

Genevieve M. Palmer, BS, Nicholas Dominick, DO, PharmD, Melissa Kane, DO, MBS, Sawyer Bawek, DO, Blake Burch, DO, PharmD, Taylor Sanders, MS, Davong Phrathep, MS, Nicole Myers, DO, MS and Santiago Lorenzo*, PhD, MS, MS

Effect of osteopathic manipulative treatment and Bio-Electro-Magnetic Energy Regulation (BEMER) therapy on generalized musculoskeletal neck pain in adults

<https://doi.org/10.1515/jom-2023-0128>

Received July 7, 2023; accepted November 1, 2023;
published online December 1, 2023

Abstract

Context: General neck pain is a prevalent complaint made by patients to their physicians and is often of a suspected musculoskeletal origin. Osteopathic manipulative treatment (OMT) is a form of manual therapy utilized by osteopathic physicians and some allopathic physicians to treat a broad variety of musculoskeletal ailments, including neck pain. Bio-Electro-Magnetic Energy Regulation (BEMER) is an emerging therapeutic modality that deploys a biorhythmically defined stimulus through a pulsed electromagnetic field and has been shown to reduce musculoskeletal pain. Studies on these treatments have independently yielded promising results. Therefore, it is possible that the utility of OMT and BEMER can produce an additive improvement in the treatment of neck pain.

Objectives: The objectives of this study are to investigate the individual and combined effects of OMT and BEMER therapy on neck pain in adults.

Methods: Adults with nonspecific neck pain were recruited for the study. A total of 44 participants met the study inclusion criteria and were randomized into one of four study groups: OMT-only, BEMER-only, OMT+BEMER, or CONTROL (light touch and sham). Forty subjects completed the study, and data

for 38 participants were included in our analyses. An OMT and BEMER protocol were specifically designed for this study under the guidance of a licensed osteopathic physician. Participants underwent intervention for a duration of 3 weeks. Data were obtained through baseline and postintervention assessments utilizing three surveys: Neck Disability Index (NDI), Visual Analog Scale (VAS), and Short Form 12-item Health Survey (SF-12, divided into Mental and Physical). One-way analysis of variance (ANOVA) analysis was performed retrospectively on pre- and postintervention absolute means between study groups. Significance was set at $p < 0.05$.

Results: One-way ANOVA analysis demonstrated a statistically significant difference in pre- vs. postintervention mean scores between BEMER and CONTROL ($p < 0.05$), BEMER compared to OMT ($p < 0.005$), and BEMER compared to BEMER+OMT ($p < 0.05$), in the NDI. The OMT+BEMER group reported an average reduction in pain on the VAS of 21.3 (± 29.3) points, or a 65.0 % reduction of pain. A similarly substantial decrease in pain was reported in the BEMER study group, which showed a 46.2 % reduction in pain from baseline. The OMT and CONTROL study groups only reported a 2.9 and 23.9 % decrease, respectively. The BEMER and OMT+BEMER study groups also demonstrated a reduction in subjective reporting on the NDI, by 53.8 and 26.3 %, respectively. The BEMER study group also achieved the most substantial improvement in mental and physical well-being as reported by the SF-12.

Conclusions: Study arms that incorporated BEMER yielded improvements on the NDI, VAS, and SF-12, indicating benefits to BEMER regarding improved overall functionality in routine daily activities as well as a reduction in nonspecific neck pain. Perceived pain, as demonstrated on the VAS, was seemingly improved in an additive fashion from the BEMER group to the OMT+BEMER group, although the results did not achieve statistical significance. Further study with greater participation could provide additional insight.

*Corresponding author: Santiago Lorenzo, PhD, MS, MS, Lake Erie College of Osteopathic Medicine, 5000 Lakewood Ranch Blvd, Bradenton, FL 34211, USA, E-mail: slorenzo@lecom.edu

Genevieve M. Palmer, BS, Nicholas Dominick, DO, PharmD, Melissa Kane, DO, MBS, Sawyer Bawek, DO, Blake Burch, DO, PharmD and Taylor Sanders, MS, Osteopathic Research Department, Lake Erie College of Osteopathic Medicine, Bradenton, FL, USA

Davong Phrathep, MS and Nicole Myers, DO, MS, Assistant Professor, Lake Erie College of Osteopathic Medicine, Bradenton, FL, USA

Keywords: Bio-Electro-Magnetic energy Regulation (BEMER) therapy; musculoskeletal pain; neck pain; osteopathic manipulative treatment (OMT)

Neck pain is defined by the Global Burden of Health 2010 Study as “pain in the neck with or without pain referred to one or both upper limbs that lasts for at least one day.” [1] It has been estimated that 66 % of the population will suffer from neck pain at some point during their lifetime, and neck pain has been reported as the fourth leading cause of disability worldwide [2]. There is considerable variation in the reported prevalence rates of neck pain, most likely because of differences in the definition of neck pain and the lack of homogeneity in the studies [3]. The currently available studies suggest that the one-year estimated incidence of neck pain ranges between 10.4 and 21.3 %, with a higher incidence noted in computer and office workers [4]. The prevalence of neck pain ranges from 10 to 20 %, and the most common cause of neck pain in adults stems from degenerative changes in the cervical spine [4]. Most cases of neck pain tend to run an episodic course over one’s lifetime, thus relapses are relatively common.

