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Dry needling versus trigger point compression of the upper trapezius: a randomized clinical trial with two-week and three-month follow-up

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ABSTRACT

Objectives: The purpose of this randomized controlled trial was to investigate the long-term clinical effect of dry needling with two-week and three-month follow up, on individuals with myofascial trigger points in the upper trapezius muscle.

Methods: A sample of convenience (33 individuals) with a trigger point in the upper trapezius muscle, participated in this study. The individuals were randomly assigned to two groups: trigger point compression (N = 17) or dry needling (N = 16). Pain intensity, neck disability, and disability of the arm, hand, and shoulder (DASH) were assessed before treatment, after treatment sessions, and at two-week and three-month follow ups.

Results: The result of repeated measures ANOVA showed significant group-measurement interaction effect for VAS (p = .02). No significant interaction was found for NPQ and DASH (p > .05). The main effect of measurements for VAS, NPQ, and DASH were statistically significant (p < .0001). The results showed a significant change in pain intensity, neck disability, and DASH after treatment sessions, after two weeks and three months when compared with before treatment scores in both groups. There was no significant difference in the tested variables after two-week or three-month as compared to after treatment sessions between the two groups. However, pain intensity after treatment sessions was significantly different between the two groups (p = .02).

Discussion: Dry needling and trigger point compression in individuals with myofascial trigger point in the upper trapezius muscle can lead to three-month improvement in pain intensity and disability.

KEYWORDS

Dry needling; myofascial trigger point; upper trapezius; trigger point compression

Introduction

Mechanical neck pain is one of the most common health-related problems in today's society. Previous studies estimated that about 45–54% of the adult population would experience neck and upper extremity pain at some time in their life time [1].

A myofascial trigger point (MTrP) has been considered as one of the main causes of myofascial pain syndrome (MPS) (30–85%) in individuals with musculoskeletal pain such as neck pain [2–6]. MTrP is a condition, which is associated with regional pain and muscle tenderness characterized by the presence of hypersensitive nodules within taut bands of skeletal muscle. Travell and Simons defined MTrPs as discrete areas of muscle tenderness in taut bands of muscle that are spontaneously painful. Three minimum clinical diagnostic criteria have been used: taut band (discreet nodule within a taut band within a muscle); spot tenderness (focal hypersensitive and painful point) and referred pain sensation with mechanical stimulation of the spot tenderness [7–9]. The snapping palpation can produce a local twitch response (LTR), jump sign, and referred pain [7–9]. Muscle weakness or muscle tightness, and pain with stretching or contraction of the affected muscle may be present [10].

MTrPs can have detrimental effects on people's social and work-related activities, and have a significant impact on the quality of life, pain, and functional disability in the neck and shoulder area [4,6,11]. It is thought that MTrPs may result from or be exacerbated by trauma, overuse, mechanical overload, postural faults or psychological stress [12].

Chemical characteristics of MTrPs may include increased levels of bradykinin, serotonin, substance P, calcitonin gene-related peptide (CGRP) as well as lowered pH [13,14]. Investigators established that the local oxygen saturation at a MTrP site is less than 5% of normal. Local tenderness and referred pain following MTrP ensues as muscle nociceptors are stimulated in response to reduced oxygen levels and increased inflammatory mediators [14–17]. It has been hypothesized that the injured muscle fibers are shortened

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(producing taut bands) either in response to excessive amounts of calcium ions being released from within the damaged fibers, or in response to the corresponding motor end plate releasing excessive amounts of acetylcholine [14,15,17,18].

The upper trapezius (UT) muscle has been found to be often affected by MTrPs [19–21]. Common symptoms in individuals with MTrPs in the UT muscle include a taut and painful muscle, tension headache, neck pain, dizziness or vertigo, limited neck, and shoulder ROM [12,22–24]. Considering the role of synergistic function of the UT muscle in scapulohumeral rhythm during shoulder movement, it is not surprising that MTrP in UT muscle can result in shoulder dysfunction and disability.

Physical therapy intervention plays a significant role in the treatment and improvement of symptoms in individuals with MTrPs. However, specific protocols or clinical practice guidelines have not been established to guide intervention for individuals with MTrPs. Trigger point compression (TPC) is one of the most common treatment methods used for subjects with MTrPs attending physical therapy clinics [5,17,25].

