MOD00003574
FSU IRB Approved
19 June 2023

Permission to Take Part in a Human Research Study

Title of research study: ***Feasibility, acceptability, and preliminary efficacy of combined transcranial direct current stimulation and mindfulness for pain after total knee arthroplasty (STUDY 00003476)***

Investigator: Geraldine Martorella, RN, PhD, FAAN, Associate professor, College of Nursing

Key Information: The following is a short summary of this study to help you decide whether to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

We invite you to take part in a research study because you are between 50 and 85 years old and are scheduled for a total knee replacement surgery.

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?

The reason that we are doing this research is to evaluate if pain relief and recovery after major surgery can be improved by using brain stimulation (tDCS) and mindfulness-based meditation. Brain stimulation provides a very weak electrical current to the scalp to help activate areas of the brain. The thought is that using this device with meditation before surgery could reduce pain after surgery.

How long will the research last and what will I need to do?

We expect that you will be in this research study for 1 month including 2 visits at our lab at Florida State University (about 2 hours each). In addition to you receiving your physician's standard of care, you will receive 5 treatments. Each treatment lasts 20 minutes. We will monitor these treatment sessions through a secure video conferencing platform (e.g. Zoom)

You will be asked to complete questionnaires at the beginning of the study (enrollment) and we will take some measures in our lab. We will also contact you to ask questions about pain and medication the first 5 days after surgery and 1 month after surgery.

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 being in this study could be bad for me?

The risks or discomforts to you of taking part in this study include that you may become uncomfortable at answering some questions and that some activities may make you tired.

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

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Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include that you may experience less pain after surgery, take less medication and find out more about yourself or your condition and you may learn some new skills about dealing with pain and postoperative recovery. You will also help researchers learn more about pain after major surgery so that service or treatment can be improved.

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

Participation in research is completely voluntary. You can decide to participate or not to participate.

Your alternative to participating in this research study is to not participate.

Your decision will not affect your relationship with your physician and the clinic.

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

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at Phone number: 850-644-6012 or 850-645-4826.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at 850-644-7900 or humansubjects@fsu.edu 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 subject.
- You want to get information or provide input about this research.

How many people will be studied?

We expect about 40 people here will be in this research study out of 40 people in the entire study nationally.

What happens if I say "yes" to being in this research?

Two groups of participants will be randomly created (by flipping a coin): one group receiving the full-length brain stimulation and meditation and one group receiving a shorter version of brain stimulation and meditation. The shorter version of stimulation is performed in the same way as the longer electrical stimulation session, but stimulation is stopped before it can have much of an effect on the brain. ***If you agree to be in this research, regardless of the group you are assigned to, your participation will include 2 visits to the FSU lab (innovation park) lasting about 2 hours before your surgery and completing questionnaires at 4 different times (at enrollment, before surgery, after surgery, and 1 month after).*** Regardless of the group you are assigned to, in addition to you receiving your physician's standard of care, you will be asked to schedule appointments for 3 days before surgery so we can guide you remotely (via zoom) with the treatment. You will receive 5 treatments. Each home treatment lasts about 20 minutes. We will tell you about any new information that may affect your willingness to continue to take part in this research.
Neither you nor the study staff will choose what treatment you get. You will have an equal chance of being given each treatment. Neither you nor the study staff will know which treatment you are getting as they both look the same. The brain stimulation technique called transcranial direct current stimulation (tDCS) involves placing two sponge-like electrodes on your head and delivering a very weak electrical current to your scalp, which is generated by a 9V battery. Then, for 3 days you will use the tDCS device at home while you practice meditation for 20 minutes. The device is preprogrammed, and you will be shown how to place and start the device. While you are receiving brain stimulation, you will also be asked to practice meditation. You will get specific meditation audio instructions via a CD player or zoom, and each session lasts about 20 minutes. The meditation instruction will include instructions on deep breathing and lower any distracting thoughts or feelings. There is a 50% chance you will receive the standard meditation and a 50% chance that you will receive focused meditation. Both of these meditations include deep breathing, but the focused version includes some more specific instructions to increase your ability to focus on lowering any distracting thoughts or feelings that might happen during the deep breathing.

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In addition, the study team will use video conferencing with you during the treatment session. They will be able to help answer any questions and can help if there are any problems. The study team will administer a brief symptom screening questionnaire at the end of each session. No matter what group you are randomly assigned to, we will collect medical history questionnaire, clinical pain assessments, and medication.

