Study Title: Delivery of an At-Home Nonpharmacologic Intervention (Transcranial Neurostimulation) to Mitigate Pain in Patients With End Stage Kidney Disease Receiving Hemodialysis
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Weill Cornell Medicine

Consent Form and HIPAA Authorization for Research

Project Title:	Delivery of an At-Home Nonpharmacologic Intervention (Transcranial Neurostimulation) to Mitigate Pain in Patients with End Stage Kidney Disease Receiving Hemodialysis
Research Project/Protocol #:	21-07023793 (WCM), #22048 (Salus IRB)
Investigators:	Cary Reid, MD, PhD Weill Cornell Medicine (WCM) Lara Dhingra, PhD Metropolitan Jewish Health System (MJHS)
Arm/Group	Patients
Subject Name or number:	

Please note, are you currently or have you been (within the last 6 months) a participant in any other research study at Weill Cornell Medicine, NewYork-Presbyterian or elsewhere? If so, please inform the research team.

INSTITUTION: Weill Cornell Medicine, Metropolitan Jewish Health System, Rogosin Institute, Atlantic Dialysis Management Systems, DaVita Kidney Care

INTRODUCTION

You are being asked to participate in a research study because you are 21 years of age or older and are currently receiving hemodialysis treatments.
Please take your time to make your decision. It is important that you are informed of several general principles that apply to all who take part in our studies:

(a) Taking part in the study is entirely voluntary.
(b) If you choose not to participate in the study or if you agree now and your decision changes, your regular care will not be affected. In addition, there will be no penalty or loss of any benefits to which you are otherwise entitled.
(c) Personal benefit to you may or may not result from taking part in the study, but knowledge gained from your participation may benefit others.

The purpose and nature of the study, possible benefits, risks, and discomforts, other options, your rights as a research participant, and other important information about the study are discussed below. Any new information discovered which might affect your decision to participate or remain in the study will be provided to you while you are a participant in this study. You are urged to ask any questions you have about this study with members of the research team. Please take whatever time you need to discuss the study with your physician and family/loved ones/friends. The decision to participate or not to participate is yours. If you decide to participate, please sign and date where indicated at the end of this form.

The research study is being funded by the National Institutes of Health (NIH). That means the NIH is providing a research grant/funds to conduct this study. Drs. Cary Reid and Lara Dhingra are the primary investigators.

The study will be conducted by:

- Rogosin Institute: Patient participants will be recruited from Rogosin Institute dialysis sites. Once recruited, participants will be registered in the study through WCM.
- Atlantic Dialysis Management Systems: Patient participants will be recruited from dialysis clinics within the Atlantic Dialysis Management Sytem. Once recruited, participants will be registered in the study through WCM.
- DaVita Kidney Care: Patient participants will be recruited from dialysis clinics within the DaVita Kidney Care system. Once recruited, participants will be registered in the study through WCM.
- Weill Cornell Medicine (WCM): All participants will be enrolled at WCM. WCM will be responsible for data collection and data management through phone or videoconference.
- Metropolitan Jewish Health System – The MJHS Institute for Innovation in Palliative Care (MJHS): MJHS research team members will be responsible for all device activities including device storage, distribution, and training. MJHS will remotely monitor the procedure performed by study participants at home. There will be no in-person study procedures conducted at the MJHS site.

WHY IS THE STUDY BEING DONE?

The purpose of this study is to evaluate the usefulness of an at home small battery-operated device using a headband that delivers transcranial Direct Current Stimulation (tDCS) to see if it reduces pain in patients receiving hemodialysis (HD) treatments. The tDCS device is non-invasive (no surgical procedure is needed) and battery-operated, and provides painless stimulation to focused areas on your head using a headband. There is minimal risk associated with using a tDCS device. It is categorized as investigational, and all trials using this device to-date have been deemed as posing non-significant risk. We want to determine the benefits of using tDCS to treat pain because the current method of managing pain for people undergoing HD normally involves the use of medications that pose health risks.

