CASTLE SLEEP-E

KING'S College LONDON

NHS
King's College Hospital
NHS Foundation Trust

NHS
Trust/Site Address 1
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Parent/Guardian Information Sheet for CASTLE Sleep-E

- You have been given this information sheet as your child might be eligible to take part in this research study. Please take time to read the following information carefully.
- Part 1 tells you the purpose of the study and what taking part means for you and your child.
- Part 2 gives you more detailed information about who is running the study and what happens to your data.
- CASTLE Sleep-E is a study for children with epilepsy who are experiencing sleep problems.
- In the study we will compare an online sleep intervention (known as COSI) against standard care
- If your child is aged between 4 years and 12 years then you and your child might be eligible to join.
- We will recruit 110 children and their families across the UK.
- All parents and children in the study will be asked to wear an actigraph (a watch-like device that records your sleep) for 2 weeks at 2 different times during the study.
- All families will be asked if they are happy to be interviewed by a researcher, however not all families who express an interest in these interviews will be contacted. If there is anything that is not clear, or you would like more information, please ask a member of the clinical team.
- If you wish, you can discuss the study with friends, relatives and/or get independent advice via your local Patient Advice and Liaison Service (PALS) or equivalent.

How to contact the study team

If you have any questions about this study, please talk to your research team:

Principal Investigator: ____________________

Research Nurse: ____________________

Telephone number: ____________________

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Part 1

Purpose of the study and what will happen if your child takes part

1.1 Why are we doing the CASTLE Sleep-E study?

Epilepsy is a common condition among children in the UK. Families have identified sleep problems in their children with epilepsy and also amongst parents as a major issue that doesn't get enough attention. Children with epilepsy sometimes have seizures at night and their seizures can be triggered by poor sleep. Sleep problems can be present while they are being followed up by their paediatrician for seizures and even persist after the seizures have gone away. Sometimes their learning, behaviour, self-esteem and mood are affected too.

Sleep problems can be managed through practice. There are guidelines to help children in general with their sleep, but there is nothing available that specifically helps children with epilepsy and their parents address sleep problems and improve their sleep quality.

Therefore, the CASTLE Sleep-E study aims to find out whether giving families access to a newly developed online sleep intervention (known as the CASTLE Online Sleep Intervention or "COSI" for short) will help improve their quality of sleep. We will compare the child and parent's sleep quality at the start and after three months. In order to make a fair and balanced comparison, half the families will receive COSI and the other half will receive standard care from their paediatrician. With these equally divided groups we'll be able to evaluate if COSI works or not, as well as review which treatment makes the best use of NHS resources and how these treatments affect your and your child's quality of life.

The information given in COSI is personalised depending on the answers provided by the family and has been designed specifically for parents of children with epilepsy. Not all families who enter CASTLE Sleep-E will receive access to COSI. Some may be treated using standard care, which will mean they will not receive access to the system.

Families who are happy to take part in CASTLE Sleep-E will be followed up for 6 months. If you are happy for your child to be part of the study, you and your child will be asked to wear an actigraph (sleep monitor) for 2 weeks and complete some questionnaires and assessments before your child is allocated to their study group. You and your child will also be asked to wear the sleep monitor and complete an assessment again 3 months after your child is allocated their study group. We will also ask you and your child to complete some questionnaires electronically 3 and 6 months after your child has received their study group. Your local research team will collect information about you and your child at the same timepoints. We collect information at different times during the study so we can compare how your child was before and after they are allocated their study group.

We will collect your and your child's questionnaire answers on a secure website, the link to which will be emailed and texted to you. You will also be given an iPad to use during your time on the study. The iPad will be sent directly to your home and you will only be able to access Apps required for the study. It will be used to complete your child's "SleepSuite" assessment and may also be used to complete the study questionnaires and access COSI (if allocated to that study group).

Sleepsuite is an iPad adventure game that children complete before bedtime, and then the next morning. It's been designed to capture changes in things like word memory and reaction time that we know improve overnight after a night's sleep.

There is also an opportunity to take part in two interviews during the study, these will be carried out 3 months and 6 months after your child is allocated their study group. If you do not wish to be interviewed, this will not impact your child taking part in the main study.

When the CASTLE Sleep-E study ends, access to the online sleep intervention used as part of the study will be closed but all families will be given the option to receive the written content of COSI to keep.

This will be sent to you in an electronic format via email (if you wish to receive it).

The results from this study will be used to help us improve treatments for children with epilepsy.

1.2 Why has my child been invited?

Your child has been invited to take part in CASTLE Sleep-E because they are between the ages of 4 and 12 with diagnosed epilepsy and are having problems with their sleep.

1.3 Does my child have to take part?

No, taking part is voluntary. It is up to you to decide whether or not your child should take part.

If you and your child decide not to take part, then your child will still receive the usual treatment their hospital offers. Their doctor can provide you with more information on this. If you decide that you and your child will take part, you can change your mind at any time later without giving a reason.

