you (or your child) are currently taking part in another research study, at your screening call, the researcher will ask for you to provide the name of the study and the study information sheet (if you have a copy). This will help them to decide whether you can take part in this study too.

  You will be asked to provide the address of your Child's GP surgery during the call, this is collected as proof that your child is a UK resident.

  The researcher will complete some other study questionnaires with you during the call which will ask about your current employment, your child's school attendance, and any health, social care or other support services that your child has used recently. The call will be done using

video call software (such as MS Teams). If you do not have access to this, the study team can help you.

- **Complete a 10-day sleep diary about your child's sleep (just three questions, 5 mins each day)**
- **Complete study questionnaires (20-30 mins)**
- **Your child will complete some attention and memory tasks online with the help of a study Researcher (35 minutes)**

You will then be put into one of two groups. This will happen within 4 weeks from the day that you complete your informed consent form. The website will randomly decide (by chance) whether you will be placed into Group 1 or Group 2. The research team will inform you of the group that you have been put into.

Group 1: Will receive the care and support that you usually receive for your child's ADHD and sleep problems **plus** access to the Sleep Buddy website for 6 months.

Group 2: Will receive the care and support that you usually receive for your child's ADHD and sleep problems.

Everyone who takes part in the study will be asked to fill in the online questionnaires again at 3 months and 6 months after starting the study, regardless of whether they are in the group with access to the website or not. **If you were in the group without use of the website, we will give you a link to access the website at the end of the study.**

A study researcher will also call you to run through some additional questions about your child's medications, any other therapies that they are using, your current employment, and your child's school attendance. At month 6 they will ask additional questions about health, social care or other support services that your child has used. Everyone will also be asked to complete the 10-day sleep diary again, and the online memory and attention tasks online with the help from a researcher (via video call). We will let you know when these are ready to complete, by sending text or email reminders.

At the end of the study, we will look at which part of the Sleep Buddy website people use, and for how long. This analysis will not be linked back to people taking part in the research. If you are in the group testing Sleep Buddy, you are free to use the website as much or as little as you choose.

6. How long will the study take?

The study will take **6 months** from the time you are put into one of the groups.

7. Interviews (optional)

We would like to interview some people participating in the study to find out their thoughts about the Sleep Buddy website. This would involve a chat which we will record. It is expected to last 30-60 minutes. If you are happy to be contacted about the chat, we will be in touch to give you more information about what is involved and will arrange a time that suits you. the chat, and it is expected

to last 30-60 minutes. You can still take part in the main study but decide not to take part in the interview.

8. If I decide to take part, can I later change my mind?

Yes. You are free to withdraw from the study (including the optional interview) at any time. We will ask you why you have changed your mind in case there is anything we could do differently, but you do not have to tell us if you prefer not to. Your decision will not affect current or future treatment, your legal rights or prevent you from taking part in future research studies.

If you decide to withdraw from the trial, we will keep and use any data we have collected from you up to that point, but you will not be asked to complete any more assessments.

If you decide to withdraw from the optional interview, you can request for any data collected to be deleted. However, it may not be possible for you to withdraw your data once the analysis has started because the data collected will already be pseudonymised and have been used but you can inform the research team if you do not want your anonymised interview content to be used in publications.

9. What are the benefits of taking part in this study?

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.

10. What are the possible disadvantages of taking part?

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.

11. Will I receive any payment?

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.

12. What will happen at the end of the study?

At the end of the study, you and your child will continue to receive the care and support that you would usually receive for your child's ADHD and sleep problems. **If you were in the group without use of the website, we will give you a link to access the website at the end of the study.**

13. What will happen to the results of the study?

At the end of the study, we will submit our results to be published in medical journals and at conferences. We may use some anonymised quotes from the information you provide (for example, if you decide to participate in the interviews too) but we will never include anything that would allow someone to identify you.

A summary of our research findings will be sent to everyone who requests to receive these. There is a section on the informed consent form where you can opt to receive the results. If you give us permission, we will also send a summary of our research findings to your child's GP.

14. Who is running the study?

The study is funded by the NIHR, which is part of the NHS and is being sponsored by the University Hospital Southampton NHS Foundation Trust and managed by the University of Southampton Clinical Trials Unit (SCTU).

15. Who has reviewed the study?

All research that is conducted in the NHS is reviewed by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed by West of Scotland REC 5 who are happy for the study to proceed. The approval reference is 25/WS/0007.

