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

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Principal Investigator:

Nicole Myers D.O., M.S.
Lake Erie College of Osteopathic Medicine, Bradenton Florida
Phone: 941-782-5732
Email: nmyers@lecom.edu

Research Title:

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

Research Purpose:

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

Study Summary:

Neck pain is a prevalent complaint made by patients to their physician [1, 2]. Many treatment approaches exist depending on the specific etiology, however, there still remains a need for more conclusive evidence regarding many treatment strategies [3-6].

Osteopathic Manipulative Treatment (OMT) is commonly utilized for an array of musculoskeletal and various other complications including neck pain. Goals of this treatment strategy include myofascial tissue release, decreased pain, and increased range of motion.

Bio Electro-Magnetic Energy 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 [7, 8]. BEMER with physiotherapy has shown reduction in pain and fatigue acutely in patients with chronic low back pain [9]. A systematic review of randomized controlled trials that investigated whether PEMF was effective in low back pain showed there was a decrease in pain intensity and improved functionality in individuals with different low back pain conditions [10].

By this mechanism, it is plausible that the combination of OMT and BEMER therapy may help increase circulation to myofascial structures that influence neck restriction and pain. The purpose

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

Review of Literature:

Neck pain is estimated to have a prevalence of 30% annually and perhaps, affect 70% of patients at some point in their life [1, 2]. Neck pain has become a very important public health problem, and social issue due to its high prevalence, unsatisfactory treatment options, large medical burden, and reduction in quality of life [11]. In fact, neck pain ranks fourth worldwide as a cause of Years Lived with Disability [12]. Many complaints of acute or chronic neck pain are musculoskeletal in nature and present with significant muscular tension in the neck, which may restrict blood flow.

Neck pain can result from a variety of etiologies, including postural, neurological and mechanical causes such as muscle strains, joint damage, and nerve compression [2]. Several treatment options are currently available for the various causes of neck pain such as nonsteroidal anti-inflammatory and steroid pharmacotherapy, surgery, and an array of more conservative treatments including Osteopathic Manipulative Treatment (OMT). Palpation of the posterior and anterior neck muscles for tissue texture changes and tender points can assist in the diagnosis of cervical dysfunctions [13]. The upper cervical and upper thoracic regions can contribute to temporomandibular joint (TMJ) dysfunction through the continuity of fascia. The utilization of OMT on these somatic dysfunctions can be greatly beneficial to these patients. Dysfunction of the occiput and atlas is associated with the temporal bone and these tender points located between the ramus of the mandible and mastoid process can be effectively treated with counterstrain, which is an osteopathic manipulative technique [13].

There have been conflicting reports that investigated the effects of spinal manipulation (an osteopathic manipulative technique) on neck pain [1, 14-22]. For example, patients with acute and subacute neck pain who received treatment with spinal manipulative therapy experienced significant pain relief compared with medication at 8, 12, 26, and 52 weeks, proving to be more effective for both short and long term pain relief [1]. On the other hand, Fredin & Loras suggested that combined treatment consisting of manipulation therapy and exercise therapy does not seem to be more effective in reducing neck pain intensity at rest, neck disability or improving quality of life in adult patients with grade I-II neck pain, than exercise therapy alone [18]. These discrepancies may be explained by differences in the specific therapeutic techniques, duration of the intervention, and characteristics of the sample population. It is clear that additional research investigating the effects of alternative treatments on neck pain is warranted.

Specific OMT approaches have been studied for the treatment of patients presenting with neck pain, but substantially less than other general complaints such as lower back pain [3, 23, 24]. In one study, it was demonstrated that treating somatic dysfunction of the cervical spine with OMT in patients with acute neck pain provides pain relief and significantly reduces pain intensity when compared to intramuscular administration of ketorolac tromethamine [21].The authors concluded that OMT is a reasonable alternative to parenteral nonsteroidal anti-inflammatory medication for patients with acute neck pain [21]. In addition, a specific osteopathic manipulative treatment called muscle energy has been shown to provide significant relief of neck pain and improve cervical range of motion [20]. Although there is some evidence to suggest OMT may be an alternative to the treatment of neck pain [20, 21], there is a clear need to better understand the effects of OMT specifically on subacute and chronic neck pain.

