

HS IRB #: 2021-0412
Lead Researcher: Bernadette Gillick, Phone # 608-262-3079
Version: April 27, 2022

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

Study Title for Participants: Baby Brain Recovery Study

Formal Study Title: Perinatal Stroke: Longitudinal Assessment of Infant Brain Organization and Recovery through Neuroexcitability, Neuroimaging and Motor Development

Lead Researcher: Bernadette Gillick, Phone # 608-262-3079

Where Lead Researcher works: Departments of Pediatrics and Waisman Center, University of Wisconsin-Madison

Invitation

We invite you and your child to take part in a research study about how the brain changes in babies after a stroke or early brain injury. We are inviting you and your child because your child is younger than 24 months of age and has a diagnosis of early brain injury like a stroke or brain bleed.

The purpose of this consent and authorization form is to give you the information you need to decide whether to be in the study. It also explains how your and your child's health information will be used for this study and requests your authorization (permission) to use your child's health information in their medical records. Please ask the study team questions about anything in this form that is not clear. If you want to talk to your family and friends before making your decision about whether to participate, you can. When we have answered all your questions, you can decide if you want to enroll yourself and your child in the study. This process is called "informed consent." As the parent or legal guardian of a minor who is invited to take part in this study, your child can participate in the study only if you give your permission.

Study Summary

What is this study about?

We want to find out how the brain changes in babies after an early injury to the brain. We are doing this research because an early brain injury has the potential to influence development and movement. To provide early therapies at a time when the brain is still developing and recovering from the brain injury, we first need to understand how the brain may have changed.

What will happen during the study?

During the study, we will create a picture of your child's brain using Magnetic Resonance Imaging (MRI). To understand how your child's brain is sending signals to the muscles, we will use non-invasive pulses of energy. We will also assess your child's movements and behavior. These assessments will be completed over two study sessions at multiple timepoints(visits), as outlined below.

Being in this study will not affect your child's standard medical care.

How much time will we spend on the study?

We expect that you and your child will be in this research study for about 2 years. You will be asked to accompany your child to the Waisman Center for 8-9

study sessions. Each session will last about 2-4 hours.

Could taking part in the study help me or my child?

Being in this study will allow you to learn more about the development of your child and their brain. This study will not directly help you or your child—it does not provide a treatment or a therapy. However, your participation in the study may benefit other people in the future by helping us learn more about early changes in children with injury to the brain. You and your child's participation may also help us develop future interventions to improve brain and movement function.

What are the main risks of taking part in the study?

Although the risks of this study are low, and we have established this study with the goal of keeping infants as safe as possible, all studies have risks. We closely monitor each child, in the presence of the family, during each step of the study. We can modify or stop at any point. To date, we have had no serious adverse events (for example, seizure) in any of our studies in over 200 infants and children in over 1,000 sessions. Safety is our primary focus at every juncture of our studies. For parent/legal guardian participants, the primary risk is a breach of confidentiality. We will do everything we can to keep your data safe and secure.

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For this study, the main risks to know about are:

- The MRI scanner uses a strong magnet to create a picture, making it unsafe for people with metal on or in the body to have an MRI scan. We will ask you questions about your child and review their medical records to ensure they can safely receive an MRI scan. One parent/guardian may also be near the child during the MRI, if they choose, so we will also ask questions to ensure the parent/guardian's safety.
- At times, the MRI scanner makes loud noises. We will ensure that your baby wears appropriate ear protection.
- Although unlikely, the non-invasive pulses could cause temporary headache, neck pain, light-headedness or tingling sensations on the head. We monitor child comfort throughout the short assessment and value parent/caregiver feedback to ensure child comfort.
- The pulses could also have other unlikely risks such as fainting, fatigue or seizure, explained in detail below.

How is research different from health care?

When you take part in a study, you are helping to answer a research question. Test results will not be used for your or your child's health care.

Questions about the study?

Contact the research team:
Phone # 608-381-2699

Questions about your rights as a research participant? Have a complaint about the research?

Contact the confidential research compliance line at 1-833-652-2506.

More information about this study

Why are researchers doing this study?

The purpose of this research study is to learn more about how the brain changes in babies after an early injury to the brain. We are doing this research because an early brain injury has the potential to influence development and movement. To provide early therapies at a time when the brain is still developing, we first need to understand changes to the brain after this early injury.