There is a growing body of evidence supporting the use of dry needling (DN) as an intervention to treat MTrPs.

Investigators have attributed the therapeutic effects of DN to various mechanisms, such as mechanical, neurophysiologic and chemical effects [14]. It is thought that DN mechanically provides a localized stretch to the shortened sarcomeres and contracted cytoskeletal structures within the MTrP. This would allow the sarcomere to resume its resting length by reducing the degree of overlap between actin and myosin filaments [14,26,27]. Simons et al[7] stated that the main therapeutic factor for the effectiveness of DN is the mechanical disruption of the MTrP by the needle and trigger points change in status from active trigger point to latent trigger point or palpably normal tissue [28].

DN can stimulate the A-delta nerve fibers (group III), which in turn, may activate the enkephalinergic inhibitory dorsal horn interneurons, resulting in opioid-mediated pain suppression (pain relief) [14,27]. Some studies have also demonstrated that the increased levels of bradykinin, CGRP, substance P and other chemicals at MTrPs are directly corrected by eliciting LTR following DN [14]. It has been suggested that DN may influence the microcirculation in muscle. Several investigators have demonstrated that needle insertion in the muscles may influence the microcirculation and enhance blood flow in the stimulated region [29,30].

Previous studies have assessed the effect of DN on MTrPs in UT. However, with the use of varying study designs, samples and testing procedures, different results have been reported regarding the effect of DN on MTrPs in the UT [31–41].

There is a paucity of literature on the effect of DN on MTrPs in the UT muscle with follow up after treatment [41,42].

The purpose of this study was to investigate the effects of DN on pain intensity and disability as compared to TPC in individuals with MTrPs in the UT muscle, with two-week and three-month follow-up.

Methods

A randomized controlled trial (RCT) was performed (registered with the Clinical Trials.gov, NCT 02107456) to investigate the effect of DN as compared to TPC on pain, neck disability, and disabilities of the arm, shoulder and hand. Forty-four (44) participants with MTrPs in the UT muscle, who had been referred for outpatient physical therapy evaluation and intervention, participated in the study. The participants were a sample of convenience made up of subjects who were between the ages of 20 and 48 years. The individuals with a known history of fibromyalgia syndrome, whiplash injury, cervical spine surgery and fracture, cervical radiculopathy and any systemic disease such as rheumatism and tuberculosis or cervical myelopathy, multiple sclerosis and history of MTP therapy one month prior to enrollment were excluded from participating in the study [16,43–46]. The individuals, who underwent DN, also had no contraindications for needling such as local infection, pregnancy with threatened abortion, allergy to metal, a history of taking anticoagulants (e.g., warfarin) and long-term steroid use.

Thirty-three (33) women with MTrPs in the UT muscle and a minimum of three clinical diagnostic criteria as inclusion criteria, were selected for this study. They were consecutive individuals who agreed to participate and fulfilled the inclusion criteria.

A physical examination was used to confirm a MTrP diagnosis, which consists of a palpation protocol, which included manual palpation and the patients' responses to specific questions about painful symptoms. Specific palpation techniques are often used to elicit pain by pressure on affected muscles. These maneuvers are important for diagnostic clinical reasoning and manual therapy [47]. The important criteria for having active MTrPs in the UT muscle were as follows [1,10,48]:

(1) The presence of a palpable taut band in the muscle; (2) presence of a hypersensitive tender spot in the taut band based on palpation with patient's report; (3) reproduction of the typically referred pain pattern of the MTrP in response to compression (perpendicular progressive and gentle compression on the tender spot to elicit pain and verify the presence of referred pain pattern). A positive reply to the

question (do you recognize this pain as a familiar complaint?) was used to confirm the presence of referred pain pattern. To detect an active MTrP, a mechanical pressure algometer (FG5005) was used to assess pressure tolerance at the MTrP. A continuous pressure was applied using the algometer with an approximate pressure of 2.5 kg/cm^2; (4) spontaneous presence of the typically referred pain pattern; (5) pain of at least 30 mm on a visual analog scale (VAS) (most and current pain).

The study protocol was approved by the Human Research Committee of the University of Social Welfare and Rehabilitation Sciences. All subjects signed an informed consent form approved by the human subjects committee before participating in the study.

