Participant Information and Consent Form – Parent/Guardian

Title	Remotely Monitored Transcranial Direct Current Stimulation in Children with Cerebral Palsy
Short Title	Non-Invasive Brain Stimulation for Children and Young People with Cerebral Palsy
Protocol Number	HREC/88381/MonH-2023-355157
Project Sponsor	Monash University
Principal Investigator	Professor Michael Fahey
Associate Investigators	Professor Iona Novak, Assoc. Professor Bernadette Gillick, Dr Manoj Kanhangad, Assoc. Prof Maria McNamara, Dr Megan Finch-Edmondson, Dr Madison Paton, Dr Alex Griffin, Mr Preston Christopher, Mr Remy Blatch-Williams
Location	Teleconference based via Monash Health and Cerebral Palsy Alliance Research Institute

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Part 1 What does the participation involve?

1 Introduction

You are invited to take part in this research project as you are a parent or guardian to a child aged 8 – 17 years with a previous diagnosis of cerebral palsy (CP). This research project is testing the safety and feasibility of delivering a treatment called transcranial Direct Current Stimulation (tDCS) to children with CP in their home. This treatment has previously been used safely and feasibly in children with CP and other conditions in a clinic. Our goal now is to expand the use of this technology into the home setting.

The first step in establishing tDCS in the home is to test its safety and feasibility. Feasibility refers to how easily and conveniently the device can be used. For this study, we will also be capturing information on the safety of the device and reporting on the feedback from you and your child.

This Participant Information and Consent Form tells you about the research project. It explains the assessments and treatments involved. Knowing what is involved will help you decide if you want your child to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether you would like your child to take part, you might want to talk about it with a relative, friend, or your child's medical team.

Participation in this research is voluntary. If you do not wish your child to take part, they do not have to. Your child will receive the best possible care whether or not they take part.

If you decide you want your child to take part in the research project, you will be asked to sign the consent section of this form. By signing it you are telling us that you:
• Understand what you have read
• Consent to your child taking part in the research project
• Consent for your child to have the tests and treatments that are described
• Consent to the use of your child's personal and health information as described.

You can download a copy of this Participant Information and Consent Form to keep.

2 What is the purpose of this research?

CP is a group of disorders that affect a person's ability to move and maintain balance and posture. Most CP arises from an injury to the developing brain. Transcranial Direct Current Stimulation (tDCS) is a brain stimulation technique that sends out a low-level electric current to the brain through electrodes placed on the scalp. The positioning of the electrodes on the scalp will determine the area of the brain that is targeted by the low-level electric current. This current may improve the way that brain cells communicate in this area of the brain. When tDCS is combined with other treatments that are designed to help movement, such as those received from a physiotherapist or occupational therapist, it may result in bigger improvements for children with CP than achieved with physiotherapy or occupational therapy alone.

The use of tDCS has been established as safe and feasible in laboratory and clinical settings. However, travelling to the laboratory or clinic can be burdensome for families, particularly families living in rural and remote communities. The recent global pandemic has also highlighted the importance of being able to access treatments from home. In this study, we aim to determine the safety and feasibility of delivering tDCS remotely, via videoconferencing, to families within their home.

The research team involved in this study are working together with experts in United States of America (USA). Recently this USA team completed a study that assessed the feasibility of providing tDCS to children with CP via videoconferencing while children and families were in their homes. The research team used live videoconferencing to deliver the treatment remotely. This study showed that children and their families were able to follow instructions over videocall with guidance from researchers and doctors to set up a tDCS session in the same way it would be set up in a clinic. Families were also able to complete tests and measurements. Because this study was only focused on whether families could set up the tDCS device, rather than use it, this study used a tDCS device that looked like a real device but did not deliver any current.

Now, in this study, we will use a real tDCS device to determine whether families can use it safely and feasibly at home with instructions from researchers via live videoconferencing. In this study, children will receive tDCS with instructions and monitoring for safety from our research team via live videoconference. The international research team conducting this study includes paediatric neurologists, scientists, physiotherapists and occupational therapists extensively experienced in CP and tDCS.

A total of 10 children and their families will participate in this study. All children will receive tDCS. This research has been funded by Cerebral Palsy Alliance Research Foundation and is sponsored by Monash University.

3 What does participation in this research involve?

After reading this form, you will have the opportunity to discuss this trial with the study team and ask any questions that you may have. If you are interested in participating, you will be asked to complete an online questionnaire. This is to check whether you and your child meet the criteria for this study. The research coordinator and study neurologist will review your questionnaire and may ask you to provide three additional documents. These will be provided via a secure online data sharing and storage platform.
These documents are described below:

- **A recent letter from your child's specialist (usually paediatric neurologist or rehabilitation specialist) containing their diagnosis.** This does not need to be a new letter; it can be letter or summary provided at any time within the last two years.
- **A report from an imaging investigation (e.g. MRI) of your child's brain (if available).** This is to give us information about how to best deliver the tDCS to your child. We aim to deliver the low-level current to the area of the brain that is likely to provide the greatest benefit.
- **An allied health report (e.g. from a physiotherapist, occupational therapist, speech pathologist etc) outlining your child's current goals.** An example of this type of report could include those provided by your therapists to the National Disability Insurance Agency (NDIA) for plan reviews.

