Informed Consent Form

Telemedicine in Early Childhood Constraint Therapy in Cerebral Palsy (APPLES-TELE)

IRB Approval Date: March 11, 2026

NCT04997109

You Are Being Asked to Be in a Research Study
Concise presentation of key concepts

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree for you and your child to be in the study, you will be one of 280 caregivers and baby pairs who are being studied at Emory, Children's Healthcare of Atlanta and elsewhere.

Why is this study being done?
This study is being done to answer the question can we help young children that have cerebral palsy (CP) or a very high-risk of having CP who have problems using their arms when they are babies, so that they can use their hands and arms more like other children as soon as possible, before they are two years old. We are trying to find out how we can help children that have CP or are at high risk of CP on only one side of their body to be able to move their bodies better. Infants and young children in this study will use a non-invasive soft mitt for games, and activities. Parents will be involved and they will be educated on how to help their children.

Do you have to be in the study?
It is your decision to be part of this research study. You do not have to be in it. Your choice will not affect your access to medical care for your condition. Before you make your decision, you should take time to learn about the study.

What do I have to do if I choose to participate in this study?
If you are eligible and want to be part of the study, you will participate for 3 months (for 2 to 13 study visits depending on your treatment group). The researchers will ask you to do the following: We will ask you to complete assessments several times either through a video call or on the Emory University Campus. If you live far from the study site, we may recommend that you go to a therapy clinic closer to your home where you can have your in-person assessments completed. We will also ask you to use a special soft mitt with a small activity monitor on your child's hand. We will give you toys and games to take home and ask you to spend 25 minutes each day playing the simple games with your child. Parents or caregivers will also be involved in parent or care giver support where they will be educated on their child's motor movement, learning strategies and positive parenting techniques. ALL of these procedures will be paid for by the study.

How is this study going to help you?
If you are in the study, you will be helping the researchers answer the study question. Your child will be receiving a therapy that helps babies develop. This may or may not benefit your child directly, but it will help other parents and children who have CP or at high-risk of CP.

What are the risks or discomforts I should know about before making a decision?
The study will take time. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious – for this study, these include only loss of privacy and breach of confidentiality.

Alternatives to Joining This Study
You have a choice to receive only the care you are currently receiving for your child.

Costs
You WILL NOT have to pay for any of the study procedures, in particular those that are not covered by your medical insurance.

What Should I Do Next?
Read this form, or have it read to you. Make sure the study doctor or study staff explains the study to you. Ask questions (e.g., about exact time commitment, about unfamiliar words, more details on specific procedures, etc.) Make sure you understand which parts of the study are research and which are standard care that you would have even if you did not join the study. Take time to consider this, and talk about it with your family and friends.

Emory University and Children's Healthcare of Atlanta
Consent to be a Research Subject / HIPAA Authorization

Title: Telemedicine in Early Childhood Constraint Therapy in Cerebral Palsy

IRB #: 00003197

Principal Investigator: Dr. Nathalie Maitre, MD, PhD

Sponsor: National Institutes of Child Health and Development

If you are the legal guardian of a child who is being asked to participate, the term "you" used in this consent refers to your child

Introduction

You are being asked to be in a medical research study. This form is designed to tell you everything you need to think about before you decide if you want to be a part of the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study.** The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.

Before making your decision:

- Please carefully read this form or have it read to you
- Please listen to the study doctor or study staff explain the study to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form you will not give up any legal rights.

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.

What is the purpose of this study?

The purpose of this study is to is to find out what parents, doctors and therapists can do to help young children that have cerebral palsy (CP) on one side of their body to have better motor abilities. Infants and young children in this study will use a non-invasive soft mitt for Constraint Induced Movement Therapy (CIMT, a standard therapy for children with CP), games, and activities. Parents will also be involved in parent/care giver centered approach where they will be educated on their child's motor movement, learning strategies and positive parenting techniques.

What will I be asked to do?

After you agree to participate in this study with your child, and sign the consent form the Study Coordinator will discuss the assessments and time frames for weekly follow up visits. At most, the study will take three (3) months. Each visit will take less than one hour. During that time you will either be talking directly to the staff about your child's development or you will be working with the therapist on hand exercises with your child. At some of your baby's study visits, you will be asked to complete a few study questionnaires. A coordinator will contact you regarding reminder calls for all appointments. If you are randomized to the group that receives their usual care, such as occupational and physical therapy or state early intervention services, you will not need to do anything except come to the Visit 1 and Visit 7 play assessments. At the second assessment, we will provide you with educational resources that can help you understand your child's development.

