Study title:
Enhancing the Success of Functional Restoration Using Integrative Therapies:
Comparative Effectiveness Analysis in Active Duty Service Members with Chronic Pain

Informed Consent

Date of Initial Approval of Original Protocol: 4/28/2015

Date of Approval of Most Recent Informed Consent Form: 4/25/2018

(see approval stamp on page 1 of Informed Consent Document)

Today's date: 11/30/20

MADIGAN ARMY MEDICAL CENTER
Tacoma, WA

Consent for Voluntary Participation in a Non-Clinical Research Study Entitled:
"Enhancing the Success of Functional Restoration using Integrative Therapies: Comparative Effectiveness Analysis in Active Duty Service Members with Chronic Pain"

Principal Investigator: Dr. Diane Flynn, MD, Primary Care Pain Advisor, Interdisciplinary Pain Management Center

Study site: Interdisciplinary Pain Management Center, Madigan Army Medical Center

Funded by: U. S. Army Medical Research and Materiel Command

1. INTRODUCTION OF THE STUDY

You are being asked to participate in this research study because you were referred to the Interdisciplinary Pain Management Center (IPMC) for pain management. Your participation is voluntary. If you decline to participate this will not result in any punishment or loss of benefits to which you are otherwise permitted. Please read the information below and ask questions about anything you do not understand before deciding whether to take part in the study.

2. PURPOSE OF THE STUDY

The purpose of the study is to determine if certain therapies, such as acupuncture, chiropractic and yoga improve the effectiveness of the functional restoration intensive outpatient program (IOP) your doctor has recommended for you.

3. PROCEDURES TO BE FOLLOWED

If you agree to be in this study, you will be assigned to one of two study groups by chance, using a process similar to the flip of a coin. This process is called randomization. Neither you nor the study staff will select the group you will be assigned to. One treatment group will receive a course of acupuncture, chiropractic, yoga and, if recommended by your treatment team, medical massage and/or biofeedback during the three weeks prior to starting the IOP. The other group will not receive these therapies prior to the IOP, but will be given the option of those therapies after completing the IOP.

4. AMOUNT OF TIME FOR YOU TO COMPLETE THE STUDY

You will be part of this study from six to twelve weeks. Participation in this study may result in 13-17 additional visits to the IPMC during a three-week period to obtain the acupuncture, chiropractic, yoga and

other care. Each visit will last between 15-60 minutes. Every attempt will be made to cluster these visits together to limit your visits to Madigan to approximately two half-days per week.

5. NUMBER OF PEOPLE THAT WILL TAKE PART IN THIS STUDY

A total of 210 individuals are expected to take part in this study at Madigan.

6. POSSIBLE RISKS OR DISCOMFORTS FROM BEING IN THIS STUDY

The types of therapies and associated possible risks and discomforts from being in this research study include:

Functional rehabilitation: You will work closely with a physical therapy and occupational therapy team who will do a complete assessment of your fitness at the beginning of the program and create a gentle program to gradually and safely increase your strength and endurance. You may experience general muscle soreness for the first week or so, but this typically resolves during the program. If you experience a pain flare, the Physical and Occupational therapy team will give you advice on how to manage the flare.

Acupuncture: The risks of acupuncture are low, if conducted by a competent, certified acupuncture practitioner. All IPMC acupuncture providers have demonstrated competence and certification. Possible side effects and complications include:

Soreness. After acupuncture, you might have soreness, minor bleeding or bruising at the needle sites.

Organ Injury. If the needles are pushed in too deeply, they could puncture an internal organ- particularly the lungs. This is an extremely rare complication in the hands of an experienced practitioner.

Infections. Licensed acupuncturists are required to use sterile, disposable needles. A reused needle could expose you to diseases such as hepatitis.

Conditions that may increase your risks of complications include:

Bleeding disorders. Your chances of bleeding or bruising from the needles increase, if you have a bleeding disorder or if you're taking blood thinners such as warfarin (Coumadin).

Having a pacemaker. Some types of acupuncture involve applying mild electrical pulses to the needles, which can interfere with a pacemaker's operation.

Pregnancy. The majority of acupuncture sites and techniques are completely safe in pregnancy. However, there are a small number of acupuncture techniques that are not recommended in pregnancy and these techniques will not be used for participants who are or think they might be pregnant.

Chiropractic: Chiropractic adjustment is safe when it's performed by someone trained and licensed to deliver chiropractic care. The IPMC chiropractor has more than 20 years of experience. Serious complications associated with chiropractic adjustment are overall rare, but may include:

A herniated disk in the spine.

