

Periosteal Electrical Dry Needling as an Adjunct to Exercise and Manual Therapy for Knee Osteoarthritis

A Multicenter Randomized Clinical Trial

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Objectives: To compare the effects of adding electrical dry needling into a manual therapy (MT) and exercise program on pain, stiffness, function, and disability in individuals with painful knee osteoarthritis (OA).

Materials and Methods: In total, 242 participants (n=242) with painful knee OA were randomized to receive 6 weeks of electrical dry needling, MT, and exercise (n=121) or MT and exercise (n=121). The primary outcome was related-disability as assessed by the Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Index at 3 months.

Results: Individuals receiving the combination of electrical dry needling, MT, and exercise experienced significantly greater improvements in related-disability (WOMAC: $F=35.504$; $P<0.001$) than those receiving MT and exercise alone at 6 weeks and 3 months. Patients receiving electrical dry needling were 1.7 times more likely to have completely stopped taking medication for their pain at 3 months than individuals receiving MT and exercise (OR, 1.6; 95% confidence interval, 1.24-2.01; $P=0.001$). On the basis of the cutoff score of ≥ 5 on the global rating of change, significantly ($\chi^2=14.887$; $P<0.001$)

more patients (n=91, 75%) within the dry needling group achieved a successful outcome compared with the MT and exercise group (n=22, 18%) at 3 months. Effect sizes were large (standardized mean differences >0.82) for all outcome measures in favor of the electrical dry needling group at 3 months.

Discussion: The inclusion of electrical dry needling into a MT and exercise program was more effective for improving pain, function, and related-disability than the application of MT and exercise alone in individuals with painful knee OA.

Level of Evidence: Level 1b—therapy. Prospectively registered February 10, 2015 on www.clinicaltrials.gov (NCT02373631).

Key Words: knee osteoarthritis, dry needling, manual therapy, exercise, clinical trial

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Osteoarthritis (OA) of the knee affects up to 37% of adults in the United States between 45 and 60 years of age.¹ A recent meta-analysis found that the crude prevalence of knee OA was 25% in patients aged above 20 years and 39% in people aged above 30 years.² In addition, hip and knee OA are ranked as the 11th highest contributors to global disability in patients with chronic pain.³ Physiological changes in OA are characterized by degeneration of articular cartilage with osteophyte formation, microfractures, subchondral sclerosis and plate thickening, and exposure of the articular end of the bone.⁴⁻⁶ The clinical manifestations of knee OA are joint pain, stiffness in the morning or after rest, limited joint motion, night pain, and/or joint deformity. The clinical diagnosis of knee OA is typically made using the American College of Rheumatology clinical criteria developed by Altman, which has been found to be 89% sensitive and 88% specific.^{7,8} The pathogenesis and temporal relationship of anatomic lesions is largely unknown, and there are currently no curative treatments for OA. Long-term use of oral nonsteroidal anti-inflammatory drugs has been discouraged, and many patients with chronic pain seek for nonpharmacological management options.^{9,10} Exercise¹¹⁻¹⁶ and acupuncture¹⁷⁻²³ are 2 nonpharmacological interventions recommended for individuals with knee OA in recent meta-analyses and international clinical guidelines.^{18,24}

A Cochrane review found a statistically significant benefit, with moderate effect sizes for pain (standardized mean differences [SMD], 0.49) and physical function (SMD, 0.52) immediately after treatment, and small effect sizes

(pain, SMD, 0.24; physical function, SMD, 0.15) at 2 to 6 months follow-up for various forms of exercise in individuals with moderate knee OA.¹¹ Another recent systematic review reported that exercise plus manual therapy (MT) for joint mobilization showed a moderate effect size (SMD, 0.69) that was significantly higher than the effect sizes observed for exercise alone (SMD, 0.34).¹²

Pain may be a potential barrier leading to underdosage of strength training and aerobic exercise stimulus in individuals with painful knee OA; therefore, needling therapies may be a reasonable nonpharmacologic adjunct intervention for the reduction of chronic pain in individuals participating in exercise programs for knee OA.^{17,18,20,21} Needling therapy refers to the insertion of thin monofilament needles, as used in the practice of acupuncture, without the use of injectate.^{25–29} Dry needling is typically used to stimulate muscles, ligaments, tendons, subcutaneous fascia, scar tissue, or peripheral nerves for the management of pain and disability associated with neuromusculoskeletal disorders.^{25,28–30} Interestingly, the most common term used to describe dry needling is “acupuncture,” that is, “acu” literally translates to needle and “puncture” to penetration.²⁹

The terminology, theoretical constructs, and philosophies may differ; however, dry needling and acupuncture overlap in terms of needling technique with the use of thin monofilament needles.³¹ Notably, several previous meta-analyses and literature reviews have chosen to consider “acupuncture and dry needling” as one category of interventions.^{32–36} Therefore, from a procedural and technical perspective, and for the purpose of evaluating and comparing efficacy and effect sizes within the broader literature on the use of needling without injectate in patients with knee OA published by acupuncturists, western medical physicians, and physical therapists alike, “electroacupuncture” and “electrical dry needling” will be considered interchangeable terms, and in this context do not rely on diagnoses from oriental medicine (eg, bi syndrome, blood stagnation, or kidney yang deficiency^{37,38}) or theoretical movement of qi along traditional Chinese acupuncture meridians.^{39,40} Importantly, none of the knee OA studies cited herein used injectate in conjunction with their needling procedure; therefore, all studies fit within the strict definition of dry needling, acupuncture, or “noninjection needling” (as opposed to “injection needling” or “wet needling”), regardless of the differing terminologies, theoretical constructs, or philosophies.^{25,29,31}