If your child meets the inclusion criteria, you and your child will again have the opportunity to ask questions and discuss the study further with our team via videoconferencing. In this discussion, we will also confirm that you have basic equipment in your home that will allow us to deliver the treatment, such as a table for your child to sit at for some of the tests. If you agree to participate, you will be asked to provide consent by signing the consent form electronically. This will be done in REDCap (i.e., Research Electronic Data Capture, a secure web platform to capture data for research). A link will be sent to you to do so. Your child will also be offered the opportunity to provide consent. To ensure that your child understands what is required of them before they consent to participating in the trial, they will be asked to take a short multiple-choice survey. If they answer all questions correctly, they will be asked to provide informed consent electronically on REDCap, just as you will. If they do not answer some of the questions correctly, they will be able to re-attempt the survey if they would like to. The survey can be

reattempted as many times as your child wishes and at any time throughout the trial.

To provide informed consent, you will be sent a link to open the survey, and you will be prompted through this participant information and consent form again. There are multiple aspects of the trial that we will ask your consent for, including how we stay in contact with you and use your information. You can select as many or as few of these options as you like. You will then 'sign' your consent by typing your name or by using REDCap's 'Signature' field type on the survey. You will select 'next page' and a read-only copy of the consent will be generated that you can review, download, and print. At the bottom of the page, you will need to select "I certify that all the information in the document above is correct. I understand that clicking "submit" will electronically sign the form and that signing this form electronically is the equivalent of signing a physical document" and "Submit".

You will then be contacted by the research team to confirm a date for participation in the trial and arrange supplies to be posted to you. You will also have the opportunity to ask any questions.

During the trial, your child will be asked to participate in 5 sessions of tDCS stimulation. Wherever possible, these sessions will run over consecutive days, but all sessions must be completed within 14 days. These sessions will be conducted by videocall (e.g., Zoom) and will be recorded. Each session involves the set-up of the tDCS device and some tests and measurements before, during and after the device is worn. Your child will wear the tDCS equipment as a head strap and this will stay in place for 20 minutes each session. Your child will be asked to stay in view of the research team during this time and may watch a video or read a book. Each of the five sessions is expected to last approximately 1 hour.

Supplies (including measuring tape, the tDCS device, electrodes and a box of blocks for a motor task) will be sent to your home. It is important that the tDCS device is stored in a dry and cool place. The storage temperature of the device must be between 10°C – 31° and it must not be kept in a humid environment.

You will be given access to a REDCap platform that contains instructional videos of how to measure your child's head to select the correct sized head strap, how to set-up the tDCS device and where to place electrodes at different locations on the scalp. During the study, the research team will step through each of these procedures with you via videoconferencing. You will not be required to perform any of these procedures on your own. The purpose of these videos is simply to provide you with an overview of what these processes entail.

During session 1, you will practice setting up the device with support from the research team via videoconference. We will record the time taken and ask you questions about how difficult you found the set-up. You will be asked to mark locations on your child's scalp using a skin pencil, then to part their hair to clean some of these areas with alcohol wipes. You will also be asked to upload images of the position of the head straps on their head to REDCap. We will ask your child some questions about how they are feeling. The device will not be turned on. At the end of the 20 minutes, we will check to see if the device has moved by asking you to mark specific locations on your child's scalp once more and take a measurement of these markings with a tape measure. We will again ask your child questions about how comfortable the device was to wear and how they are feeling.

During session 2, the device will be set up in the same way that it was on day 1, and with guidance by the research team. We will time the duration of set-up and again ask you questions about how difficult or easy the set-up was. While the device is still off, we will ask your child about whether they are feeling any specific sensations while wearing the headgear. They will also be asked to do a test called the Box and Block test, to look at how they are using their

hands to grasp and move blocks. The device will then be turned on and your child will receive 1 minute of low-level tDCS stimulation. The first 30 seconds will gradually increase in intensity and the second 30 seconds will gradually decrease in intensity. This will occur again, 20 minutes later. Your child may experience a mild skin tingling sensation, and if it is uncomfortable, we will adjust the intensity for the next session. You can stop the stimulation at any time. You will be asked the same questions by the research team about how easy or difficult the steps were. Your child will also be asked again about any specific sensations they are feeling. They will be asked to keep the headgear on for the 20-minute period, as they did on Day 1. At the end of the 20 minutes, after the second gentle ramp up and down, we will again ask them about any sensations they are experiencing and ask them to complete the Box and Blocks test again.