The differential diagnosis for neck pain is extensive, and a methodical approach is essential to rule out potentially life-threatening conditions [5]. The vast majority of neck pain is not due to organic pathology, and thus, has been termed “nonspecific” or “mechanical.” [6] Interventions available to manage neck pain include analgesics, physiotherapy, educational modalities, exercise, and manual therapy [6]. Although useful in acute, short-term reduction of pain, analgesic therapy such as nonsteroidal anti-inflammatory drugs (NSAIDs) produces the significant side effects of gastrointestinal bleeding, dysfunction of renal homeostasis, and cardiovascular events [7]. The use of opioids, although helpful in acute, short-term pain relief, carries significant risk of opioid dependence and hyperalgesia syndromes [7].

Osteopathic manipulative treatment (OMT) is a fundamental skill set that osteopathic physicians acquire early during their medical training and is widely utilized among practicing osteopathic physicians to treat neck pain and other musculoskeletal complaints [8]. OMT is a unique, hands-on treatment modality utilized by osteopathic physicians to augment the conventional management of neck pain and has been shown to demonstrate favorable outcomes in the treatment of neck pain [9–11].

In addition to conventional treatment modalities, Bio-Electro-Magnetic Energy Regulation (BEMER) therapy (BEMER International AG) has emerged as a proposed therapeutic option. BEMER therapy utilizes a biorhythmically defined stimulus through a pulsed electromagnetic field. The assumed therapeutic mechanism of action for an electromagnetic field

is the ion cyclotron resonance effect, through modulation of ion bindings, an effect on free radicals, and an effect on heat shock proteins [12]. BEMER devices operate with unique parameters and are postulated to have a primary effect of improving tissue microcirculation [12, 13]. BEMER therapy leads to an increase in the number of open capillaries, vasomotion of micro vessels, arteriovenous oxygen difference, arteriolar and venular flow volume, and a flow rate of red blood cells in a specific microcirculatory area [14]. Multiple studies have demonstrated positive results in musculoskeletal pain management with the utilization of BEMER therapy [15–18]. One study in particular demonstrated a potential additive, subjective decrease in reported back pain and improved functional ability after treatment with both OMT and BEMER therapy [19].

The musculoskeletal, lymphatic, and fascial concepts of OMT have long been comprehensively and collectively proposed as the mechanisms by which the therapy alleviates common musculoskeletal ailments [20, 21]. The existing literature suggests benefit from OMT, however, the need for further exploration of manual therapy remains [9–11, 19, 22]. As previously discussed, BEMER therapy can reduce musculoskeletal pain via enhanced microcirculation. Therefore, it is plausible that the combination of OMT and BEMER therapy may potentially enhance circulation to the vascular beds in myofascial tissue and could substantially reduce neck pain. The objective of this study was to assess the individual and combined effects of OMT and BEMER therapy in patients with nonspecific neck pain.

Methods

This study was approved by the Lake Erie College of Osteopathic Medicine Institutional Review Board (Protocol 26-164). Before the study began, written and informed consent was obtained from all research participants. The authors did not prospectively submit this study to a clinical trial registry, but it was registered post hoc at ClinicalTrials.gov (NCT05889039).

Participants were assigned a unique, de-identified number, and the Microsoft Excel RANK function was utilized to randomize participants into each of the four treatment groups: OMT, BEMER, OMT+BEMER, and CONTROL. The final participant breakdown is shown in Figure 1.

Study participants

A standardized recruitment email was sent in September of 2019 to all faculty, staff, and students at a medical college. No inclusion or exclusion criteria were applied at the time of the recruitment email. A total of 63 volunteers responded and were screened for eligibility based on inclusion and exclusion criteria at the time of receiving the informed consent.

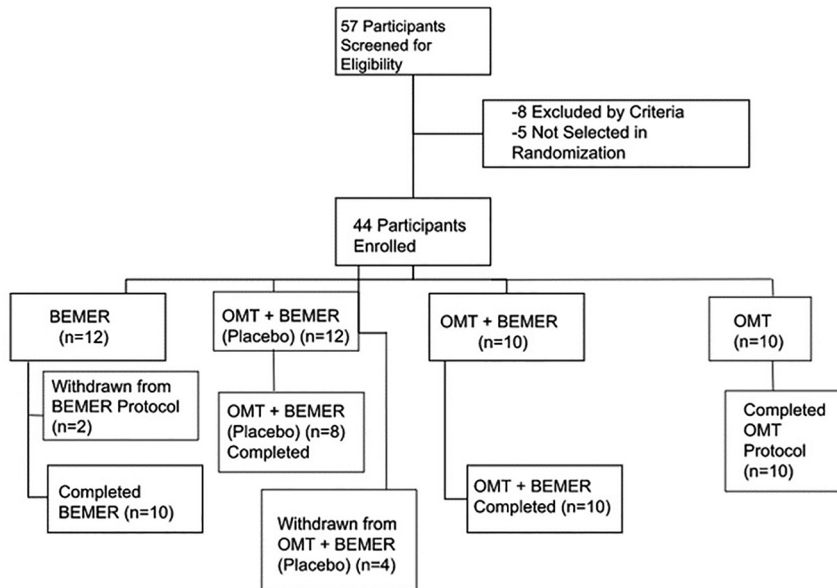


Figure 1: Diagrams demonstrating the randomization of participants into study group.