The current body of evidence seems to support the use of dry needling therapies without injectate, that is, acupuncture for treating the pain, stiffness, and related-disability associated with knee OA.^{17,21,23,29,41–43} Zhang et al⁴⁴ cited a 69% consensus following a Delphi study recommending the use of acupuncture for the symptomatic treatment of OA and reported a moderate effect size for this needling modality (ie, acupuncture). The OARSI guidelines²⁰ for hip and knee OA reported acupuncture to have a moderate effect size for pain (0.51), stiffness (0.41), and function (0.51). In addition, based on the individual effect sizes of 11 trials reported by Manheimer et al,⁴⁵ Zhang et al⁴⁴ concluded that acupuncture was superior to usual care and wait list controls with a pooled effect size of 0.58 for pain relief. Although it is not always appropriate to compare effect sizes among various treatments,²⁰ to our knowledge, a pooled standard effect size for pain relief of 0.58 for acupuncture in patients with knee OA is higher than most other conservative treatments applied to this pain population, including nonsteroidal anti-inflammatory drugs (0.32), muscle strengthening exercises (0.32), and aerobic exercises (0.52).^{20,44}

Electrical dry needling and the combination of MT and exercise, when applied separately, have been found to be moderately effective for knee OA. Although 3 previous studies^{46–48} investigated the combined effects of acupuncture and exercise in patients with knee OA, they used manual acupuncture rather than electroacupuncture. No previous study has investigated the combination of the effectiveness of electrical dry needling in addition to MT and exercise in patients with knee OA. Therefore, the purpose of this multicenter randomized clinical trial was to compare the effects of adding electrical dry needling, into a MT and exercise program on pain, stiffness, function, and disability in individuals with painful knee OA. We hypothesized that individuals receiving electrical dry needling combined with MT and exercise would exhibit greater improvements in pain, stiffness, function, and disability than those receiving only MT and exercise.

MATERIALS AND METHODS

Study Design

This randomized, single-blinded, multicenter, parallel-group trial compared 2 treatment protocols for the management of knee OA: MT and exercise versus MT and exercise plus electrical dry needling. The primary outcome was related-disability as assessed by the Western Ontario and McMaster Universities (WOMAC total score) Osteoarthritis Index at 3 months. Secondary outcomes included knee pain intensity as measured by the Numeric Pain Rating Scale (NPRS), all WOMAC subscales (pain: WOMAC-P; stiffness: WOMAC-S; physical function: WOMAC-PF), medication intake, and the global rating of change (GROC). The current clinical trial was conducted following the Consolidated Standards of Reporting Trials (CONSORT) extension for pragmatic clinical trials.⁴⁹ The study was approved by the ethics committee at Universidad Rey Juan Carlos, Madrid, Spain (URJC-DPTO 31-2014) and the trial was prospectively registered (ClinicalTrials.gov: NCT02373631).

Participants

Consecutive individuals with painful knee OA from 18 outpatient physical therapy clinics in 10 different states (Arizona, Florida, Georgia, Illinois, New Hampshire, New York, North Carolina, Rhode Island, South Carolina, Virginia) were screened for eligibility criteria and recruited over a 24-month period (from February 2015 to 2017).

For patients to be eligible, they had to have met the American College of Rheumatology criteria for the diagnosis of knee OA^{7,8} and have had chronic pain in the knee joint for >3 months. Patients had to have at least 3 of the following criteria^{7,8,49} to be included in the study: (1) above 50 years of age; (2) <30 minutes of morning stiffness; (3) crepitus on active motion; (4) bony tenderness; (5) bony enlargement; and (6), no palpable warmth of synovium.⁷ In addition, participants had to have a minimum knee pain intensity score of 2 points and be older than 18 years of age.

Patients were excluded if they exhibited: (1) a history of surgery to the painful knee; (2) a history of surgery to either of the lower extremities in the last 6 months; (3) any red flags to MT, dry needling, or exercise; (4) had received physical therapy, acupuncture, massage therapy, chiropractic, or intra-articular injections for the painful knee in the last 3 months; (5) presented with ≥ 2 positive neurological signs; or (6) had involvement in litigation or worker's compensation regarding their knee pain. Patients were also excluded if they were pregnant. All participants signed an informed consent before their participation in

the study. All participants were naïve to the use of dry needling procedures and had not previously experienced needling without injectate for their knee pain.

Treating Therapists

In total, 18 physical therapists (mean age, 38.4 y; SD, 10.44) participated in the delivery of treatment for patients in this study. They had an average of 12.5 (SD, 9.54) years of clinical experience, an average of 4.3 (SD, 1.88) years using dry needling, and all had completed a 54-hour post-graduate certification program that included practical training in electrical dry needling for knee OA. All participating physical therapists were required to study a manual of standard operating procedures and participate in a 6-hour training session with the principal investigator.

Randomization and Blinding

Following the baseline examination, patients were randomly assigned to receive MT and exercise alone or in combination with electrical dry needling. Concealed allocation was conducted using a computer-generated randomized table of numbers created by a statistician who was not otherwise involved in the trial and did not participate in analysis or interpretation of the results. Individual and sequentially numbered index cards with the random assignment were prepared for each of the 18 data collection sites. The index cards were folded and placed in sealed opaque envelopes. Blinded to the baseline examination, the treating therapist opened the envelope and proceeded with treatment according to the group assignment. The examining therapist remained blind to the patient's treatment group assignment at all times; however, based on the nature of the interventions it was not possible to blind patients or treating therapists.

Interventions

All participants received between 8 and 10 treatment sessions at a frequency of 1 to 2 times per week over a 6-week period. Both groups received MT (passive joint mobilizations and muscle stretching) and exercise (riding a stationary bicycle, range of motion, and strengthening exercises to the lower extremity) on each session. In addition, the dry needling group also received electrical dry needling using a standardized 9-point protocol for 20 to 30 minutes on each treatment session.

