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

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Research Title:

Effects of Osteopathic Manipulative Treatment (OMT) and Bio Electro-Magnetic Regulation (BEMER) Therapy on low back pain in adults.

Research Purpose:

The aim of this project is to investigate the individual and combined effects of Osteopathic Manipulative Treatment (OMT) and Bio Electro-Magnetic Regulation (BEMER) Therapy on low back pain in adults.

Study Summary:

It is clear that low back pain (LBP) is a major challenge in our society, which can lead to severe disability in many individuals. Although there are several different treatments and approaches to help individuals with LBP, the number affected by this condition has been steadily increasing.

OMT has been shown to be helpful in the treatment of LBP. In fact, the use of OMT has been shown to increase mobility of the lumbar myofascial tissues, visceral motion and decrease pain in patients with LBP. Bio Electro-Magnetic Regulation (BEMER) Therapy is a therapeutic modality that deploys a biorhythmically defined stimulus through a Pulsed Electromagnetic Field (PEMF), which leads to an increase in blood flow. The positive effects of BEMER on the circulation has been shown to result in significant increases in arteriovenous oxygen difference, number of open capillaries, arteriolar and venular flow volume, and flow rate of red blood cells in the microvasculature [1, 2]. Therefore, BEMER can potentially be used in the treatment of LBP by improving microcirculation in muscular tissue. In fact, BEMER with physiotherapy showed reductions in pain and fatigue acutely in patients with chronic low back pain [3]. A systemic review of randomized controlled trials that investigated whether PEMF was effective in low back pain showed there was decrease in pain intensity and improved functionality in individuals with different low back pain conditions [4].

Therefore, it is plausible that the combination of OMT and BEMER therapy may help increase circulation to myofascial structures that influence low back restriction and pain. The purpose of

this study is to investigate the individual and combined effects of OMT and BEMER therapy on low back pain.

Review of Literature:

Low back pain (LBP) has become a major challenge in our society and has a relatively high incidence and prevalence [5]. Moreover, LBP currently affects people of all ages and is a leading contributor to disease burden worldwide [6]. Individuals affected by LBP may experience this discomfort and associated disability for several months, and a proportion may remain severely disabled [7]. For nearly all people with low back pain, it is not possible to identify a specific nociceptive cause. Most people with new episodes of LBP may recover quickly; however, recurrence is common and in many cases, LBP becomes persistent and disabling [8].

Despite the overabundance of treatments and approaches devoted to LBP, this back related disability and the number of individuals affected have steadily been increasing [9, 10]. During the past three decades, changes have been made to key recommendations in national clinical practice guidelines. In fact, currently there is a bigger emphasis placed on self-management, physical and psychological therapies, and some forms of complementary medicine (such as spinal manipulation, massage, acupuncture), and less emphasis on pharmacological and surgical treatments [11].

Despite multiple clinical guidelines providing similar recommendations for managing low back pain, a substantial gap between evidence and practice exists [12]. Osteopathic manipulative treatment (OMT) is a distinctive modality used by osteopathic physicians to complement conventional management of LBP. There is considerable variability in OMT approaches when treating for LBP. Furthermore, osteopathic physicians combine conventional and complementary treatments when caring for patients with LBP. This increased variability in the approach to care for LBP patients requires more empirical data to determine the best approaches to treat LBP [13]. Franke *et al*. [14] conducted a meta-analysis that investigated the effect of OMT in LBP. The authors reported that some studies observed significant effect of OMT on pain [15-17], whereas other reported either a non-significant effect [18-20], or an effect in favor of the control treatment [19, 20]. It is clear that more research to better describe the effects of OMT on LBP is warranted.

OMT is the application of hands-on forces to help improve physiologic function and/or support homeostasis that has been negatively altered by somatic dysfunction [21], which is an impairment of function of any area of the body system [22]. These impairments can occur at the muscles, fascia, bones, joints, ligaments, vasculature, lymphatics and nerves. When somatic dysfunction is diagnosed, using an osteopaths' manual palpatory skills, it is treated with OMT. In general, OMT techniques can be classified as direct or indirect. Direct techniques such as muscle energy (ME), high velocity low amplitude (HVLA), soft tissue (ST), and myofascial release (MFR) engage the restrictive barrier and use a specifically applied force to correct the somatic dysfunction [21]. Indirect techniques such as MFR, counterstrain (CS), balanced ligamentous

tension (BLT) disengage from the restrictive barrier and the affected body part is moved into its freedom of motion [21].

