



PARTICIPANT INFORMATION STATEMENT

HREC Project Number:	HRE2021-0056
Project Title:	Assessing sleep biomechanics in typically developing children and children with cerebral palsy: A feasibility study.
Chief Investigator:	Dr. Jenny Downs, PhD
Version Number:	Version 2
Version Date:	20/01/21

What is the Project About?

People with physical disabilities develop changes in the shape of their skeleton (such as the shape of the ribcage and the curves of the spine) at a much higher rate than typically developing people. This may cause pain and make it difficult for the person to sit, stand and walk. One idea that has been proposed for this higher rate of skeletal shape change is that people with physical disabilities can't change their position as much as typically developing people while they are sleeping. We spend a third of our lives asleep – spending a long time in one or two positions may result in changes in the shape of peoples' skeletons due to gravity and reduced muscle function.

Proving a difference in sleep repositioning frequency between typically developing people and people with physical disabilities is key to investigating this theory. However, this is difficult because there is currently no good way to measure movement and position during sleep. Small, wearable activity monitoring devices have been used to measure movement during sleep before; however, we're going to use them in a different arrangement than they have been previously used. Our project will focus on creating a new tool using these devices, and make sure it is feasible, meaning it isn't hard or unpleasant for people to use the measurement.

This research is important because, if proven, the lack of repositioning in people with severe physical disabilities may represent a way to better support them during sleep, and help prevent the painful and disabling changes in skeleton shape in the first place.

The aim of this study is to gather information of movement and positions adopted from both children who are typically developing and those with cerebral palsy, and see how they are similar. And how they are different. This study is a pilot study, meaning it is a small study that is completed first to see if it is worth doing a bigger study in the future. We are aiming to have 50 children and adolescents (5-18 years old) take part in this study; 25 who are typically developing, and 25 with cerebral palsy. We will use small, wearable monitors to collect sleep movement/position data for 5 nights for each person.

Who is doing the Research?

The project is being conducted by Nicholas Buckley, supervised by Associate Professor Jenny Downs, Associate Professor Amity Campbell, Dr Lynn Jensen, Mr Bas Jansen and Mr Kevin Baptist.

The results of this research project will be used by Nicholas Buckley to obtain a Doctor of Philosophy at Curtin University and is funded by the University.

There will be no costs to you and you will not be paid for participating in this project.

Why am I being asked to take part and what will I have to do?

We are looking for children and adolescents (5-18 years old) in the Perth Metro area to be involved in our research. We are recruiting typically developing people and people with cerebral palsy.

As we are studying movement during sleep, we would like to complete the assessment in the environment that your child usually sleeps in. We will come out to your house for an initial 1.5 hour session to show you how to use the equipment, and also to complete a measure of body shape with your child. This assessment is called the Goldsmith Indices of Body Shape, and assesses three main things; the shape of the chest, the range of movement of your lower back/pelvis and the range of movement of your hips. It is gentle and non-invasive. This measure will let us know the baseline body measurements of each participant before they start.

The main assessment will consist of measuring your child's sleeping position from the time they go to bed until they wake up. We will do this by using four small activity monitors called XSENS DOTs (or DOTs, for short) – they are about the size of two 50c coins stuck together. These DOTs will be secured to the chest, tummy, and above both knees with either Fixomull or Tegaderm medical dressing. They will send information to a Samsung Galaxy smartphone that we will provide. Children may need the assistance of an adult to apply the DOTs each night. Sticking the DOTs on and programming them to start using the phone will take approximately 10-15 minutes each night. The DOTs will record the position of the chest, hips and legs during sleep. If your child need to get up during the night (e.g. to get a drink or go to the bathroom) they are free to do so; this will not affect the recording of data. We would like you to record for five (5) nights in a row, including at least one weekend night. After you have finished the 5 nights of recording, we will collect the recording equipment from your home.

Before the recording nights, we will ask you to answer a short questionnaire about your child's general health and sleep habits. This will take approximately ten minutes. During the assessment period, we would like you to keep a sleep diary for each night of sleep; this will take approximately five minutes per night. Following the nights of recording, we will ask you to answer a questionnaire about your child's experience sleeping with the DOTs in place. This will take approximately ten minutes. These questionnaires will be provided electronically with a URL link or at your request, we can provide you hard copies to fill out.