The decision you make on whether your child will take part or not doesn't affect the standard of medical care they receive now or in the future

1.4 What organisations are involved in this study?

The CASTLE Sleep-E trial involves a number of different activities which are carried out by different organisations across the UK. The below table will provide a bit more information about these organisations and the study activities they are responsible for.

Name of organisations	CASTLE Sleep-E Activities
Liverpool Clinical Trials Centre (also known as "LCTC")	The Liverpool Clinical Trials Centre is responsible for the day-to-day management of the CASTLE Sleep-E study. They ensure the trial is carried out in line with strict standards. LCTC is responsible for collecting and reviewing clinical and questionnaire data. At the end of the study, the team at LCTC will review whether COSI (sleep intervention) has been effective.
Bangor University	Bangor University is responsible for conducting the health economics analysis which will assess the cost-effectiveness of the COSI compared to standard care.
Edge Hill University	The team at Edge Hill University is responsible for carrying out interviews with families (if they consent to this activity) to find out about family's experiences with epilepsy and sleep.
Oxford Brookes University	Oxford Brookes University manage the actigraphy (sleep monitor) activity within CASTLE Sleep-E. The Sleep Team will be in contact with participants at a number of different times during the trial to arrange delivery and collection of study devices, such as actigraphs and iPads.

Further information about the different study activities mentioned above can be found in section 1.5 of this information sheet.

1.5 What does taking part involve for my child and me?

If you agree for your child to take part, you will first be asked to sign a consent form electronically. Signing this consent form will be completed following a discussion with your local research team. The research team will provide you with a paper or electronic copy of the completed consent form after your visit or telephone/video call.

Your local study team will then check and confirm that this study is suitable for your child, and you and your child will be asked to follow the study plan. Your child will be enrolled in the study for 6 months. During your time in the study, you and your child will be followed up by your paediatrician and research/specialist nurse. You and your child will also be asked to do the following:

- Complete some electronic questionnaires
- Wear a wrist actigraph (sleep monitor) for two weeks at the start and again part way through the study (at 3 months)
- Your child will complete a special iPad game called SleepSuite at the start of the study and 3 months after their treatment allocation.

We will email and text a link to the electronic questionnaires when they are due to be completed, which you can access using an electronic device (for example, a smartphone, tablet, or computer). The "SleepSuite" task must be completed on the study iPad, not on any other device. The iPad and wrist actigraph will be delivered directly to your home by courier.

Research nurses will collect information about your child's health and well-being at your clinic appointments with your paediatrician (which will be held either face to face in clinic or via telephone/video call depending on your local hospital and the coronavirus situation).

If you are happy to be interviewed as part of the study, you and your child might be selected to take part in two extra telephone or video-calls with a researcher.

Further information about the study visits can be found below.

Consent

Joining the study

If you are happy for you and your child to participate in CASTLE Sleep-E, you and your child will be asked to provide consent and assent (if appropriate) electronically.

You and your child will be asked to wear an Actigraph (sleep monitor) for 2 weeks and complete some electronic questionnaires/assessments during this time.

Your research team will also record some information about you and your child at this time.

Study allocation
(up to 8 weeks after consent)

Study allocation

At this visit, your child will receive their study allocation. If allocated to COSI, you will be emailed log in details.

3 and 6 months after study allocation

Data Collection

Regardless of study allocation, you and your child will be followed up at 3 and 6 months timepoints. At 3 months, you and your child will complete actigraphy, electronic questionnaires and assessments. At 6 months, you and your child will only complete electronic questionnaires. Your local research team will also collect some information from you and your child at these times. If you consented to being interviewed, a member of the interview team may contact you at these timepoints.

End of trial

Health Economic Data

LCTC will request non-identifiable data from your hospital site and NHS Digital for the Health Economic Analysis. This data will be transferred from your hospital/NHS Digital to Bangor University.

Consent Visit (Visit 1)

This visit will be with a member of your hospital research team and may be face-to-face in clinic or via a telephone/video call. It will take around 1 hour. It is important to know that your child's study group will not be decided at this visit.

Your research team will ask you some questions at this visit about you and your child. The questions asked will help confirm if this study is right for you and your child.

You will be able to ask any questions that you may have about the study. If you have had all of your questions answered and you are happy for your child to take part, then you will be asked to sign a consent form electronically.

You will receive an email with a secure link to the consent form which you can sign in clinic or at home, depending where your visit is held. You will be asked to provide your contact details as part of the consent form, which includes your name, mobile telephone number, email address and home address (including postcode).

If your child is 7 years or older, we will also ask if he/she is happy to take part in the study and to sign an assent form electronically by writing their name, if they can.

The researchers at site will provide you with a copy of the completed consent form along with the child's completed assent form (if one has been completed) after your visit or telephone/video call.

As part of the consent form, you will be asked to consider how you'd like your and your child's information to be used. Bangor University, who are undertaking the Health Economic analysis, will request consent to use information collected during the study as well as routinely collected NHS data for patients taking part in CASTLE Sleep-E. The data collected during the study will be transferred by LCTC to Bangor University. The data collected at the end of the study will be transferred directly to Bangor University by NHS Digital and the NHS hospital that your child attends. In both instances, the data will be coded prior to transfer so that it is not possible to identify you or your child.

