Mapping Corticoreticulospinal Motor Control Using Brainstem and Spinal Cord fMRI in Chronic Hemiparetic Stroke

Principal Investigator: Dr. Molly Bright, D.Phil.

NCT06598150

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Permission to Take Part in a Human Research Study

Title of Research Study: ***Functional MRI to investigate cortical, brainstem, and spinal cord activity during grasping tasks post-stroke***

Investigator: ***Dr. Molly Bright, D.Phil.***

Supported By: This research is supported by the National Institutes of Health (F31NS134222, R03HD113915, AHA 25PRE1356822).

Key Information:
The first few pages of this document include a summary of this study to help you decide whether or not to participate. Detailed information is provided after the summary.

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 have had a stroke that resulted in weakness in your arm and hand.

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?
We are interested in using a specific type of MRI scan to measure brain and spinal cord activity while you do a common motion – squeezing your hand as if you were gripping something. After a stroke, injury to the brain can make it difficult to do these types of everyday movements. Our goal is to measure the relationship between brain and spinal cord activity and impaired movement after stroke. To interpret these findings, we need to compare them to the relationship between brain and spinal cord activity and movement in healthy participants.

In order to properly measure brain or spinal cord activity, we first need to understand how the duration and strength of your hand grip affects your muscle activity and causes your head to move. We want to choose the right duration and strength to minimize head motion, because when your head moves too much in the scanner it makes the pictures of your brain less accurate. We also want to minimize fatigue, because when your muscles are strained it affects our interpretation of your brain activity. In this project, we are going to compare different durations and strengths of hand grips while we measure the amount your head moves with a special type of video camera. We will also use a device that can record the strength of your hand grip and sensors that attach to your skin to measure your arm muscle activity.

Next, we want to understand how the duration and strength of your hand grip changes your brain and spinal cord activity. We will do a very similar experiment inside the MRI scanner and ask you to grip your hand at different strengths and for different periods of time while we measure your brain or spinal cord activity. Based on all of this information, we will determine the

relationship between brain and spinal cord activity and movement in healthy participants and those who have experienced a stroke.

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

We expect that you will be in this research study for no more than 4 hours on the first visit and 2 hours on the second visit. You will be invited to complete up to 7and have the option to decline additional visits. On the first visit, you will be asked to come to the Northwestern Physical Therapy Department, 645 N. Michigan Ave., Chicago, IL. We will use a device called the ANVILgrip, which has two handlebars and measures grip strength when the handlebars are squeezed together. You will be asked to grip for different amounts of time and different strengths while laying down. You may also be asked to perform other simple movements with your arms using a similar device that measures forces at your elbow and shoulder. In addition, you may be asked to hold your breath for a short period of time or take a series of deep breaths while we record your breathing and heart rate. You may also be asked to listen to music or other sounds. We may also apply light to moderate, repetitive touch to your hands, arms, and/or feet using a tool such as a brush, a sponge, or fingertips.

On the second visit, you will be asked to come to the Olson Pavillion, 710 North Fairbanks (Lower Level), Chicago, IL to undergo an MRI scan. Upon arrival, you will be screened to confirm that it is safe for you to be scanned, and you will be given more detailed instructions about the session. You will follow a similar procedure to the first visit and use the same device to perform different grasping movements. If at any time you are uncomfortable and want to stop, you can contact the researchers through an intercom system.

You can find more detailed information about the study procedures in the **What happens if I say, "Yes, I want to be in this research"?** section.

Is there any way being in this study could be bad for me?

Although MRI is a safe tool for imaging the brain and spinal cord, some people under certain circumstances cannot have an MRI safely. You will complete a safety questionnaire to make sure it is safe for you to be scanned. There is also a possibility that you will experience side effects, like muscle soreness or fatigue from the repeated hand grips you will be doing. The MRI scan itself can make some people uncomfortable due to the loud banging sounds that the scanner makes while taking an image or being in a small, enclosed space. If you become uncomfortable during the scan for these or any other reasons, you will be able to communicate with the researcher and stop the scan at any time.

You can find more detailed information about the risks of this study in the **Is there any way being in this study could be bad for me? (Detailed Risks)** section.

Will being in this study help me in any way?

There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include development of improved rehabilitation strategies for impaired motor control following stroke.