Although specific recommendations cannot be made regarding the type of exercise¹² or the optimal exercise dosage in patients with knee OA,¹¹ patients received the following interventions at all treatment sessions: 30 minutes of lower extremity strengthening (weight bearing, non-weight-bearing, concentric, eccentric), range of motion (riding a stationary bicycle), stretching exercises (static muscle stretching), and passive accessory and physiological joint mobilizations.⁵⁰ The exercise program was taught to the patient by an experienced physical therapist on the first session and supervised on subsequent sessions. Strengthening, range of motion, and stretching exercises were gradually progressed according to tolerance of each individual patient. That is, progression only occurred if patients reported a decrease in symptoms and in the absence of excessive soreness. Details regarding the exercise and MT program have previously been described by Deyle et al.⁵⁰

All patients in both groups were asked to complete a daily home exercise program.⁵⁰ The home exercise program consisted of the same strengthening, range of motion, and stretching exercises that were prescribed and supervised in the clinic.⁵⁰ Patients were asked to complete the home

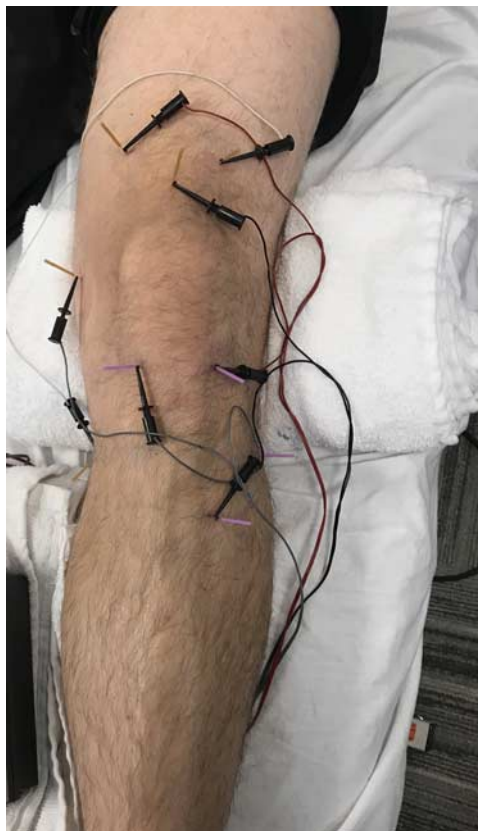


FIGURE 1. Standardized 9-point protocol of periosteal electrical dry needling for knee osteoarthritis.

exercise program during all days that they did not receive supervised physical therapy in the clinic. Patients were asked to monitor their compliance with the home exercise program by maintaining a home exercise program logbook.

In addition to MT and exercise, patients allocated to the dry needling group also received 8 to 10 sessions of periosteal electrical dry needling at a frequency of 1 to 2 times per week over 6 weeks. Electric dry needling included a 9-point standardized protocol as depicted in Figure 1. Each needle insertion site and anatomic target is summarized within Appendix 1. In addition to the obligatory 9-point standardized protocol, clinicians were also permitted to insert needles at up to 4 additional locations based on the presence of the symptoms.

Sterilized disposable stainless steel acupuncture needles were used with 3 sizes: 0.25 mm×30 mm, 0.30 mm×40 mm, and 0.30 mm×50 mm. The depth of needle insertion ranged from 15 to 45 mm and depended on the point selected (intramuscular, periosteal, joint line, intra/periarticular) and the patient's physical constitution. Following topical skin cleansing with sterile alcohol prep pads, all needles were inserted and then manipulated bidirectionally to illicit a sensation of aching, tingling, deep pressure, heaviness, or warmth.^{51,52} In addition, at least 3 of the 9 obligatory needles (ie, over the posteromedial aspect of the medial tibial condyle, within the depression posterior to the femoral epicondyle, and over the anterolateral crest of the tibia 1 fingerbreadth lateral to the tibial tuberosity) were repeatedly thrust and tapped on to the respective bone using a "periosteal stimulation" technique.⁵³ Notably, with the exception of the 2 obligatory needles inserted at the level of the tibiofemoral joint

margin within the medial or lateral infrapatellar sulcus, and depending on the patient's physical constitution, the needle length selected by the practitioner and the patient's tolerance to such, the remaining obligatory needles were also advanced toward the underlying bone to facilitate direct mechanical and electrical "periosteal stimulation."⁵³ The needles were then left in situ for 20 to 30 minutes^{41-43,54-56} with electric stimulation (ES-160 electrostimulator ITO co.) in pairs (crossing through the knee joint in a superior-inferior and diagonal orientation) using 4 channels to 8 of the needles using a low frequency (2 Hz), moderate pulse duration (250 μ s), biphasic continuous waveform at a maximum tolerable intensity.^{55,56} In cases of bilateral knee OA, both knees were treated, but only the most painful side at baseline was recorded and analyzed throughout the study to satisfy the assumption of independent data.⁵⁷

Outcome Measures

Participants received a standardized physical examination during which the affected knees were examined for conditions other than OA; that is, referred pain from the hip joint or lumbopelvic region were ruled out. The physical examination included, but was not limited to, measurements of passive and active knee range of motion.

The primary outcome was related-disability as assessed with the WOMAC total index score, whereas each WOMAC subscale (WOMAC-P, WOMAC-S, and WOMAC-PF) were considered as secondary outcomes. The WOMAC is a valid and reliable instrument and has been used extensively to evaluate 3 dimensions (pain, stiffness, and physical function) in patients with hip or knee OA.⁵⁸⁻⁶⁰ In patients with OA of the lower extremities participating in rehabilitation programs, the minimum clinically important difference (MCID) for the WOMAC has been calculated to range from 9% to 12% of the baseline score.⁶¹⁻⁶³ However, in our study, we used 36% change in the WOMAC (ie, triple the value of the 12% MCID) to represent a successful outcome.

