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Improving Human Cerebrovascular Function Using Acute Intermittent Hypoxia
NCT05164705

The following document is the IRB-approved Informed Consent Document for the *AIHvasc* Clinical Trial, uploaded by Principal Investigator Dr Molly Bright.

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Permission to Take Part in a Human Research Study

Title of Research Study:

Improving Human Cerebrovascular Function Using Acute Intermittent Hypoxia
(STU# STU0021555)

Investigator: Dr. Molly Bright, D.Phil.

Supported By: This research is supported by NIH grant R21NS121742

Financial Interest Disclosure: None.

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 are a healthy individual, aged 21–50 years old, with no known respiratory, vascular, or neurological condition.

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?

In previous research, it has been shown that short periods of breathing low levels of oxygen (also known as “acute intermittent hypoxia”) can help improve muscle function, walking, and brain function in individuals with spinal cord injury. Research in animals suggests that some of these improvements might be associated with an increase in blood delivered to the injured spinal cord. There is also research showing that this therapy improves brain function in people with early stages of dementia, and this might be associated with better blood delivery to the brain. One study reports that even healthy adults may show better blood delivery to the brain after receiving this therapy.

The purpose of this new study is to find out if this therapy improves blood flow to the brain in healthy adults. To do this, we will give healthy people this therapy several times a week, for three weeks. We will use Magnetic Resonance Imaging (MRI) to look at brain blood flow before and after. We will also have you breathe different air mixtures during the MRI to measure how much your blood flow responds. All of this will be repeated a second time with a slightly different dose of the therapy. We anticipate that acute intermittent hypoxia therapy will improve the brain’s blood supply, and this therapy may one day help protect or repair the brain after an injury like stroke.

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

We expect that you will be in this research study for 5–7 months.

You will then be asked to come 2–4 times per week, for 3 weeks, to receive the therapy. Each of these visits will take approximately 45 minutes. Before and after this 3-week period you will have an MRI scan, and these visits will take approximately 2 hours. Then you will have 3 months where you do not need to do anything. Finally, you will repeat the MRI scans and 3-weeks of visits to receive the therapy for a second time.

More detailed information about the study procedures can be found under the section **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?

There is a possibility to experience side effects from the breathing challenges we use, including light headedness, dizziness, feeling short of breath, or increased heart rate. During the therapy, we will be giving very short bouts of breathing air with lower oxygen levels (i.e. 60 seconds each), and in the MRI scans we will give you longer periods of breathing different air mixtures (25 minutes). Although we do not anticipate these side effect to occur, we will nonetheless be monitoring for them, and you can stop the study and breathe room air at any time. The effect of breathing challenges in this study lower levels of oxygen during pregnancy is unknown, and if you are currently pregnant you should not participate in this study. If there is a chance you might be pregnant, we will provide you with a pregnancy test before you start the study.

Although MRI is a very safe tool for imaging the brain, 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. 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 for any reason, you will be able to communicate with the researcher to stop the scan.

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)"**

Will being in this study help me 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 the develpment of a therapy to protect the brain from stroke and similar diseases.

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 to not 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 to not participate.

Detailed Information:

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

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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 AIHvasc@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) 503-9338 or irb@northwestern.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 participant.
- 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, I want to be in this research"?

We will first speak with you to make sure you meet the criteria for this study and to answer any questions you might have. In order to make sure that you will be safe to participate, you will be asked to fill out multiple screening forms before starting the study. It is important that you tell the researchers in this study if you have any history of:

- Metal on or inside your body that cannot be removed
- Working with metal
- Body piercings or tattoos
- 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)
- Neurological, respiratory, cardiac or vascular conditions. Note: mild well-controlled asthma is not immediate grounds for exclusion.
- Allergy to Tegaderm™ – a type of medical tape
- Prescription medications such as (but not limited to) Aripiprazole and Lamotrigine

You should also tell them if you are pregnant or could be pregnant, or if it has been more than 28 days since your last period, and we will provide you with a pregnancy test. We will also ask you to not wear nail polish to any study visits, as it can interfere with our oxygen sensors. Then you will be asked to visit one or more of the Center for Translational Imaging (CTI, Lower Concourse, Olson Pavilion, 710 N. Fairbanks Ct., Chicago, IL 60611), the ABC laboratory (Room 7-240, Galter Pavilion of Northwestern Memorial Hospital, 675 N. St. Clair St. Chicago, IL 60611), or the ANVIL laboratory (Room 851, 645 N. Michigan Ave., Chicago, IL 60611) for additional in-person screening and a chance to practice all of the breathing challenges used in this study. We expect this first visit to take 1 hour.

There are two types of breathing challenges you will be asked to practice: 1) the therapy that we are studying, which is called Acute Intermittent Hypoxia, and 2) the longer breathing challenges that we use during MRI scanning.

