EFFECTIVENESS OF DRY NEEDLING THERAPY ON PAIN, HIP MUSCLE STRENGTH AND PHYSICAL FUNCTION IN PATIENTS WITH HIP OSTEOARTHRITIS: A RANDOMIZED CONTROLLED TRIAL.

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This study design, protocol and consent forms were performed in accordance with the Helsinki Declaration of 1964 (revised in Fortaleza, 2013). The ethical approval for this study was obtained from the Clinical Research Ethics Committee of Aragón (PI17/0182/B) and it was registered in ClinicalTrials.gov, NCT04195464.

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ABSTRACT

Objective: To investigate the short-term effects of dry needling (DN) on physical function, pain and hip muscle strength in patients with hip osteoarthritis (OA).

Design: A double-blind, placebo-control, randomized clinical trial.

Setting: Private practice physiotherapy clinic.

Participants: Patients with unilateral hip OA (N=45) were randomly allocated to DN group, sham DN group or control group.

Interventions: Patients in the DN and sham groups received three treatment sessions. Three active Myofascial Trigger Points (MTrPs) were treated in each session with DN or sham needle procedure. The treatment was applied in active MTrPs of the iliopsoas, rectus femoris, tensor fasciae latae and gluteus minimus muscles.

Main Outcomes Measures: Physical function was assessed with the Western Ontario and McMaster Universities (WOMAC) physical function subscale, the Timed Up & Go test and the 40-m self-paced walk test. Intensity of hip pain related to physical function was evaluated using visual analogue scale and WOMAC pain subscale. The maximal isometric force of hip muscles was recorded with a handheld dynamometer.

Results: Significant group by time interactions were shown for physical function, pain and hip muscle force variables. Post hoc tests revealed a significant reduction in hip pain and significant improvements in physical function and hip muscle strength in DN group compared to sham and control groups. DN groups showed within and between groups large effect sizes (d >.8).

Conclusion: DN therapy in active MTrPs of the hip muscles reduced pain and improved hip muscle strength and physical function in patients with hip OA. DN in active MTrPs of the hip muscles should be considered for the management of hip OA.

KEYWORDS

Hip osteoarthritis; Trigger points; Physical function; Strength.

ABBREVIATIONS

ADL: Activities of Daily Living

ANOVA: One-way Analysis of Variance

BMI: Body Mass Index

CI: Confidence Interval

DN: Dry Needling

K-L: Kellgren & Lawrence

MCID: Minimal Clinically Important Difference

MTrP: Myofascial Trigger Point

OA: Osteoarthritis

SEM: Standard Error of Measurement

TUG: Timed Up & Go

VAS: Visual Analogue Scale

WOMAC: Western Ontario and McMaster Universities

WOMAC-P: Western Ontario and McMaster Universities physical pain subscale

WOMAC-PF: Western Ontario and McMaster Universities physical function subscale

SPW: 40-m Self-paced Walk

INTRODUCTION

Hip osteoarthritis (OA) is the second most common degenerative disease,[1] with a prevalence of 4.2% among people aged 50 years and older.[2,3]

Individuals with OA often experience pain, decreased range of motion, joint stiffness and muscle weakness resulting in disability to performance of activities of daily living (ADL).[4–6] Murphy et al[7] suggested that muscle weakness associated with hip OA could be related to pain inhibition, muscle disuse atrophy or aberrant joint mechanics. All these mechanisms could explain the reduction in physical function in patients with hip OA.

Previous studies have provided substantial evidence about the association between osteoarthritic symptoms and active myofascial trigger points (MTrPs).[8–11] An active MTrP is a hyperirritable tender nodule in a taut band of skeletal muscle that cause spontaneous pain, referred pain, limited joint range of motion and muscle weakness.[12] The force that a muscle can generate depends on the cross-sectional area and the level of muscle activation.[13] Gerwin[12] suggested that the muscle weakness related to MTrP appears to be a form of muscle inhibition and could be reversed as the MTrP is inactivated. Therefore, the treatment of active MTrPs could improve the muscle activation and reduce disability in patients with hip OA. However, there is no evidence about this phenomenon in the hip region.

Dry needling (DN) is a common procedure to eliminate or inactivate the MTrPs and consists of the insertion of a solid filiform needle into a MTrP.[14] Recent studies demonstrated that DN reduces joint pain, increase range of motion and improve physical function in patients with knee[15–17] and hip OA.[11,18] However, the mechanisms related to improvement of the physical function and the effects of DN in muscular strength are unknown.

Targeted research into the muscular changes associated with DN therapy is required to understand the role of the periarticular muscles in the management of hip OA. Thus, the aim of this study was to investigate the short-term effects of DN on physical function, pain and hip muscle strength in patients with hip OA.

METHODS

Study design

A double-blind, placebo-control, randomized clinical trial was conducted between December 2019 and May 2020. This study was registered at www.clinicaltrials.gov (NCT04195464) and was designed according to CONSORT guidelines. The study was approved by an institutional ethical committee (PI17/0182/B). All patients provided written informed consent.

Patients recruitment and selection

Patients were recruited from private practice physiotherapy clinics or referred by general practitioners and orthopedic surgeons. The inclusion criteria were: unilateral primary hip OA according to the American College of Rheumatology criteria,[19] a grade II or III Kellgren & Lawrence (K-L) classification, age between 50 and 70 years and at least one active MTrP in the hip muscles. Manual palpation was used for identifying active MTrPs. Manual palpation is the current gold standard,[20] and has shown moderate to excellent reliability in lower limb muscles.[21,22] Presence of MTrP was confirmed based on Travell and Simons' criteria[23]: 1) presence of a palpable taut band; 2) local pain upon pressure applied to the nodule of the taut band; 3) reproduction of the patients' pain by palpation. Exclusion criteria: neurological, vascular or other lower extremity musculoskeletal conditions that affected sensation, gait or functional performance, previous surgery in

lower limbs, previous physiotherapy treatment for hip OA in the last 3 months, MTrP therapy experience (to maintain blinding of patients) and DN contraindications.

Randomization and blinding

Patients were randomly allocated to one of the three groups: DN group, sham DN group and control group. An external assistant, not involved in the study, used a random-number generator (Research Randomizer. Version 4.0) for randomization. The examiners and the patients of DN and sham DN groups were blinded to the assigned group.

Interventions

Interventions were carried out by a blinded physiotherapist with more than 5 years of clinical experience in DN therapy.