Secondary outcomes included knee pain intensity, the 3 WOMAC subscales, medication intake and the GROC. A NPRS measured knee pain intensity. Patients were asked to indicate the average intensity of knee pain over the past week using an 11-point scale ranging from 0 (no pain) to 10 (worst pain imaginable) at baseline, 2 weeks, 6 weeks, and 3 months following the initial treatment session.⁶⁴ The NPRS is a reliable and valid instrument to assess pain intensity.⁶⁵⁻⁶⁷ The MCID for the NPRS has been shown to be 1.74 in patients with chronic pain conditions⁶⁷; however, the MCID for knee-related pain has not yet been established. Nevertheless, a change of 2 points or a 30% decrease in pain from baseline can be considered as a MCID in patients with chronic musculoskeletal pain.^{67,68}

Medication intake was measured as the number of times the patient had taken prescription or over-the-counter analgesic or anti-inflammatory medication in the past week for their knee pain, with 5 options: (1) not at all, (2) once a week, (3) once every couple of days, (4) once or twice a day, or (5) ≥ 3 times a day. Medication intake was assessed at baseline and at 3 months after the first treatment session.

At 2 weeks, 6 weeks, and 3 months following the initial treatment session, patients completed a 15-point GROC question based on a scale described by Jaeschke et al⁶⁹ to rate their self-perceived improved function. The MCID for the GROC has not been specifically reported but scores of +4 and +5 have typically been indicative of moderate changes in patient status.⁶⁹

Treatment Side Effects

Patients were asked to report adverse events that they experienced during any part of the study. In the current study, an adverse event was defined as a sequelae of 1-week duration with any symptom perceived as distressing and unacceptable to the patient that required further treatment.⁷⁰ Particular attention was given to the presence of ecchymosis and postneedling soreness within the group receiving electrical dry needling.

Sample Size Determination

The sample size calculations were based on detecting a between-groups moderate effect size of 0.4 at 3 months, assuming a 2-tailed test, an alpha level (α) of 0.05 and a desired power (β) of 90%. The estimated desired sample size was calculated to be at least 105 patients per group. A dropout percentage of 15% was expected, so 120 patients were included on each group.

Statistical Analysis

Statistical analysis was performed using SPSS software, version 24.0 (Chicago, IL) and it was conducted according to intention-to-treat analysis. We performed Little's Missing Completely at Random (MCAR) test⁷¹ to determine whether missing data points associated with dropouts were missing at random or missing for systematic reasons. Intention-to-treat analysis was performed by using expectation-maximization whereby missing data were computed using regression equations.

The effects of treatment on pain, stiffness, physical function, and related-disability were each examined with a 2-by-4 mixed-model analysis of covariance (ANCOVA) with treatment group as the between-subjects factor, time as the within-subjects

TABLE 1. Baseline Characteristics by Treatment Assignment

Baseline Variables	n = 242	
	Manual Therapy +Exercise	Manual Therapy +Exercise+ Electrical Dry Needling
Sex (male/female)	55/56	56/55
Age (y)	58.1 \pm 13.1	57.1 \pm 13.2
Weight (kg)	83.8 \pm 16.6	83.4 \pm 15.6
Height (cm)	172.0 \pm 8.9	172.1 \pm 8.6
Years with knee pain	4.6 \pm 5.1	4.5 \pm 4.7
Medication intake (n [%])		
Not at all	39 (32)	36 (30)
Once a week	13 (11)	13 (11)
Once every couple of days	29 (24)	28 (23)
Once or twice a day	37 (31)	40 (33)
≥ 3 times a day	3 (2)	4 (3)
No. treatment sessions	8.9 \pm 1.9	8.7 \pm 1.8
Mean intensity of knee pain (NPRS, 0-10)	5.4 \pm 1.8	5.7 \pm 1.6
WOMAC Pain Scale (0-20)	8.0 \pm 3.3	8.7 \pm 3.2
WOMAC Stiffness Scale (0-8)	3.8 \pm 1.4	4.0 \pm 1.6
WOMAC Physical Function Scale (0-68)	28.1 \pm 11.1	28.9 \pm 10.6
WOMAC total score (0-96)	39.9 \pm 14.6	41.6 \pm 14.3

NPRS indicates Numeric Pain Rating Scale; WOMAC, Western Ontario and McMaster Universities.

