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The Effect of Interactive Neurostimulation Therapy on Myofascial Trigger Points Associated with Mechanical Neck Pain: A Preliminary Randomized, Sham-Controlled Trial

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Abstract

Objectives: This trial was conducted to assess the effectiveness of interactive neurostimulation (INS) therapy on the treatment of pain associated with myofascial trigger points (MTPs) in adults with mechanical neck pain.
Design: This was a preliminary, randomized, sham-controlled trial.
Setting: The trial was conducted in a tertiary-care institution.
Subjects: The participants were 23 adults with pain and MTPs in the neck or shoulder lasting > 2 weeks.
Interventions: INS (active or sham) was delivered for 10 minutes in a single session over the MTP area in each patient.
Outcome measures: Immediately following the intervention, subjects were tested for pressure pain thresholds (PPTs) and 10-cm visual analogue scale score (VAS) for pain intensity. At the 5 day follow-up, two additional tests were performed: the neck disability index (NDI) and the patient specific functional scale (PSFS) for function.
Results: Improvements in function (PSFS) were observed in the treatment group, which were of clinical significance in selected subjects. These effects were statistically greater than those obtained in the sham group but were overall not at a level of clinical significance in this small population. Improvements in pain intensity (VAS) and neck disability (NDI) were observed in both the treatment and sham groups, indicating that INS had no greater benefit using these measures. There was no change in PPTs following either the active or sham treatment.
Conclusions: INS is a new and emerging therapy, which may be efficacious for managing musculoskeletal conditions, such as myofascial pain syndrome. This study demonstrated improvements in function in individuals with MTPs following INS therapy, which may be of clinical significance in certain patients with neck or shoulder pain. Further large-scale clinical trials are required to confirm this effect and to determine if INS also reduces pain and neck disability.

Introduction

Myofascial pain syndrome is a common muscle disorder arising from myofascial trigger points (MTPs).[1] MTPs are defined as discrete, localized, hyperirritable nodules in a taut band of skeletal muscle,[2] and are recognized as one of the most frequent causes of musculoskeletal pain and dysfunction.[3] Symptoms manifest in the motor, sensory, and autonomic systems, and include local and referred pain, dizziness, fatigue, headaches, decreased range of movement (ROM) and impaired function.[2] Prevalence rates are high, with up to 85% of patients presenting to a comprehensive pain center reporting symptoms of MTPs.[4] Treatments include alternative and complementary techniques, such as acupuncture, acupressure and shiatsu massage as well as techniques more commonly associated with the Western medical model, such as transcutaneous electrical nerve stimulation (TENS), pharmacologic interventions, and physical therapy. Despite the wide range of therapies available, relatively few have undergone rigorous testing in controlled clinical trials.

Acupuncture and TENS are two of the most popular techniques used in the treatment of MTPs.[3] Evidence from a number of studies suggests that acupuncture may reduce MTP symptoms[3] by disrupting the hyperirritable nodule

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mechanically.[5] Although evidence for the efficacy of this technique is not yet definitive, clinical audits suggest that the majority of individuals experience reduction or resolution of symptoms with dry needling.[6] Similarly, positive effects of TENS—including reduction in pain, increased pressure pain thresholds, and increased ROM—have been reported.[7,8]

Interactive neurostimulation (INS) is a new therapy that combines aspects of acupuncture and TENS for managing musculoskeletal conditions. INS is delivered using a handheld, battery operated device and is thought to act on the energetic system of the body.[9] The TENS waveform is distributed via two mobile, concentric stainless steel electrodes that are moved in a scanning motion across the skin. This electrode configuration, in combination with a short pulse width, allows a high-frequency high-intensity current to be delivered to body tissues without eliciting muscle contractions.