The inclusion criteria required participants to be currently experiencing nonspecific neck pain for at least 2 weeks. Participants were excluded if they were unable to provide informed consent, were currently pregnant, or had a positive screening test (Spurling's and Wallenberg tests). Participants were also excluded if they had a known medical history of: psychiatric conditions; skin disorders or open wounds; fasciitis or fascial tears; myositis; neoplasia; bone fracture; osteomyelitis; osteopenia; osteoporosis; coagulation abnormality; deep vein thrombosis; adrenal diseases or syndromes; numbness, tingling, or weakness in the upper extremities; acute respiratory infection; immunosuppressive syndromes or therapies; radiation or chemotherapy within the previous 3 years; lupus; congestive heart failure; body mass index greater than 30; medication changes or asthma exacerbations within the last 4 weeks; anticoagulant therapy; autoimmune diseases; known sensitivity to carotid sinus reflex; advanced carotid disease; or Down syndrome. Participants were excluded if they received any external manual intervention, physical therapy, chiropractic therapy, or massage therapy. Awareness of study group assignment also excluded participants from continuing in the study.

Among the 63 participants who responded, 44 met the inclusion criteria. Each of the 44 participants were randomly assigned to one of four study groups: OMT-only, BEMER-only, OMT+BEMER, or CONTROL (light touch and sham) utilizing the Microsoft Excel RAND and RANK functions. The participants in each study group were not made aware of the other treatment arms. Four subjects withdrew from the study. Forty subjects completed the study, and data for 38 of these subjects (excluding data for two participants in the CONTROL group) are included in our analyses.

Treatment groups

The duration of the intervention was 3 weeks. During that time, participants in the OMT group received OMT treatment three times per week, and those in the BEMER group received treatment five times per week. Participants in the OMT+BEMER group received three OMT treatments and five BEMER treatments weekly, and those in the

CONTROL group received three light-touch OMT and five sham-BEMER treatments weekly. The frequency of both OMT and BEMER therapy was modeled after a previously published study that was performed to evaluate the individual and combined effects of BEMER therapy and OMT on low back pain [19]. There were 10 participants in each of the OMT group, BEMER group, and OMT+BEMER group, and eight participants in the CONTROL group. One subject was removed due to treatment by a chiropractor during the intervention phase. Another subject was removed due to awareness of inclusion in the CONTROL study arm.

Assessment and treatment protocols

A standardized osteopathic assessment and treatment protocol for neck pain was developed with a board-certified neuromusculoskeletal medicine (NMM)/OMM osteopathic physician (N.M.). The osteopathic structural examination and motion testing focused on the cervical and upper thoracic spine, temporomandibular joint, and first rib to diagnose dysfunctions commonly associated with neck pain. Second-year osteopathic medical students (N.D., G.P., M.D., S.B., B.B., T.S., and D.P.) were trained and assessed by a board-certified NMM/OMM osteopathic physician (N.M.) to ensure uniform technique on the standardized protocol that was developed for each group. Each participant received a standardized osteopathic structural examination and diagnosis of somatic dysfunctions during each treatment session. If a somatic dysfunction was not found, the associated treatment protocol for that area was not performed.

The students performed the following examination protocol for each session and recorded the findings on a standard form:

- Observe and palpate cervical and thoracic muscles for tenderness, asymmetry, restriction of motion, and tissue texture (TART) changes
- Perform atlanto-occipital (OA) joint, atlanto-axial (AA) joint, cervical vertebrae 2–7 (C2–C7), and thoracic vertebrae 1–4 (T1–4) intersegmental diagnosis
- Assess the temporomandibular joint (TMJ) by opening and closing the jaw

- Perform counterstrain tender-point screening for the following muscles: Medial pterygoid, Anterior C7, Anterior C8, and Posterior C1 inion
- Assess for a first-rib somatic dysfunction

Treatment was provided after the osteopathic structural examination sequence was performed and recorded. Participants receiving OMT were treated with a standardized sequence to the areas where somatic dysfunctions were found:

- Suboccipital release (constant inhibitory pressure), supine
- Cervical contralateral traction, supine
- Upper thoracic spine unilateral soft tissue pressure, prone
- Thoracic inlet/outlet myofascial release (direct or indirect), supine
- OA, AA, C2–7 somatic dysfunction muscle energy (postisometric relaxation), supine
- T1–4 somatic dysfunction muscle energy technique (post-isometric relaxation), seated,
- First-rib elevation dysfunction articulation, seated
- Submandibular myofascial release (direct or indirect), supine
- Counterstrain technique for the following muscles/locations: Medial pterygoid, Anterior C7, Anterior C8, and Posterior C1 inion

Participants receiving BEMER therapy laid supine on the BEMER mat (BEMER International AG, Carlsbad, CA). The BEMER was set at intensity 3 for week 1, intensity 4 for week 2, and intensity 5 for week 3. The B.Pad (BEMER International AG) was placed under their cervical region. B.Pad settings were set at Program 1 (8 min long) in week 1 through week 3. These settings were selected based on the manufacturer's recommendations. OMT was performed before BEMER therapy for those in the combined group.