16. How will we use information about you?

We will need to use information from you for this research project.

This information will include:

- Your email address
- Your mobile contact number
- Your child's initials
- Your date of birth (month and year)
- Your child's date of birth (month and year)
- Your child's GP surgery address
- Your postcode

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

The University Hospital Southampton NHS Foundation Trust (UHS) is the sponsor of this research, and the University of Southampton Clinical Trials Unit (SCTU) are managing this research on their behalf. SCTU is responsible for looking after your information. We will keep all information about you safe and secure by:

- Securely storing personally identifiable data about you and your child within an encrypted database on the study website. All personally identifiable information about you and your child will be kept strictly confidential and in accordance with applicable data protection

legislation. Information would only be shared outside the study if it seemed someone was in danger.

- All research data collected during the study about you and your child will be held on servers located in the UK, but access to this data will be strictly controlled by SCTU and all applicable Data Protection legislation will be abided by.

- Data collected from the online tasks are stored on the PsyToolkit server (https://www.psytoolkit.org/). PsyToolkit is a web-based software to create online research tools to help to study cognition and psychology. Psytoolkit servers are located in the EU and the data will be deleted from the servers at the end of the study.

- To help the study team match the data collected from the online tasks with other research data that we have collected about you and your child (e.g. sleep diary, questionnaires), we will collect your child's initials and month and year of birth, and this will be stored securely on the PsyToolkit server. Access to data managed by the SCTU will be strictly controlled. Applicable Data protection Legislation will be abided by.

- Only members of the research team and responsible and delegated members of the SCTU may be given access to data about you for monitoring purposes and/or to carry out an audit of the trial to ensure that the research is complying with applicable regulations. Individuals from regulatory authorities (people who check that we are carrying out the trial correctly) may require access to your data. All of these people have a duty to keep your information, as a research participant, strictly confidential.

- With your permission, a copy of your consent will be sent to the SCTU (where it will be kept securely), to allow confirmation of your consent.

International transfers

We may share data about you outside the UK for research related purposes to:

- Inform future research.

If this happens, we will only share the data that is needed. We will also make sure you can't be identified from the data that is shared. If your data is shared outside the UK, it will be with the following sorts of organisations:

- Academic research institutions who want to use the data collected in this study to inform other related research.

We will make sure your data is protected. Anyone who accesses your data outside the UK must do what we tell them so that your data has a similar level of protection as it does under UK law. We will make sure your data is safe outside the UK by doing the following:

- (some of) the countries your data will be shared with have an adequacy decision in place. This means that we know their laws offer a similar level of protection to data protection laws in the UK.
- We use specific contracts approved for use in the UK which give personal data the same level of protection it has in the UK. For further details visit the Information Commissioner's Office (ICO) website
- We do not allow those who access your data outside the UK to use it for anything other than what our written contract with them says.
- We need other organisations to have appropriate security measures to protect your data which are consistent with the data security and confidentiality obligations we have. This includes having appropriate measures to protect your data against accidental loss and unauthorised access, use, changes or sharing.
- We have procedures in place to deal with any suspected personal data breach. We will tell you and applicable regulators when there has been a breach of your personal data when we legally have to. For further details about UK breach reporting rules visit the Information Commissioner's Office (ICO) website.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

We will keep your study data for a maximum of 10 years. The study data will then be destroyed.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- You have the right to ask us to remove, change or delete data we hold about you for the purposes of the study. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

Where can you find out more about how your information is used?

You can find out more about how we use your information, including the specific mechanism used by us when transferring your personal data out of the UK.

- At: **www.hra.nhs.uk/patientdataandresearch**
- our leaflet is available from the Southampton Clinical Trials Unit website: https://www.southampton.ac.uk/research/institutes-centres/clinical-trials-unit/take-part-in-trial
- by asking the Trial Management Team at Southampton Clinical Trials Unit: sleepbuddysupport@soton.ac.uk
- by ringing the Southampton Clinical Trials Unit on 023 8120 5154
- by sending an email to dataprotection@uhs.nhs.uk

17. What if there is a problem?

If you have a concern about any aspect of this study, if there is an emergency or you are in need of some help and advice please contact the study Trial Manager: sleepbuddysupport@soton.ac.uk, 0330 1334 689, who will do their best to help you. If you would like to discuss your concerns or wish to seek

advice from someone outside of the study team then we advise for you to please contact your doctor or GP.

