Remotely Monitored Transcranial Direct Current Stimulation in Children With Cerebral Palsy

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University of Wisconsin-Madison
Consent to Participate in Research
and
Authorization to Use Protected Health Information for Research

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Study Title for Participants: Pediatric Brain and Movement

Formal Study Title: ***Remotely Monitored Transcranial Direct Current Stimulation in Children with Cerebral Palsy***

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Key Information

The information in this section is to help you (or you and your child) decide if you wish to be a part of this study. You can find more detailed information later in this form. For simplicity, the terminology "you and your child" will be used throughout the form to refer to the fact that participation requires a child and parent\caregiver team to complete the study. As a part of this team, a "child" may be over the age of 18. In this case, they will need to read, understand and sign this consent for themselves. A parent (or potentially a caregiver if the child is under 18) will also need to sign the consent, regardless of the age of the child participant.

Why are researchers doing this study?

Cerebral palsy (CP) is a group of disorders that affect a person's ability to move and maintain balance and posture. Most CP is related to when an infant has an injury in the part of the brain that controls movement. Transcranial Direct Current Stimulation (tDCS) is a form of non-invasive brain stimulation. Applying tDCS in combination with clinical therapy may result in significant improvements for children with CP.

We recently completed a study that assessed the feasibility of performing remotely monitored 'mock' non-invasive brain stimulation study in children with cerebral palsy. This past study looked at the ability of children with CP and their families to follow remote instructions to set up a "mock" tDCS session and the ability to perform and record remote movement assessments for both the upper and lower extremity of the body.

Our next study will explore using remotely monitored 'active' non-invasive brain stimulation in children with cerebral palsy. In this study, participants will receive active non-invasive brain stimulation with synchronous safety monitoring and guided instruction with laboratory staff after appropriate training.

We invite you and your child to take part in this research study because your child is within the age range of 8 -21 years old and has a diagnosis of hemiparetic cerebral palsy with a history of a perinatal stroke or brain bleed.

What will my child and I need to do in this study?

A study monitor study team member will bring the transcranial direct current brain stimulation device and movement assessment supplies to your home. There will also be another remote team member from our laboratory with whom you will be communicating virtually. Prior to this, you will be sent videos through an online platform that will provide step-by-step instructions on the study procedures. You will also be sent supplies to practice the setup. Procedures will include taking measurements of your child's head, placing electrodes (which look like square shaped sponges), and helping your child perform motor tasks. You will be asked to watch these videos before videoconferencing with the remote study team member. You will complete the procedures with the guidance of the remote study team during the videoconferencing session. The study monitor will be at your home only to observe sessions and take vitals (blood pressure, heart rate, and respiration rate). The remote study team will enter the information into a survey as we go through the procedures together.

The first session will be a practice session without active stimulation. The second session will involve a sham stimulation involving stimulation for 1 minute. The current will ramp up to the desired level over 30 seconds and then immediately ramp down. After 20 minutes, it will again ramp up and then ramp down over 30 seconds. If completed successfully, the next three sessions will include active stimulation with the brain stimulation device for the entire 20-minute period. You and your child will complete 3 types of surveys asking about how you feel. Your child will complete a motor function test before and after stimulation on days 2-5. During each session, your child will be given the option to watch videos on an iPad.

There will be a total of 5 sessions for this study on 5 consecutive days. Each session is expected to take about one hour.

You can find detailed information about the study procedures in the section called **If I take part in the study, what will I do?**

What are some reasons my child and I might – or might not – want to be in this study?

You may want to be in this study if you are:	**You may NOT want to be in this study if you:**
• Comfortable having researchers ask questions about your demographics and experience with the study procedures. • Willing to upload images of yourself completing the procedure steps for research analysis.	• Want to be in a study that might directly help improve your own health or the health of your child. • Are nervous about transcranial direct current brain stimulation

• Willing to participate in the study for 5 consecutive days. • Interested in contributing to scientific knowledge even though you won't benefit directly from the study.	• May not have time to complete study questionnaires. • Are uncomfortable about having a study team member come to your home to observe sessions

Do my child and I have to be in the study?

No, you do not have to be in this study. Taking part in research is voluntary. If you decide not to be in this study, your choice will not affect your healthcare or any services you receive. There will be no penalty to you. You will not lose medical care or any legal rights. You can ask all the questions you want before you decide. If you decide not to participate, you do not have to disclose any information about your decision.

