Effects of Chronic Pain, Dyspnea, and Physical Activity Promotion on Functional Connectivity of the Brain in COPD

NCT04291131

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Participant Name: _____ Date:_____

Title of Study: Effects of Chronic Pain, Dyspnea, and Physical Activity Promotion on Functional Connectivity of the Brain in COPD

Principal Investigator: [redacted] VA Facility: VA Boston

KEY SUMMARY INFORMATION ABOUT THIS STUDY

We are asking you to be in a research study that is being supported by VA Rehabilitation Research and Development. We are enrolling participants at VA Boston Healthcare System. Before you decide to take part, you should know why the study is being done and what it will involve. This form tells you what to expect if you agree to be in the study. Taking part in this study is completely voluntary; it is your decision whether to participate in the study.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

We are doing the research to examine resting state functional connectivity of the brain in persons with COPD. Magnetic resonance imaging (MRI) of the brain assesses functional connectivity. Functional connectivity refers to patterns of how different parts of the normal brain "talk" to each other. We will study if there are patterns in the way different parts of the normal brain "talk" to each other that are related to symptoms of shortness of breath and chronic pain, and whether they change in response to physical activity and exercise, in persons with COPD

If you agree, you will undergo two brain MRI scans, approximately 3 months apart, at the Jamaica Plain Campus of VA Boston. You will be in the study for approximately 3 months if you decide to stay for the whole study. We will describe your involvement in more detail later in this form.

If you participate in this study, you will continue to receive all your usual medical care services. Taking part in this research study is completely voluntary, and you may withdraw from the study at any time. If you decide to leave the study, your regular medical care and health benefits will not be affected. You will find more information about alternate treatment/procedures later in this form.

Your doctor may also be an investigator in this research study. Being an investigator means your doctor is interested in both you and the study. You may want to get a second opinion about being in the study. You can do so now or at any time during the study. Another doctor who is not an investigator can give you a second opinion about being in the study. You do not have to agree to be in this study even though it is offered by your doctor.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

You might choose to volunteer in the study because you are interested in helping us understand how the brain processes symptoms and how they may change with physical activity and exercise in COPD.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

You may choose not to volunteer to be in the study because you do not wish to undergo MRI scanning of your brain. However, MRI does not expose you to ionizing radiation. You will find more information about these risks later in this form.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is [redacted] at the Boston VA. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study her phone number is [redacted].

DETAILED INFORMATION ABOUT THE STUDY

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study being conducted at VA Boston Healthcare System with the VA Boston Neuroimaging Center, and is funded by the VA Rehabilitation Research & Development Service. The study examines how different parts of the brain communicate with each other in persons with COPD who may have pain and shortness of breath, and how this pattern of communication changes in response to physical activity and exercise. We will enroll 30 males with COPD. You are being asked to participate in this research study because you have COPD and you will be receiving a physical activity or exercise intervention. You are eligible to participate in this research study because either (1) you are receiving the web-based intervention (ESC) as part of RR&D Merit I01 RX002855 (VA Boston IRB #3199) or (2) you will be enrolled in conventional Pulmonary Rehabilitation (PR) at VA Boston as part of your usual clinical care.

HOW LONG WILL I BE IN THE STUDY?

If you are eligible and agree to participate in this study, you will undergo a MRI of your brain twice approximately 3 months apart, once before you start your physical activity or exercise program and once after you finish your program.

WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

The MRI is performed at the VA Boston Jamaica Plain Campus. At the visit, you will complete 4 questionnaires which will take up to 15 minutes. The MRI scan will be completed in one session divided into two parts.

The first part is the preparation for scanning. A member of the research team will meet with you prior to starting the scan. This person will explain to you exactly what will happen during the scan and will answer any questions that you may have. During this time, we will also confirm with you that you do not have any metal in your body or other reasons why you cannot have an MRI using a standardized checklist. During the MRI, metal becomes magnetized and can heat up. You should not have the MRI scan if you have shrapnel, surgical metal clips, or implants, including but not limited to a pacemaker, in your body. Dental fillings are not a problem. If there is a question about your having metal in one part of your body that can be answered by a clinical x-ray, we will bring you to the VA Radiology Department to obtain a clinical x-ray, if you agree. If you do not agree to a clinical x-ray, then you will be unable to participate in this MRI research study. If there is a chance that you may have metal in more than one part of your body, you will not be eligible to have the MRI.