Several features of INS suggest that it may be effective for treating MTPs. First, the INS device senses changes in the impedance of underlying skin and muscle tissue, and automatically alters the dosage to reflect these changes. This automatic updating ensures that an optimal dosage is delivered throughout the treatment. As studies suggest that autonomic reactions occur over MTP sites[10,11] decreasing skin impedance,[12] this feature may enhance detection and treatment of MTPs significantly. Second, it is feasible that the combination of acupuncture and TENS may reduce the symptoms of MTPs beyond that of either therapy alone. Based on this potential, INS may be an appropriate treatment strategy for MTPs. However, this device has, to the current authors' knowledge, never been tested for its efficacy in the management of MTPs.

The current trial was designed to assess the effectiveness of INS for treating pain associated with MTPs in adults with mechanical neck pain. Based on studies demonstrating reductions of pain and improvements in function using acupuncture and TENS, the current authors hypothesized that INS would reduce pain and improve function associated with MTPs, compared with sham therapy.

Methods

Participants

Ethical approval was obtained from The University of Queensland's Human Medical Research Ethics Committee. A prospective power analysis was performed using the power-calculation tool for analysis of variance (ANOVA) statistical tests in Sigmaplot software (Systat Software Inc., main office in Chicago, IL). Using established minimum clinically detectable change values for the visual analogue scale (VAS),[13] neck disability index (NDI),[14] and patient specific functional scale (PSFS),[14] as well as standard deviations from Vitiello et al.,[15] 10 subjects were required for each group in the study to detect a statistically significant change, should one emerge, with an α of 0.05 and a power of 90%. Following recruitment, 23 subjects consented to participate. Participants were included if they were between 18 and 55 years of age, had pain in the neck or shoulder region lasting > 2 weeks, and reported small zones (approximately 1 cm in diameter) of intense tenderness in the neck and shoulder muscles consistent with MTPs.[16] Suitability for participation in this study was determined by an experienced physiotherapist who determined if the MTP was a palpable taut band of skeletal muscle that reproduced a characteristic pattern of referred pain on sustained compression.[3] Subjects were excluded if they: had neurologic signs; were diagnosed with cervical radiculopathy; were receiving treatment for neck pain; were pregnant; had whiplash-associated disorders; had prior orthopedic surgery in the cervical or thoracic spine; and/or had signs of vertebrobasilar insufficiency or contraindications for electrical stimulation.

Study design

This preliminary randomized controlled trial compared the effectiveness of INS treatment with a sham therapy. Participants were allocated using a random numbers table and an allocation ratio of 1:1. The InterX® 5002 (NeuroResource Group, Plano, TX) was used for the treatment group. The sham group received the same treatment protocol using the same device but without any power in the device. This study was a single-treatment intervention. Participants and pre–post assessors were blinded to group allocation. Thus, only the treatment investigator was aware of group allocation, minimizing potential bias.

Procedure

Participants completed the VAS for pain intensity, NDI, and PSFS. The participants then went into to a sectioned room, where MTPs were identified and marked by a trained physiotherapist. If more than one MTP was identified, or if bilateral neck pain was present, the most painful MTP was used. MTPs were measured with a pressure algometer by placing the tip of the device over the MTP. The participant was instructed to indicate when the sensation changed from pressure to pain. Treatment with the InterX® 5002 device followed in a separate room (Fig. 1). Participants were treated with either the active or the sham (unpowered) device. Post-treatment assessments—including pressure pain threshold (PPT) measurements and the VAS for pain intensity—were completed immediately after the treatment intervention.

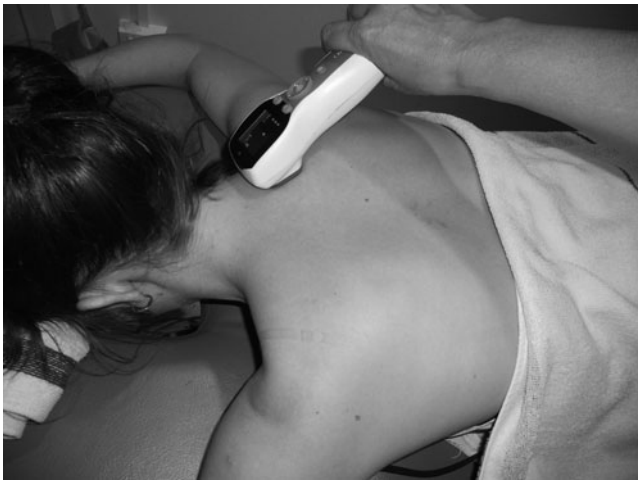

FIG. 1. The application of interactive neurostimulation to a subject with myofascial trigger points. The InterX® 5002 (NeuroResource Group, Plano, TX) was used for this procedure.

