Combined HIPAA-Consent Form
Cohorts 1 and 2

Title of Research Study: Increased thalamocortical connectivity in tDCS-potentiated generalization of cognitive training

Investigator Team Contact Information:

For questions about research appointments, the research study, research results, or other concerns, call the study team at:

Investigator Name: Kelvin O Lim, MD Department of Psychiatry Phone Number: 612-626-6772 Email Address: kolim@umn.edu	Study Coordinator – Cohort 1: Name: Lei Xuan Phone Number: 612-626-7302 Email Address: lei@umn.edu	Study Coordinator – Cohort 2: Name: Melanie Stimac Phone Number: 612-301-2449 Email Address: stima011@umn.edu

Supported By: This research is supported by the National Institutes of Health (NIH).

Key Information About This Research Study

The following is a short summary to help you decide whether or not to be a part of this research study. More detailed information is listed later on in this form.

What is research?

Doctors and investigators are committed to your care and safety. There are important differences between research and treatment plans:

- The goal of research is to learn new things in order to help groups of people in the future. Investigators learn things by following the same plan with a number of participants, so they do not usually make changes to the plan for individual research participants. You, as an individual, may or may not be helped by volunteering for a research study.
- The goal of clinical care is to help you get better or to improve your quality of life. Doctors can make changes to your clinical care plan as needed.

Research and clinical care are often combined. One purpose of this informed consent document is to provide you clear information about the specific research activities of this study.

You have the right to discuss this study with another person who is not part of the research team before deciding whether to participate in the research.

Why am I being asked to take part in this research study?

We are asking you to take part in this research study because you either have schizophrenia or a related disorder and you have expressed interest in participating, or you are an adult without one of these disorders and have expressed interest in participating.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.

Version Date: 03.07.2023

- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

This study is being done to learn how transcranial direct current stimulation (tDCS) with working memory (WM) training affects connections between parts of your brain, and if there are differences in how the number of sessions and the dose affects your ability to apply your training to new experiences. We are also interested in learning how long these brain changes last after you finish the training.

Additionally, we are interested in whether genetic differences between people might affect how they respond to the tDCS and WM training. Some evidence suggests that genetic differences that affect the brain may play a role in how people respond to psychiatric treatments. If we can find genetic differences between individuals that have different responses to the research treatment being used in this study, then we will be able to better "personalize" treatment in the future by providing people with a treatment plan based on their individual genetic make-up.

tDCS is considered to be a non-invasive investigational device that involves applying a weak electrical current to the scalp. This device has been labeled as a non-significant risk device by the FDA for investigational purposes.

How long will the research last?

We expect that you will be in this research study for 24 weeks, with 11-12 weeks of training. You can expect at least 2 sessions of WM training and tDCS each week, but aiming for 3 sessions per week if possible, for a maximum of 36 sessions, in addition to 4 lab assessment visits (baseline, week 6, week 12, and week 24; details can be found under ***"What happens if I say yes, I want to be in this research?"***)

What will I need to do to participate?

You will be asked to complete questionnaires and interviews, take cognitive tests, provide samples of saliva for a drug screen, provide saliva samples for genetic analyses (optional), complete 3 MRIs (if in-person visits are available), undergo tDCS, and undergo WM training. Visits will occur either in person at our lab, or remotely. If you will be participating in remote study visits, you will be provided a Linux-based device and tDCS stimulation device and headband to complete the activities at home. The samples collected will be done at home and we will send you vials and shipping materials to submit back to the study team.

More detailed information about the study procedures can be found under ***"What happens if I say yes, I want to be in this research?"***

Is there any way that being in this study could be bad for me?

Side effects typically only occur when there is not enough saline on the stimulation headband and/or the headband is applied incorrectly. To reduce the occurrence of any side effects, an attendant will teach you how to properly apply the saline and will visually check the positioning of your headband before stimulation begins at each session.

Common side effects during stimulation include temporary skin redness, itching, or tingling underneath electrodes. Less common side effects that may occur during stimulation are headache, fatigue, or nausea. These typically resolve when the stimulation stops. A rare side effect of tDCS is a burn on the skin underneath the electrodes (less than 1 out of 500 sessions). If you feel discomfort at any point during the tDCS stimulation, please let the attendant know so they can help troubleshoot the issue promptly.

Seizures are not a risk of tDCS, but if you have a history of seizures, you should not take part in this study. Tell a study staff member if you think this applies to you.