At this visit you will also be asked if you are happy to be interviewed by the qualitative research team based in Edge Hill University. This is optional and if you do not wish to be interviewed, you can still join the main study. If you are happy to be interviewed, you will be asked to give your consent and for your child to assent (if appropriate). You may be contacted 3 months and 6 months after your child has received their study group allocation. Only around half of all families taking part in the main part of the CASTLE Sleep-E study will be selected for interview but we would be grateful if you could take part.

During this first visit your doctor or research nurse will give you information relating to your sleep monitor, study iPad and questionnaires. There is more information about wearing a sleep monitor, your study iPad and the questionnaires you need to complete below.

Wearing a sleep monitor (actigraph)

Children who take part in CASTLE Sleep-E and one of their parents will be asked to wear a sleep monitor for 14 days (2 weeks) at 2 different times in the study. After signing your consent form, you and your child will be asked to wear a sleep monitor for 14 days once you receive it. After that period your child will be allocated to one of the two study groups.

The sleep team for CASTLE Sleep-E (who are based at Oxford Brookes University) will receive your contact details after you consent to the study and will give you a call to arrange a suitable delivery time for the sleep monitor and study iPad. You will be able to contact the sleep team via email, call/text to help with any questions you may have about the sleep monitors.

You will be provided with instructions for the sleep monitor and how to return it (at no cost to you), as well as the sleep team's contact details in case you have any queries. You will also be asked to complete a sleep diary for you and your child whilst you are wearing the monitors. This is to help us interpret the information recorded by the monitors.

The study iPad

The sleep team will send you a study iPad at the same time as the sleep monitors. There is no cost to you to use the iPad, but we ask that you keep it safe as you will need to complete your child's "SleepSuite" assessments on it twice during the study. The iPad will be specially set up to limit access to other apps. You will be asked to complete your child's assessments on this iPad at two different times during the study. You will be provided with instructions on how to use the iPad.

At the end of your child's participation in the study, you must return the study iPad, charger and cable to your local research team at your next visit. If you are unable to leave your study iPad with your local research team, a member of the CASTLE Sleep-E team will contact you to arrange an alternative solution.

Questionnaires

Before your child is allocated to their study group, you and your child will be asked to complete some questionnaires. These questionnaires are completed electronically and will be sent to you via email and text in a secure weblink. The web link can be accessed on an electronic device with access to your emails, such as a computer, smartphone or tablet. You may also use the study iPad to complete these questionnaires. These questionnaires should be completed in the same 2 week period that you and your child are wearing the sleep monitors. Your local research team will contact you if this has not been done. If you have any difficulties with the questionnaires, please contact a member of your local research team.

All the questionnaires included in CASTLE Sleep-E are being used as research tools. They are only analysed at the end of the study, and the data are analysed as 'groups' rather than as individuals. The CASTLE Trial Management Group are therefore unable to comment clinically or otherwise feedback on individual results - either child or carer. If you have concerns about any issues raised in these questionnaires, please discuss them with your local research team or GP.

Randomisation Visit (Visit 2)

This appointment will take place once you and your child have worn your sleep monitors for 2 weeks (if possible). The appointment will take place a maximum of 8 weeks after your first visit and will be held via telephone/video call, unless your research team have specifically requested a face-to-face visit. This appointment will take around 30 minutes. During this appointment, a member of your research team will confirm you are still happy to take part in the study and check your contact details are correct.

If you are happy to take part, you will be asked some questions about your child's general health, their seizures, any medication they may be taking and any school absences they may have had due to their epilepsy. Once these questions have been answered, your child will be allocated into one of the two study groups (sleep intervention or standard care) using a computer programme. Your doctor or research nurse will tell you which group your child has been allocated to.

Accessing the sleep intervention

If your child is allocated to the group which receives sleep intervention, you will receive an email with a link to a website called "COSI" (Castle Online Sleep Intervention). The email will also contain the login details (username and password) to access your account in the COSI website. You will be able to access the system from any electronic device from which you access your emails (such as a computer, tablet or smartphone). As with the study questionnaires, you may wish to use the study iPad to access COSI.

Once you are logged in, you will have access to information, including a series of videos and explanations that will give you sleeping strategies/tips to apply to your child's sleep to try and improve their sleep, as well as yours.

If you don't access COSI within the first couple of days after the account has been created, you will receive an automated text reminder, which will be followed up by an email reminder if the system is still not accessed within a further few days. If the COSI system is not accessed within 6 days of the account being created, you will receive a quick telephone call from a member of the CASTLE Sleep-E team.

The CASTLE Sleep-E team will contact you again by telephone 6 weeks after the account is created to discuss COSI and how you are finding using the system. The team will be unable to offer any specific clinical advice during this phone call.

3 months after your account is created, you will be contacted by email and asked to complete an online evaluation questionnaire about COSI. If you don't complete this questionnaire within a few days, you will receive an automated text reminder which will be followed by a telephone call from the sleep team if the evaluation questionnaire has still not been completed.

