Title: Effects of Osteopathic Manipulative Treatment and Bio Electro-Magnetic Regulation Therapy on Low Back Pain in Adults.

NCT04704375

June 13, 2019

CONSENT FORM for OMT Research Study
LECOM – Bradenton

Introduction

You are invited to take part in a research study at LECOM-Bradenton. Researchers and medical students at LECOM-Bradenton are investigating the individual and combine effects of osteopathic manipulative treatment (OMT) and BEMER therapy on low back pain. This study may yield information that will benefit future students and could extend benefits to other members of society, especially those with severe low back pain.

Research Methods

The length of the study is 3 weeks. A sample of approximately 40 participants is anticipated. If you decide to participate, you will be randomly assigned one of 4 treatments groups. Depending on the group you are assigned, you will receive OMT treatment 3 times per week for 3 weeks, or BEMER therapy five times per week for 3 weeks, or both. All treatments will be performed during the span of three consecutive weeks. You will complete brief questionnaires regarding low back pain and quality of life before the beginning of study and will complete the same questionnaires following the completion of the three week treatment. Each treatment session should last between 10-30 minutes. You will be assigned a study coordinator group in order to individually schedule your treatment sessions at your convenience. A licensed osteopathic physician will be available at all times a treatment is being given.

All of your answers to the questionnaire and data collected during the treatment sessions will be entered electronically via a secure website and de-identified using your randomized study number.

Confidentiality

Your information will be kept confidential to anyone outside of the study. Individuals involved in the study include trained LECOM-Bradenton faculty and medical student research assistants. After we collect your survey and treatment results, we will not keep a record of your name or any other information that could identify you. This de-identified information will be kept confidential to the extent legally possible. In the case of an emergency, only the principal investigator will link your information to your identity by asking you to disclose your identity in a private setting. Emergencies are considered to be hospitalization, illness, an abnormal lab value, grave injury, or legal matters. This information will only be shared with the principal investigator; neither the researchers nor anyone else at LECOM-Bradenton will be able to link the results of the surveys or treatments to you.

Subject Risks

The effectiveness of OMT is considered experimental in the context of this study. All research studies have some degree of risk or discomfort. In this study, you may risk feeling slight discomfort during manipulative or standard treatment. Following the treatment, it is possible

that you will feel some muscle tenderness or generalized discomfort 24-48 hours after the session. Much more rarely, more serious adverse effects include: substantial injury, excessive muscle soreness, loss of consciousness, vertigo, dizziness, shortness of breath, chest pain, and any type of paresthesia in arms, leg, or neck. If you experience any of these symptoms they should be brought to the attention of the supervising physician immediately.
Your treatment will be performed by trained medical students, supervised by licensed osteopathic physicians. Medical students will disclose their true identity to avoid any misconception that they are licensed physicians. There is little empiric data about the "hazards" to patients of student-performed procedures. However, absence of confirmatory data does not mean that a risk does not exist. Considering students' inexperience, student-performed procedures would be expected to carry a higher risk of complication to patients (Marracino, MD & Orr, MD, 1998). After OMT therapy, muscle tenderness and generalized discomfort may be noted 24-48 hours after treatment in a small number of patients. There are no funds designated to compensate subjects for injury. The principal investigator will work with injured subjects to provide them with further information to the best of his ability.

There are no anticipated adverse effects associated with BEMER therapy.

There could be a potential risk of loss of privacy or confidentiality if an unauthorized person gained access to the sample data. However, we believe that the security measures taken in the study protocol make it highly unlikely that such an event would occur. Additionally, some risks to the subject (or to the fetus/embryo if the subject is or may become pregnant) are currently unforeseeable.

Compensation
Your participation is voluntary; refusal to participate will result in no penalties. You may choose to discontinue participation at any time without penalty, but you will not receive compensation. Additionally, there will be no costs for participation. Your participation will not provide any benefit/negative impact with respect to your status at LECOM. Should you choose to participate, you will be compensated for your time with a $50 gift certificate after the successful completion of your final treatment session. If you consent to the study but do not attend all treatment sessions or fail to complete all survey questions, the principal investigator will terminate your participation and you will not receive compensation.

Eligibility
Students are not eligible to participate if currently pregnant as the procedure may involve risks to the unborn fetus or embryo. Additional exclusion criteria include any individual who has a current medical history of:

- Psychiatric conditions
- Skin disorders or open wounds precluding skin contact
- Fasciitis of fascial tears
- Myositis
- Neurological symptoms such as numbness, tingling, weakness in lower extremities

- Neoplasia
- Bone fracture, osteomyelitis, or osteoporosis
- Coagulation problem
- Deep vein thrombosis
- Adrenal diseases/syndromes
- Acute upper or lower respiratory infection
- Immunosuppressive syndromes
- Radiation or chemotherapy within the past 3 years
- Lupus
- Osteopenia
- Pregnancy
- Congestive heart failure
- BMI greater than 30
- Any other autoimmune disease not stated above
- Medication changes within the last 4 weeks
- Asthma exacerbations within the last 4 weeks
- Immunosuppressive therapy as a consequence of organ transplantation
- Immunosuppressive therapy as a consequence of allogeneic cellular transplantations or bone marrow stem cell transplantation
- Other conditions often requiring immunosuppressive therapy
- Pregnancy
- Anticoagulant therapy with Rivaroxaban (Xarelto®)
- Deep Vein Thrombosis
- Known sensitivity to the carotid sinus reflex

If you develop any of these issues during the course of the study, you will be removed from the study without penalty and still receive compensation.

References

Marracino, MD, R. K., & Orr, MD, R. D. (1998). Entitling the student doctor. J Gen Intern Med , 13 (4), 266-270. Retrieved from http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1496940/

If you have questions about the research or incur a research related injury please contact:

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If you have questions about your rights as a research subject, please contact
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Signature of Subject Date

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