After we have determined that you are safe to have an MRI, you will be asked to remove all metal objects - including but not limited to - watches, jewelry, change, wallet (with credit cards), and shoes. Before you enter the scanner, you will also need to remove your glasses, hearing aids, and dentures (if removable). You will be provided with a locker where you can safely keep all personal items. We will additionally ask you to change into comfortable clothing that is safe to wear in the MRI room for the imaging session and prepare for the session by using the restroom if necessary.

The second part is the imaging session. You will be requested to lie supine on the bed of the scanner, and we will make you as comfortable as possible. We may apply some sensors on your hand and chest, as well as install a respiration belt around your torso and a gas mask that will record your breathing rate. You may require that a person of the same sex help apply the sensors. We will give you earplugs to reduce the noise experienced while in the scanner. Once in the MRI scanner, we will give you a squeeze ball that will allow you to communicate with the investigators at any time you feel necessary. We will ask you to remain as still as possible during the imaging session because motion during the scanning affects image quality.

The investigators will leave the scanning room but will observe the scanning through the glass window. The investigators will talk to you on the intercom system and will confirm that you are comfortable. You will be able to communicate with the investigators through this intercom system. You will be in the scanner for approximately 90 minutes. We will announce the beginning of each scan and ask you to confirm that you are prepared through squeezing the squeeze ball. During the imaging, you will hear loud noises. This is a normal function of the scanner and should be at a comfortable level through use of the earplugs. Additionally, the scanner bed may shake, and this is also a normal function of the scanner.

When imaging is complete, the investigators will notify you that the session is over. Once outside of the scanner, you will change back into your clothes and the imaging will be complete.

If you will be enrolled in Pulmonary Rehabilitation as part of your usual clinical care, you will also undergo the following assessments either by USPS mail or at an in-person research visit before the MRI scan.

You will travel to VA Boston Jamaica Plain campus for two study visits, one before you start the Pulmonary Rehabilitation program and one after you complete the program at approximately 3 months. Each visit will last approximately 1 hour. At the visit, you will complete 4 questionnaires which will take up to 15 minutes. You will undergo the MRI scan described in detail above.
If you are in Pulmonary Rehabilitation:
At the first study visit, you will be asked to do the following to see if you are eligible to join the study.

a. You will be asked to provide information about yourself, such as your age and race, and about your medical history such as medications, oxygen use, and smoking history.

b. You will fill out questionnaires that ask about your health, how you feel, and your physical activity.

c. You will receive questionnaires to complete via the USPS and you will return them to research staff using the pre-paid mailer before you start Pulmonary Rehabilitation and after you complete the program.

d. You will receive paper exercise logs to fill out every day.

e. You will perform a 6-minute walk test and wear a FitBit pedometer to measure daily step counts as part of your usual clinical care in Pulmonary Rehabilitation. Information from the 6-minute walk test obtained during the clinical PR entry and exit evaluation will be used in this research study. Step count information from the FitBit pedometer will also be used in this research study. This will minimize the burden to you and avoid the need to repeat the tests during the research study.

f. You will return to VA Boston approximately 3 months after the first study visit. We will collect your exercise logs. If you are taking part in Pulmonary Rehab, you will provide an updated medical history and questionnaires. You will have your second MRI scan.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

You may not have the MRI procedure if you have certain metal, surgical clips, or implants, including a brain aneurysm clip or a pacemaker in your body because during the procedure metal can heat up and move, or clips and implants can stop working. Dental fillings are not a problem. You will need to remove all jewelry

or clothing with metal before having the MRI scan. Lying down in the MRI scanner may cause back discomfort or anxiety, particularly if you tend to be claustrophobic. Extended periods of time in the MRI scanner can become uncomfortable. We will use all reasonable means to promote comfort including but-not limited to use of pillows and padding. Some people experience a "closed-in" feeling due to the relatively restricted space within the MRI machine. If you should experience such feelings, you can let the researchers know by squeezing the squeeze ball. You can do this at any time to stop the scan. There is a risk of falling getting on and off the scanner table. During the MRI procedure, you will hear many different sounds. These sounds are sharp and repetitive and can cause anxiety in some subjects. We will minimize this with the use of earplugs. While they may be annoying, these sounds are not harmful to your hearing.

