Guardian and/or Parent
PARTICIPANT INFORMATION SHEET

IRAS ID: 340181

Mapping the impact of sleep interventions on children with ASD

Invitation to take part

You and your child are invited to participate in a research study aimed at understanding sleep issues in autistic children and other neurodevelopmental conditions. Before you decide, it is important that you understand why the study is being conducted and what it will involve. Please read this information carefully, and feel free to ask any questions.

What is the purpose of this study?

Many children with autism or other neurodevelopmental conditions experience difficulties with sleep. This study seeks to understand why some children benefit from a sleep course while others may require melatonin. In addition to assessing children's sleep, this study will also explore parents' mental well-being to understand how sleep interventions impact both the child and their caregiver. By gaining this understanding, we aim to improve sleep treatments for children with ASD, potentially reducing the need for medication and enhancing their overall well-being.

Why are you telling me about the study?

Sleep disturbances are common in autistic children and in other neurodevelopmental conditions can significantly impact their quality of life. Currently, interventions such as sleep courses or melatonin are used, but it is not clear why some children respond better to one method over the other. This research is being conducted to understand the underlying factors influencing these outcomes. By identifying these factors, the study aims to create more effective and personalised treatment options for children with ASD. Additionally, improving sleep can have a positive impact on overall well-being, behaviour, and learning outcomes for autistic children and their caregivers.

Why have I been invited to take part?

Your child has been diagnosed with Autism Spectrum Disorder or another neurodevelopmental conditions and is experiencing sleep issues. Under the care of a consultant at Dingley, your child is eligible to participate in this study to help us understand the different responses to sleep interventions. The criteria to join the study is:

- Children between the ages of 2-15 with a diagnosis of Autism Spectrum Disorder (ASD) (or other neurodevelopmental conditions).

Do I have to take part?

Participation is entirely voluntary. If you decide to take part, you will be asked to sign a consent form. You are free to withdraw at any point without providing a reason, and this will not affect your child's standard of care.

What will happen to me if I take part

How many visits are there?

The study includes up to three visits that can be conducted at either the University of Reading, the Dingley Clinic, or your home. You have the flexibility to choose your preferred location.

- **Baseline visit**
- **Post-sleep hygiene course visit**
- **Post-melatonin visit** (If melatonin is prescribed)

If you agree to participate, each visit will involve the following:

- **Meeting with a Research Assistant**: You and your child will have a few short sessions with a research assistant to discuss your child's sleep behaviours and overall well-being, as well as your own mental well-being.
- **Completing Questionnaires**: You will fill out questionnaires regarding your child's sleep habits and daily routines, as well as some about your own well-being.
- **Completing a Sensory Assessment**: Your child will take part in engaging sensory activities, which may include looking at different visual stimuli, listening to various sounds, and feeling different textures. After this, we will also interview you about your child's sensory behaviours. This assessment typically takes about 20 minutes.
- **Wearing a Sleep Watch**: You and your child will wear wrist devices (similar to smartwatches) for up to 7 nights. Each morning, you will answer questions about what time your child went to sleep, what time they woke up, and how you both felt about the quality of sleep.
- **Qualitative Interview**: At the final visit, you will be invited to take part in an interview to discuss your experience with the sleep intervention(s). This will happen either after completing the sleep hygiene course or after trying melatonin, if prescribed. The interview will be audio recorded using Microsoft Teams and later transcribed onto a password-protected system at the university. Once transcribed, the original recording will be permanently deleted.

How long will each visit take?

- 1 hour for sessions involving questionnaires and sensory assessments.
- Up to 2 hours if the qualitative interview (1 hour) is included in your final visit.

What happens at home?

Between visits, we ask that you:

- Use the sleep watch as instructed for up to 7 nights per assessment point.

What are the benefits of taking part?

While your child may not experience direct benefits from the study, your participation will contribute to a better understanding of sleep interventions for children with ASD (and other neurodevelopmental conditions), potentially improving treatment options in the future.

We recognise that participating in this study requires your time, and we appreciate your contribution. To acknowledge this, you will receive £20 per visit to cover your time and travel expenses.

What are the possible disadvantages of taking part?

There are no significant risks associated with participating in this study. The devices used for monitoring are non-invasive, and all collected information will remain confidential. Participating may require some of your time, but we will do our best to accommodate your schedule.

What if new information becomes available?

If any new relevant information arises during the study, we will inform you immediately. You will have the choice to withdraw from the study if the new information affects your decision.

What if I do not wish to take part or change my mind?

The study is voluntary so that you should not feel under any pressure to take part. If you do decide to take part you are still free to withdraw at any time. In either case, you do not have to give a reason for your decision and this will not prejudice your future medical care.

How will we use information about you?