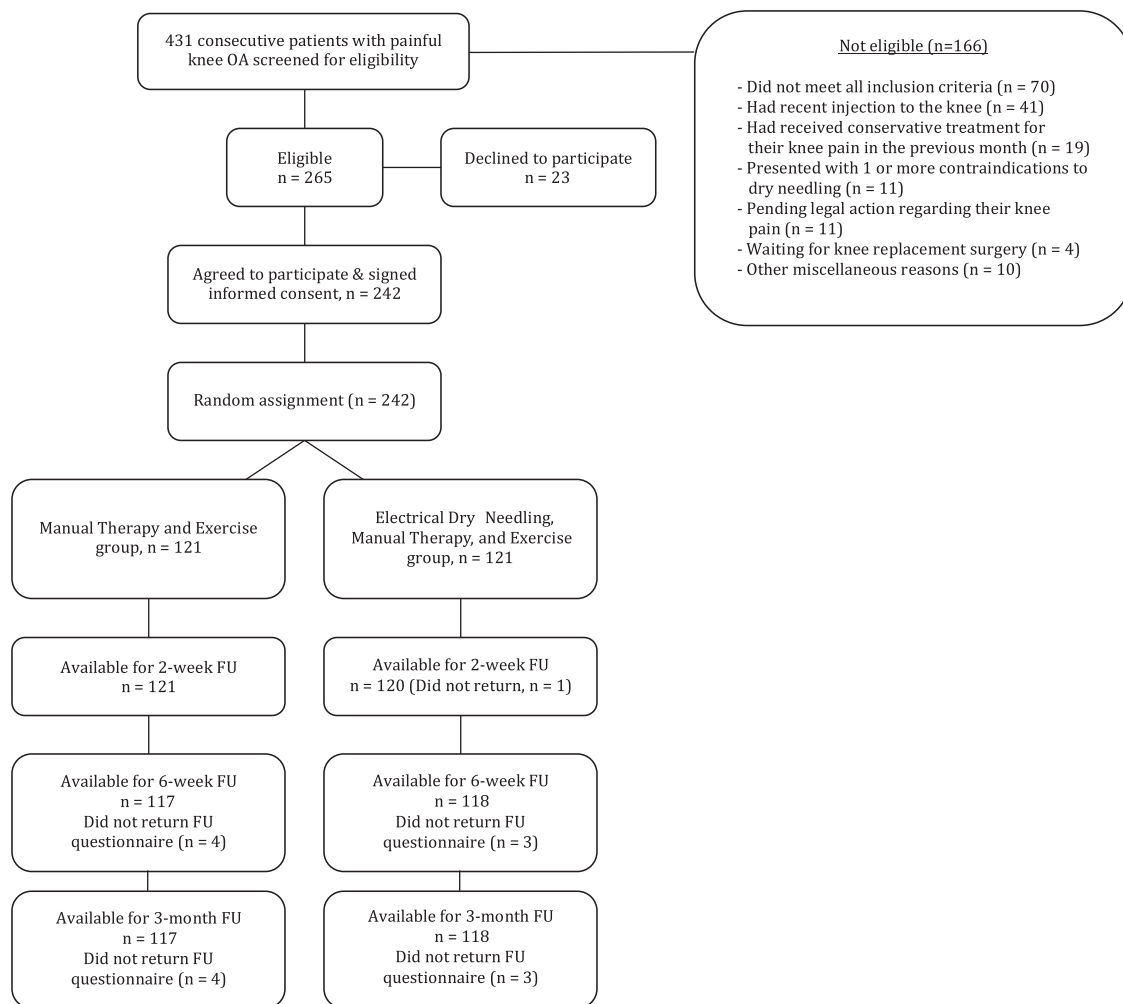


FIGURE 2. Flow diagram of patient recruitment and retention. FU indicates follow-up; OA, osteoarthritis.

factor, and adjusted for baseline data. Separate ANCOVAs were performed with each outcome as the dependent variable. For each ANCOVA, the main hypothesis of interest was the 2-way interaction (group by time) with a Bonferroni-corrected α level of 0.0125 (4 timepoints). We used χ^2 tests to compare self-perceived improvement with GROC and changes in medication intake. To enable comparison of between-group effect sizes, SMDs were calculated by dividing mean score differences between groups by the pooled SD. Numbers needed to treat (NNT) and 95% confidence intervals (CI) were also calculated at the 3-month follow-up period using each definition for a successful outcome.

RESULTS

Between February 2015 and 2017, 431 consecutive patients with knee pain were screened for possible eligibility criteria. In total, 242 (56.15%) satisfied all the inclusion criteria, agreed to participate, and were randomly allocated into the MT and exercise (n=121) or MT and exercise plus electrical dry needling (n=121) group. Randomization resulted in similar baseline characteristics for all variables (Table 1). The reasons for ineligibility are found in Figure 2, which provides a flow diagram of patient recruitment and retention. There was no significant

difference ($P=0.468$) between the mean number of completed treatment sessions for the MT, exercise plus electrical dry needling group (mean, 8.7 ± 1.8) and the MT and exercise group (mean, 8.9 ± 1.9). In total, 235 of the 242 patients completed all outcome measures through 3 months (97% follow-up). Of the 7 patients that dropped out or failed to complete outcome

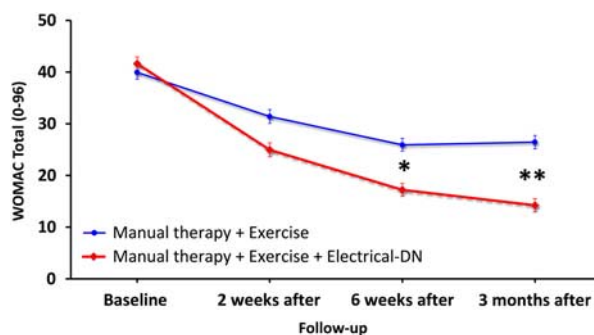


FIGURE 3. Evolution of the WOMAC Osteoarthritis Index throughout the course of the study stratified by randomized treatment assignment. Data are means (SE). DN indicates dry needling; WOMAC, Western Ontario and McMaster Universities.

measures, 3 were from the electrical dry needling group and 4 were from the MT and exercise group.

In total, 87 patients assigned to the MT and exercise plus electrical dry needling group (71.9%) experienced postneedling muscle soreness and 57 (47.1%) experienced mild bruising (ecchymosis) that most commonly resolved spontaneously within 48 hours and 2 to 4 days, respectively. In addition, 6 patients (4.9%) in the electrical dry needling group experienced drowsiness, headache, or nausea, which spontaneously resolved within several hours. No other adverse events were reported.