Compression of nerves in the lower spinal column, which can cause pain, weakness, loss of feeling in your legs, and loss of bowel or bladder control.

A certain type of stroke after neck manipulation.

Yoga: Like any exercise, yoga can have risks. People with herniated disks or osteoporosis, for example, should avoid deep forward bends. The IPMC yoga therapy assistant will instruct you not to do any movements that are uncomfortable.

Aquatics (pool) therapy: Pool therapy will be supervised by a trained medical professional and flotation devices will be used, so even people who cannot swim can safety participate. The pool is monitored to ensure it meets standards for chlorination and cleanliness.

Medical massage therapy: Medical massage is a low risk therapy, but may temporarily increase muscle soreness.

Biofeedback: Biofeedback is a method to help you increase awareness the effects of pain and muscle tension on your heart rate, breathing rate and muscle tone. There are no known risks of this method of monitoring.

Psychological Distress. If something in this research makes you uncomfortable or upset, you have the right to stop taking part in this research at any time without loss of benefits, and you may contact the investigator for referral. If the investigator notes that you are distressed or anxious about your participation in this research, you will be evaluated by the IPMC psychologist or referred to your primary care physician or professional counselor for help.

7. POSSIBLE BENEFITS FROM BEING IN THIS STUDY

You may benefit from this study because acupuncture, chiropractic, yoga and other non-conventional therapies may increase the effectiveness of the Intensive Outpatient Functional Restoration Program. This information will help us design effective treatment approaches for other service members with pain. However, no benefit can be guaranteed.

8. CONFIDENTIALITY/PRIVACY OF YOUR IDENTITY AND YOUR RESEARCH RECORDS

The principal investigator will keep your research records. These records may be looked at by staff from the Representatives of the Department of Defense, Madigan Department of

Clinical Investigation, Regional Health Command - Pacific Institutional Review Board (IRB), the Army Human Research Protections Office (AHRPO), the study sponsor (Defense Health Program, Defense Medical Research and Development Program, U.S. Army Medical Research and Materiel Command), and other government agencies as part of their duties. These duties include making sure that the research participants are protected. Confidentiality of your records will be protected to the extent possible under existing regulations and laws but cannot be guaranteed. Complete confidentiality cannot be promised, particularly for military personnel, because information bearing on your health may be required to be reported to appropriate medical or command authorities. Your name will not appear in any published paper or presentation related to this study.

This research study meets the confidentiality requirements of the Health Insurance Portability and Accountability Act (HIPAA).

9. ADDITIONAL INFORMATION ABOUT THIS STUDY

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.

10. CONDITIONS UNDER WHICH YOUR PARTICIPATION IN THIS STUDY MAY BE STOPPED WITHOUT YOUR CONSENT

Your taking part in this study may be stopped without your consent if remaining in the study might be dangerous or harmful to you. Your taking part in this study may also be stopped without your consent if the military mission requires it, or if you lose your right to receive medical care at a military hospital, any monitoring procedures that you are involved in that might result in injury for you or inadequate cooperation on your part.

11. ELIGIBILITY AND PAYMENT FOR BEING IN THIS STUDY

You will not receive any payment for your participation this study.

12. COMPENSATION IF INJURED AND LIMITS TO MEDICAL CARE

There are no plans for you to receive any compensation (payment) should you be injured as a direct result of being in this study. This is not a waiver or release of your legal rights or any legal remedy available to you. You should discuss this issue thoroughly with the principal investigator before you enroll in this study.

Should you be injured as a result of your participation in this study, you will be given medical care for that injury at no cost to you. Medical care is limited to the care normally allowed for Department of Defense health care beneficiaries (patients eligible for TRICARE coverage and care at military hospitals and clinics). Necessary medical care does not include in-home

care or nursing home care. If you need to be hospitalized, you may have to pay the normal fees for subsistence (hospital meals), as per standard regulations.

If at any time you believe you have suffered an injury or illness as a result of participating in this research project, you should contact the Madigan Human Subjects Administrator at 253-968-0147.

13. COSTS THAT MAY RESULT FROM TAKING PART IN THIS STUDY

There is no charge to you for taking part in this study.

14. IF YOU DECIDE TO STOP TAKING PART IN THIS STUDY AND THE INSTRUCTIONS FOR STOPPING EARLY

You have the right to withdraw from this study at any time. If you decide to stop taking part in this study, you should tell the principal investigator as soon as possible; by leaving this study at any time, you in no way risk losing your right to medical care.