If you are randomized to one of the 2 treatment groups, we will ask you to complete assessments several times either through video calls or in person. We will also ask you to use a special soft mitt with a small activity monitor on your child's hand. We will give you toys and games to take home and ask you to spend 25 minutes each day playing the simple games with your child. Parents/caregivers will also be involved in parent/caregiver approach where they will be educated on their child's motormovement, learning strategies and positive parenting techniques.

The chance of being randomly assigned to one of the two intervention groups is twice the chance of being assigned to the standard care group. If you are assigned to the standard care group, after 6 weeks and participating in your two assessment time points, you will be offered the study materials and teaching at no cost should you wish to have either the parent support or the movement treatment. If you are part of the standard care group and chose to have the interventions after the initial 6 week period, you will not need to have any further assessments.

Visit #	Approx. visit time	Location	Purpose
1	**2 Hours**	**Emory and Children's**	**Baseline: Assessments & Parenttraining**
2-6	**1 Hour**	**Video call**	**Telehealth Session**
7	**2.5 Hours**	**Emory and Children's**	**Assessment repeat & new intervention training**
8-12	**1 Hour**	**Video call**	**Telehealth Session**
13	**1.5 Hours**	**Emory and Children's**	**End of interventions: Repeat assessments**

Children can be enrolled in this study if they are identified as having a high risk of cerebral palsy. If your child does not have a cerebral palsy diagnosis when they are in the study, we may look in your child's medical chart or call you for up to two years after your child participates in the study to determine if your child received a cerebral palsy diagnosis.

We will videotape the behavioral assessments, study visit, and tele-health sessions for the purpose of scoring assessments and supervision and training of study team members. These recordings are a required part of study participation.

It is impossible to remove identification from vision recognition on videos, but the videos will be stored in secure research institute servers, and they are not accessible except to trained and authorized personnel.

Options for families who live far from the study site:

We know that some families live a long distance from the study site. If that's the case, we may be able to provide home visits or may refer you to an outside clinic to complete your assessments. Home visits and visits to an outside clinic for study assessments are not guaranteed and are subject to study personnel availability and PI approval.

Visit #	Approx. visit time	Location	Purpose
1 (part 1)	**45 minutes**	**Virtual Platform**	**Consent and Pre-Screening**
1 (part 2)	**1 hour**	**Study Site, Outside Clinic, or Participants' Home**	**Screening & Baseline In-Person Assessments**
1 (part 3)	**30 minutes**	**Virtual Platform**	**Parent surveys, virtual assessments & randomization**
1 (part 4)	**1 hour**	**Virtual Platform**	**Parent Training for First intervention**
2-6	**1 Hour**	**Virtual Platform**	**Telehealth Session**
7 (part 1)	**1 hour**	**Study Site, Outside Clinic, or Participants' Home**	**In-person Assessments**
7 (part 2)	**30 minutes**	**Virtual Platform**	**Parent surveys & virtual assessments**
7 (part 3)	**1 hour**	**Virtual Platform**	**Parent Training for Second Intervention**

8-12	**1 Hour**	**Virtual Platform**	**Telehealth Session**
13 (part 1)	**30 minutes**	**Study Site, Outside Clinic, or Participants' Home**	**In-person Assessments**
13 (part 2)	**30 minutes**	**Virtual Platform**	**Parent surveys**

In addition, reimbursement for reasonable travel & lodging expenses may be provided separate from the compensation you will receive. Reimbursement of travel expenses is not guaranteed and is subject to budget availability.

Information about Study Assessments at an Outside Clinic:

If you live near a therapy clinic that can perform assessments that can be used for this study, you will be notified, and study staff will assist you in connecting with the clinic. Only assessments will be done at the clinic. The assessments that are performed in the clinic will be assessments are standard therapy assessments that the clinicians are authorized to do as part a of their clinic. The clinician performing the assessments will send the results to the study staff via a secure and protected electronic storage system. You may need to sign an additional permission form for your assessing therapist to release your records to the research staff. The clinicians at the clinic will not have access to your research record. All research activities will be done with study staff either virtually or in-person.

Who owns my study information and samples?

If you join this study, you will be donating your study information. You will not receive any compensation if your information is used to make a new product. If you withdraw from the study, data that were already collected may be still be used for this study.

What are the possible risks and discomforts?

The most common risks and discomforts expected in this study are:

It is possible that you could feel upset when answering questions about your child's diagnosis or medical treatment. It is possible that your child will feel itching under the mitt, or that s/he will be frustrated when not able to use their stronger arm, and you may become frustrated watching your child upset. Your child's frustration will go away shortly as they get used to the mitt and this frustration is not harmful.