Participants in the CONTROL group received light-touch and BEMER sham treatments. Researchers placed their hands lightly on the subject's cervical paraspinal muscles in the supine position and on the upper thoracic paraspinal muscles in the prone position for approximately 5 min. This was done to mimic myofascial release techniques; however, no pressure or action was done. In addition, the subjects laid supine on the BEMER mat (as they would do during a BEMER session), but the device was not activated.

Outcome assessment

At the first session (immediately prior to the intervention) and at the last session (immediately after the final intervention), the participants were required to fill out validated surveys. The three surveys utilized were the Neck Disability Index (NDI), Short Form 12-item Health Survey (SF-12), and Visual Analog Scale (VAS) [23–25]. The NDI, VAS, and SF-12 were completed electronically. The NDI is a questionnaire that provides information as to how neck pain has affected the subject's ability to manage in everyday life. The SF-12 is a self-reported survey that measures the effects of health on daily activities; results of this survey are computed to yield both a 'SF12-Physical' and 'SF12-Mental' score based on responses to a single survey. The VAS is a 100 mm line that measures the participants' subjective pain from "no pain" to "pain as bad as it could possibly be."

The data were organized to represent average means scores at preintervention and postintervention for each of the four outcome measures:

- Visual Analog Scale (VAS)
- Neck Disability Index (NDI)

- SF12 – Physical Component
- SF12 – Mental Component

Blinded analysis of all data occurred after the conclusion of our 3-week intervention period. All responses were de-identified. Absolute changes in questionnaire scores from preintervention to postintervention were calculated for each participant. A one-way analysis of variance (ANOVA) was utilized to determine any statistical significance between the mean changes in the four groups. Normal distribution and equal variances were confirmed by Shapiro–Wilk test and Brown–Forsythe test, respectively. Significance was set at $p < 0.05$, and values are presented as means \pm standard deviation (SD).

Results

There were 40 participants that completed this study. Data from 38 participants were randomized into an OMT group ($n=10$; 25.4 ± 2.4 years), BEMER group ($n=10$; 25.1 ± 2.0 years), OMT+BEMER group ($n=10$; 24.8 ± 1.8 years), and CONTROL group ($n=8$, 25.0 ± 1.8 years) and were utilized in the final analysis. Among the 38 participants studied, 73 % identified as female and 27 % as male. The breakdown per group was: OMT group (70 % female), BEMER group (80 % female), and OMT+BEMER group (70 % female). Preintervention mean scores for all groups are shown in Table 1. One-way ANOVA analyses showed that the preintervention mean values were not statistically different between the groups (Table 2).

Data from the outcome measurements are shown in Figure 2. One-way ANOVA analysis from the NDI scores demonstrated a statistically significant difference in pre- vs. postintervention mean scores between BEMER (-9.8 ± 2.9) compared to OMT (-1.8 ± 2.7 ; $p < 0.001$), CONTROL (-2.8 ± 4.1 ; $p < 0.005$), and OMT+BEMER (-4.0 ± 4.3 ; $p < 0.01$). The BEMER study arm also produced the greatest improvement in NDI scores in general (Figure 2A). Of note, data from one subject in the BEMER study group were removed due to an error in the completion of the NDI survey.

One-way ANOVA analyses showed that absolute-change values (pre- vs. postintervention) were not statistically different between the groups in the VAS scores, SF12–Physical, and SF12 Mental components ($p > 0.05$). That said, the greatest improvement in pain after intervention as measured by the VAS was seen in the OMT+BEMER study group (Figure 2B). OMT+BEMER demonstrated a substantial improvement in subjective pain measurement after intervention (21.3 ± 29.3), which correlates to a 65.0 % decrease in pain postintervention. The BEMER study group also demonstrated a substantial improvement in participant pain (8.0 ± 6.3 ; 46.2 %). Data from one subject in the BEMER study group was removed due to an error in the completion

Table 1: Pre- and postintervention scores.

