



VA RESEARCH CONSENT FORM

Subject Name: _____

Date: _____

Title of Study: **Impact of Exercise Training on Pain and Brain Function in Gulf War Veterans**

Principal

Investigator: **Dane B. Cook**

VAMC: **Madison, WI**

STUDY SPONSOR: The Department of Veterans Affairs

INVITATION:

You are being invited to participate in a research study because you are a Gulf War Veteran and you have chronic muscle pain. Participation in this study is voluntary. It is important that you read and understand the information on this form.

THE PURPOSE OF THE STUDY AND HOW LONG IT WILL LAST:

Purpose. The purpose of this research is to determine the effects of exercise training on the structure and function of your brain. Information on the way your brain responds to heat stimuli and a mental task using colored words will be collected with the use of functional magnetic resonance imaging (fMRI).

Summary. Participants for the current study will be randomly assigned to one of two groups for this study, an exercise training group or a control group. This will be done with a method similar to flipping a coin. Thus, everyone will have an equal chance of being assigned to either group. You will be told what group you have been assigned to at the end of the baseline test day (Day 1).

If you are assigned to the exercise training group, you will be asked to take part in exercise training twice per week for 16 weeks at the Madison VA Hospital. If you are assigned to the control group, you will be asked to maintain your current level of physical activity for the duration of the 16-week study period.

For both groups, participation will involve having your brain scanned six times by functional magnetic resonance imaging (fMRI) over the course of 16 months. You will be asked to lie in the MRI machine, which is a large donut shaped magnet that allows us to make a picture of your brain. FMRI is the same as regular MRI except it is done faster and lets the doctor see how the brain works. For this study we want to see how your brain responds to pain so, while you are in the MRI scanner we will administer several painful heat sensations. We will also take pictures of your brain while you are responding to tests of your ability to identify colors and words. All fMRI testing will take place at the Waisman Laboratory for Brain Imaging and Behavior located on the campus of the University of Wisconsin-Madison.

Additionally, all participants in this study will be asked to undergo a clinical mental health interview. During this interview you will be asked questions about certain behaviors and moods. You will also be asked to submit to a physical exam, which will be done at the Madison VA. For participants assigned to the exercise training condition, we will also ask you to provide blood samples from your arm during the study to examine your body's genetic and immune responses to our testing procedures. This process is detailed later in this consent document.

Why are you being asked to participate?

You have been asked to participate because you are a Gulf War Veteran and you have muscle pain.



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DESCRIPTION OF STUDY INCLUDING PROCEDURES TO BE USED:

What are the procedures for this study?

The procedures for the study are described below. Medical records will be reviewed to be sure you are eligible to be in this study. We will review information about your chronic pain condition, the medication you are taking and whether you are currently struggling, or have in the past struggled, with depression or other mental illnesses.

We will begin by explaining the experiment and giving you the chance to ask questions. If you decide to participate in this research you will be asked to undergo a clinical mental health interview that asks you about certain behaviors and moods, as well as a physical exam. You will then be asked to fill out a number of questionnaires that ask you about your symptoms, your mood and how you feel about certain situations, and how much time you spent being physically active during the last 7 days. These include questions about depression, anxiety, painful symptoms, how you cope with pain, and physical activity levels. This is described in detail below.

1. Clinical Interview. The clinical interview will take place at the VA Hospital with a trained interviewer. During the clinical interview, questions will be asked about your feelings of depression and anxiety, and specific behaviors and thoughts that may be related to certain mental health disorders. Also, questions will be asked about illegal drug use over the past year and will include questions on what you have used. If you use illegal drugs, you will not be able to participate in this study. However, the information concerning illegal drug use will only be used to determine study eligibility. If the interviewer discovers that you are a danger to yourself (suicidal) or to others, the interviewer is required to help you get treatment. The interview will take approximately 20 minutes to complete.

2. Physical Exam. The physical exam will take place at the VA Hospital. During this exam, a trained member of our study staff will perform a general examination and review your medical history to be sure you are healthy enough to be in this study. In addition, you will be asked about your pain history and your current pain symptoms.

3. Questionnaire Battery. Once the procedures above have been completed you will travel to the Waisman Center where the rest of the testing will take place. After arriving at the Waisman Center, study personnel will escort you to a private interview room where you will be asked to complete a battery of 17 questionnaires. These questionnaires will ask you about your feelings, moods, emotions, attitudes, pain symptoms, usual physical activity and sleep. It will take you about 1 hour to complete all of the questionnaires. Your responses on these questionnaires will be used to help us understand potential differences between individuals in the way they respond to the tasks and stimuli administered during the MRI scans.

