

Patient-reported Adverse Events From Osteopathic Manipulative Treatment

Study Protocol and Statistical Analysis Plan

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PATIENT-REPORTED ADVERSE EVENTS FROM OSTEOPATHIC MANIPULATIVE TREATMENT

STUDY PROTOCOL

A prospective observational cohort study design will be used to accomplish the specific aims of the proposed study. Patients receiving OMT at one of the research sites will receive a coded information packet inviting them to participate in the study. Patients will have the option of completing the 24-hour, 72-hour, and 1-week survey either electronically or using the paper surveys included in the information packet. The clinician will provide documentation of the diagnoses, osteopathic technique(s) used, and body region(s) treated for all patients who complete the 24-hour survey.

i. Participants

DO-Touch.NET members will be recruited to join the proposed study as a research site. The goal is to have at least 50 clinicians contributing to this study. All patients from the research sites who receive OMT and who are age 18 years and above will be eligible to participate in the proposed study. Patients who are unable to communicate in English, Spanish, French, German, or Portuguese will be excluded. Participation is voluntary and informed consent will be elicited from eligible patients prior to their completion of the surveys. A total of 1000 participants will be included in the study.

ii. Recruitment and Procedures

An informational poster will be placed in the waiting room to introduce the study to the patients being seen that day. Following completion of their office visit, eligible patients will be provided an informational packet with a unique code number, paper copies of the surveys, and instructions on how to access the online survey. The code will be recorded by the staff on a tracking sheet to facilitate linking the patient-reported data on adverse events with the clinic treatment documentation.

Informed consent will be obtained as the first page of the 24-hour survey and will include consent for the clinician who treated the patient to provide de-identified documentation of the OMT provided. Participants completing the 24-hour survey online who provide their email address will receive an automated invitation to complete the 72-hour and 1-week surveys. Participants who choose to complete the surveys on paper will be provided a postage-paid envelope to return the surveys to the central coordinating center. Participants who complete all 3 surveys will receive \$10 in the form of a gift card or money order.

When a participant completes the 24-hour survey online or when a completed survey packet is received, the network manager at the central coordinating center will inform the research site that they need to provide documentation of the OMT from the corresponding patient-encounter including the diagnoses treated with OMT, what techniques were performed on that patient, and the clinician's assessment of patient response to the treatment.

iii. Data Collection Instruments

Study data will be collected and managed using REDCap electronic data capture tools hosted at A.T. Still University. Data from participants that is submitted using paper surveys will be entered into REDCap at the central coordinating center.

Patient-reported Adverse Events: Basic demographic information (i.e., sex, age, race, and ethnicity) will be obtained from participants at the beginning of the 24-hour survey. The 24- and 72-hour surveys will assess the severity, duration, and location of potential adverse events including pain or discomfort, stiffness, unexpected tiredness or fatigue, headache, light headedness, numbness or tingling, muscle weakness, difficulty talking, vision disturbance, tinnitus, nausea or vomiting, problems sleeping, irritability or crying, and difficulty walking. Participants will also be able to add other potential adverse events to the list. They will be asked to assess whether the symptom is definitely, probably, possibly, unlikely, or not related to the OMT received. Additionally, the 24- and 72-hour surveys will assess the existence of these symptoms within the week prior to treatment and whether the participants have sought urgent care, visited the emergency room, or been hospitalized. The 1-week survey will follow-up on adverse events reported on the 72-hour survey. The timing of these surveys is designed to provide information regarding whether the onset of adverse events after OMT is immediate (<24 hours) or delayed (24-72 hours) and whether the duration is short (<72 hours), medium (≥72 hours but less than 1 week), or long (≥1 week).

Documentation of OMT: Documentation of the OMT provided will consist of a standard matrix of checkboxes designating which osteopathic technique(s) were used in which body region(s). The potential osteopathic techniques include articulatory/still, balanced ligamentous tension/ligamentous articular strain, osteopathy in the cranial field, counterstrain/facilitated positional release, high velocity/low amplitude (thrust), indirect/functional method, muscle energy, myofascial release, soft tissue, and visceral. An area will be provided to describe techniques used which are not included in any of these technique groupings. The standard 10 body regions (head/face, neck, thoracic, ribs, lumbar, sacrum, pelvis, abdomen/other, upper extremities, and lower extremities) will be included in the matrix. For each region treated, the physician will be asked to quantify the patient's response to treatment as resolved, improved, unchanged, or worsened.

STATISTICAL ANALYSIS PLAN

The de-identified data will be downloaded from the REDCap system at the end of data collection. The incidence of each adverse event will be estimated from the entire sample using 95% confidence intervals obtained by fitting generalized linear mixed models to account for the clustering of responses from patients treated by the same clinician. Additionally, generalized linear mixed models will be used to test whether certain techniques or body regions have higher incidence of adverse events than others.