Groups	Visual Analog Scale (VAS)			Neck Disability Index (NDI)			SF-12 Physical			SF-12 Mental		
	Preintervention mean (SD)	Postintervention mean (SD)	% change	Preintervention mean (SD)	Postintervention mean (SD)	% change	Preintervention mean (SD)	Postintervention mean (SD)	% change	Preintervention mean (SD)	Postintervention mean (SD)	% change
OMT (n=10)	16.5 (13.8)	16.0 (14.2)	-3.0 %	14.0 (12.2)	12.2 (10.9)	-12.9 %	43.2 (13.4)	43.7 (14.7)	1.0 %	30.3 (17.0)	40.7 (14.1)	34.3 %
BEMER (n=10)	13.2 (14.0)	7.1 (10.8)	-46.2 %	16.0 (10.7)	7.4 (8.5)	-53.8 %	41.6 (10.1)	45.4 (9.0)	9.0 %	19.5 (25.3)	30.3 (24.4)	55.5 %
OMT+BEMER (n=10)	32.9 (33.4)	11.5 (8.4)	-64.9 %	15.2 (8.0)	11.2 (7.6)	-26.3 %	44.8 (11.8)	45.6 (13.0)	1.7 %	29.0 (16.2)	34.1 (15.2)	17.0 %
Placebo (n=8)	20.3 (20.2)	15.5 (13.4)	-23.9 %	15.8 (10.0)	13.0 (7.6)	-17.5 %	46.1 (10.5)	47.5 (11.1)	3.0 %	25.9 (16.6)	23.0 (12.6)	-11.0 %

BEMER, Bio-Electro-Magnetic Energy Regulation; NDI, Neck Disability Index; NS, Not Statistically Significant; OMT, Osteopathic Manipulative Therapy; SD, Standard Deviation; SF, Short Form 12-Item Health Survey; VAS, Visual Analog Scale.

Table 2: Paired t test pre- vs. postintervention.

Groups	Visual Analog Scale (VAS)	Neck Disability Index (NDI)	SF-12 Physical	SF-12 Mental
OMT (n=10)	NS	NS	NS	NS
BEMER (n=10)	p<0.05	p<0.001	p<0.05	NS
OMT+BEMER (n=10)	p<0.05	p<0.05	NS	NS
Placebo (n=8)	NS	NS	NS	NS

BEMER, Bio-Electro-Magnetic Energy Regulation; NDI, Neck Disability Index; NS, Not Statistically Significant; OMT, Osteopathic Manipulative Therapy; SD, Standard Deviation; SF, Short Form 12-Item Health Survey; VAS, Visual Analog Scale.

of the VAS survey. Although there were no statistically significant differences between groups, these results could potentially have very important clinical implications in the treatment and management of nonspecific neck pain.

The BEMER study arm demonstrated the greatest improvement in SF-12 Physical reporting, with an average improvement in scoring of 3.8 (±4.8) points from pre-to postintervention. The CONTROL study arm produced an improvement of 1.4 (±7.8) points from pre-to post-intervention. Finally, the OMT and OMT+BEMER group produced an improvement of only 0.5 (±10.9) and 0.8 (±9.2) points, respectively (Figure 2C).

Of note, only the CONTROL study group demonstrated a negative percentage change in the SF-12 Mental, indicating a decrease in mental well-being after intervention (Figure 2D). Otherwise, the BEMER study arm produced the greatest improvement in the SF-12 Mental scoring with an increase of 10.8 (±22.4) points. The OMT and OMT+BEMER study arms produced a similarly substantial increase in mental well-being after intervention, with an average improvement of 10.4 (±22.5), or 34.3 %, and 5.1 (±10.1), or 17.7 %, respectively.

Discussion

General musculoskeletal pain, including neck pain, is a common medical complaint made by patients to their physician. As with many ailments of musculoskeletal origin, there is often no single, identifiable cause that can be entirely defined by imaging or laboratory analysis. A diagnosis, and thus a treatment plan, is ordinarily clinical. The nature of this process therefore entails multiple treatment options, often utilized in conjunction. Two options are OMT and BEMER therapy. This study evaluated the individual and additive effects of these two treatment options for adults with generalized neck pain.