Assignment

Participants were randomly assigned to the TPC group (N = 17, mean age = 26.5 ± 8.57 years) and DN group (N = 16, mean age = 30.06 ± 9.87 years). The coin tossing method was used for randomization. Once a subject was registered for the trial after screening, a coin was tossed for determination of group allocation, and the systematic assignment was used to restrict groups. Power analysis was used to determine the sample size. Power of test analysis and sample size estimation were performed by PS software (PS Power and Sample Size Calculations, Version 3.0, January 2009, 1997–2009, by William D. DuPont and Walton D. Plummer) [9]. Based on an a priori power analysis, 33 participants were recruited to account for 20% attrition at follow-ups, 80% power, and a minimum of 28 participants needed to achieve significance.

Demographic characteristics of the participants in each group are shown in Table 1.

Interventions

The treatment protocol for the TPC group consisted of the TPC technique for MTrPs in the UT muscle. The individuals in the DN group received DN on the UT muscle.

Individuals in each group received three treatment sessions over one week (every other day).

Table 1. Demographic data of participants. (Mean ± SD).

Variables		TPC (n = 17)	DN (n = 16)
Age (years)		26.5 ± 8.57	30.06 ± 9.87
Weight (kg)		56 ± 5.92	60.37 ± 6.96
Height (cm)		163.7 ± 4.49	165.3 ± 7.56
Affected side	Right	(n = 7)	(n = 7)
	Left	(n = 10)	(n = 9)

SD = Standard deviation
DN = Dry Needling
TPC = Trigger point compression

Trigger point compression (TPC)

Individuals who were randomized into the TPC group were placed in either the supine or prone position with the cervical spine in the neutral position. The therapist manually applied increasing pressure to the MTrP gradually until the onset of a sensation of pressure and pain. At that moment, the pressure was maintained until the discomfort or pain was relieved by about 50%, as perceived by the individuals. At that time, the pressure was increased until discomfort was felt again. This process was maintained for about 90 s and repeated until the reported tenderness and palpable tension of the TrP was released [1,43].

Dry needling (DN)

The DN for MTrPs was performed with 'solid filiform needles' (50 × .3 mm). The procedure for DN was as follows: The participant was asked to lie in the prone position. The overlying skin was cleaned with alcohol. The taut band, localized between the thumb and index finger, the solid filiform needle within its plastic guide tube was placed over the MTrP. A tapping motion was used to insert the needle. The needle was moved to the muscle around the bundle and moved forward and backward to the tissue to elicit a small muscle twitch called LTR. After eliciting LTR, needling was stopped. If no twitch was elicited, needling was stopped after two or three stellate movements [34,40,41].

Outcome measures

Pain intensity, and neck, shoulder and arm disabilities were measured before treatment and immediately after three treatment sessions (one week), and at two-week and three-month follow-ups after treatment in both groups to investigate the effectiveness in the treatment of the individuals with MTrP in the UT muscle.

Assessment of pain intensity

Pain intensity was measured using the visual analog scale (VAS). The VAS is a simple, sensitive and reproducible instrument often used for the assessment of variations in the intensity of pain. In clinical practice, the level of pain relief, assessed by VAS, is often considered as a measure of the efficacy of treatment. In this study, a 10-cm VAS for pain was used. The level of pain on the VAS was recorded on a 10 cm line distinct at one end 'no pain' and marked at the other end 'the worst pain that you can imagine.' Subjects were asked to state their pain level by placing a mark on this horizontal line [35].

Assessment of neck disability

The Northwick Park Neck Pain Questionnaire (NPQ) was used to assess neck disability before and after treatment. NPQ is commonly used to measure neck pain and disability. It provides an objective method to evaluate and monitor symptoms in individuals with neck pain over time. The questionnaire is divided into nine five-part sections. The NPQ has been shown to have good repeatability, high internal consistency and sensitivity to change. Thus, it provides a minimal clinically important difference that allows individuals with varying levels of severity to show improvement. Higher numbers indicate higher levels of disability [49–51].

