EFFECTIVE

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MCW IRB

Medical College of Wisconsin
INTRODUCTION TO THE INFORMED CONSENT

A Randomized, Double-Blinded, Placebo Controlled Pilot Trial of the Feasibility of High Definition Transcranial Direct Current Stimulation and Cognitive Training in Patients with Mild Cognitive Impairment

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Definitions

High-Definition Transcranial Direct Current Stimulation (**HD-tDCS)** a technique used to stimulate the brain using weak electric currents. High-definition means more focal and precise stimulation than earlier techniques.

Magnetic Resonance Imaging (MRI), a noninvasive diagnostic technique that uses a powerful magnet, radio waves and a computer to produce detailed pictures of organs, bones and other internal body structures.

Sham means a faked intervention that omits the therapeutic step being studied. In this research project, the sham treatment will not deliver any electric currents.

Purpose

This project is being done to test our hypothesis that HD-tDCS will improve your thinking with participants who have been diagnosed with mild cognitive impairment (MCI).

Length

1. You will be in this research project for up to 12 months.

Procedures

There are two groups in this project. You will be randomly enrolled in one of the two groups.

List of visits:

- Baseline Visit
  - Total Number: 2-3 (more if needed)
  - Total Time: 7 hours
- Treatment Visits
  - Total Number: 15
  - Total Time: 2.5-3 hours each
- Post Treatment Follow up
  - Total Number: 2-3 (more if needed)
  - Total Time: 10 hours

Procedures that will occur at various visits:

Invasive Procedures

- HD-tDCS

Non-invasive Procedures

- TMS Neuronavigation
- Physical and Neurological exam
- Vital signs
- Questionnaires
- Cognitive testing
- MRI
- Cognitive Training (CT)

Risks

This is a brief list of the most commonly seen side effects. The ***full consent form*** after this introduction contains a more complete list of potential research risks.

Device/Intervention risks:

- HD-tDCS
  - Localized burning sensation
  - Mild fatigue
  - Mild headache
  - Itching
  - Tingling
- MRI:
  - Claustrophobia
  - Anxiety

Benefits

We don't know if this project will help you. Your condition may get better but it could stay the same or even get worse.

My Other Options

You do not have to join this project. Your other options may include:

1. Joining a different project
2. Routine care for this condition
3. Getting no treatment for this condition

If you have more questions about this project at any time, you can call Elias Granadillo Deluque, MD at 414-955-0650.

If you have questions about your rights as a participant, want to report any problems or complaints, or offer input, you can call the MCW/Froedtert Hospital Research Subject Advocate at 414-955-8844.

CONSENT TO PARTICIPATE IN RESEARCH

A1. INTRODUCTION – WHY ARE WE ASKING YOU TO PARTICIPATE?

You are being invited to participate in this research because you have amnestic mild cognitive impairment (MCI). Because of your condition, you may be eligible for a research project to test the High-Definition Transcranial Direct Current Stimulation (HD-tDCS) device on people with MCI to see if it will hopefully improve your thinking and reasoning ability.

A total of about 20 people and their study partners are expected to participate in this research including about 10 subjects and their study partners at the Medical College of Wisconsin/Froedtert Hospital.

The Director of the project is Elias Granadillo, MD in the Department of Neurology. A research team works with Dr. Granadillo. You can ask who these people are.

Dr. Granadillo has received funds for this project through the 2020 CTSI Traditional Pilot Award, with funding provided by Advancing a Healthier Wisconsin Research and Education Program.

A2. DO I HAVE TO PARTICIPATE?

You can decide whether to take part in this research or not. You are free to say yes or no. If you do not agree to join, or if you leave, you will not be penalized or lose any benefits that you had before starting the research project. Even if you join this project, you do not have to stay in it. You may stop at any time. Take as much time as you need to make your choice.

A research project is different from routine medical care in three ways: 1) there are extra risks that we will tell you about in this form; 2) you may have some extra medical tests and visits; 3) the research procedures, tests and visits follow a set plan that must be kept.