Adjusting for baseline outcomes, the mixed-model ANCOVA revealed a significant group×time interaction for the primary outcome (WOMAC: $F=35.504$; $P<0.001$): patients receiving electrical dry needling experienced significantly greater improvements in related-disability at 6 weeks (Δ , -10.4 ; 95% CI, -13.7 to -7.1 ; $P<0.001$) and 3 months (Δ , -13.9 ; 95% CI, -17.4 to -10.4 ; $P<0.001$) than those receiving MT and exercise alone (Fig. 3). Similarly, significant group×time interactions were also found for all WOMAC subscales (WOMAC-P: $F=30.131$, $P<0.001$; WOMAC-S: $F=29.665$, $P<0.001$; WOMAC-PF: $F=30.114$, $P<0.001$) in favor of the dry needling group (Table 2). For the WOMAC and all subscales, between-groups effect sizes were moderate ($0.53<SMD<0.76$) at 6 weeks and large

($0.82<SMD<0.94$) at 3 months after the first treatment session in favor of the dry needling group (Table 3). Within-group percentage change from baseline to 3 months for the primary outcome (WOMAC) was 67.0% and 32.9% for the electrical dry needling group and nondry needling group, respectively.

The intention-to-treat analysis also revealed a significant group×time interaction for knee pain (NPRS) intensity ($F=29.094$; $P<0.001$): individuals receiving electrical dry needling experienced significantly greater decrease in knee pain at 6 weeks (Δ , -1.2 ; 95% CI, -1.7 to -0.7 ; $P<0.001$) and 3 months (Δ , -2.7 ; 95% CI, -3.4 to -2.0 ; $P<0.001$) than those receiving MT and exercise alone (Fig. 4). For knee pain intensity (NPRS), between-groups effect sizes were moderate (SMD, 0.60) at 6 weeks and large (SMD, 0.96) at 3 months in favor of the dry needling group (Table 3). Within-group percentage change from baseline to 3 months for knee pain intensity (NPRS) was 67.2% and 28.9% for the electrical dry needling group and nondry needling group, respectively.

Patients receiving electrical dry needling were 1.7 times more likely to have completely stopped taking medication for their pain at 3 months than individuals receiving MT and exercise alone (OR, 1.6; 95% CI, 1.24-2.01; $P=0.001$). On the basis of the cutoff score of $\geq +5$ on the GROC,

TABLE 2. WOMAC Osteoarthritis Index at Baseline, 2 Weeks, 6 Weeks, and 3 Months After the First Treatment Sessions as Well as Within-group and Between-groups Mean Scores by Randomized Treatment Assignment

Outcomes	Timeline Scores: Within-group Change Scores (n = 242) (Mean ± SD [95% CI])		Between-group Differences (Mean [95% CI])
	MT+EX	MT+EX+EDN	
WOMAC-P: pain (0-20)			
Baseline	8.0 ± 3.3 (7.4-8.6)	8.7 ± 3.2 (8.1-9.3)	
2 wk	6.1 ± 3.0 (5.6-6.6)	5.4 ± 3.2 (4.8-6.0)	
Change baseline → 2 wk	-1.9 ± 2.5 (-1.5 to -2.3)	-3.3 ± 2.6 (-2.8 to -3.8)	-1.4 (-2.1 to -0.7)
6 wk	4.8 ± 2.8 (4.3-5.3)	3.4 ± 2.6 (2.9-3.9)	
Change baseline → 6 wk	-3.2 ± 3.1 (-3.8 to -2.6)	-5.3 ± 3.0 (-5.9 to -4.7)	-2.1 (-2.9 to -1.3)
3 mo	5.2 ± 3.2 (4.7-5.7)	2.8 ± 2.5 (2.3-3.3)	
Change baseline → 3 mo	-2.8 ± 3.2 (-3.4 to -2.2)	-5.9 ± 3.3 (-6.5 to -5.3)	-3.1 (-3.9 to -2.3)
WOMAC-S: stiffness (0-8)			
Baseline	3.8 ± 1.4 (3.6-4.0)	4.0 ± 1.6 (3.7-4.3)	
2 wk	3.0 ± 1.5 (2.7-3.3)	2.5 ± 1.4 (2.2-2.8)	
Change baseline → 2 wk	-0.8 ± 1.4 (-1.1 to -0.5)	-1.5 ± 1.3 (-1.8 to -1.4)	-0.7 (-1.0 to -0.4)
6 wk	2.4 ± 1.5 (2.1-2.7)	1.7 ± 1.4 (1.5-1.9)	
Change baseline → 6 wk	-1.4 ± 1.6 (-1.7 to -1.1)	-2.3 ± 1.5 (-2.6 to -2.0)	-0.7 (-1.0 to -0.4)
3 mo	2.4 ± 1.5 (2.2-2.6)	1.3 ± 1.3 (1.1-1.5)	
Change baseline → 3 mo	-1.4 ± 1.6 (-1.8 to -1.2)	-2.7 ± 1.5 (-3.0 to -2.4)	-1.3 (-1.6 to -0.9)
WOMAC-PF: physical function (0-68)			
Baseline	28.1 ± 11.1 (26.1-30.1)	28.9 ± 10.6 (27.0-30.8)	
2 wk	22.3 ± 11.6 (20.3-24.3)	17.1 ± 10.6 (15.1-19.1)	
Change baseline → 2 wk	-5.8 ± 8.7 (-7.0 to -4.6)	-11.8 ± 9.6 (-13.6 to -10.0)	-6.0 (-8.4 to -3.6)
6 wk	18.7 ± 10.9 (16.8-20.6)	12.1 ± 9.8 (10.2-14.0)	
Change baseline → 6 wk	-9.4 ± 9.0 (-11.0 to -7.8)	-16.8 ± 10.2 (-18.7 to -14.9)	-7.4 (-9.9 to -4.9)
3 mo	18.7 ± 11.7 (16.8-20.6)	10.1 ± 9.3 (8.2-12.0)	
Change baseline → 3 mo	-9.4 ± 9.8 (-11.1 to -7.7)	-18.8 ± 10.6 (-20.7 to -16.9)	-9.4 (-12.0 to -6.8)
WOMAC: Total Index (0-96)			
Baseline	39.9 ± 14.6 (37.4-42.4)	41.6 ± 14.3 (39.0-44.2)	
2 wk	31.4 ± 15.1 (28.8-34.0)	25.0 ± 14.3 (22.3-27.7)	
Change baseline → 2 wk	-8.5 ± 11.0 (-10.5 to -6.5)	-16.6 ± 12.3 (-18.9 to -14.3)	-8.1 (-11.1 to -5.1)
6 wk	25.9 ± 14.3 (23.5-28.3)	17.2 ± 13.1 (14.7-19.7)	
Change baseline → 6 wk	-14.0 ± 12.4 (-16.2 to -11.8)	-24.4 ± 13.4 (-26.9 to -21.9)	-10.4 (-13.7 to -7.1)
3 mo	26.4 ± 15.6 (23.9-28.9)	14.2 ± 12.5 (11.7-16.7)	
Change baseline → 3 mo	-13.5 ± 13.3 (-15.9 to -11.1)	-27.4 ± 14.1 (-29.9 to -24.9)	-13.9 (-17.4 to -10.4)