In sessions 3 to 5, the procedures for Day 2 will be repeated, however as long as your child is comfortable, the stimulation will run for 20 minutes, rather than the 30 second ramp-up and 30 second ramp-down. The intensity can be adjusted as needed and you may always turn off the device if you wish. The research team will accompany you through all of these steps in a live videoconference at every session to ensure safety.

The study will last for 5 days. One week after the study has finished, we will follow-up with you and your child to see how you are doing and if you would like to be contacted again for participation in future studies. We will also ask you if you have any feedback about how we could improve our study for the future.

This research project has been designed to ensure the researchers interpret the results in a fair and appropriate way and avoids the research team or participants jumping to conclusions.

4 Does my child have to take part in this research project?

Participation in any research project is voluntary. If you do not wish for your child to take part, they do not have to. If you decide that they can take part and later change your mind, you are free to withdraw your child from the project at any stage.

Your decision that your child can or cannot take part, or that they can take part though are then withdrawn, will not affect their routine treatment or relationship with those treating them or their relationship with Monash University or Cerebral Palsy Alliance now, or in the future.

5 What are the alternatives to participation?

Your child does not have to take part in this research project. Your child's routine care will not change if you decide not to take part in this project.

6 What are the possible benefits of taking part?

This is a safety and feasibility study. We cannot guarantee or promise that your child will receive any benefits from this research; however, your participation in the study may benefit other children with CP and their families in the future, by helping us learn more about the safety and feasibility of remote tDCS in the home. Once we have established the safety and feasibility of remotely delivered tDCS for children or adolescents with CP, we can investigate whether it has benefits, alone or in conjunction with other therapies. Thank you for considering taking part in this important first step.

There are no costs associated with participation in this research project, nor will you or your

child be paid. All assessments and treatments required as part of the research project will be provided to your child free of charge.

7 What are the possible risks and disadvantages of taking part?

Medical treatments often cause side effects. Your child may experience none, some or all of the effects listed below, and they may be mild, moderate or severe. If your child has any of these side effects, or you are worried about them, talk with the study neurologist. The study neurologist will also be looking out for side effects. There may be side effects that the researchers do not expect or do not know about and that may be serious. Tell the study neurologist immediately about any new or unusual symptoms that your child experiences.

In the rare case that people do experience side effects from tDCS, they tend to be minor and transient in nature. They usually last under one hour and have been reported to fully resolve with no lasting effects. These side effects may include:

- **Local site reactions**

Whenever an electrode is placed on the scalp there is potential for a local reaction – itching, tingling, or burning sensation, skin redness, neck or scalp pain.

- **Systemic reactions**

There is potential for whole body, or "systemic", reactions, including headache, sleepiness, concentration or mood changes

The effects of tDCS on the unborn child and on the newborn baby are not known. Because of this, it is important that research project participants who receive tDCS are not pregnant or breastfeeding and do not become pregnant during the course of the research project. Individuals must not participate in the research if they are pregnant or trying to become pregnant, or breastfeeding. If childbearing is a possibility, the participant will be required to undergo a pregnancy test prior to commencing the research project.

If your child does become pregnant during the research project, you should advise their study neurologist immediately. The study neurologist will withdraw them from the research project and advise on further medical attention should this be necessary. Your child must not continue in the research if they become pregnant. You should advise the study neurologist if your child fathers a child during the research project. The study neurologist will advise on medical attention for your child's partner should this be necessary

If you or your child become upset or distressed as a result of participation in the research, the study neurologist will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified staff who are not members of the research project team. This counselling will be provided free of charge.

8 How will my child be monitored for risks?

The study team is comprised of experienced researchers trained in the delivery of tDCS and in working with children and adolescents with CP. The study team will be present via video conference for each of the 5 sessions. Their primary role will be to ensure the safety of your child when participating in the study. During the videocall, they will be giving instructions on how to perform the procedures and will complete several questionnaires and tests with you and your child. These questionnaires and tests will ensure that if your child is experiencing any symptoms of concern, these are identified. The research team members will be monitoring your child

throughout the duration of the session.

9 What if new information arises during this research project?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, the study neurologist will tell you about it and discuss with you whether you want your child to continue in the research project. If you decide that your child can continue in the research project, you may be asked to sign an updated consent form.

On receiving new information, the study neurologist might consider it to be in your child's best interests to withdraw them from the research project. If this happens, the doctor will explain the reasons for this.

10 What if I withdraw my child from this research project?

If you decide to withdraw your child from the project, please notify a member of the research team. Your reason for withdrawal will be discussed and this will allow the study neurologist to further discuss any health risks or special requirements linked to withdrawing.

11 Could this research project be stopped unexpectedly?

This research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as unacceptable side effects observed or new information becoming available about tDCS.