Bio-Electro-Magnetic-Energy-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 [7, 8]. Although there has not been any studies on the effects of BEMER on neck pain, BEMER with physiotherapy has shown reduction in pain and fatigue acutely in patients with chronic low back pain [9]. A systematic review of randomized controlled trials that investigated whether PEMF was effective in low back pain showed there was a decrease in pain intensity and improved functionality in individuals with different low back pain conditions [10]. By this mechanism, it is plausible that the combination of OMT and BEMER therapy may help increase circulation to myofascial structures that influence neck restriction and pain. With promising evidence, there remains ample opportunity to study treatment modalities and the use of complementary techniques and therapies combined with OMT [4, 6, 16]. The purpose of this study is to investigate the individual and combined effects of OMT and BEMER therapy on neck pain.

In summary, there is generally moderate and favorable evidence supporting the utility of OMT, and a growing body of evidence regarding BEMER therapy. However, plentiful literature also indicates the need for further exploration of these therapies individually as well as in combination, and their effect on neck pain. It is a goal of this project to further investigate the effects of individual and combined therapies in a controlled, single-blinded study.

Methodology

I. Study Design

A. Prospective, noninvasive study to examine the individual and combined effects of OMT and Bio Electro-Magnetic Energy Regulation (BEMER) therapy on neck pain in adults.

B. Study treatment location

1. 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, a licensed osteopathic physician, will be on call in the vicinity of the treatment location, however not necessarily in the room of treatment. Dr. Myers will be in the building and, if not in the treatment room, will be available by phone and/or text message at all times during treatments and will respond immediately to matters involving the study participants and/or treatments. She will have access to participant schedules and times, so that her schedule can accommodate any and/or all circumstances requiring her immediate assistance. All researchers will have her contact information available and readily accessible as a requirement of participation.

C. Data Collection

1. After written consent is obtained, the study coordinator will assign the participant a randomized study number to de-identify the participant.

2. To achieve our project's goal, we will have 4 separate groups (OMT, BEMER, OMT+BEMER, and Combined Placebo of OMT+ Sham BEMER). All treatments will be performed by osteopathic medical students. Dr. Nicole Myers will provide students

additional training on OMT and placebo treatments, and Tim Trout, a BEMER representative, will provide additional training on BEMER treatments.

3. To control for anchoring bias, subjects will be randomized into one of the four groups: OMT, BEMER, OMT+BEMER, and Placebo.

D. Osteopathic Manipulation Diagnosis and Treatment Protocol (OMT)

1. Osteopathic Diagnosis and Screening
   a) Screening Special tests: Spurling's test, Wallenberg test
   b) Observe and Palpate Cervical and Thoracic spine muscles for TART (tissue texture change, asymmetry, restriction of motion, and tenderness) changes- AROM and PROM of the cervical spine (using head and neck motion for T1-4)
   c) OA (atlanto-occipital joint), AA (atlanto-axial joint) , C2-C7 (cervical vertebrae 2-7), and T1-4 (thoracic vertebrae 1-4) intersegmental diagnosis
   d) TMJ (temporomandibular joint) assessment – opening and closing of jaw
   e) Counterstrain Tenderpoint screening for the following muscles: Medial pterygoid, Anterior C7, Anterior C8, Posterior C1 inion
   f) 1st rib somatic dysfunction
2. Osteopathic Manipulative Treatment/Techniques
   a) Suboccipital Release (constant inhibitory pressure), supine – myofascial release/soft tissue technique
   b) Contralateral Traction, supine - soft tissue technique
   c) Upper thoracic spine unilateral prone pressure, prone - soft tissue technique
   d) Direct or Indirect Thoracic inlet/outlet, supine – myofascial release technique
   e) Occipitoatlantal somatic dysfunction muscle energy (post-isometric relaxation) supine
   f) Atlantoaxial somatic dysfunction muscle energy technique (post-isometric relaxation) supine
   g) C2-C7 somatic dysfunction muscle energy technique (post-isometric relaxation) supine
   h) T1-4 Dysfunction muscle energy technique (post-isometric relaxation) - seated
   i) 1st rib elevation dysfunction – articulatory technique – seated
   j) Direct or indirect Sub mandibular release, supine - myofascial release technique
   k) Counterstrain technique for the following muscles/locations: Medial pterygoid, Anterior C7, Anterior C8, Posterior C1 inion

3. Second year osteopathic medical students will perform the duties of diagnosing and screening for somatic dysfunction in these regions (as listed above). These same 4-6 students will also be trained to perform all of the treatment modalities by the osteopathic principles and practice (OPP) course director and OPP clinical faculty at LECOM-Bradenton.