Patients in the DN group received three sessions of DN (one session per week) into active MTrPs in the hip muscles. Iliopsoas, rectus femoris, tensor fasciae latae and gluteus minimus muscles were examined for the presence of active MTrPs and three active MTrPs were treated at most in each session, according to the protocol described by Ceballos-Laita et al.[19].

Patients were in supine to treat iliopsoas and rectus femoris muscles or in contralateral side lying for tensor fasciae latae and gluteus minimus muscles. The MTrP taut band was held between the physiotherapist's index and middle fingers, while a 0.25 x 50 mm needle was inserted performing the fast-in fast-out technique.[24] This technique consists of rapid multiple introductions of the needle into the MTrP. When the needle stimulates mechanically the MTrP, a brisk contraction of the taut band called local twitch response, can be elicited. The needle was repeatedly inserted until the local twitch responses

125 became extinct. After the needle was removed, the injected area was compressed firmly
126 to achieve hemostasis.

127 Patients in the sham DN group received three sessions of a sham needle procedure (one
128 session per week). Three active MTrPs were treated at most in each session with the sham
129 needle procedure. A blunted needle with insertion tube was used. The needle was placed
130 on the MTrP area and was pressed up and down against the skin without penetrating.[25]
131 Non-penetrating techniques have shown to be valid and enable the patient to be blinded
132 to group allocation.[26] Patients assigned to the control group did not receive any treatment,
133 education or advice during the study.
134 All patients were asked to continue with the same daily routines and not to take any
135 analgesic, anti-inflammatory or muscle relaxant drugs medications 24h prior the testing.
136

137 **Outcomes and measurement instruments**
138 Outcome measures were assessed by two blinded examiners at baseline and 48 hours after
139 the end of the intervention to avoid postneedling soreness.[27] Sociodemographic and
140 clinical data were obtained prior to testing. The primary outcome was physical function
141 and the secondary outcomes were pain and hip muscle strength.
142 **Physical function**
143 Physical function was assessed with the self-administered Western Ontario and
144 McMaster Universities physical function subscale (WOMAC-PF), the Timed Up & Go
145 test (TUG) and the 40-m self-paced walk test (40-m SPW).
146 WOMAC-PF has shown excellent psychometric properties to measure activity limitation
147 in patients with OA (Intraclass Correlation Coefficient $(ICC)_{1,k}$ = .81).[28] Answers are
148 provided on a five-point scale ranging from 0 (no difficulty at all) to 4 (very much
149 difficulty).

The TUG test measures the time, in seconds, required to stand up from a standard arm chair, walk 3 meters, turn, walk back to the chair, and sit down again quickly and safely. The 40-m SPW test measures the time, in seconds, required to walk as far as possible 2 lengths of a 20-m indoor course. Both test present excellent psychometric properties (TUG: $ICC_{2,1}$ = .75, 95%CI= 0.51 – 0.98,[29] 40-mSPW: $ICC_{2,1}$ = .91 95% CI= 0.81- 0.97).[30]

Pain

Hip pain intensity after the physical functions tests was assessed using a horizontal 10 cm visual analogue scale (VAS). The reliability of VAS in patients with OA is excellent ($ICC_{1,k}$ = .97, 95% CI= 0.96 – 0.98).[31] Severity of pain during the last 24 h was questioned for the self-administered WOMAC pain subscale (WOMAC-P). WOMAC-P consists of five items and all items are scored on a five-point scale (0–4). The reliability of WOMAC-P in patients with OA is excellent ($ICC_{1,k}$ = .93).[32]

Hip muscle strength

Muscle strength was assessed with Lafayette handheld dynamometer according to the procedure described by Pua et al.[33] This procedure has shown an excellent reliability in patients with hip OA ($ICC_{2,2}$ ranged from .84 to .97).[33] The maximal isometric force of hip muscles was recorded in newtons and then was multiplied by to the lever arm length measured from the joint axis of rotation to the point of force application (torque values). For the hip flexors, the lever-arm length was measured from the greater trochanter to 5 cm proximal to the superior pole of the patella; for the hip abductors from the greater trochanter to 5 cm proximal to the lateral femoral condyle; for the hip extensors, from the most prominent aspect of the greater trochanter to 5 cm proximal to the lateral malleolus and for the hip rotators, from the lateral femoral condyle to 5 cm proximal to the lateral malleolus. All participants performed two trials for 3 to 5 seconds with a 1-minute rest

interval. The maximum isometric force of each trial was recorded and the mean of the 2 valid trials was taken.

Sample size

The sample size was calculated using Minitab® 13.0 program. The sample size was determined by 40-m SPWT test. Considering a standard deviation of 3.10 based on pilot data, a mean difference between groups of 4.04 seconds considered as the minimal clinically important difference (MCID),[34] $\propto$ = 0.05 and power = 80%, the sample size was estimated to be 13 patients. Expecting at least 15% of dropouts, 15 patients per group were included.

Statistical analysis

Statistical analyses were performed using SPSS version 22. A p value < 0.05 was considered statistically significant.

Descriptive statistics were calculated to describe the sample. Normal distribution of the variables was analysed using the Shapiro-Wilk test. Baseline demographic and clinical variables were compared between groups using a one-way analysis of variance (ANOVA) or Kruskal-Wallis analysis for continuous data according to the normally distributed data or non-normally distributed data respectively, and Chi-square test (χ^2 test) or Fischer exact test for categorical data.

Differences in physical function, pain and hip muscle strength between the three groups were tested with repeated measurements ANOVA with 2 factors (group and time interaction). When a significant interaction was identified, the Bonferroni test was used for multiple comparisons.

198 The effect size was calculated with Cohen coefficients that were interpreted as follows:
199 large effect sizes, d > 0.8; moderate effect sizes, d=0.5–0.79; and small effect sizes,
200 d=0.2–0.49.[35]

201 **RESULTS**

202 Forty-five patients aged between 50 and 67 years were recruited and randomly assigned
203 to one of the three groups (Figure 1). There were no significant differences in
204 demographic and clinical data between groups at baseline (Table 1).

205 All 45 participants (100%) presented an active MTrP in iliopsoas muscle. Forty-four
206 participants (97.7%) presented an active MTrP in rectus femoris and 43 participants
207 (95.5%) in tensor fasciae latae muscle. An active MTrP in the anteroinferior part of
208 gluteus minimus was presented in 22 participants (48.8%). The main muscles treated in
209 DN and sham DN groups were iliopsoas, rectus femoris, tensor fasciae latae, and gluteus
210 minimus without statistical differences between them ($\chi^2 = 1.44$, $P = .628$).

