Using Real-time fMRI Neurofeedback and Motor Imagery to Enhance Motor Timing and Precision in Cerebellar Ataxia

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If appropriate for this study, a scanned copy of the signed consent form should be uploaded to the participant's Epic/EMR record

Patient I.D. plate

RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol Title: **Using real-time fMRI neurofeedback and motor imagery to enhance motor timing and precision in cerebellar ataxia**

Application No.: **IRB00300264**

Sponsor/Supporter/Funded By: **National Institute of Neurological Disorders and Stroke (NINDS)**

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You are being asked to join a research study. Participation in this study is voluntary. Even if you decide to join now, you can change your mind later.

1. Research Summary (Key Information):

The information in this section is intended to be an introduction to the study only. Complete details of the study are listed in the sections below. If you are considering participation in the study, the entire document should be discussed with you before you make your final decision. You can ask questions about the study now and at any time in the future.

The purpose of this study is to improve motor function in people with cerebellar ataxia by using neuroimaging methods and mental imagery to "exercise" motor networks in the brain. We will do this by getting magnetic resonance imaging (MRI) scans of the brain while participants perform cognitive (thinking) and motor (movement) tasks. We are testing people with movement disorders that include cerebellar ataxia and spinocerebellar ataxias.

You will be in this study for a total of 24 days. Participation involves 1 in-person visit and 23 days of at-home research tasks. We would also like your permission to access your medical records. The first visit lasts about 3-4 hours, while the at-home tasks last approximately 10 minutes each day (5 days/week).

During the first visit, assessments will initially take place at Reed Hall (Dr. Marvel's laboratory) where you will be asked questions about your health and if applicable, you will be asked to fill out surveys that ask about your symptoms related to cerebellar ataxia or spinocerebellar ataxia. You will also be videotaped while completing balance and coordination tests. Afterwards, you will be escorted to Kennedy Krieger Institute where you will be asked to perform motor tasks inside and outside of the MRI scanner that will take about 60 minutes. Finally, you will be asked to complete at-home testing for 10-minute daily motor tests that will be performed on your home computer.

The main risks are that you may become tired or frustrated during testing or filling out surveys, bothered by the MRI machine noise, and by feelings of being closed in (claustrophobia). There is also the chance that information about you may become known to people outside of the study.

This is not a treatment study. You will not benefit directly from being in the study and there is no cost for participation

You will be paid $100 after completion of the study. If you park in a Johns Hopkins parking facility, you will receive a voucher for parking.

2. Why is this research being done?

This research is being done to study motor imagery as a means of rehabilitation to improve motor function in people with ataxia. We hope that the research will lead to a deeper understanding of how the brains of people with cerebellar ataxia reorganizes after "mental exercise". This research may identify therapeutic targets in the treatment of ataxia and other movement disorders.

Who can join this study?

Thirty people between the ages of 18-100 years who have been diagnosed with cerebellar ataxia or spinocerebellar ataxias may join.

3. What will happen if you join this study?

If you agree to be in this study, we will ask you to do the following things:

Visit #1

The entire duration of Visit #1 will last about 3-4 hours.

The first part of the visit will take place in Reed Hall (Dr. Marvel's laboratory). Note that as COVID-19 precautions warrant, we may choose to conduct some procedures remotely (e.g., at home via teleconference); however, the videorecorded assessment of balance and coordination will only be conducted in person.

- You may be asked to refrain from taking certain medications (e.g., sedatives) for an appropriate period of time prior to your in-person visit.
- We will ask you a series of questions about your health history, including conditions you may have, medications you may take or have taken, and if applicable, the impact of these on your symptoms. Completing these questions and the surveys will take about 30 minutes.
- Additional medical record information may be collected (not just limited to confirming diagnosis).
- We will perform neuropsychological assessments that will measure functions such as attention, short-term memory, language, and motor skills.
- We will administer the International Cooperative Ataxia Rating Scale (ICARS), which is an ataxia assessment in which you will undergo tests of balance and coordination that will be video recorded at Reed Hall.