1) Acute Intermittent Hypoxia involves breathing air with less oxygen that normal. For 30-minutes, you will breathe air through a face mask. You will receive brief bouts of normal

air and air with low oxygen in an alternating pattern. This will be done using the Hyp-123™, which is an investigational device. An investigational device is one not approved by the food and drug administration for use in medical diagnosis or treatment of medical conditions. We will monitor your blood pressure and the oxygen in your blood to make sure you stay in safe limits. We may also ask you to breathe at a speed that matches cues that we show you.

2) During MRI scans at the Center for Translational Imaging, you will also breathe different air mixtures for longer periods of time (up to 25 minutes). This is done using the Respiract™, which is an investigational device. An investigational device is one that is not approved by the food and drug administration for use in medical diagnosis or treatment of medical conditions. We will use the Respiract™ to change the levels of oxygen and carbon dioxide in the air you are breathing during an MRI scan. The purpose of these breathing challenges is to increase blood flow to your brain while the MRI scanner can measure it. We will ask you to lie down on a bed, and a plastic face mask will be positioned over your mouth and nose, and you can adjust it to make it comfortable. The edges of the mask will be taped to your skin using special medical tape in order to keep the mask in position and prevent any leaks. If you know you are allergic to Tegaderm™ tape, please let us know. This mask will be connected to a gas delivery system. Most of the time, you will be breathing normal air. There will be periods when we adjust the amount of carbon dioxide or oxygen in the air you are breathing. We will tell you before we are going to make any changes. You will always have enough oxygen in the air you are breathing. If you feel uncomfortable with the mask or the air mixtures, you will always be able to communicate with the researcher. They may be able to make some adjustments to improve your comfort, or you can ask to stop the study at any time.

During the practice session, you will try both breathing challenges outside of the MRI scanner. We will monitor your breathing, oxygen levels, and heart rate to make sure you are staying within safe limits. If we feel it is necessary, we may adjust the gas you are breathing to make it more mild. We can also do this if you feel uncomfortable. You may also stop the breathing challenges at any time, and you will only continue participating in the study if you agree.

If you agree to continue participating in the study, we will work with you to schedule the rest of the study visits. You will have 8–14 visits in a 1-month period. Then you will have at least 3 months where you do not need to do anything. Then you will have another 8–14 visits in a 1-month period. The two halves of the study will be identical except you will get a different dose of the therapy. The order in which you receive the two doses will be chosen by chance, like flipping a coin. The figure below shows the timeline of the study.

Your visits to receive the therapy will take place in Northwestern Memorial Hospital, in the “ABC” lab of Dr. Farzaneh Sorond, a neurologist and member of the research team. Alternatively, we may have you receive the therapy in the “ANVIL” lab of the Principal Investigator, Dr. Molly Bright. This lab is not in a main hospital building, but we will have clinical staff there for your visit. We will provide you with instructions on how to find the lab, and a member of the study team will meet you in the lobby to show you the way on your first visit. After each visit, you will be asked to complete a short questionnaire indicating whether you consumed any substances that may affect your physiology (e.g., caffeine, nicotine, ibuprofen, etc.), whether you have exercised, how much sleep you got the night before, the time of your

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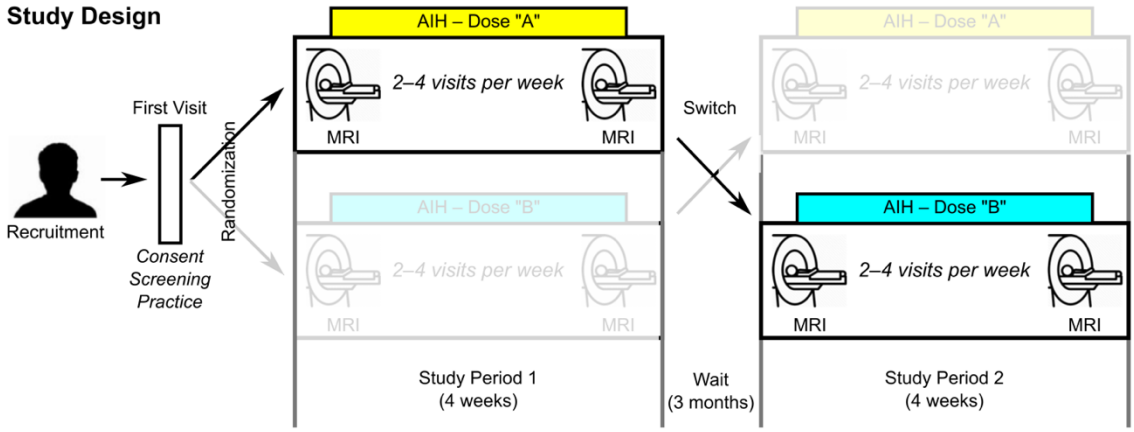

