Critique author	Linda Metzger

Bibliographic Data	
Authors	Cerezo-Tellez E, Torres-Lacomba E, Fuentes-Gallardo I, and et al.
Title	Effectiveness of dry needling for chronic nonspecific neck pain: a randomized, single-blinded, clinical trial
PMID	27537209
Citation	PAIN 157(9) 2016 pp.1905–1917.
Other information if relevant	Trial Registration with ISRCTN Trial Registry, number ISRCTN22726482

Methods	
Aim of study	To compare the effectiveness of deep dry needling (DDN) of active myofascial trigger points (MTrPs) on pain and disability in people with chronic nonspecific neck pain attributed to myofascial pain syndrome (MPS) in their cervical muscles.
Design	Single-blinded parallel group randomized clinical trial

Participants	
Population from which participants are drawn	Subjects with a diagnosis of chronic nonspecific neck pain by their primary care doctor were recruited from 3 Primary Health Care Centers at Alcala´de Henares Health Area in Madrid, Spain during routine medical visits.
Setting (location and type of facility)	The study was conducted at a public Primary Health Care Center in Madrid, Spain.
Age	adults 18 years of age or over, mean age 50 years
Sex	Unclearly identified
Total number of participants for whom outcome data were reported	64 in each group = 128 total
Inclusion criteria	Over 18 years old, diagnosis of chronic nonspecific cervical pain > 6 months, presence of at least one active myofascial active trigger point in one of these muscles; multifidus, splenius cervicis, levator scapulae or trapezius muscles, and pain greater than 3 on the Visual Analogue Scale (VAS).
Exclusion criteria	Major trauma documented from the medical history, pregnancy, widespread pain, inflammatory, hormonal, and neurological disorders, tendinopathy in the upper extremities, severe psychiatric illness, unable to speak or write Spanish, use of certain medications within one week before the study, fibromyalgia syndrome, or had any contraindication to conservative or invasive physiotherapy (infection, fever, hypothyroidism, wounds in the area of the puncture, metal allergy, cancer or systemic disease, or fear of needles.
Other information if relevant	There were no significant differences between groups in participants' baseline sociodemographic, clinical characteristics, or outcome measure scores.

Intervention Groups

Group 1	
Group name	Deep dry needling (DDN) plus passive stretching group
Number in group	64
Description of intervention	Each group had a single physical therapist who performed the DDN and passive stretching, and they were the only study members aware of group allocation. The **DDN** consisted of dry needling every active MTrP found in the trapezius (all 3 divisions), cervical multifidi, splenius cervicis, and levator scapulae muscles, using a 40- X 0.32-mm acupuncture needle with a guided tube. The needle was inserted into the active MTrP, previously marked by the blinded physical therapist assessor, 4 to 5 local twitch responses were obtained by performing multiple rapid insertions of the needle, in and out of the MTrP, similar to the fast-in and fast-out technique. Then, the needle was withdrawn, compression was applied, and passive stretch was performed on the needled muscles. A **passive stretch** of splenius cervicis, cervical multifidi, levator scapulae, and all 3 divisions of the trapezius muscles was applied whenever they showed active MTrPs. During the stretch, the physical therapist took up the slack, avoiding pain elicitation, maintaining the tension for 4 seconds, and releasing the tension for 8 seconds; this cycle was repeated 3 times, completing a stretch of 36 seconds. This stretch was repeated 4 times.
Duration of treatment period	The treatment program (DDN or control) lasted 2 weeks and sessions were conducted twice a week (with 3 days between consecutive sessions), involving a total of 4 treatment sessions. A total of 4 DDN treatments and 4 sessions of passive stretching were conducted.
Co-interventions if reported	none
Additional information if relevant	No home stretching assignments were given.

Group 2	
Group name	Passive stretching group (control)
Number in group	64
Description of intervention	Both groups received the same passive stretching program. One physical therapist, different from the intervention group, performed the passive stretching for this group, and they were the only study members aware of group allocation. Every active MTrP found in the trapezius (all 3 divisions), cervical multifidi, splenius cervicis, and levator scapulae muscles was previously marked by the blinded physical therapist assessor. A **passive stretch** of splenius cervicis, cervical multifidi, levator scapulae, and all 3 divisions of the trapezius muscles was applied whenever they showed active MTrPs. During the stretch, the physical therapist took up the slack, avoiding pain elicitation, maintaining the tension for 4 seconds, and releasing the tension for 8 seconds; this cycle was repeated 3 times, completing a stretch of 36 seconds. This stretch was repeated 4 times.

