







## Participant Information Sheet - Child/Adolescent

Title Remotely Monitored Transcranial Direct Current Stimulation in Children with Cerebral Palsy

Principal Investigator Professor Michael Fahey

Associate Investigator(s)

Professor Iona Novak, Assoc Professor

Bernadette Gillick, Dr Manoj Kanhangad, Assoc

Prof Maria McNamara, Dr Megan Finch-Teleconference based via Cerebral Palsy

Location Alliance Research Institute, University of Sydney

# It's OK to say no

#### What are we doing?

We are asking for your help in our research because you have cerebral palsy (CP). CP may affect how you move, your balance and posture. We are looking at ways to help treat CP. Our idea is to use a machine that helps stimulate the brain. This is called "Transcranial Direct Current Stimulation" or tDCS for short. You can wear this device on your head.

We need to find out if this tDCS device is safe and comfortable enough for children with CP to use at home. You are reading this sheet because you may be able to help. This sheet explains the research and what we will ask you to do if you participate. You can say no to participating if you want. And you can ask us lots of questions if you have any.

What will you do?

If you participate in this research, we will ask for your help over 5 days. Each day, you will have a 1-hour session in your home. Researchers will video call you and your family and we will go through the process of using the device together.

The tDCS device and other tools you need to participate will be sent to your house. You and your family will also watch some videos that will help you understand what to do. On the first day we will practice how to setup the device that you will wear on your head. We will ask your parents to take photos of it on your head, so we can check it is in the right position. We will also do some checks to make sure the device is working. We will ask you questions about how you are feeling and how you thought it went. You can tell us to stop at any time.



We will do the same thing on the second day, but this time your family will help us to turn the tDCS device on for a very short time. This is to let you see how the tDCS feels. Some people say it feels a bit tingly. We will ask you how it feels and also make sure that it feels comfortable. If it does not feel comfortable, we can adjust it for you so that it feels better. We will ask you lots of questions about how you are feeling and take some more photos. We will also ask you to do a test with your hands that involves picking up and moving blocks. This will be done at the beginning and the end.



For the next 3 days we will do the same thing, but the tDCS device will be turned on for a bit longer. While it is on, you can read a book or watch a video. There may be other things you can do, but we need to make sure that you stay on the videocall with us for the whole time. We will ask you lots of questions about how you are feeling again.

At the end of the sessions, you will again be asked how you thought it went. About one week after the study is finished, we will check back in with you and your family to see how you are going. We might also ask for your help in future studies if you are interested.

#### Is it safe for me to participate and what could happen?

Research has shown us that the tDCS device is safe when used in children and adults. It is not likely that you will get hurt. But, some things could happen that are not nice or that are uncomfortable.

These could include:

- Itching, tingling or burning where some of the device sits on your head
- Skin redness, neck or head pain where some of the device sits on your head
- Headache
- Sleepiness
- Difficulty concentrating
- Mood changes

If these happen, we don't expect them to last more than 1 hour. Your study doctor and family will do their best to keep you safe and prevent these things from happening.

### Will this study help me?

We cannot promise that you will notice an improvement in your skills or that this will help with your CP. But if you participate, we can learn more about the device at home which may benefit other children with CP in the future.

### Can I stop the study at any point?

You can stop doing the study at any time. All you have to do is tell your family that you don't want to do the study anymore. If you stop doing the study, nothing bad will happen to your regular appointments with other doctors and therapists. Nobody will be mad with you if you say you want to stop.

Please ask us any questions if you have them. If you need more information, you can talk to your parent(s) or the researchers.