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08/26/2022

MCW IRB

Medical College of Wisconsin

INTRODUCTION TO THE INFORMED CONSENT

Hand Dexterity Training in Degenerative Cervical Myelopathy (DCM)

CENTRAL SITE
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Definitions

Degenerative cervical myelopathy (DCM) – most common cause of non-traumatic spinal cord injury.
Electroencephalography (EEG) – sensors placed on the scalp to measure brain activity.
Actuated Virtual Keyboard (AVK) – a virtual training program. You will wear a glove and movement of your finger(s) produces corresponding movement of virtual finger(s) to play the virtual keys.

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Purpose

This project is being done to improve hand dexterity in participants with DCM who have undergone surgical spinal cord decompression.

Length

- You will be in this research project for about 11 weeks.

Procedures *or* Activities

List of visits:

- Baseline/Week 1
  - Total Time: 1-2hr
  - Functional hand tests, questionnaires, and EEG
- Weeks 2-5
  - Total Time: 1hr/day; 3 days/week
  - AVK Training Sessions
- Week 5 or 6
  - Total Time: 1-2hr
  - Functional hand tests, questionnaires, and EEG
- Weeks 6-8
  - No research activities
- Week 9 or 10
  - Total Time: 1-2hr
  - Functional hand tests, questionnaires, and EEG

Procedures/Activities that will occur at various visits:

Invasive Procedures/Activities

- None

Non-invasive Procedures/Activities

- Functional hand assessments
- Questionnaires about your diagnosis, symptoms, and recovery
- Perform hand/finger muscle activation activities while wearing a glove
- Record brain activity from sensors placed on your scalp

Risks

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

EEG & Functional Tests risks:

- Physical discomfort or pain
- Fatigue
- Scalp irritation

There is also a risk to confidentiality as more people will see your private health information.

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Benefits

This project may or may not help you, but we hope the information from this project will help us develop a better treatment for finger individuation and hand dexterity in DCM.

My Other Options

You do not have to join this project. You are free to say yes or no.

- Whether or not you join this project, your usual medical services will not change.

If you have more questions about this project at any time, you can call Dr. Aditya Vedantam at 414-955-7300.

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

CONSENT TO PARTICIPATE IN RESEARCH

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

You are being invited to participate in this research because you have been diagnosed with cervical myelopathy and had surgery for your condition.

Under federal regulations, a group of people (called an Institutional Review Board) is required to review human research projects to make sure appropriate protections are in place for research subjects. The IRB at the Medical College of Wisconsin (MCW) will be reviewing this project for all sites involved, which is why MCW contact information and the MCW Principal Investigator's name have been included in this consent form.

A total of about 30 people are expected to participate in this research all at the Medical College of Wisconsin/Froedtert Hospital.

The Director of the project at Medical College of Wisconsin is Dr. Aditya Vedantam in the Department of Neurosurgery. A research team works with Dr. Aditya Vedantam. You can ask who these people are.

The research doctor will be paid by the Sponsor, Advancing a Healthier Wisconsin Endowment (AHW) for carrying out this project.

A2. DO I HAVE TO PARTICIPATE?

You can decide whether to take part in this research or not. You are free to say yes or no. Even if you join this project, you do not have to stay in it. You may stop at any time. Take as much time as you need to make your choice.

A3. WHY IS THIS PROJECT BEING DONE?

The purpose of this project is to implement a novel virtual-reality based intervention to train hand dexterity in people after surgery for DCM. We will also perform EEG before and after training to assess alterations in brain activity patterns and their relationship with improved hand function after training. This project will potentially expand access to hand therapy, as well as improve health and reduce disability for people with DCM.

B1. WHAT WILL HAPPEN IF I PARTICIPATE?

For this project, the research team will assign you a unique code, such as a series of numbers and/or letters. When sending your project data to AHW, the research doctor will use your unique code instead of other information that could easily identify you.

The data that is recorded with your unique code rather than your name is called "key-coded data". The research doctor will keep a confidential list linking your name to your code and only the research doctor and authorized research team members will have access to this list.

Some study data will identify you (such as medical records), and the ways this data may be used and shared is described later in this form.

Baseline/Week 1: The visit will take place at Marquette University. It will take 1-2hr. At this visit you will perform functional hand tests that will involve writing, lifting, stacking, moving blocks and pegs, and pinching. You will also answer questionnaires. You will wear a cap on your head with EEG electrodes and respond to auditory cues by finger tapping.

Weeks 2-5: These visits will take place at Marquette University. They will take 1hr/day for 3 days a week. You will wear a custom glove with sensors to measure individual joint angles and control an avatar hand on the virtual scene by movement of the joints of you own fingers.