Duration of treatment period	The treatment program (DDN or control) lasted 2 weeks and sessions were conducted twice a week (with 3 days between consecutive sessions), involving a total of 4 treatment sessions of passive stretching.
Co-interventions if reported	none
Additional information if relevant	No home stretching assignments were given.

Primary outcome	
Outcome name and criteria for definition	The primary outcome measure was current pain intensity measured using a 100-mm visual analogue scale (VAS). Higher scores reflect greater pain. A minimal detectable change of 15 mm is required and a change over 24 mm is considered to be clinically meaningful in subjects with nonspecific neck pain.
Time points measured and/or reported	At baseline, after 2 sessions of the treatment(one week), after completion of the intervention (3 weeks), and 15, 30, 90, and 180 days after the completion of treatment by a blinded physical therapist assessor.
Differences between groups	Both groups demonstrated statistically significant and clinically meaningful reductions in pain at the completion of the treatment and at the 6 month follow-up ($P<0.00001$). At the end of treatment, the DDN group reduced their VAS score from baseline by 4.81 points, and the stretching group reduced the VAS by 1.57 points. For between-group differences at treatment completion, the DDN group exhibited a statistically significant ($P < .00000$) and clinically greater reduction in pain of 3.24 points on the VAS than those receiving stretching alone. The beneficial effect of DDN was maintained throughout the 6-month follow-up. At the 6 months follow-up, the DDN group reduced their VAS score from baseline by 4.08 points, and the stretching group reduced the VAS by 1.60 points. For between-group differences at the 6-month follow-up, the DDN group again exhibited a statistically significant ($P < .00000$) and clinically greater reduction in pain of 2.48 points on the VAS than those receiving stretching alone. By one week after the end of treatment, both groups exceeded the MCID of 1.5 points. Even after just 2 treatments (one week), pain intensity decreased significantly in both groups. The DDN group reduced their VAS score from baseline by 3.73 points, and the stretching group reduced the VAS by 1.06 points. For between-group differences, the DDN group again exhibited a statistically significant ($P < .00000$) and clinically greater reduction in pain of 2.67 points on the VAS than those receiving stretching alone. This decrease of pain intensity in the DDN group was clinically meaningful.

Additional information if relevant	The mean number of treatments received was 3 in the DDN group and 3.6 in the control group. In the DDN group, 12 participants (19%) received 3 treatment sessions, 37 participants (58%) received 2 sessions, and 3 participants (5%) only 1 session indicating that these subjects (82%) reported complete relief of their symptoms and did not require the 4th scheduled session. Only 18% required 4 treatment sessions of DDN. In the control group, 15 participants (23%) reported complete relief of neck pain after 2 sessions, while the remaining 77% required all 4 sessions of treatment and did not reach complete recovery of their pain. No serious clinical adverse effects were reported. Soreness and local hemorrhages at the needling site occurred after DDN in some cases, but they resolved within one week. Two participants dropped out because they moved to another city.

Secondary outcomes	
Outcome name and criteria for definition	The secondary outcome measures were mechanical hyperalgesia, neck active range of motion, neck muscle strength, and perceived neck disability. The Pressure Pain Threshold was used to measure mechanical hyperalgesia of every active myofascial trigger point. Neck disability was measured with the Neck Disability Index (NDI) score. The NDI is a self-report instrument for the assessment of the condition-specific functional status of subjects with neck pain with 10 items including pain, personal care, lifting, reading, headaches, concentration, work, driving, sleeping, and recreation. The NDI has a maximum score of 50 points, lower scores indicate less disability, and a 10-point change is required for the result to be clinically meaningful.
Time points measured	At baseline, after 2 sessions of the treatment(one week), after completion of the intervention (3 weeks), and 15, 30, 90, and 180 days after the completion of treatment by a blinded physical therapist assessor.
Differences between groups	Both groups demonstrated statistically significant and clinically meaningful reductions in pain at the completion of the treatment and at the 6 month follow-up ($P<0.00001$). After just 2 treatments (one week), the DDN group reduced their NDI score from baseline by 10.5 points, and the stretching group reduced the NDI by 4.52 points. At the end of treatment (4 treatments), the DDN group reduced their NDI score from baseline by 17.3 points, and the stretching group reduced the NDI by 6.47 points. At the 6 months follow-up, the DDN group reduced their NDI score from baseline by 18.5 points, and the stretching group reduced the NDI by 8.43 points. For between-group differences, the DDN group exhibited a statistically significant and clinically greater reduction in the NDI of 5.98 points after 2 treatments ($P =0.04$), 11.9 points at treatment completion (4 treatments) ($P =0.0001$), and 10.1points at the 6 month follow-up ($P =0.0006$), than those receiving stretching alone.
Additional information if relevant	ITT analysis results were reported.