Follow-up visits at 3 months and 6 months (Visits 3 and 4)

You and your child will be followed up by your paediatrician and research nurse 3 and 6 months after your child is allocated to their study group. These follow up visits may take place face-to-face in clinic or via a telephone/video call. Each follow up visit will take around 30 minutes.

During these visits, your local research team will ask you if you are still happy to remain in the study and if so, will ask questions around your child's seizures, any medication they may be taking and their general well-being, including any school absences they have had. A member of the research team will also check your contact details are correct.

Around the time of your visits, you will be sent an email and a text from the CASTLE Sleep-E team asking you and your child to complete some questionnaires. You will also be sent an email regarding assessment completion on the study iPad (the iPad "SleepSuite" assessment will only be completed at 3 months). You will also receive text reminders. You and your child will also be asked to wear your sleep monitors for 2 weeks at 3 months.

If you gave consent at Visit 1 for an interview, you may be contacted a few weeks after your follow up visits by the interview team at Edge Hill University. Further information about the interviews can be found below.

Interviews

If you are selected, then you will be invited to take part in two interviews. The first one will be a few weeks after Visit 3 and the second one a few weeks after Visit 4. We will arrange the interviews at a time to suit you (and your child).

The interviews will be done remotely using a telephone or secure video-calling system. Although we will only record the audio part of the interview, we hope you will be happy to use the video option when we are talking. Each interview is likely to last between 30-60 minutes but this can be tailored to suit how much time you have available and how much you want to share with us. We will send you a list of the sorts of questions we expect to ask you about a week before the interview. We hope this will help you feel confident in the interview.

If your child is aged 7 years or older, they will also be able to take part in the interview study. The interviews will be done by telephone or video-call. We plan to send your child an activity booklet about a week before we talk to them. We will send the activity booklet by email and/or post, as you prefer. The booklet or sheet will help them think about what they would like to tell us. The booklet/sheet will give your child a chance to share their ideas in different ways (for example, using pictures, writing down their ideas, choosing emojis to represent their feelings). If your child would prefer just to talk to us, they don't need to fill in the booklet/sheet.

We hope you will share a copy of the completed booklet/sheet with us before the interview by email (or other suitable means) or share it at the interview by showing it to us.

The sorts of things we are likely to ask you and/or your child questions about include:

- Your experiences of living with epilepsy (including what you think about your child's seizures, treatment and how your ideas might change over time);

- Your experiences of your child's sleep issues and any impact that this has on your family and how you manage them;
- Your experiences of using COSI, wearing the sleep monitors and what you liked and what we could improve; and
- How you make decisions about your child's epilepsy, their sleep and using COSI.

We will audio-record your interview. The audio recordings of the interviews will be sent to be typed up by a third-party transcription company. This company will remove any information from the transcriptions which may identify you or your child. This company have signed a confidentiality agreement with Edge Hill University and will not use your recording for anything other than the purposes of the study. The recording of your interview will be deleted one week after they have been typed up and the researcher has checked that we have an accurate record of the interview. If you would like, we can send you a summary of the key things we talked about in your interview. We will use the typed-up version of the interview as the basis for our analysis.

With your and your child's consent, we will keep a copy of their activity booklet. We would also like your and your child's consent to use their drawings and responses to the activities (including direct quotes) in our reports and presentations. We will remove anything that will identify you or your child.

Postcards

With your permission, we would like to send your child a postcard at three different times during the study. Two of the postcards will provide an update on the study, as well as a fun activity for your child. The final postcard will be sent with an accompanying certificate to thank them for taking part.

1.6 What exactly is COSI?

The CASTLE Online Sleep Intervention is known as "COSI" for short. The system is accessed using a web link, which will be emailed to those families allocated to the sleep intervention group.

The information in COSI gives parents advice about strategies that are helpful for improving the sleep of children, specifically designed to meet the needs of parents of children with epilepsy.

COSI includes information about many different types of sleep problems and gives ideas for things you can do to try and improve your child's sleep and how to deal with common issues along the way, including some of the special issues faced by children with epilepsy and their families.

COSI is interactive; it will ask for some information about your child and their sleep so that COSI knows which type of information is likely to be of most use to you. Of course, you can look at any section in COSI but, to save you time, you can also look just at the sections which are highlighted as being relevant for you and your child's sleep problems.

1.7 How will I know which study group my child is going to be in?

In research studies we often split patients up into groups to look at how different treatments or interventions work. In the CASTLE Sleep-E study patients will be split into two study groups. Neither the families or the researchers get to choose who goes in which study group and this is to create fair and balanced groups of children and parents in each group.

- One group will receive access to the online sleep intervention (known as the CASTLE Online Sleep Intervention or "COSI" for short)
- The other group will receive standard care from their paediatric team (no access to COSI)

It is really important that each group in the CASTLE Sleep-E study has a similar mix of patients in it so we know that if one group of patients does better than the other it is very likely to be because of the intervention and not because there are differences in the types of patients in each group.