More detailed information about the risks of this study can be found under ***"What are the risks of this study? Is there any way being in this study could be bad for me? (Detailed Risks)"***

Will being in this study help me in any way?

There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research.

What happens if I do not want to be in this research?

You do not have to participate in this research if you do not want to. The study doctor can discuss alternatives with you if you have any questions about your medical care.

Please INITIAL HERE to confirm you have reviewed the previous information: _____

Detailed Information About This Research Study

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

How many people will be studied?

We expect about 90 participants without schizophrenia or related disorders and 90 participants with schizophrenia or related disorders will be enrolled in this research study at the University of Minnesota.

What happens if I say "*Yes, I want to be in this research*"?

If you decide you want to participate in this research, you can expect the following procedures at these study visits:

Screening/Baseline Visit (2-5 hours; can be split into multiple sessions on separate days):

- You will be randomly assigned to receive tDCS (right or left side) or to receive sham stimulation. Neither you nor the study team will know which therapy you are receiving during the study, although the study team can find out if needed.
- You will complete some cognitive tasks, interviews, and questionnaires; several questionnaires and one task are optional and you will be offered additional compensation for completing them. Interviews may be recorded for reliability and training purposes, please see the optional section at the end of this consent form.
- You will provide a saliva sample for a drug screen test
- You may provide an optional saliva sample for genetic testing
- The study team will ask you about any medications you are taking
- If in-person visits are available, you will have an MRI. The MRI takes about an hour and a half (90 minutes). You will be asked to lie down quietly in the scanner while the scanner takes pictures of your brain. You will be asked to complete some tasks while you are in the scanner.

Sessions 1-15 (Weeks 1-6) (1 hour per session)

You will have 2-3 sessions per week. At each session:

- The study team will ask you about any medications you are taking
- You will have WM training during tDCS. The WM training consists of a variety of different computer exercises designed to be both challenging and fun. During tDCS, you will wear a headband that has electrodes in it. Video and audio may be recorded during the session to help the study team monitor your performance and engagement with the training. Each session will last 1 hour.
- At the end of the session, you will complete a questionnaire that asks you about how your training went that day.

Mid-Test (Week 6) (2-5 hours; can be split into multiple sessions on separate days)

- You will complete some cognitive tasks, interviews, and questionnaires; several questionnaires and one task are optional and you will be offered additional compensation for completing them. Interviews may be recorded for reliability and training purposes, please see the optional section at the end of this consent form.
- You will provide a saliva sample for a drug screen test
- The study team will ask you about any medications you are taking
- If in-person visits are available, you will have an MRI. The MRI takes about an hour and a half (90 minutes). You will be asked to lie down quietly in the scanner while the scanner takes pictures of your brain. You will be asked to complete some tasks while you are in the scanner.

Sessions 16-36 (Weeks 7-12) (1 hour per session)

You will have 2-3 sessions per week. At each session:

- The study team will ask you about any medications you are taking
- You will have WM training during tDCS. The WM training consists of a variety of different computer exercises designed to be both challenging and fun. During tDCS, you will wear a headband that has electrodes in it. Video and audio may be recorded during the session to help the study team monitor your performance and engagement with the training. Each session will last 1 hour.
- At the end of the session, you will complete a questionnaire that asks you about how your training went that day.

Post-Test (Week 12) (2-5 hours; can be split into multiple sessions on separate days)

- You will complete some cognitive tasks, interviews, and questionnaires; several questionnaires and one task are optional and you will be offered additional compensation for completing them. Interviews may be recorded for reliability and training purposes, please see the optional section at the end of this consent form.
- You will provide a saliva sample for a drug screen test
- The study team will ask you about any medications you are taking
- If in-person visits are available, you will have an MRI. The MRI takes about an hour and a half (90 minutes). You will be asked to lie down quietly in the scanner while the scanner takes pictures of your brain. You will be asked to complete some tasks while you are in the scanner.

Follow-Up (Week 24) (3-5 hours; can be split into multiple sessions on separate days)

- You will complete some cognitive tasks, interviews, and questionnaires; several questionnaires and one task are optional and you will be offered additional compensation for completing them. Interviews may be recorded for reliability and training purposes, please see the optional section at the end of this consent form.
- You will provide a saliva sample for a drug screen test
- You may provide an optional saliva sample for genetic testing.
- The study team will ask you about any medications you are taking

Visit windows: we will attempt to schedule study visits within a one week window of the intended timeline.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible for attending all study visits and following instructions given to you by study staff.