A3. WHY IS THIS PROJECT BEING DONE?

Mild cognitive impairment (MCI) is currently an area of considerable clinical and research interest because of the high rate of conversion from MCI to Alzheimer disease (AD). Currently, no drug has proven effective in treatment of MCI.

HD-tDCS is a recently developed system that allows researchers to more focally and intensely stimulate the brain. It remains unclear if this approach can be clinically beneficial for patients with MCI, and as a result, there is a need to investigate not only if this tool works, but also how it works. Without this information, the clinical use of HD-tDCS for the treatment of this and other related conditions will remain only a remote possibility.

The U.S. Food and Drug Administration considers the device we are studying, High-Definition Transcranial Direct Current Stimulation (HD-tDCS), to be experimental while researchers study how safe it is and how well it works. We do not know all the ways that HD-tDCS may affect people.

There is also literature suggesting that cognitive training (CT) can improve cognitive performance in older adults, who are at risk for dementia and MCI. Reports state that CT may

significantly reduce the risk of dementia. There are encouraging studies which show that CT can slow cognitive decline in individuals with MCI and improve memory in older adults.

Our goal is to assess the feasibility of multi-field, extended HD-tDCS plus simultaneous computerized CT as a viable intervention to improve cognitive function in patients with MCI.

B1. WHAT WILL HAPPEN IF I PARTICIPATE?

You will need to have a **study partner** who is willing to answer questions about your cognitive functioning and abilities to perform activities of daily living. Information collected about you from your study partner can be done over the telephone or in-person at a study visit. Your study partner may change throughout the study, but a study partner is required to participate in the study.

You may be eligible to complete the following study procedures at both sites (e.g., baseline MRI at UW-Madison and Month 3 MRI at the Medical College of Wisconsin) depending on your ability to travel between sites, study team availability, and investigator approval.

Transcranial Magnetic Stimulation (TMS) neuronavigation is used to determine optimal electrode positioning. This means your head and brain anatomy can be modeled along with a structural brain MRI obtained for routine standard of care prior to enrollment or the baseline research MRI collected during the study. Once optimal electrode positions are determined, your structural MRI and the coordinates of the electrode positions will be uploaded into the neuronavigation software. The neuronavigation software comes equipped with algorithms that allow us to create a 3D reconstruction of your brain, allowing us to determine the appropriate location used for stimulation. This procedure will be conducted by a trained member of the study team. The entire procedure may take up to 1 hour.

Vitals and Medical Evaluation
Vitals include height and weight measurements, resting blood pressure, heart rate, respirations, and body temperature. An examination conducted by a clinician will include an assessment of family history of dementia, physical exam, and neurological exam.

Interviews and questionnaires:
Participants will complete a series of questionnaires. The questionnaires are intended to clarify medical history, family history for disease, cerebrovascular risk factors, psychiatric symptoms, and level of awareness of cognitive deficits.

Cognitive Battery
These tests will take approximately 3 hours. You will undergo a series of cognitive tests designed to assess language, memory, problem solving, judgement, motor function, visuospatial skills, and emotion. Your performance on these tests will help us detect and understand any potentially beneficial effects of the tDCS intervention on your thinking abilities.

Mock Magnetic Resonance Imaging (MRI) training
Participants will be offered the option to engage in a mock scanner training session. The purpose of this session is to acclimate participants to the scanner and to assess their comfort level, minimize any anxiety, and provide practice and training to remain still. Training in the mock

scanner will take approximately 20 minutes and will occur prior to their imaging sessions. A visual feedback system will be employed to inform the subject about her or his performance of remaining stationary. Participants that have been previously engaged in MRI as part of research may be excused from the mock scanner training.

MRI (Magnetic Resonance Imaging) is a way for us to see inside your body. MRI uses a powerful magnet, radio waves and a computer to produce detailed pictures of organs, bones and other internal body structures. For the MRI, you will lie on a table inside a scanner tube for about 60 minutes, while the scanner moves the reading unit over the areas of your body to be scanned. The MRI used for research is not for diagnosis or treatment and will not look for abnormalities.