Detailed Information

The following is more detailed information about this study in addition to the information listed above.

How is research different from health care?

When you go to a health provider for care, the provider focuses on how to help you as an individual. When you take part in a study, you are helping to answer a research question. Study tests and procedures are not for your health care.

Who can I talk to about this study?

If you have questions, concerns, or complaints, or think that participating in the research has hurt you, talk to the research team at:

Research Coordinator: Preston Christopher, BS
Phone Number: 608-381-2699
Email Address: pnl@waisman.wisc.edu

If you have any questions about your rights as a research participant or have complaints about the research study or study team, call the confidential research compliance line at 1-833-652-2506. Staff will work with you to address concerns about research participation and assist in resolving problems.

If my child and I take part in the study, what will we do?

Supplies (including measuring tape, a brain stimulation device, electrodes, and a box and blocks for a motor task) will either be sent ahead of time or brought to your home.
You will be sent a link to instructional videos of how-to set-up the brain stimulation device and where to place electrodes at different locations on the head. There will be a total of 5 sessions for this study on 5 consecutive days. Each session is expected to take about one hour.

The first session will include the following steps during a simultaneous videoconference with a remotely based study team member:

- First, the study team will ask if your child is experiencing any of the sensations or symptoms from a prepared list.
- You will then be instructed to measure out and record two locations on your child's head based on circumference and width.
- You will be asked to connect the cables to the device.
- You will then be asked to help the child place and align the headgear and snap the two electrodes (square sponges) to the marked locations.
- You will be asked to upload images of the device setup to REDCap (via a secure link).
- During the 20 minute period of wearing the device, you will be asked again if your child is experiencing any of the sensations or symptoms from a prepared list
- Next you will be asked questions by the study team on the ease/difficulty of performing these procedures.
- Finally, the study team will ask your child once again if they experienced any of the sensations or symptoms from a prepared list.

Session 2-5 will include the following steps during a simultaneous videoconference with a remotely based study team member as well as a study monitor in your home:

- First, the study team will ask if your child is experiencing any of the sensations or symptoms from a prepared list.
- Before set-up, your child will complete a hand movement assessment with a box and blocks test which is brought to your home.
- The study member at your home will take the child's vitals (blood pressure, heart rate, and respiration rate).
- You will be asked to connect the cables to the device. The device is not active and there is no electricity flowing through cables at this point.
- You will then be asked to help the child place and align the headgear, snap the two electrodes (square sponges) to the marked locations.
- You will be asked to upload images of the device setup to REDCap.
- Now, you will activate the brain stimulation device.
    - During session 2 (sham stimulation) the electrodes will only have electricity flowing through them for approximately 30 seconds at the beginning and 30 seconds at the end of the 20-minute session.
    - During sessions 3 – 5 (active stimulation) the electrodes will have electricity flowing through them, as long as the child is comfortable, for the entire 20

minutes session. The intensity can be adjusted as needed and you may always turn off the device stimulation if you wish.
    - During both sessions, the study team will ask your child if they are experiencing any of the sensations or symptoms from a prepared list.
- Afterwards, the child will complete the 1-minute hand movement assessment with box and blocks.
- The in-person study monitor will take the child's vitals once again.
- Next, you and your child will be asked questions by the study team on the ease/difficulty of performing these procedures.
- Finally, the study team will again ask your child if they are experiencing any of the sensations or symptoms from a prepared list.

The primary role of the in-person study monitor is to monitor safety during stimulation.

At the end of the study, 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.

Protected health information (PHI) used in this study

Protected health information, also called PHI, is information about your physical or mental health that includes your name or other information that can identify you, like your date of birth or medical record number. To do this study, we will use the following kinds of protected health information:

- Results of procedures done as part of the study
- Things you tell the researchers about your health and demographics
- Information currently in your medical records to verify eligibility criteria.

What is the role of the study monitor?

The study monitor is a trained team member who will be in-person for the 4 active sessions. Their role will be solely to ensure the safety of the participant when participating in our study procedures. They will bring the active device to the participant's home and take the device after the sessions is complete. The in-person study monitor will take vitals pre and post stimulation on days 2-5. This in home study team member will not be giving instructions on how to perform the procedures. The participant will receive instructions from the remote study team member over the videoconference call and through the instructional videos sent through REDCap.

What happens if my child and I say yes, but we change our mind later?