If you wish to complain, or have any concerns about the way you have been approached or treated during the Sleep Buddy interview, please contact the R&D Department at University Hospital Southampton NHS Foundation Trust by email to sponsor@uhs.nhs.uk.If you remain unhappy and wish to complain formally, you can do this by contacting your local Patients Advice and Liaison Service Office. Details can be obtained from www.pals.nhs.uk.

Please be aware that if you are harmed as a result of taking part in this study, there are no special compensation arrangements. University Hospital Southampton NHS Foundation Trust provides clinical trials indemnity insurance for negligence in its management or design of the trial. NHS Indemnity covers NHS staff, medical academic staff with honorary contracts, and those conducting the trial. NHS Indemnity does not offer no-fault compensation and is unable to agree in advance to pay compensation for non-negligent harm. If you are harmed because of someone's negligence, you may be able to take legal action but you may have to pay your own legal costs.

TODAY

Read the Information Sheet & Ask Questions

Let us know if you would like to take part by clicking **'Sign up for this trial'**

If you don't want to take part, we'd be grateful if you could let us know why

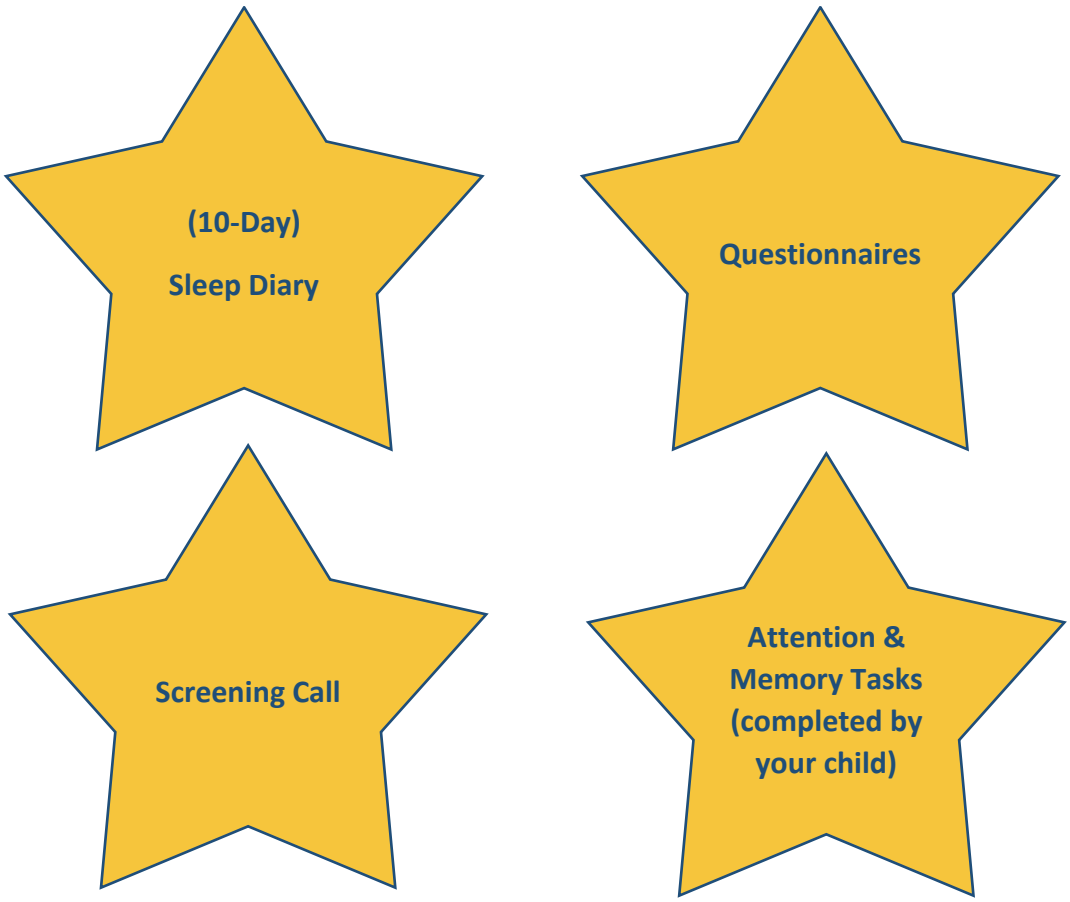
Complete some **screening questions** on the study website.

Complete your **Informed Consent** on the study website.

Book a time on the study website for our Researcher to call you.