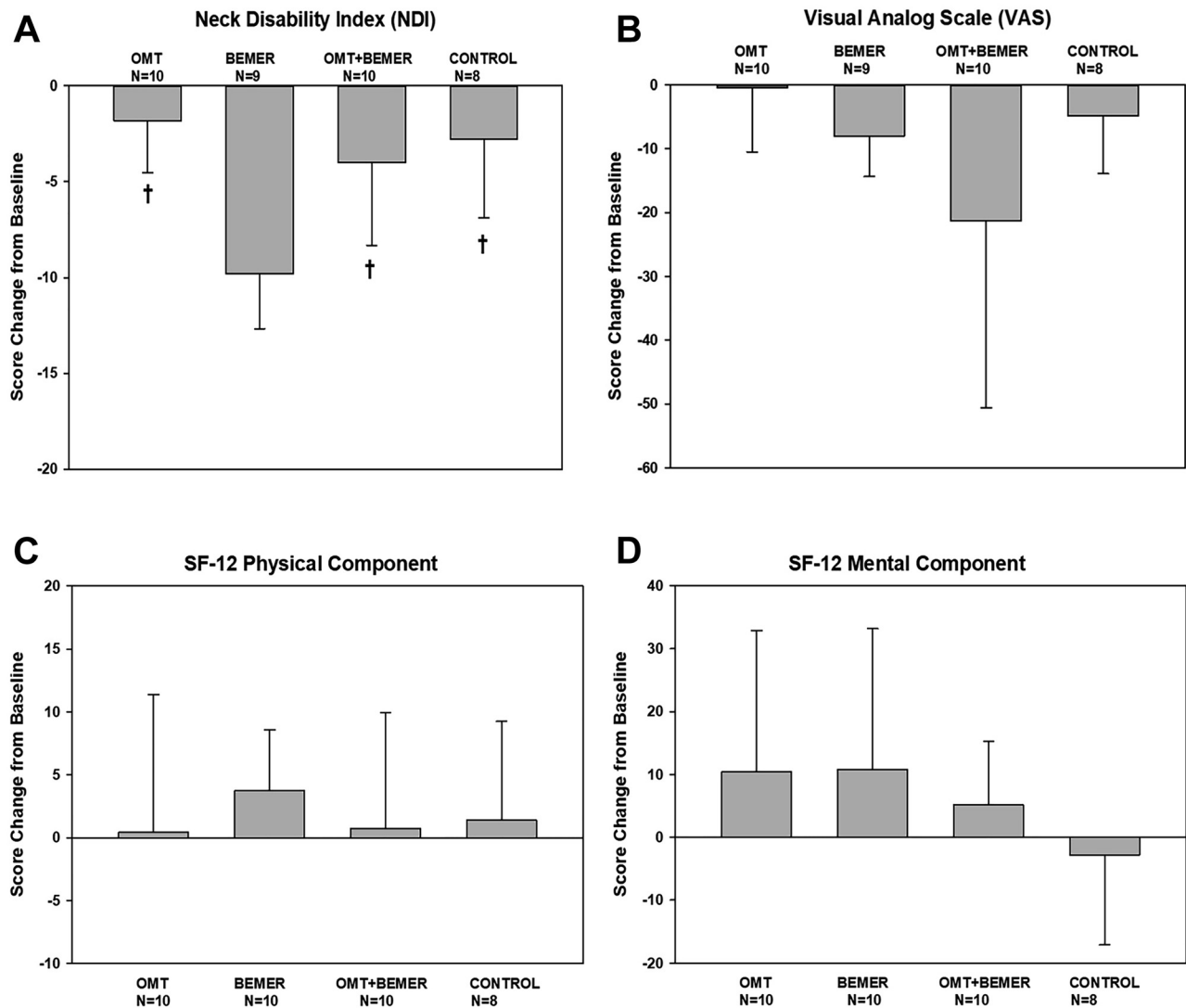


Figure 2: (A) Neck Disability Index (NDI) score changes from baseline. There were statistically significant differences (†) between BEMER (-9.8 ± 2.9) compared to OMT (-1.8 ± 2.7 ; $p < 0.001$), CONTROL (-2.8 ± 4.1 ; $p < 0.005$), and OMT+BEMER (-4.0 ± 4.3 ; $p < 0.01$). (B) Visual Analog Scale (VAS) score changes from baseline. There were no statistically significant differences between the groups on the (C) Short Form-12 (SF-12) questionnaire physical component score changes from baseline. There were no statistically significant differences between the groups. (D) In the Short Form-12 (SF-12) questionnaire mental component score changes from baseline, there were no statistically significant differences between groups. All values shown are absolute mean changes from preintervention to immediately after 3-week treatment intervention (\pm standard deviation [SD]).

A unique finding of this study is that the BEMER study arm produced a statistically significant reduction in pre- to post-intervention mean scores on the NDI compared to mean score changes in the CONTROL group. This result suggests that the use of BEMER therapy improved the participants' abilities to perform daily activities via a reduction in pain as well as potential improvement in functional parameters such as range of motion and decreased somatic dysfunction. The confirmation of the statistical significance of these findings further contributes to the theory that BEMER therapy has the potential to reduce generalized neck pain as well as to improve the daily ability to function in patients with neck pain [14, 17].

Another unique finding of this study is that both study arms incorporating BEMER therapy demonstrated substantial improvements in mean survey scores on the NDI and the VAS. The NDI evaluates a patient's overall functionality in routine daily activities such as driving, sleeping, work, and so on [25]. We cannot directly align the findings of this study to that of other studies due to differing outcome measures. However, it is possible that the proposed mechanisms of tissue healing, as well as recovery and microvascular clearance, might play a substantial part in the overall mechanisms of musculoskeletal neck pain [12–18]. Similarly, the significant improvement in neck pain as demonstrated by the reduction in postintervention

VAS mean scores suggests that, along with improved functional status, BEMER therapy may also reduce pain.

The primary proposal of this study was that a combination of OMT and BEMER could yield a benefit to a patient in an additive fashion. Auger et al. [19] studied the additive benefit of OMT and BEMER on low back pain. Utilizing a similar treatment protocol and outcome measures, their study demonstrated a potential additive improvement in low back pain, particularly in survey responses to the VAS, although this was not found to be statistically significant [19]. Our study demonstrated a similar additive reduction in neck pain, as evident by a substantial reduction in the VAS. The OMT-only and BEMER-only study arms achieved a 2.9 and 46.2% decrease in mean survey responses, respectively. The OMT+BEMER group achieved a 65.0% change in mean VAS scores. The BEMER group also achieved a statistically significant improvement in pre- to postintervention means compared to the CONTROL. We suspect that further investigations might indicate favorable utility of OMT+BEMER compared to individual therapies, as demonstrated by improvements in the mean VAS scores and reporting on the NDI. As such, further studies may be able to shed light on the patient's perception of pain when combining these therapies. The utility of combined OMT and BEMER therapy could yield improved patient outcomes as well as reduced healthcare costs.