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

Participation in research is completely voluntary. You decide whether or not to participate. If you choose not to participate, there will be no penalty to you or loss of benefit to which you are entitled. Your alternative to participating in this research study is not to participate.

Permission to Take Part in a Human Research Study

Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

Whom can I talk to?
If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at (312) 503-5870 or at anvil@northwestern.edu. You can also reach the principal investigator, Dr. Molly Bright, at 645 N. Michigan Ave., Suite 1100, Chicago, IL 60611.

This research has been reviewed and approved by an Institutional Review Board (IRB). You may talk to them at (312) 503-1376 or irb@northwestern.edu if:

- The research team is not answering your questions, concerns, or complaints.
- 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.

How many people will be studied?
We expect about 60 people here will be in this research study.

What happens if I say "Yes, I want to be in this research"?
This study will consist of two different parts. During both parts, we will ask you to make hand grips with different amounts of strength and for different periods of time. We have a device that can measure your hand grip when you squeeze two handlebars together. You will be asked to look at a computer screen while you make these hand grips and it will show you how hard and how long to squeeze the handlebars together. You may also be asked to perform other simple movements with your arms using a similar device that measures forces at your elbow and shoulder. You will be asked to look at a computer screen while you perform these arm movements and it will show you how to move and how long to perform the movement. In addition, you may be asked to hold your breath for a short period of time or take a series of deep breaths while we record your breathing and heart rate.

The first part of this study will take place at the Department of Physical Therapy and Human Movement Sciences, which is located at 645 N. Michigan Avenue. This part of the study uses motion capture video cameras, which are a special kind of video camera that can measure how much your body moves. They work by using light to track stickers that are placed on different parts of your body. Some of the cameras use “infrared light”, which is used in devices like television remote controls, and is invisible to the human eye.

You will also have the option of allowing the research team to take photos or video of you during your participation in this part of the study. The video will be used to help us understand your head movement, and the photos may be used in scholarly research presentations or publications.

First, you will be given instructions about the experiment before we start. Next, you will be asked to lie down on a physical therapy exam table. Both of your arms will be strapped into a device

that measures hand grip. Each of your elbows will rest on a base and your fingers will be wrapped around the two handlebars. We will make sure your arms are in a comfortable position and we might need to measure the angle of your elbows. We may also ask you to wear some equipment to monitor your breathing and heart beat, such as a clip on your finger or toe, a belt around your waist, or a soft plastic tube under your nostrils. Then, we will place stickers at a few points on your face. These stickers will help our motion tracking cameras to find your head position and measure how much your head moves. We will also tape a few electrodes to your arms that will allow us to record your muscle activity; this recording of muscle activity is called electromyography.

Next, we will ask you to squeeze the handlebars together as hard as you can and repeat this three times with each hand. After this, we will start the experiment and you will alternate between making hand grips and resting. A program on the computer screen will show you when and how hard to squeeze the handlebars together and which hand to use. Our motion capture video cameras will be turned on to measure your head movement during this time. If you are uncomfortable in any way, tell the researcher as soon as possible. They may be able to make some adjustments to improve your comfort, or you can ask to stop the study at any time. We may also attach one of your arms to a device that measures elbow and shoulder forces and ask you to perform simple arm movements instructed by a program on the computer screen. To securely attach your arm to this device, we will create a cast of your wrist and/or forearm. We will make sure your arm is in a comfortable position, and we might need to measure the angle and length of your arm in this position. Next, we will ask you to perform different arm movements as hard as you can and repeat this up to 10 times with each arm. The experiment session will take around 60 minutes to complete.

At the end of the experiment, we will unstrap you from the hand grip devices and you will be able to sit up. We will also take the stickers off your face. The final step is to complete a short questionnaire to let us know if certain hand grips were easier than others. Your total participation for the first part of the study should last no more than 4 hours.