MRI

Visit #1 will include an in-person MRI at the Kennedy Krieger Institute

- You will be asked to perform a motor and cognitive test inside the magnetic resonance imaging (MRI) scanner. In this test, you will tap in time with a cursor that flashes on the screen. Sometimes you will simply imagine that you are tapping in time with the cursor. Prior to the scan, you will be given instructions for the cognitive and motor test that will be done inside the MRI scanner.
- A study team member will escort you to the Kennedy Krieger Institute (KKI). At KKI, you will have a MRI exam as part of your participation in this research study.
- MRI scans create images of the body using a strong magnet and radio waves. There is no radiation involved in an MRI exam.
- To be sure that it is safe for you to have an MRI exam, you will be asked to complete standard MRI screening questionnaires.
- You may not take part in this study if you have any metal or device in your body which is not compatible with MRI. Examples include certain pacemakers, defibrillators, aneurysm clips, or other implanted electronic or metallic devices, shrapnel, or other metal.
    - If you have a history of metal in your head or eyes, you cannot take part in this study.
    - If you are a female capable of becoming pregnant, you may be asked to give a urine sample for pregnancy testing. The urine sample you provide for this research study will be processed and then immediately discarded. Your samples will be used as part of this research study only and will not be used or distributed for future research
- The MRI machine periodically makes loud banging noises. We will provide earplugs or headphones for you to wear during the MRI exam.
- During the exam, you will be able to hear the MRI staff. They will be able to see and hear you.
- We will study how the brain works by scanning your brain while you perform specific tasks that involve pressing buttons with your fingers.
- We will use EMG to record movement of your finger muscles while in the scanner. We will apply a skin prepping gel to the arm before applying the electrodes, and the electrodes will be removed after the scan.
- The MRI itself will take about 60 minutes.

Days 2-23

For days 2-23, we will ask you to do the following things at your home:

- You will be asked to perform motor tasks on your computer using an online website 5 times weekly using the strategies identified during your in-person visit. These tasks consist of measuring your progress from the beginning of therapy (baseline measure - day 2) with the end of therapy (final measure - day 23).
- You will be asked to fill out questionnaires following the motor tasks 5 times weekly.
- The motor tasks and questionnaires will take about 10 minutes to complete daily.

Video recordings:

As part of this research, we are requesting your permission to create and use video recording to help answer the research question. We use video recordings for certain tests to ensure correct scoring. Any recordings will not be used for advertising or non-study related purposes.

You should know that:

- You may request that the recordings be stopped at any time.
- Because your voice is considered identifiable and will be captured on these recordings, you must provide your consent for your personal health information (PHI) to be used in this study.

- Your face may be captured in the videos.
- If you agree to allow the recording and then change your mind, you may ask us to destroy that recording. If the recording has had all identifiers removed, we may not be able to do this.
- We will only use these recordings for the purposes of this research. Specifically, these videos will only be used for scoring purposes.

Please indicate your decision below by checking the appropriate statement:

_____I **agree** to allow the Principal Investigator and Johns Hopkins study team members to make and use video recordings of me for the purpose of this study.

_____I **do not agree** to allow the Principal Investigator and Johns Hopkins study team members to make and use video recordings of me for the purpose of this study.

_____ _____
Participant Signature Date

Incidental Findings

As part of this research study, you will undergo an imaging procedure. A qualified professional will review your research imaging. This research imaging will not include the full diagnostic information that you would get if your primary doctor referred you for imaging.

There is a possibility that while reviewing your imaging we may see an unexpected abnormality. This is called an "incidental finding."

We will let you know if we see such an incidental finding. Depending on the type of incidental finding, we may contact you by mail, email, or phone. In the case of a potential serious emergency, someone may go to your home.

A qualified person (usually a member of the research team) will talk to you if there is an incidental finding. You do not have an option to decline information about an incidental finding from an imaging procedure.

If you want, we will give information about this incidental finding to your primary doctor or we will refer you to an appropriate doctor for further evaluation.

What could happen if there is an incidental finding?

- An incidental finding may cause you to feel anxious.
- Since a report of the incidental finding will be part of your medical record, it will be available to those accessing your medical record for your clinical care and may affect your current or future life or health insurance coverage. This risk will vary depending on the type of insurance plan involved.

The costs for any care that may come from the incidental finding, such as the need to see a doctor to diagnose or treat an incidental finding, will not be paid for by this research study. These costs would be your or your insurance company's responsibility.

Will research test results be shared with you?

This study involves several different MRI scans. The clinical MRI scan can be released to you upon request. However, we do not expect the research MRI scans will be useful for your clinical care. We will not share these results with you.

Results from your cognitive tests may be clinically useful and can be released to you upon request.