Conclusions	
Key Conclusions Of Study Authors	- Deep dry needling with passive stretching applied to participants with chronic nonspecific neck pain attributed to myofascial pain syndrome was associated with better and clinically meaningful results for pain, mechanical hyperalgesia, range of cervical motion, neck muscle strength, and neck disability when compared with passive stretching only (control group) in the short-term and at 6-month follow-up. - Significant and clinically relevant differences were found in favor of dry needling in all the outcomes (all $P < 0.001$) at both short and long follow-ups. Deep dry needling and passive stretching are more effective than passive stretching alone in people with nonspecific neck pain. The results support the use of DDN in the management of myofascial pain syndrome in people with chronic nonspecific neck pain. - This study shows that DDN is a safe form of treatment for chronic nonspecific neck pain and offers clear clinical advantages over passive stretching in the reduction of pain and improvement of mechanical hyperalgesia, active cervical ROM, and cervical muscle strength and function. Deep dry needling treatment improves the clinical signs and symptoms of patients with chronic nonspecific neck pain, achieving very meaningful clinical differences. - DDN can help to relieve chronic nonspecific neck pain. These results were maintained after a 6-month follow-up and would support the use of DDN in the management of chronic nonspecific neck pain attributed to myofascial pain syndrome.

Risk of bias assessment		
Domain	Risk of bias Low High Unclear	Comments
Random sequence generation *(selection bias)*	Low	Randomization was done using a computer-generated randomized table of numbers using the computer program EPIDAT.
Allocation concealment *(selection bias)*	Low	Equal numbers of participants were randomly allocated by the computer program EPIDAT version 3 to either DDN-plus passive stretching (DDN group) or only passive stretching (control group).
Blinding of participants and personnel *(performance bias)*	High	Each group had a single physical therapist who performed all interventions, and they were the only study members aware of group allocation. Participants were instructed to not reveal their group allocation.
Blinding of outcome assessment *(detection bias)*	Low	The physical therapist who performed the initial and all 6 follow-up assessments of all participants remained blinded to group allocation.
Incomplete outcome data *(attrition bias)*	Low	Loss to follow up was low and relatively equal between groups.

Selective outcome reporting? *(reporting bias)*	Low	The trial was registered with ISRCTN Trial Registry, number ISRCTN22726482.
Other bias		Intention to treat analysis was used.

Sponsorship if reported		
Study funding sources if reported	Funded by Carlos III National Health Care Institute (Spain) and Mapfre Foundation (Spain). The Physiotherapy in Women's Health Research Group of the Physical Therapy Department at Alcala´ University, Madrid provided the material required for the study and the Primary Healthcare Regency and Primary Healthcare Centre Juan de Austria provided the facilities to develop the study.	
Possible conflicts of interest for study authors	The authors have no conflicts of interest to declare.	
Notes:		

Comments by DOWC staff

- This study found that 4 sessions of trigger point deep dry needling with passive stretching over 2 weeks was significantly more effective in reducing neck pain and improving neck disability than passive stretching alone in the short-term and at 6-month follow-up in people with chronic nonspecific neck pain.

- Participants receiving DDN in addition to passive stretching exhibited clinically better outcomes in neck pain and related disability at all follow-up periods than those individuals who received the passive stretching alone. Between-group change scores surpassed the MCID of 15 points for pain and 5 points for disability in favor of the DDN group at all follow-up periods, supporting a clinically meaningful effect of this intervention.

- The findings of this study showed that there were significant reductions in pain intensity over the 6 month study period for both groups, but these reductions in pain were significantly larger in the DDN group then in the control group at all follow-ups.

