Consent Form (includes HIPAA Authorization)

Title of Research Study: tDCS and cognitive training for restrictive eating disorders

Investigator Team Contact Information:

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

Investigator Name: Lisa M. Anderson, PhD Investigator Departmental Affiliation: Psychiatry and Behavioral Sciences Phone Number: (763) 742-8136 Email Address: ande8936@umn.edu	Study Staff (if applicable): Maya Day Phone Number: 612-625-1542 Email Address: day00186@umn.edu

If your doctor is also the person responsible for this research study, please note that she is interested in both your clinical care and the conduct of this research 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.

Supported By: This research is supported by department funding.

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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.

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 reported that you are currently receiving eating disorder treatment and have symptoms consistent with a restrictive eating disorder such as anorexia nervosa (AN) and atypical anorexia nervosa (AAN).

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.
- 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?

Restrictive eating disorders such as anorexia nervosa (AN) and atypical anorexia nervosa (AAN) are associated with cognitive alterations that may be associated with eating disorder symptoms and may interfere with recovery. Current eating disorder treatments do not target the brain processes underlying these cognitive alterations. Researchers hope that this study will learn more information about a new non-invasive brain stimulation method, transcranial direct current stimulation (tDCS), and cognitive training exercises in people with a restrictive eating disorder.

How long will the research last?

We expect that you will be in this research study for about 2 months.

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What will I need to do to participate?

You will be asked to complete a series of visits in which you will be asked to complete brain training tasks while using a tDCS device.

tDCS is a non-invasive device that applies constant, low current to a small region of the scalp. tDCS is considered experimental in this study. This stimulates the brain. Participants will be randomly assigned to one of two groups. While performing cognitive training tasks, you will either be receiving real tDCS treatment or a sham (placebo) treatment.

There will be 13 different visits. The first visit will be a screening visit where you will have behavioral assessments and questionnaires to complete. If you are eligible based on the screening/baseline visit, we will invite you to participate in 12 additional study visits. The next 10 visits (visits 2-11) will be the brain training intervention sessions. The sessions will be scheduled for 5 consecutive days per week for a 2-week period. Depending on which group you are randomly assigned to, you will either receive tDCS or sham while doing cognitive training exercises. Your last two visits (12 and 13) will be follow up visits. In these visits, you will perform the same assessments and questionnaires as in the first visit.

These visits will take place in the follow locations: Ambulatory Research Center (ARC) in the Psychiatry Department (2nd floor), tDCS sessions will take place either at the Ambulatory Research Center (ARC), the Non-Invasive Neuromodulation Lab (NNL) at the University of Minnesota Medical School or at the Masonic Institute for the Developing Brain.

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?

Intervention Risks: tDCS is considered to be a non-invasive investigational device that involves applying a weak electrical current to the head. There is currently no evidence of serious side-effects. Mild side-effects that typically resolve upon discontinuing tDCS include light itching under the electrode at the beginning of administration, headache, fatigue, and nausea. You may choose to stop stimulation at any time during the session if experiencing excessive discomfort or side effects. No other risks related to tDCS are anticipated. To minimize risks regarding tDCS, study staff will be using standards of administration that have been shown as safe in numerous other studies using transcranial direct current stimulation.

Risks of Assessments: As with all assessments, there is the potential that we will ask questions that make you feel uncomfortable, embarrassed, or stressed. You will be reminded you only need to provide the information that you are willing to answer and can ask to skip questions at any time. In addition, due to the length of the assessment visits, it is possible that you can feel fatigued or stressed by the interview. We will invite you to take short breaks in the middle of sessions to prevent fatigue when possible.

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Confidentiality risks: The other potential risks pertain to the maintenance of confidentiality. There is some risk of a data breach involving the information we have about you. We comply with the University's security standards to secure your information and minimize risks, but there is always a possibility of a data breach. You will be asked for personal information during the interviewing process. All information you provide will be kept behind two locks and available only to the research team members who are involved in this study. De-identified data will be labeled with your study ID number and will not contain personally identifying information. Your training sessions will be audio and video recorded. These recording will be stored using your study ID number and only accessible to authorized specific study staff. These recordings will be stored per university security standards. While researchers will do everything in their power to protect your personal information, confidentiality is not absolute. Research staff are mandated reporters and are legally required to report suspicion of child or vulnerable adult abuse or neglect to the relevant authorities.

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

Risk of Emotional Distress

As part of the research, we may ask questions about how you feel mentally and emotionally. We are providing a list of resources to you in case you would like to talk to someone and get help. If you are thinking about hurting yourself or someone else, please tell someone who can help immediately. Call the toll-free 24-hour National Suicide Prevention Lifeline at 1-800-273-TALK (1-800-273-8255) to talk to a counselor near 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)" and in the "What happens to the information collected for the research?" section***

Will being in this study help me in any way?