You will have a first visit to go through the details of the study. We will have safety screening forms to make sure it is safe for you to participate. We will also have you practice the breathing challenges used in the study to make sure you are comfortable with them. Then you will be assigned by chance to do either Dose "A" or Dose "B" of the therapy in Study Period 1, which lasts four weeks. After 3 months of waiting, you will then come back for Study Period 2 and do the other Dose of the therapy. During each study period, you will come in 2–4 times per week to get the therapy. You will also have two MRI scans, one before each study period begins and one after each finishes. In this example, the person completes Dose "A" first and Dose "B" second; you may or may not have it in the same order.

last meal, and whether you experienced any side effects such as drowsiness during the visit. We will also ask about changes in prescription medications and medical diagnoses in this questionnaire. This information helps researchers better understand responses to hypoxia.

The visits to have an MRI scan (4 in total) will take place at the Center for Translational Imaging and each scan visit will last approximately 2 hours. We ask that you refrain from eating or having coffee for at least 2 hours prior to the scan, and to refrain from smoking or consuming cannabinoids on the day of the scan. When you arrive for your scan, we will go through additional safety screening forms with you.

You will be given instructions outside the MRI scanner about the scanning process, and we will ask you to change into scrubs and leave all personal belongings in a secure locker. In the MRI room, you will be asked to lie still on the MRI patient table. The plastic face mask will be positioned onto your face, and taped to your skin, as done in the practice session. The researcher will adjust the fit of the mask, to make you as comfortable as possible. You will be given a ball to squeeze to alert the researcher if you feel uncomfortable, or you can disconnect the face mask yourself (the researchers will show you how to do this). We may also ask you to wear additional items on your finger, waist or chest to measure and record your heart-beat, oxygen levels, and breathing during the scan. The researchers will do a short set-up procedure, with different air mixtures being delivered to your mask, before the scanning begins. When ready, your head will be placed in a specially-designed head holder. Your head will be cushioned by a firm foam pillow. 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 or with the face mask on. If you feel uncomfortable, you should notify the research team. The MRI scanning session will take up to 60 minutes to once you are in the scanner.

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. In some of these scans, you will breathe normal air for the entire time. In other scans, you will breathe a modified air mixture. After the session is complete, the MRI bed will slide out of the scanner and you will be able to sit up. The final stage of the visit is to complete a short questionnaire to let us know if you noticed the changing air mixtures and to collect information on any activities that may have altered your physiology.

Overall, your total participation in this research study should last no more than 2 hours in any given day, with a total of approximately 23 hours over 5–7 months.

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 are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to maintain communication with the study team and appear promptly for study visits. If you need to reschedule, you will inform the study team as soon as possible. You will also be responsible for maintaining communication about changes in medications or medical diagnoses, including new medications and diagnoses, that may make it unsafe for you to continue participating in the study.

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 upcoming study visits.

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 NU), or your present or future employment (for employees at NU or its affiliates).

If you choose to withdraw from the study, we may still use any data from your participation up to that point in our research. If you agree, we will document your reasons for withdraw in your study file.

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

Risks of Breathing Challenges

This research using breathing challenges may hurt you in the following ways.

We use Tegaderm™ tape to seal the mask over your nose and mouth. Although this tape is latex-free and considered hypoallergenic (unlikely to cause allergies), some people may exhibit an allergic reaction to it. You should let us know if you start to feel any itchiness or pain where the tape is placed.

There are several possible temporary side effects that you may experience when breathing different air mixtures with less oxygen in it or more carbon dioxide in it. These include general discomfort, shortness of breath, dizziness or light-headedness, headache, anxiety or claustrophobia (being scared or anxious in small spaces). These effects should stop quickly once you go back to breathing normal air. You will practice the breathing challenges in your first visit, to make sure that you are comfortable with continuing the study. We can also make breathing challenges more mild if you feel uncomfortable in this practice session.

Breathing challenges may also have rare but severe side effects, such as stroke or heart attack. In the largest study involving the Respiract™, which examined over 400 scans, no severe side effects were observed. However, you should alert the study team if you experience nausea, vomiting, headache, confusion or disorientation, abnormal or slurred speech, difficulty understanding what is happening, numbness or weakness (particularly on one side of the body), pain or discomfort in arms, back, neck, jaw, or stomach, vision problems, chest pressure or fullness, chest pain, severe shortness of breath, or cold sweats. These symptoms might be a warning that you are responding badly to the breathing challenge, and we will stop it immediately. During MRI scans, you should get the attention of the study team by squeezing the emergency alert buzzer that you will hold during the scan.