211 Table 2 provides before and after treatment session data, within-group differences,
212 interactions effects, post-hoc analysis as well as the effect sizes for all pain and physical
213 function variables. Two-way ANOVA showed significant group by time interactions for
214 the intensity of pain after physical function tests ($F_{2,42} = 3.879$, $P = .028$), WOMAC-P
215 ($F_{2,42} = 0.361$, $P < .001$), WOMAC-PF ($F_{2,42} = 42$, $P < .001$), TUG test ($F_{2,42} = 22.427$, P
216 $< .001$) and 40-m SPW test ($F_{2,42} = 29.808$, $P < .001$). The adjusted Bonferroni
217 comparisons indicated significant between-group differences. DN group showed
218 significant differences in the intensity of pain (95% CI: 0.77, 3.04, $P = .039$), WOMAC-
219 P (95% CI: 0.61, 4.33, $P = .034$), WOMAC-PF (95% CI: 7.15, 15.36, $P < .001$), TUG
220 test (95% CI: 0.91, 3.72, $P = .003$) and 40-m SPW test (95% CI: 2.20, 8.53, $P = .005$)
221 compared to DN sham group.

Bonferroni test also showed significant differences in the intensity of pain (95% CI: 1.02, 2.63, $P = .049$), WOMAC-P (95% CI: 1.12, 4.61, $P = .034$), WOMAC-PF (95% CI: 7.00, 19.11, $P < .001$), TUG test (95% CI: 0.9, 3.31, $P = .008$) and 40-m SPW test (95% CI: 2.00, 8.68, $P = .005$) between DN and control groups. DN treatment showed large effect sizes in all pain and physical function variables ($d > 0.8$). Sham DN group and control group did not show any significant differences from baseline data.

Table 3 shows a generalized increase in the strength of the hip muscles was shown in DN group. A significant group by time interaction was detected for hip flexor ($F_{2,42} = 29.917$, $P = .001$), extensor ($F_{2,42} = 10.213$, $P = .001$), abductor ($F_{2,42} = 13.015$, $P < .001$), internal rotators ($F_{2,42} = 40.751$, $P < .001$) and external rotators ($F_{2,42} = 13.283$, $P < .001$) muscles. Post-hoc comparations showed significant differences in hip muscles force ($P < .05$) after treatment in DN group compared to DN sham and control groups. Effect sizes for hip muscle force variables were large in DN group ($d > 0.8$). Hip flexors force decreased significantly in DN sham ($P = .005$) and control ($P = .043$) groups. No changes were found for the rest of variables.

DISCUSSION

Our results reveal that DN was an effective treatment to reduce pain and improve hip muscle strength and physical function in patients with hip OA, with large effect sizes. The sham DN and the control groups showed a decrease in the strength of hip flexor muscles without changes in pain and physical function.

Previous research had demonstrated that DN reduced pain and improved physical function in patients with hip OA,[11] however, in the present study the intensity of pain was assessed during physical function tests and ADL, and physical function was evaluated with self-reported and performance-based measurements. The patients of the DN group experienced a significant reduction in pain related to functional performance compared

247 to the sham and the control groups. The difference between groups for the change in the
248 intensity of pain exceeded the MCID for VAS,[36] and the standard error of measurement
249 (SEM) for WOMAC-P,[37] but not the MCID. The patients of DN group also showed
250 significant improvements in TUG and 40-m SPW tests with between groups differences
251 higher than the MCID.[38] The DN group differed significantly from both sham and control
252 groups in WOMAC-PF, exceeding the MCID.[39] Therefore, after DN therapy, patients
253 with hip OA not only showed a better objective physical function but also a better self-
254 reported physical function.
255 Recent studies suggested no effect of DN on force production.[17,40] However, in our study
256 the patients of the DN group demonstrated a significant increase of hip muscle strength
257 compared to the sham and control groups, showing large effect sizes. The difference
258 between groups exceeded the SEM for hip flexors, extensors and abductors and the MCID
259 for hip internal and external rotators muscles.[33] To our knowledge, this is the first study
260 that analyze the effects of DN on muscle strength in patients with hip OA. Despite
261 strength being assessed under isometric conditions, the improvement in hip muscle
262 strength could contributed to the changes showed in muscle function during dynamic
263 conditions including ADL. Previous studies suggested that the improvements in physical
264 function could be related to the reduction in pain,[11,41,42] however, according to the results
265 of the present study the changes in muscle strength should be taken into consideration.
266 An integrated hypothesis based on mechanical and neurophysiological mechanisms have
267 been proposed to explain DN effects.[14] DN appears to be able to reduce the amplitude
268 and the frequency of the endplate noise of the MTrP area, the acetylcholine levels and the
269 neuromuscular junction response.[43,44] Besides, DN appears to reduce both peripheral and
270 central sensitization.[14] The insertion of the needle enhances the secretion of endogenous
271 opioid and provokes an increase in β-endorphin. Opioids are anti-inflammatory and

produce an immediate drop in the concentration of pro-inflammatory cytokines and interleukins, neurotransmitters and neuromodulators such as substance P within the extracellular fluid of the MTrP producing a strong analgesic effect.[45,46] The reduction of peripheral nociception would decrease substance P level and neuron activity in the dorsal horn of the spinal cord.[47] Louw et al[48] suggested that DN may activate enkephalinergic inhibitory dorsal horn interneurons that would explain supraspinal mechanisms underlying its effects.

The patients in sham and control groups decreased the strength in hip flexors muscles, but in both groups no changes in pain and physical function were observed. Longitudinal cohort studies showed that muscle strength decreased in patients with mild to moderate hip OA after 1 to 5 years of follow-up. [49,50] However, in our study the muscular changes were observed in 3-weeks. These changes in hip flexor muscles strength may be related to other factors that were not measured in this study, such as psychological distress, motivation and apprehension that have shown to negatively affect to strength test performance.[51,52] Although future studies are required to understand factors that influence disease progression across all affected tissues, there is evidence that suggests that hip flexor and extensor muscle weakness could alter mechanical function of the joint, and have important implications for disease progression.[6]

The results of the current study show the positive short-term effects of DN on pain, hip muscle strength and physical function in patients with hip OA. These outcomes could lead the implementation of other therapies after DN intervention. Clinical practice guidelines recommend exercise as part of the management of hip OA.[5,53] Therefore, DN could be a promising approach prior to physical exercise and may allow the patients to perform exercises with less pain and greater isometric strength.