Limitations

Variability with multiple practitioners is always a potential challenge. Although there is some inevitable variability when several practitioners provide the treatment, all OMT was provided by second-year medical students who underwent over 10 h of training, along with baseline competency in OMT. Continuity between the participant and practitioner was not always feasible due to scheduling restraints.

The provision of treatment by second-year osteopathic medical students represents another limitation of this study. It is likely that there were certain components of the results, particularly the minimal beneficial effect of OMT seen reflected in the data, that were related to the relative inexperience of student providers. The medical students underwent extensive training by a board-certified NMM/OMM osteopathic physician, and were frequently re-evaluated as the study progressed; however, the results could certainly be strengthened if they are replicated by experienced osteopathic providers.

One important consideration in the analysis of the NDI and VAS data is that the population of subjects selected could have begun treatment at a lower baseline NDI and VAS than the

general population. Although there was limited research on the average NDI and average reporting of pain on the VAS for comparison, the population of the majority of students in their 20s could have decreased the likelihood of producing a more substantial change from baseline. Due to their potentially lower experience of disability and pain, it would take more intervention for there to be a significant drop in neck pain and impaired functionality. Similarly, baseline health status may vary significantly between participants, and further analysis of individual survey responses may provide useful insight.

Additionally, the heightened awareness and caution of COVID-19 during the completion of the study created some challenges during the intervention period. Two participants, who were far along in their course of treatment/control, experienced a gap in treatments due to potential exposure to COVID-19. Although the course was completed in its entirety, it is possible that this gap as well as potential infection interfered with the results of the surveys provided.

Future studies

There remains a need for further investigation. Particularly, a larger sample size of participants is preferred. There is an additional need to evaluate the variety of neck pain ailments (acute, chronic, and acute-on-chronic) and accompanying symptoms, and how targeted protocols of treatment might be utilized to achieve more specific goals of treatment. Future studies, utilizing the study protocols defined in the present investigation, may shed further light on the applicability of OMT and BEMER therapy for a variety of musculoskeletal complaints. Data from this study might also be valuable for analysis in conjunction with data gathered from other studies utilizing this protocol, such as a previously coordinated study of a similar protocol for the study of OMT and BEMER on low back pain [19].

Conclusions

This study compared the individual and combined effects of BEMER therapy and OMT for the treatment of neck pain in adults. The study arms that incorporated BEMER therapy yielded substantial improvement on both the NDI and the VAS. This indicates the benefit to BEMER therapy regarding overall functionality in routine daily activities in the setting of generalized neck pain. Additionally, the OMT+BEMER study arm demonstrated the greatest reduction in mean scores on the VAS, which gauges a person's perceived pain.

Acknowledgments: The authors acknowledge Luke McFarland DO, Susan Tucker DO, Daniel Barnebee DO, Conrad Wright DO, Taylor Alfonso DO, Sara Mustafa DO, Nathan Seigrist DO, Marcela Gallardo DO, Francisco Centeno DO, Troy Clark, Hunter Chuchla, and Jared Lehman, for their contributions to data collection.

Research ethics: The study was approved by the Institutional Review Board at Lake Erie College of Osteopathic Medicine (Protocol 26-164). The authors did not prospectively submit this study to a clinical trial registry, but it was registered post hoc at ClinicalTrials.gov (NCT05889039).

Informed consent: Written and informed consent was obtained from all participants prior to enrollment into the study.

Author contributions: All authors provided substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; all authors drafted the article or revised it critically for important intellectual content; all authors gave final approval of the version of the article to be published; and all authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Competing interests: None declared.

Research funding: This study was funded by the Internal Seed Grant through Lake Erie College of Osteopathic Medicine for BEMER device and participant compensation.

Data availability: The raw data can be obtained on request from the corresponding author.