Assessment of the arm, shoulder and hand disabilities

Disability of the arm, hand and shoulder (DASH) questionnaire is commonly used as an appropriate method to investigate the efficacy of different treatment modalities in the management and improvement of disability in individuals with shoulder disorders. Investigators have shown that the DASH questionnaire could be used to detect the level of shoulder disability and a relationship was found between DASH score, disability, and quality of life [52]. The DASH outcome measure is a 30-item self-report questionnaire designed to measure physical function and symptoms in people with musculoskeletal disorders of the upper limb. It is a single and reliable instrument that can be used in a wide variety of upper extremity disorders [53]. The Persian version of the DASH has been shown to be a reliable and valid instrument to measure functional status in Persian-speaking individuals with upper extremity disorders [54].

Statistical analysis

Kolmogorov-Smirnov test was used to assess the normality of distribution for the tested variables before and after treatment. Normal distribution was observed for variables in both groups. Repeated measures ANOVA was used to determine any significant change in the tested variables (VAS, NPQ, DASH) after three treatment sessions (one week, two week, and three month(as compared to pretreatment scores in TPC and DN groups. Repeated measures ANOVA, accounting for measurements (three measurements: after three treatment sessions, two-week follow up and three-month follow up), treatment group (DN and TPC) and interaction of measurement and group, was used to determine and compare significant changes in the tested variables after three treatment sessions in the groups. To measure the magnitude of a treatment effect, Cohen's effect size was calculated. Statistical significance was set at $p = .05$.

Results

The participant flow diagram presented in Figure 1 shows the numbers and timing of randomization assignment, interventions and measurements for each group.

Demographics of the participants in both groups are summarized in Table 1. Detailed descriptive statistics (Mean ± SD) of the pre- and postmeasurement scores (after three treatment sessions, two-week, and three-month follow-up) for the TPC and DN groups are provided in Table 2.

The result of repeated measures ANOVA showed significant group-measurement interaction effect for VAS ($p = .02$). No significant interaction was found for NPQ and DASH ($p > .05$). The main effect of measurements for VAS, NPQ and DASH was statistically significant ($p < .0001$). DN and TPC groups had no statistically significant effect on VAS, NPQ, and DASH ($p > .05$) (Table 3).

Post hoc analysis showed significant change in VAS, NPQ, or DASH disability after three treatment sessions, two-week and three-month follow-up as compared to before treatment scores in both groups (DN and TPC) ($p < .05$) (Table 4).

However, based on the comparison between the measurements done after two-week or three-month follow-up and the measurements done immediately after three treatment sessions, there was no significant difference in VAS, NPQ, and DASH in the DN group.

However, change in VAS, NPQ, and DASH after two weeks or three months was not significantly different between the two groups ($p > .05$) when compared with the pretreatment scores. Only change in pain intensity (VAS) obtained immediately after three treatment sessions was significantly different between the two groups ($p = .02$).

The effect size of both treatment methods (DN vs. TPC) for estimation of the size of the treatment effect after treatment sessions and two weeks or three months after treatment as compared to before treatment scores, and the estimated power of the analysis is presented in Table 4. The results showed that the effects size of the DN method on the tested variables (VAS, NPQ, and DASH) is greater than that of TPC technique after treatment sessions and after two weeks and three months.

Discussion

The result of this study showed a significant change in pain intensity, neck disability and DASH scores after treatment (one week, two weeks, and three months(when compared with pretreatment scores in the DN and TPC groups. The data also revealed a significant difference in change in VAS between the two groups after three treatment sessions (one week). There was no statistically