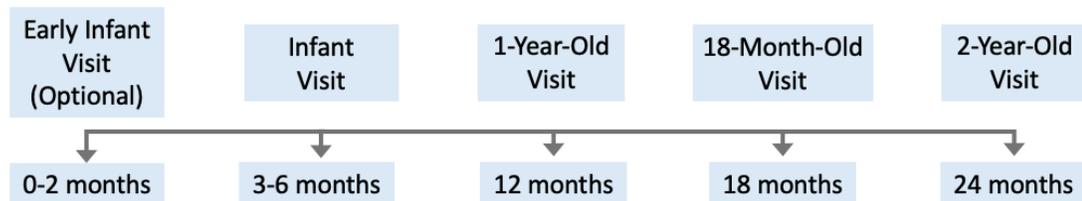
This study is being done at the University of Wisconsin-Madison (UW-Madison). A total of about 65 children will participate in this study.

What will happen in this study?

If you decide to participate in this research study, the researchers will ask you and your child to participate in study visits at four or five different time points as your child grows. All study sessions last about 2-4 hours. Most visits will have two sessions scheduled within one week—an MRI Session and an Assessment Session. The MRI Sessions involve taking a picture of your child's brain while they are comfortably sleeping. The Assessment Sessions include assessment of the communication between your child's brain and arm muscles, as well as movement assessments (up to 2-3 different movement assessments, depending on your child's age).

The study happens over the first two years of your child's life.

Study Timeline (corrected age of infant)



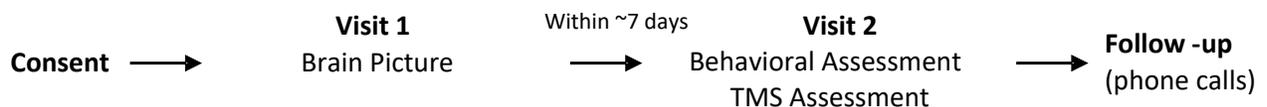
At the optional Early Infant Visit, there is one study session. At other visits over the two years, there are 2 study sessions, for a total of 8-9 sessions. The way we determine the "corrected age" of your child is based on their original due date, with adjustments made if they were born early. The first visit is optional, if the timing works for you and your child. The remainder of the visits occur as close as possible to the adjusted ages, as shown in the figure above. We will help determine the timing of each visit and help find a time to participate that works for you and your schedule.

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At least one parent or legal guardian will need to accompany the child to each session.

All study visits are at the Waisman Center, located at 1500 Highland Ave, Madison, WI 53705.

In addition to assessing how your child is doing at the end of each session, we will also call you within 24 hours after each session to ask how your child is doing and to answer any questions you may have.



This is what will happen at each visit in more detail:

MRI Session (2-4 hours)

In this session, we will create a picture or image of your child's brain to look at how the brain is developing. We will create this image with a Magnetic Resonance Imaging (MRI) machine when your child is comfortable and sleeps naturally. Taking pictures of the brain is a way to look at the brain structure using a powerful magnet. The machine that takes the pictures is shaped like a tunnel and has a comfortable and secure area for your child to rest. This session will take about 2-4 hours, depending on how long it takes for your child to fall asleep.

Before the first MRI Session, we will send you a link to our website, which has an audio recording of the sounds that the MRI machine makes. We will ask you to play the recording at home to familiarize yourself and your child with the sounds.

At your first MRI Session, we will also ask you to fill out a short survey to collect information about you and your family, such as your age, race, ethnicity, and household income. You may choose to skip any question you do not wish to answer. The survey will take approximately 5-10 minutes to complete. If you are unable to complete the survey at the first study session, we will email you a secure link so that you can complete the survey on a computer or mobile device. If needed, you may also complete a paper-based survey and mail it to the study team.