The second part of the study will be on a different day and it will take place at the Center for Translational Imaging at Northwestern University, Olson Pavillion, 710 N. Fairbanks Ct., Lower Concourse, Chicago, Illinois 60611. Your participation for the second part of the study should last no more than 2 hours. This part of the study uses functional magnetic resonance imaging (MRI) to look at the brain and spinal cord. Functional magnetic resonance imaging is a type of brain or spinal cord scan that uses magnetic fields and radio waves to make an image of changes in blood flow in your brain or spinal cord while you do certain tasks. While you are having an MRI scan, we will ask you to do something very similar to the first part of the study. You will be asked to make hand grips by squeezing the handlebars of our device, and you will be able to see a computer screen that tells you when and how hard to grip. We may ask you to wear some equipment to monitor your breathing and heart beat, such as a clip on your finger or toe, a belt around your waist, or a soft plastic tube under your nostrils. We may also attach one of your arms to a device that measure elbow and shoulder forces and ask you to perform simple arm movements instructed by a program on the computer screen. You may also be asked to hold your breath for a short period of time or take a series of deep breaths, or to listen to music or other sounds. We may also apply light to moderate, repetitive touch to your hands, arms, and/or feet using a tool such as a brush, a sponge, or fingertips. The touch sensation will not be sharp or painful. You may request that this touch be stopped at any time by squeezing an alert ball.

Permission to Take Part in a Human Research Study

In order to make sure the MRI procedure will be safe, you will be asked to fill out a screening form before starting the study. It is important that you tell the researchers in this study if you have any history of:

- Metal fragments in your eyes or face.
- Implantation of any electronic devices such as (but not limited to) cardiac pacemakers, cardiac defibrillators, cochlea implants or nerve stimulators.
- Surgery on the blood vessels of your brain or the valves of the heart
- Claustrophobia (fear of enclosed places)
- Body piercing or tattoos

You will be given instructions outside the MRI scanner about the scanning. Next you will be asked to lie still on the MRI patient table and your head will be placed in a specially-designed head holder. Your head will be cushioned by a firm foam pillow. The front of the head-holder will be open, which lets you look through a special mirror and see pictures presented to you on a projection screen behind your head.

Then, like in the first part of the study, your arms will be strapped into our devices that measure hand grip. We will make sure your arms are in a comfortable position and we might need to measure the angle of your elbows. We may alternately attach your arms to our device that measures elbow and shoulder forces. The table will then slide into the enclosed space of the MRI scanner. Some people feel tired, uncomfortable or claustrophobic (afraid of small spaces) in the MRI scanner. The MRI scan will take up to an hour to complete.

The information from the MRI scanner is only useful if you are able to complete the whole imaging session, and hold your head very still the whole time. Therefore you will be encouraged to hold as still as possible and to let the investigators know if you are uncomfortable in any way as soon as possible after the imaging session begins.

The MRI scanner makes loud banging noises while taking a measurement, so ear plugs and/or specially designed headphones will be used to reduce the noise. The researchers will be in communication with you through an intercom system to tell you how the study is going. The earplugs or headphones should not get in the way of communicating with the researchers.

The MRI session will consist of several short scans. After the session is complete, the MRI bed will slide out of the scanner. We will unstrap your arms from the measurement devices and you will be able to sit up.The final step is to complete a short questionnaire to let us know if certain hand grips were easier than others inside the MRI scanner.

You will be invited to complete up to 5 visits per year and have the option to decline to additional visits. We would also like to contact you in the future about other research studies taking place. This is also optional, and you can agree or opt out of this at the end of this form.

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.

If you decide to leave the research, contact the investigator so that the investigator can cancel the session. If you choose to stop participating during the motion capture session or MRI scan, we may still access and use any data already collected in the session before we stopped.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. Specifically, your choice not to be in this study will not negatively affect your right to any present or future medical treatment, your class standing (for students enrolled in a class at Northwestern University), or your present or future employment (for employees at Northwestern University or its affiliates).

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

Risks of MRI

Some people cannot have an MRI because they have some type of metal in their body. For instance, if you have a heart pacemaker, artificial heart valves, metal implants such as metal ear implants, bullet pieces, chemotherapy or insulin pumps or any other metal such as metal clips or rings, you cannot have an MRI. During this test, you will lie in a small closed area inside a large magnetic tube. Some people are scared or anxious in small places (claustrophobic). The MRI scanner makes loud banging noises while taking a measurement, so either ear plugs or specially designed headphones will be used to reduce the noise.

The MRI pictures from this study will not be in a form readable by either you or your doctor. Therefore, a copy of the MRI pictures or the results of your individual study will not be given either to you or your doctor. While the MRI pictures in this study are not formally reviewed by a radiologist, if in the course of processing the images we notice any abnormality that would be possibly important to your health we will tell you and a doctor you name.