The etiology of low back pain is varied from visceral causes, to a lack of adequate blood flow to the muscles and musculoskeletal imbalance. Inadequate blood supply and/or inadequate oxygen consumption can influence muscle pain [23, 24]. The role of OMT is thought to primarily address the musculoskeletal component of back pain, which may help improve muscle blood flow. Two of the primary goals of treatment with osteopathic techniques are to restore mobility and decrease pain. Using trained palpatory skills to diagnose alterations in the fascial connections within the body, it is proposed that OMT techniques can help alleviate these alterations in the body that may lead to musculoskeletal disorders such as low back pain [25]. Many studies that use OMT as the intervention to reduce low back pain, utilize a combination of direct and indirect techniques [15, 18, 26, 27]. The use of myofascial release technique has been shown to increase mobility of the lumbar myofascial tissues, visceral motion and decrease pain in patients with non-specific low back pain using ultrasound diagnostics [28].

One very promising alternative approach for the treatment of LBP is the use of Bio Electro-Magnetic Regulation (BEMER) Therapy. BEMER is a therapeutic modality that deploys a biorhythmically defined stimulus through a Pulsed Electromagnetic Field (PEMF). This stimulus has a targeted effect on the microvasculature, and the primary effect is an improvement in tissue microcirculation [3]. The positive effects of vasomotion on the microcirculation has been shown to result in significant increases in arteriovenous oxygen difference, number of open capillaries, arteriolar and venular flow volume, and flow rate of red blood cells in the microvasculature [1, 2]. Therefore, BEMER can potentially be used in the treatment of LBP by improving microcirculation in muscular tissue.

Though OMT has been shown to be effective clinically for patients in decreasing pain, little is known behind the specific mechanisms of action. It is believed all osteopathic techniques use the concepts of fascial connectivity throughout the body and therefore can help increase circulation and lymphatic flow [21, 29]. In one study, the use of OMT helped decrease autonomic and neuroendocrine markers in response to mental stress [30]. In modeled studies, OMT modalities like MFR and CS showed possible effects in modifying cytokine secretion, improving wound healing, and modifying muscle contraction [31]. These effects were shown to sometimes reverse repetitive muscle strain in the tissues. It is postulated that these strains may represent the phenomenon of somatic dysfunction. Another study showed improvement in lower extremity blood pressure, cell mass, intracellular water, basal metabolism, venous velocity, skin temperature, pain, and quality of life post MFR and physical therapy for post-menopausal women with venous insufficiency [32]. As discussed previously, BEMER therapy has been shown to increase microcirculation. BEMER with physiotherapy showed reductions in pain and fatigue acutely in patients with chronic low back pain [3]. A systemic review of randomized controlled trials that investigated whether PEMF was effective in low back pain showed there was decrease in pain intensity and improved functionality in individuals with different low back pain conditions [4]. Therefore the results from these studies suggest that the combination of

OMT and BEMER therapy can potentially help increase circulation to myofascial structures that influence low back restriction and pain.

Methodology

I. Study Design
   a. Prospective, noninvasive study to examine the individual and combined effects of OMT and Bio Electro-Magnetic Regulation (BEMER) Therapy on low back pain in adults.
   b. Study treatment location: All treatments and post treatment measurements will be performed in the osteopathic manipulative therapy laboratory at Lake Erie College of Osteopathic Medicine, Bradenton. Dr. Nicole Myers or Dr. Thomas Quinn, who are licensed osteopathic physicians, will be on call in the vicinity of the treatment location, however not necessarily in the room of treatment.
   c. Data Collection
      i. After written consent is obtained, the study coordinator will assign the participant a randomized study number to de-identify the participant.
      ii. To achieve our project's goal, we will have 4 separate groups (OMT, BEMER, OMT+BEMER, and Placebo). OMT, BEMER, and placebo treatments will be performed by osteopathic medical students who have completed additional training given by a licensed osteopathic physician, to ensure uniform technique.
      iii. To control for anchoring bias, subjects will be randomized into one of the four groups: OMT, BEMER, OMT+BEMER, and Placebo.
      iv. <u>Osteopathic Manipulation Diagnosis and Treatment Protocol</u>