If there is any question about whether there is metal in your body, you may be requested to have an x-ray to determine if metal is present. The x-ray will expose you to a small dose of radiation, equivalent to about two-day's worth of natural radiation in the environment. In case you are pregnant you will not be subject to x-ray as unborn children are more sensitive to radiation than adults. If you are of child-bearing age, you will be required to have a pregnancy test before you can receive an x-ray. If you have already had many x-rays, you should discuss this with the researchers before agreeing to be in this study. The x-ray is painless. If a clinical x-ray is indicated, it is critical that you inform research personnel if there is any possibility you could be pregnant. If you believe you may be pregnant, you will not receive an x-ray and you will not be able to participate in this MRI study. The results of the x-ray will be placed in your medical records.

The scans performed in this study are for specific research purposes and are not meant to find any medical abnormalities. We will not routinely provide you or your provider with a report of the brain MRI unless you request one. However, if the investigators or MRI technician notice any potential incidental finding, the scan will be reviewed by a clinical radiologist who will determine whether a clinical evaluation is warranted. If there is a finding that warrants clinical follow-up, study personnel will discuss this with you.

In addition to the risks listed above, you may experience a previously unknown risk or side effect of the MRI scan.

If you will be enrolled in Pulmonary Rehabilitation as part of your usual clinical care and have the additional research assessments, you may have the following additional risks:

- Questionnaire items - It is possible that some questions on the questionnaires may make you feel uncomfortable. You do not need to answer these questions.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

There are no known direct benefits to you for being in this study.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO JOIN THIS STUDY?

This is not a treatment study and therefore, will not alter any treatment you are receiving at the VA.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

Information collected for the purpose of this research study will be kept confidential as required by law. The results of this study may be published for scientific purposes, but your records or identity will not be revealed unless required by law.

Information about you is protected in the following way:
We will store your information in ways we think are secure. To protect your confidentiality, we will use a unique study code instead of your name to identify your information. One master list links your study ID with your name and other identifiable information. This master list is located on a secured network behind the VA Boston firewalls. All paper records (including signed informed consent forms and questionnaires) will be kept in locked cabinets in offices with restricted access. Electronic data will be stored in secure password protected databases and repositories without personal identifiers behind the VA firewall with restricted access to qualified research personnel only. Research personnel who will have access to the data include research assistants and coordinators as well as the principal investigator who are working on the study. All personnel are trained in and maintain valid certifications for VA Privacy and HIPAA training policies. Access to such files will be terminated if an individual leaves his/her VA employment/position or if they fail to maintain the required training and certifications.

In order to do this study, researchers will be collecting information about you and your health. This will include your prior health history and medical tests or records from other sites. The researchers will need to share your information in the following ways:

- If you report a health problem for which you received medical care, study staff may request medical records from institutions outside the VA in order to obtain the details of your medical care. We will use your personal information in order to request the medical records. By signing this informed consent document, you authorize research study staff to use your personal information to request medical records from institutions outside the VA for health problems you have reported to research study staff.

- Your data will be entered into a data repository at VA Boston and used for future studies approved by an IRB. The data repository is located on a VA server within the VA Boston firewall. Only researchers who are approved to use these data will have access.

By signing this consent form, you are agreeing that we may use and share your study data as explained above. There is no date when this agreement expires. You do not have to agree to the above uses.

However, if you do not, you cannot take part in this study. If, in the future, you decide to withdraw this permission after enrolling in this study, no new study data will be gathered from you after you withdraw your permission. However, data gathered from you before you withdrew your permission will be used and shared as explained above.

Identifiers might be removed from the identifiable private information that are collected. After that removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

While this study is being conducted, you will not have access to your research related health records. This will not affect your VA healthcare including your doctor's ability to see your records as part of your normal care.

Your data will be entered into a data repository at VA Boston and used for future studies approved by an IRB. The data repository is located on a VA server within the VA Boston firewall. Only researchers who are approved to use these data will have access.

WHO ELSE MIGHT SEE MY DATA?