MRI

For the MRI, we will do the following:

- We will ask you to feed your child and then allow them to fall asleep in a quiet, separate room.
- We will place child-appropriate earplugs in your child's ears before they fall asleep. After your child falls asleep, we will then bring you and your child to the room for the MRI.
- We will put your child on a memory foam mattress on the scanner and use additional ear protection to diminish the machine noises.
- The MRI will take around 1 hour and 15 minutes.
- A member of the study staff will stay in the room with your child throughout the scanning to monitor if your child wakes up and to ensure the safety of your child. One parent/legal guardian will also be allowed to stay with the child during scanning, if they would like to and are able to safely be near the MRI magnet. We would conduct an MRI Safety Screening with the parent or legal guardian to determine safety. To fill out this form, we will ask you for detailed information about your health history. All parents/legal guardians are allowed to watch the MRI process on a live video feed from the comfort of the control room.
- If your child moves during the MRI but falls asleep again within a couple of minutes, the assessment will continue.
- If your child wakes up fully during the MRI, the researcher will bring them out of the machine. You will be asked if you are willing to try to get your child to sleep again. If you decide that your child will not fall back asleep, we will ask you to schedule another MRI session.

The MRI is designed to answer research questions, not for diagnosis of a medical condition. The research MRI is not a substitute for what a doctor would order for diagnostic imaging.

Some of the MRI data will be acquired using investigational software and hardware, in addition to the standard MRI technology. The investigational software and hardware enable newly developed features that are not yet FDA approved for clinical use. Although not approved by the FDA, the system is being operated under the FDA safety specifications.

Assessment Session (3-4 hours)

In this session, we will learn more about your child's movement. We will also test how their brain communicates with their arms/hands. This session will occur within 7(+/-7) days of the MRI session and take a total of 3-4 hours.

Movement Assessments: Your child will undergo a movement assessment including at least one or more of the following measures:

General Movement Assessment (GMA): This test will only be completed at the Early Infant (0-2 months) and the Infant (3-6 months) Visits. Your child will be placed lying on their back wearing only a diaper or short-sleeve onesie. We will videotape them for 3-5 minutes, as the child moves their body naturally, in an awake but calm state without playing with toys or interacting with people (unless they are fussy). At the Early Infant Visit (0-2 months), the GMA may be performed at the MRI Session, or we may ask you to provide us with a video of your child's movements that you take at home, following specific instructions that the study team would provide. Because the GMA is most accurate for infants less than 5 months old, depending on when your child is scheduled for their Infant (3-6 months) Visit, we may ask you to provide us with a video of your child's movements that you take at home, following specific instructions that the study team would provide.

Hammersmith Infant Neurological Examination (HINE): A pediatric physical therapist will complete an assessment of your child, looking at your child's reflexes, muscle tone, and movement patterns. The investigators will videotape this assessment using a video camera focused on your child. This typically takes about 10-15 minutes, and your child is allowed to sit in your lap for parts of the assessment. Since you may be holding your child during the session, you may be captured in the video recording, as well.

The Bayley Scales of Infant and Toddler Development-4th edition (BSID—IV) is another movement assessment that will be completed by a physical therapist. We will focus on the component of this Scale that measures movement or 'motor' function. The investigators will videotape this assessment using a video camera focused on your child, and you may be included in the video, as well. This test takes anywhere from 30-60 minutes and is used for infants/children between 1 and 42 months of age.

When your child is 12 months or older, we will also complete the Gross Motor Functional Classification System (GMFCS) and the mini-Manual Ability Classification System (mini-MACS). These brief scales are used to assess your child's gross motor and fine motor development. These scales will be completed by the pediatric therapist based on observation of your child throughout the Assessment Session.

Non-Invasive Pulses – Brain Stimulation Assessment: This test measures how your child's brain sends signals to their muscles. We will use non-invasive pulses of energy on the head with a Transcranial Magnetic Stimulation (TMS) device. The device rests on the outside of the head, gently on the scalp, and we stimulate using brief painless pulses, which allow us to measure the response. When the TMS device delivers a stimulation pulse and sounds off a click, we measure the response in a muscle in the arm. Older children in our studies tell us the click feels like a brief and tolerable light

tapping on the head. We will assess brain function on both sides of the brain.