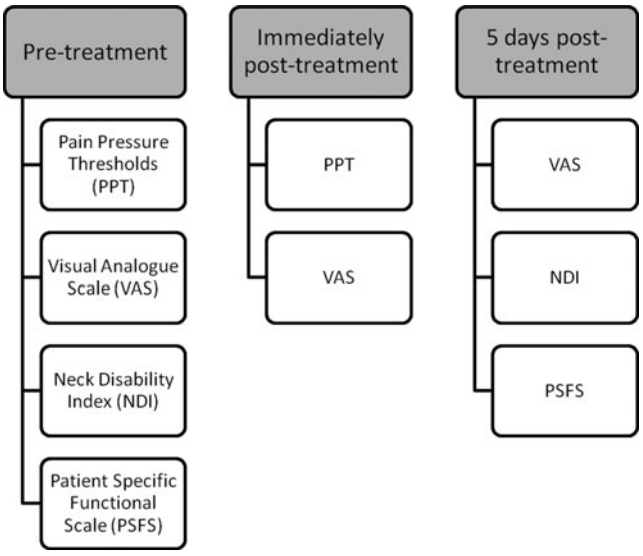

FIG. 2. Timeline of outcome-measure recording throughout the study.

Follow-up was completed 5 days later; participants were required to complete the NDI, VAS, and PSFS (Fig. 2). Participants did not begin any new treatments during the 5-day follow-up period.

Application protocol

The INS treatment, using the InterX® 5002, was applied to each participant for 10 minutes. As there is a paucity of evidence regarding the duration of treatment needed to induce a beneficial effect, treatment duration was set in accordance with the manufacturer's product literature. The applying therapists received training from a manufacturer's representative prior to the study. The sham group received an identical treatment protocol using the same device except the device was turned on and then off again immediately before application. This resulted in a short (~2-second period of electrical stimulation) accompanied by the lights and noises associated with active treatment. Care was taken to avoid mechanical stimulation of the tissues during sham treatment. All participants were advised that they might not feel the electrical stimulation during the treatment, thus minimizing the perception of a treatment occurring or not. Prior to the commencement of the treatment the sharp/blunt discrimination test was administered over the treatment area for safety.[17] Using a toothpick, subjects were asked to close their eyes and identify whether the sensation they experienced was sharp or blunt. Subjects were required to discriminate correctly between the two sensations with 100% accuracy.

Parameters

The INS was applied with a variable sweeping frequency of 15–60 Hz in a crossdiagonal fashion. Intensity was increased until the subject felt a strong tingling, but comfortable, sensation. The device was positioned over the MTP with comfortable ischemic pressure for a total of 10 minutes. Participants felt the initial current at the point of electrode placement before reporting stimulation in a referral pattern, as expected. The sham intervention imitated the treatment protocol but without the delivery of INS. False information such as beeping and flashing lights was provided at the beginning and end of the sham treatment.

Outcome measures

The order of each outcome measure is detailed in Figure 2. Primary outcome measures were PPT and pain intensity (VAS). Secondary outcome measures included the NDI and the PSFS. Each measure is described in detail below, with information on its reliability and effectiveness.

Pain pressure threshold. A pressure algometer (Electronic Engineering Corporation) with a sensor area of 1 square cm was used for assessment and reassessment. The pressure algometer measured the smallest amount of pressure that caused pain over the symptomatic area. An average of three pressure readings was derived from each subject pre- and post-treatment. PPT measurements have demonstrated reliability over a week period in both healthy patients as well as those with chronic neck pain.[18]

Visual analogue scale. Each subject's pain was measured on a 10-cm VAS. with 0 representing no pain and 10 representing the worst pain imaginable. The VAS has been shown to be a reliable and robust subjective measure of pain intensity.[19] The VAS was completed twice in this study: before treatment and 5 days after treatment.