12 What happens when the research project ends?

All tests done as part of a research study are only for research and do not yet have clear meaning for health care. In this study, you will be informed of the overall results of the trial, if you consent to be contacted for this purpose. Individual results will not be provided.

tDCS will not be offered as a treatment after this study has finished. This study will help us to learn more about the safety and feasibility of tDCS when delivered to children with CP in their homes. Once we have established the safety and feasibility of remote tDCS, we will need to conduct more research to test whether it has benefits for children and adolescents with CP.

Part 2 How is the research project being conducted?

13 What will happen to information about my child?

By signing the consent form, you consent to the study neurologist and relevant research staff to collect and use personal information about your child for the research project. Any information obtained in connection with this research study that can identify you or your child will remain confidential and will only be used for the purpose of this research study. It will only be disclosed with your permission, except as required by law.

It is anticipated that the results of this research project will be published and or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that your child cannot be identified, except with your permission. Once the information has been collected it will be stored with a study number and not your child's name. Nobody outside of the research team will have access to this information. Information is stored until the youngest participant attains the age of 33. After this, this information will be disposed of confidentially.

14 Complaints and Compensation

If your child suffers an injury or complication as a result of participating in this research study, hospital care and treatment will be provided by the public health service at no extra cost to you.

15 Who is organising and funding the research?

This research project is being conducted by Professor Michael Fahey. This research is being funded by Cerebral Palsy Alliance Research Foundation and sponsored by Monash University.

16 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of Monash Health.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2018)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

17 Further information and who to contact

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or if your child has any medical problems which may be related to their involvement in the project (for example, any side effects), you can contact the study neurologist as below:

Clinical contact person

Name	Dr Manoj Kanhangad
Position	Paediatric Neonatologist, Monash Children's Hospital
Telephone	0401834072
Email	neuromodulation@cerebralpalsy.org.au

For general information concerning the project, you can contact the trial coordinator as below:

Trial coordinator contact information

Name	Dr Alex Griffin

Position	Trial coordinator
Telephone	0401 841 195
Email	alex.griffin@cerebralpalsy.org.au

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	Monash Health Human Research Ethics Committee
HREC Executive Officer	HREC Executive Officer
Telephone	(03) 9594 4611
Email	research@monashhealth.org

Consent Form – Parent/Guardian

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Location	Teleconference based via Cerebral Palsy Alliance Research Institute, University of Sydney and Monash Health

Consent Agreement

I have read the Participant Information Sheet, or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to my child participating in this research project as described and understand that I am free to withdraw them at any time during the research project without affecting their future health care.

I understand that I need to store the tDCS device in a cool, dry place for the duration of the time that it is in my home.

The following items are optional and may be selected to indicate agreement:

☐ I consent to the study team contacting me by email to confirm appointment times and for other study-related matters.
If yes, please provide email address: _____

☐ I would like to be sent a summary of research findings via email.
If yes, please provide email address (if not provided above): _____

☐ I consent to the research team sending my treating specialist a letter to advise them of my participation in this study.
If yes, please provide name and contact information: _____

☐ I consent to being approached to participate in future projects

Optional additional consent for use of photos and videos [link to be provided here]

I understand that I will be given a signed copy of this document to keep.

Declaration by Parent/Guardian – for Parent/Guardian who has read the information

Name of Child _____

_____

Name of Parent/Guardian _____

Signature of Parent/Guardian _____ Date_____

Declaration - for Parent/Guardian <u>unable</u> to read the information and consent form

Witness to the informed consent process
Name (please print) _____

Signature _____ Date _____
* Witness is <u>not</u> to be the Investigator, member of the study team or their delegate. Witness must be 18 years or older.

<u>Declaration by Study Neurologist/Senior Researcher†</u>

I have given a verbal explanation of the research project; its procedures and risks and I believe that the parent/guardian has understood that explanation.

Name of Study Neurologist/
Senior Researcher† _____

Signature _____Date _____

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Optional additional consent for use of photos and videos

Photos During Study Sessions
We would like to take photos during the study sessions to help us share with others about our research. We may use photos on our website, on recruitment materials for this or other studies, or on presentation slides for academic or public presentations. These photos will be different to the close-up photos we will ask you to take of the head gear on your child's head (photos of head gear set-up form part of the study protocol and are necessary for participation in the study).

☐ Yes, the study team may take photos of all or part of select study sessions

☐ No, I do not want the study team to take photos of all or part of select study sessions

Videos During Study Sessions
During the study, we will take video recordings of your child. We would like to use these videos – or still shots from the videos – to help us share with others about our research. We may use videos on our website, on recruitment materials for this or other studies, or on presentation slides for academic or public presentations.

☐ Yes, the study team may use my child's video recordings for the purposes described

☐ No, I do not want the study team to use video recordings for anything other than study analysis