Osteopathic Diagnosis and Screening

1. Observe and Palpate Thoracic and lumbar muscles for TART (tenderness, asymmetry, restriction of motion, and tenderness) changes
2. Lumbar intersegmental diagnosis: used to guide treatment with muscle energy technique
3. Counterstrain Tenderpoint screening for the following muscles: psoas major, quadratus lumborum and piriformis- used to guide treatment with counterstrain technique
4. Sacrum diagnosis: Spring test at the base of the sacrum for palpation of flexed or extended dysfunction
5. Sacroiliac dysfunction: ASIS compression test – used to lateralize somatic dysfunction at sacroiliac joints

Osteopathic Treatment/Techniques

6. Regional thoracic myofascial release technique prone
7. Lumbosacral fascia myofascial release technique prone
8. Lumbar soft tissue unilateral pressure technique prone
9. Lumbar muscle energy technique seated or lateral recumbent

10. Psoas, piriformis, quadratus lumborum counterstrain technique supine
11. Sacrum balanced ligamentous tension technique supine
12. Lumbosacral/Pelvic fascia Myofascial Release technique supine

v. Second year osteopathic medical students will perform the duties of assessing and screening for somatic dysfunction in these regions, as well as the treatment modalities (as listed above). All treatment modalities were previously learned by the students during the osteopathic principles and practices (OPP) course. In addition, the students performing the treatments will receive further training by the OPP course director and OPP clinical faculty at LECOM-Bradenton. The diagnosis/screening exam and OMT techniques will last approximately 15-20minutes.

vi. <u>BEMER Protocol</u>

1. Subject will lay supine on the BEMER mat, and place the B.Pad® in their lower back. BEMER mat intensity 3 will be selected in week 1, intensity 4 for week 2, and intensity 5 for week 3. B.Pad® will be set for Program 1 in week 1, Program 2 in week 2, and Program 3 in week 3. Treatments last approximately 15-20 minutes.

d. Description of Therapies used

i. OMT

1. Myofascial release (MFR) is a system of diagnosis and treatment which engages continual palpatory feedback to achieve release of myofascial tissues [33].MFR can be performed in a direct or indirect manner. If direct MFR is being performed the area of myofascial tissue restriction is engaged for the myofascial tissues and the tissue is loaded with a constant force until tissue release occurs. If indirect MFR is being performed the area of the body with dysfunctional myofascial tissues are guided along the path of least obstruction until free movement is achieved. For this study, the student doctors will perform MFR in the thoracic, lumbar and sacral regions with the patient lying on their back and on their stomach.
2. Soft tissue (ST) is a system of diagnosis and treatment directed toward tissues other than bony or joint origins [33]. Soft tissue technique involves direct engagement of myofascial tissues and is applied with lateral stretching, linear stretching, deep pressure, traction and/or separation of muscle origin and insertion while monitoring tissue response and motion changes by palpation. Soft tissue techniques will be applied to the lumbar region in this study.
3. Muscle energy (ME) is a form of osteopathic manipulative diagnosis and treatment in which the patient's muscles are actively used on request, from a precisely controlled position, in a

specific direction, and against a distinctly executed physician counterforce [33]. The precisely directly muscle contraction from the subject, that is resisted equally by the treater, is proposed to increase tension on the Golgi tendon organ proprioceptors within a muscle [21]. Reflexively this will cause inhibition and subsequent increase in the muscle length within a hypertonic muscle [33]. This temporary increase in muscle length and relaxation are what the treater is monitoring [33]. We will use muscle energy technique in the lumbar region in either the seated or lateral recumbent position in this study.

4. Counterstrain (CS) technique is a system of diagnosis and treatment that considers the dysfunction to be a continuing, inappropriate muscle/tendon/ligament strain reflex, which is stopped by applying a position of mild strain in the direction exactly opposite to that of the reflex; this is accomplished by specific directed positioning about the point of tenderness to achieve the desired therapeutic response [33]. We will screen for counterstrain tenderpoints associated with psoas, quadratus lumborum, and piriformis muscles. These muscles have attachments to the lumbar spine, pelvis and the lower extremity and have been postulated to be a contributing factor to musculoskeletal causes of low back pain [34, 35]. Some of this techniques proposed mechanisms of action includes change in muscle spindle reflex, alpha Ia afferents and gamma efferent system with the corrective positioning [21, 33].
5. Balanced ligamentous tension (BLT) technique takes into account that all the joints in the body are balanced ligamentous articular mechanisms [21]. The ligaments provide somatosensory information that guides the muscle response for positioning the joint and the ligaments themselves guide the motion of the bony components. The goal of treatment is to balance the tension in contrasting ligaments where there is inappropriate tension present. BLT will be performed in the study in the lumbar, pelvis and sacrum. The common proposed mechanism of action for all the techniques used in the study include using the physiologic properties of connective tissue and the fascial continuum of the body to help relieve myofascial restrictions [21].