We will not utilise pre-existing medical information about you; your paediatric consultant will advertise the study to you based on concerns about your child's sleep. We will need to use information from you and your child for this research project. This information will include your child's name, your name, and contact details. Alongside this, all further information collected during this study will be stored in secure, password-protected servers at the University of Reading and will be pseudo-anonymised.

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

Your GP may be informed of details from the interviews.

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

The Royal Berkshire NHS Foundation Trust, in partnership with the University of Reading, is the sponsor of this research, and is responsible for looking after your information. We will keep all information about you safe and secure by. We will keep all information about you safe and secure by:

- Storing data in password-protected files
- Ensuring that only authorized research personnel have access to identifiable information
- Keeping any paper forms with personal information in locked cabinets
- Anonymising data before analysis to ensure confidentiality
- Regularly reviewing the data retention policy to ensure information is not held longer than necessary

What are your choices about how your information is used?

- If, at any point, you or your child decide to withdraw from the study, this can be done easily and without any consequences. You can inform the Research Assistant or any member of the study team, and your participation will stop immediately. You are not required to provide a reason for

your decision, and this will not affect your child's standard of care in any way. We will keep information about you that we already have.

- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

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

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from the research team

by asking the research assistant who gave you this leaflet

- Visit www.hra.nhs.uk/information-about-patients/
- Speak with a member of the research team
- Email our data protection officer, *Caroline Lynch, at caroline.lynch@royalberkshire.nhs.uk*
- www.hra.nhs.uk/patientdataandresearch

What will happen to the results of the study?

The results will be analysed by the researchers working on this study, not only from the Royal Berkshire Hospital, but also from the University of Reading. We will share the results with the University of Reading and with colleagues within Dingley at the Royal Berkshire Hospital. Results may be used for conference presentations, presented at meetings or published in associated journals. With your consent, anonymised quotes from interviews may be included in the study results, such as publications or presentations. With your permission, anonymised data from this study may also be used in future research or shared anonymously with other researchers. This is optional, and you will be asked to indicate your preference on the consent form.

You will not be identified in any publications / reports. Once the study has been completed you will receive a copy of the results of the study if you requested this on the consent form. We will discuss with you how you would like to receive the results of the study if you requested this.

Who is organising and funding the research?

This study is a collaborative venture between the University of Reading and the Royal Berkshire NHS Foundation Trust. This study is sponsored by the University of Reading and financed by the Health Innovation Partnership (HIP) through the Collaborative Innovation Fund (CIF) available between the two organisations.

Who has reviewed and approved this study?

All research conducted in the NHS is reviewed by an independent group of people known as a Research Ethics Committee. Their role is to protect your safety, rights, well-being, and dignity. This study has received a favourable opinion from an independent Research Ethics Committee and the Health Research Authority (HRA). It has also been reviewed and approved by the Royal Berkshire NHS Foundation Trust Research &

Innovation Office and the University of Reading Research Ethics Committee (UREC). Additionally, members of the Health Innovation Partnership (HIP) have reviewed the study

What if there is a problem?

If taking part in this research study harms you, there are no special compensation arrangements. In the case of a patient suffering harm, NHS indemnity operates in respect of the treatment which is provided. If any information disclosed during the interview suggests a risk of harm to yourself, your child, or others, the research team will take appropriate steps to escalate and report this in line with safeguarding procedures.

Regardless of this, if you have a concern about any aspect of this study, you should ask to speak to Dr Teresa Tavassoli (t.tavassoli@reading.ac.uk) and Catherine Hagan (catherine.hagan@royalberkshire.nhs.uk). If you wish to make a complaint or raise concerns about any aspect of this study and do not want to speak to any of the researchers, you can contact: Hospital Patient Advice and Liaison Service (PALs) on 0118 322 8338 or email talktous@royalberkshire.nhs.uk / PALS@royalberkshire.nhs.uk

Further information and contact details

The research staff will be happy to answer any questions you might have. In the meantime, if you would like any more information, please do not hesitate to contact the study team (details below).

Contacts for further Information

University of Reading
Chief Investigator: Teresa Tavassoli – Associate Professor in Psychology
Email (t.tavassoli@reading.ac.uk)
Harry Pitt Building, Earley Gate, Reading RG6 6ES

Royal Berkshire Hospital
Catherine Hagan. Telephone – 0118 322 7531 Option 1
Email catherine.hagan@royalberkshire.nhs.uk
Dingley Childrens Center, Erleigh House, Whiteknights Road, Reading RG6 6BZ

Research Assistant
Rhea Varghese– Research Assistant
Email rhea.varghese@reading.ac.uk
Harry Pitt Building, Earley Gate, Reading RG6 6ES

Thank you for taking the time to read this information leaflet. Once you have had time to consider this study and have had any questions answered, please sign the consent form if you agree to take part.