Week 5 or 6: The visit will take place at Marquette University. It will take 1-2hr. At this visit you will perform functional hand tests that will involve writing, lifting, stacking, moving blocks and pegs, and pinching. You will also answer questionnaires. You will wear a cap on your head with EEG electrodes and respond to auditory cues by finger tapping.

Weeks 6-8: No research activities

Week 9 or 10: The visit will take place at Marquette University. It will take 1-2hr. At this visit you will perform functional hand tests that will involve writing, lifting, stacking, moving blocks and pegs, and pinching. You will also answer questionnaires. You will wear a cap on your head with EEG electrodes and respond to auditory cues by finger tapping.

Video recording will be done during the AVK training sessions and functional hand testing to help us check for data quality. Videos will be saved in MCW password-protected storage. Permissions to the videos will be restricted to trained study staff.

Initial either 1 or 2:

1._____I do not want to be video recorded in this study. I understand I still can participate in other parts of the study.

2._____I agree to be video recorded in this study.

B2. HOW LONG WILL I BE IN THE PROJECT?

You will be in this research project for about 11 weeks.

B3. CAN I STOP BEING IN THE PROJECT?

You may stop at any time. If you decide to leave the project, please let the research team know. The research doctor may stop your participation in the project at any time for any reason without your consent. He will tell you if this happens.

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

We watch everyone in the project for unexpected problems. **You need to tell the research doctor or a member of the research team immediately if you experience any problems or become too upset.**

Questionnaires: You may feel that some of the questions we ask are stressful or upsetting. If you do not wish to answer a question, you may skip it and go to the next question, or you may stop immediately.

Risks of functional hand tests and EEG tasks: There are minor risks including muscle soreness, fatigue, and mild discomfort or scalp irritation due to the scalp electrodes and EEG cap. The electrodes do not produce any sensation and there is no risk of electric shock. A research technician will always observe you, but please tell him or her if you experience any discomfort, fatigue, or feel faint. If you cannot tolerate the test, the research technician will stop the task right away.
Another risk may be loss of confidentiality. Every effort will be made to keep your research records confidential but we cannot guarantee it. If you have questions, you can talk to the project director about whether this could apply to you.

C3. ARE THERE ANY BENEFITS TO TAKING PART IN THE PROJECT?

This project may or may not help you, but we hope the information from this project will help us develop a better treatment for finger individuation and hand dexterity in DCM.

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

There are no costs to you for any of the visits or services you receive in this project. If you have questions regarding costs, please contact Dr. Aditya Vedantam.
If you participate in this research, the costs of any necessary emergency medical treatment in the event of a research-related injury will be billed to you or your health insurance.

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

You will be paid $100 after your first training session week. You will be paid $100 after the post-training evaluation. You will be paid $200 after the follow-up evaluation. To pay you, we need your social security number. Any payment may be reportable as income on your taxes.

D3. WHAT OTHER HEALTHCARE CHOICES DO I HAVE?

You do not have to join this project. You are free to say yes or no.
Whether or not you join this project, your usual medical services will not change

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

Emergency medical treatment for injuries directly related to your participation in this research project will be provided to you. You or your health insurance will be billed for the costs of this emergency treatment. MCW will decide on a case by case basis if they will reimburse you or your insurer for emergency treatment costs. If your research-related injury requires medical care beyond this emergency treatment, you or your insurer will be responsible for the costs of this follow-up care. Currently, there is no plan for any additional financial payments.

If you believe that you have been injured because of your participation in this project, contact the research doctors right away. Contact information: Dr. Aditya Vedantam; 414-955-7300.

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

D6. WHO CAN ANSWER MY QUESTIONS ABOUT THE PROJECT?

- If you have more questions about this project at any time, you can call Dr. Aditya Vedantam at 414-955-7300.
- If you have questions about your rights as a research participant, want to report any problems or complaints, or offer input, you can call the MCW/Froedtert Hospital Research Subject Advocate at 414-955-8844.

E. PERMISSION TO COLLECT, USE AND SHARE HEALTH INFORMATION

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

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

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

The health information we will collect and use for this project is:
Health information collected during this project, such as, questionnaires
Medical records dating from when you join this project until the end of the study.
CT & MRI scans taken when you were first diagnosed with cervical myelopathy.

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

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

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

The research team may share your information with people who are not part of the research team because they planned, pay for, or work with us on this project. The federal Privacy Rule may no longer protect your health information once it leaves MCW/Froedtert Hospital/Marquette University. For this project, we plan to share information with those doctors, researchers or government representatives working with us on this project at the institutions or companies listed here:

Advancing a Healthier Wisconsin Endowment; Milwaukee, Wisconsin
Marquette University; Milwaukee, Wisconsin

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

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

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

If you sign this form, we plan to keep your information for 10 years after the research project ends in case we need to check it again for this project.

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

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

CONSENT TO PARTICIPATE

By signing my name below, I confirm the following:

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

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

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

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