Cognitive Training (CT)
During treatment sessions, participants will play computerized brain games designed to train attention, memory, processing speed, people skills and navigation. CT sessions will be performed at each HD-tDCS/sham HD-tDCS session.

Research groups
For this study, you will have a 50-50 chance of being assigned to one of two research groups. One will include real HD-tDCS stimulation plus cognitive training and the other will include sham HD-tDCS plus cognitive training. The treatment in each group will look the same and neither the person delivering the treatment, nor you will know if it was real or sham. A third person will set up the equipment ahead of time.

Since the expectations of patients and doctors can influence the results, neither you nor your research doctor can know which treatment you will get at which time until the research is over. In an emergency, your research doctor can find out which treatment you were given

Because no one knows which of the treatments is best, you will be “randomized” into one of the two groups. Randomization means that you are put into a group by chance. It is like flipping a coin. You will have an equal chance of being placed in either group. Neither you nor the research doctor can choose what group you will be in.

Summary of Procedures:

Baseline (screening) – Visit 1
Visit procedures will take up to 7 hours but may be more or less depending on time needed for breaks, participant comfort, and scanner set-up. This baseline visit will likely be completed in 2-3 days but can be completed over multiple days prior to Visit 2.

At this visit, the following procedures and test will occur:

- Document informed consent
- Demographics (age, sex, race, ethnicity, year of birth)
- Review medications
- Obtain Medical history
- Physical/Neuro exam including vitals

- Determine eligibility based on inclusion/exclusion criteria
- Screening for MRI eligibility
- Cognitive Battery
- Study Partner Questionnaires
- TMS Neuronavigation (for stimulation planning)
- MRI of the brain, including mock scanner training if necessary

After subjects have been enrolled, the On-Study/Follow-up visits and the procedures performed at each visit are described in detail below.

Treatment Period, Visits 2-16
HD-tDCS/sham HD-tDCS sessions combined with CT will be administered in monthly blocks of 5 consecutive daily sessions for a total of 15 treatments or 3 monthly blocks. For that, treatments will be administered at the MCW facilities or the UW Hospital. Study personnel may also visit subjects at their homes to administer the intervention if the subjects prefer. Both HD-tDCS and sham-HD-tDCS treatments will be administered during a cognitive training session. We will sequentially stimulate or sham stimulate four areas of the brain, left and right frontal and left and right temporoparietal. Each area will be stimulated/sham-stimulated for 20 min for a total of an 80 min stimulation session. On Mondays prior to CT and Fridays after CT, subjects will be assessed on competency and ability to perform the CT. The CT blocks will start after 5 min of stimulation of each network and will last 15 min/network (total 60min/session).

Post Treatment, Visit 17 (Month 3)
At this visit, the following procedures and tests will occur:

- Neuro and physical Exam
- Vital signs
- Cognitive battery
- Study Partner Questionnaires
- Structural MRI

This visit will be approximately 6 hours and will likely be completed in 1-2 days but can be completed over multiple days.

Post Treatment, Visit 18 (Month 6)
At this visit, the following procedures and tests will occur:

- Cognitive battery
- Study Partner Questionnaires

This visit will be approximately 4 hours and will likely be completed in 1 day but can be completed over multiple days.

Early Termination/Withdrawal Visit
If you are withdrawn early from the study, you will have one final visit to report adverse events. This will include a physical exam and vital signs. This will take about 1 hour.

PRIMARY CARE PHYSICIAN / SPECIALIST NOTIFICATION OPTION
Please indicate below whether you want us to notify your primary care physician or your specialist of your participation in this study.

_____ Yes, I want the research doctor to inform my primary care physician / specialist of my participation in this study.

_____ No, I do not want the research doctor to inform my primary care physician / specialist of my participation in this study.