You will not receive the results from the other tests because they will be done for research purposes only and will not be useful for your healthcare decisions.

How long will you be in the study?

You will be in this study for a total of 24 days. Visit #1, which is in-person, will take about 3-4 hours. For days 2-23, these will be conducted at your home and will take about 10 minutes daily, where you will perform motor tasks on your computer using an online website and fill out questionnaires 5 times weekly.

4. What happens to data that are collected in the study?

If you join this study, your data will be used to answer the research question and your data will be used to publish the findings of this study.

You will not own the data collected from you as part of this research study. If researchers use them to create a new product or idea, including those that may have commercial value, you will not benefit financially from those efforts.

Johns Hopkins, Kennedy Krieger Institute researchers, and their collaborators may use the data collected in this study for future research purposes and may share some of the data with others.

Because science constantly advances, we do not yet know what future use of research data may include. This future research may be unrelated to the current study and may include outside collaborators.

Sharing data is part of research and may increase what we can learn from this study. Often, data sharing is required as a condition of funding or for publishing study results. It also is needed to allow other researchers to validate study findings and to come up with new ideas. Your data may be shared with researchers at Johns Hopkins, Kennedy Krieger Institute, and other institutions, for-profit companies, sponsors, government agencies, and other research partners. Your data may also be put in government or other databases/repositories. However, videos will not be shared with third parties.

We (Johns Hopkins and Kennedy Krieger Institute) will do our best to protect and maintain your data in a safe way. One of the ways we protect data is by limiting the uses of the information and the type of information that is shared, especially your personal information. This may occur through data sharing agreements and review by oversight groups within Johns Hopkins and the Kennedy Krieger Institute.

If data are used or shared with types of information that may be likely to identify, you such as your name, address or medical record number, further institutional review and approval would be required. In these cases, Johns Hopkins and the Kennedy Krieger Institute will review whether additional consent from you is required.

Generally, if your data are used/shared without any personal identifiers or with information that is less likely to identify you (such as the date of a procedure), further review and approval is not needed.

Data sharing could change over time, and may continue after the study ends.

The use and sharing of your data is required for participation in this research study. If you are not comfortable with the use and sharing of your data in future research without further consent, you should not participate in this study.

5. What are the risks or discomforts of the study?

MRI Exam
While no significant risks have been found from the use of MRI scans, you may be bothered by the noise made by the MRI scanner and by feelings of being closed in (claustrophobia).

EMG Recording
You may find the skin prepping gel slightly uncomfortable because it feels like a gentle exfoliating cream. Minor skin irritation is possible from the gel and removing the electrodes, which is similar to taking off a band-aid.

Cognitive and Behavioral Tests
You may become fatigued or frustrated during testing. You may take breaks as needed between tests.

Interviews or questionnaires
You may get tired or bored when we are asking you questions, or while you are completing questionnaires. You do not have to answer any question you do not want to answer.

Identifiable private information
There is the risk that information about you may become known to people outside this study.

6. Are there risks related to pregnancy?
There are no known risks associated with having MRI imaging without contrast during pregnancy. There may be risks that are currently unknown.

If you are pregnant, you will not be able to participate in the study. If you are a female capable of becoming pregnant, you must be willing to take a urine pregnancy test before the MRI exam (Visit #1).

7. Are there benefits to being in the study?
There is no direct benefit to you from being in this study. If you take part in this study, you may help others in the future.

8. What are your options if you do not want to be in the study?
You do not have to join this study. If you do not join, your care at Johns Hopkins and Kennedy Krieger Institute will not be affected.

9. Will it cost you anything to be in this study?
No.

10. Will you be paid if you join this study?
You will be paid $100 for completing the study. If you park in a Johns Hopkins parking facility, you will receive a voucher for parking.

If you are an out-of-town ataxia patient, we may be able to provide one night of complimentary hotel lodging at Residence Inn Baltimore at the Johns Hopkins Medical Campus if needed, along with transportation to and from the hotel and our scanning facility if needed.

If you leave the study early, or if you are taken out of the study by the study doctor, you will only be paid for the parts of the study that you have completed. The study will not reimburse you for, or replace, a gift card that has been lost, stolen, or expired. However, if you believe the gift card defective, please contact us immediately.