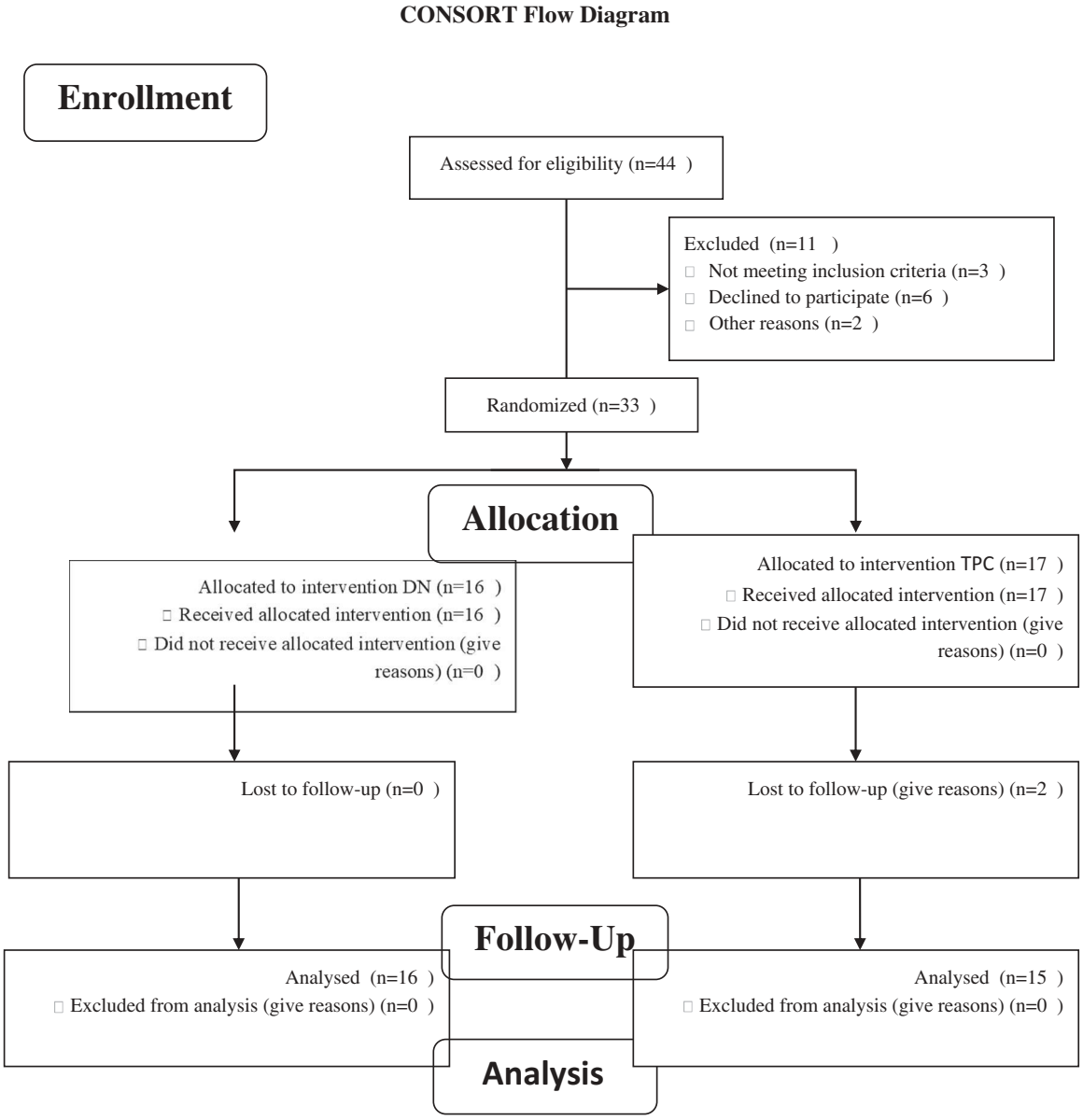

Figure 1. Flow diagram.

Table 2. The (Mean ± SD) of the pre- and postmeasurement scores (after three treatment sessions, two weeks and three months) for the DN and TPC groups.

		Group			
Variable	Time	DN	TPC	Mean difference	*p* value
VAS	Before treatment	6.56 ± 1.63	6.23 ± 1.26	.32	.52
	After one week	1.34 ± 1.93	3.2 ± 2.3	−1.71	.02
	After two weeks	1.90 ± 1.54	2.6 ± 1.7	−.69	.2
	After three months	2.4 ± 1.74	3.33 ± 2.22	−.92	.2
DASH	Before treatment	24.7 ± 10.81	26.44 ± 8.56	−1.7	.61
	After one week	12.81 ± 10.15	17.7 ± 11.5	−4.11	.29
	After two weeks	8.89 ± 9.98	11.35 ± 7.8	−2.45	.45
	After three months	9.89 ± 7.08	15.55 ± 12.01	−5.61	.12
NPQ	Before treatment	32.65 ± 9.9	33 ± 7.09	−.35	.9
	After one week	13.17 ± 11.5	21.39 ± 12.36	−7.46	.08
	After two weeks	13.31 ± 13.5	13.04 ± 10	.26	.95
	After three months	12.4 ± 8.6	19.32 ± 12.20	−6.9	.07

VAS = Visual analog scale
DASH = Disability of arm, hand, and shoulder
NPQ = Northwick Park Neck Pain Questionnaire

Table 3. Results of repeated measures ANOVA, accounting for measurements, group, and interaction of measurement and group in tested variables.