ii. Bio Electro-Magnetic Regulation (BEMER) Therapy

1. BEMER is a therapeutic modality that deploys a biorhythmically defined stimulus through Pulsed Electromagnetic Field (PEMF). This stimulus has a targeted effect on the microvasculature, and the primary effect is an improvement in tissue microcirculation [3]. The positive effects of vasomotion on the microcirculation has been shown to result in significant increases in arteriovenous

oxygen difference, number of open capillaries, arteriolar and venular flow volume, and flow rate of red blood cells in the microvasculature [1, 2]. Therefore, BEMER can potentially be used in the treatment of LBP by improving microcirculation in muscular tissue.

iii. Placebo (Light touch, and BEMER Sham): Treaters will place their hands lightly on the subject's lumbar paraspinal muscles in the supine and prone positions in the same area as where one would place your hands for lumbar MFR technique for the same amount of time as it would take to perform MFR in this area (approximately 5 minutes). However, no lifting or action will be done. In addition, the subject will lie down on the BEMER mat (as they would do during a BEMER session), but the device will not be activated. This treatment will be used as a control.

e. The research assistants will individually coordinate experimental times with the subjects. A licensed osteopathic physician will be in the vicinity of the treatment location at all times while treatments are being given.
f. OMT, BEMER, and placebo will be performed by osteopathic medical students who have completed additional training given by a licensed osteopathic physician to ensure uniform technique. A licensed osteopathic physician will be in the vicinity of the treatment location at all times while treatments are being given.
g. All data collection logs will be de-identified of personal information and only contain the randomized participant ID number linking the participant to the data collected. Thompson Fillmer, who is one of the research coordinators, will be the data analyst.
h. The identifying information will be maintained by the principal investigator in a locked cabinet, which he alone has access to.

II. Study Procedures and Timeline

a. Study duration
    i. The study duration is three weeks. The subjects will be required to have either OMT, BEMER, OMT+BEMER, or Placebo treatments during the course of the study. Each subject in the OMT groups (i.e. OMT and OMT+BEMER) will receive treatment 3 times per week for a period of 3 weeks. Subjects in the BEMER groups (i.e. BEMER and OMT+BEMER) will receive treatment 5 times per week for a period of 3 weeks. Finally, subjects in the Placebo group will receive the light touch and BEMER sham treatments at same intervals as the corresponding experimental groups. OMT, BEMER, and placebo treatments will be performed by osteopathic medical students who have completed additional training given by a licensed osteopathic physician, to ensure uniform technique.
b. Recruitment:

i. LECOM-Bradenton faculty, staff, osteopathic medical, dental, pharmacy, and master's students will be informed via email of the opportunity to participate in the research study and will be given contact information to confirm eligibility with a study coordinator (Appendix A).

c. Experimental Sessions
    i. Following written consent (Appendix B), subjects will be given a randomized study ID number. They will be randomized into their treatment group.
    ii. Each subject in the OMT groups (i.e. OMT and OMT+BEMER) will receive treatment 3 times per week for a period of 3 weeks. As previously mentioned, subjects in the BEMER groups (i.e. BEMER and OMT+BEMER) will receive treatment 5 times per week for a period of 3 weeks. Finally, subjects in the Placebo group will receive the light touch and BEMER sham treatments at same intervals as the corresponding experimental groups. OMT, BEMER, and placebo treatments will be performed by osteopathic medical students who have completed additional training given by a licensed osteopathic physician, to ensure uniform technique. All treatments will be performed during the span of three consecutive weeks.
    iii. Subjects 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 (Appendices C, D, E).