For the brain stimulation assessment:

- We will complete a short safety questionnaire to ensure that it is safe for the parent/legal guardian to be near the brain stimulation machine. To fill out this form, we will ask questions about your health history.
- Depending on the results of the safety screening, you may help maintain your child in a comfortable position (e.g. in your lap, seated, standing). Otherwise, you will be able to observe the assessment from nearby (a few feet away). In this case, a study team member will hold your child in a comfortable position during testing.
- The researchers will place small sticker like sensors attached to wires (called electrodes) that are designed for infants on your child's arms to detect their muscle activity.
- The researchers will measure heart rate, respiration, and blood pressure using a manual infant blood pressure cuff.
- Your child will wear earplugs during the test to make it less noisy for them.
- The researcher will hold the magnetic stimulation coil on different places on your child's head. This test tells us the precise place in your child's brain that controls muscles of their arms. This test also tells us the lowest possible level of stimulation that will activate this part of your child's brain.
- This assessment will last at most 60 minutes. We will monitor your child's heart rate, blood pressure, respiratory rate, and pain/stress responses throughout the assessment.
- We will provide a break if your child shows any discomfort. This break time can depend on your child's needs.
- You can decide to stop the assessment at any time.

Post-test Follow-up (5 minutes)

We will call you 24 hours after each session to ask how your child is doing and to answer any questions that you may have regarding this study. We also encourage you to call us at any time.

Ongoing Eligibility Calls (5 minutes)

Before the study visits at 12, 18, and 24 months, we will confirm that your child is still eligible to participate in the study. We will call you to ask a few questions about your child's health. This call will take about 5 minutes. We will also review their medical records again.

Protected health information (PHI) used in this study

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

- Results of tests or procedures done as part of the study
- Things you tell the researchers about your or your child's health
- Information currently in your child's medical records, as well as information added to your child's medical records during the course of this study. This information could include the following: your child's medical history; your child's diagnosis, lab test results, X-rays, MRIs, CTs or other kinds of medical imaging; progress notes; psychological tests; EEG/EKG/ECHO reports; and billing records. We will get this information from your child's health care providers, such as UW Health or any other locations your child has received care.

How long will my child and I be in this study?

You and your child will be part of the study for about 2 years.
You will be asked to bring your child to the study site for a total of 8-9 study sessions.
Each session will last about 3-4 hours.

The researchers may take your child out of the study, even if you want to continue, if

- your child is unable to tolerate participation safely or comfortably,
- your child acquires any of the study's exclusion criteria (see *Note below),
- your child's well-being, in the opinion of the researchers, would be compromised by study continuation,
- the medical monitor and/or IRB recommend withdrawal, or
- you are unable to follow the protocol.

*Note: The exclusion criteria specify that children will be excluded or withdrawn if they:

- Have a other neurologic diagnosis
- Have a brain cancer
- Have breathing difficulties or need for mechanical assistance with breathing
- Have any metal in the body that is not MRI/TMS compatible
- Have received surgeries that may constrain their current spontaneous movements

How is being in this study different from my and my child's regular health care?

This study is not part of you or your child's health care.

Do my child and I have to be in the study? What if I say “yes” now and change my mind later?

No, you and your child do not have to be in this study. Taking part in research is voluntary. This means that you decide if you want your child to be in the study. If you decide now to take part, you can choose to leave the study at any time.

If you decide to be in the study, the researchers will tell you about new information or changes in the study that may affect your willingness to continue in the study.

Let the researchers know if you choose to leave the study. The researchers will ask if you are willing to provide a reason for your decision to withdraw, as this information is important for us to understand and incorporate in any modifications to this or future studies.

If you decide not to take part in the study, or if you choose to leave the study, your choice will not affect any treatment relationship you or your child have with healthcare providers at UW-Madison, UW Health or any affiliated organizations, or any services you receive from them. No matter what decision you make, and even if your decision changes, there will be no penalty to you or your child. You will not lose medical care or any legal rights.

If you choose to withdraw from the study at any time, we will continue to use data collected prior to withdrawal.

Your authorization for researchers to use you and your child's protected health information (PHI) will last until the research study is done. However:

- You can choose to take back your authorization for researchers to use your and your child's 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 or your child.
- If you take back your authorization, you and your child 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, Dr. Bernadette Gillick, at the Waisman Center, 1500 Highland Ave, Madison, WI 53705.

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

Being in this study will not help you or your child directly. Your and your child's participation in the study may benefit other people in the future by helping us learn more about brain changes in children with early brain injury, and also by helping to develop future interventions to improve brain function.

This study is not a substitute for your child's regular medical care. You should continue to see your regular medical providers.