_____ I do not have a primary care physician / specialist.

B2. HOW LONG WILL I BE IN THE PROJECT?

You will be in this research project for up to 12 months.

B3. CAN I STOP BEING IN THE PROJECT?

You are free to withdraw from the project at any time. If you leave, your regular medical care will not change. If you are thinking about leaving, please tell the research doctor.
⇒ The research doctor can tell you about the effects of stopping, and you and the research doctor can talk about what follow-up care would help you the most.
⇒ You might be asked to come back for one more visit to check your health.
⇒ You may stop at any time, including during the MRI scan

The research doctor may take you out of this project at any time. This would happen if:
- They think it is in your best interest.
- You do not follow the project rules.
- The whole project is stopped.

If this happens, the research doctor will tell you.

C1. WHAT HEALTH RISKS OR PROBLEMS CAN I EXPECT FROM THE PROJECT?

There are risks to taking part in any research project. There is a risk that you may get a treatment that does not help your condition or may make it worse. There also may be problems (side effects) we do not know about yet, from the HD-tDCS itself. If we learn about new important side effects, we will tell you.

We watch everyone in the project for problems (side effects). **You need to tell the research doctor or a member of the research team immediately if you experience any problems, side effects, or changes in your health.**

C2. RISKS OF HD-tDCS Device

The research device itself may cause problems (side effects). Side effects may be mild or very serious. Some can last a long time or never go away.
This study uses a well-known HD-tDCS montage at a safe dose of current. Previous studies have shown this dose is associated with no serious adverse effects. The AEs most often associated with HD-tDCS are not associated with long-term, harmful effects, and instead are typically mild and brief in nature.

The side effects that other people have experienced so far with the device are:

- Itching
- Tingling
- mild headache
- mild fatigue
- localized burning sensation at the site of stimulation

C3. OTHER RISKS OF THIS RESEARCH PROJECT

Other procedures that are part of the research also involve some risks:

MRI: There is no exposure to x-rays or radioactivity during an MRI (Magnetic Resonance Imaging) scan, and the risk of injury is very low. However, MRI is not safe for everyone. Serious injury or death can result if you go into the scanner with certain metal objects in or attached to your body. For example, it is not safe to have an MRI scan if you have a cardiac pacemaker, defibrillator, certain metal or implants in your body or have metal in or near your eye.

The MRI scanner makes loud banging sounds that can cause hearing damage, but with earplugs properly worn, there is no known risk of permanent hearing damage. Rarely, your hearing may be less sensitive for several days after an MRI scan, but if this happens your hearing should return to normal within a few days. Some individuals may feel hot or dizzy during the MRI scan. This varies from person to person. You may feel some discomfort because you are lying still for a long time, or because of the padding used to keep your head from moving. Some people feel anxious being in closed or narrow spaces. The scanner operator will be in constant contact with you, and if you choose, you can be taken out of the scanner quickly. Please alert staff to any concerns during the procedure.

In addition, there may be some unknown or unanticipated risks or discomforts in addition to those specified above because some of the procedures are relatively new and are attempts to advance medical knowledge. Every known precaution will be taken to ensure your personal safety and to minimize discomfort.

The safety of an MRI during pregnancy is unknown. Pregnant women will not be allowed to participate in this study. Therefore, one of the following must be indicated (please initial one of the following):

_____ I am not pregnant.
_____ I am pregnant; therefore, I cannot take part in this study.
_____ I don't know if I am pregnant, therefore I cannot take part in this study.

Language and Cognitive Assessments and Language Tasks Risks:
You may experience distress or anxiety during these assessments. Please let us know if you need to take a break.

Another risk may be loss of confidentiality. Every effort will be made to keep your research records confidential but we cannot guarantee it. Depending on the kind of information being collected, if your research information were accidentally seen, it might be used in a way that could embarrass you or affect your ability to get insurance. If you have questions, you can talk to the project director about whether this could apply to you.