Neck disability index. The NDI has been shown to be a valid and reliable outcome measure of a person's pain and disability as a result of neck pain.[20] The NDI is a 10-item self-rated questionnaire designed to assess how a person's neck pain has affected activities of daily living. The items include: (1) Pain intensity; (2) Personal care; (3) Lifting; (4) Reading: (5) Headaches; (6) Concentration; (7) Work; (8) Driving; (9) Sleeping; and (10) Recreation. Participants of both groups completed the NDI twice; immediately before treatment and at the 5-day follow-up.

Patient specific functional scale. The PSFS is a self-reporting disability measure used to quantify activity limitation and functional outcomes.[21] Participants of both groups were required to choose up to three activities that they had difficulty completing as a result of their neck pain. Each activity was scored on a 0–10 rating scale, for which 0 equals no function and 10 represents full function. The PSFS was completed twice: before treatment and 5 days after treatment.

Statistical analyses

To ensure the appropriateness of parametric testing, all data were examined for normality, using Shapiro-Wilk tests. All analyses were completed using a two-way repeated measures ANOVA, with factors group (treatment/sham) and time (pre/post/follow-up) to determine if there were any changes following the intervention in VAS, PSFS, NDI and PPT scores. The significance level was set at $p < 0.05$. A Holm-Sidak correction was used for posthoc testing when appropriate. Using an intention-to-treat analysis, any missing observations were included as the last value carried forward.

Results

Participants

Twelve participants (7 female, 5 male) were randomized to the treatment group and 11 participants (8 female, 3 male) to the sham group. The age of participants ranged between 18 and 29 years with a mean of 23.15 years (standard deviation [SD] = 3.63). Two (2) participants failed to return their follow-up questionnaires 5 days postintervention. This equated to an overall participation rate of 87%. Groups were not significantly different for age, NDI, VAS, PSFS, or PPT scores at baseline (all $p > 0.05$). (All values in this text are given as mean ± SD.) A CONSORT [*CON*solidated *S*tandards *o*f *R*eporting *T*rials] flow chart shows the enrollment, allocation, follow-up, and analysis stages of this study (Fig. 3).[22]

Visual analogue scale

Reductions in pain scores were statistically significant for both groups (no effect of group $p = 0.90$) immediately after the intervention and at the 5-day follow-up (effect of time $p < 0.001$; Fig. 4A). VAS scores for the treatment group decreased from 2.6 ± 2.0 to 1.5 ± 1.6 (57%) immediately post-treatment. Five (5) days later, the treatment group experienced a further reduction in pain scores (1.4 ± 1.6; 54%). The sham group scores decreased from 2.7 ± 1.7 to 1.3 ± 1.1 (48%) immediately post-treatment, with a slight increase at the 5-day follow-up (1.5 ± 1.4; 55%). There were no significant differences between groups at either timepoint (effect of group $p = 0.9$; group × time interaction $p = 0.18$).

Neck pain disability index

Significant reductions in neck pain disability scores were observed across time for both intervention groups (effect of time $p < 0.001$; no effect of group $p = 0.69$; Fig. 4B). Neck pain disability index scores decreased from 17.2 ± 8.7 to 8.3 ± 5 .0 (48%) in the treatment group and from 18.1 ± 13.1 to 9.8 ± 8.5 (54%) in the sham group. There was no significant difference between the two groups (effect of group $p = 0.60$; group × time interaction $p = 0.37$).

Patient specific functional scale

The PSFS increased for both groups (treatment from 6.2 ± 1.5 to 7.1 ± 1.7; sham from 7.4 ± 1.1 to 7.9 ± 1.3), indicating an improvement in function (effect of time $p = 0.006$; no effect of group $p = 0.18$; Fig. 4C). However, this improvement was greater in the treatment group than in the sham group (group × time interaction $p = 0.047$; posthoc treatment $p = 0.002$; sham $p = 0.47$). The minimally detectable clinical change in PSFS score is reported to be 2.0 or 20%.[23] Improvements in the treatment group represented a mean improvement of 15%. Three (3) subjects in the treatment group had improvements that exceeded 20%. Conversely, the mean improvement in the sham group was 7%. It is noteworthy, that no subjects in the sham group had improvements large enough to reach a minimally detectable clinical change.