III. Analysis

a. Study Statistics
    i. Primary outcome variable
        1. Questionnaire ratings before and after treatments
    ii. Statistical plan including sample size justification and interim data analysis
        1. Paired T-tests (N~10 subjects) to investigate the changes in low back pain after each treatment protocol.
        2. One-Way ANOVA to investigate any statistically significant differences between the means of each of the 4 experimental groups.
    iii. Early stopping rules
        1. Any adverse effect, as determined by the attending licensed osteopathic physician. No adverse effects are anticipated.

b. Blinding
    i. All outcome analyses will be performed in a blinded fashion. Subject survey and corresponding data will be de-identified and analyzed retrospectively by investigators with no exposure to the treatment sessions. Doing so will eliminate bias associated with investigator self-interest and ensure subject anonymity.

IV. Drugs/Substances/Devices

a. Drugs will not be used in this trial. Instead, subjects will be given osteopathic manipulative treatment, BEMER therapy, and placebo light touch.
b. The device utilized is BEMER Pro set.

Research Participants

The target population is LECOM-Bradenton faculty, staff, osteopathic medical, dental, pharmacy, and master's students who are currently experiencing low back pain. The study will not target participants from a vulnerable or at-risk population. Our target population will be informed via email of the opportunity to participate in the research study and will be given contact information to confirm eligibility with a study coordinator.

I. Inclusion

a. LECOM-Bradenton faculty, staff and Students currently enrolled in LECOM-Bradenton's osteopathic medical program, pharmacy program, dental program, and master's program who are currently experiencing low back pain will be approached for recruitment.

II. Exclusion

a. Subjects will be excluded if they are unable to provide informed consent, are currently pregnant, or have a known medical history of current
    i. Psychiatric conditions
    ii. Skin disorders or open wounds precluding skin contact
    iii. Fasciitis of fascial tears
    iv. Myositis
    v. Neurological symptoms such as numbness, tingling, weakness in lower extremities
    vi. Neoplasia
    vii. Cancer
    viii. Bone fracture, osteomyelitis, or osteoporosis
    ix. Coagulation problem
    x. Deep vein thrombosis
    xi. Adrenal diseases/syndromes
    xii. Acute upper or lower respiratory infection
    xiii. Immunosuppressive syndromes
    xiv. Radiation or chemotherapy within the past 3 years
    xv. Lupus
    xvi. Osteopenia
    xvii. Congestive heart failure
    xviii. BMI greater than 30
    xix. Any other autoimmune disease not stated above
    xx. Medication changes within the last 4 weeks
    xxi. Asthma exacerbations within the last 4 weeks
    xxii. Immunosuppressive therapy as a consequence of organ transplantation
    xxiii. Immunosuppressive therapy as a consequence of allogeneic cellular transplantations or bone marrow stem cell transplantation

xxiv. Other conditions often requiring immunosuppressive therapy
xxv. Anticoagulant therapy
xxvi. Known sensitivity to the carotid sinus reflex

b. Subjects will be screened for eligibility based on the inclusion and exclusion criteria described above at the point of subject consent. No protected health information will be collected from subjects who are not eligible to participate in the study.
c. If subjects develop any of the above issues during the course of the study, they will be removed from the study without penalty and will still receive compensation.

III. Definition of treatment failure or subject removal criteria

a. Subjects who do not adhere to the full treatment regimen will be removed from the study.
b. Subjects who experience any adverse effects from treatment, as determined by a licensed osteopathic physician, will be immediately removed from the study. However, we do not anticipate any adverse effects during the study.

Risks and Benefits

I. Risks

a. Anticipated medical risks

i. After OMT, muscle tenderness and generalized discomfort may be noted 24-48 hours after treatment in a small number of patients.
ii. There is little empiric data about the "hazards" to patients of student-performed procedures. Further, this study does not employ any inherently forceful techniques.
iii. There are no anticipated adverse effects associated with BEMER therapy.

b. Steps taken to minimize the risks

i. All Osteopathic Medical students performing osteopathic manipulation will receive additional special training by a licensed osteopathic physician, member of the LECOM-Bradenton OMM Department, and will disclose their true identity to the subjects to avoid any misconceptions that they are licensed physicians. Student-treaters will be critiqued by a physician until they are approved to perform OMT on the subjects.
ii. A licensed osteopathic physician will be in the vicinity of the treatment location at all times a treatment is being given.
iii. The operation of the BEMER Pro Set will be done by students, who will be trained by a BEMER representative. The BEMER representative will ensure students are well trained in the operation of the device. In addition, the Principal Investigator will also be available during the training and throughout the study duration to assist the students.
iv. 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

c. Plan for reporting adverse events

i. All serious or unanticipated adverse events must be reported to the LECOM IRB promptly.

ii. All protocol amendments will be submitted to IRB for approval, with the exception of changes that must be made in order to eliminate any imminent risk of harm to subjects or to others. In this circumstance, the investigator will act to eliminate the immediate risk but must subsequently submit an appropriate protocol amendment and await approval before proceeding with the revised protocol.