What happens if I say "Yes", but I change my mind later?

You can leave the research study at any time and no one will be upset by your decision.

If you decide to leave the research study, contact a study staff member so that the investigator can decide if any follow-

up assessments are needed. If it is unsafe for you to be in the study, you will not have any follow-up assessments.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. This means that your choice not to be in this study will not negatively affect your right to any present or future medical care.

If you stop being in the research, information about you that has already been collected will not be removed from the study database.

What are the risks of being in this study? Is there any way being in this study could be bad for me? (Detailed Risks)

In addition to the risks described in Key Information, above, this study has the following risks:

Confidentiality

During the study, you will be asked for personal information. This information will be stored securely to protect your privacy, but there is a risk that it could be accidentally shared with people who do not have access to this information. To comply with retention requirements, records including HIPAA and consent forms will be retained for at least six years after completion of the research.

A risk of genetic research is loss of confidentiality. If your results were to get out, it could cause emotional distress for you and your family, or lead to discrimination against you by insurance companies or employers. To protect against these risks, we will not put any information from this study in your or medical record. Any physical copies of your genetic results will be stored in a locked file cabinet within a secured office. Any electronic genetic results will be encrypted and stored on a password protected computer according to current University of Minnesota policy for protection of confidentiality. Your donated saliva sample and genetic material will not be stored with your name or any other identifying information, but instead will be given a code number to protect your identity.

Certificate of Confidentiality:

To help protect your privacy, the National Institute of Health has granted a Certificate of Confidentiality. The researchers can use this Certificate legally to refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate does not prevent a researcher from reporting information learned in research when required by other state or federal laws, such as mandatory reports to local health authorities for abuse or neglect of children/vulnerable adults, or information to the Food and Drug Administration (FDA) when required in an FDA audit. However, the Certificate limits the researcher from disclosing such information in follow up civil, criminal, legislative or administrative legal proceedings if the information was created or compiled for purposes of the research.

You also should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information."

The Certificate of Confidentiality will also not be used to prevent disclosure for any purpose you have consented to in this informed consent document, such as the limited data set shared with the NIMH National Data Archive (explained below under "National Institute of Mental Health Data Archive").

Saliva collection for genetic testing

The collection of saliva for genetic material is painless with little risk to your health. This part of the study is optional--you may choose not to take part in the genetic sample procedure and still be eligible for the rest of the study procedures. If you choose to provide a saliva sample, you will not be allowed to eat, drink, smoke, or chew gum at least 30 minutes prior to the saliva collection. After 30 minutes, the study member will ask you to spit into a hand-held plastic container multiple times in order to fill the container to a designated line. The total amount of saliva collected will be 2 milliliters (less than half of a teaspoon) and will take about 5 minutes to complete. Some people may experience dry mouth after saliva collection. Water may be provided to you by the study staff member if you experience dry mouth or discomfort after the saliva sample collection.

MRIs

MRI machines use a strong magnet and radiofrequency magnetic fields to take images of your 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:

- Projectiles: Objects with magnetic properties can be pulled into the magnet and turn into projectiles. To minimize this risk we ask that subjects remove all metallic items (watches, cell phones, hair pins, etc.) prior to entering the scanner and by controlling 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 you do not wear hearing protection. Hearing protection is required and is provided by the investigator.
- Nerve Stimulation: Some people experience localized tingling, twitching, or muscle contractions during MRI scans. This is expected, but if it is uncomfortable please notify the investigator.
- 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 have any implanted device notify the investigator.
- 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 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. You will be in constant contact with the investigator and should notify the investigator immediately, via the squeeze ball, if you notice anything unusual, become claustrophobic, think that your hearing protection is not adequate, or if you experience nerve stimulation that 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 their mouth, or sensations of flashing lights. These symptoms, if present, subside shortly after leaving the magnet. If any sensations experienced during participation cause discomfort or pain, notify the researcher right away and your participation will stop and you will be taken out of

the magnetic field. The risks of exposure to high magnetic fields are unknown for fetuses. Therefore, if you are a female who is capable of becoming pregnant, and you have any reason to believe that you might be pregnant, you should not participate in this study.

Will it cost me anything to participate in this research study?