Will I receive the results of research tests?

Possible Discovery of Findings Related to Medical Imaging

Whenever an MRI of the brain is done, there is the chance of finding something unexpected. Unexpected findings can have clear clinical significance, or uncertain clinical significance. Clear clinical significance means that the MRI shows a problem that may be treatable, and we generally know what the risks are of not treating the problem. Uncertain clinical significance means that the imaging shows something unusual in the brain, but we do not know if it might affect your child's health, and treatment may not be appropriate or possible. In this study, if we believe that we may have found a medical problem in your child's MRI of clear clinical significance you will be informed. In order to assist us in interpreting the results of your child's MRI, we are also seeking your permission to review your child's medical records.. The MRI and report from this research study will not be placed in your child's medical record.

There may be benefits to learning such results (such as early detection and treatment of a medical condition), but there are risks as well (such as problems with getting insurance or a job or feeling worried about a finding for which no treatment is required or appropriate). The MRI we are using in this research study is not the same quality as an MRI that you may have as part of your health care. If you believe your child is having symptoms that may require clinical imaging, you should contact your child's primary care physician.

This study involves a series of research MRIs, and the first MRI your child has will be reviewed by a physician who normally reads such images (such as a neuroradiologist). Each MRI after that will not necessarily be reviewed by such physician. We will only inform you of findings of clear clinical significance that we discover from MRI scans that are reviewed.

If you have additional questions about the test results or concerns about your child's health, contact your primary care provider. You (or your insurance company) will be responsible for costs related to any follow-up care.

Results of TMS and Movement Assessments

The individual results of the movement and TMS assessments will not be shared. However, parents/legal guardians can receive an copies of publications and informational plain language summary of published material related to the study.

Travel Passport

You will receive regular updates throughout the study in the form of a "Passport". This passport will be updated throughout the study with information about your child's progress through the study. Information in the passport will include:

1. MRI-an overview of what imaging was completed
2. TMS-a visual as to where on a brain we searched for a response from the pulses and if/where the responses were found
3. Assessments-a review which assessment were performed, what parts the child was able to complete

What are the risks?

We list the risks of participation in this study below. Most of the information we have about the risks associated with MRIs or brain stimulation are from adult studies, with fewer studies in children and very few in infants.

MRI risks

MRI machines use a strong magnet and radiofrequency magnetic fields to take images of your child's body. The scanning process is similar to an x-ray or CT scan, but MRI does not use ionizing radiation (high-energy radiation that can potentially cause damage to DNA) like x-rays or CT scans. The risks associated with MRI scans are these:

- **Projectiles:** Objects with magnetic properties can be pulled into the magnet and turned into projectiles. To minimize this risk, we ask that participants remove all metallic items (watches, cell phones, hair pins, etc.) prior to entering the scanner, and we control access to the scanner.
- **Claustrophobia:** The scanner is a long, narrow tube that may cause some people to feel claustrophobic.
- **Hearing Damage:** The noise generated by the operation of the scanner during a study is loud enough to cause hearing damage if your child does not wear

hearing protection. Hearing protection is required and is provided by the study team.

- Nerve Stimulation: Some people experience localized tingling, twitching, or muscle contractions during MRI scans. This is expected, but we will monitor the child for any signs of discomfort.
- Disruption of Devices: Some devices can be damaged by magnetic fields and should not be brought into the scanner room. This includes some implanted devices such as pacemakers, cochlear implants, insulin pumps, nerve stimulators, etc. If you or your child has any implanted device, please notify the study team.
- Heating of Devices: The radiofrequency waves used in MRI can heat conductive materials such as metal implants (screws, plates, rods, wires, artificial joints, etc.), certain tattoo inks, certain clothing fabrics, jewelry, medication patches, wigs, etc. You will be asked to remove these items from yourself and your child if possible. If they cannot be removed you will be asked to provide more information to allow MRI staff to be able to make determination on the safety of proceeding with the scan.

A thorough pre-scan questionnaire will allow us to minimize the risk of device disruption and heating. As the parent and/or caregiver, you will be able to observe the MRI process and should notify the study team immediately if you notice anything unusual with your child, think that your child's hearing protection is not adequate, or if you sense that your child is uncomfortable.

