Study: The Effects of OMT on the Expression of Immune Cell Biomarkers

Informed Consent

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WRITTEN INFORMED CONSENT FOR PARTICIPATION IN RESEARCH ACTIVITIES (KCOM)

Participant's name (printed)_____

Wayne Zhou, Ph. D. (Primary Investigator), Karen T. Snider, D.O. (Co-Primary Investigator), and Shalini Bhatia, M.S., of the AT Still University - Kirksville College of Osteopathic Medicine (ATSU-KCOM) have requested my participation in a research project entitled, "The effects of Osteopathic Manipulation on the expression patterns of immune cell biomarkers". The major purpose of this project is to study the effects of osteopathic manipulative treatment (OMT) on the body's immune system by analyzing the changes immune cell proteins in white blood cells of participants, before and after intervention – OMT or seated control. Changes in immune cell proteins will be analyzed using a novel technology, known as Protein Subcellular Localization (PSL). Included in the study will be approximately 40 men and women of ages ranging from 20 to 55 years old from the surrounding area of Kirksville, MO. The participants will be divided at random into two groups, a control group consisting of 20 people, and an OMT group also consisting of 20.

In order to participate in this study, I will need to have experienced at least one or more episodes of LBP in the past two weeks, I must be able to lie on my back for 30 minutes, and I must be able to tolerate OMT. I may not participate if I have had any prior spinal surgery, fractures, or known birth defects of the lumbar vertebra and sacrum. I will not be able to participate if I am pregnant woman. I cannot participate if I have a body mass index (BMI) over 30 kg/m^2 or have had any form of spinal manipulation, such as osteopathic or chiropractic manipulation, or have had corticosteroids, in the last 2 weeks, or have had nonsteroidal anti-inflammatory medication in the last 48 hours.

My participation as a volunteer participant will include completion of a brief medical history questionnaire, an initial physical exam identifying somatic dysfunction related to the low back pain, and then an initial blood draw of 8 ml (less than 2 teaspoons) at the Gutensohn Clinic building in Kirksville, MO. After the initial blood draw, the control group will wait in another room for approximately 30 minutes and the participants in the OMT group will receive OMT for my low back pain to improve the somatic dysfunctions. The types of OMT techniques performed will include such techniques as muscle energy, articular, or high velocity-low amplitude (HVLA) and will be at the discretion of the treating physician with the total treatment time not to exceeding 20 minutes. Following the wait period for the control group and the OMT for the OMT group, all participants will receive a second draw blood of 8 ml for the project. After the second blood draw, participants in the control group will then be offered OMT for their low back pain. My total time commitment for this study is approximately 50 minutes. If I am in the control group and choose to accept the OMT after the second blood draw, then my time commitment will be approximately 70 minutes.

This study carries no significant foreseeable risk other than that ordinarily encountered in my daily life or from a standard blood draw, physical examination, or OMT treatment. The OMT performed in this study will focus on improving my low back pain via correcting somatic dysfunction. The most common side-effect from the blood draw is localized bruising. OMT carries a risk of post-treatment soreness similar to what a person may experience after exercising. Potential for psychological injury from the physical examination, OMT, or blood draw are minimal. As this is a study uncovering the effect of OMT on immune cell proteins, there will be no alternative procedures performed. During the course of the study I will need to expose the skin around my elbow for drawing blood. Should I be injured, the Primary Investigator of this study will arrange for me to receive appropriate care. ATSU-KCOM assumes neither liability for this research project nor makes any commitment to provide any compensation for such injuries.

The results of this research may be published; however, neither my name nor identity will be revealed and my records will remain confidential. Confidentiality will be maintained by using coded identification numbers on all forms. Only this consent form will contain my name. All consent forms will be kept and treated like my personal medical record and kept in a locked file accessible only to the primary investigator. As required by new Federal law, all personal health information will be maintained in accordance with the Health Insurance Portability and Accountability Act (HIPAA) to ensure privacy. There is a possibility that the Food and Drug Administration (FDA) staff may review pertinent medical records associated with this.

Participant initials: _____

My participation in this study may or may not have direct personal benefits, including relief of low back pain. However, the results of the study may benefit others by providing scientific information which could have important implications for future clinical trials, future clinical research, and ultimately diminishing future debilitating conditions such as LBP.

To compensate me for my time, travel, and effort as a volunteer participant in this study I will receive one free osteopathic manipulation treatment and a $25 Walmart gift card.

My participation is voluntary and refusal to participate will involve no penalty to me or loss of benefits to which I am otherwise entitled. I also understand that I may withdraw from the research study at any time without any penalty or prejudice. I may also cancel authorization to use my personally identifiable health information at any time, though the research team may continue to use non-identifiable information that has already been collected. The investigators, with or without my consent, may terminate my participation. There will be no charges to me for the physical exam, blood drawing, or OMT. Any questions that I may have will be answered by Karen T. Snider, D.O., who may be reached by telephone at 660-626-2304 (after hours 660-785-1000) or any one of the other above mentioned investigators. If I have any questions about my rights as a research participant, the HIPAA notice of Privacy, or in the event I have suffered any injury as a result of my participation in the research project, I may contact the chair of the ATSU-KCOM Institutional Review Board: Robert J. Theobald, Ph.D., (phone: 660-626- 2320), 800 West Jefferson, Kirksville, MO 63501, who will discuss any questions or will be able to refer me to an individual who will review the matter with me, and/or identify other resources that may be available to me, and/or provide information as to how to proceed.

I have read and understand the previous statements and have been able to ask questions and express concerns which have been satisfactorily responded to by one of the above mentioned investigators or his/her designee. I believe I understand the purpose of the study as well as the potential benefits and risks that are involved. I hereby give my informed and free consent to be a participant in this study and allow my personal health information to be used by the Principal Investigator and the research team in this medical research project.

Signature of Participant _____ Date_____

Name_____

Address_____

Telephone_____ ATSU

employee Yes☐ No☐

I certify that I have explained to the above individual the nature, purpose, potential benefits, and possible risks associated with participation in this research study; have answered all questions that have been raised; and have witnessed the above signature. These elements of Informed Consent conform to the assurance given by KCOM to the DHHS to protect the rights of human participants in accordance with the HIPAA Privacy Rule. I have provided the participant/patient with a copy of this document.

Signature of Investigator or Designee _____Date_____