You will have to pay for basic expenses like any childcare, food, parking, or transportation related to study activities. Some assistance may be available for travel and parking expenses incurred to attend lab assessment visits only. Please ask the research staff for more information if you need assistance covering these expenses.

If you need treatment for side effects while you are on the study, you or your insurance will need to pay for this treatment.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete confidentiality. Organizations that may inspect and copy your information include the Institutional Review Board (IRB), the committee that provides ethical and regulatory oversight of research, and other representatives of this institution, including those that have responsibilities for monitoring or ensuring compliance, as well as representatives of the NIH.

Data or Specimens Collected

The sponsor, monitors, auditors, the IRB, the University of Minnesota Research Compliance Office and other University compliance units, the US Office of Research Integrity (ORI), the US Office for the Protection of Human Research Protections (OHRP), the US Food and Drug Administration (FDA) may be granted direct access to our records to conduct and oversee the research. By signing this document you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

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

National Institute of Mental Health Data Archive

Data from this study will be submitted to the National Institute of Mental Health Data Archive (NDA). NDA is a data repository run by the National Institute of Mental Health (NIMH) that allows researchers studying mental illness to collect and share information with each other. A data repository is a large database where information from many studies is stored and managed. All personal information about research participants such as name, address, and phone number is removed and replaced with a code number. With an easier way to share, researchers hope to learn new and important things about mental illnesses more quickly than before. During and after the study, the researchers will send information about your health, behavior and biology, to NDA. Other researchers nationwide can then file an application with the NIMH to obtain access to your study data for research purposes. Experts at the NIMH who know how to protect health and science information will look at every request carefully to minimize risks to your privacy.

You may not benefit directly from allowing your information to be shared with NDA. The information provided to NDA may help researchers around the world treat future children and adults with mental illnesses so that they have better outcomes. NIMH will also report to Congress and on its website about the different studies that researchers are conducting using NDA data. However, you will not be contacted directly about the data you contributed to NDA.

You may decide now or later that you do not want to share your information using NDA. If so, contact the researchers who conducted this study, and they will tell NDA, which can stop sharing the research information. However, NDA

cannot take back information that was shared before you changed your mind. If you would like more information about NDA, this is available on-line at http://data-archive.nimh.gov.

If you do not want to share your information using NDA, you will not be allowed to continue on this study.

Genetic Samples
The saliva samples collected in this study can be stored for a long time, many years after the study is completed. This allows for the possibility of future genetic research beyond the current study, either by the researchers of the current study or by other researchers who may request access to this study's data in the future. Any future genetic research that is not a part of the current study will only be done after approval by a special committee (Institutional Review Board) that protects the interest of research participants. You may choose whether or not your genetic samples are stored for future research by indicating your choice at the end of this form.

If you agree to allow your saliva and genetic material be used for future genetic research, your sample will be stored with a number code, not with any identifiable information. This unique number code will be linked to your clinical research data by an encrypted and secure database. Only the study investigators will have access to this database. If you agree to allow your saliva and genetic material be used for future genetic research, you will not be asked again for consent to use your sample in future genetic research studies. There is no limit to how long we will store your sample. We may keep using them for research studies until they are used up. If you choose to withdraw from the study, any genetic samples you have already provided to the study will be retained.

Genetic study results
Information from these genetic studies or future studies using this data will not be made available to you or your doctors and will not affect you or your clinical care. The genetic analyses performed in this study are not for clinical use, therefore none of the genetic results performed in this study will be put in your medical records. We will not contact you about specific genetic results of this study, and you will not be contacted about results of future studies using this data. All study information, including genetic results, is stored under conditions that limit access in order to protect your privacy. Genetic results will be de-identified and stored separately from your contact and personal information. Individualized identifiable genetic results will not be published. Results obtained from this study or future genetic research studies will not provide any direct benefits to you.

Will anyone besides the study team be at my consent meeting?
You may be asked by the study team for your permission for an auditor to observe your consent meeting. Observing the consent meeting is one way that the University of Minnesota makes sure that your rights as a research participant are protected. The auditor is there to observe the consent meeting, which will be carried out by the people on the study team. The auditor will not document any personal (e.g. name, date of birth) or confidential information about you. The auditor will not observe your consent meeting without your permission ahead of time.

What happens to the information collected for the research, including my health information?

We try to limit the use and sharing of your information, including research study records, any medical records and any other information about you, to people who have a need for this information. But we cannot promise complete confidentiality.