Pressure pain threshold

There was no significant change in PPTs for either group across time (effect of time $p = 0.23$; no effect of group $p = 0.65$; group × time interaction $p = 0.58$; Fig. 4D). Values for the

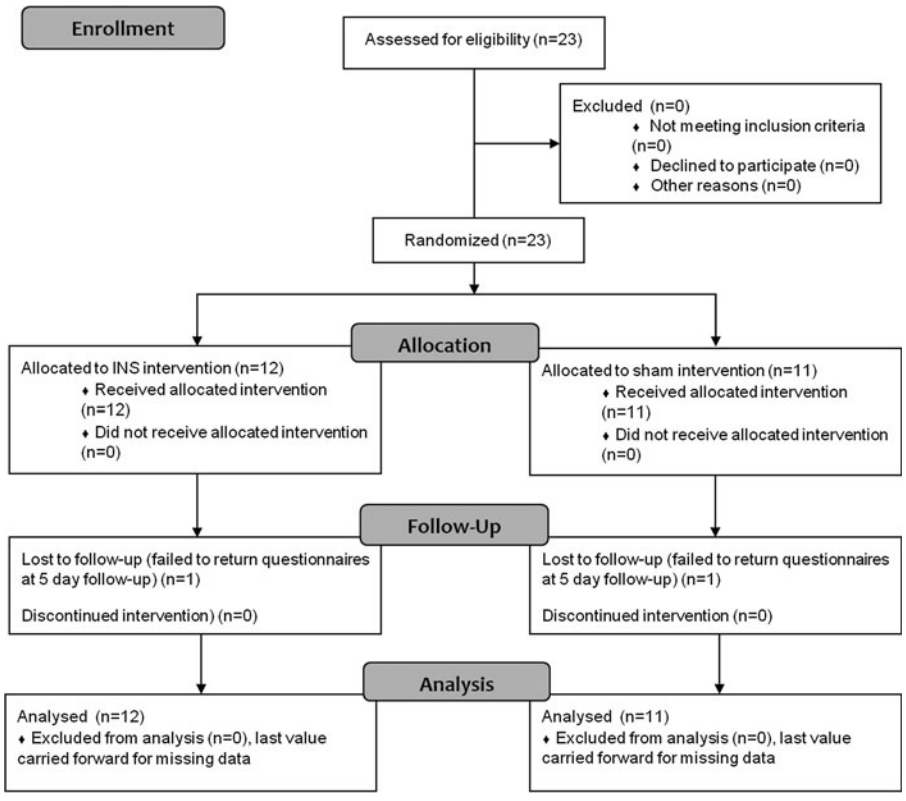

FIG. 3. CONSORT [*CON*solidated *S*tandards *o*f *R*eporting *T*rials] flow chart demonstrating the enrollment, allocation, follow-up, and analysis stages of this study.

