Research Study: Airway Drainage and Positioning at Night-time (ADAPT).

Parent Information Sheet

We are inviting children and young people with complex neurodisability who are at risk of recurrent chest infections, and their families, to take part in a research study to compare two night-time sleeping positions..

The study will introduce a *new* night-time sleeping position to children and their families which hopes to improve night-time breathing and sleep, aiming to improve respiratory health.

We will also collect information from children and young people and their parents about their experiences using night-time interventions.

Please take time to read the following information carefully. You may want to talk to others about the study before taking part.

Part 1 tells you the purpose of this study and what will happen to you if you take part.

Part 2 gives you more detailed information about the conduct of the study.

Please ask us if there is anything that is not clear, or if you would like more information. Take time to decide whether or not you wish to take part. Taking part in this study is your decision. It’s OK to decide not to take part.

Thank-you for taking the time to read this information sheet.

Part 1 – Summary of the study

What is this research about?

This research considers two different approaches to sleeping positions at night-time for children who find it difficult to move, communicate, eat, drink and swallow and are dependent upon others to move and position them. We are comparing:

The standard approach to night-time positioning which focusses on children's posture at night.	 (Child lying on their back with arms and legs supported)

With:

A new night-time position focusing on improving night-time breathing and sleep.	 (Child lying part-way onto their front with top arm and leg supported)

Why are we doing this research?

The purpose of this study is to see if this new positioning overnight may help **reduce risk of chest infections in comparison to the usual position.** We will be inviting **50 children** and their families to participate in this study.

If you take part in the study, you will be randomly allocated to either **continue with their usual night-time position** *or* to **try the new postural position** for 6 months. The experiences of children and their parents, and the child's respiratory health and sleep will be compared between the two groups.

Why am I being invited?

You have been identified as the **parent or guardian of a child or young person aged between 2 and 18 years with complex neurodisability**, who has difficulties with swallowing and relies on others to position their body at night. Your child has had chest infections within the last year that may have been caused by aspiration; fluid, food or secretions going down into the lungs.

Part 2 – Further Information

What is the new night-time intervention?

This approach involves positioning children safely part-way over to their fronts on a flat bed, using their night-time positioning equipment (sleep system) or pillows to support the body if needed. The aim is to achieve a position where gravity can help drain upper airway secretions (e.g. saliva) from the back of the throat and mouth. To reduce the risk of reflux and aspiration into the lungs of any stomach contents, it also involves draining children's stomach overnight via their existing feeding tube.

Do I have to take part?

Taking part in the study is voluntary and whatever you decide will **not affect the standard of care and other support or benefits you and your child receive.**

What will happen if I decide to take part?

You will need to complete and sign the **consent form** which the research team will provide and go through it with you.

Children who participate in this study will **be randomly allocated to either continue with their usual care (called the 'control group') or to try the new postural position (the 'intervention group')** for 6 months. Children are allocated by chance, to one of these two groups, and the experiences of children and their parents will be compared between the two groups. Your participation in this study will help us to understand and compare the experiences of children and parents between the two different approaches, to test the feasibility of using the new intervention.

- **Step 1: Once you have agreed to join the study**

The research physiotherapist and your physiotherapist will visit you and your child at home to see how they are sleeping at night, and ask some questions about your child's sleep, their respiratory health and quality of life. They will ask questions about any pain or discomfort at night. They will ask key members of your child's healthcare team about your child's health and medical history and to access your child's medical records for this information.

If your child is in the control group (continuing their usual sleep positioning):

The research physiotherapist will talk to you about your child's comfort at night-time and how acceptable the usual position is for them. They will monitor this through your child's breathing, body language, facial expressions and vocalisations, and any other form of communication they use. Photographs will be taken to support consistent use of the usual position across settings.

Your child will continue to sleep in their usual position throughout the 6-month trial period.

If your child is allocated to the intervention group (trying the new sleep position):

You and your child will meet with the research physiotherapist and your physiotherapist. They will visit your child at home to try the new intervention position with your child. If acceptable, they will ask your child to try this during the daytime for 1 hour a day for at least 1 week.

We will make sure that your child is set up in the new position:

- where they are safe and comfortable enough to go to sleep
- so that saliva or secretions drain out through the mouth
- where breathing is quiet and comfortable
- where they are comfortable with no pressure areas
- where postural needs are considered
- where they are protected from aspiration of stomach contents overnight.

When you and your child are comfortable with the changes proposed, you will introduce the new intervention to the first part of your child's night-time before you go to bed. You can then monitor your child's safety by monitoring oxygen levels and heart rate. You can make observations about whether your child is comfortable and able to go to sleep and stay asleep in this new position. When your child's oxygen levels and heart rate are stable, and when you are sure that your child is comfortable and able to go to sleep, the new intervention will be introduced overnight.

For both groups:

Your child's safety will be monitored by observing them and measuring their oxygen levels and heart rate. Your child's comfort and how acceptable their night-time position is for them, will be monitored through their breathing, body language, facial expressions and vocalisations, and any other form of communication they use. Photographs will be taken to support consistent use of this new position across settings.