II. Benefits

a. Description of probable benefits

i. Subjects may experience a decrease in low back pain. This can translate to healthy and natural ways to improve quality of living in patients with disabling low back pain. Individually, patients could see significant increases in quality of life.

ii. With regards to society, this study could provide patients with an efficient and inexpensive way to alleviate many of the disabilities that are associated with living with low back pain.

Consent Process and Privacy Protection

I. Consent Process

a. Participants will be introduced to the study through classroom announcements and recruitment emails. If they decide to participate we will provide participants with a written informed consent form (Appendix B) for them to read. In addition, a researcher will thoroughly explain the study to them to ensure that the subject is willing to participate in the experiment. The participant will then sign the form after comprehension is assessed via verbal reiteration and opportunity has been provided for questions.

II. Privacy Protection/Confidentiality

a. Any document that can be identified with the participant including informed consent, emergency information, and project data will be stored in a locked filing cabinet in the principal investigator's office. It will remain confidential unless provided with the participant's permission or required by law. Three years after completion of the study, any personal identifiers (names, addresses, birth dates, phone numbers, etc.) will be destroyed.

b. All participants will be given a numerical subject ID to ensure anonymity. Both recorded and survey data will be labeled with study number only. This ID will also be kept in the secured, locked filing cabinet, and only the Principal Investigator will have access to these documents. The materials will be saved for three years and then shredded.

c. Members of the research team have completed the required CITI training modules prior to working on the proposed research. Identity unlinking

procedures and use of de-identified database ensure that results of surveys and patient demographics remain confidential.

d. We will not be making any photograph, audio, or video recordings of participants without participant consent.
e. Our study does not involve collection of data that might produce a regulatory mandate or duty to inform authorities about potentially harmful or illegal activities.
f. Certification of Confidentiality and application for Federal Exemption to Reporting are unnecessary.

Payment and Costs

I. Payment

a. All subjects will receive a compensation of $50 the form of a gift card for a local eating/shopping establishment at the time of completion of the study.
b. Subjects who cannot complete the protocol due to adverse events will still be compensated.
c. Subjects who are noncompliant with protocol will not receive compensation.
d. No fees for participation
e. No penalties for participation or non-completion

II. Costs

a. Payment to subjects:
    i. BEMER Pro Set: $5,990
    ii. 3 week compensation: $50 per individual (estimating 40) = $2,000
b. Total = **$7,990**
c. All paid by grants TBD

Appendices

Appendix A: Recruitment email

The LECOM Student American Academy of Osteopathy (SAAO), is conducting a study, and we would like to welcome all LECOM faculty, staff, and students to participate. The study will evaluate the individual and combine impact of osteopathic manipulative treatment (OMT) and Bio Electro-Magnetic Regulation (BEMER) Therapy on low back pain.

This study will take place over a three-week period. Each subject in the OMT group will receive treatment 3 times per week for a period of 3 weeks. Subjects in the BEMER groups will receive treatment 5 times per week for a period of 3 weeks. Each subject in the OMT+BEMER group will receive OMT 3 times per week and BEMER therapy 5 times per week for a period of 3 weeks. Subjects 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 will be individually scheduled with your assigned study coordinators. Each treatment session will last approximately 10-30 minutes. You will be compensated with a $50 gift card for your time.

If you are interested and would like to learn more about the study, please contact Kasey Coutinho (Study Coordinator) at KCoutinho11315@med.lecom.edu for more information. Thank you for your consideration in helping with this very important research.

Appendix B: Consent Form

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. Bio Electro-Magnetic Regulation (BEMER) Therapy is a therapeutic modality that deploys very small electric pulses that cause blood vessels to open up, and leads to an increase in blood flow. You will not feel the electric pulses as they are very small. 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. Each subject in the OMT+BEMER group will receive OMT 3 times per week and BEMER therapy 5 times per week for a period of 3 weeks. 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. The effectiveness of OMT and BEMER is considered experimental in the context of this study.