Overview

If you participate in this study, your information, including your health information, will be used and shared for purposes of conducting this research. As described later in this Consent Form, your information may also be used and shared for publishing and presenting the research results, future research, and any optional elements of the research you agree to in this Consent Form, which may include creating audio and video recordings of you. If you sign this Consent Form, you are giving us permission to use and share your health information for these purposes, and if we are using your medical records, you are giving permission to any health care providers who are treating you to share your medical records with us.

What health information will be made available?

Health information about you to be used and shared for the research includes those items checked by the research team below:

☐ Your medical records, which may include records from hospital and clinic visits, emergency room visits, immunizations, medical history and physical exams, medications, images and imaging reports, progress notes, psychological tests, EEG/EKG/ECHO reports, lab and pathology reports, dental records and/or financial records. These records may be used and shared for as long as this research continues.

☒ Information collected as part of this research study, including research procedures, research visits, and any optional elements of the research you agree to, all as described in this Consent Form. This information might not be part of your medical record, and may include things like responses to surveys and questionnaires, and information collected during research visits described in this Consent Form.

What about more sensitive health information?

Some health information is so sensitive that it requires your specific permission. If this research study requires any of this sensitive information, the boxes below will be marked and you will be asked to initial to permit this information to be made available to the research team to use and share as described in this Consent Form.

☐ My drug & alcohol abuse, diagnosis & treatment records _____ (initial)

☐ My HIV/AIDS testing records _____ (initial)

☐ My genetic testing records _____ (initial)

☐ My mental health diagnosis/treatment records ____ (initial)

☐ My sickle cell anemia records _____ (initial)

Who will access and use my health information?

If you agree to participate in this study, your information will be shared with:

- The University of Minnesota research team and any institutions or individuals collaborating on the research with us;

- Others at the University of Minnesota and M Health/Fairview who provide support for the research or who

oversee research (such as the Institutional Review Board or IRB which is the committee that provides ethical and regulatory oversight of research at the University, systems administrators and other technical and/or administrative support personnel, compliance and audit professionals (Such as the Quality Assurance Program of the Human Research Protection Program (HRPP)) , individuals involved in processing any compensation you may receive for your participation, and others);

- The research sponsor(s), any affiliates, partners or agents of the sponsor(s) involved in the research, organizations funding the research, and any affiliates, partners or agents of the funding organization(s) involved in the research;

- Organizations who provide accreditation and oversight for research and the research team, and others authorized by law to review the quality and safety of the research (such as U.S. government agencies like the Food and Drug Administration, the Office of Human Research Protections, the Office of Research Integrity, or government agencies in other countries); and

- Organizations that process any payments that may be made to you for participating in this study, and any other individuals or organizations specifically identified in this Consent Form.

Additional sharing of your information for mandatory reporting

If we learn about any of the following, we may be required or permitted by law or policy to report this information to authorities:

- Current or ongoing child or vulnerable adult abuse or neglect;
- Communicable, infectious or other diseases required to be reported under Minnesota's Reportable Disease Rule;
- Certain wounds or conditions required to be reported under other state or federal law; or
- Excessive use of alcohol or use of controlled substances for non-medical reasons during pregnancy.

How will my information be used in publications and presentations?

We may publish the results of this research in scientific, medical, academic or other journals or reports, or present the results at conferences. Information that makes it easy to identify you (such as your name and contact information, SSN and medical records number) will not be part of any publication or presentation. If you have an extremely unique or rare condition that is not shared by many others, it is possible that some people may be able to determine your identity even without these identifiers.

What will be done with my specimens when this study is over?

We will ask you to consent in the optional section of this form for your permission to share specimens for future research. They may be shared with researchers/institutions outside of University of Minnesota. This could include for profit companies. We will not ask for your consent before using or sharing them. We will remove identifiers from your specimens, which means that nobody who works with them for future research will know who you are. Therefore, you will not receive any results or financial benefit from future research done on your specimens.

Do I have to sign this Consent Form and give my permission to make my information, including my health information, available for use and sharing?

No, you do not have to sign this Consent Form. But if you do not sign, you will not be able to participate in this research study. Treatment available outside of the study, payment for such treatment, enrollment in health insurance plans and

eligibility for benefits will not be impacted by your decision about signing this Consent Form.

Does my permission for making my health information available for use and sharing ever expire?

No, there is no expiration date.

May I cancel my permission for making my health information available for use and sharing?