4. Explanation of each Osteopathic Manipulative Treatment (OMT) technique and screening tests

   a) Myofascial release (MFR) is a system of diagnosis and treatment which engages continual palpatory feedback to achieve release of myofascial tissues [25]. 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 suboccipital and cervical regions with the patient lying on their back.

b) Soft tissue (ST) is a system of diagnosis and treatment directed toward tissues other than bony or joint origins [25]. 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 cervical and thoracic regions in this study.

c) 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 [25]. We will use muscle energy technique in the cervical spine and thoracic regions in the supine position in this study.

d) 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 [25]. We will screen for counterstrain tender points associated with medial pterygoid, sternocleidomastoid, Suboccipital muscles. These muscles have attachments to the temporal bone, mandible, occiput, cervical spine, and clavicle and have been postulated to be a contributing factor to musculoskeletal causes of neck pain [26].

e) Articulatory treatment (ART) is a low-velocity-to high-amplitude technique where a joint is carried through its full motion with the therapeutic goal of increased freedom with range of movement. The activating force is either a springing motion or repetitive concentric movement of the joint through the restrictive barrier. The technique may be direct, indirect, or combined, and there can be a variation of rhythms, amplitude, or acceleration catered to the patient's presentation. This technique is indicated when there is presence of articular or myofascial somatic dysfunction, as well as circulatory and lymphatic congestion [25]. In this study student doctors will use an articulatory technique to treat a 1st rib elevation dysfunction.

f) Spurling's Test/Maneuver - This test will assess for cervical nerve root irritation or compression. The test is performed with the subject in the seated position. The evaluating student will then place the subjects head and neck in an extended and sidebent position towards one side. Once in this position, a gentle but deliberate compressive force will be applied from the top of the subjects head. If this maneuver produces a radicular pain in a distinct dermatomal pattern down the affected sides upper extremity then the test is considered positive. A positive test will exclude the subject from the study. The test is performed bilaterally [10].

g) Wallenberg test - This test will assess for possible vertebral artery insufficiency. The test is performed with the subject in the supine position. The evaluating student will then place the subjects head and neck in an extended

position and then rotate the head and neck to one side. This position will be held for 30 seconds. If at any time the subject complains of dizziness, visual changes, lightheadedness and/or the evaluating student notes eye nystagmus then this is considered a positive test. A positive test will exclude the subject from the study. The test is performed bilaterally [27].

E. Bio Electro-Magnetic Energy Regulation (BEMER)

1. Protocol

a) Subject will lay supine on the BEMER mat, and place the B.Pad® on their cervical neck. 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 at Program 1 for the duration of the intervention. Treatments last approximately 15-25 minutes.

2. Explanation of BEMER

a) 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 [9]. The positive effects of vasomotion (i.e. opening of the blood vessels) 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 [7, 8]. Therefore, BEMER can potentially be used in the treatment of neck pain by improving microcirculation in muscular tissue. Last year we have successfully utilized the BEMER therapy without any adverse effects in a prior study on low back pain.

F. Placebo

1. Placebo (Combined light touch and BEMER Sham): Treaters will place their hands lightly on the subject's cervical paraspinal muscles in the supine position in the same area as one would place their hands for cervical MFR, and on the subjects upper thoracic paraspinal muscles in the prone position in the same area as one would place their hands for thoracic MFR (approximately 5 minutes). However, no pressure 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.

G. 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.

H. 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.

I. 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.

J. The identifying information will be maintained by the principal investigator in a locked cabinet, which they alone have access to.

II. Study Procedures and Timeline

A. Study duration

1. 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 combined 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.
2. Recruitment:
   a) 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).
3. Experimental Sessions
   a) Following written consent (Appendix B), subjects will be given a randomized study ID number. They will be randomized into their treatment group.
   b) 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 combined 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.
   c) Subjects will complete brief questionnaires regarding neck 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, E, F).