In addition, there is a risk of unknown effects related to participation in MRI research. Long-term effects of exposure to high magnetic fields are unknown. Most people experience no short-term ill effects from the strong magnetic field, but some people report dizziness, mild nausea, headache, a metallic taste in the mouth, or sensations of flashing lights. These symptoms, if present, subside shortly after leaving the magnet. If any sensations experienced during participation seem to you to cause discomfort or pain to you or your child, notify the researcher right away and your child's participation will stop, and your child will be taken out of the MRI machine.

Brain stimulation testing (TMS) risks

The risks of brain stimulation (TMS) are mainly related to using the brain stimulation as a treatment with repetitive stimulation, during which repeated pulses are delivered continuously over a period of time. In this study, we will use single pulses, and we are not using brain stimulation as a treatment. However, we include below the risks that have been reported while using it as a treatment, and mainly in adults. None of the risks below have been reported in the few published studies investigating brain stimulation in children and infants with early brain injury.

Risks:

- a. Fainting: The brain stimulation testing may cause fainting. We will measure your child's blood pressure before and after the test and ask you to feed your child before the test if needed.
- b. Fatigue or sleepiness: The brain stimulation testing may cause fatigue or a tired feeling. Your child's arousal state will be monitored and recorded regularly during this test.
- c. Pain: We will assess pain/distress signs throughout the TMS testing. Age-appropriate heart rate, respiratory rate, blood pressure, skin integrity, and distress responses will be monitored for determination of pausing or stopping.
- d. Skin Redness: Your child's skin may show temporary redness after we take off the electrode stickers.

Unlikely Risks for brain stimulation testing:

- a. Seizure: A few reports of seizure, mainly in adults, have been documented with non-invasive brain stimulation. There have been no reported seizures with single pulse stimulation in infants (the same type of stimulation as used in this study). Additionally, we have had no seizures occur in our laboratory in any infant or child. If a seizure does occur, we will follow a laboratory seizure management plan.
- b. Temporary mild hearing loss: The brain stimulation testing makes a clicking sound, which could cause temporary mild hearing loss. One study, using a different application of stimulation through repetitive pulses, reported a hearing loss in one person that lasted for 10 months. To prevent this, your child will wear earplugs during the brain stimulation procedure.
- c. Temporary concentration or mood change: This has been reported in studies using repetitive stimulation, yet in an effort to assess how your child responds to the session, one researcher will monitor and record the arousal state using a six-stage classification.
- d. Temporary numbness or twitching of the face: The brain stimulation testing may cause temporary numbness or twitching of the face for up to one hour. The researcher will watch your child's face very carefully for any signs of twitching. If this happens, we will stop the test.
- e. Stimulation in participant with reduced sensation: We will assess the sensory level using a light touch and observing the response. If impaired, we will visually monitor for any signs of redness in response to TMS. We will observe and attend to any changes in behaviors during the session.
- f. Temporary mania or intense mood: Studies have reported mood swings in patients being treated with repetitive stimulation (a different type of stimulation from that used in this study) for bipolar disorder, post-traumatic stress disorder, or depression. Symptoms varied across patients and included euphoria, sensitivity to criticism, rage, restlessness, over-optimism, grandiose ideas, and

reduced sleeping. The duration of these symptoms lasted from hours up to 5 days.

- g. Temporary difficulty with movement: Possible movement problems include a tingling feeling, stiffness, or twitching of muscles in the arm that may last minutes to hours.
- h. Temporary neck pain or scalp pain: Stiffness or a dull ache in the neck may last for minutes to hours.
- i. Difficulty breathing because of pain. Your child's breathing will be continually assessed.
- j. Dental pain: One person being treated for depression experienced a pulsating pain in the teeth of the left upper jaw. The pain stopped after the treatment.