Study limitations

Several limitations exist in the present study. First, subjective manual palpation was used for MTrPs diagnosis. Imaging tools such as ultrasonography and ultrasound elastography could have been used.[54,55] Second, motivational factors, psychological distress, pain, or fear of pain during muscle strength measurement could have had an effect on the results of the hip muscle strength. Third, short-term effects have been evaluated and only one therapy was applied. Clinical guidelines recommend a multimodal physical therapy intervention as part of the management of patients with mild to moderate hip OA.[56,57] Further clinical trials should include multimodal therapeutic approaches in a long-term treatment.

CONCLUSIONS

DN therapy in active MTrPs of the hip muscles reduced pain and improved hip muscle strength and physical function in patients with hip OA. According to this, DN of hip periarticular muscles should be considered as part of a multimodal strategy for management of hip OA.

Conflicts of Interest: The authors declare no conflict of interest.

FIGURE LEGEND

Figure 1. Participants' distribution between groups. Flowchart diagram.

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EFFECTIVENESS OF DRY NEEDLING THERAPY ON PAIN, HIP MUSCLE STRENGTH AND PHYSICAL FUNCTION IN PATIENTS WITH HIP OSTEOARTHRITIS: A RANDOMIZED CONTROLLED TRIAL.

ABSTRACT

Objective: To investigate the short-term effects of dry needling (DN) on physical function, pain and hip muscle strength in patients with hip osteoarthritis (OA).

Design: A double-blind, placebo-control, randomized clinical trial.

Setting: Private practice physiotherapy clinic.

Participants: Patients with unilateral hip OA (N=45) were randomly allocated to DN group, sham DN group or control group.

Interventions: Patients in the DN and sham groups received three treatment sessions. Three active Myofascial Trigger Points (MTrPs) were treated in each session with DN or sham needle procedure. The treatment was applied in active MTrPs of the iliopsoas, rectus femoris, tensor fasciae latae and gluteus minimus muscles.

Main Outcomes Measures: Physical function was assessed with the Western Ontario and McMaster Universities (WOMAC) physical function subscale, the Timed Up & Go test and the 40-m self-paced walk test. Intensity of hip pain related to physical function was evaluated using visual analogue scale and WOMAC pain subscale. The maximal isometric force of hip muscles was recorded with a handheld dynamometer.

Results: Significant group by time interactions were shown for physical function, pain and hip muscle force variables. Post hoc tests revealed a significant reduction in hip pain and significant improvements in physical function and hip muscle strength in DN group compared to sham and control groups. DN groups showed within and between groups large effect sizes (d >.8).

Conclusion: DN therapy in active MTrPs of the hip muscles reduced pain and improved hip muscle strength and physical function in patients with hip OA. DN in active MTrPs of the hip muscles should be considered for the management of hip OA.

KEYWORDS

Hip osteoarthritis; Trigger points; Physical function; Strength.

ABBREVIATIONS

ADL: Activities of Daily Living

ANOVA: One-way Analysis of Variance

BMI: Body Mass Index

CI: Confidence Interval

DN: Dry Needling

K-L: Kellgren & Lawrence

MCID: Minimal Clinically Important Difference

MTrP: Myofascial Trigger Point

OA: Osteoarthritis

SEM: Standard Error of Measurement

TUG: Timed Up & Go

VAS: Visual Analogue Scale

WOMAC: Western Ontario and McMaster Universities

WOMAC-P: Western Ontario and McMaster Universities physical pain subscale

WOMAC-PF: Western Ontario and McMaster Universities physical function subscale

SPW: 40-m Self-paced Walk

INTRODUCTION

Hip osteoarthritis (OA) is the second most common degenerative disease,[1] with a prevalence of 4.2% among people aged 50 years and older.[2,3]

Individuals with OA often experience pain, decreased range of motion, joint stiffness and muscle weakness resulting in disability to performance of activities of daily living (ADL).[4–6] Murphy et al[7] suggested that muscle weakness associated with hip OA could be related to pain inhibition, muscle disuse atrophy or aberrant joint mechanics. All these mechanisms could explain the reduction in physical function in patients with hip OA.

Previous studies have provided substantial evidence about the association between osteoarthritic symptoms and active myofascial trigger points (MTrPs).[8–11] An active MTrP is a hyperirritable tender nodule in a taut band of skeletal muscle that cause spontaneous pain, referred pain, limited joint range of motion and muscle weakness.[12] The force that a muscle can generate depends on the cross-sectional area and the level of muscle activation.[13] Gerwin[12] suggested that the muscle weakness related to MTrP appears to be a form of muscle inhibition and could be reversed as the MTrP is inactivated. Therefore, the treatment of active MTrPs could improve the muscle activation and reduce disability in patients with hip OA. However, there is no evidence about this phenomenon in the hip region.

Dry needling (DN) is a common procedure to eliminate or inactivate the MTrPs and consists of the insertion of a solid filiform needle into a MTrP.[14] Recent studies demonstrated that DN reduces joint pain, increase range of motion and improve physical function in patients with knee[15–17] and hip OA.[11,18] However, the mechanisms related to improvement of the physical function and the effects of DN in muscular strength are unknown.

Targeted research into the muscular changes associated with DN therapy is required to understand the role of the periarticular muscles in the management of hip OA. Thus, the aim of this study was to investigate the short-term effects of DN on physical function, pain and hip muscle strength in patients with hip OA.

METHODS

Study design

A double-blind, placebo-control, randomized clinical trial was conducted between December 2019 and May 2020. This study was registered at www.clinicaltrials.gov (NCT04195464) and was designed according to CONSORT guidelines. The study was approved by an institutional ethical committee (PI17/0182/B). All patients provided written informed consent.

Patients recruitment and selection

Patients were recruited from private practice physiotherapy clinics or referred by general practitioners and orthopedic surgeons. The inclusion criteria were: unilateral primary hip OA according to the American College of Rheumatology criteria,[19] a grade II or III Kellgren & Lawrence (K-L) classification, age between 50 and 70 years and at least one active MTrP in the hip muscles. Manual palpation was used for identifying active MTrPs. Manual palpation is the current gold standard,[20] and has shown moderate to excellent reliability in lower limb muscles.[21,22] Presence of MTrP was confirmed based on Travell and Simons' criteria[23]: 1) presence of a palpable taut band; 2) local pain upon pressure applied to the nodule of the taut band; 3) reproduction of the patients' pain by palpation. Exclusion criteria: neurological, vascular or other lower extremity musculoskeletal conditions that affected sensation, gait or functional performance, previous surgery in

lower limbs, previous physiotherapy treatment for hip OA in the last 3 months, MTrP therapy experience (to maintain blinding of patients) and DN contraindications.