We use a computer programme that puts patients into groups ‘at random’ – you might hear this described as ‘randomisation’ or ‘random allocation’, but they all mean the same thing. It means that neither you nor your child’s doctor choose who gets to be in which group so that the groups are fair and balanced.

In the CASTLE Sleep-E study your child is equally as likely to be in the group receiving online sleep intervention as they are in the group receiving standard care

1.8 What are the alternatives for treatment?

If you do not wish to take part in CASTLE Sleep-E, you will be treated as per standard care, which means your doctor will advise you on the course of treatment which is right for your child.

1.9 What are the benefits and risks of taking part?

Families who take part in CASTLE Sleep-E will receive standard NHS care for their time on the study. There are no additional risks to taking part in the study.

The main benefit anticipated from the sleep intervention (“COSI”) is improved sleep compared to standard care. It is possible that there may also be a reduction in seizures when following the sleep intervention compared to standard care. If, however, your child’s doctor decides that seizures are not being controlled well, they may discuss additional treatments (such as anti-seizure medicine) with you.

We hope that the results from the study will help doctors and patients in the future when making decisions about treatment.

1.10 What happens if I change my mind?

You and your child have the right to withdraw from the study at any time, without giving a reason. Your child can choose to withdraw independently of your wishes and in this instance, both you and your child will not take part in the study.

If at any point you or your child decide to stop taking part in the study, your child will still receive medical treatment and the follow up usually offered by their hospital.

If you do decide that you both should stop taking part, we will ask you if you and your child would like to:

- continue to complete follow up visits for the study or
- stop taking part with no more study visits.

Information on how we will handle your and your child’s information in the event of you both withdrawing is detailed in Part 2 of this Information Sheet.

1.11 What if new information becomes available?

Sometimes during the course of a research project, important new information becomes available about the treatment or intervention that is being studied. If this happens, the doctor will tell you about it and discuss with you whether you want your child to continue in the study. If you decide to withdraw your child your doctor will make arrangements for their care to continue. If you decide they should continue in the study you will be asked to sign an updated consent form.

On receiving new information, the doctor might consider it to be in your child’s best interests to withdraw them from the study. He/she will explain the reasons and arrange for their care to continue.

If the study is stopped for any other reason you will be told why and your child’s continuing care will be arranged.

1.12 What happens when the study stops?

When the CASTLE Sleep-E study ends, access to the online sleep intervention used as part of the study will be closed but all families will be given the option to receive the written content of COSI to keep. If COSI is found to be helpful, ultimately we plan to make an online version of COSI available to all families of children with epilepsy.

It is intended that the results of the study will be presented at conferences and published in medical journals so that we can explain to the medical community what our research results have shown. They may be used to apply to the necessary authorities to make the intervention widely available, if shown to be beneficial.

Confidentiality will be ensured at all times and neither you nor your child will be identified in any publication.

Any information derived directly or indirectly from this research, as well as any patents, diagnostic tests, drugs, or biological products developed directly or indirectly as a result of this research may be used for commercial purposes. Neither you nor your child have any right to this property or to any share of the profits that may be earned directly or indirectly as a result of this research. However, in signing this form your child does not give up any rights that they would otherwise have as a participant in research.

1.13 What if there is a problem?

Any complaint about the way you or your child have been dealt with during the study or any possible harm they might suffer will be addressed. Detailed information is given in Part 2 of this information sheet.

1.14 Will taking part in the study be kept confidential?

Yes. All the confidential information about your child's participation in this study will be kept confidential. Detailed information is given in Part 2

Part 2

Detailed Information about the conduct of the study

2.1 Who is running the study?

King's College Hospital NHS Foundation Trust and King's College London are the Co-Sponsors of this study and are responsible for managing it. They are based in the United Kingdom. They have asked that the day to day running of the study is carried out by a team based at the Liverpool Clinical Trials Centre (LCTC, part of the University of Liverpool) with help from the Health Economics Researchers from Bangor University, Qualitative Researchers from Edge Hill University and the Sleep Team from Oxford Brookes University.

The study has been reviewed by the Health Research Authority and the East Midlands - Nottingham 1 Research Ethics Committee to make sure that the study is scientifically and ethically acceptable.

This study is publicly funded by the National Institute for Health Research (NIHR). Your child's doctor will not receive any payment for including them in this study.

2.2 How will my and my child's information be collected and handled?

King's College London and King's College Hospital NHS Foundation Trust are the joint Data Controllers for this study. Bangor University (along with King's College London and King's College Hospital) will be a joint data controller for the subset of NHS Digital data obtained at the end of the study. These organisations will need to use information from you, your child and his/her medical records for this research project.

This information will include:

- Your name
- Your child's name/gender/initials/date of birth
- Your child's NHS/CHI/H&C* number

*NHS number is only used in England and Wales. CHI number used in Scotland and H&C number in Northern Ireland.