Risks found in pediatric study:

Below we have listed risk information from a pediatric safety study published in 2020. 382 participants received more than 500,000 single pulse TMS stimulations, and the following side effects were observed:

- No serious adverse events (0%) - <1 in 382
- No seizures (0%) - <1 in 382
- Headache reported in 13% (95% of headaches were mild or moderate) - 1 in 8
- Neck pain in 17.8% - 1 in 5 (in this study, this incidence is expected to be lower because your child will be sitting supported on your lap or in another preferred position, without the head tipped back)
- Unpleasant tingling in 12% - 1 in 8
- Light-headedness in 13% - 1 in 8
- Nausea in 2% - 1 in 50
- No reported decrease in function in either hand (0%) <1 in 382

Potential Risks for movement assessment and others:

Concern for facial recognition: your or your child's face may be recognizable from the videos used to perform the movement assessment. The videos will only be used by our study team to evaluate your child's movement, unless you give us permission to use the videos for other purposes (see "Optional Study Activities" section below).

If you record a video of your child at home, rather than the study team recording the video at the lab, then you will be responsible for the security of the video recording on your own device and wherever you choose to save the video file. Once you share the video with the study team, we will store it in a secure location. However, we are not able to ensure the security of the file before it is transferred to us.

There is a risk that your or your child's information could become known to someone not involved in this study.

Will being in this study cost me anything?

- There will be no cost to you for any of the study activities or procedures.

Will I be paid or receive anything for being in this study?

We will pay you \$50 for completing each MRI Session and Assessment Session, for a total of up to \$450 possible for completing all sessions.

There may be situations when we ask you to come back for an additional session. For example, if your child wakes up during the MRI and is unable to fall back asleep, we may ask you to schedule another MRI Session to finish the imaging. For each additional session, you will receive \$25.

What happens if you or your child are injured or get sick because of this study?

If your child is injured or gets sick because of this study, medical care is available to your child through UW Health, your local provider, or emergency services, as it is to all sick or injured people.

- If it is an emergency, call 911 right away or go to the emergency room.
- For non-emergency medical problems, contact the study team for instructions, and contact your or your child's regular health care provider.
- Call the Lead Researcher, Dr. Bernadette Gillick, at 608-262-3079 to report your or your child's sickness or injury.

Here are some things you need to know if you or your child gets sick or is injured because of this research:

- If the sickness or injury requires medical care, the costs for the care will be billed to you or your insurance, just like any other medical costs.
- Your health insurance company may or may not pay for this care.
- No other compensation (such as lost wages or damages) is usually available.
- UW-Madison and UW Health do not have a program to pay you if your child gets sick or is injured because of this study.
- By signing this consent form and taking part in this study, you are not giving up any legal rights you may have. You keep your legal rights to seek payment for care required because of a sickness or injury resulting from this study.

How will researchers keep my and my child's research information confidential?

We have strict rules to protect your and your child's personal information and protected health information (PHI). We will limit who has access to your and your child's name, address, phone number, and other information that can identify you and your child. We will also store this information securely. 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. We may publish and present what we learn from this study, but none of this information will identify you and/or your child directly without your permission.

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 access to your child's medical records so that study monitors, auditors, the Institutional Review Board and regulatory authorities can verify study procedures and/or data. These groups will maintain your confidentiality. By signing this consent form, you are authorizing this access to your child's records. 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 research team to use your and your child's PHI means that we can release it to the people or groups listed below for the purposes described in this form. Once your or your child's 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 institutional permissions and confidentiality protections, we might use information that we collect during this study for other research or share with other researchers without additional consent or authorization from you or your legally authorized representative.

Who at UW-Madison can use my information?

- Members of the research team
- Offices and committees responsible for the oversight of research
- Personnel who schedule or perform medical tests or procedures, handle accounting and billing, or do other tasks related to this study

Who outside the UW-Madison may receive my information?

- U.S. Office for Human Research Protections
- The U.S. Food and Drug Administration (FDA)
- Collaborating researchers outside UW-Madison

Will information from this study go in my and my child's medical record?

- A medical record may be created for your child if the child does not already have one. None of the information we collect for this study will go in your child's medical record, but your child's medical record might say that your child participated in this study. A copy of this consent and authorization form might go in your child's medical record. Nothing related to this study will be added to your medical record.

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

National Institutes of Health Data Archiving

Data from this study, including MRI scan images, TMS data, developmental assessments, responses to questionnaires, and basic de-identified information about you and your child (e.g., gender, age, etc.), may be submitted to the National Institute of Child Health and Development Data and Specimen Hub (DASH)) or another NIH-designated data repository. DASH is a data repository run by the National Institute of Child Health and Development (NICHD) that allows researchers to collect and share de-identified information with each other. A data repository is a large database where information from many studies is stored and managed. De-identified information means that all personal information about research participants, as name, address, and phone number, is removed and replaced with a code number. The link to the code would be kept securely at the UW.