People that use tDCS in research studies can continue taking their medications and receive their other treatments as usual.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

About 5000 participants will be screened and about 125 will be eligible and enrolled in the study. Some participants may need help using the device and can choose to have a caregiver assist during the study. All participants will be recruited at participating Rogosin Institute, Atlantic Dialysis Management System, or DaVita Kidney Care hemodialysis centers or at Weill Cornell Medicine/NewYork-Presbyterian offices, all of which are located in New York City and Long Island.

WHAT IS INVOLVED IN THE STUDY?

You will be “randomized” into one of two study groups: neurostimulation treatment (Group 1) or placebo treatment (Group 2). Placebo means that there is no real treatment (sham/fake). Randomization means that you are put into a group by chance. It is like flipping a coin. Neither you nor the researchers will choose what group you will be in. You will have an equal chance of

being placed in either group. Neither you nor the study staff interacting with you will know what group you are in, but the study doctor can find out if medically necessary.

After completing the informed consent process with a trained research team member, all participants—Groups 1 and 2—will complete the following study visits with the possible assistance of their selected caregiver:

- ***Consent and Screening (approx. 15 minutes).*** A Weill Cornell Medicine (WCM) research team member will ask you questions over the phone or by videoconference including questions about yourself (e.g., gender, marital status), thinking abilities, and level of pain. Some information will also be collected from your electronic medical record such as when you started to receive dialysis treatments, a list of your medications, and other chronic conditions you have (e.g., high blood pressure, arthritis).
- ***Device Training (approx. 75 minutes).*** A research team member will provide instructions on how to use the device. This training will take place in your home (or depending upon COVID restrictions may take place virtually, for example by way of Zoom). The research team member will answer all questions and ensure you are comfortable and ready to use the device at home. You will also be able to call at any time if you have questions about the device; a member of the study team will answer your questions. You will be randomized into Group 1 (neurostimulation) or Group 2 (placebo) following this visit. At the end of the study, you will be told the group you were in.
- ***Baseline Survey (approx. 45 minutes).*** You will complete a baseline survey (that will include questions about your pain, medication use, mood, and quality of life) over the phone or videoconference with a WCM staff member. Then, you will go over how to use the device again and ensure you are prepared for the 8 weeks of at-home device self-administration with an MJHS staff member in-person or via videoconference. This assessment and the training can be split into two visits for your convenience. Additionally, prior to this visit, you will be given a personalized 5-day medication look back worksheet or survey links and will receive text or email reminders to fill this out for the 5 days prior to the visit.
- ***Medication Look Back (prior to study surveys).*** One week prior to each survey visit, a study staff member will call you to learn whether any of the medications you take to help manage pain have changed and to remind you about recording your pain medication use over a 5-day period. You will also receive daily text messages reminding you to write this information down and asking if you did it. Some individuals may get links directly to personalized surveys to fill out instead.
- ***Self-Administration of Device Treatments Sessions (8 weeks).*** After the first 20-minute session, the sessions will continue five times a week (Monday through Friday) for 8 consecutive weeks for a total of 40 sessions. MJHS study staff will contact you before your session to give you a unique session start code and again at the end of your session to collect your unique completion code from your device. The staff will also be available via phone or videoconference for technical assistance. You will not need internet access to do any of these sessions since the tablet that comes with the device will be able to connect to the internet. You and/or your caregiver will take a photo (of only the forehead, never the face) during these sessions to make sure the stimulation pads are in the right place. You will send these photos to the study team via text or email and they will be stored on secure servers.

- ***Follow-Up Surveys (Weeks 2, 8, 12, 16, and 26; approximately 45 minutes each).*** You will complete follow-up surveys 5 times after your initial assessment. Surveys will be completed with a research staff member at 2, 8, 12, 16, and 26 weeks after the initial stimulation visit and will include many of the same questions. Some additional questions will be asked in week 8 (end of tDCS device use) and at week 26 (end of study). All of these visits will be done over the phone or by videoconference.

