Title of Study: The Effect of Osteopathic Manipulative Treatment (OMT) on Proprioception in Adults: A Pilot Study

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Project Purpose

The purpose of this proposed study is to investigate the mechanism of osteopathic manipulative treatment (OMT). Previous studies have shown the effectiveness of OMT on decreasing patient symptoms by removing somatic dysfunctions. The procedure (OMT) of removing somatic dysfunctions has been explained and the mechanism of removing somatic dysfunction by OMT has been theorized. It is thought that by removing somatic dysfunction, OMT changes proprioception. This study seeks to identify if proprioception is the mechanism by which OMT exerts its effect on correcting somatic dysfunction. The investigators will investigate this affect globally throughout the body. Proprioception is the body's position sense, meaning, the mind's ability to know where the body is in space. The measurement of proprioception will include having participants complete standing tests with both legs and single-leg on a force plate. The force plate is a measurement of balance and sway of a participant. Balance has input from proprioception, the cerebellum, vision, and the vestibular system. While the investigators cannot eliminate all of the components, the investigators will test participants with eyes closed to get closer to isolating proprioception. The hypothesis is that OMT will improve proprioception supporting the thought that OMT removes somatic dysfunction by affecting proprioception.

Study design and procedures:

Participants will go through an informed consent process, fill out a screening questionnaire and will undergo neurological testing. If there are any abnormalities in their neurological testing or they meet exclusion criteria, they will not be included in the study. The neurological testing will include reflex testing, sensation testing, strength testing, and coordination and balance tests.

Participants will then be randomized into 2 groups. One control and one treatment.

Each group will have their balance measured using the portable force plate. Participants will be tested on both feet with arms crossed and eyes open for 60 seconds, and both feet with arms crossed and eyes closed for 60 seconds. Then they will be given 15 seconds to practice standing on the force plate on only their right leg with eyes open and arms crossed. The investigators will then test their balance on their right leg with arms crossed and eyes open for 30 seconds. They will be given 15 seconds to practice standing on their right leg with their arms crossed and eyes closed, and then will have their balance tested on their right leg with arms crossed and eyes closed for 30 seconds. The same sequence of events will take place for the left leg as their right leg. This sequence of measurements will take place at the beginning and end of their first treatment visit. For the standing test with eyes closed and all single leg tests a fellow will be standing beside the force plate with an arm and either side of the patient to prevent the participant from falling and hurting themselves.

The force plate calculates the center of mass of the participant, the area that is covered by the center of mass, the length of the path of center of mass, the velocity of its motion, and the maximum sway in the x and y planes.
During the single leg tests, The investigators will also record the time of when the participant brings the other foot down, touches the two legs together, or if the sternum becomes outside the borders of the pelvis, if they do lose their balance The test duration will be 30 seconds, as stated previously.

Between the two balance tests, the treatment group will receive a full-body osteopathic manipulative treatment according to the Common Compensatory Pattern (CCP). CCP is a

treatment approach developed by Dr. Zinc that addresses the transition areas of the body. The treatment will be given by one of the four fellows under supervision by a licensed physician and last 10-20 minutes. The treatment will include the following body regions:
Occipito-atlantal Joint
Thoracic Inlet
Thoraco-lumbar shift
Lumbo-pelvic roll
Ribs
Sacrum
Pelvis
Upslip
Upper extremity
Lower extremity

The fellows will diagnose somatic dysfunctions within these body regions, treat, and reassess to make sure the somatic dysfunctions are resolved. The physician will perform a spinal sweep and side-to-side height assessments before and after treatment to verify there was improvement in somatic dysfunctions.

After the treatment, the treatment group will walk around the perimeter of the OMM lab three times before retesting their balance.

The control group will be asked to lay on an OMM treatment for 15 minutes. They will then walk around the perimeter of the OMM lab three times before retesting their balance.

The treatment group will come for five visits. The first visit will include the informed consent and neurological exam. The second visit will include a balance measurement, a treatment, and a follow-up balance measurement immediately after the treatment. The next two visits will consist only of osteopathic treatments. Each visit will be spaced one week apart. The participant will come back a week after their last treatment and complete follow-up balance testing.