CI indicates confidence interval; EDN, electrical dry needling; EX, exercise; MT, manual therapy; WOMAC, Western Ontario and McMaster Universities.

TABLE 3. Between-group Effect Sizes (Standardized Mean Difference) in Favor of the Dry Needling Group When Compared With the Combination Manual Therapy and Exercise

Outcome	WOMAC Total	WOMAC Pain	WOMAC Stiffness	WOMAC Function	NPRS Pain
6 wk	0.76	0.67	0.53	0.74	0.60
3 mo	0.94	0.90	0.82	0.87	0.96

Large between-group effect size: Cohen's $d \geq 0.8$. Medium effect size: Cohen's $d = \geq 0.5$. Small size: Cohen's $d \geq 0.2$. Effect size provides information about the magnitude or strength of the difference between the 2 groups.

NPRS indicates Numeric Pain Rating Scale; WOMAC, Western Ontario and McMaster Universities.

significantly ($\chi^2 = 14.887$; $P < 0.001$) more patients ($n = 91$, 75%) in the dry needling group achieved a successful outcome compared with the nondry needling group ($n = 23$, 19%) at 3 months (Table 4). Therefore, based on the cutoff score of $\geq +5$ on the GROC, the NNT was 1.78 (95% CI, 1.50-2.18) in favor of the electrical dry needling group at 3-month follow-up. Likewise, based on the cutoff score of 36% improvement (ie, triple the MCID) on the WOMAC, the NNT was 2.37 (95% CI, 1.89-3.19) in favor of the electrical dry needling group at 3-month follow-up.

DISCUSSION

To our knowledge, this study is the first randomized clinical trial comparing the effectiveness of MT and exercise plus electrical dry needling to MT and exercise alone in patients with painful knee OA. The results suggest that a mean of 9 sessions of MT and exercise plus electrical dry needling, using a 9-point standardized protocol targeting the knee locally at a frequency of 1 to 2 times per week over 6 weeks, resulted in greater improvements in pain, stiffness, function, related-disability, and medication intake than MT and exercise alone. For the primary outcome of related-disability (WOMAC), between-groups effect sizes were moderate at 6 weeks and large at 3 months in favor of the dry needling group. The between-groups difference for change in related-disability, as measured by the WOMAC (34.1%; 95% CI, 26.6-41.4) exceeded the reported MCID (ie, 12%⁶¹) at 3 months. In addition, for knee pain intensity, the point estimate for the between-groups change (3.23 points; 95% CI, 2.4-4.0) also exceeded the reported MCID (ie, 1.74 points^{67,68}) at 3 months. Finally, the NNT suggests for every 2 patients treated with electrical dry needling, rather than MT and exercise alone, 1 additional patient with knee OA achieves clinically important reductions in related-disability at 3-month follow-up.

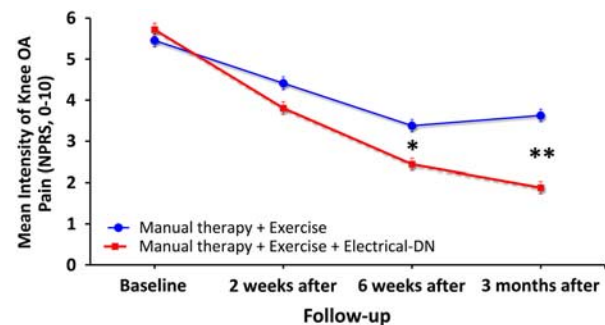


FIGURE 4. Evolution of knee pain intensity (NPRS, 0 to 10) throughout the course of the study stratified by randomized treatment assignment. Data are means (SE). NPRS indicates Numeric Pain Rating Scale.

Three previous studies found nonsuperior results when adding acupuncture as an adjunct therapy to exercise-based physical therapy in knee OA.⁴⁶⁻⁴⁸ Notably, Foster et al⁴⁷ reported no statistically significant between-groups difference in WOMAC pain subscale scores after adding a course of acupuncture to exercise in knee OA. Nevertheless, in the Foster et al⁴⁷ trial, the acupuncture points were not standardized but selected based on the “clinical opinion” of 67 different physiotherapists at different centers. Considering the recent findings regarding the influence of acupuncture on cartilage repair⁷² and the efficacy of periosteal stimulation⁵³ in knee OA, it is also possible that the needles in these previous studies (0.2 to 3.5 cm) were not inserted deep enough.⁴⁶⁻⁴⁸ In addition, a recent meta-analysis⁷³ and a separate secondary analysis that pooled data from the Cochrane review^{19,74} concluded that electroacupuncture is superior to manual acupuncture in knee OA; however, neither the Foster et al⁴⁷ nor Chen et al⁴⁶ trials used electrical stimulation with the needles.