References

1. Wang H, Naghavi M, Allen C, Barber RM, Bhutta ZA, Carter A, et al. Global, regional, and national life expectancy, all-cause mortality, and cause-specific mortality for 249 causes of death, 1980–2015: a systematic analysis for the Global Burden of Disease Study 2015. *Lancet* 2016;388:1459–544.
2. Côté P, Cassidy JD, Carroll L. The Saskatchewan Health and Back Pain Survey. The prevalence of neck pain and related disability in Saskatchewan adults. *Spine* 1998;23:1689–98.
3. Fejer R, Kyvik KO, Hartvigsen J. The prevalence of neck pain in the world population: a systematic critical review of the literature. *Eur Spine J* 2006;15:834–48.
4. Hoy DG, Protani M, De R, Buchbinder R. The epidemiology of neck pain. *Best Pract Res Clin Rheumatol* 2010;24:783–92.
5. Maccagnano J. Urgent evaluation of traumatic neck pain. *J Urgent Care Med.* 2016;11–14.
6. Coulter ID, Crawford C, Vernon H, Hurwitz EL, Khorsan R, Booth MS, et al. Manipulation and mobilization for treating chronic nonspecific neck pain: a systematic review and meta-analysis for an appropriateness panel. *Pain Physician* 2019;22:E55–70.
7. Babatunde OO, Jordan JL, Van der Windt DA, Hill JC, Foster NE, Protheroe J. Effective treatment options for musculoskeletal pain in primary care: a systematic overview of current evidence. *PLoS One* 2017;12:e0178621.
8. Klein R, Bareis A, Schneider A, Linde K. Strain-counterstrain to treat restrictions of the mobility of the cervical spine in patients with neck pain: a sham-controlled randomized trial. *Complement Ther Med* 2013;21:1–7.
9. McReynolds TM, Sheridan BJ. Intramuscular ketorolac versus osteopathic manipulative treatment in the management of acute neck pain in the emergency department: a randomized clinical trial. *J Am Osteopath Assoc* 2005;105:57–68.
10. Rotter G, Fernholz I, Binting S, Keller T, Roll S, Kass B, et al. The effect of osteopathic medicine on pain in musicians with nonspecific chronic neck pain: a randomized controlled trial. *Ther Adv Musculoskelet Dis* 2020;12:1759720X20979853.
11. Gyulai F, Rába K, Baranyai I, Berkes E, Bender T. BEMER therapy combined with physiotherapy in patients with musculoskeletal diseases: a randomized, controlled double blind follow-up pilot study. *Evid Based Complement Alternat Med* 2015;2015:245742.
12. Klopp RC, Niemer W, Schmidt W. Effects of various physical treatment methods on arteriolar vasomotion and microhemodynamic functional characteristics in case of deficient regulation of organ blood flow. Results of a placebo-controlled, double-blind study. *J Complement Integr Med* 2013;10:S39-46–S41-9.
13. Klopp RC, Niemer W, Schulz J. Complementary-therapeutic stimulation of deficient autorhythmic arteriolar vasomotion by means of a biorhythmically physical stimulus on the microcirculation and the immune system in 50-year-old rehabilitation patients. *J Complement Integr Med* 2013;10:S29-37–S31-9.
14. Franke H, Franke JD, Fryer G. Osteopathic manipulative treatment for chronic nonspecific neck pain: a systematic review and meta-analysis. *Int J Osteopath Med* 2015;18:255267.
15. Haase R, Piatkowski J, Ziemssen T. Long-term effects of Bio-Electromagnetic-Energy Regulation therapy on fatigue in patients with multiple sclerosis. *Altern Ther Health Med* 2011;17:22–8.
16. Piatkowski J, Kern S, Ziemssen T. Effect of BEMER magnetic field therapy on the level of fatigue in patients with multiple sclerosis: a randomized, double-blind controlled trial. *J Altern Complement Med* 2009;15:507–11.
17. Kanaparthi A, Kesary SPR, Pujita C, Gopalaiah H. Bio Electro Magnetic Energy Regulation (BEMER) therapy in myofascial pain dysfunction syndrome: a preliminary study. *J Oral Biol Craniofac Res* 2020;10:38–42.
18. Benedetti MG, Cavazzuti L, Mosca M, Fusaro I, Zati A. Bio-Electro-Magnetic-Energy-Regulation (BEMER) for the treatment of type I complex regional pain syndrome: a pilot study. *Physiother Theory Pract* 2020;36:498–506.
19. Auger K, Shedlock G, Coutinho K, Myers NE, Lorenzo S. Effects of osteopathic manipulative treatment and bio-electromagnetic energy regulation therapy on lower back pain. *J Osteopath Med* 2021;121:561–9.
20. Chikly BJ. Manual techniques addressing the lymphatic system: origins and development. *J Am Osteopath Assoc* 2005;105:457–64.
21. Ettliger H, Willard FH. Anatomy and physiology of the lymphatic system. In: Seffinger M, editor. *Foundations of osteopathic medicine: philosophy, science, clinical applications, and research*, 4th ed. Philadelphia, PA: Wolters Kluwer; 2018:174–94 pp.

22. Smith MS, Olivas J, Smith K. Manipulative therapies: what works. *Am Fam Physician* 2019;99:248–52.
23. Ware J Jr., Kosinski M, Keller SD. A 12-Item Short-Form Health Survey: construction of scales and preliminary tests of reliability and validity. *Med Care* 1996;34:220–33.
24. Vernon H, Mior S. The Neck Disability Index: a study of reliability and validity. *J Manip Physiol Ther* 1991;14:409–15.
25. Hawker GA, Mian S, Kendzerska T, French M. Measures of adult pain: Visual Analog Scale for Pain (VAS Pain), Numeric Rating Scale for Pain (NRS Pain), McGill Pain Questionnaire (MPQ), Short-Form McGill Pain Questionnaire (SF-MPQ), Chronic Pain Grade Scale (CPGS), Short Form-36 Bodily Pain Scale (SF-36 BPS), and measure of Intermittent and Constant Osteoarthritis Pain (ICOAP). *Arthritis Care Res* 2011;63: S240–52.