III. Analysis

A. Study Statistics
1. Primary outcome variable
   a) Questionnaire ratings before and after treatments
      (1) Neck Disability Index (Appendix E) [28-31]
      (2) SF-12 Health Survey (Appendix F) [32]
      (3) Visual Pain Analog (Appendix C) [33]
2. Statistical plan including sample size justification and interim data analysis
   a) Paired T-tests (N~10 subjects) to investigate the changes in neck pain after each treatment protocol.
   b) One-Way ANOVA to investigate any statistically significant differences between the means of each of the 4 experimental groups.
3. Early stopping rules

a) Any adverse effect, as determined by the attending licensed osteopathic physician. No adverse effects are anticipated.

B. Blinding

1. 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 neck 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 the 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 neck pain will be approached for recruitment.

II. Exclusion

A. Subjects will be excluded if they are unable to provide informed consent, are currently pregnant, have a positive screening test (listed above) or have a known medical history of any of the following:

1. Psychiatric conditions
2. Skin disorders or open wounds precluding skin contact
3. Fasciitis or fascial tears
4. Myositis
5. Neurological symptoms such as numbness, tingling, weakness in upper extremities
6. Neoplasia
7. Bone fracture, osteomyelitis, or osteoporosis
8. Coagulation problem
9. Deep vein thrombosis
10. Adrenal diseases/syndromes
11. Acute upper or lower respiratory infection
12. Immunosuppressive syndromes
13. Radiation or chemotherapy within the past 3 years
14. Lupus
15. Osteopenia
16. Congestive heart failure
17. BMI greater than 30

18. Any other autoimmune disease not stated above
19. Medication changes within the last 4 weeks
20. Asthma exacerbations within the last 4 weeks
21. Immunosuppressive therapy as a consequence of organ transplantation
22. Immunosuppressive therapy as a consequence of allogeneic cellular transplantations or bone marrow stem cell transplantation
23. Other conditions often requiring immunosuppressive therapy
24. Anticoagulant therapy
25. Known sensitivity to the carotid sinus reflex
26. Advanced carotid disease
27. Down syndrome

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.

D. All female patients will be screened in the selection process by self-report as to whether or not they are pregnant. Under any suspicion of pregnancy, the participant will ineligible for participation.

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. Last year we have successfully utilized OMT and the BEMER therapy without any adverse effects in a prior study on low back pain.

Risks and Benefits

I. Risks

A. Anticipated medical risks

1. After OMT, muscle tenderness and generalized discomfort may be noted 24-48 hours after treatment in a small number of patients.

2. There is little empirical data about the "hazards" to patients of student-performed procedures. Further, this study does not employ any inherently forceful techniques (such as high velocity low amplitude HVLA).

3. There are no anticipated adverse effects associated with BEMER therapy. In addition, we have already utilized the BEMER therapy in a prior study on low back pain. No adverse effects were noted.

B. Steps taken to minimize the risks

1. 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.

2. A licensed osteopathic physician will be in the vicinity of the treatment location at all times a treatment is being given. Dr. Myers will be in the building and, if not in the treatment room, will be available by phone and/or text message at all times during treatments and will respond immediately to matters involving the study participants and/or treatments.

3. All treatments will be performed by osteopathic medical students. Dr. Nicole Myers will provide students additional training on OMT and placebo treatments, and Tim Trout, a BEMER representative, will provide additional training on BEMER treatments.

4. 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

1. All serious or unanticipated adverse events will be reported to the LECOM IRB promptly.

2. All protocol amendments will be submitted to the 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

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

2. 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 neck 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, written contact 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. A secured Google Drive account will be utilized to collect de-identified data throughout the study. Access to this account is exclusive to the Principal Investigator, Principal Co-

Investigator and designated medical students as identified in the IRB. All electronic submissions of de-identified data will be treated in the same manner as stated above regarding written information.

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 a 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 the 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:

1. BEMER Pro Set: $6410
2. 3 week compensation: $50 per individual (estimating 40) = $2,000

B. Total = $8410

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 combined impact of osteopathic manipulative treatment (OMT) and Bio Electro-Magnetic Energy Regulation (BEMER) therapy on neck 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 neck 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 Nicholas Dominick at NDominick85519@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

Concise Overview

This is a study to investigate the individual and combined effects of osteopathic manipulative treatment (OMT) and Bio Electro-Magnetic Energy Regulation (BEMER) therapy on neck pain. If enrolled, you will receive either OMT 3 times weekly for three weeks, BEMER therapy 5 days weekly for 3 weeks, both of these treatments combined, or the placebo treatment. You will be asked upon enrollment to provide information about yourself. Specific risks include generalized muscle tenderness and/or discomfort and confidentiality breach.

