

Patient-reported Adverse Events From Osteopathic Manipulative Treatment

Informed Consent Form

NCT02386085

02/01/2015

RESEARCH OPPORTUNITY

In conjunction with A.T. Still University in Kirksville, MO, we are conducting a research study entitled "Patient-reported Adverse Events from Osteopathic Manipulative Treatment (OMT)" and we are seeking research volunteers. If you are receiving this informational packet, you have just received OMT at this office visit and you are eligible to participate. Please read the following "Consent for Clinical Research" information. If you agree to participate in this research study, please complete either the enclosed paper survey or the online survey by going to:

www.do-touch.net/aesurvey/

You should begin either survey the **day after** your office visit. If you complete the online survey, you will need to enter the study code found in the blue box on the paper survey. If you are required to complete the W-9 form included with this packet, you may return it in the postage-paid envelope.

If you agree to participate and complete the required surveys, you will receive \$10 in compensation (in the form of a gift card or money order) for your time. If you have further questions or would like more information, contact the DO-Touch.NET Network Manager, Lisa Norman, at lnorman@atsu.edu or 660-626-2443.

CONSENT FOR CLINICAL RESEARCH

A.T. Still Research Institute - A.T. Still University (ATSU)

Title of Study: Patient-reported Adverse Events from Osteopathic Manipulative Treatment (OMT)

Principal Investigators: Jane Johnson, MA, and Brian Degenhardt, DO

Site Director: _____

This is to certify that I have been given the following information with respect to my participation as a volunteer in a research study under the supervision of Jane Johnson, MA, and Brian Degenhardt, DO.

Throughout this consent form, the terms "I", "me", or "my" will refer only to the participant.

1. Purpose of the Study: The purpose of this study is to evaluate the incidence and severity of osteopathic manipulative treatment (OMT) side effects and to examine the relationship of these side effects with the methods used by my clinician and the areas of my body that he/she treated.
2. Procedures to Be Followed: I understand that there will be no change in the care I receive from my clinician by participating in this study. If I agree to participate, I will be asked to complete a paper or online survey regarding any side effects I experience 24 hours, 72 hours, and 1 week after my treatment. Information regarding the osteopathic techniques used in each body region and my medical diagnoses will be obtained from my clinician. My clinician will be informed if my survey responses might indicate a significant change in my health.
3. Time Commitment: My office visit will take the same amount of time regardless of my study involvement. The 24-hour, mid-week, and 1-week surveys will take approximately 5-10 minutes each to complete.
4. Voluntary Participation and Alternative Procedures: My participation in this research study is voluntary. I understand that I may withdraw at any time. My withdrawal from this study or my refusal to participate will in no way affect my care or access to medical services. I understand that my participation in the study may be stopped by the investigator without my consent if this action is deemed appropriate. Any significant findings that develop during the course of this research that may relate to my willingness to continue providing consent for participation will be given to me. The only alternative procedure is to decline participation in this research.

5. a. Benefits to Me: None.
- b. Potential Benefits to Society: Information gained from this research may lead to improved understanding of various osteopathic techniques and side effects associated with each individual technique. This may eventually lead to improved medical interventions for multiple common conditions.
6. Risks: I will have no increased risk by participating in this study beyond what I would have at a usual office visit.
7. Statement of Confidentiality: All records associated with my participation in the study will be subject to the current confidentiality standards applicable to medical records, and in the event of any publication resulting from the research, no personally identifiable information will be disclosed.

If I agree to participate, my medical records containing protected health information (individually identifiable information about me) will be accessed for this research study. This protected health information created prior to and during this study may be used for purposes related to the conduct of this research and for a period afterward necessary to review the results for publication and prepare for a related follow-up study. I will be assigned a coded number that will be used on all research documents. The record that identifies my name with this coded number will be maintained for at least three years in a secure location at my clinician's office, separate from any research data, and will be reviewed by my clinician only. All necessary precautions will be taken to reduce any risk of loss of confidentiality.

A description of this research study is available at <http://www.ClinicalTrials.gov>. This website will not include information that can identify me. At most, the website will include a summary of the results. I can search this website at any time.

8. Compensation and/or Financial Responsibility: I understand that I will receive \$10 (in the form of a gift card or money order) for my time after I complete and return all the surveys associated with this study (24-hour, midweek, and 1-week). To be eligible for this compensation, I must disclose if I am involved with any additional research studies being conducted at A.T. Still University (ATSU) and the amount of compensation received in the current calendar year.

Participants who receive \$500 from ATSU research studies within one calendar year will be required to complete and return a W-9 form (included in this packet; identifies my name, address, and social security number; and will be submitted to the ATSU Controller's Office upon receipt) for IRS tax purposes. Failure to complete and return the form once a total of \$500 has been received in research compensation will render me ineligible to participate further in the study until the following tax year. Study payments that reach IRS limits of \$600 in a calendar year will be reported to the IRS as required by law.

9. Right to Ask Questions: If I believe I may have developed an injury that is related to this research, if I decide to withdraw from the research, or if I have other questions, I can contact Jane Johnson, MA, at 660-626-2331; she will answer my questions or refer me for evaluation. I understand that medical care is available from ATSU in the event of injury resulting from research but that neither financial compensation nor free medical treatment is provided. I also understand that I am not waiving any rights that I may have against ATSU for injury resulting from negligence of ATSU or investigators.

If I have questions or concerns related to this study, my rights as a research subject, or I believe I may have developed an injury that is related to this research, I should contact the chair of the ATSU Kirksville Institutional Review Board: Robert J. Theobald, PhD, telephone: 660-626-2320, 800 West Jefferson St., Kirksville, MO 63501.

If I have any questions about this consent form or contents contained within, I can contact Lisa Norman, Network Manager, at lnorman@atsu.edu or 660-626-2443.

Instructions: A checkbox to provide consent is on the 24-hour Survey. After you have read and understood the content of this consent form, please make sure you check the consent form box on the 24-hour Survey if you wish to participate in this study. Any set of surveys that does not have a checked consent box on the 24-hour Survey will not be included in this research.