You can leave the research at any time. If you choose to leave the study, your choice will not affect your healthcare or any services you receive. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

If you stop being in the research, already collected data may not be removed from the study database.

Your authorization for researchers to use your protected health information (PHI) does not have an end date. However:

- You can choose to take back your authorization for researchers to use your health information. You can do this at any time before or during your participation in the research.
- If you take back your authorization, information that was already collected may still be used and shared with others, but the researchers will no longer be able to collect NEW information about you.
- If you take back your authorization, you will not be able to take part in the research study.
- To take back your authorization, you will need to tell the researchers by writing to the Lead Researcher, Bernadette Gillick at 1500 Highland Ave Madison, WI 53703

Will being in this study help me and my child in any way?

Being in this study will not help you or your child directly. Your participation in the study may benefit other people in the future by helping us learn more about the safety and feasibility of remote tDCS for future use in the home.

What are the study risks?

There are minor potential transient risks that in the rare case that they occur, last under one hour and have been reported to fully resolve with no lasting effects associated with this study including:

- Itching, tingling, or burning sensation
- Headache
- Neck or scalp pain
- Skin redness
- Sleepiness
- Concentration or mood changes

If your child becomes pregnant at any time during the study, they will not be able to participate.

- What happens to the information collected for the research?

We have strict rules to protect your personal information and protected health information (PHI). We will limit the use and disclosure of your personal information, including research study and medical records. The study has a Certificate of Confidentiality from the National Institutes of Health. A Certificate of Confidentiality prohibits researchers from disclosing

information that may identify you in a legal proceeding or in response to a legal request without your consent.

However, we cannot promise complete confidentiality. Federal or state laws may permit or require us to show information to university or government officials and to study sponsors responsible for monitoring this study. This includes University of Wisconsin and its representatives and affiliates, including those responsible for monitoring or ensuring compliance, such as the Human Research Protection Program, Food and Drug Administration and the funding sponsor for this study, the National Institutes of Health and National Pediatric Rehabilitation Resource Center (C-PROGRESS).

We may also have to tell appropriate authorities, such as child protective services or health care providers, if we learn during the study that you or others are at risk of harm (for example, due to child or elder abuse, or suicidal thoughts).

Authorizing the study team to use your protected health information means that we can release it to the people or groups listed above for the purposes described in this form. Once your health information is released outside UW-Madison or UW Health it may not be protected by privacy laws and might be shared with others.

Also, with appropriate confidentiality protections, we might use information that we collect during this study for other research or share it with other researchers without additional consent from you.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Will information from this study go in my medical record?

None of the information we collect for this study will go in your medical record. The researchers are not required to release health information to you if it is not part of your medical record.

Will I receive the results of research tests?

All tests done as part of a research study are only for research and have no clear meaning for health care. In this study, you will not be informed of any test results or unexpected findings.

Can my child and I be removed from the research without my agreement?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include:

- your child's health changes, and the study is no longer in your best interest
- you do not follow the study rules or no longer meet the requirements to be in the study
- the study is stopped by the sponsor or researchers

Will I receive anything for participating?

If you agree to take part in this research study, we will pay you and your child up to $100 for your time and effort upon completion of the 5 sessions. If the study is stopped at any time for any reason, we will compensate at a prorated amount based on the number of sessions completed.

Permission to communicate about the study by email

We are requesting your email address so we can coordinate videoconferencing dates that work best for you and your child and discuss any information relevant to the study. Email is generally not a secure way to communicate about your health as there are many ways for unauthorized users to access email. You should avoid sending sensitive, detailed personal information by email. Email should also not be used to convey information of an urgent nature. If you need to talk to someone immediately, please contact Bernadette Gillick, PhD, MSPT, PT at 608-262-3079. You do not have to provide your email address to participate in this study.

How many people will be in this study?

We expect about 10 people will be in this research study.

Who is funding this study?

This research is being funded by the National Institutes of Health and the National Pediatric Rehabilitation Resource Center (C-PROGRESS).

What will happen to my data after my participation ends?

We will keep your data for at least 7 years following completion of the study per UW-Madison institutional policy, or at least 2 years after the last approval of a marketing application in their country and until there are no pending or contemplated marketing applications in their country, or at least 2 years have elapsed since the formal discontinuation of clinical development of the investigational product, whichever comes last.