You will receive training in how to position your child overnight. Parents/carers in the intervention group will receive training in how to monitor oxygen levels and heart rate. You will receive training and the equipment you need to drain the contents of your child's stomach overnight.

The research physiotherapist will be in frequent contact with you in these early stages to offer support and advice, address any concerns you may have and answer any questions. The research physiotherapist will make regular phone contact with you throughout the study.

• Step 2: 3-month follow-up

For all participants, after 3 months, the research physiotherapist will check how your child is sleeping, find out how things are going, and ask you the same questions you were asked before about your child's sleep, their respiratory health, pain and quality of life. Your answers will let us know whether there have been any changes.

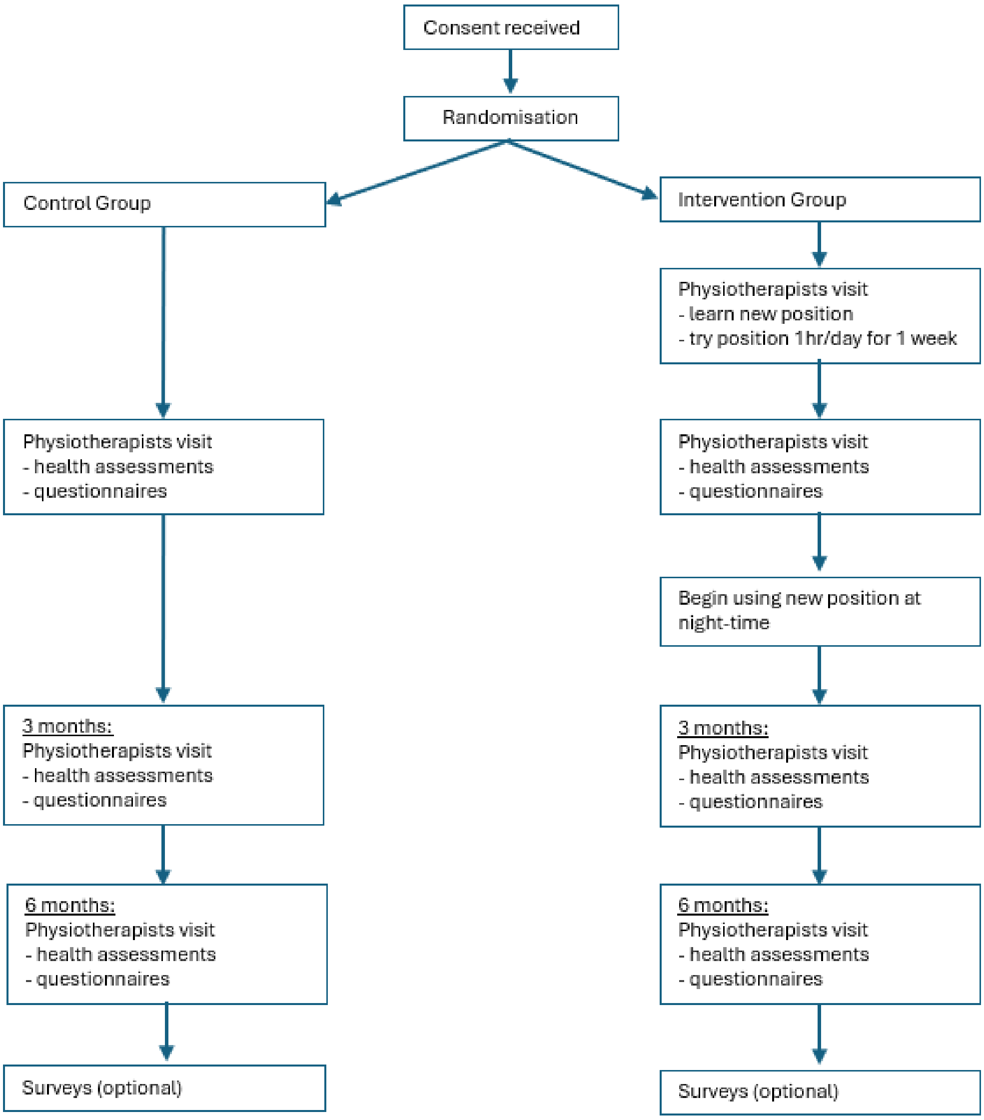
- ## Step 3: 6-month follow-up

For all participants, after 6 months, the research physiotherapist will visit again for the final time. You will be asked the same questions about your child's sleep, respiratory health, pain and quality of life. Your answers will let us know whether there have been any changes.

- ## Step 4: Tell us your thoughts.

The final part of the project is when you and / or your child tell us what you think and feel about being part of this study, via surveys sent to you and a conversation with your child if they are able to participate. It is important for us to hear the views from participants in both groups. We want to hear about all your experiences, even if you chose to discontinue part way through.

We will not use your names and will anonymise all information that could identify you or your child. You and / or your child do not have to take part in the survey if you do not want to.