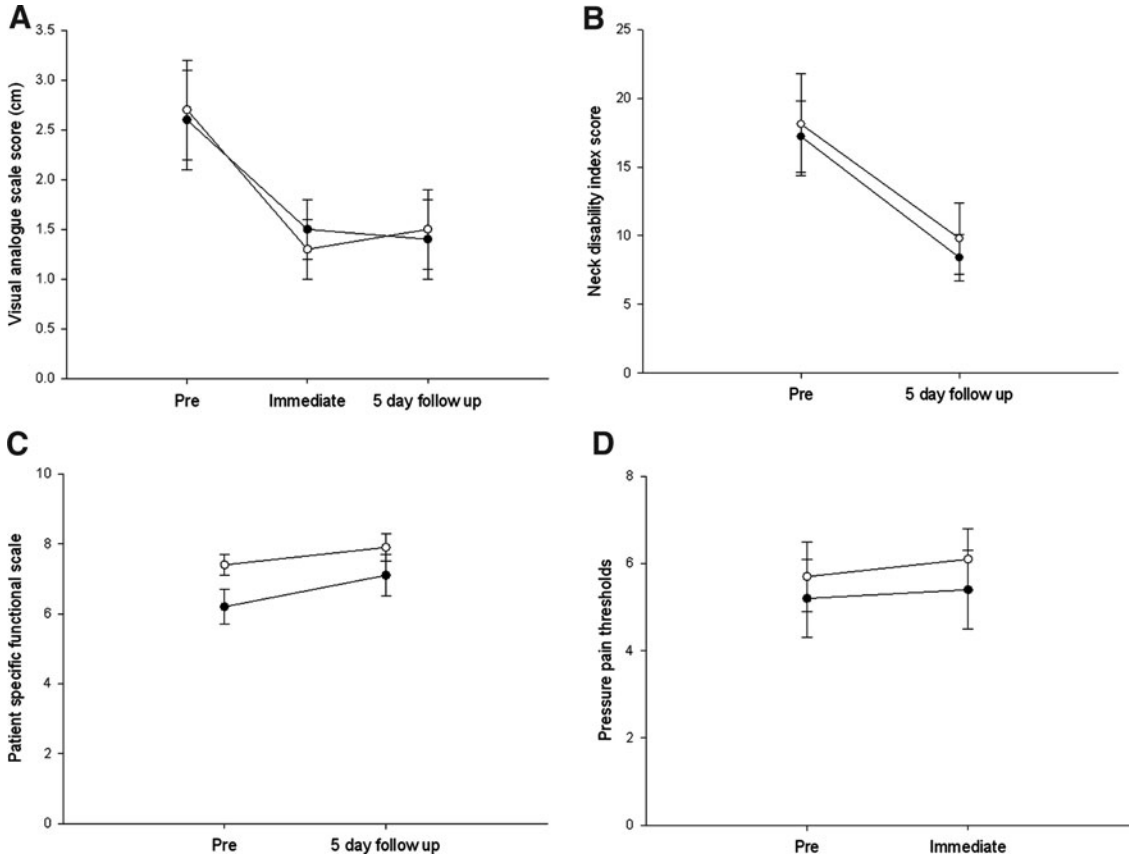

FIG. 4. Mean ± standard error in the interactive neurostimulation (INS) therapy (black circles) and sham therapy (white circles) groups for: **(A)** visual analogue scale (VAS); **(B)** neck disability index (NDI); **(C)** patient specific functional scale (PSFS); and **(D)** pressure pain thresholds (PPT). Measures of pain intensity (VAS) and neck disability (NDI) reduced significantly in both the INS and sham therapy groups. Both groups' scores improved significantly on the PSFS. However, the improvement was greater in the INS group, compared with the sham group and this change was clinically meaningful. There was no change in PPT for either group.

treatment group were 5.2 ± 2.9–5.4 ± 2.9 (4%) and for the sham group 5.7 ± 2.9–6.1 ± 2.5 (7%).

Discussion

This is the first study to examine the effectiveness of INS therapy for treating MTPs associated with mechanical neck pain. In this preliminary, randomized controlled trial, INS therapy resulted in improvements on the PSFS scores in the treatment group that were statistically greater than those obtained in the sham group. Although these improvements did not reach clinical significance overall, a clinically meaningful improvement (>20%) was detected in selected subjects. Both groups experienced significant reductions in neck pain and disability, indicating that no greater benefit was derived from INS therapy according to the measures used to assess its efficacy.

INS is a new and emerging technique with considerable therapeutic promise. However, its recent addition to the market means there is a paucity of evidence regarding its effectiveness as a therapeutic intervention. Although this is the first study to examine the effect of INS on myofascial trigger points, previous studies have shown positive benefits of INS in osteoarthritis of the knee,[9] ankle and femur fractures,[24,25] and chronic neck pain.[15] Using a similar sample size ($N = 24$) and identical outcome measures to the current study, Vitiello and colleagues[15] reported a significant reduction in neck pain (VAS), disability (NDI); and improvements in function (PSFS), compared with subjects receiving TENS therapy and placebo electrotherapy. The finding of improved function following INS, as measured with the PSFS, concurs with that of the present study.