There are no proven benefits to being in this study, and the investigators do not know whether tDCS will affect eating disorder symptoms, nor how long any changes may last.

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

There are no known alternatives, other than deciding not to participate in this research study.

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 20 people will be in this research study.

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

If you chose to enroll in this study, you will be randomly assigned to one of two groups. You will either

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receive 10 real tDCS sessions or 10 sham (placebo) tDCS sessions. Your group membership will be assigned by chance, like flipping a coin. Neither you nor the study doctor will choose what experimental intervention you get. You will have an equal chance of being given either experimental intervention. You will not be told which experimental intervention you are getting . The sessions will be scheduled for 5 consecutive days per week for a 2-week period

The screening/baseline visit (Visit 1) will take about 3-4 hours total and can be completed either remotely or in person. If needed, the assessments can be split into two days. At the screening/baseline visit, research staff will interview you and administer self-report measures related to medical history, demographic information and behavior, personality, and eating disorder symptoms. All participants who are able to become pregnant will also be asked to provide a urine sample for pregnancy testing. If you learn that you are pregnant while a part of this study, please alert the study team immediately so that we can make sure you stop the study safely. You will also be asked to complete cognitive assessment and behavioral tasks.

Within 2 weeks of your first/baseline visit, brain training intervention sessions will be scheduled. You may complete these intervention sessions while enrolled in your eating disorder treatment program or remote, depending on when you discharge from your program. Each of the intervention visits will be about 1 hour. During each visit, you will be asked how you are feeling each day. You will then complete 45 minutes of cognitive training. During this time you will complete four brain training exercises, and tDCS or sham will be applied during the first 20 minutes of the 45 minutes of cognitive training. You will be asked to complete a questionnaire about how you feel after the tDCS treatment. Your responses of the cognitive training may be audio and video recorded. These recordings will be stored on a secure server that is only accessible to members of the study team.

After you have completed your 10 intervention sessions, you will complete the same behavioral tasks, self-report measures and clinical interview assessments as completed during your first visit. This visit will last about 1.5-2 hours.

About 1 month after you complete your intervention, you will complete the same behavioral tasks, self-report measures and clinical interview assessments as completed during your first visit. This visit will last about 1.5-2 hours.

	Visit 1	Visit 2-11	Visit 12	Visit 13
	Baseline	Intervention visits	Post-intervention assessment	1-Month follow-up assessment
Informed consent	x			
Assessment/questionnaires	x	x	x	x
Cognitive assessments	x		x	x
Behavioral tasks	x		x	x
Cognitive training programs		x		
tDCS		x		

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

If you take part in this research, you will be responsible for: attending the required research, answering questionnaires and completing behavioral tasks as outlined above.

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

If you take part in this research study, and want to leave, you should tell us. Your choice not to be in this study will not negatively affect your right to any present or future medical care, your academic standing as a student, or your present or future employment.

We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

Can I be removed from the research?

It's possible that we will have to ask you to leave the study before you finish it. If this happens, we will tell you why. Some of the reasons could include a decrease in your weight of 2lbs or more per week or an increase in AN symptom. If you develop sores at the tDCS administration site, headaches, or if the study staff is concerned about your overall health.

You should not be or become pregnant while in this research study. If you think you may be pregnant, please let the study staff know right away. If you become pregnant you will be asked to stop the study treatment.

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

Taking part in this research study will not lead to any costs to you. All assessments and procedures performed for the study will be covered by the research.

You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay. In some cases, insurance will not pay for services ordinarily covered because these services are performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.

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

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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 to be collected and used by study teams as part of the research study you are participating in.

If the research study you are participating in requires the sensitive information below, the "Applicable" box will be marked by the study team and you will be asked to indicate whether you permit or refuse the collection of this information by the research team, as described in the Consent Form, by providing your initials next to the correlating statement. Note, if you refuse the collection of this information, you may not be able to participate in the study. Please let the study team know if you have any questions about this.

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If the research study you are participating in will not be collecting the sensitive information below, the N/A box will be marked by the study team and you will be asked to provide your initials under "**N/A"** next to the correlating statement.

Note: Initials must be obtained for each line item to acknowledge either 1) permission or refusal granted to collect the applicable information or 2) non applicability. Furthermore, if any of the sensitive health information becomes relevant at any point in the study (i.e. changing from "N/A" to "Applicable"), study teams are required to update this section accordingly and request that participants complete and sign the entirety of this form again.