Yes. You may cancel your permission at any time by writing to the researcher at the address on the first page of this Consent Form. If you cancel your permission, you will no longer be in the research study. You may also want to ask someone on the research team in canceling will affect any research related medical treatment. If you cancel your permission, any health information about you that was already used and shared may continue to be used and shared for the research study and any optional elements of the study to which you agree in this Consent Form.

What happens to my health information after it is shared with others?

When we share your information with others as described in this Consent Form, privacy laws may no longer protect your information and there may be further sharing of your information.

Will I be able to look at my records?

It is possible that the research team may not allow you to see the information collected for this study. However, you may access any information placed in your medical records after the study is complete.

Genetic Information
A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that this federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

Will I receive research test results?

NO Results will be shared
Most tests done on samples in research studies are only for research and have no clear meaning for health care. The investigators will not contact you or share your individual test results.

NO genetic results will be shared with you, even if a medically significant results should be discovered and even if the testing reveals information that could be used by you to make healthcare or lifestyle choices that could prolong your life or prevent or delay the development of a life threatening condition.

Whom do I contact if I have questions, concerns or feedback about my experience?

This research has been reviewed and approved by an IRB within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research experience, call the Research Participants' Advocate Line at 612-625-1650 (Toll Free: 1-888-224-8636) or go to z.umn.edu/participants. You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Will I have a chance to provide feedback after the study is over?

The HRPP may ask you to complete a survey that asks about your experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous.

If you are not asked to complete a survey, but you would like to share feedback, please contact the study team or the HRPP. See the "Investigator Contact Information" of this form for study team contact information and "Whom do I contact if I have questions, concerns or feedback about my experience?" of this form for HRPP contact information.

Can I be removed from the research?

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

- if the study staff feels it is unsafe for you to continue
- if you do not comply with study procedures
- if you are unable to tolerate the tDCS
- if you are no longer able to provide your consent for research

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

Please INITIAL HERE to confirm you have reviewed the previous information: _____

What happens if I am injured while participating in this research?

In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner, to you or your insurance company. If you think that you have suffered a research related injury let the study physicians know right away.

Will I be compensated for my participation?

If you agree to take part in this research study, we will pay you the following amounts for your time and effort. If you do not complete the study, you will be paid for the visits you have completed:

- Baseline: $30
- Week 6 follow-up: $50
- Week 12 follow-up: $75
- Week 24 follow-up: $100
- Average of $11 per WM/tDCS session (up to $396 for 36 possible sessions)*
- Attendance bonus (for each week you attend 3 study visits you will receive $5, for up to $60)

- $50 per MRI (up to $150 for 3 possible MRIs)
- Optional questionnaires: $10 per assessment visit (up to $40 for 4 possible assessment visits)
- Optional task: $0 to $5 per visit (up to $20 for 4 possible visits). Payment for this task determined randomly based on a set of choices you make in the task.

If you complete all study procedures, you could earn up to $921 total for participating in this study.

*Graded compensation for WM/tDCS sessions: Compensation for WM/tDCS sessions increases as you progress through the study. Payment per session increases after you complete 3 sessions at a given rate. If you attend all 3 sessions per week, payment will increase every week (except for weeks 6 and 7, which have the same rate). If you miss a session, the payment does not go up until you have completed 3 sessions at a given rate. Sessions rates by week, from week 1-12 respectively, are as follows: $8, $10, $12, and $14 per session. Payment tiers increase $2 every 9 completed sessions (if you attend all 9 sessions at a given rate, the payment will increase to the next tier). If you miss a session, the payment does not go up until you have completed 9 sessions at a given rate.

Payment for additional visits: in some cases, we may ask you to complete another visit in addition to the standard visit plan outlined in this document. Sometimes this is necessary to finish or redo certain study procedures. In cases like these, you will be compensated for the extra time you spend completing these additional study activities according to the following guidelines:

- For additional visits that involve assessment activities (activities normally completed at the Baseline or follow up visits at week 6, 12, or 24), you will be compensated at a rate of $15/hr.
- For additional visits that involve training session activities (activities normally completed at the tDCS + cognitive training sessions), you will be compensated for a full training session at the rate corresponding to your progress through the graded compensation plan mentioned above. You must still complete 3 successful sessions at a given rate in order to progress to the next compensation tier.
- If you terminate a visit early resulting in incomplete data, your compensation for that visit may be prorated according to the time spent during that visit.
- For other cases, compensation for additional visits or activities will be commensurate to the time and demands required of you for that visit/activity.