Randomization and blinding

Patients were randomly allocated to one of the three groups: DN group, sham DN group and control group. An external assistant, not involved in the study, used a random-number generator (Research Randomizer. Version 4.0) for randomization. The examiners and the patients of DN and sham DN groups were blinded to the assigned group.

Interventions

Interventions were carried out by a blinded physiotherapist with more than 5 years of clinical experience in DN therapy.

Patients in the DN group received three sessions of DN (one session per week) into active MTrPs in the hip muscles. Iliopsoas, rectus femoris, tensor fasciae latae and gluteus minimus muscles were examined for the presence of active MTrPs and three active MTrPs were treated at most in each session, according to the protocol described by Ceballos-Laita et al.[19].

Patients were in supine to treat iliopsoas and rectus femoris muscles or in contralateral side lying for tensor fasciae latae and gluteus minimus muscles. The MTrP taut band was held between the physiotherapist's index and middle fingers, while a 0.25 x 50 mm needle was inserted performing the fast-in fast-out technique.[24] This technique consists of rapid multiple introductions of the needle into the MTrP. When the needle stimulates mechanically the MTrP, a brisk contraction of the taut band called local twitch response, can be elicited. The needle was repeatedly inserted until the local twitch responses

125 became extinct. After the needle was removed, the injected area was compressed firmly
126 to achieve hemostasis.

127 Patients in the sham DN group received three sessions of a sham needle procedure (one
128 session per week). Three active MTrPs were treated at most in each session with the sham
129 needle procedure. A blunted needle with insertion tube was used. The needle was placed
130 on the MTrP area and was pressed up and down against the skin without penetrating.[25]
131 Non-penetrating techniques have shown to be valid and enable the patient to be blinded
132 to group allocation.[26] Patients assigned to the control group did not receive any treatment,
133 education or advice during the study.
134 All patients were asked to continue with the same daily routines and not to take any
135 analgesic, anti-inflammatory or muscle relaxant drugs medications 24h prior the testing.
136

137 **Outcomes and measurement instruments**
138 Outcome measures were assessed by two blinded examiners at baseline and 48 hours after
139 the end of the intervention to avoid postneedling soreness.[27] Sociodemographic and
140 clinical data were obtained prior to testing. The primary outcome was physical function
141 and the secondary outcomes were pain and hip muscle strength.
142 **Physical function**
143 Physical function was assessed with the self-administered Western Ontario and
144 McMaster Universities physical function subscale (WOMAC-PF), the Timed Up & Go
145 test (TUG) and the 40-m self-paced walk test (40-m SPW).
146 WOMAC-PF has shown excellent psychometric properties to measure activity limitation
147 in patients with OA (Intraclass Correlation Coefficient $(ICC)_{1,k}$ = .81).[28] Answers are
148 provided on a five-point scale ranging from 0 (no difficulty at all) to 4 (very much
149 difficulty).

The TUG test measures the time, in seconds, required to stand up from a standard arm chair, walk 3 meters, turn, walk back to the chair, and sit down again quickly and safely. The 40-m SPW test measures the time, in seconds, required to walk as far as possible 2 lengths of a 20-m indoor course. Both test present excellent psychometric properties (TUG: $ICC_{2,1}$ = .75, 95%CI= 0.51 – 0.98,[29] 40-mSPW: $ICC_{2,1}$ = .91 95% CI= 0.81- 0.97).[30]

Pain

Hip pain intensity after the physical functions tests was assessed using a horizontal 10 cm visual analogue scale (VAS). The reliability of VAS in patients with OA is excellent ($ICC_{1,k}$ = .97, 95% CI= 0.96 – 0.98).[31] Severity of pain during the last 24 h was questioned for the self-administered WOMAC pain subscale (WOMAC-P). WOMAC-P consists of five items and all items are scored on a five-point scale (0–4). The reliability of WOMAC-P in patients with OA is excellent ($ICC_{1,k}$ = .93).[32]

Hip muscle strength

Muscle strength was assessed with Lafayette handheld dynamometer according to the procedure described by Pua et al.[33] This procedure has shown an excellent reliability in patients with hip OA ($ICC_{2,2}$ ranged from .84 to .97).[33] The maximal isometric force of hip muscles was recorded in newtons and then was multiplied by to the lever arm length measured from the joint axis of rotation to the point of force application (torque values). For the hip flexors, the lever-arm length was measured from the greater trochanter to 5 cm proximal to the superior pole of the patella; for the hip abductors from the greater trochanter to 5 cm proximal to the lateral femoral condyle; for the hip extensors, from the most prominent aspect of the greater trochanter to 5 cm proximal to the lateral malleolus and for the hip rotators, from the lateral femoral condyle to 5 cm proximal to the lateral malleolus. All participants performed two trials for 3 to 5 seconds with a 1-minute rest

interval. The maximum isometric force of each trial was recorded and the mean of the 2 valid trials was taken.

Sample size

The sample size was calculated using Minitab® 13.0 program. The sample size was determined by 40-m SPWT test. Considering a standard deviation of 3.10 based on pilot data, a mean difference between groups of 4.04 seconds considered as the minimal clinically important difference (MCID),[34] $\propto$ = 0.05 and power = 80%, the sample size was estimated to be 13 patients. Expecting at least 15% of dropouts, 15 patients per group were included.

Statistical analysis

Statistical analyses were performed using SPSS version 22. A p value < 0.05 was considered statistically significant.

Descriptive statistics were calculated to describe the sample. Normal distribution of the variables was analysed using the Shapiro-Wilk test. Baseline demographic and clinical variables were compared between groups using a one-way analysis of variance (ANOVA) or Kruskal-Wallis analysis for continuous data according to the normally distributed data or non-normally distributed data respectively, and Chi-square test (χ^2 test) or Fischer exact test for categorical data.

Differences in physical function, pain and hip muscle strength between the three groups were tested with repeated measurements ANOVA with 2 factors (group and time interaction). When a significant interaction was identified, the Bonferroni test was used for multiple comparisons.