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. Any document that can identify you, including a record of subject identification numbers will be kept in a locked filing cabinet in the PI's office for three years. This de-identified information will be kept confidential to the extent legally possible.

Subject Risks

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 numbness and tingling 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.

Although OMT and BEMER therapy may be helpful in alleviating low back pain, there are several alternative treatments such as medications, physical therapy, massage therapy, and acupuncture. Any significant new findings developed during the course of research that may relate to your willingness to continue participation in the study will be provided to you.

Benefits

Subjects may experience a decrease in low back pain. This can translate to healthy and natural ways to improve quality of living in patients with disabling low back pain. Individually, patients could see significant increases in quality of life.
With regards to society, this study could provide patients with an efficient and inexpensive way to alleviate many of the disabilities that are associated with living with low back pain.

Voluntary Consent

You may choose to participate or may choose not to participate. If you choose not to participate in this study there will be no penalty or loss of benefits to which you are otherwise

entitled. If you choose to participate in this study you may withdraw from further participation at any time by contacting the Principal Investigator. If you withdraw, there will be no penalty or loss of benefits to which you are otherwise entitled. Your participation will not provide any benefit/negative impact with respect to your status at LECOM.

Compensation

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

Interested volunteers 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
- Cancer
- 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
- 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
- Anticoagulant therapy
- 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.

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_____ _____
Signature of Subject Date

_____ _____
Signature of Study Coordinator Date

Appendix C:
SF-12 Health Survey

SF-12 HEALTH SURVEY (STANDARD)

INSTRUCTIONS: This questionnaire asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Please answer every question by marking one box. If you are unsure about how to answer, please give the best answer you can.

1. In general, would you say your health is:

❒	❒	❒	❒	❒
Excellent	**Very good**	**Good**	**Fair**	**Poor**

The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	Yes, Limited A Lot	**Yes, Limited A Little**	**No, Not Limited At All**
2. **Moderate activities,** such as moving a table, pushing a vacuum cleaner, bowling or playing golf	❒	❒	❒
3. Climbing **several** flights of stairs	❒	❒	❒

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	Yes	**No**
4. **Accomplished less** than you would like	❒	❒
5. Were limited in the **kind** of work or other activities	❒	❒

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	Yes	No
6. **Accomplished less** than you would like	❒	❒
7. Didn't do work or other activities as **carefully** as usual	❒	❒

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

❒	❒	❒	❒	❒
Not at all	**A little bit**	**Moderately**	**Quite a bit**	**Extremely**

These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks –

	All of the Time	**Most of the Time**	**A Good Bit of the Time**	**Some of the Time**	**A Little of the Time**	**None of the Time**
9. Have you felt calm and peaceful?	❒	❒	❒	❒	❒	❒
10. Did you have a lot of energy?	❒	❒	❒	❒	❒	❒
11. Have you felt downhearted and blue?	❒	❒	❒	❒	❒	❒

12. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

❒	❒	❒	❒	❒	❒
All of the time	**Most of the time**	**A Good Bit of the time**	**Some of the time**	**A little of the time**	**None the time**

Appendix D:

Visual Analog Scale

The Visual Analog Scale (VAS) is a 100-millimeter line with “no pain” on one end and “pain as bad as it can be” at the other end. This scale is a very simple form of assessment. Patients are expected to mark on the line the amount of pain they are experiencing.

|_____|

No pain **Pain as bad as it could possibly be**

Appendix E:
Oswestry low back pain questionnaire

Instructions

This questionnaire has been designed to give us information as to how your back or leg pain is affecting your ability to manage in everyday life. Please answer by checking ONE box in each section for the statement which best applies to you. We realise you may consider that two or more statements in any one section apply but please just shade out the spot that indicates the statement which most clearly describes your problem.

section 1 - pain intensity

- ❑ I can tolerate the pain I have without having to use pain killers
- ❑ the pain is bad but I manage without taking pain killers
- ❑ pain killers give complete relief from pain
- ❑ pain killers give moderate relief from pain
- ❑ pain killers give very little relief from pain
- ❑ pain killers have no effect on the pain and I do not use them

section 2 - personal care (washing, dressing, etc)