4. Testing in the MRI Simulator Room. Before undergoing the brain scan you will have a chance to get used to the MRI scanner in our "Simulator Room." The Simulator Room is like the actual scanning room in every detail, except that there is no magnetic field, which means that we will not actually be getting pictures of your brain during this session. This mock scanning session will take approximately 1½ hours. During the mock scanning session we will attach all of the same

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equipment to you that will be used in the real scanner. You will then be asked to undergo a series of tests that examine your perceptions of heat and your ability to identify words and colors. The investigators will teach you how to rate the heat stimuli and how to perform the color and word tasks. The heat stimuli will be given at a number of warm temperatures and will be delivered on the palm of your hand. Your ratings of these different stimuli will help us understand how you perceive different degrees of pain. In total you will receive about 18 heat stimuli during the practice scan. These temperatures may be temporarily painful, but will not result in any injury to the skin on your hand. The heat-generating device is permitted for experimental use by the FDA, and has been used safely for more than a decade. It has several features to ensure that the heat produced is safe and well-controlled. Some of the heat stimuli will be warm, but not painful, while others will be painfully hot. You will be able to alert the study team if at any time you are feeling too much heat pain. If you would like more information on this test, do not hesitate to ask the researchers.

You will also be viewing scales and different colored words through a pair of "goggles" (very similar to looking through binoculars) or on a small mirror positioned above your eyes. You will be asked many questions about your comfort level. This will help us make sure you will be comfortable in the actual scanner. For example, you will be asked if your position in the scanner is comfortable, if the goggles are comfortable, if the simulated noise of the scanner is too disturbing, and if you are experiencing any claustrophobia. You are free to leave at any time if you feel claustrophobic or uncomfortable. These questions will be asked a number of times during the mock experiment.

Following the completion of testing in the Simulator Room, you will be given an ActiGraph activity monitor which we would like you to wear on a belt around your waist for a 7-day period. We will ask you to wear the ActiGraph monitor whenever possible and only to remove it when you are sleeping, bathing or swimming. You will also be given a log sheet to record when you put the monitor on and take it off, including the time out of/into bed each day. You will be asked to wear the monitor for three additional 7-day periods at weeks 5, 10, and 16.

5. Testing in the MRI Scanner. Following the mock scanning session, we will make arrangements for you to come back in about one week for your first brain scanning session. This session takes approximately 2 hours and will be like the mock scan described above. First, you will be asked to complete a few questionnaires regarding your mood and pain symptoms. Then you will be asked to lie on a bed in the center of the MRI machine, a large donut-shaped magnet. The MRI machine creates pictures of your brain using magnets and radio waves. The researchers will position you in the scanner and will make sure that you are comfortable. While in the scanner, you will view the colored words and scales that will be used during testing through a set of goggles. Your eye movement will be monitored using small cameras attached to the goggles. Your heart rate, blood pressure and breathing will also be monitored during the scan. A button box will be placed in your hand. During your time in the fMRI scanner you will again be asked to rate the heat stimuli and perform the color and word tasks in the same fashion as in the simulated MRI. The same heat-generating device used in the simulated-MRI scan will be used to during the MRI scan. Your pain ratings from the first day of testing will be used to determine the temperatures of the stimuli you are exposed to during the MRI scan. You will receive 31 heat stimuli delivered to the palm of your hand, some of which will be at temperatures known to be painful and each lasting for 20 seconds. You will also complete 20 of the color-word tests, each will be about 20 seconds long.



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While in the MRI unit, you will hear loud tapping and pinging noises as the MRI machine images your head. Earplugs or headphones will be provided to make this noise less unpleasant. During the entire procedure you will have to lie still and try to not move your head. The total amount of time you are in the scanner may be up to 1½ hours. This will include tuning and calibration of the MRI machine as well as making sure you are comfortable. Finally, you will be asked to complete a few questionnaires after the scan, before leaving. You will complete 6 scanning sessions in total. The first will be one week following the simulated MRI session. The remaining scans will be at weeks 6, 11, and 17 and 10 and 16 months following baseline testing (Day 2).

6. Exercise Training Condition. Participants assigned to the exercise training group will be asked to perform resistance training exercises twice per week for 16 weeks at the Madison VA Hospital. All exercise training sessions will be performed individually and supervised by certified personal trainers or exercise specialists with the appropriate education and experience. During the first training session, your personal trainer will demonstrate proper use of the exercise equipment and you will be given a chance to practice correct training techniques. Very light loads will be used during the first few sessions until you are comfortable with the movements. After the first few sessions, each training session will begin with a warm-up, followed by completion of 10-15 repetitions of 7-10 different resistance exercises. The load for each exercise will increase gradually over the 16 weeks, as you become stronger. Exercise sessions will last about 90 minutes in duration.