15. YOUR RIGHTS IF YOU TAKE PART IN THIS STUDY

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care.

16. AUTHORIZATION FOR RESEARCH USE OF PROTECTED HEALTH INFORMATION

The Federal Health Insurance Portability and Accountability Act (HIPAA) includes a Privacy Rule that gives special safeguards to Protected Health Information (PHI) that is identifiable, in other words, can be directly linked to you (for example, by your name, Social Security Number, birth date, etc.). We are required to advise you how your PHI will be used.

(1).What information will be collected?

For this research study, we will be collecting information about your pain intensity, mood, distress, muscle tension, medication use and functional level. To determine how these factors change during and after your participation, the PHI we will collect includes your name, date of birth, gender, race, ethnicity, social security number, DoD ID number, medications prescribed, and medical evaluation board (MEB) status.

(2).Who may use your PHI within the Military Healthcare System?

The members of the research team will have access to your health information in order to find out if you qualify to participate in this study, to administer research therapy, to monitor your progress and to analyze the research data. Additionally, your PHI may be made

available to health oversight groups such as the Madigan Department of Clinical Investigation and the Regional Health Command – Pacific Institutional Review Board.

(3).What persons outside of the Military Healthcare System who are under the HIPAA requirements will receive your PHI?

The study sponsor may need to do an audit of your research records. If you experience a complication, we may be required to provide information about your medical history (with your name and other personal identifying information blocked out) to the study sponsor.

(4).What is the purpose for using or disclosing your PHI?

The members of the research team need to use your PHI in order to analyze the information and to monitor your safety.

(5). How long will the researchers keep your PHI?

The research team in the Interdisciplinary Pain Management Center will keep the research data for up to six years after the end of the study. Then all the information will be destroyed. The master code, which links your name and social security number to your response to pain care, will be destroyed as soon as all data collection is completed.

(6). Can you review your own research information?

You will not be able to look at your research information until the study has ended.

(7). Can you cancel this Authorization?

Yes. If you cancel this Authorization, however, you will no longer be included in the research study. The information we collected from you can be destroyed at your request. If you want to cancel your Authorization, please contact the Principal Investigator in writing.

(8).What will happen if you decide not to grant this Authorization?

If you decide not to grant this Authorization, you will not be able to participate in this research study. Refusal to grant this Authorization will not result in any loss of your medical benefits.

(9). Can your PHI be disclosed to parties not included in this Authorization who are not under the HIPAA requirements?

There is a potential that your research information will be shared with another party not listed in this Authorization in order to meet legal or regulatory requirements. Examples of persons who may access your PHI include representatives of the Food and Drug Administration, the Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP), and the DHHS Office for Civil Rights. This disclosure is unlikely to occur, but in that case, your health information would no longer be protected by the HIPAA Privacy Rule.

(10).Who should you contact if you have any complaints?

If you believe your privacy rights have been violated, you may file a written complaint with the Madigan HIPAA Officer, 9040 Jackson Ave, Tacoma, WA, 98431. Telephone: 253-968-1642. Your signature at the end of this document acknowledges that you authorize Madigan personnel to use and disclose your Protected Health Information (PHI) collected about you for research purposes as described above.

17. CONTACTS FOR QUESTIONS ABOUT THE STUDY

If you have questions about the study, or if you think you have a study-related injury, you should contact the Principal Investigator, Dr. Diane Flynn at 253-968-5165. For questions about your rights as a research participant, contact the Regional Health Command – Pacific IRB Office at 253-968-0149, or the Madigan Staff Judge Advocate Office, telephone 253-968-1525.

A copy of this signed consent form will be provided to you.

SIGNATURE OF RESEARCH PARTICIPANT

You have read the information in this consent form. You have been given a chance to ask questions and all of your questions have been answered to your satisfaction.

BY SIGNING THIS CONSENT FORM, I FREELY AGREE TO TAKE PART IN THE RESEARCH IT DESCRIBES.

_____ _____

Subject's Signature Date

_____

Subject's Printed Name

SIGNATURE OF INVESTIGATOR / PERSON CONDUCTING CONSENT

You have explained the research to the volunteer and answered all of his/her questions. You believe that the volunteer subject understands the information described in this document and freely consents to participate.

_____

Investigator/Person Conducting Consent Signature Date (must be same as the subject's)

_____

Investigator/Person Conducting Consent Printed Name