C5. ARE THERE ANY BENEFITS TO TAKING PART IN THE PROJECT?

We don't know if this study will help you. Your condition may get better but it could stay the same or even get worse. We hope the information from this study will help us develop better treatments for mild cognitive impairment.

D1. ARE THERE ANY COSTS TO BEING IN THE PROJECT?

There are no costs to you for any of the visits or services you receive in this project. All costs will be paid by the project. If you have questions regarding costs, please contact Dr. Granadillo.

If you participate in this research, the costs of any necessary emergency medical treatment in the event of a research-related injury will be billed to you or your health insurance.

D2. WILL I BE PAID FOR PARTICIPATING IN THE PROJECT?

You will receive $50 for each of the 3 cognitive batteries, at Baseline, Visit 2, and Visit 3. You will receive $50 for each if the 2 MRIs, at Baseline and Visit 2. You will also be paid $20 for each of the 15 stimulation sessions. The total payments possible will amount to $550. Your study partner will be paid $25 for his/her participation.

If you live 25 miles or more one way from the study site, you will be reimbursed at the standard MCW travel rate.

On a case-by-case basis, you may be reimbursed for an overnight stay in a hotel or other form of lodging if necessary, up to 5 days per week, to complete a study visit. If your visit requires an overnight stay, you will receive a $25 meal reimbursement per night.

To pay you, we need your social security number. Any payment may be reportable as income on your taxes.

Kathy's House

If you reside at a permanent address 50 miles or greater from Milwaukee, you may be eligible for lodging at Kathy's House. Kathy's House is located on the Froedtert Hospital campus and provides housing for research subjects who require a stay greater than 3 days.

Each room includes the following:

- Most rooms have both a queen and a single bed
- Private bathroom with walk-in shower
- Bed and bath linens
- Television, small refrigerator, and telephone (local)

While lodging at Kathy's House, guests also have access to the following communal amenities:

- Fully equipped kitchen
- Refrigerator, pantry, and freezer storage space
- Free Wi-Fi
- Living Room
- Dining Room
- 6 interior & 4 exterior lounge spaces
- Fitness Center
- Meditation Room
- Laundry facilities
- Library, including computer workstations

Food

- Guests are responsible for their own meals
- Each room has designated pantry, refrigerator, and freezer storage space in the kitchen
- A meal from a local restaurant is provided once a week.

Parking and Transportation

- Parking is available for guests on a surface lot.
- Complimentary shuttle service is available during the week on a limited basis due to the COVID-19 pandemic.

<u>Guest Responsibilities</u>
It is important that guests staying at Kathy's House are comfortable in a communal environment. There is no maid service, so guests are asked to clean up behind themselves in the common areas and in their rooms. Rooms are thoroughly cleaned upon guest check-out.

Guests staying at Kathy's House must have a caregiver with them for the duration of their stay. Guests must also be able to perform basic mobility and care functions, including:

- do personal laundry as needed
- plan, prepare and clean up following meals

Payment for lodging at Kathy's House will be arranged and covered by the study team. Care givers are expected to lodge with subjects to the extent possible.

With the subject's verbal consent, a referral can be sent by the study team to Kathy's House. The following personal information will be included in the referral to Kathy's House: subject and care giver name, date of birth, gender, city, state, zip code, phone number, email address, and reason for visit.

Upon reception of the referral, Kathy's House will conduct a formal background check using TruthFinder.com. The subject and caregiver's names and birthdates will be used to check for any criminal charges associated with either person. Kathy's House has the right to reject any referral based on this background check.

You may visit kathys-house.org for more information.

D3. WHAT OTHER HEALTHCARE CHOICES DO I HAVE?

You do not have to join this project. You are free to say yes or no. If you do not join this project, your research doctor can discuss other healthcare choices with you.
Your other choices may include:

- Joining a different research study
- Doing nothing

The research doctor can explain both the possible benefits and the risks of other options that are available to you.

D4. WILL I BE GIVEN NEW INFORMATION ABOUT THE PROJECT?