You will have the option to identify a caregiver to help you in this study. Participation of a caregiver is recommended, though not required. If you agree, this individual can be with you for your study visits, receive training on how to use and set up the device, help you to fill out the study surveys, and provide any other help while you take part in this study. We will not reveal any information obtained from your participation in this study to your caregiver without your permission. If you choose to include a caregiver study partner, they will be provided with an information sheet to help explain their role in the study. The research team members will be available to answer any questions. Please indicate if you agree to involve a caregiver study partner:

☐ I do agree to include a caregiver study partner.

☐ I do not agree to include a caregiver study partner.

Some patients may be asked to be "patient ambassadors" that will speak about their experiences with the study with other potential participants. These ambassadors may speak to other potential participants on the phone, by videoconference, and/or in-person (at their own clinic) or may be asked to be recorded for a short video. This is optional for only interested participants. No data will be collected as part of this program.

HOW LONG WILL I BE IN THE STUDY?

You will be in the study for a maximum of 7 months. You can stop participating at any time. However, if you decide to stop participating, we encourage you to talk to the researcher and your regular doctor first. If you choose to leave the study, your regular care will not be affected, nor will you lose any benefits to which you are otherwise entitled. In addition, your relations with the Rogosin Institute, Atlantic Dialysis Management Systems, DaVita Kidney Care, WCM, NewYork-Presbyterian, MJHS, your physicians, or other personnel will not be affected.

WITHDRAWAL BY INVESTIGATOR, PHYSICIAN, OR SPONSOR

The investigators, study physicians, or sponsors may stop the study or take you out of the study at any time if they feel it is in your best interest, if you experience a study-related injury, if you need additional or different medication, or if you do not follow the study plan. They may remove you from the study for various other administrative and medical reasons. They can do this without your consent.

WHAT ARE THE RISKS OF THE STUDY?

Participating in research involves some risks.

All questions asked of you (in your baseline and follow-up assessments) pose minimal risk, but may cause increased stress, anxiety, and fatigue as they may ask you to relay information regarding sometimes sensitive emotions and feelings.

There is also a risk of breach of confidentiality resulting in embarrassment or even prejudicial treatment by others. All efforts and strict procedures will be made to protect your personal and health information to the extent allowed by law.

Risks and possible side effects related to the device we are studying include: Slight itching, tingling, and reddening of the skin under the stimulation pads. The risks associated with this device are considered to be minimal. tDCS has been used on thousands of people around the world and has not caused any serious side effects. In all previous tDCS studies examining the device, the US Food and Drug Administration (FDA) and human subjects' protection boards (Institutional Review Boards) have labeled the device to not pose a significant risk to users. However, we will be monitoring you closely for any side effects.

If you have any questions about risks and side effects, please speak with a member of the research team.

ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?

You may not receive any benefits from this study. If you are in Group 1, the effects of neurostimulation for some participants may include pain relief, decreased medication intake, and improved quality of life. Some participants may get no pain relief from the stimulation.

If you are in Group 2, you will not receive any benefit from the sessions, any pain relief would be a result of a placebo effect.

We hope this device, developed for easy use at home and in HD centers, could improve the ability to manage pain in HD patients.

WHAT OTHER OPTIONS ARE THERE?

Instead of being in this study, you may choose not to participate in this study. You are also encouraged to continue your regular treatment plan for ESKD with your medical provider.

WHAT ABOUT CONFIDENTIALITY?

Efforts will be made to protect your medical records and other personal information to the extent allowed by law. However, we cannot guarantee absolute confidentiality. Records of study participants are stored and kept according to legal requirements and may be part of your medial record. You will not be identified personally in any reports or publications resulting from this study. Organizations that may request to inspect and/or copy your research and medical records for quality assurance and data analysis include groups such as:

- Weill Cornell Medicine/NewYork-Presbyterian
- Metropolitan Jewish Health System
- Rogosin Institute
- Atlantic Dialysis Management Systems
- DaVita Kidney Care
- Cornell University
- The WCM Institutional Review Board (IRB)
- Salus Institutional Review Board (IRB)
- The Office of Human Research Protections (OHRP)
- Department of Health and Human Services
- National Institutes of Health

By signing this consent form, you authorize access to this confidential information. You also authorize the release of your medical records to Weill Cornell Medicine/NewYork-Presbyterian by any other hospitals or institutions where you might receive medical care of any kind while you are participating in this study.