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 combined effects of osteopathic manipulative treatment (OMT) and Bio Electro-Magnetic Energy Regulation (BEMER) therapy on neck pain. Osteopathic manipulative treatment (OMT) is a manual, hands-on treatment provided by a licensed physician and/or supervised medical student for the treatment of miscellaneous ailments including musculoskeletal neck pain. 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 neck 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: OMT only, BEMER only, OMT+BEMER, or Placebo OMT+BEMER. 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; placebo treatment schedule will mimic the OMT+BEMER schedule. All treatments will be performed during the span of three consecutive weeks. You will complete brief questionnaires regarding neck 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 secured Google Drive account 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. All electronic submissions of de-identified data will be treated in the same manner as stated above regarding written information. Access to this Google Drive account is exclusive to the Principal Investigator, Principal Co-Investigator and designated medical students as identified in the IRB.

Subject Risks

All research studies have some degree of risk or discomfort. In this study, you may risk feeling slight discomfort during manipulative 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 neck 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 neck pain. This can translate to healthy and natural ways to improve quality of living in patients with disabling neck 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 neck 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.

Data Collection

Data will be retrieved through four surveys:
-SF-12 Health Survey. This will be an online, de-identified survey given once weekly with the Neck Disability Index. You will answer questions regarding overall personal wellness.
-Visual Analog Pain Scale. This will be a de-identified scale administered once weekly. You will rate your overall neck pain on a visual scale.
-Neck Disability Index. This will be an online, de-identified survey given once weekly with the SF-12 Health Survey. You will answer questions regarding Neck Disability.
-OMT evaluation data and diagnostic data (Spurling's Test and Wallenburg Test). This data will be collected at every OMT or OMT-Placebo treatment. This data will not be collected for the BEMER-only group. This data will be collected by the researcher online based upon their evaluation of your physical responses to treatment and their specific diagnosis. This data will be de-identified.

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. Volunteers will have the following screening tests performed prior to participating in the study:

- Spurling's Test/Maneuver - This test will check for nerve irritation in your neck. The test will take place with you in the seated position. The evaluating student will then place your head and neck in an extended and sidebent position towards one side. Once in this position,

a gentle but deliberate compressive force will be applied from the top of the your head. If this test produces pain that shoots down your arm it is considered positive. A positive test will exclude you from the study. The test is performed on the left and right.

- Wallenberg test - This test will check for the openness of the vertebral artery which is in your neck. The test is performed with you lying on your back. The evaluating student will then slowly place your head and neck in an extended position and then rotate your head and neck to one side. This position will be held for 30 seconds. If at any time you complain of dizziness, visual changes, lightheadedness and/or the evaluating student notes abnormal eye movements then this is considered a positive test. A positive test will exclude the subject from the study. The test is performed on the left and right.

Additional exclusion criteria include any individual who has a current medical history of:

- Psychiatric (mental health) conditions
- Skin disorders or open wounds precluding skin contact
- Fasciitis or fascial tears (tear and/or inflammation of connective tissue under your skin)
- Myositis (inflammation of muscles)
- Neurological symptoms such as numbness, tingling, weakness in upper extremities
- Neoplasia or Cancer
- Bone fracture, osteomyelitis, osteopenia, or osteoporosis
- Blood coagulation (clotting or bleeding) disorder
- Deep vein thrombosis (blood clotting)
- Adrenal diseases/syndromes
- Acute upper or lower respiratory infection
- Immunosuppressive syndromes (problems with your immune system)
- Radiation or chemotherapy within the past 3 years
- Lupus
- 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 (‘blood thinner’, ‘clot-buster’)
- Known sensitivity to the carotid sinus reflex (a regulatory mechanism for maintaining blood pressure)
- Advanced carotid disease (disease of the arteries in your neck)
- Down syndrome

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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If you have questions about the research or incur a research related injury, please contact:
Nicole Myers D.O., M.S.
Lake Erie College of Osteopathic Medicine, Bradenton Florida
Phone: 941-782-5732
Email: nmyers@lecom.edu

If you have any questions about the research study contact:
Nicholas Dominick, Study Coordinator
Phone: (724) 980-6055
Email: NDominick85519@med.lecom.edu