We will also continuously monitor your pulse, breathing, and oxygen levels during all breathing challenges, inside and outside the MRI scanner, to make sure you stay within safe limits, and we will stop the breathing challenge if you ever go outside safe limits. For example, we will stop the breathing challenge during an MRI scan if your blood oxygen levels go below 85%. These levels can happen when you drive up tall mountains in Colorado, and healthy adults do not typically have any long-term side effects from even lower oxygen levels (50-70%) for up to 30 minutes.

We will be able to communicate with you throughout all study visits. During MRI scans, we will communicate with you over the intercom system, and we will check that you are happy to keep going between each scan starts, before we begin any breathing challenge, and in the first few minutes of a breathing challenge while you get used to it. We will also use a video camera to observe you during the scan, so you can give us “thumbs up” or “thumbs down” if you prefer that to speaking while wearing the mask. (Please note, video monitoring is not recorded and stored.) You should tell us if you ever want us to stop or simply pause the session, for any reason.

If you ever feel uncomfortable during breathing challenges, either in the therapy visits or during MRI scanning, you can stop at any time by disconnecting the face mask or alerting the researcher. We will have you practice disconnecting the face mask before your scan to make sure you are comfortable doing that. If our oxygen monitoring tells us that your oxygen levels are too low, and they do not go back to normal after we stop the breathing challenge, we can give you oxygen to breathe outside of the MRI scan room to help you recover.

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, they 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 combination of being in an MRI scanner and having a mask on your face may also make claustrophobia feel worse and cause anxiety. 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 unexpected abnormality that would be possibly important to your health we will tell you and a doctor you name.

In addition to these risks, this research may hurt you in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death.

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?

The research involves breathing challenges and MRI, which may hurt a pregnancy or fetus in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death. If you are pregnant or may be pregnant, or if you plan to become pregnant, you should not participate in this study. We will provide pregnancy tests to participants who are not sure if they are pregnant, and/or who have not had a menstrual period in over 28 days. We will ask you about this at least twice during the study, however you may request a pregnancy test at any time if you are unsure.

If you are sexually active, both men and women should use at least one effective means of birth control while participating in this research study. According to the World Health Organization and the United States Center for Disease Control and Prevention, the most effective forms of birth control include complete abstinence, surgical sterilization (both male and female), intrauterine devices (IUDs), and the contraceptive implant. The next most effective forms of birth control include injectables, oral contraceptive pills, the contraceptive ring, or the contraceptive patch. Acceptable but least effective methods of birth control include male condoms (with or without spermicide) and female condoms.

If you become pregnant while participating in this research study or for 1 month after you complete the study, it is important that you tell the study doctor or other research team member immediately. You may be required to stop participation in this study; however, other treatment options will be discussed with you at that time if necessary.

If you are considered to be postmenopausal, you are not required to use contraception while participating in this research study. Postmenopausal women rarely become pregnant. If you become pregnant while participating in this research study or for 1 month after you complete the study, it is important that you tell the study doctor or other research team member immediately. You may be required to stop participation in this study; however, other treatment options will be discussed with you at that time if necessary.

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.

You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay. In some cases, insurance will not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.

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 the development of a therapy that can improve blood flow to the brain.

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. An exception to our promise of confidentiality is when we in good faith are permitted by law or policy to report evidence of child [or elder] abuse or neglect.

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 also 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 Image Processing System (NURIPS). 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 NURIPS for research purposes only.

The sponsor, monitors, auditors, the IRB, the Northwestern University Office for Research Integrity, the US Office of Research Integrity (ORI), the US Office for the Protection of Human Research Protections (OHRP), and the US Food and Drug Administration (FDA) may be granted direct access to your medical records to conduct and oversee the research. By signing this document, you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

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.

Data Sharing

De-identified data from this study may be shared with the research community at large to advance science and health. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

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 difficulty with administering the therapy or breathing challenges to you in a consistent or safe way. 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?

If you become ill or are injured as a result of this study (medications, devices or procedures), you should seek medical treatment through your doctor or treatment center of choice. You should promptly tell the study doctor about any illness or injury.

The hospital [university, researchers] will not pay for medical care required because of a bad outcome resulting from your participation in this research study. This does not keep you from seeking to be paid back for care required because of a bad outcome.

If you agree to take part in this research study, we will pay you up to $650 for your time and effort. You will be paid immediately with $20 for participating in the practice session. If you enroll in the study, then you will receive $45 per MRI visit and $25 per therapy visit for the remainder of the study. However, not all payments will take place immediately in full. You will be paid after Study Period 1 and again after Study Period 2. Note, you will receive 50% of your compensation if you decide to withdraw from the study early.

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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.

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

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 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