198 The effect size was calculated with Cohen coefficients that were interpreted as follows:
199 large effect sizes, d > 0.8; moderate effect sizes, d=0.5–0.79; and small effect sizes,
200 d=0.2–0.49.[35]

201 **RESULTS**

202 Forty-five patients aged between 50 and 67 years were recruited and randomly assigned
203 to one of the three groups (Figure 1). There were no significant differences in
204 demographic and clinical data between groups at baseline (Table 1).

205 All 45 participants (100%) presented an active MTrP in iliopsoas muscle. Forty-four
206 participants (97.7%) presented an active MTrP in rectus femoris and 43 participants
207 (95.5%) in tensor fasciae latae muscle. An active MTrP in the anteroinferior part of
208 gluteus minimus was presented in 22 participants (48.8%). The main muscles treated in
209 DN and sham DN groups were iliopsoas, rectus femoris, tensor fasciae latae, and gluteus
210 minimus without statistical differences between them ($\chi^2 = 1.44$, $P = .628$).

211 Table 2 provides before and after treatment session data, within-group differences,
212 interactions effects, post-hoc analysis as well as the effect sizes for all pain and physical
213 function variables. Two-way ANOVA showed significant group by time interactions for
214 the intensity of pain after physical function tests ($F_{2,42} = 3.879$, $P = .028$), WOMAC-P
215 ($F_{2,42} = 0.361$, $P < .001$), WOMAC-PF ($F_{2,42} = 42$, $P < .001$), TUG test ($F_{2,42} = 22.427$, P
216 $< .001$) and 40-m SPW test ($F_{2,42} = 29.808$, $P < .001$). The adjusted Bonferroni
217 comparisons indicated significant between-group differences. DN group showed
218 significant differences in the intensity of pain (95% CI: 0.77, 3.04, $P = .039$), WOMAC-
219 P (95% CI: 0.61, 4.33, $P = .034$), WOMAC-PF (95% CI: 7.15, 15.36, $P < .001$), TUG
220 test (95% CI: 0.91, 3.72, $P = .003$) and 40-m SPW test (95% CI: 2.20, 8.53, $P = .005$)
221 compared to DN sham group.

Bonferroni test also showed significant differences in the intensity of pain (95% CI: 1.02, 2.63, $P = .049$), WOMAC-P (95% CI: 1.12, 4.61, $P = .034$), WOMAC-PF (95% CI: 7.00, 19.11, $P < .001$), TUG test (95% CI: 0.9, 3.31, $P = .008$) and 40-m SPW test (95% CI: 2.00, 8.68, $P = .005$) between DN and control groups. DN treatment showed large effect sizes in all pain and physical function variables ($d > 0.8$). Sham DN group and control group did not show any significant differences from baseline data.

Table 3 shows a generalized increase in the strength of the hip muscles was shown in DN group. A significant group by time interaction was detected for hip flexor ($F_{2,42} = 29.917$, $P = .001$), extensor ($F_{2,42} = 10.213$, $P = .001$), abductor ($F_{2,42} = 13.015$, $P < .001$), internal rotators ($F_{2,42} = 40.751$, $P < .001$) and external rotators ($F_{2,42} = 13.283$, $P < .001$) muscles. Post-hoc comparations showed significant differences in hip muscles force ($P < .05$) after treatment in DN group compared to DN sham and control groups. Effect sizes for hip muscle force variables were large in DN group ($d > 0.8$). Hip flexors force decreased significantly in DN sham ($P = .005$) and control ($P = .043$) groups. No changes were found for the rest of variables.

DISCUSSION

Our results reveal that DN was an effective treatment to reduce pain and improve hip muscle strength and physical function in patients with hip OA, with large effect sizes. The sham DN and the control groups showed a decrease in the strength of hip flexor muscles without changes in pain and physical function.

Previous research had demonstrated that DN reduced pain and improved physical function in patients with hip OA,[11] however, in the present study the intensity of pain was assessed during physical function tests and ADL, and physical function was evaluated with self-reported and performance-based measurements. The patients of the DN group experienced a significant reduction in pain related to functional performance compared

247 to the sham and the control groups. The difference between groups for the change in the
248 intensity of pain exceeded the MCID for VAS,[36] and the standard error of measurement
249 (SEM) for WOMAC-P,[37] but not the MCID. The patients of DN group also showed
250 significant improvements in TUG and 40-m SPW tests with between groups differences
251 higher than the MCID.[38] The DN group differed significantly from both sham and control
252 groups in WOMAC-PF, exceeding the MCID.[39] Therefore, after DN therapy, patients
253 with hip OA not only showed a better objective physical function but also a better self-
254 reported physical function.
255 Recent studies suggested no effect of DN on force production.[17,40] However, in our study
256 the patients of the DN group demonstrated a significant increase of hip muscle strength
257 compared to the sham and control groups, showing large effect sizes. The difference
258 between groups exceeded the SEM for hip flexors, extensors and abductors and the MCID
259 for hip internal and external rotators muscles.[33] To our knowledge, this is the first study
260 that analyze the effects of DN on muscle strength in patients with hip OA. Despite
261 strength being assessed under isometric conditions, the improvement in hip muscle
262 strength could contributed to the changes showed in muscle function during dynamic
263 conditions including ADL. Previous studies suggested that the improvements in physical
264 function could be related to the reduction in pain,[11,41,42] however, according to the results
265 of the present study the changes in muscle strength should be taken into consideration.
266 An integrated hypothesis based on mechanical and neurophysiological mechanisms have
267 been proposed to explain DN effects.[14] DN appears to be able to reduce the amplitude
268 and the frequency of the endplate noise of the MTrP area, the acetylcholine levels and the
269 neuromuscular junction response.[43,44] Besides, DN appears to reduce both peripheral and
270 central sensitization.[14] The insertion of the needle enhances the secretion of endogenous
271 opioid and provokes an increase in β-endorphin. Opioids are anti-inflammatory and

produce an immediate drop in the concentration of pro-inflammatory cytokines and interleukins, neurotransmitters and neuromodulators such as substance P within the extracellular fluid of the MTrP producing a strong analgesic effect.[45,46] The reduction of peripheral nociception would decrease substance P level and neuron activity in the dorsal horn of the spinal cord.[47] Louw et al[48] suggested that DN may activate enkephalinergic inhibitory dorsal horn interneurons that would explain supraspinal mechanisms underlying its effects.