During and after the study, the researchers will send de-identified information about your child's health and behavior to DASH or other data repository. These data repositories will store your information and other researchers nationwide can file an application with the NIH to obtain access to your de-identified study data for research purposes. Experts at the NIH who know how to protect health and science information will look at every request carefully to minimize risks to your privacy. With an easier way to share data, researchers hope to learn new and important things about child health more quickly than before.

You will not benefit directly from allowing your information to be shared with DASH or other data repository. The information provided to a data repository may help

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researchers around the world treat future children and adults so that they have better outcomes. The NICHD will also report to Congress and on its website about the different studies that researchers are conducting using data from these repositories. However, you will not be contacted directly about the data you contributed to a repository. You may decide now or later that you do not want to share your information with a data repository. If so, contact the researchers who conducted this study, and they will tell the data repository, which can stop sharing the research information. However, the data repositories cannot take back information that was shared before you changed your mind. If you would like more information about data repositories such as DASH, this is available on-line at <http://data-archive.nimh.gov>.

What will happen to my data after my participation ends?

At the end of this study, we will destroy your and your child's names and contact information. We will keep all other data, including screening information, study data, MRI scans, and TMS data for an indefinite period of time, meaning we have no plans of ever destroying your data. Keeping data for future research is called "banking." The banked data will be kept in a secure location for use by researchers.

This is what will happen with your banked data:

- We will use the data in future research projects research on child development. We may also use them for other types of research.
- The data may be shared with other researchers at University of Wisconsin-Madison and outside the University. Outside researchers may be at other universities, private companies, or other kinds of organizations.
- The banked data will be labeled with a code instead of your child's name.
- When we share your data with other investigators for research projects, they will not be able to use the code to figure out which data are your child's.
- The research team will maintain a link between your child's data and identifiable information (such as their date of birth) kept by the study team.
- You can request to have your child's data removed from the bank by contacting the research team at any time.

This is what will NOT happen with your banked data:

- Banked data will not be shared with your healthcare providers or used in any treatment.

What if I have questions?

If you have questions about this research, please contact the study team at 608-381-2699. You may also contact the Lead Researcher, Dr. Bernadette Gillick, at 608-262-3079. If you have any questions about your and your child's rights as a research subject or have complaints about the research study or study team, call the confidential

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research compliance line at 1-833-652-2506. Staff will work with you to address concerns about research participation and assist in resolving problems.

Permission to communicate about the study by email

We are requesting your email address so we can communicate information and updates about the study, answer any questions, and send instructions and reminders. 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 the study team at 608-381-2699. You do not have to provide your email address to participate in 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 research team **may** keep my contact information for possible future studies conducted in the Pediatric Neuromodulation Lab.

_____ **No, I do not want** the research 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 research team **may** keep my contact information for updates about the lab.

_____ **No, I do not want** the research 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 research team **may** take photos of all or part of select study sessions.

_____ **No, I do not want** the research team to take photos of all or part of select study sessions.

Use of Video Recordings

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

_____ **Yes**, the research team **may** use my child's video recordings for the purposes described.

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

Agreement for me and my child to participate in the research study and Permission to use and/or disclose my and my child's health information

You are making a decision whether or not to have you and your child participate in this study. You do not have to sign this form. If you refuse to sign, however, you and 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 and your child's participation, and received answers to your questions
- decided to participate and also allow your child to participate in this study
- given authorization for your and your child'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

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

Select your relationship to the child:

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

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.

Signature of parent

Date

Printed name of parent

If signature of second parent not obtained, indicate why: (must select one)

- | | |
|--|---|
| <input type="checkbox"/> Second parent is deceased | <input type="checkbox"/> Second parent is incompetent |
| <input type="checkbox"/> Second parent is unknown | <input type="checkbox"/> Second parent is not reasonably available |
| <input type="checkbox"/> Other: _____ | <input type="checkbox"/> Only one parent has legal responsibility for the care and custody of the child |

Signature of person obtaining consent

Date

Printed name of person obtaining consent

****You will receive a copy of this form****