Payment will be made using a pre-paid debit card called Greenphire ClinCard. It works like a bank debit card. We will give you a debit card and each time you receive a payment for participation in this study, the money will be added to the card after each completed visit.

You may use this card at any store that accepts MasterCard or you can use a bank machine to remove cash. However, there may be fees drawn against the balance of the card for cash withdrawals (ATM use) and inactivity (no use for 3 months). We will give you the ClinCard Frequently Asked Questions information sheet that answers common questions about the debit card. You will also receive letters with additional information on how you can use this card and who to call if you have any questions. Be sure to read these letters, including the cardholder agreement, for details about fees.

The debit card system is administered by an outside company. The company, Greenphire, will be given your name and social security number. They will use this information only as part of the payment system. Your information will not be used for any other purposes and will not be given or sold to any other company. Greenphire will not receive any information about your health status or the study in which you are participating.

Additionally, you will have the option to receive updates related to appointment reminders and payment reminders and updates via text message and email message (Standard text messaging rates will apply). You will have the opportunity to opt-in to receive these messages, you are not required to provide your cell phone or email address to be enrolled in the study or use a ClinCard. If you choose to receive messages and decide at a later date that you want to stop these messages, you will have the ability to opt-out.

Any demographic information collected and provided to Greenphire is stored in a secure fashion and will be kept confidential, except as required by law.

Payment you receive as compensation for participation in research is considered taxable income. If payment to an individual equals or exceeds $600 in any one calendar year, the University of Minnesota is required to report this information to the Internal Revenue Service (IRS). Research payments to study participants that equal or exceed $600 during any calendar year will result in a FORM 1099 (Miscellaneous Income) being issued to you and a copy sent to the IRS.

Use of Identifiable Health Information

We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Those persons who get your health information may not be required by Federal privacy laws (such as the 1099 Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission. Please read the HIPAA Authorization form that we have provided and discussed.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

Release of Information

In order to verify your eligibility for this study, we may in some cases request that you grant permission for your health care provider or case manager to release information relevant to the screening process to our study team. In these cases, there is a separate form we would ask you to fill out in order for you to grant this authorization. You are not required to share this information with us, but doing so may help us ensure that the study is a good fit for you and verify that certain information (e.g. medical history) is accurate and complete. The study team member will discuss this with you if it is relevant to your participation. There is a section below where you can initial to opt-in to this process.

Please INITIAL HERE to confirm you have reviewed the previous information: _____

At this time, the study staff would like to ask you some questions to make sure that this form was explained to you properly.

Optional Elements:

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

Yes, I agree	No, I disagree	
_____	_____	I would like to receive reminders using Greenphire. If yes, provide the following contact: Email Address: _____ Phone Number: _____
_____	_____	I give permission to collect saliva for genetic studies. I understand that my saliva may be collected multiple times over the duration of this study.

_____ _____ I give permission to store my saliva and genetic material after the completion of this study for future genetic research. I understand that my stored sample will be kept in a non-identifiable form to prevent anyone from identifying me.

_____ _____ You may contact me in the future about other research opportunities. If you contact me in the future, I may choose at that time whether or not I would like to participate in that research study.

_____ _____ You may record audio and/or video of my assessment interviews*
*This helps us as a research team to maintain consistency in interviewing methods across different researchers.

_____ _____ I give study staff permission to use data from and share data with the Consortium of Psychosis Research Recruitment (COPRR) if I am enrolled in it.

_____ _____ I give permission for you to contact my medical provider / case manager for the purpose of releasing information relevant to the screening process. I understand that I am not required to release this information.

Version Date: 03.07.2023

Approved for use by UMN IRB
Effective on 3/21/2023
IRB Study Number: STUDY00003506

SIGNATURES
Your signature documents your permission to take part in this research. You will be provided a signed copy of this consent form

Participant signature: _____
[Please hold down your cursor and sign your name electronically]

Please type your FULL NAME here: _____

Please type today's date: _____

Email address of participant: _____

Please type the FULL NAME of the research staff member who went over this consent with you:
_____

Please type today's date: _____

Please type the CODE provided to you by the research staff member: _____

PLEASE CLICK ON THE LINK BELOW TO DOWNLOAD A COPY OF THIS FORM FOR YOUR RECORDS:

[Blank PDF copy of consent form]