There will be no cost to you for taking part in this research and you will not be paid for taking part.

Are there any benefits to being in the research project?

There may be no direct benefit to you or your child from participating in this research. By participating you will assist us in achieving the aim of this project, to contrast the sleep movements and positions of typically developing children and those with cerebral palsy.

We hope the results of this research will allow us to use the DOTs in future studies. This will let us do more research into how people reposition themselves while they are asleep, and understand the differences in sleep repositioning patterns between different groups.

We are happy to provide you with the results of the Goldsmith Indices of Body Shape assessment on request.

Are there any risks, side-effects, discomforts or inconveniences from being in the research project?

There are minimal risks associated with being involved in this research project.

Some people's skin can be sensitive to certain adhesive dressings, such as the ones used in our study. We will test whether your child's skin tolerates the dressing we are using (Fixomull or Tegaderm) by putting a small patch on for 15-20 minutes during our first visit, and then removing that patch and making sure the skin underneath is okay. Most people's skin tolerates these dressings well; however, these dressings may cause redness and mild itching at the application site in some people. If your child's skin reacts to the test patch or your child have had a sensitivity to the dressing previously, we will provide the alternative dressing (e.g. if sensitive to Tegaderm, use Fixomull instead). If your child develop a sensitivity to the dressing during the study, we will discontinue use of that dressing. Once the redness and itching completely go away if you wish to continue we will provide the alternative dressing.

Apart from giving up your time, we do not expect that there will be any risks or inconveniences associated with taking part in this study.

Who will have access to my information?

The information collected in this research will be re-identifiable (coded). This means that we will collect data that can identify your child, but will then remove identifying information on any data or sample and replace it with a code when we analyse the data. Only the research team have access to the code to match your child's name if it is necessary to do so. Any information we collect will be treated as confidential and used only in this project unless otherwise specified. The following people will have access to the information we collect in this research: the research team and, in the event of an audit or investigation, staff from the Curtin University Office of Research and Development.

Electronic data will be password-protected and hard copy data will be in locked storage.

The information we collect in this study will be kept under secure conditions at Curtin University for 7 years after the research is published and then it will be destroyed.

The results of this research may be presented at conferences or published in professional journals. Your child will not be identified in any results that are published or presented.

Will you tell me the results of the research?

We will write to you at the end of the research (in the next 12 months) and let you know the results of the research. Sleep repositioning results will not be individual but based on all the information we collect and review as part of the research. We will provide the results via email (or a hard copy letter, if requested).

If you would like a record of the Goldsmith Indices of Body Shape assessment results for your child, this is available on request.

Do I have to take part in the research project?

Taking part in a research project is voluntary. It is your choice to take part or not. You do not have to agree if you do not want to. If you decide to take part and then change your mind, that is okay, you can withdraw from the project.

You do not have to give us a reason; just tell us that you want to stop. Please let us know you want to stop so we can make sure we deal with the information we collected according to your wishes. If you chose to leave the study we will use any information collected unless you tell us not to.

Participation in this study will not affect your child's treatment or relationship with their allied health or medical team, now or in the future.

What happens next and who can I contact about the research?

If you wish to obtain further information or have any questions you would like answered, please contact Dr. Jenny Downs on jenny.downs@telethonkids.org.au or +61 8 6319 1763.

If you decide to take part in this research we will ask you to sign the consent form. By signing it is telling us that you understand what you have read and what has been discussed. Signing the consent indicates that you agree to be in the research project and have your health information used as described. Please take your time and ask any questions you have before you decide what to do. If requested, you will be given a copy of this information and the consent form to keep.

At the start of the online questionnaire, available via the link provided, there is a checkbox to indicate you have understood the information provided here in the information sheet.

Curtin University Human Research Ethics Committee (HREC) has approved this study (HREC number HRE2021-0056). Should you wish to discuss the study with someone not directly involved, in particular, any matters concerning the conduct of the study or your rights as a participant, or you wish to make a confidential complaint, you may contact the Ethics Officer on (08) 9266 9223 or the Manager, Research Integrity on (08) 9266 7093 or email hrec@curtin.edu.au.