Improved function on the PSFS was the only outcome measure in the current study to produce an improvement that was greater than that observed in the sham group. That the PSFS was a more-sensitive measure of change than the NDI is perhaps not surprising. The PSFS is a self-report disability questionnaire for which individuals select activities that are most relevant to their daily functioning. This is in contrast to the NDI, which includes a standard set of activities that may or may not be affected by an individual's condition. The inclusion of activities that are specific to each individual is likely to enhance the sensitivity of the PSFS. It is noteworthy, that 3 subjects in the treatment group reported improvements via the PSFS that exceeded the 20% cutoff for a minimally detectable clinical change. Although the overall mean improvement for the treatment group was 15%, it is possible that greater, more clinically meaningful improvements may be obtained with more frequent INS interventions. Indeed, following twelve treatment sessions over a

period of 6 weeks, Vitiello and colleagues[15] produced significant, clinically meaningful improvements with INS therapy, compared with TENS and sham therapy.

The absence of an improvement in VAS and NDI scores beyond that of sham therapy is in contrast to the findings of Vitiello and colleagues.[15] Although the reason for this discrepancy is unclear, several possible explanations exist. First, Vitiello and colleagues[15] included a treatment regime of twelve 15-minute treatment sessions over a period of 6 weeks. It is feasible that the single session INS intervention used in the present study was not sufficient to induce changes in pain intensity and neck disability measures beyond that of the sham group. Future studies should determine whether longer-lasting interventions induce more-robust improvements in pain and disability. Second, levels of pain and disability differ between chronic neck pain and myofascial pain syndrome. Indeed, VAS and NDI scores were significantly lower in the current study's sample of patients with MTP (VAS 2.6; NDI 17.2) than in those with chronic neck pain (VAS 5; NDI 30.7).[15] Lower initial scores may have masked any greater effect of the INS intervention.

The precise mechanism underlying INS therapy is unknown. It has been hypothesised that INS induces pain relief by rebalancing the body's vital energy (*qi*), similar to effects achieved using classical acupuncture.[9] Studies using a Western biomedical approach suggest that the TENS component of INS may release endogenous opioids,[26] modulate bidirectional communication between cutaneous, nervous, and immune systems,[27] or stimulate C and A-δ fibers reducing pain via the gate-control mechanism.[28] Further research is required before definitive conclusions on the mechanism underlying INS can be drawn.

Preliminary randomized controlled trials such as this are essential to provide early proof of concept information on which large scale clinical trials can be based. However, it must be acknowledged that this type of study also has limitations. First, this preliminary study used a small sample size of 23 subjects. Inadequate statistical power may be responsible for the insignificant findings obtained using the VAS, NDI, and PPT. Future studies examining the effect of INS on MTPs should use larger sample sizes to ensure that any significant difference between treatment and sham groups can be observed. Second, it was not possible to blind the therapist to group allocation. However, bias was minimized by ensuring that participants and reviewers assessing the outcome measures were blinded. Finally, the results of this study cannot be generalized to MTPs outside the neck and shoulder muscles or to other musculoskeletal conditions. Further studies examining other body regions and conditions are required before the effects of INS therapy in these populations can be ascertained.

Conclusions

INS is a new and emerging therapy that may be efficacious for managing musculoskeletal conditions such as myofascial pain syndrome. Although there was no significant change in pain levels or NDI scores, this trial demonstrates improvements in function in individuals with MTPs following INS therapy, which may be of clinical significance for certain patients with neck or shoulder pain. Further large-scale clinical trials are required to confirm this effect and to determine if INS also reduces pain and neck disability.

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Disclosure Statement

This study received one free-of-cost INS device from the Neuro Resource Group, Inc., and independently purchased a second device. No competing financial interests exist for any of the authors.

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