If we learn any important new information about the device that might change your mind about being in the project, we will tell you about it right away. You can then decide if you want to stay in the project.

When research images are collected and analyzed , there is the chance of finding something clinically relevant. 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 feeling worried about a finding for which no treatment is required or appropriate).

In this study, you will be informed of any findings of possible clinical significance that may be discovered during review of results from your research images. The results of your research images will not be placed in your medical record.

The results from the images we collect in this research study are not the same quality as what you would receive as part of your health care. The images will not be reviewed by a physician who normally reads such results. We will provide you with this information so that you may discuss it with your primary care physician.

D5. WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THE PROJECT?

Emergency medical treatment for injuries directly related to your participation in this research project will be provided to you. You or your health insurance will be billed for the costs of this emergency treatment. MCW will decide on a case by case basis if they will reimburse you or your insurer for emergency treatment costs. If your research-related injury requires medical care beyond this emergency treatment, you or your insurer will be responsible for the costs of this follow-up care.

At this time, there is no plan for any additional financial payments.

If you believe that you have been injured because of your participation in this project, contact the research doctors right away. Contact information: Dr. Granadillo at 414-955-0650.

Nothing in this consent form affects any legal rights you may have nor does it release the investigator, the sponsor, the institution, or its agents from liability for negligence.

D6. WHO CAN ANSWER MY QUESTIONS ABOUT THE PROJECT?

- If you have more questions about this project at any time, you can call Dr. Granadillo at 414-955-0650.
- If you have questions about your rights as a research participant, want to report any problems or complaints, or offer input, you can call the MCW/Froedtert Hospital Research Subject Advocate at 414-955-8844.

E. PERMISSION TO COLLECT, USE AND SHARE HEALTH INFORMATION

E1. What health information will be collected and used for this project?

To be in this research project, the research team needs your permission to access, collect and use some of your health information. If you say no, you cannot be in the project. This information may come from questions we ask, forms we ask you to fill out, or your medical record, as described below. We will only collect and use information needed for the project.

The protected health information (PHI) originates from services you will or have received at one or more of the following locations: the Medical College of Wisconsin (MCW); Versiti, Inc.; Children's Hospital of Wisconsin (CHW); any Froedtert Health Affiliate- Froedtert Hospital (FH), Inc.; Froedtert Menomonee Falls Hospital; Froedtert West Bend Hospital; Froedtert & The Medical College of Wisconsin Community Physicians Clinics, Inc. (FMCWCP); the West Bend Surgery Center, LLC; and the Froedtert Surgery Center, LLC.

The health information to be collected and used for this project is:

- ⇨ Medical records of the care you receive for this project
- ⇨ Past medical records supporting your eligibility for the study including MRI of Brain.
- ⇨ Heath information collected during this research.

E2. Who will see the health information collected for this project?

The only MCW/Froedtert Hospital employees allowed to handle your health information are those on the research team, those on the Institutional Review Board (IRB) and those who check on the research activities to make sure the hospital's rules are followed.

If the costs of any necessary emergency medical treatment in the event of a research-related injury are billed to your health insurance, your health information may need to be disclosed to the insurer for billing purposes.

The research team may share your information with people who don't work at MCW/Froedtert Hospital because they planned, pay for, or work with us on this project. The federal Privacy Rule may no longer protect your health information once it leaves MCW/Froedtert Hospital.

For this project, we plan to share information with those doctors, researchers or government representatives working with us on this project at the institutions or companies listed here:

- Hrissanthi Ikonomidou, M.D. Ph.D, UW-Madison, Madison, WI

Because this project involves the use of drugs and/or devices, the FDA also has the right to inspect all project records.

We may record your research information, including results of tests and procedures done for research, in your Froedtert Hospital and/or Medical College of Wisconsin medical record. As a result, this research information may be seen by people allowed to see your medical records for healthcare operations or treatment, by those you allow to see your medical records by giving written permission, and by others when required by law.