Variable	Source	Type III Sum of Squares	Mean Square	*F*	*P*
VAS	Measurements	355.43	118.47	56.35	< .0001
	Group	18.77	18.77	2.63	.11
	Measurements * Group	21.67	7.21	3.43	.02
DASH	Measurements	4240.5	1413.5	24.05	< .0001
	Group	414.7	414.7	1.9	.17
	Measurements * Group	83.6	27.8	.47	.7
NPQ	Measurements	7168.5	2389.5	29.8	< .0001
	Group	430.82	430.82	1.85	.18
	Measurements * Group	463.4	154.4	1.9	.13

significant differences in variables (VAS, DASH, and NPQ) between the groups at any time (one week, two weeks, and three months(, except for VAS at one week.

Results of other studies show effects of DN on individuals with MTrPs in the UT muscle. A systematic review on the effect of DN on upper-quarter myofascial pain recommends DN as compared to placebo treatment in this region [55]. Majority of the highest-quality studies on DN in the literature indicate that DN is effective for reducing pain and tenderness in different body regions, including the head, trunk, upper, and lower extremities [56].

Other studies showed moderate evidence for TPC and strong evidence for DN, to have a positive effect on pain intensity. However, there is weak evidence regarding effects on functionality and quality of life. TPC and DN are both suggested in the treatment of neck pain with trigger points in the upper trapezius muscle [57].

Although, the goal of DN and TPC is often rapid relief of pain, most studies have evaluated the immediate effect of TPC and DN, with only a few studies describing longer term effects.

Different study designs and testing procedures have been reported to examine the effect of DN on MTrPs [30–35]. However, the importance of this study is that it directly investigated the effect of DN on MTrPs at the end of the treatment sessions and then after two weeks and three months rather than just immediate effects.

Three months after treatment sessions, pain intensity and neck and shoulder disability scores increased as compared to the end of treatment sessions, but this measurement scores were significantly lower than before treatment scores. This suggests that improvements in pain and disability using both DN and TPC are maintained three month after intervention (Table 4). Investigators have attributed the therapeutic effects of DN to mechanical neurophysiologic and chemical effects [13,14]. It has also been suggested that DN stimulates the A-delta nerve fibers, which in turn may activate the enkephalinergic inhibitory dorsal horn interneurons. Several studies have demonstrated changes in the chemical properties of MTrP combined with eliciting LTR following dry needling [14,27]. It is thought that DN normalizes the chemical properties of the MTrP site in the muscle. The importance of LTR has previously been stated and better results were obtained in the DN group [58,59]. Local twitch responses have been thought to reduce the concentration of sensitizing substances in the MTrP and are considered as an important parameter in breaking the centrally mediated vicious cycle of the MTrP phenomena [60]. According to Hong [60], an LTR elicited during needling is the most definitive objective indication that the needle has been inserted exactly in the MTrP. They found local twitch responses were elicited in 100% of participants in the DN group throughout the course of the treatment [60].

It is believed that the longer-term effects following DN application are due to chemical and mechanical changes and increase in blood flow and oxygen in the MTrP site due to the application of DN [13,14,29,30].

The findings of the present study complement the results of the study conducted by Sim et al. [52] showing that MTrP in muscles can affect function. Investigators attributed the prolonged or permanent relief of pain after DN to the chemical and physiological tissue changes. The focal injury and micro trauma following needle insertion probably produced a current of injury that persisted for several days or months until the micro-wound healed. The end of repeated needling and repeated micro trauma probably led to the formation of scar tissue, which eventually displaced the number of functioning nociceptors and may explain the prolonged relief of pain [7,13,29,61].

Limitations

In this study, there were missing data at follow-up and they were excluded from analysis. Other areas of concern are potential variability in the pressure of the TPC and experience level of the practitioner. Further research is needed to examine results longer than

Table 4. Pairwise comparison between different treatment sessions, Cohen's effect size, and power of analysis in DN and TPC group.