For participants assigned to this group, the total time commitment for your participation will be approximately 65 hours over a 16-month period. This estimate includes the amount of time you will spend in exercise training and completing weekly symptom questionnaires (approximately 48 hours over 16 weeks) as well as taking part in laboratory visits (17 hours over 16 months).

7. Control Condition. Participants assigned to the control group will be asked to maintain their current level of physical activity. For participants assigned to this group, the total time commitment for your participation will be approximately 21 hours over a 16-month period. This estimate includes the amount of time you will spend completing weekly symptom questionnaires (approximately 4 hours over 16 months) as well as taking part in laboratory visits (17 hours over 16 months).

8. Blood Samples. For participants in the exercise training condition, blood samples will be drawn at the beginning and end of 3 testing days (during weeks 2, 7, and 15). We will collect a small amount of blood at each draw (~40 milliliters or 8 teaspoons per sample). This sample will be used to examine how your body responds to exercise and how this response relates to your brain responses during MRI testing. Your blood will be analyzed for certain markers on your white blood cells. You may choose not to participate in this part of the study. If you choose not to participate, you will be asked to complete all aspects of the study described above, but blood samples will not be collected at any point during the study.

Please indicate your willingness to participate in this part of the study by answering the question below:



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If I am assigned to the Exercise Training Condition, I agree to provide blood samples during weeks 2, 7, and 15 of exercise training:

_____ Yes _____ No

9. Restarting the Intervention. If you are assigned to the exercise training condition and an injury, illness or medical condition unrelated to your participation causes you to miss more than 4 weeks of training before you have completed 12 weeks of the intervention, we will offer you a one-time option of restarting the intervention from the beginning. If offered and you agree to restart the intervention you will also be asked to recomplete the MRI testing sessions collected during your original exercise intervention period. This would mean redoing at least one but no more than three of the MRI testing sessions. You would be compensated at the full rate (\$75) for each additional testing session. Travel expenses for any additional testing sessions will also be reimbursed, provided you have not already received the maximum reimbursement amount (\$750).

EXPECTED RISKS, DISCOMFORTS, OR INCONVENIENCES OF PARTICIPATION IN STUDY:

What are the potential risks, discomforts and inconveniences to me?

Resistance Exercise Training

Your participation in exercise training may result in muscle soreness during and following the training sessions. The risk of muscle soreness will be minimized by starting your training slowly with light resistance, teaching you proper training techniques and having your training sessions supervised by a certified personal trainer.

Painful Stimulation

The heat stimuli will result in brief amounts of pain and may result in local tenderness at the site of stimulation. If local tenderness does occur it will likely disappear within a day or two. Pain as a result of the heat stimulus is often described as being similar to touching a hot surface such as a toaster or the roof of a car on a hot summer day. During the fMRI portion of the study, more heat stimuli are delivered and therefore may result in increased pain. Only qualified investigators trained in delivering the heat stimuli will be involved. All stimuli will be delivered within ranges known to be safe and not to result in any permanent discomfort.

fMRI

During the MRI portion of the study, some individuals may experience feelings of claustrophobia, or fatigue and/or physical discomfort from lying still on their back during the scanning session. Some people have also reported tingling or tapping sensations, or muscle twitches in different parts of their body during the imaging procedure. These sensations are not hazardous and should not cause you any discomfort. Occasionally, people who have clasped their hands tightly together during the study have reported a feeling of electrical shock in their hands and arms. This is also not hazardous; however, to avoid any possible discomfort, you should not clasp your hands together during the study. You are free to stop your participation in the MRI at any time if you feel claustrophobic or uncomfortable, or for any other reason.

Blood Samples

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There may be a risk of slight discomfort when the blood is drawn from your arm. The main risks associated with having blood drawn may include infection, bruising, redness, discomfort, or bleeding at the needle puncture site. Most people feel a brief, sharp pain as the needle used to collect the blood sample enters the vein. There is little risk of serious complications from having blood drawn from a vein. You may develop a small bruise at the puncture site. You can reduce the risk of bruising by keeping pressure on the site for at least 10 minutes after the needle is withdrawn. Continued bleeding can be a problem for people with bleeding disorders. Aspirin, warfarin (Coumadin), and other blood-thinning medications can also make bleeding more likely. On rare occasions, the needle may damage a nerve or the vein, causing the vein to become blocked. There is a rare risk of inflammation around the vein used for the blood sampling. This risk will be minimized by using experienced technicians or research coordinators to draw the blood.

