U.S. Department of Veterans Affairs

New York/New Jersey VA Health Care Network
VA New Jersey Health Care System
385 Tremont Avenue | East Orange, NJ 07018
973-676-1000

151 Knollcroft Road | Lyons, NJ 07939
908-647-0180

www.newjersey.va.gov

INFORMATION SHEET FOR
HEALTH COACHING FOR CHRONIC MULTI-SYMPTOM ILLNESS (CMI)

You are being asked to participate in a research study conducted by Lisa McAndrew, Ph.D. at VA New Jersey Health Care System (VA NJHCS). You are being asked to participate in this study because you are a Veteran who reports symptoms of chronic pain. Your participation in this research study is voluntary. You may choose not to participate or leave the study at any time without penalty or loss of benefits to which you were otherwise entitled. You can also find a description of this study on clinicaltrials.gov.

WHY IS THIS STUDY BEING DONE?

We are conducting a study where we hope to learn how helpful remote-delivered health coaching is in reducing the disability and impairment caused by Veterans' chronic pain. We will be comparing results to Veterans who are receiving remote-delivered attentional control. Up to 250 Veterans will participate in this study nationwide.

WHAT WILL HAPPEN IF I PARTICIPATE IN THIS STUDY?

If you agree to participate, you will have the option of completing the baseline questionnaire that has been included with this packet prior to your scheduled telephone informed consent appointment. Completing this questionnaire packet should take no longer than 30-40 minutes to complete. You may mail the completed questionnaire packet in the pre-paid envelope provided. If you have a scheduled or will schedule an in-person appointment with us, you may also bring it with you when you come in. If you do not wish to answer any question in the questionnaire packet, you do not have to.

During your scheduled telephone informed consent appointment with us, you will complete the informed consent process over the phone. If you participate, the total duration of your participation in this study will be approximately 6 months.

In this study, you will be randomized (like flipping a coin) into one of two groups; one group will receive 12 sessions of remote-delivered health coaching and the other group will receive 12 session of remote-delivered attentional control. Health coaching and attentional control can be delivered through the VA's Video Connect (VVC) technology or by telephone. Sessions will last ~1 hour and may be recorded with your permission.

You will also be asked to complete questionnaire packets at 4 different timepoints: at the beginning of the study (this baseline questionnaire packet is enclosed), after the 6th session of either health coaching or attentional control, post treatment (after the 12th session of either health coaching or attentional control), and 24 weeks after the first packet is collected.

ARE THERE ANY RISKS OR DISCOMFORTS?

Any research study may have risks and discomforts. Risks that may occur include:

Loss of confidentiality: There is a risk that information (data) collected from this study could be connected to your name. This is called "loss of confidentiality." Data collected from the study will be kept in a secured shared network folder in a VA password protected computer within the secure VA server. Only the research team can look at the data. All paper documents will be kept in a locked cabinet in a locked office and will be accessible only to the research team. Our plan for data storage and security is consistent with the Veterans Affairs. In addition, you will be assigned a Unique ID# that will be used on all data collected by you. Your name will not be attached to any data.

Risk of emotional distress: It is possible you could find some of the questions upsetting.
If you are experiencing emotional distress you may contact the National VA CRISIS LINE at 1-800-273-8255. The Crisis Line is available 24 hours a day, every day of the year.

You may also call the NJ WRIISC during regular business hours and ask to speak with a mental health provider that is part of our study team at 1-800-248-8005.

As part of health coaching, you may decide to make changes to your daily activities (e.g., starting a new diet, doing physical activity, increase social activities). If and how you make these changes is your choice. There could be risks associated with any changes you make to your daily life. You should consult with your primary care provider or other medical provider to minimize any risks and address any concerns you may have about changes you may wish to make. We may also contact your health care provider.

- You will be encouraged to eat a diet consistent with the Mediterranean diet. This is a high fiber diet and could cause bloating, gas, or indigestion.

• You will be encouraged to increase social activities of your choosing; there could be risks with any change that you make.

• You will be encouraged to slowly increase physical activity. Physical activity may cause an increase in heart rate, an increase in blood pressure, shortness of breath, general fatigue, and in some cases muscle soreness or injury to the muscle, bone, or joint. Exercise may cause you to experience a serious cardiac event, an arrhythmia, or chest pain. The possibility of experiencing a serious cardiac event has been estimated to be approximately 6 per 10,000 in exercising adults.

Risks of the usual care you receive are not risks of the research. Those risks are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

ARE THERE ANY BENEFITS?

There are no direct benefits to you from taking part in this research study. However, the information we get from this study might help us better understand how best to treat chronic pain. It is possible you may experience improvement in pain and disability.

WHO WILL SEE AND HAVE ACCESS TO MY INFORMATION?

All data collected from the study will be maintained in a secured shared network folder within the secure VA server. Only VA members of the research team will have access to the shared network folder and its electronic files. Some of the data analysis will be completed by our University collaborator, Rutgers University School of Public Health.

The information collected for this study will be kept confidential. There are times when we might have to show your records to people outside of the research team. For example, someone from the Office of Human Research Protections, the Government Accountability Office, the Office of the Inspector General, the VA Office of Research Oversight, our local IRB, our local Research and Development Committee, and other study monitors may look at or copy portions of records that identify you.

WILL I RECEIVE ANY PAYMENT IF I PARTICIPATE IN THIS STUDY?

You will be compensated up to $275 for completing questionnaires as follows:

•Baseline questionnaire = $50

•6-week mid treatment questionnaire = $50

•Post-treatment (12-week) questionnaire = $100

•24-week follow-up questionnaire = $75

IS THERE COMPENSATION IF I AM INJURED FROM MY PARTICIPATION IN THE STUDY?

If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you unless the injury was due to your not following the study procedures.

WHO CAN I TALK TO ABOUT THE STUDY?

If you have any questions, comments or concerns about the research or in the event of a research related injury, please immediately contact Dr. Lisa McAndrew at 973-676-1000 ext. 1+201167. If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the VANJHCS IRB at 973-676-1000 ext.1- 202778.

WHAT HAPPENS TO MY INFORMATION IF I WITHDRAW FROM THE STUDY?

Your participation in this study is voluntary; if you decide to take part, you may still withdraw at any time. If you do not wish to be in this study or leave the study early, you will not lose any benefits to which you are entitled. If you don't take part, you can still receive all usual care that is available to you. Your decision not to take part will not affect the relationship you have with your doctor or other staff, and it will not affect the usual care that you receive as a patient.

If you decide to withdraw from the study prior to completion, data already collected prior to your withdrawal may still be reviewed and analyzed.

WHAT HAPPENS TO MY DATA AFTER MY PARTICIPATION IN THE STUDY?

Your data or health information may be reused at a later date for additional research purposes. With your permission, your data will be stored in a data repository created by the War Related Illness and Injury Study Center (WRIISC). All the data in the repository will be coded and will reside on a secure server administered by the Information Resource Management (IRM).