Risks of Hand Grip and Arm Movements

You may experience discomfort from maintaining your arm in a fixed position for an extended period of time. Researchers will check on you regularly both inside and outside the scanner and you may choose to rest or stop the hand grip task completely at any time. You may also experience muscle fatigue or soreness in the upper arm, forearm, and/or hand during or after the experiment due to repetitive gripping or arm movements. However, the range and duration of grip strengths in this experiment are chosen to minimize this risk. Any muscle fatigue or soreness is expected to be brief and not more severe than that experienced after a moderate workout.

Risks of Casting

There is some risk of skin injury, such as burning from the cast saw, during the removal of the fiberglass casting material from the arm. We will minimize this risk by adding an extra cotton layer under the cast and by using proper technique.

Risks of Motion Capture

There are no known risks associated with the motion tracking cameras. The adhesive markers may cause minor skin irritation. If you experience any discomfort, the markers can be removed or adjusted at any time.

Permission to Take Part in a Human Research Study

Risks of Electromyography

There are no known risks associated with surface electromyography. The adhesive electrodes may cause minor skin irritation. If you experience any discomfort, the electrodes can be removed or adjusted at any time.

Risks of Breathing Challenges

You may experience some discomfort while holding your breath. If you feel too uncomfortable, you may stop holding your breath at any time. Researchers will also be monitoring your breathing and heart rate closely throughout the experiment and checking on you frequently.

Risks of Auditory Sounds

We will confirm that the volume of any sounds or music played is at a comfortable level before beginning the experiment. If you experience any discomfort, the sounds can be stopped at any time.

Risks of Touch Stimulus

You may experience discomfort from application of the touch stimulus to your hands, arms, or feet. If you experience any discomfort, the touch sensation can be adjusted or stopped at any time.

This study involves the use of your identifiable, personal information and there is a chance that a loss of confidentiality could occur. The researchers have procedures in place to lessen the possibility of this happening. See the section below titled: "**What happens to the information collected for the research?".**

What do I need to know about reproductive health and/or sexual activity if I am in this study?

This research involves MRI, which may hurt a pregnancy or fetus in ways that are unknown. If you are pregnant or may be pregnant, you should not participate in this study.

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.

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 institution.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health (NIH). The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings; for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you. You should understand that a Certificate of Confidentiality does not prevent you or a member of

your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

The results of this study may be published in scientific journal articles and may be widely disseminated. However, your name or personal identifiers will not be used in any of these reports of results. Unidentified data (information with no names or other personal identifiers) collected in this study will be stored in registries or other research-related databases such as the Northwestern University Research Imaging Processing System (NURIPS) and the Feinberg School of Medicine encrypted data storage. Your research data may be shared with your treatment team. After the study is over, we may make available the unidentified data to other qualified researchers in the wider scientific community.

Please note that by signing this consent you agree that your unidentified research data (information with no names or other personal identifiers) will be stored in the Northwestern University Research Imaging Processing System (NURIPS) for research purposes only.

Will my data or samples be used for future research?

This study is collecting data from you. We would like to make your data available for other research studies that may be done in the future. The research may be about similar diseases or conditions to this study. However, research could also be about unrelated diseases, conditions, or other types of research. These studies may be done by researchers at this institution or other institutions, including commercial entities. Your data may be shared with researchers around the world. Our goal is to make more research possible. To get your data, future researchers must seek approval from this institution, and review by an IRB may be required. We will protect the confidentiality of your information to the extent possible. Your data and samples will be coded to protect your identity before they are shared with other researchers. Only the study team will have a code key that can be used to link to your identifying information. The code key will be securely stored.

What else do I need to know?

If you agree to take part in this research study, we will pay you $20 per hour for each visit. We will also pay for parking at a nearby garage (up to 6 hours) during each visit.

The Accounting Services at Northwestern University will be given your name, address, and Social Security Number in order to issue a check for your study participation. Study payments are considered taxable income and reportable to the IRS. A Form 1099 will be sent to you if your total payments are $600 or more in a calendar year.

You may alternately be issued the Stored Value Card (VISA), which is a type of bank debit card with a specific dollar value programmed into it. Once a visit that qualifies for compensation is completed, funds will be approved and loaded onto your card.

You will need to set a PIN to use the card at an ATM. Using the PNC automated service number and Account Access Code provided on the card, follow the prompts to establish a PIN. You may also call this number to obtain the current balance on the card and to verify your activity. A fee will be charged to speak to a live operator. This information can also be checked online at pncprepaidcard.com. Please note that neither PNC nor Northwestern can obtain the PIN if forgotten.