It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

Will I benefit directly from the study?

Possible benefit to you is a better understanding your child's motor development.

Possible benefit to all participants with cerebral palsy is better use of their more affected arm and hand.

Possible benefit to other children with CP in the future are better understanding of the disorder and availability of better therapies to children with CP in areas that have a difficult time obtaining care.

Will I be compensated for my time and effort?

For your time and inconvenience, you will receive the following compensation:

Visit #1 (Enrollment visits): $65.00

Visit #2 (5 Telehealth visits): $10 per visit (5 visits total = $50.00)

Visit #7 (Midpoint visit): $80.00

Visit #8- (5 Telehealth visits): $10 per visit (5 visits total = $50.00)

Visit #14 (End of study visit): $90.00

Please note that if you are assigned the standard of care group, you will only participate in and receive compensation for Visit #1 and Visit # 7.

You will be issued a debit card specially designed for clinical research. When a study visit is completed, funds will be approved and automatically loaded onto your card.

You will be asked to fill out a tax form, including your Social Security or Taxpayer Identification Number, in order to be reimbursed, depending on the amount and method of payment. You can decline payment if you are concerned about confidentiality, or you can talk to the study team to see if there are other payment options.

International Participants will be issued payment through generous donor donations from the Cerebral Palsy Foundation.

What are my other options?

If you decide not to enter this study, there is care available to you outside of this research study such as early intervention services and occupational and physical therapy. The study doctor will discuss these with you. You do not have to be in this study to be treated for cerebral palsy.

How will you protect my private information that you collect in this study?

Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

Certain offices and people other than the researchers may look at study records. Government agencies and Emory employees overseeing proper study conduct may look at your study records. These offices include the Office for Human Research Protections, the Emory Institutional Review Board, the Emory University

Institutional Review Board, and the Emory Office of Research Compliance. Emory University will keep any research records we create private to the extent we are required to do so by law. A study number rather than your name will be used on study records wherever possible. Your name and other facts that might point to you will not appear when we present this study or publish its results.

Certificate of Confidentiality

There is a Certificate of Confidentiality from the National Institutes of Health for this Study. The Certificate of Confidentiality helps us to keep others from learning that you participated in this study. Emory University will rely on the Certificate of Confidentiality to refuse to give out study information that identifies you. For example, if Emory received a subpoena for study records, it would not give out information that identifies you.

The Certificate of Confidentiality does not stop you or someone else, like a member of your family, from giving out information about your participation in this study. For example, if you let your insurance company know that you are in this study, and you agree to give the insurance company research information, then the investigator cannot use the Certificate to withhold this information. This means you and your family also need to protect your own privacy.

The Certificate does not stop Emory from making the following disclosures about you:

- Giving state public health officials information about certain infectious diseases,
- Giving law officials information about abuse of a child, elderly person or disabled person.
- Giving out information to prevent harm to you or others.

Giving the study sponsor or funders information about the study, including information for an audit or evaluation.

Storing and Sharing your Information

De-identified data from this study (data that has been stripped of all information that can identify you), may be placed into public databases where, in addition to having no direct identifiers, researchers will need to sign data use agreements before accessing the data. We will remove or code any personal information that could identify you before your information is shared. This will ensure that, by current scientific standards and known methods, it is extremely unlikely that anyone would be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Your data from this study may be useful for other research being done by investigators at Emory or elsewhere. To help further science, we may provide your deidentified data and/or specimens to other researchers. If we do, we will not include any information that could identify you. If your data or specimens are labeled with your study ID, we will not allow the other investigators to link that ID to your identifiable information.

We will use your data only for research. We will not sell them. However, the results of this research might someday lead to the development of products that could be sold by a company. You will not receive money from the sale of any such product.

Once the study has been completed, we may send you a summary of all of the results of the study and what they mean. We will not send you your individual results from this study.

Costs

There will be no costs to you for participating in this study, other than basic expenses like transportation. You will not be charged for any of the research activities.

Withdrawal from the Study

You have the right to leave a study at any time without penalty.
The researchers also have the right to stop your participation in this study without your consent for any reason, especially if they believe it is in your best interest or if you were to object to any future changes that may be made in the study plan.