If information about your participation in this study is stored in a computer, we will take the following precautions to protect it from unauthorized disclosure, tampering, or damage by requiring a unique ID and password to log into the database. Master lists linking participants with their questionnaire and device-use data will be stored in locked file cabinets and/or as password protected documents on a secure server. In addition, only personnel who are associated with the study will have access to the study specific records in the database.

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.

HIPAA AUTHORIZATION TO USE OR DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH

Purposes for Using or Sharing Protected Health Information: If you decide to take part in this study, WCM researchers need your permission to use your protected health information. If you give permission, Weill Cornell Medicine (WCM) and/or NewYork-Presbyterian (NYP) researchers may use your information or share (disclose) information under strict guidelines about you for their research that is considered to be protected health information. Additionally, if your health provider is outside the Weill Cornell Medicine/NewYork-Presbyterian, Atlantic Dialysis Management Systems, or DaVita Kidney Care network we may request to speak to your physician (e.g., nephrologist, primary care doctor). We may also ask you to share your medical record concerning your care (e.g., sharing from app, requesting from physician). In this case we will ask you to fill out a Medical Release Consent form. This will not affect your ability to get treatment from those health care providers nor affect your participation in the study, and you have the right to decline access anytime.

Voluntary Choice: The choice to give WCM and/or NYP researchers permission to use or share your protected health information for their research is voluntary. It is completely up to you. No one can force you to give permission. However, you must give permission for WCM and/or NYP researchers to use or share your protected health information if you want to participate in the study. If you decline to sign this form, you cannot participate in this study, because the researchers will not be able to obtain and/or use the information they need in order to conduct their research. Refusing to give permission will not affect your ability to get usual treatment, or health care, from WCM and/or NYP.

Protected Health Information To Be Used or Shared: Government rules require that researchers get your permission (authorization) to use or share your protected health information. Your medical information may be disclosed to authorized public health or government officials for public health activities when required or authorized by law. If you give permission, the researchers could use or share with the entities identified above any protected health information related to this research study from your electronic medical records.

Other Use and Sharing of Protected Health Information: If you give permission, the researchers could also use your protected health information to develop new procedures or commercial products. They could share your protected health information with the study sponsor, the WCM Institutional Review Board, Salus Institutional Review Board, inspectors who check the research, government agencies, and research study staff. The researchers could also share your protected health information with researchers at MJHS, the Rogosin Institute, Atlantic Dialysis Management Systems, DaVita Kidney Care, and Cornell University.

The information that may be shared with the sponsor and/or government agencies could include your medical record and your research record related to this study. They may not be considered covered entities under the Privacy Rule and your information would not be subject to protections under the Privacy Rule.

CANCELING AUTHORIZATION

Canceling Permission: If you give the WCM and/or NYP researchers permission to use or share your protected health information, you have the right to cancel your permission whenever you want. However, canceling your permission will not apply to information that the researchers have already used or shared.

If you wish to cancel your permission, you may do so at any time by contacting the Privacy Office:

Address: Weill Cornell Medicine Privacy Office

1300 York Avenue, Box 303 Email: privacy@med.cornell.edu

New York, NY 10065

If you have questions about this and would like to discuss, call (646) 962-6930.

Permission Period: Unless you cancel it, permission for WCM and/or NYP researchers to use or share your protected health information for their research will never end.

ACCESS TO RESEARCH RECORDS

During the course of this study, **you will have access** to see or copy your protected health information in accordance with WCM and/or NYP policies. During your participation in this study, you will have access to your research record and any study information that is part of that record with the exception that the group assignment (neurostimulation treatment or placebo treatment) will not be shared until you complete the study.