Flow chart of your journey through the study.

Will our taking part be kept confidential?

With your permission, your child’s healthcare team will be informed about you and your child taking part in this study. This is so we can collect some information about your child’s health from them. We will only collect information that we need for the study. Only the research team will know your name or contact details, and only if they really need it for this study. People who do not need to know who you are will not be able to see your name or contact details.

We will keep what you tell us in the surveys and during telephone calls with the research team completely confidential unless there is anything you say that makes us concerned that you or someone else is at risk of serious harm. If this happens, we would talk to you first about the best thing to do.

What are the possible benefits of taking part?

We cannot guarantee any benefits, however our aim is to ensure that night-time positioning will keep your child safe and comfortable, and not increase risks to your child's health. Sleeping in the new position may help with breathing, sleep and reduce the risk of chest infections. We hope that this research will be beneficial to other families with a child with a similar condition. Information collected from you and other families will help us understand more about the new and usual night-time sleeping positions and whether we can continue to test the new intervention with more children in a bigger trial.

We would really like to listen to your viewpoint even if you think that this intervention will not work for your child.

What are the possible risks of taking part?

We do not know whether children using the new position will have less chesty illnesses compared to the usual care. We do not know the potential impact on muscles, bones and joints long term.

There will be an increase in the demands on your time to take part in the study. It will involve a visit of approximately one and a half hours to assess your child's sleeping position. It may disrupt your lives a little bit if your child is in the group trying the new intervention. Changes to your child's night-time feed regimes may be required. We will discuss this with you and the usual health professionals involved to agree planned changes. You may feel nervous about introducing the new intervention which will introduce some changes your child's usual night-time routines.

It will take you additional time to provide us with the information we need. You might think that we ask you about things of no direct benefit to you. However, by taking part in our study you will be helping others.

It is possible that by providing detailed information about your child's respiratory health and night-time routines may be upsetting or distressing. The experienced research physiotherapist will support you and your child. If you would like to talk more about some these things that are distressing, please contact the research physiotherapist (see below for contact details). We can provide details of local individuals and organizations who can help. Also remember that taking part is entirely your decision and you can withdraw from the study at any time without giving a reason.

What if I change my mind during the study?

You and your child can decide to stop taking part in the study at any time by letting your physiotherapist or the research physiotherapist know that you would like to withdraw. Whatever you decide, it will not affect the standard of care and other support or benefits you and your child receive. You do not have to give us a reason for changing your mind.

You can still give your views in the final survey even if you decide to stop taking part in this study. We want to find out about all your views and experiences of being part of this study, whether these are positive or negative.

How will you use information about me?

We will use information from you, your child, your child’s healthcare team and your child’s medical notes for this research project. This information will include your name and contact details as well as your child’s name, NHS number and contact details held by your clinical teams. People will use this information to do the research or to check your records to make sure the research is being done properly.

People who do not need to know who you and your child are will not be able to see your name or contact details. You and your child’s information will have a code number instead.

We will keep your study data for a maximum of 5 years. The study data will then be fully anonymized and securely archived or destroyed.

Sussex Community NHS Foundation Trust is the Sponsor of this research, and is responsible for looking after your information. We will keep all information about you and your child safe and secure by:

- Storing paper information securely within lockable filing cabinets and/or in strictly restricted access rooms on NHS premises.
- Storing electronic information on encrypted, password protected NHS systems with restricted access.

- Anonymising the data you and your child provide with a unique study ID number.
- Ensuring that people who do not need to know who you or your child are will not be able to see any of your personally identifiable details.

Your data will not be shared outside the UK.

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 and your child took part in the study. If we use any direct quotations in our reports or publications, you and your child's names and personal details with not be included. If you have consented to receive a copy of the study results, we will share this with you by your preferred method as indicted on the consent form.

What are my choices about how my 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 I find out more about how my information is used?

You can find out more about how we use your information:

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team (see contact details below)
- by contacting The Sussex Community NHS Foundation Trust's Data Protection Officer:

  Email: sc-tr.infogov@nhs.net or call 01273 666 473.

Who has reviewed this study?

The project is being carried out by researchers from Sussex Community NHS Foundation Trust, University Hospitals Sussex NHS Foundation Trust, Universities of Exeter, Surrey, Liverpool and Sussex, and Brighton & Sussex Clinical Trials Unit.

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by Yorkshire & The Humber - Leeds East Research Ethics Committee.

What if I have a question to ask?

If you have any questions please contact:

Study Leads: Dr Sarah Crombie or Dr Akshat Kapur.
Email address: sc-tr.adaptclinical@nhs.net

Who do I contact if I have concerns about the study?

If you have any concerns or wish to make a complaint, please contact:

Patient Advisory Liaison Service
Brighton General Hospital
Elm Grove, Brighton
BN2 3EW
Tel: 01273 242292
Email: sc-tr.PALS@nhs.net

Thank you for taking this the time to read this information.

Please keep this copy.