Final study data, without any identifiable information, will be stored for future research. Keeping data for future research is called “banking.” The banked data will be kept in a secure location and may be shared with other researchers at the University of Wisconsin-Madison and outside the University. Outside researchers may be at other universities, private companies, or other kinds of organizations.

Banked data will not be shared with your health care providers or used in your treatment outside this study.

Optional Study Activities

This part of the consent form is about additional research activities that you can choose to take part in. You and your child can still take part in the main study even if you say "no" to these activities. The optional activities will not help you or your child directly, and we will not tell you the results or put the results in your medical record.

Please state your preference by initialing the appropriate line for each of the following research activities.

Contact for Future Studies

We would like to keep your contact information so that we can reach you for possible future studies, furthering our efforts to understand child development. Your contact information will be kept in a secure location. This is completely voluntary and optional. You can choose to have the study team destroy your contact information after this study is completed, and you will not be contacted for any follow-up studies.

_____ **Yes,** the study team **may** keep my contact information for possible future studies conducted in the Pediatric Neuromodulation Lab.

_____ **No, I do not want** the study team to keep my contact information after this study is completed.

Contact Information for Updates

We would like to keep your contact information so that we can reach you with updates about our lab, such as biannual newsletters, publications, and plain language summary of publications related to the study. Your contact information will be kept in a secure location. This is completely voluntary and optional. You can choose to not receive updates, and you will not be contacted with updates about our lab.

_____ **Yes,** the study team **may** keep my contact information for updates about the lab.

_____ **No, I do not want** the study team to send updates about the lab.

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 in our lab, or on presentation slides for academic or public presentations.

_____ **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 for anything other than study analysis.

Use of Video Recordings

During the study, we will take video recordings of you and 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 in our lab, or on presentation slides for academic or public presentations.

_____ **Yes**, the study team **may** use our video recordings for the purposes described.

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

Agreement to participate in the research study

(For participants under the age of 18 AND their parent\caregiver*)

You are making a decision whether or not to have your child participate in this study. You do not have to sign this form. If you refuse to sign, however, your child cannot take part in this research study. If you sign the line below, it means that you have:

- read this consent and authorization form describing the research study procedures, risks and benefits
- had a chance to ask questions about the research study and your child's participation, and received answers to your questions
- decided to allow your child to participate in this study
- given authorization for the person's protected health information to be used and shared as described in this form

Printed name of child

Signature of parent or individual legally authorized to consent to the child's general medical care

Date

❑ Parent
❑ Individual legally authorized to consent to the child's general medical care (See note below)

Printed name of parent or individual legally authorized to consent to the child's general medical care

Note: Investigators are to ensure that individuals who are not parents can demonstrate their legal authority to consent to the child's general medical care. Contact legal counsel if any questions arise.

***only one signature is needed above**

Assent

❑ Obtained

Signature of person obtaining consent and assent

Date

Printed name of person obtaining consent and assent

Agreement to participate in the research study

(For participants over the age of 18 AND their parent*)

You are making a decision whether or not to participate in this study. You do not have to sign this form. If you refuse to sign, however, you cannot take part in this research study. If you sign the line below, it means that you have:

- read this consent and authorization form describing the research study procedures, risks and benefits
- had a chance to ask questions about the research study and your participation, and received answers to your questions
- decided to participate in this study
- given authorization for the person's protected health information to be used and shared as described in this form

Printed name of adult child (18 + years old)

Signature of adult child (18 + years old) | Date

Signature of parent teammate | Date

Printed name of parent teammate

***two signatures needed above**

Signature of person obtaining consents | Date

Printed name of person obtaining consents

Agreement to participate in the research study

(For Participants 18-21 who are unable to consent and LAR*)

If you are a Legally Authorized Representative (LAR) for the person being invited to take part in this study, you are deciding whether the person can be in this research study. You do not have to sign this form. If you refuse to sign, however, the person cannot take part in this research study. If you sign the line below, it means that:

- you believe the person wants, or would want, to be in the study;
- OR, if you cannot find out if the person wants to take part, you believe that participating in the study is in the person's best interest
- you give authorization for the person's protected health information to be used and shared as described in this form

Printed name of participant	
Signature of legally authorized representative	Date
Printed name of legally authorized representative	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	

Assent

- ❑ Obtained
- ❑ Not obtained because the capability of the participant is so limited that the participant cannot reasonably be consulted.