WHAT ARE THE COSTS?

There are no costs to you for participating in this study. Upon completion of the study, you will be asked to return the device to the study team. While you will not be held responsible if the device is damaged, lost, or stolen, we do ask that you keep the device in its protective case and store in a safe place.

POLICY/PROCEDURES FOR RESEARCH RELATED INJURY

The Policy and Procedure for Weill Cornell Medicine are as follows:

We are obligated to inform you about WCM's policy in the event injury occurs. If, as a result of your participation, you experience injury from known or unknown risks of the research procedures as described, immediate medical care and treatment, including hospitalization, if necessary, will be available at the usual charge for such treatment. No monetary compensation is available from WCM. You are not giving up any of your rights by participating in this study.

COMPENSATION FOR PARTICIPATION

You will be compensated up to $400 for participating in this study. This amount is broken down as follows: $50 upon completion of your baseline questionnaire and device training visit, $50 per completed questionnaire at weeks 2, 12, and, 16, and $100 for completing the 8 week and for the final study survey at 26 weeks. This will be given to you in the form of a ClinCard. ClinCard can be used as a credit or debit card and funds will be available to you within 5 business days after you complete your study visit. Please also review the ClinCard letter and ClinCard Frequently Asked Questions provided to you by the study staff.

If we find that you are not a good fit for the study at the screening visit or initial training visit, you will receive a $25 gift card (e.g., American Express, VISA, Amazon) for your time and effort.

Patient ambassadors will be paid by a choice of gift card (e.g., Amazon, American Express) and the amount will vary based on their role. This will be determined individually with a range from $25-500.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

Taking part in this study is voluntary. You may choose to not take part in the study or to leave the study at any time. If you choose to not participate in the study or to leave the study, your regular care will not be affected nor will your relations with Weill Cornell Medicine, NewYork-Presbyterian, the Rogosin Institute, Atlantic Dialysis Management Systems, DaVita Kidney Care, Metropolitan Jewish Health System, your physicians, or other personnel. In addition, you will not lose any of the benefits to which you are entitled.

We will tell you about new information that may affect your health, welfare, or participation in this study.

A Data Safety and Monitoring Board, an independent group of experts, will be reviewing the results generated from this research throughout the study. We will tell you about the new information from this or other studies that may affect your health, welfare, or willingness to stay in this study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

To provide input, for questions about the study, to report a research-related injury, any problems, unexpected physical or psychological discomforts, or if you think that something unusual or unexpected is happening, call Dr. Cary Reid at 212-746-1378 or email him at mcr2004@med.cornell.edu. If you are calling on a Saturday or Sunday, or on a weekday before 9am or after 5pm, call the Center on Aging at 212-746-7000 and ask to be connected to the physician on call. Be sure to inform the physician of your participation in this study.

If you have questions about your rights as a research participant, contact the Salus IRB. Reference study 22048 and direct your questions by phone at (800) 472-3241 or by email at subject@salusirb.com.

PARTICIPANT'S STATEMENT

I have been informed about this study's purpose, procedures, possible benefits and risks, and I have received a copy of this consent. I have been given the opportunity to ask questions before I sign, and I have been told that I can ask other questions at any time. I voluntarily agree to participate in this study. I am free to withdraw from the study at any time without need to justify my decision. This withdrawal will not in any way affect my future treatment or medical management and I will have no penalty or will not lose any benefits to which I otherwise am entitled. I agree to have my forehead photographed, if needed. I agree to cooperate with Dr. Cary Reid and the research staff and to inform them immediately if I experience any unexpected or unusual symptoms.

Signature of Participant	Print Name of Participant	Date

RESEARCHER'S STATEMENT

I have fully explained this study to the participant. As a representative of this study, I have explained the purpose, the procedures, the benefits and risks that are involved in this research study. Any questions that have been raised have been answered to the individual's satisfaction.

Signature of person obtaining consent (Study Investigator or designated staff)	Print Name of Person	Date