Confidentiality

When providing information for study purposes, there is the risk that this information will not remain confidential. This includes the accidental disclosure of sensitive and potentially stigmatizing information such as illegal drug usage or psychological diagnoses. The investigators take this issue very seriously and every effort will be made to keep your information in a locked, secure environment. Additionally, your name will be removed from all documentation and you will be identified by a number only.

Although this study will include genetic testing, results of genetic testing will not be shared with you because the results are considered to be experimental. Genetic information is very sensitive and we will do our best to maintain your information in confidence. A new federal law called the Genetic Information Nondiscrimination Act (GINA) makes it illegal for health insurers and employers to discriminate against you based on your genetic information. But you should know that there are limitations to this law; for example, it does not apply to businesses that employ fewer than 15 people or life insurance, disability insurance or long term care insurance. An abnormal genetic test could result in denial or much higher rates for life insurance, disability insurance, or long term care insurance if your genetic test results were to become known.

To help us protect your privacy, we have applied for a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below. The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

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, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. In addition, the Certificate of Confidentiality will not be used to prevent disclosure to federal, state, or local authorities of a stated intent to harm yourself or others.

Who should not participate in this study?

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Some subjects should not participate in MRI studies. These include persons with metallic implants, such as prostheses or aneurysm clips, or persons with electronic implants, such as cardiac pacemakers. The magnetic field generated by the MRI machine can cause a displacement or malfunctioning of these devices. We know of no risks or adverse effects from the radio signals used in this study. Some subjects report some anxiety or claustrophobia in the MRI scanner since the head must be placed fully inside the scanner tube. In addition, fatigue and physical discomfort due to the length of the MRI session are possible. You must be right-handed and be free of neurological problems (for example, brain injury or dysfunction, epilepsy, Parkinson's disease, tumor) to participate in this study.

Will the brain images from this study be used to diagnose medical problems?

The MRI scans that we perform for the purposes of this study are not designed to detect or diagnose medical problems. As such the images we collect as part of our MRI scans will **not** be read by a qualified reviewer (a neuroradiologist). This means that an abnormality of the brain may go undetected in the brain images we collect. If you are concerned that the physical symptoms you are experiencing may be related to a brain disease, you should see your primary physician, who will decide what types of tests are needed to arrive at a diagnosis.

Will there be compensation for injury if I am injured?

In the event that you sustain injury as a result of participating in this investigation, the VA Hospital will provide all necessary and appropriate care. However, the VA may not pay for the costs of treatment for injuries that result from your non-compliance with study procedures.

Will the UW Hospital provide any injury compensation in addition to that provided by the VA Hospital?

In the event that you are injured as a result of participating in this research at a UW Health facility, emergency care will be available. There is no commitment by UW-Madison, UW Medical Foundation or UW Hospital to provide any compensation for research-related injury. The VA Hospital will reimburse UW-Madison, UW Medical Foundation or UW Hospital for any charges that may result from emergency care at the UW Health facility. You have not released UW-Madison, UW Medical Foundation or UW Hospital from liability for negligence. Please contact the investigator, Dr. Dane Cook at 608-262-7737 if you are injured or for further information.

If I decide to start the study can I change my mind?

Yes, your participation in this study is entirely voluntary. You can refuse to participate now or you can withdraw from the study at any time after giving your consent.

EXPECTED BENEFITS OF THE STUDY:

What are the potential benefits to me for my participation?

For participants assigned to the exercise training condition, you will receive personalized exercise training twice a week for 16 weeks at the Madison VA hospital. Therefore, you may have an increase in strength and fitness, as well as certain cardiovascular benefits, as a result of this training. For participants assigned to the control condition who complete 80% of testing sessions, there is the opportunity to receive 16 weeks of free personal training at the



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Madison VA hospital. Therefore, you may also experience an increase in strength and fitness, as well as certain cardiovascular benefits, as a result of this training.

Are there any costs?

Veteran-subjects, or non-Veteran subjects participating in this VA study, will not be required to pay for care received as a subject in a VA research project. Some Veterans are required to pay co-payments for medical care and services provided at the VA. These co-payments requirements will continue to apply to medical care and services provided by the VA that are not part of this study.

Will I be paid for my participation in the study?