We will not use your personal health information for a different project without your permission or the permission of a hospital research review board (IRB). Once all personal identification is removed from your health information and images, the information and images may be used for future research or distributed to another investigator for future research without additional informed consent from you or your legally authorized representative. The information might also be used or released for other purposes without asking you. Results of the project may be presented in public talks or written articles, but no information will be presented that identifies you.

E3. What are the risks of sharing this health information?

One risk of taking part in a research project is that more people will handle your personal health information collected for this project. The research team will make every effort to protect the information and keep it confidential, but it is possible that an unauthorized person might see it. If you have questions, you can talk to the research doctor about whether this could apply to you.

E4. How long will you keep the health information for this project?

If you sign this form, we plan to keep your information without any end-date in case we need to check it again for this project.

E5. Can I cancel my permission to share this health information?

If you change your mind later and do not want us to collect or share your health information, you need to send a letter to Dr. Granadillo at *8701 Watertown Plank Road, Milwaukee, WI 53226*. The letter must say that you have changed your mind and do not want the researcher to collect and share your health information. At that time, we will decide that you cannot continue to be part of the project. We may still use the information we have already collected.

F1. FOR MORE INFORMATION ABOUT THE PROJECT

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.

You can look up this project by referring to the ClinicalTrials.gov number NCT04246164 or by asking the research team for a printed copy.

CONSENT TO PARTICIPATE

By signing my name below, I confirm the following:

- I have read (or had read to me) this entire consent document
  All of my questions have been answered to my satisfaction.
- The project's purpose, procedures, risks and possible benefits have been explained to me.
- I agree to let the research team use and share the health information and other information gathered for this project.
- I voluntarily agree to participate in this research project. I agree to follow the procedures as directed. I have been told that I can stop at any time.

IMPORTANT: You will receive a signed and dated copy of this consent form. Please keep it where you can find it easily. It will help you remember what we discussed today.

Subject's Name *please print*	**Subject's Signature**	**Date**

Name of Legally Authorized Representative, if applicable *please print*	**Signature of Legally Authorized Representative**	**Date**
Name of Subject *please print*	***Relationship to Subject*** *(e.g. Court-appointed guardian, healthcare power of attorney, next of kin, etc.)*	

*** Name of person discussing/ obtaining consent** *please print*	**Signature of person discussing/obtaining consent**	**Date**

** A member of the research team trained and authorized by the Principal Investigator to act on her/his behalf in obtaining informed consent according to the protocol. The Principal Investigator is responsible and accountable for the research project.*

Name of Principal Investigator *please print* __ I participated in consent process __ I acknowledge enrollment of this subject into the project	**Signature of Principal Investigator**	**Date**

Attachment 1 – Visit Calendar

	Baseline	Treatment Period			Month 3	Month 6	Early Withdrawal
Visit	**1**	**2-6**	**7-11**	**12-16**	**17**	**18**	
Visit Window	**-6 months**		**±4 weeks**	**±4 weeks**	**Up to 6 weeks post Visit 16**	**3 months post Visit 16 ± 8 weeks**	
Timeframe		**Week 1 (Month 1)**	**Week 2 (Month 2)**	**Week 3 (Month 3)**			
Informed Consent	X						
Review Eligibility Criteria	X						
Demographics	X						
Review Concomitant Medications	X				X		X
Obtain Medical History	X						
Physical Exam	X				X		X
Vital Signs[1]	X				X		X
Randomization	X						
Study Partner Questionnaires	X				X	X	
Cognitive Battery	X				X	X	
MRI	X				X[2]		
TMS Neuronavigation (for stimulation planning) MCW only	X						
Device Administration		X	X	X			
Adverse Events Review/Assessment		X	X	X	X	X	X

1 Vitals include: pulse rate, body temperature, blood pressure, respiration rate, height, and weight
2 MRI will aim to be completed within 6 week window, but can be completed up to 12 months after Visit 16 if scheduling problems arise