You may be required to provide your social security number to be paid for taking part in this study. Federal tax law requires that you report your research payments when you file your taxes. If your total payments from Johns Hopkins and Kennedy Krieger Institute exceed $600 per year, Johns Hopkins and Kennedy Krieger Institute will report these payments to the Internal Revenue Service and you will receive a 1099-MISC form from us.

11. Can you leave the study early?

- You can agree to be in the study now and change your mind later.
- If you wish to stop, please tell us right away.
- Leaving this study early will not stop you from getting regular medical care.

If you leave the study early, Johns Hopkins and the Kennedy Krieger Institute may use or share your health information that it has already collected if the information is needed for this study or any follow-up activities.

12. Why might we take you out of the study early?

You may be taken out of the study if:

- Staying in the study would be harmful.
- You need treatment not allowed in the study.
- You fail to follow instructions.
- You become pregnant.
- The study is cancelled.
- There may be other reasons to take you out of the study that we do not know at this time.

If you are taken out of the study early, Johns Hopkins and the Kennedy Krieger Institute may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities.

13. How will your privacy be maintained and how will the confidentiality of your data be protected?

HIPAA Authorization for Disclosure of Protected Health Information

What information is being collected, used, or shared?

To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Johns Hopkins Medicine, Kennedy Krieger Institute, and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as

well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?
The people who may request, receive, or use your private health information include the researchers and their staff who may be a part of Johns Hopkins Health System, Johns Hopkins University or the Johns Hopkins Applied Physics Laboratory. Additionally, we may share your information with other people at Johns Hopkins and the Kennedy Krieger Institute, for example if needed for your clinical care or study oversight. To improve coordination of your research and clinical care, some information about the study you join will be included in your electronic medical record.

By signing this form, you give permission to the research team to share your information with others outside of Johns Hopkins and the Kennedy Krieger Institute. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by the study team.

We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?
You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?
Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?
You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

How will your information be protected?
Your results will be coded with a unique number and will not use your name.

Your private health information and the results from the assessments will be stored on a secured database that is protected behind a firewall. Your research data does not include private health information but is given a study code. Your private health information is stored in a separate location on the secured database. A code key that links your research data to your private health information is kept in yet another location on the secured database. Only our research team members will have access to the database and code key.

14. Will the study require any of your other health care providers to share your health information with the researchers of this study?

As a part of this study, the researchers may ask to see your health care records from your other health care providers. If deemed necessary by the study team, you will be asked to give us a list of other health care providers that you use.

15. What is a Certificate of Confidentiality?

Your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

This study is protected by a Certificate of Confidentiality that helps keep your information private when stored in the U.S.

16. What other things should you know about this research study?

During the study, we will tell you if we learn any new information that might affect whether you wish to continue to participate.

What is the Institutional Review Board (IRB) and how does it protect you?
This study has been reviewed by an Institutional Review Board (IRB), a group of people that reviews human research studies. The IRB can help you if you have questions about your rights as a research participant or if you have other questions, concerns or complaints about this research study. You may contact the IRB at 410-502-2092 or jhmeirb@jhmi.edu.

How is this study funded?
This study is funded by the National Institute of Neurological Disorders and Stroke (NINDS).

What should you do if you have questions about the study?
Call the principal investigator, Dr. Cherie Marvel at 410-502-4664. If you wish, you may contact the principal investigator by letter. The address is on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-502-2092.

17. Optional Study Components:

This part of the consent form is about optional component(s) of the study that you can choose to take part in or not. You can still take part in the main study even if you say "no" to this/these optional component(s).

Future Contact

We would like your permission for our research team to contact you in the future. Please note that your decision below does not prevent other researchers at Johns Hopkins and Kennedy Krieger Institute from contacting you about other research.

Please sign and date your choice below:

YES ☐ _____ _____
Signature of Participant Date

NO ☐ _____ _____
Signature of Participant Date

18. What does your signature on this consent form mean?

Your signature on this form means that you have reviewed the information in this form, you have had a chance to ask questions, and you agree to join the study. You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

Signature of Participant	(Print Name)	Date/Time

Signature of Person Obtaining Consent	(Print Name)	Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR AND A COPY MUST BE GIVEN TO THE PARTICIPANT. IF APPROPRIATE FOR THIS STUDY, A SCANNED COPY OF THE SIGNED CONSENT FORM SHOULD BE UPLOADED TO THE PARTICIPANT'S EPIC/EMR RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).