You will be compensated for travel associated with training and testing at the standard VA rate up to a maximum reimbursement of \$750. You will receive \$525 for participating in all seven planned testing sessions of the study. If you do withdraw prior to the end of the study, you will receive \$75 for each day of testing completed. If any testing session is interrupted due to equipment failure and must be rescheduled, you will be paid \$75 for the partially completed session and an additional \$75 for the completed rescheduled session. Payment for any rescheduled sessions will not count toward the \$525 total for planned sessions. If you are offered the option to restart the intervention and agree to do so, you would be paid \$75 for each additional testing session, up to a maximum of three sessions. Payment for any additional sessions will not count toward the \$525 total for planned sessions, but will not exceed a maximum of \$125. In addition, participants in the exercise training group completing at least 80% of training and testing sessions will receive a \$300 certificate to apply towards a membership at a local gym. Participants in the control group completing at least 80% of testing sessions will receive a \$300 certificate to apply towards a membership at a local gym. To receive payment for your participation in this study, you may be required to provide your social security number and bank account information. This information will be used by the VA to pay you for this study and will not be kept by the study team.

HOW WILL MY CONFIDENTIALITY BE PROTECTED?

Your information used for this study will be kept confidential as required by law. The results of your participation in this study may be used for publication or for scientific purposes, but the results will not include any information that could identify you. Current VA regulations require us to keep study records indefinitely. Your data and/or samples will be shared with researchers at the University of Georgia and lab analysts at the Pharmacogenomics Analysis Laboratory at the Central Arkansas Veterans Healthcare System, Little Rock, AR, who are working on this study with us. By signing this consent form and the HIPAA authorization form you are giving us permission to share your data with these researchers. Your identity will not be disclosed unless you give specific consent or if required by law. There are times when we may have to show your records to other people. For example, representatives from offices and agencies that oversee research may review your records, such as UW and Madison VA research oversight offices or other federal agencies that oversee research such as the FDA, the Office for Human Subjects Protections, the VA Office of Research Oversight, or the VA Office of the Inspector General.



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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.

OTHER TREATMENTS AVAILABLE:

You do not have to take part in this study if you do not want to. If you do not take part in this study, your doctor will treat your medical condition in the usual way.

USE OF RESEARCH RESULTS:

Your participation in this study is confidential, which means that nobody outside of authorized study personnel will have access to the information you give us. The information collected during this study will be coded with a number assigned to you. All of the information collected will be kept in locked cabinets or on secure computers. The only list matching the study code number to your name will be kept in a locked cabinet in the office of the Principal Investigator (Dr. Cook). The results of this study may be published or presented at professional conferences, but you will not be identified by name. In the unlikely event that we would receive a court order to release your study records to authorities, we would be obligated to do so. In order to confirm your eligibility for the study and confirm medication use your medical record will be reviewed by Dr. Bridges or a member of the study team under his supervision.

SPECIAL INFORMATION:

1. You are not required to take part in this study. Your participation is entirely voluntary.
2. You can refuse to participate now or you can withdraw from the study at any time after giving your consent. This will not interfere with your regular medical treatment, if you are a patient.
3. There will be no costs to you for any of the treatment or testing done as part of this research study.
4. Eligibility for medical care is based upon the usual VA eligibility policy and is not guaranteed by participation in a research study.
5. For information about the rights of research subjects, contact the VA Patient Representative at (608) 280-7078.
6. If you are a patient, a copy of this consent form will be placed in your VA medical record.
7. Risks to confidentiality will also be minimized by keeping the lone copy of the document linking study assignment number and the participant's unique identifiers with the participant's informed consent in a locked cabinet of the office of Dr. Cook.
8. I have been told that if I complete all planned study visits, I will receive a total of \$525.00 (\$75.00 for each study day) for my participation and a maximum of \$750 for travel reimbursement.

WHAT IF I HAVE QUESTIONS?

If you have questions or concerns about this research, please contact the VA study investigator, Dr. Dane Cook at (608) 262-7737. For information on the right of research subjects, please contact the VA Hospital patient relations representative at (608) 280-7182. If you want to confirm this is a VA study, please call the VA Research Office at (608) 280-7007.



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In case there are medical problems or questions, call Dr. Dane Cook at (608) 262-7737 during the day and Dr. Dane Cook at (608) 262-7737 after hours. If any medical problems occur in connection with this study, the VA will provide emergency care.

AUTHORIZATION SECTION

I have read the information in this consent form, reviewed any questions, and I voluntarily agree to participate in this study. I have received a signed copy of this consent form.

Subject's Signature

Date

Last 4 digits of Subject's Social Security Number

Signature of Person Obtaining Consent

Date

PREGNANCY STATUS – FEMALE SUBJECTS ONLY

The regulations for this type of research do not allow the participation of female subjects who are pregnant. Female subjects are therefore asked either to sign the following statement, or to have a pregnancy test performed before proceeding. Please sign this statement only if you are certain you are not pregnant. If you are not certain, please do not sign this statement, but ask the Investigator to perform a pregnancy test before proceeding.

I confirm that I am not pregnant.

Signature of Subject

Date