- ❑ I can look after myself normally without causing extra pain
- ❑ I can look after myself normally but it causes extra pain
- ❑ it is painful to look after myself and I am slow and careful
- ❑ I need some help but manage most of my personal care
- ❑ I need help every day in most aspects of self care
- ❑ I do not get dressed, wash with difficulty and stay in bed

section 3 - lifting

- ❑ I can lift heavy weights without extra pain
- ❑ I can lift heavy weights but it gives extra pain
- ❑ pain prevents me from lifting heavy weights off the floor, but I can manage if they are conveniently positioned, eg on a table
- ❑ pain prevents me from lifting heavy weights but I can manage light to medium weights if they are conveniently positioned
- ❑ I can lift only very light weights
- ❑ I cannot lift or carry anything at all

section 4 - walking

- ❑ pain does not prevent me walking any distance
- ❑ pain prevents me walking more than 1 mile
- ❑ pain prevents me walking more than 1/2 mile
- ❑ pain prevents me walking more than 1/4 mile
- ❑ I can only walk using a stick or crutches
- ❑ I am in bed most of the time and have to crawl to the toilet

section 5 - sitting

- ❑ I can sit in any chair as long as i like
- ❑ I can only sit in my favourite chair as long as i like
- ❑ pain prevents me from sitting more than 1 hour
- ❑ pain prevents me from sitting more than 1/2 hour
- ❑ pain prevents me from sitting more than 10 minutes
- ❑ pain prevents me from sitting at all

section 6 - standing

- ❑ I can stand as long as I want without extra pain
- ❑ I can stand as long as I want but it gives me extra pain
- ❑ pain prevents me from standing for more than 1 hour
- ❑ pain prevents me from standing for more than 1/2 hour
- ❑ pain prevents me from standing for more than 10 minutes
- ❑ pain prevents me from standing at all

section 7 - sleeping

- ❑ pain does not prevent me from sleeping well
- ❑ I can sleep well only by using tablets
- ❑ even when I take tablets I have less than six hours sleep
- ❑ even when I take tablets I have less than four hours sleep
- ❑ even when I take tablets I have less than two hours sleep
- ❑ pain prevents me from sleeping at all

section 8 - sex life

- ❑ my sex life is normal and causes no extra pain
- ❑ my sex life is normal but causes some extra pain
- ❑ my sex life is nearly normal but is very painful
- ❑ my sex life is severely restricted by pain
- ❑ my sex life is nearly absent because of pain
- ❑ pain prevents any sex life at all

section 9 - social life

- ❑ my social life is normal and gives me no extra pain
- ❑ my social life is normal but increases the degree of pain
- ❑ pain has no significant effect on my social life apart from limiting my more energetic interests, eg dancing etc
- ❑ pain has restricted social life and I do not go out as often
- ❑ pain has restricted my social life to my home
- ❑ I have no social life because of pain

section 10 - travelling

- ❑ I can travel anywhere without extra pain
- ❑ I can travel anywhere but it gives me extra pain
- ❑ pain is bad but I manage journeys over two hours
- ❑ pain restricts me to journeys of less than one hour
- ❑ pain restricts me to short necessary journeys of less than 1/2 hour
- ❑ pain prevents me from travelling except to the doctor or hospital

from: Fairbank J C T, Couper J, Davies J B & O'Brien J P
Physiotherapy 1980; 66: 271-73

Research Roles and Support Documentation

All research project personnel, unless otherwise noted have completed, within the past two years, the on-line CITI training appropriate to their roles. Documentation of which are attached to this proposal.

a. Principal Investigator
    i. Santiago Lorenzo, Ph.D., M.S., M.S. (Med Ed) CITI expiration: 01/03/2021
b. Co-Investigator
    i. Nicole E. Myers, DO, MS CITI expiration: 05/07/2021
    ii. Thomas Quinn, DO CITI expiration: 05/10/2021
c. Graduate Student Researchers
    i. Study Coordinator: responsible for consenting patients and maintaining study protocol
        1. Kasey Coutinho CITI expiration: 05/20/2021
    ii. Research coordinators: responsible for coordination, patient scheduling, maintaining study database, treatment administration, data collection, and study adherence
        1. Kyle Herout CITI expiration: 05/14/2021
        2. Thompson Fillmer CITI expiration: 05/16/2021
        3. Kyle Auger CITI expiration: 05/15/2021
        4. Gregory Shedlock CITI expiration: 05/16/2021

CITI Program Certificates

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

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