- Your contact details (including address, postcode, mobile phone number and email address)

Members of the CASTLE Sleep-E research team from King's College London, King's College Hospital NHS Foundation Trust, LCTC and regulatory organisations will use this information to do the research or to check your child's records to make sure that the research is being done properly. Members of the CASTLE Sleep-E research team may also look at your child's medical and your and your child's research records, and the consent form you sign, to check the accuracy of the research study. Bangor University will only view and use non-identifiable information.

People who do not need to know who you and your child are, will not be able to see your or your child's name or contact details. Your and your child's data will have a code number (study ID) instead.

Medical and study information

Your child's NHS hospital will collect information from you, your child and his/her medical records for this research study in accordance with our instructions.

Your child's NHS hospital will use the above listed contact information, along with your child's study ID number, to contact you and your child about the research study. They will also use these data to make sure that relevant information about the study is recorded for your child's care and to oversee the quality of the study.

The contact information collected on the consent form you complete will be securely stored by the

Liverpool Clinical Trials Centre (LCTC), which is part of the University of Liverpool and coordinates the study. LCTC will then securely pass yours and your child's contact details to Oxford Brookes University electronically. LCTC will also pass your mobile phone number onto a third-party text messaging company. This company will use your mobile phone number for study purposes only (namely the purpose of sending of automated text reminders) and will not share it more widely. LCTC may also securely pass your contact details to Edge Hill University, if you consent to being interviewed during Visit 1.

Your email address and mobile telephone number will also be collected to give you access to COSI (if allocated to this treatment arm) and send you email/ text and telephone reminders. Some of these text reminders will be automated and sent to you from a third party text messaging company (as mentioned in above). Your telephone number will be used to arrange the delivery of the sleep monitor and study iPad, which will be sent to your home address. To do this your name and mobile number will be stored on a passcode protected mobile phone which is used purely for the research project to help facilitate ease of communication between you and the research team.

The CASTLE Sleep-E team at Oxford Brookes University will transfer your name, postal address and telephone number to a reputable courier for the purposes of delivering and collecting your study iPad and Actigraph. The information provided to the courier will be used for study purposes only and not shared more widely.

The only people from the trial co-sponsors, LCTC, Oxford Brookes and Edge Hill University who will have access to information that identifies you/your child will be people who need to contact you/your child, audit the data collection process or share your information with NHS Digital for the purpose of health economic analysis.

The people who analyse the information at LCTC and Bangor University will not be able to identify you and your child and will not be able to find out your/his/her name, NHS/CHI/H&C number or contact details. Every effort will be made to ensure that any further information about you and your child that leaves her/his NHS hospital (captured on forms and databases used to collect data for the study) will have your/her/his name removed so that you/she/he cannot be recognised from it; this information will usually be removed by a member of the study team at your child's NHS hospital, but may also be removed by LCTC upon receipt.

Pseudo-anonymised data (data that will not directly identify you) collected by researchers and from you and your child at the clinic visits and by questionnaires will be entered directly into the CASTLE Sleep-E study database, held by LCTC, for storage and analysis. Relevant data needed by other members of the research teams at Bangor University, Edge Hill and Oxford Brookes will also be held for analysis and storage.

With your consent, your contact details will be sent to the CASTLE Sleep-E team at Oxford Brookes University and Edge Hill University via a secure database (managed by LCTC). Oxford Brookes will use this information so they can send you the sleep monitors and iPads, as well as to contact you to discuss the sleep intervention (if allocated to this group). Edge Hill University will only be able to access and use this information if you agree to take part in the interview study.

If you and your child wear a sleep monitor, you will send the monitor back to the CASTLE Sleep-E team at Oxford Brookes University and then the data will be sent to the LCTC for analysis. The data will only be accessed by people working on the study or people working to ensure the study is being run correctly. If you log in to the COSI website, pseudo-anonymised data will be collected by LCTC on the usage of this website so we can see if it was useful.

When your child completes the iPad SleepSuite game, pseudo-anonymised data will be securely uploaded to a cloud (online backup) where only authorised CASTLE Sleep-E members from LCTC and King's College London can access the information. At the end of the study, your child's data will be removed from the cloud storage services and transferred to LCTC for analysis.

If you consent to being interviewed as part of the study, a recording of your/your child's interview will be sent by Edge Hill University to a third-party transcription company who will type up your responses. Once a researcher from Edge Hill University confirm that the transcription is accurate, this recording will be deleted.

With your consent, we will send a letter to your child's GP to let them know your child is taking part in the CASTLE Sleep-E study.

The routine Electroencephalography (EEG) report (test that measures the electrical activity of the brain) conclusions (if available) will be uploaded by your doctor or the research nurse as part of the seizure questions asked at the randomisation visit to assess the epilepsy diagnosis made by your local clinician. The report conclusions will not have yours or your child's personal details on them. As identifiable information will not be present on the EEG report conclusion, it will not be possible to feed back any findings to you.

At the end of the study, the Health Economics team working at Bangor University (courtesy of LCTC) will request information on your child's hospital appointments (including inpatient, outpatient and A&E attendances) either directly from your NHS hospital and/or via the central NHS Digital system (NHS Digital records attendances at hospital in England only). Bangor University will not receive any identifiable information about you/your child.