Authorization to Use and Disclose Protected Health Information (THIS SECTION IS NOT APPLICABLE FOR INTERNATIONAL PARTICIPANTS)

The privacy of your health information is important to us. As part of this study, we will be requesting health care entities who are covered by the Health Insurance Portability and Accountability Act and regulations (HIPAA) to provide us with health information that identifies you ("individually identifiable health information" or "IIHI"). Because the health care entities are covered by HIPAA, we must have your authorization to obtain your IIHI from them. However, the researchers who get your IIHI from the health care entities are not covered by HIPAA. Once they receive your IIHI from the health care entities, they will put it in a separate research record that is not a part of your medical record. IIHI placed in the separate research record is not be covered by HIPAA.

Purpose of this Authorization:

By signing this form, you give us permission to get your IIHI from health care entities and to use and share your IIHI as described in this document. You do not have to sign this form. If you do not sign this form, then you may not participate in the research study.

Research-Related Treatment

This study involved research-related treatment that will not be electronically billed to any insurance company or government benefits program (e.g., Medicare, Medicaid). You may not receive the research-related treatment unless you sign this authorization. You may receive any non-research related treatment whether or not you sign this form.

IIHI that Will be Used/Disclosed:

The IIHI that we will use or share for the research study includes:

- Medical information about you including your medical history and present/past medications.
- Results of exams, procedures and tests you have before and during the study.
- Laboratory test results.

Purposes for Which Your IIHI Will be Used/Disclosed:
We will use and share your IIHI for the conduct and oversight of the research study. Once we have your IIHI we will keep it in a separate research record that will be used for the conduct of the study. If you leave the study, we may use your IIHI to determine your vital status or contact information.

Use and Disclosure of Your IIHI That is Required by Law:
We will use and disclose your IIHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults.

People Who will Use/Disclose Your IIHI:
The following people and groups will use and disclose your IIHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your IIHI to conduct the study.
- The Principal Investigator and research staff will share your IIHI with other people and groups to help conduct the study or to provide oversight for the study. This includes sharing your IIHI with people and groups at other sites who are helping conduct the study.
- The National Institutes of Health is the Sponsor of the study. The Sponsor may use and disclose your IIHI to make sure the research is done correctly and to collect and analyze the results of the research. The Sponsor may disclose your IIHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.
- The following people and groups will use your IIHI to make sure the research is done correctly and safely:
    - Emory, Children's Healthcare of Atlanta, Children's Hospital of Philadelphia, the University of Utah, and the Kennedy Krieger Institute offices that are part of the Human Research Participant Protection Programs in those locations and those that are involved in study administration. These include the IRBs, Compliance Offices, and the Office for Clinical Research at these institutions.
    - Government agencies that regulate the research including: Office for Human Research Protections
    - Public health agencies.
    - Research monitors and reviewer.
    - Accreditation agencies.
- Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your IIHI may be shared with that new institution and their oversight offices.

Expiration of Your Authorization
Your IIHI will be used until this research study ends.

Revoking Your Authorization
If you sign this form, at any time later you may revoke (take back) your permission to use your IIHI. If you want to do this, you must contact the study team at: [redacted].

At that point, the researchers would not collect any more of your IIHI. But they may use or disclose the information you already gave them as described in this Authorization. If you revoke your authorization you will not be able to stay in the study.

Other Items You Should Know about Your Privacy

Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. HIPAA does not apply to research that does not include treatment that is billed to insurers or government benefit programs. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them. The researchers and people with them are not covered by the Privacy Rules. They will only use and disclose your information as described in this Consent and Authorization.

To maintain the integrity of this research study, you generally will not have access to your IIHI related to this research until the study is complete. When the study ends, and at your request, you generally will only have access to your IIHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. You will not have a right of access to IIHI kept in a separate research record used only for research purposed. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your IIHI. Information without identifiers is not subject to HIPAA and may be used or disclosed with other people or organizations for purposes besides this study.

Contact Information

Contact Dr Maitre at: [redacted]

- if you have any questions about this study or your part in it
- if you have questions, or concerns about the research

Contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu:

- if you have questions about your rights as a research participant.
- if you have complaints about the research or an issue you rather discuss with someone outside the research team.

If you are a patient receiving care at Children's Healthcare of Atlanta and have a question about your rights, please contact the Director of Research Administration at 404-785-7477.

TO BE FILLED OUT BY SUBJECT ONLY

Please **print** your name, **sign**, and **date** below if you agree to be in this research study. By signing this consent and authorization form, you will not give up any of your legal rights.

_____

Name of Subject

_____ _____

Signature of Legally Authorized Representative **Date** **Time**

_____

Authority of Legally Authorized Representative or Relationship to Subject

TO BE FILLED OUT BY STUDY TEAM ONLY

_____

Name of Person Conducting Informed Consent Discussion

_____ _____

Signature of Person Conducting Informed Consent Discussion **Date** **Time**