- There exists no current scientific data on the adequate frequency of trigger point dry needling sessions and dose of therapy. This study adds some data to clarify the adequate frequency of DDN. Eighty-two percent of subjects in this study that received DDN reported complete relief of their symptoms with 3 or less treatments. Only 18% of study participants continued to have symptoms after 3 treatments and required 4 DDN treatment sessions.

- Because deep dry needling is applied to active trigger points, it is possible that subgroups of individuals with subacromial pain syndrome without active trigger points would not benefit from this intervention.

- The non-specific effects of patient expectations about DDN or other factors, such as treatment time, may have had an influence on the outcomes of the study. Treatment time was slightly different between groups as the subjects in the DDN group received an additional procedure and spent more time with the physical therapist than did the subjects in the control group. This may have had a placebo effect thus influencing outcomes.

Comments by DOWC staff

- This study included several methodological and DDN techniques that added to the robustness of the trial. 1) Since the size of the effect of DDN on myofascial trigger points increases with the number of local twitch responses obtained, it is important to elicit an adequate number of local twitch responses from each active myofascial trigger point. This study obtained 4 to 5 local twitch responses which should be clinically sufficient to achieve good results. 2) It is also important to provide a satisfactory number of DDN treatment sessions. This study provided 4 treatment sessions which is sufficient to obtain significant results in a chronic neck pain population. 3) It is essential to treat all the muscles involved in chronic nonspecific neck pain in order to obtain successful results. In this study, they treated as many active myofascial trigger points as could be found bilaterally in 4 relevant muscles. 4) To be sure that treatments and assessments were done in the same location in consecutive visits, proper marking of the active myofascial trigger points was done judiciously.

- Study strengths included an adequate sample size with adequate statistical power to detect clinically meaningful effects, trial registration, a pre-specified protocol, 6 follow-ups to monitor the effect of pain and DDN over a 6 month period, adequate number of DDN treatments, adequate description of the local twitch responses obtained and the DDN technique used, design features known to minimize bias such as investigator and assessor blinding, concealed allocation, an intention-to-treat analysis, and a mid-term follow-up with high rates of follow-up. This study also included essential information on the MCIDs of the outcome measures and included the clinical relevance of the results.

- The main limitations of this study were not clearly indicating the primary follow-up endpoint, not including a no-intervention control group to distinguish effects from the natural course of disease, the difficulty of controlling external interventions, such as physical therapy, self-medication of analgesics, anti-inflammatories, muscle relaxants, or other drugs.

- One major limitation of the study was that each group had a single unblinded physical therapist who administered the passive stretching of muscles, and the one physical therapist for the DDN group performed all the dry needling as well. Even though both received the same special training on passive stretching, if the stretching was administrated differently in the 2 groups, this could introduce performance bias. The direction of the bias is unknown, so you don't know if it undermines the conclusions of the study.

- Several inaccuracies/misprints in the article text raise concerns on whether the article was carefully edited and also calls to question the overall quality of the study. The article claims to be registered at ClinicalTrials.gov, but it is not. It is registered with ISRCTN Trial Registry. In the results for neck disability on page 1912, the mean decreased value after treatment in the control group at the A2 follow-up is incorrectly printed as -1.77. According to Table 7, the 1.77 is the standard error, and the correct mean is -6.47. In Table 2 under sex, mean or percent column, it is unclear if a number or percent is listed and if the number or percent refers to males or females. One cannot determine the number of males or females in this study. Lastly, on page 1908 under neck disability, the paragraph states that a 10-point change is required for the result to be clinically meaningful. The NDI Questionnaire states that at least a 5-point change is required to be clinically meaningful. I believe that the authors meant to say that a 10% change is required.

Assessment by DOWC staff	
Overall assessment as suitability of evidence for the guideline ☐ High quality ☒ Adequate ☐ Inadequate	This adequate quality study provides some evidence that 4 sessions of trigger point deep dry needling with passive stretching over 2 weeks was significantly more effective in reducing neck pain and improving neck disability than passive stretching alone in the short-term and at 6-month follow-up in people with chronic nonspecific neck pain.
If inadequate, main reasons for recommending that the article not be cited as evidence	

Additional references if relevant

- Vernon, H. and Mior, S. The Neck Disability Index: A study of reliability and validity. Journal of Manipulative and Physiological Therapeutics. 1991(14): 409-415.