Your child's personal details, which will include their name, gender, NHS number, date of birth and postcode, will be shared with NHS Digital by LCTC in order for NHS Digital to provide information already in their possession on your child's hospital attendances from 6 months before their entry into the study to when they leave the study. NHS Digital will then share this health information, which is regarded as a special category of information, with relevant members of the CASTLE Sleep-E research team at Bangor University. The data NHS Digital provides the CASTLE Sleep-E research team will have your child's name, date of birth and other identifiers removed. At the end of the period specified in the NHS Digital Data Sharing Agreement, the data provided by NHS Digital will be securely destroyed.

For more information about how routine NHS data is collected and used please see the Appendix at the end of this document.

2.3 What are my choices about how my information is used?

You and your child can choose for your child to stop being part of the study at any time, without giving a reason, but we will keep information about you and your child that we already have. You can also choose to participate in the study but for us not to collect your NHS Digital information for the health economics analysis.

We need to manage your and your child's research records, and the consent form you sign 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 or your child.

2.4 Information sharing for other research

When you agree for you and your child to take part in a research study, the information about their health and care may be beneficial to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. You and your child's information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research, or equivalent standards. You and your child's information will be non-identifiable.

If you and your child agree for your child to take part in this study, you will have the option for you both to take part in future research using the data saved from this study.

2.5 Where can I find out more about how my and my child's information is used?

You can find out more about how we use yours and your child's information:

- at the study website: www.castlesleepetrial.org.uk
- at www.hra.nhs.uk/information-about-patients
- in the Health Research Authority leaflet available from www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by contacting the Data Protection Officers listed below;

  King's College London (info-compliance@kcl.ac.uk)

  King's College Hospital (kch-tr.dpo@nhs.net)

  Bangor University (for matters relating to the NHS Digital subset – gwenan.hine@bangor.ac.uk)
- by sending an email to castlesleepe@liv.ac.uk or;
- by ringing us on 0151 795 8774

2.6 What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to your study doctor who will do their best to answer your questions (details found one the first page of this document). If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints procedure by contacting your local Patient Advice Liaison Service (PALS) office. Details of your local office can be obtained by asking your study doctor, GP, telephoning your local hospital or looking on the NHS choices website: http://www.nhs.uk/pages/home.aspx

Every care will be taken in the course of this study. However, in the unlikely event that you are injured by taking part, compensation may be available.

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against King's College London and King's College Hospital but you may have to pay your legal costs.

Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated by members of staff or about any side effects (adverse events) you may have experienced due to your participation in the study the normal National Health Service complaints mechanisms are available to you. Please ask your study doctor if you would like more information on this.

If you are concerned about how your information has been used during the trial, you can discuss this with the Information Commissioners Office (https://ico.org.uk/)

Thank you for taking the time to read and consider this information sheet. Should you decide that you and your child can take part in the study, you will be given a copy of the completed consent form to keep.

Appendix

How routine (NHS Digital) hospital data is collected and used

Step 1

To gather your child's hospital attendances and treatment data LCTC will send your child's details (including name, gender, NHS number, date of birth and postcode) and Study ID to NHS Digital. You can find out more about NHS Digital by visiting https://digital.nhs.uk/.

Step 2

NHS Digital will obtain your child's routine NHS records for the financial years that cover the duration of the study, starting 6 months before your child enters the study, from their Health Episode Statistics (HES) database. This includes details of any hospital attendance(s) your child has had for the duration of the study period.

Step 3

NHS Digital will remove the name, NHS number, date of birth and postcode from this information, but keep it "linked" to your Study ID.

Step 4

NHS Digital will send your child's routine NHS records to Bangor University with only the Study ID included.

Step 5

Bangor University will use the routine NHS records to undertake a Health Economics analysis. They will not have your child's name, NHS number, date of birth or postcode and will be unable to identify you from the data. In CASTLE Sleep-E we want to find out whether giving families access to an online behavioural sleep intervention (COSI) compared to standard care will help improve their quality of sleep, but we also want to know whether it is more cost-effective in the long term. This will be looked at as part of the Health Economic analysis.

CASTLE SLEEP-E

King's College LONDON

NHS
King's College Hospital
NHS Foundation Trust

NHS
Trust/Site Address 1
Trust/Site Address 1 | Postcode
Telephone Number: 00000 000 000

Parent/Guardian Consent Form

FOR SITE USE ONLY:

Site Name: ____________________

Participant Study Number ____________________

Participant Initials ____________________

Participant DOB: ____________________

To be completed by the Parent/Guardian:

Once you have read and understood each statement please tick each box.