Checked by Study Team			**Initialed by Research Participant**		
Yes (Applicable to study)	**N/A (Not applicable to study)**		**Yes (willing)**	**No (unwilling)**	**N/A (Not applicable to study)**
☐	☒	My drug and alcohol abuse, diagnosis and treatment records	_____	_____	_____
☐	☒	My HIV/AIDS testing records	_____	_____	_____
☐	☒	My genetic testing records	_____	_____	_____
☐	☒	My mental health diagnosis/treatment records	_____	_____	_____
☐	☒	My sickle cell anemia records	_____	_____	_____

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;

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- 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.

The study team may break confidentiality in an effort to keep you safe, which may include informing parents, local authorities, and/or health care professionals.

If you tell us that you are thinking about hurting yourself or others, the research staff may ask more questions. Depending on how intense your thoughts are or how much you feel like hurting yourself or others, the research staff may give you referrals for treatment, work with you to contact a personal doctor, trusted family member, or therapist to discuss your thoughts of harming yourself . We may need to work with you on a plan that might include getting to a medical facility for safety.

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 within preceding three years 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.

- *More information about Minnesota's Reportable Disease Rule:
  - FAQ Link: chrome-https://www.health.state.mn.us/diseases/reportable/rule/hippacomm.pdf
  - List of diseases: chrome-https://www.health.state.mn.us/diseases/reportable/rule/poster.pdf

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

We will use and may share data and/or specimens for future research. They may be shared with researchers/institutions outside of the 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 data and/or 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 or data.

Optional Consent for Future Use of Identifiable Data

At the completion of this research study, we would like to store and be able to use and share your identifiable data and/or health information with researchers
other research related to restrictive eating disorder. Any research that involves identifiable information will be reviewed by an Institutional Review Board (IRB), which is the committee that provides ethical and regulatory oversight of research at the University, prior to use. Because these specimens and/or health information are identifiable, we are asking your permission to store, use and share these for other research.

If you leave the study, you can ask to have the data collected about you removed or the samples destroyed. You can also ask us to remove information that identifies you from the data or samples. This may not be possible if your samples and data have already been shared.

Please indicate whether you will allow the identifiable data to be used for future research by putting your initials next to one of the following choices:

_____ (initials) NO, my identifiable data may not be used for future research. They may be used for this study only.
_____ (initials) YES, my identifiable data may be used for other future research studies

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.

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You may also want to ask someone on the research team if 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.

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

Will 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 (or a recording of 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 (or a recording of your consent meeting) without your permission ahead of time.

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

To reach the research team: Please see the "Investigator Contact Information" section at the beginning of this form.

To reach someone outside of the research team: 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.

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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.

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 a total of up to $120 in an amazon gift card for your time and effort. You will receive payment at the end of your participation. You will be reimbursed for parking or transportation expenses at follow up visits. Your payment for participation will be based on attempted and/or completed procedures as follows:

- $60 for Visit 1 – screening/baseline visit
- $30 for end of treatment follow-up session – Visit 12
- $30 for 1-month follow-up session – Visit 13

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.

Optional research activity:

The research study that you are participating in might have optional research activities associated with it, meaning that you do not have to agree to these activities in order to participate in the research study. Please indicate your willingness to participate in these optional activities and authorize use of your information from these optional activities as described below by placing your initials next to each activity.

If the research study you are participating in has optional research activities associated with it, the "**Applicable**" box will be marked by the study team and you will be asked to indicate whether or not you are willing to participate in these optional activities by providing your initials next to the correlating statement.

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If the research study you are participating in will not have optional research activities associated with it, the N/A box will be marked by the study team and you will be asked to provide your initials under "**N/A**" next to the correlating statement.

Checked by Study Team			Initialed by Research Participant		
Yes (Applicable to study)	**N/A (Not applicable to study)**		**Yes (willing)**	**No (unwilling)**	**N/A (Not applicable to study)**
☒	☐	The investigator for this research may contact me in the future to see whether I am interested in participating in other research studies conducted by the investigator.	_____	_____	_____

Signature Block for Capable Adult:

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

_____ _____

Signature of Participant Date

_____

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Printed Name of Participant

_____ _____
Signature of Person Obtaining Consent Date

_____
Printed Name of Person Obtaining Consent

Signature Block for Witness:

WITNESS STATEMENT:
The participant was unable to read or sign this consent form because of the following reason:

☐ The participant is illiterate

☐ The participant is visually impaired

☐ The participant is physically unable to sign the consent form. Please describe:

_____

☐ Other *(please specify)*:

_____

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