								95% CI for Difference	
Variable	Group	Session	Session	Mean Diff.	*p* value	Effect size	Power	Lower Bound	Upper Bound
VAS	DN	Before treatment	Week 1	5.21	< .0001	.87	.98	4.14	6.29
		Before treatment	Week 2	4.65	< .0001	.85	.99	3.61	5.7
		Before treatment	Month 3	4.15	< .0001	.79	.99	3	5.30
		Week 1	Week 2	−.56	.19	—	—	−1.43	.31
		Week 1	Month 3	−1.06	.03	—	—	−2.01	−.11
	TPC	Before treatment	week 1	2.86	< .0001	.64	.98	1.52	4.2
		Before treatment	Week 2	3.53	< .0001	.73	.99	2.32	4.72
		Before treatment	Month 3	2.80	< .0001	.60	.98	1.49	4.1
		Week 1	Week 2	.66	.17	—	—	−.33	1.66
		Week 1	Month 3	−.06	.91	—	—	−1.38	1.24
DASH	DN	Before treatment	Week 1	11.88	.001	.52	.96	5.62	18.14
		Before treatment	Week 2	15.8	< .0001	.61	.99	8.91	22.7
		Before treatment	Month 3	14.81	< .0001	.68	.99	9.30	20.32
		Week 1	Week 2	3.9	.06	—	—	−.32	8.16
		Week 1	Month 3	2.9	.19	—	—	−1.69	7.55
	TPC	Before treatment	Week 1	8.65	.02	.34	.74	1.06	16.23
		Before treatment	Week 2	15.02	< .0001	.71	.99	9.56	20.48
		Before treatment	Month 3	10.86	.01	.57	.98	5.46	16.27
		Week 1	week 2	6.37	.01	—	—	1.55	11.19
		Week 1	Month 3	2.21	.5	—	—	−4.8	9.23
NPQ	DN	Before treatment	Week 1	19.47	< .0001	.69	.99	12.38	26.7
		Before treatment	Week 2	19.34	< .0001	.68	.99	12.04	26.63
		Before treatment	Month 3	20.24	< .0001	.73	.99	13.56	26.92
		Week 1	Week 2	−.13	.95	—	—	−5.32	5.05
		Week 1	Month 3	.76	.73	—	—	−4.02	5.55
	TPC	Before treatment	Week 1	11.3	.01	.41	.85	2.87	19.73
		Before treatment	Week 2	19.66	< .0001	.71	.99	12.56	26.75
		Before treatment	Month 3	13.37	.001	.52	.95	6.11	20.63
		Week 1	Week 2	8.35	.003	—	—	3.36	13.34
		Week 1	Month 3	2.07	.6	—	—	−6.38	10.52

3 months to determine the functional impact of DN and TPC after longer periods of time.

Conclusion

This study revealed that both DN and TPC produced three-month improvement in pain intensity and disability, therefore, could be a potential treatment for individuals with MTrPs in the UT muscle.

Disclosure statement

No potential conflict of interest was reported by the authors.

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CONSORT 2010 checklist of information to include when reporting a randomized trial*.

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomized trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	1
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	2,3
	2b	Specific objectives or hypotheses	3,4
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	5,6,7
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	-
Participants	4a	Eligibility criteria for participants	5,6
	4b	Settings and locations where the data were collected	6
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	7,8
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	8,9
	6b	Any changes to trial outcomes after the trial commenced, with reasons	-
Sample size	7a	How sample size was determined	-
	7b	When applicable, explanation of any interim analyses and stopping guidelines	
Randomisation:			6,7
Sequence generation	8a	Method used to generate the random allocation sequence	
	8b	Type of randomization; details of any restriction (such as blocking and block size)	6,7
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	-
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	5,6
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	-
	11b	If relevant, description of the similarity of interventions	-
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	10
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	-
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analyzed for the primary outcome	10
	13b	For each group, losses and exclusions after randomization, together with reasons	19
Recruitment	14a	Dates defining the periods of recruitment and follow-up	7,8
	14b	Why the trial ended or was stopped	-
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	20
Numbers analyzed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	19
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	10,11
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	-
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing prespecified from exploratory	-
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	-
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	14
Generalizability	21	Generalizability (external validity, applicability) of the trial findings	13,14
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	14
Other information			
Registration	23	Registration number and name of trial registry	5
Protocol	24	Where the full trial protocol can be accessed, if available	-
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	-

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomized trials, noninferiority and equivalence trials, nonpharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.