Please tick

1. I have read and understood the information sheet for this study. I have had the opportunity to ask questions and have had these answered satisfactorily. ☐
2. I understand that participation is voluntary and that I am free to withdraw my child and myself from the study at any time, without giving a reason, and without my child's care or our legal rights being affected. ☐
3. I give permission for a copy of this fully completed consent form to be sent to the Liverpool Clinical Trial Centre (where it will be kept in a secure location) to allow confirmation that my consent was given. I understand that a copy of this consent form which includes my name, and my child's data will be kept by the Data Controllers and all others archiving data and at my hospital in a confidential manner for 25 years from the end of the study. ☐
4. I understand that relevant sections of my child's medical notes and any data collected during the study from me or my child may be looked at by authorised individuals from the research team and representatives of the Sponsor, regulatory authorities and the local NHS Trust. I give permission for these individuals to have access to mine and my child's records and mine and my child's data. ☐
5. I agree to my child's GP being informed of their participation in the study. ☐
6. I agree for data on my child's NHS hospital attendances and treatment to be collected for the purpose of this study and understand this will include routine paper records, and electronic NHS health care records for the financial years commencing 6 months before the start of the study and covering the duration of the study, for health economic analysis. ☐
7. I agree to my child's name, gender, NHS/CHI/H&C number, date of birth and postcode being recorded and used as necessary to obtain relevant information on NHS hospital attendances and treatment.

NHS/CHI/H&C* number: ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐
(*CHI if in Scotland; H&C if in Northern Ireland)

Please tick

8. I agree for my child's name and my contact details entered below to be securely stored in a LCTC database and used to contact me for the purposes of actigraphy (sleep monitors), delivery of study iPad, reminders and interviews (if I consent to being interviewed). ☐

Mobile phone number: ____________________

Email address: ____________________

Home address and postcode: ____________________

9. I agree to my child and I wearing a sleep monitor (actigraph) on two occasions during the trial. These sleep monitors will be sent to me by the CASTLE Sleep-E study team at Oxford Brookes University using the contact details which I have provided. ☐

10. I agree to a study iPad being sent to my home address at no additional cost to myself and to it being returned to the CASTLE Sleep-E team at the end of study participation (courtesy of my local research team or alternative arrangement agreed by LCTC). ☐

11. I agree for an email and a text containing a secure web link to complete mine and my child's study questionnaires being sent to the contact details I have provided. ☐

12. I agree for my child's EEG report conclusions (if available) to be uploaded as part of the seizure review. ☐

13. I agree to my child's name and to my email address being used to create an account for the sleep training plan, if allocated this intervention. ☐

14. I agree to receive reminder texts/calls from the CASTLE Sleep-E study team at Oxford Brookes if I haven't accessed the COSI website after a few days / if I haven't completed the COSI evaluation a few days after being given access to it. ☐

15. I agree for my telephone number to be transferred to a third party text messaging company for the purpose of receiving automated text reminders relating to the questionnaires and the COSI system. ☐

16. I agree for me and my child to take part in the above study. ☐

The statements below are optional – you and your child can still take part in the main study even if you do not wish to agree to the below:

Please tick
'Yes' or 'No'

17. I agree for my child's personal data (including name, gender, NHS number, date of birth and postcode) to be shared with NHS Digital so they can provide Health Economic researchers working on the study with information regarding my child's medical data and hospital attendances. ☐ Y ☐ N

18. I agree to allow information or results arising from this study to be used in future healthcare and/or medical research providing mine and my child's confidentiality is maintained. ☐ Y ☐ N

19. I agree that I may be contacted in the future in relation to this or other related studies using the contact details I have provided. ☐ Y ☐ N

20. I agree for my child to receive study postcards at three intervals during and shortly after their participation in CASTLE Sleep-E. ☐ Y ☐ N

Please tick
'Yes' or 'No'

The statements below relate to the optional qualitative interview study (your child can still take part in the main study even if you don't agree to these):

21. I agree for my child (if appropriate) and I to take part in the interview study and that I may be contacted by a researcher from the interview team after Visit 3 to discuss this but I understand that we may not be selected. Y N

22. I agree to my interview and my child's interview (if appropriate) being audio-recorded. Y N

23. I agree to the researchers keeping a copy of my child's activity booklet/sheet. Y N

24. I agree that the anonymised typed up version of my and my child's interviews and any researchers' notes will be stored securely for 25 years at Kings College Hospital NHS Foundation Trust after completion of the study. I agree for these to be securely stored in this way. Data will be destroyed after 25 years. Y N

25. I agree that some of the things I say or my child says in the interview(s) may be quoted and that some of my child's drawings or images of the activities they completed may be used in a final report, publications/papers, conference presentations and online resources. I understand that all quotations and images will be anonymised, and we will not be identified in any of the outputs mentioned. Y N

26. I agree to the researcher sharing information about me or my child if they are worried that someone is being harmed. Y N

27. I agree to the researchers keeping the information I have already shared with them if I decide to leave the study. Y N

28. I agree that the typed-up version of the interviews/booklets/sheets may be shared and looked at by other CASTLE Sleep-E researchers, where relevant for the purpose of the study overall. Y N

To be completed by the Parent/Guardian:

Your child's full name (please print) ______________________

Your full name (please print): ______________________

Your signature: ______________________

Date: ______________________

To be completed by the Researcher (after participant has completed the form):

Researcher full name (please print): ______________________

Researcher signature: ______________________

Date: ______________________