Screening and Baseline (within 4 weeks from TODAY)

You'll be asked to complete a 10-Day Sleep Diary and some Questionnaires. We will ask you to book a time to complete your screening call and for your child to complete their attention and memory tasks online with a researcher.



Trial Starts (Up to 4 weeks from TODAY)

The study website will Randomly assign you to one of two Groups:

Group 1:

Will receive the care and support that you usually receive for your child's ADHD and sleep problems.

plus

access to the Sleep Buddy website.

Group 2:

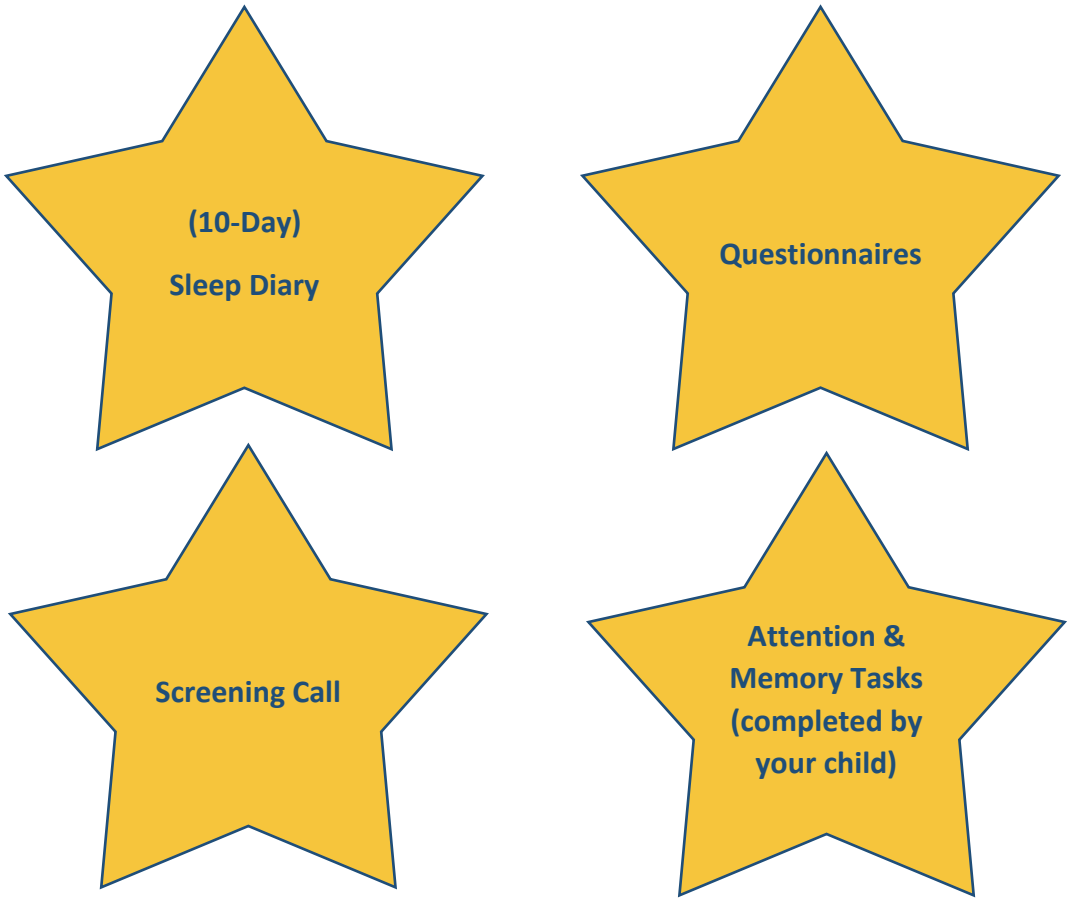
Will receive the care and support that you usually receive for your child's ADHD and sleep problems.

You'll have access to the website at the end of the study.

Follow Up at 3 & 6 Months

We'll let you know when you have reached your Month 3 and Month 6 Follow-Up.

You'll be asked to complete a 10-Day Sleep Diary and some Questionnaires. We will ask you to book a time to complete your Month 3 or Month 6 call with the researcher and for your child to complete their attention and memory tasks online.



End of the Study

Everyone will receive access to the Sleep Buddy website. We will also let you know the results of the study if you agreed for us to share this with you in your consent form.

Everyone who took part will have helped to contribute to our understanding of how best to help sleep problems in this population.