The control group will have a total of five visits. They will have the same initial visit as the treatment group with informed consent and neurological exam. Their second visit will consist of a balance measurement, have somatic dysfunctions be diagnosed, yet not be treated and have an immediate follow-up measurement. The third and fourth visits will consist of diagnosing somatic dysfunctions without any treatment. The last visit will consist of a follow-up balance testing. Each of these visits will be one week apart.

The data from the force that will be used includes area that the center of mass covers, length of pathway of center of mass, velocity of the center of mass, medial-lateral sway, and anterior-posterior sway. The investigators will also use the length of time participants were able to stand on one leg without losing their balance (without moving their knee or chest outside of their midline, their foot leaving the platform, touching their opposite foot to the ground, or letting their legs touch).

Inclusion criteria:

Participants must be 18-40 years old, have the ability to give consent, and be able to bare weight on both feet.

Exclusion criteria:

Participants will be excluded from the study if they have had manipulation performed by a D.O., physical therapist, or chiropractor in the last two months, have had surgery in the six months, had broken or fractured a bone in the last six months, have an abnormal neurological exam, or has a cerebellar dysfunction or ataxia, has a condition that impairs balance (including orthostatic hypertension, otoneurologic conditions, or arrhythmias). Patient will also be asked about dizziness, fainting, previous falls, fever, weight loss, pain that wakes them up at night, morning stiffness or localized bone pain and would be evaluated if participants needed to be excluded for medical treatment.

Recruitment:

Recruitment will occur through advertisements using social media, flyers, word of mouth, and class announcements. The advertisement is attached and will also function as a script for the class announcements. Email addresses will be collected from participants for appointment scheduling and reminders.

Informed Consent:

The investigators will schedule the informed consent process to be 45 minutes to allow participants to decide if they wish to go forward with the study. Informed consent will begin by explaining the purpose of the study. The investigators will then explain the timeline of the study including the randomization of a treatment and control group and scheduling of visits. The fellows will also give an overview of what OMM is and some examples of the treatment styles that will be used, and the body regions that will potentially be treated. There will be five minutes provided for questions. The OMM fellows will then explain how the force plate is used and demonstrate what participants will have to perform on the force plate, and explain when balance measurements will be taken. The reimbursement schedule will then be discussed and what is required for full reimbursement. Lastly, 15 minutes will be provided for any questions. After completion of consent, the participants will fill out a screening questionnaire and go through a neurological examination.

The principal investigator and four research participants will be involved with the informed consent process. They have all completed CITI training. The four research assistants will be explaining the study and answering questions during the informed consent process with the supervision of the principal investigator. The informed consent documents will be signed with a research assistant present after all questions have been answered and will collected by the research assistant. The forms will be kept in a locked drawer within a locked office for the duration of the study.

Data analysis:

According to the project study design, data will be collected at three occasions for six balance measurement variables of interest. The six variable include length of pathway of center of mass, area covered by center of mass, velocity of center of mass, medial-lateral sway, posterior-anterior sway, and time lapsed during the single leg tests. Summary descriptive statistics will be first obtained for the selected variables and demographics covariates as appropriate. For a particular variable, the change between pre- (or baseline) and post- treatment during the first week reflects the immediate treatment effect while the difference between the pre-treatment baseline and the last measurement during week 4 represents the long-term lasting accumulative effect. The data bear the characteristics of repeated measurements on the same study participants since more than one measurements are taken on the same study participant over time. Thus, it is usually plausible to assume the measurements on the same individual subjects

are correlated. Ignoring the covariance between such measurements may result in erroneous statistical inference, and avoiding it by data transformation may result in inefficient statistical inference. The statistical technique of linear mixed model allows the covariance structure to be integrated into the modeling while accounting for the randomness of the study subjects. Thus, the data will be analyzed separately for each variable with a linear mixed-effect model with repeated measures design to assess the OMT effects on the balance measurement metrics over time. In the model fitting process, several candidate covariance structures will be selected and evaluated according to the experimental design (i.e., unequal spacing of the time points but with the same time points across the study participants, within-subject correlation over time and convergence of model fitting), out of which one optimal covariance structure will be selected by the Akaike information criterion (AIC) criteria. On the basis of the chosen models for the respective variables, statistical contrasts will be set up to compare the mean values of variable measurements between time points to assess the immediate and long-term effects of OMT treatment. Tukey procedure for the multiple testing adjustment will be used to compute the adjusted p-value in case of need.