If you have questions about your rights as a research subject, please contact
Irv Freeman, PhD., J.D., Chair, LECOM Institutional Review Board
Phone: (724) 552-2870
E-mail: ifreeman@lecom.edu

_____ _____
Signature of Subject **Date**

_____ _____
Signature of Study Coordinator **Date**

Appendix C: 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 D: 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:

Nicole E. Myers, DO, MS CITI expiration: 07/31/2022

b. Co-Investigator:

Santiago Lorenzo, Ph.D., M.S., M.S. (Med Ed) CITI expiration: 01/03/2021

c. Graduate Student Researchers:

Study Coordinator: responsible for consenting patients and maintaining study protocol

Nicholas Dominick CITI expiration: 01/28/2022

Research coordinators: responsible for coordination, patient scheduling, maintaining study database, treatment administration, data collection, and study adherence

Melissa Damaske	CITI expiration: 01/20/2022
Luke McFarland	CITI expiration: 02/26/2022
Susan Tucker	CITI expiration: 05/11/2022
Blake Burch	CITI expiration: 05/02/2022
Courtney Crowley	CITI expiration: 01/28/2022

CITI Program Certificates

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

Appendix E: Neck Disability Index

Neck Disability Index

This questionnaire has been designed to give us information as to how your neck pain has affected your ability to manage in everyday life. Please answer every section and mark in each section only the one box that applies to you. We realize you may consider that two or more statements in any one section relate to you, but please just mark the box that most closely describes your problem.

Section 1: Pain Intensity

= I have no pain at the moment
= The pain is very mild at the moment
= The pain is moderate at the moment
= The pain is fairly severe at the moment
= The pain is very severe at the moment
= The pain is the worst imaginable at the moment

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 can manage most of my personal care
= I need help every day in most aspects of self care
= I do not get dressed, I 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 lifting heavy weights off the floor, but I can manage if they are conveniently placed, for example 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 only lift very light weights
= I cannot lift or carry anything

Section 4: Reading

= I can read as much as I want to with no pain in my neck
= I can read as much as I want to with slight pain in my neck
= I can read as much as I want with moderate pain in my neck
= I can't read as much as I want because of moderate pain in my neck
= I can hardly read at all because of severe pain in my neck
= I cannot read at all

Section 5: Headaches

= I have no headaches at all
= I have slight headaches, which come infrequently
= I have moderate headaches, which come infrequently
= I have moderate headaches, which come frequently
= I have severe headaches, which come frequently
= I have headaches almost all the time

Section 6: Concentration

= I can concentrate fully when I want to with no difficulty
= I can concentrate fully when I want to with slight difficulty
= I have a fair degree of difficulty in concentrating when I want to
= I have a lot of difficulty in concentrating when I want to
= I have a great deal of difficulty in concentrating when I want to
= I cannot concentrate at all

Section 7: Work

= I can do as much work as I want to
= I can only do my usual work, but no more
= I can do most of my usual work, but no more
= I cannot do my usual work
= I can hardly do any work at all
= I can't do any work at all

Section 8: Driving

= I can drive my car without any neck pain
= I can drive my car as long as I want with slight pain in my neck
= I can drive my car as long as I want with moderate pain in my neck
= I can't drive my car as long as I want because of moderate pain in my neck
= I can hardly drive at all because of severe pain in my neck
= I can't drive my car at all

Section 9: Sleeping

= I have no trouble sleeping
= My sleep is slightly disturbed (less than 1 hr sleepless)
= My sleep is mildly disturbed (1-2 hrs sleepless)
= My sleep is moderately disturbed (2-3 hrs sleepless)
= My sleep is greatly disturbed (3-5 hrs sleepless)
= My sleep is completely disturbed (5-7 hrs sleepless)

Section 10: Recreation

= I am able to engage in all my recreation activities with no neck pain at all
= I am able to engage in all my recreation activities, with some pain in my neck
= I am able to engage in most, but not all of my usual recreation activities because of pain in my neck
= I am able to engage in a few of my usual recreation activities because of pain in my neck
= I can hardly do any recreation activities because of pain in my neck
= I can't do any recreation activities at all

Scoring:
For each section the total possible score is 5:
If the first statement is marked the section score = 0, if the last statement is marked it = 5.

Score: ____/50 Transform to percentage score x 100 = %points

Appendix F: 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**

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