The patients in sham and control groups decreased the strength in hip flexors muscles, but in both groups no changes in pain and physical function were observed. Longitudinal cohort studies showed that muscle strength decreased in patients with mild to moderate hip OA after 1 to 5 years of follow-up. [49,50] However, in our study the muscular changes were observed in 3-weeks. These changes in hip flexor muscles strength may be related to other factors that were not measured in this study, such as psychological distress, motivation and apprehension that have shown to negatively affect to strength test performance.[51,52] Although future studies are required to understand factors that influence disease progression across all affected tissues, there is evidence that suggests that hip flexor and extensor muscle weakness could alter mechanical function of the joint, and have important implications for disease progression.[6]

The results of the current study show the positive short-term effects of DN on pain, hip muscle strength and physical function in patients with hip OA. These outcomes could lead the implementation of other therapies after DN intervention. Clinical practice guidelines recommend exercise as part of the management of hip OA.[5,53] Therefore, DN could be a promising approach prior to physical exercise and may allow the patients to perform exercises with less pain and greater isometric strength.

Study limitations

Several limitations exist in the present study. First, subjective manual palpation was used for MTrPs diagnosis. Imaging tools such as ultrasonography and ultrasound elastography could have been used.[54,55] Second, motivational factors, psychological distress, pain, or fear of pain during muscle strength measurement could have had an effect on the results of the hip muscle strength. Third, short-term effects have been evaluated and only one therapy was applied. Clinical guidelines recommend a multimodal physical therapy intervention as part of the management of patients with mild to moderate hip OA.[56,57] Further clinical trials should include multimodal therapeutic approaches in a long-term treatment.

CONCLUSIONS

DN therapy in active MTrPs of the hip muscles reduced pain and improved hip muscle strength and physical function in patients with hip OA. According to this, DN of hip periarticular muscles should be considered as part of a multimodal strategy for management of hip OA.

Conflicts of Interest: The authors declare no conflict of interest.

FIGURE LEGEND

Figure 1. Participants' distribution between groups. Flowchart diagram.

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Figure 1

Figure 1. Participants' distribution between groups. Flowchart diagram.

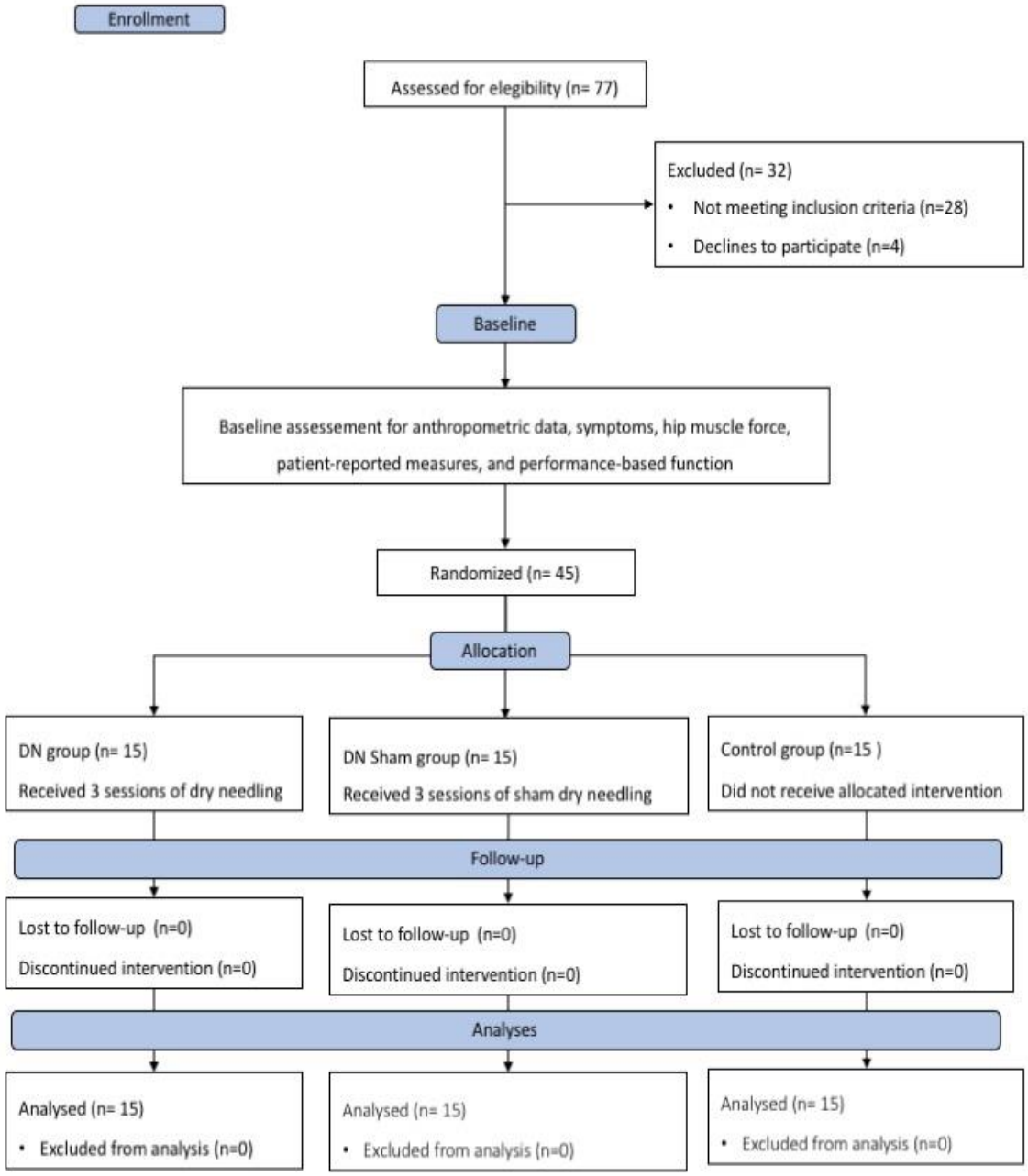

Table 1. Demographic characteristics for the three groups

Characteristics	**DN group (n=15)**	**Sham DN group (n=15)**	**Control group (n=15)**	**P**
Gender (male/female)	6/9	6/9	8/7	χ^2= 1.24, *P* = .698
Age (years)	57.53±3.88	58.20±5.08	54.67±4.48	F= 1.55, *P* = .087
Time since diagnosis (months)	66.33±76.61	72.20±53.76	68.13±56.36	H=0.36, *P* = .639
BMI (kg/cm^2)	26.85±3.00	27.18±3.74	28.50±4.48	F= 0.63, *P* = .457
Grade K/L (II/III)	7/8	6/9	6/9	χ^2= 0.58, *P* = .913

Abbreviations: DN: dry needling, BMI: Body Mass Index.
Values are expressed as mean ± SD, except where otherwise indicated.