You consent to the access of your VA research and medical records that may identify you by persons approved for this purpose. Such access may be by the Institutional Review Board and Research & Development Committees of VABHS, the VA, Federal agencies, or national research oversight and accreditation organizations. You may expect the same confidentiality from these persons that is given to you by the Investigator and his/her research staff.

WHAT ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?

A participant will not be required to pay for medical care and services received as a participant in an approved VA research study. Some participants are required to pay co-payments for medical care and services provided by the VA. These co-payment requirements will continue to apply to medical care and services (including, but not limited to, pulmonary rehabilitation classes, dental services, supplies, medicines, orthopedic and prosthetic appliances, and domiciliary or nursing home care) provided by the VA that are not part of this research study.

You will be compensated $65 for your time and effort completing each research visit and MRI scan.

The government may garnish the compensation against outstanding debts a Veteran has to the federal government. Payment will be made to you by the VA based on your preference: EFT (electronic fund transfer) or direct express debit card. An IRS Form 1091 will be generated regardless of the amount you are paid.

If payments are made by EFT you consent to the release of personally identifying information about you including your name, address, bank account number and the last 4 of your social security number to the Fiscal Office of the VA Boston Healthcare System so that we may provide compensation to you. You should expect to receive payment in your bank account within 2 weeks.

If payments are by direct express debit card you consent to the release of personally identifying information about you including your name, address, and social security number to the VA Boston Fiscal Office so that we may provide compensation to you. You can expect to receive a debit card within 2-6 weeks.

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

In the event that you are injured as a result of your being in this research study, you will receive medical care, including emergency treatment. This care or treatment is governed by federal law and VA policy. You would also have the right to file any legal action, as in any instance of alleged negligence.

DO I HAVE TO TAKE PART IN THE STUDY?

Participation in this MRI study is voluntary, and refusal to take part in the study will involve no penalty or loss of VA benefits to which you are otherwise entitled. You may withdraw from the study at any time without any penalty, loss of rights, or loss of VA or other benefits that you have a right to receive. If you withdraw, the research team may continue to use or disclose the information that it has already collected before you withdrew, which the research team has relied upon for the research. Further information, except from public records, such as survival data, will not be collected.

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

The researchers may have to end your participation in this study for the following reasons:

- The researcher believes that it is not in your best interest to stay in the study
- You become ineligible to participate
- Your condition changes and you need treatment that is not allowed while you are taking part in the study
- You do not follow instructions from the researchers
- The study is suspended or canceled
- You choose to withdraw consent
- You lose too many pedometers

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

I understand that if I have any medical questions about this research study, I can call [redacted] **at** [redacted] during normal working hours. I understand that if I have any general questions about this

research study, I can call [redacted] **at** [redacted] during normal working hours. I understand that if I have any medical problems that might be related to this study that **during the day**, I can call [redacted] **at** [redacted] and **after hours** I can call the **Medical Center operator at** [redacted] and ask for the pulmonary doctor on call.

I understand that, if at any point during or after this study I have any questions about my rights as a research participant or I want to discuss problems, complaints, concerns, and questions about the research, obtain information, or offer input, I may contact the Research Compliance Officer at (857) 364-4182.

If you have questions about your rights as a study participant or any other questions, complaints, concerns or suggestions about this study, you may contact the Institutional Review Board at (617) 637-3794. This is the Board that oversees all human research at VA Boston Healthcare Systems and has the responsibility to ensure the safety of human participants in this study.

WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

You will be told of any significant new findings that come to light during the course of this study and that may relate to your wanting to stay in the study.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

I have read or have had read to me all of the above. Study staff have explained the study to me and answered all my questions. I have been told of the discomforts and risks of the study. I have been told of other choices of treatment that I could have.
I understand that my participation in this study is voluntary, that I do not have to take part in this study and that, if I do take part, I may withdraw from the study at any time. I also understand that, if I refuse to take part or if I decide to withdraw, I will not suffer any penalty, loss of rights, or loss of VA or other benefits that I have a right to receive.

I voluntarily consent to be in this study. I will receive a signed copy of this consent form.

I agree to participate in this research study as has been explained in this form.		
_____ Participant's Name	_____ Participant's Signature	_____ Date

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