If the card is used at a PNC ATM, there is no fee; however, there will be a $2.50 charge for non-PNC ATM withdrawals. One card will be issued for the duration of your participation. If your card is lost or stolen, please call the study team on the contact information provided on this consent document.

Please be advised: You will incur a fee if the card is not used in 6 months and a monthly fee for each additional month of non-use. However, as long as there is activity (funds are added or card is used), on the card within 6 months the month period will reset and no monthly fee will be assessed. If the card is used at a restaurant, there will be a 20% "hold" above the tab amount. The card will be declined if used at a gas pump. Rather, the card must be physically presented to the gas station attendant.

We will announce developments form this study and from future studies on our lab webpage: http://brightlab.northwestern.edu

HIPAA Authorization

We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Your health information we may collect and use for this research includes:

- Name, Address, and Telephone number
- Date of Birth
- Information from a physical examination including only: blood pressure reading, upper extremity range of motion, strength, and functional movement assessment.
- Current magnetic resonance imaging (MRI) or computed tomography (CT) brain scan and past surgical history will be requested from your medical records to identify the stroke brain lesion location and confirm MRI safety requirements. (No other information from medical records is required or will be requested).
- Social Security Number - needed for the Accounts Payable Department at Northwestern University in order to issue the study stipend to you and for the medical records department of most hospitals to identify your medical record file.

The following clinical providers may give the researchers information about you: all current and previous health care providers, including but not limited to the Shirley Ryan AbilityLab (SRALAB) and Northwestern Memorial HealthCare/Northwestern Medicine entities and its current and future affiliates. A member of the study team may also access your medical records at Northwestern Memorial HealthCare/Northwestern Medicine.

Once we have the health information listed above, we may share some of this information with the following offices or entities outside of Northwestern University and its clinical partners (or affiliates): the Northwestern University Institutional Review Board Office and Office for Research Integrity; the US Office of Research Integrity; the US Office for Human Research Protections; the US Food and Drug Administration.

Any research information shared with outside entities will not contain your name, address, telephone or social security number or any other personal identifier unless disclosure of the identifier is necessary for review by such parties or is required by law or University policy

Permission to Take Part in a Human Research Study

[except that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigator's office].

The following entities may receive your health information:

- Authorized members of the Northwestern University, who may need to see your information, such as administrative staff members from the Office for Research, Office for Research Integrity and members of the Institutional Review Board.
- Clinical affiliates, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Memorial HealthCare, and the Ann & Robert H. Lurie Children's Hospital of Chicago (Lurie Children's). Your participation in this clinical trial may be tracked in an electronic database and may be seen by investigators running other trials that you are enrolled in and by your healthcare providers.
- Clinical affiliates, including but not limited to Northwestern Memorial HealthCare, for purposes including, but not limited to, the affiliate's provision of care to you and/or the affiliate's scheduling of appointments and/or billing activities.
- Other University research centers and University contractors who are also working on the study,
- Study monitors and auditors who make sure that the study is being done properly,

Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

Unless you revoke your consent, it will not expire at the end of the research study.

Although you may revoke consent to participation in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing. To revoke your authorization, write to:

PI's Name: Molly Bright, D.Phil.
Institution: Northwestern University
Department: Physical Therapy and Human Movement Sciences
Address: 645 N Michigan Avenue, Suite 1100, Chicago, IL 60611You do not have to authorize the use or disclosure of your health information; however, you will not be allowed to take part in this research study. If you do not authorize the use or disclosure of your health information, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits.

Optional Elements:

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

I agree	**I disagree**	
_____	_____	The researcher may audio or video record me to aid with data analysis. The researcher will not share these recordings with anyone outside of the immediate study team.

Permission to Take Part in a Human Research Study

I agree	I disagree	
_____	_____	The researcher may audio or video record me for use in scholarly presentations or publications. My identity may be shared as part of this activity, although the researcher will attempt to limit such identification. I understand the risks associated with such identification.
_____	_____	The researcher may contact me in the future to see whether I am interested in participating in other research studies by the Principal Investigator of this study.

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

_____
Printed Name of Participant

_____ _____
Signature of Person Obtaining Consent Date

_____
Printed Name of Person Obtaining Consent