Pregnancy Test. If you are a woman of childbearing potential age, you will be asked to do a pregnancy test at our laboratory by providing a sample of urine. Please tell study staff if you had surgery to remove your uterus.
Questionnaires. We will ask you to fill out a few questionnaires to help us understand about arthritis pain you are having and your thoughts and feelings about it. Some questionnaires ask how you are feeling at the present or how you have felt over the last week. We will also ask questions about your physical activity and if you use drugs. Some of these questions may cause you to feel upset or sad, and if that happens, please tell the study team member so that we can discuss these feelings with you. You do not have to answer any questions that you are not comfortable to answer.
Thermal Pain Stimulation. Thermal pain stimulation will be used via a commercially available thermal sensory testing machine (Medoc, Inc.).
This machine used widely in clinical settings and has a small (about 1 inch by 1 inch) square piece that is used to apply heat to the skin. We will apply the heat to one of arms. You can stop the procedures at any time so that you do not experience pain you find unacceptable.
Assessment of Sensitivity to Pressure. Pressure sensitivity will be tested using a commercially available handheld device (Wagner, Inc.) used widely in clinical settings. We will use a handheld device with a small (less than ½ an inch wide) rubber tip to apply pressure to the knee that hurts you the most, and to your shoulder. The pressure will be slowly increased, and you will be asked to tell the examiner when you begin to feel discomfort or mild pain. As soon as you tell us you feel pain, the pressure will be removed.
Assessment of Sensitivity to Mechanical Stimulation. Mechanical stimulation sensitivity will be tested using a commercially available handheld probe (North Coast Medical, Inc.) used widely in clinical settings. We will use a handheld probe that has a small nylon tip to tap your knee and your hand. We will ask you to tell us how painful this feels.
Assessment of Sensitivity to Combined Pressure and Cold. We will measure pressure sensitivity combined with cold test by putting your hand in cold water and telling us how painful it feels. While your hand is in the water and after you take your hand out of the cold water, we will repeat the pressure sensitivity test.
We will monitor all the sessions of brain stimulation with meditation through a secure video conferencing platform (e.g., Zoom). You must have a device with internet access (e.g., smart phone or laptop) that can be used for secure video conferencing for real-time remote supervision. The study team member will contact you by phone, mail, or e-mail in order to schedule your study visits.

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

If you take part in this research, you will be responsible to do two visits to our lab at Florida State University (innovation park). Each lab visit will last approximately 2 hours. Also, we will ask you to do 2 sessions of 20-minute of brain stimulation (tDCS) and meditation at your home daily for 2.5 days (total of 5 sessions), and we will monitor through a video conferencing platform (e.g. Zoom).

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

You can leave the research at any time it will not be held against you. Your decision will not affect your relationship with your physician and the clinic. If you decide to leave the research, contact the investigator at 850-644-6012 or 850-645-4826. If you withdraw from this study, your research information will no longer be collected. However, information that has already been collected may continue to be used to the retain integrity of the research data.

Is there any way being in this study could be bad for me? (Detailed Risks)

While on this study, you are at risk for side effects. The study team member will discuss these risks with you. This study may include risks that are unknown at this time.
This study might involve the following risks and discomforts:
Pregnancy Test. You may not know that you are pregnant, and the results of the pregnancy test will alert you to the fact. Pregnant women will be excluded from the study. If you are a woman able to become pregnant, a urine pregnancy test will be done, and it must be negative before you can continue in this study.
Questionnaires. You may get tired while answering questions or completing questionnaires. You do not have to answer any questions you do not want to answer.
Self-Brain Stimulation. Brain Stimulation is considered safe and has been used in more than 3,000 research subjects around the world. This type of stimulation has not caused serious side effects. A small number of people do experience some side effects. The most common side effects include itching and tingling or mild discomfort at the area of stimulation, and headache. Other possible side effects include dizziness and nausea.
Thermal Pain Stimulation. Thermal pain stimulation procedure may be uncomfortable or unpleasant. You will experience some temporary discomfort. However, if your pain is greater than you wish to tolerate, you can stop any of the procedures at any time and decide not to participate. There is a very low risk that the heating device may produce a burn.
Assessment of Sensitivity to Pressure/Mechanical Stimulation/Cold. The pain testing procedures may be uncomfortable or unpleasant. You will experience some temporary discomfort from the pressure, and cold pain testing. However, if your pain is greater than you wish to tolerate, you can stop any of the procedures at any time and decide not to participate.
Confidentiality. Researchers will take appropriate steps to protect any information they collect about you. However, there is a possible risk of breach of confidentiality.

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 secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.
If identifiers are removed from your identifiable private information or identifiable samples that are collected during this research, that information or those samples could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.
We may publish the results of this research. However, we will keep your name and other identifying information confidential to the extent allowed by law.
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.

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Can I be removed from the research without my OK?

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: failure to comply with the instructions given to you by the investigators, failure to complete all testing sessions, if the study is discontinued for administrative reasons, should you develop a health condition that could interfere with your participation, or the investigator may determine that it is not in your best interest. We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

What else do I need to know?

The study is supported by the *Florida State University's Institute for successful longevity*.

You will receive $100 for participating in this study ($25 per completed questionnaire) in the form of gift cards.

If you need medical care because of taking part in this research study, contact the investigator and medical care will be made available. Generally, this care will be billed to you, your insurance, or other third party. Florida State University has no program to pay for medical care for research-related injury. If you agree to take part in this research study, you will be paid for your participation in this study.

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Signature Block for Capable Adult

Your signature documents your permission to take part in this research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	

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