Ultrasonographic Evaluation of the Effect of Osteopathic Manipulative Treatment on Sacral Base Asymmetry

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WRITTEN INFORMED CONSENT FOR PARTICIPATION IN RESEARCH ACTIVITIES (KCOM)

Participant's name (printed)_____

Karen T. Snider, D.O. (Primary Investigator), Tatyana Kondrashova, M.D., Crystal Redman, D.O., Chris Edwards, D.O., 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, "Ultrasound Evaluation of the Effect of Osteopathic Manipulative Therapy on Sacral Base Asymmetry". The major purpose of this project is to demonstrate the effect of osteopathic manipulative treatment (OMT) on sacral base asymmetries as measured by ultrasound. The sacral bases are the right and left sides of the upper part of your sacrum (tailbone). Asymmetry of the sacral bases is often present in people with low back pain (LBP). 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 stomach 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. If pregnant (women only), I may be able to participant, if I meet the above criteria. I cannot participate if I have a body mass index (BMI) over 28 kg/m^2 or have had any form of spinal manipulation, such as osteopathic or chiropractic manipulation, in the last 2 weeks. I should not participate nor be actively participating in any other medical research during the course of this study.

My participation as a volunteer participant will include completion of a brief medical history questionnaire, an initial physical exam looking for sacral base asymmetry and then an initial ultrasound measurement of sacral base asymmetry in the ATSU-KCOM McConnell Information and Technology building in Kirksville, MO. After the ultrasound measurement, the control group will wait in another room for approximately 30 minutes and the participants in the OMT group will receive OMT to correct the sacral base asymmetry. Following the wait period for the control group and the OMT for the OMT group, all participants will receive a second ultrasound measurement of sacral base asymmetry. The ultrasonographer will be blinded on whether the participant received OMT or not. After the second ultrasound measurement, participants in the control group will then be offered OMT to correct any sacral base asymmetry detected during the physical exam. My total time commitment for this study is approximately 60 minutes. If I am in the control group and choose to accept the OMT after the final ultrasound, then my time commitment will be approximately 90 minutes.

This study carries no significant foreseeable risk other than that ordinarily encountered in my daily life or from a standard physical exam or OMT treatment. The OMT performed in this study will focus on correcting sacral base asymmetry by treating the sacrum and the surrounding regions (lumbar, pelvis, and legs). 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. OMT carries a risk of post-treatment soreness similar to what a person may experience after exercising. Potential for psychological injury from the physical exam, OMT, or ultrasound measurement are minimal. As this is a study demonstrating the effect of OMT on sacral base asymmetries as measured by ultrasound there will be no alternative procedures performed outside of those already discussed. During the course of the study I will need to expose the skin overlying my low back and upper part of my sacrum to allow for the ultrasound measurements. Should I be injured, the Primary Investigator of this study will arrange for me to receive appropriate care to resolve my injury. 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.

My participation in this study may or may not have direct personal benefits. 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 $25 Walmart gift card upon completion of the initial physical exam and ultrasound measurement, OMT (if applicable), and final ultrasound measurement. In order to receive this compensation I must include my current address on the consent form. If I am an employee of ATSU I may be taxed on the gift card on my ATSU paycheck. 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, ultrasound measurements, 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 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_____