Table 2

Table 2. Baseline, final values, change scores and effect size for pain and physical function outcomes

Outcome group	Baseline	End of treatment	Within-group Changes Mean	(95% CI)	Within-group Effect sizes	Interaction Effect F	P value	Between-group Effect sizes
VAS (0-10)								
DN group	2.68±1.96	0.4±0.95*	-2.28	-3.15,-1.40	1.48	3.879	.028	1.38
Sham DN group	2.14±1.91	2.29±1.97	.15	-.88,1.18	-0.07			
Control group	2.48± 2.16	2.23±1.20	-0.24	-1.49,.99	0.14			
WOMAC-P (0-20)								
DN group	8.13±3.09	3.4±1.95*	-4.73	-6.66,-2.79	1.83	.361	<.001	1.86
Sham DN group	6.53±3.29	5.87±2.94	-.66	-1.8,0.49	0.21			
Control group	6.8±2.48	6.27±2.65	-.53	-1.31,0.24	0.20			
WOMAC-PF (0-68)								
DN group	25.4±8.6	10.47±6.18*	-14.93	-19.93,-9.93	1.99	42	<.001	1.90
Sham DN group	19.27±7.08	21.73±4.71	2.46	.53,4.39	-0.40			

Control group	22.73±9.72	23.53±9.64	.8	-0.78,2.38	-0.08			
TUG test (seconds)								
DN group	10.5±2.43	7.98±1.58*	-2.51	-3.33,-1.69	1.23	22.427	<.001	1.29
Sham DN group	9.63±2.03	10.3±2.14	.67	0.09,1.24	-0.32			
Control group	9.5±1.97	10.09±1.65	.59	-0.42,1.60	-0.29			
40-m SPW test (seconds)								
DN group	33.69±6.08	28.26±4.24*	-5.43	-6.79,-4.06	1.03	29.808	<.001	1.22
Sham DN group	31.86±3.75	33.63±4.23	1.76	0.36,3.16	-0.44			
Control group	32.15±6.15	33.60±4.68	1.44	-0.49,3.39	-0.26			

VAS: Visual Analogue Scale; WOMAC-P: Western Ontario & McMaster Universities Osteoarthritis Index pain scale; WOMAC-PF: Western Ontario & McMaster Universities Osteoarthritis Index function scale; TUG: Time Up & Go; 40-m SPW: 40 m Self Placed Walk.

*Superscript denote significant differences between DN groups and the other groups.

Values are expressed as mean ± SD for baseline and final means and as mean (95% confidence interval) for within-group change scores. $P < 0.05$, significant difference.

Table 3

Table 3. Baseline, final values, change scores and effect size for hip muscles maximal force

Outcome group	Baseline	End of treatment	Within-group Changes		Within-group Effect sizes	Interaction Effect		Between-group Effect sizes
			Mean	(95% CI)		F	P value	
Hip flexor muscles								
DN group	29.14±12.15	42.79±12.11*	13.64	9.45,17.83	-1.12	29.917	.001	2.54
Sham DN group	28.72±6.56	22.45±6.01	-6.28	-10.34,-2.20	0.99			
Control group	27.20± 8.29	22.22±6.09	-4.98	-9.79,-.16	0.68			
Hip extensor muscles								
DN group	29.49±16.00	40.32±15.33*	10.83	5.78,15.89	-0.69	10.213	.001	1.33
Sham DN group	26.87±12.98	25.07±10.77	-1.79	-5.78,2.18	0.15			
Control group	23.78±8.94	24.24±9.98	.45	-4.01,4.92	-0.04			
Hip abductor muscles								

DN group	26.15±13.00	38.1±15.64*	11.95	5.79,18.11	-0.83	13.015	.001	1.84
Sham DN group	25.51±8.99	21.33±5.31	-4.17	-8.83,0.47	0.57			
Control group	22.71±7.58	22.04±6.37	-.06	-3.91,3.79	0.09			
Hip internal rotators								
DN group	33.59±9.60	44.95±11.76*	11.35	5.72,16.99	-1.05	40.751	.001	1.47
Sham DN group	30.87±11.99	29.19±10.8	-1.67	-6.21,2.85	0.14			
Control group	29.94±6.02	29.82±9.46	-.12	-4.44,4.19	0.01			
Hip external rotators								
DN group	36.13±16.93	54.65±19.49*	18.51	10.7,26.33	-1.01	13.283	.001	1.42
Sham DN group	35.62±10.29	33.35±10.22	-2.27	-8.52,3.98	0.22			
Control group	36.37±10.48	36.13±15.14	-.24	-6.27,5.78	0.01			

DN: Dry needling

*Superscript denote significant differences between DN groups and the other groups.

Values are expressed as mean ± SD for baseline and final means and as mean (95% confidence interval) for within-group change scores. $P < 0.05$, significant difference.

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

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	Page nº1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	Page nº1
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	Page nº2-3
	2b	Specific objectives or hypotheses	Page nº3
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Page nº3
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	Page nº3-4
Participants	4a	Eligibility criteria for participants	Page nº3-4
	4b	Settings and locations where the data were collected	Page nº3
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Page nº4-5
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	Page nº6
	6b	Any changes to trial outcomes after the trial commenced, with reasons	Not applicable
Sample size	7a	How sample size was determined	Page nº6
	7b	When applicable, explanation of any interim analyses and stopping guidelines	No applicable
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	Page nº4
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Page nº4
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	Page nº4
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Page nº4
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	Page nº4

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	Page nº4-5
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	Page nº7
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	Page nº7
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 analysed for the primary outcome	Figure 1 Page nº8
	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 1 Page nº8
Recruitment	14a	Dates defining the periods of recruitment and follow-up	Page nº3
	14b	Why the trial ended or was stopped	Page nº3
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1 Page nº9
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Figure 1 Page nº8
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)	Table 3 Figure 1 Page nº11
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Table 3 Figure 1 Page nº11
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	Not applicable
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	Table 3 Figure 1 Page nº11
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	Page nº16
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Page nº16
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	Page nº14-15
Other information			
Registration	23	Registration number and name of trial registry	Page nº1

Protocol	24	Where the full trial protocol can be accessed, if available	Not available
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Not applicable

*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 randomised trials, non-inferiority and equivalence trials, non-pharmacological 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.