Mechanisms of Periosteal Electrical Dry Needling

The underlying mechanisms as to why the electrical dry needling group in the current study experienced greater improvements than the MT and exercise group remains to be elucidated. However, appropriate needle depth may be an important component to consider when using dry needling therapies for joint OA. A number of studies have shown that periosteal needling, that is, getting the needle close to the bone, cartilage or joint line, or tapping the

TABLE 4. Self-perceived Improvement With GROC in Both Groups

GROC (-7 to +7)	N = 242	
	Manual Therapy + Exercise	Manual Therapy + Exercise + Electrical Dry Needling
2 wk after first treatment session		
Moderate changes (+4/+5)	18 (14.9)	49 (40.5)
Large changes (+6/+7)	2 (1.7)	11 (9.1)
6 wk after first treatment session		
Moderate changes (+4/+5)	39 (32.2)	59 (48.8)
Large changes (+6/+7)	8 (6.6)	36 (29.8)
3 mo after first treatment session		
Moderate changes (+4/+5)	27 (22.3)	45 (37.2)
Large changes (+6/+7)	10 (8.3)	57 (47.1)

Values are represented as n (%). GROC indicates global rating of change.

needle repeatedly on to the bone, leads to significant and clinically meaningful improvements in pain and disability in hip and knee OA.^{53,75,76} Zhang et al⁷² recently reported significantly lower T2 values on magnetic resonance imaging at the anteromedial and anterolateral tibial subregions of 100 knees following 20 minute sessions over 4 weeks of 7-point, low-frequency electroacupuncture; that is, electroacupuncture seems to play a role in cartilage repair in individuals with knee OA.⁷² Moreover, acupuncture has been shown to reduce interleukin-6 mRNA expression in bone marrow, thereby limiting inflammation and inhibiting myelogenic osteoclast activity driving degeneration.⁷⁷

Electroacupuncture to local points at the knee has been found to modulate knee joint microcirculation, significantly increase endogenous opioid levels, and significantly reduce plasma cortisol levels.^{78,79} In addition, electroacupuncture has been found to block the local release of inflammatory cytokines (ie, interleukin-1 β and tumor necrosis factor- α) in the synovia of osteoarthritic joints⁸⁰ and the systemic release of inflammatory factors in the periaqueductal gray of the brain stem.⁸¹ Acupuncture may also stimulate an increase in hyaluronic acid, allowing the synovial fluid to better lubricate the joint.⁸²

Strengths and Limitations

Major strengths of the current study include the inclusion of a large sample size with 18 treating physical therapists from 18 clinics in 10 different geographical states, and the use of the same standardized 9-point needling protocol and dosage parameters. However, we only assessed mid-term follow-up; thus, we do not know if the significant between-groups differences observed at 3 months would be sustained in the long term. We also cannot be certain that the results are generalizable to other dry needling protocols, dosages, techniques, or needle placements. In addition, we did not include a dry needling placebo group; which should be included in future studies. Finally, therapist and patient treatment preferences were not collected and could potentially affect the results.

CONCLUSIONS

The results of the current randomized clinical trial demonstrated that patients with painful knee OA who received MT and exercise plus electrical dry needling experienced significantly greater improvements in pain intensity, stiffness, physical function, related-disability, and medication intake as compared with the group that received MT and exercise alone. Future studies should examine the effectiveness of different types and dosages of electrical dry needling and include a long-term follow-up.

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APPENDIX 1: DESCRIPTION OF PERIOSTEAL ELECTRICAL DRY NEEDLING INTERVENTION

Technique

9-point electrical dry needling protocol for knee OA.

Technique Description

The technique is performed with the patient supine with the treated knee slightly flexed over a towel roll. Sterilized disposable stainless steel Seirin J-type acupuncture needles were used with 3 sizes: 0.25 mm \times 30 mm, 0.30 mm \times 40 mm, and 0.30 mm \times 50 mm. The depth of needle insertion ranged from

10 mm to 45 mm and depended on the point (intramuscular, periosteal, joint line, intra/periarticular) and the patient's constitution (ie, size and bone depth, muscle and/or connective tissue thickness). The following 9 needles were inserted:

- (1) Superolateral and anterior insertion within the popliteus, with periosteal stimulation over the posteromedial aspect of the medial tibial condyle.
- (2) Inferolateral insertion angle within the distal adductor magnus, with periosteal stimulation within the depression posterosuperior to the femoral epicondyle.
- (3) Perpendicular insertion within the tibialis anterior, with periosteal stimulation over the anterolateral crest of the tibia one fingerbreadth lateral to the tibial tuberosity.
- (4) Perpendicular insertion within the quadriceps tendon, one fingerbreadth proximal to the superior border of the patella.
- (5) Perpendicular insertion within the vastus lateralis, 3 fingerbreadths proximal to the superolateral border of the patella.
- (6) Perpendicular insertion within the vastus medialis, 3 fingerbreadths proximal to the superomedial border of the patella.
- (7) Perpendicular insertion at the level of the tibiofemoral joint margin within the medial infrapatellar sulcus.
- (8) Perpendicular insertion at the level of the tibiofemoral joint margin within the lateral infrapatellar sulcus.
- (9) Perpendicular insertion within the extensor digitorum longus, one thumb width distal and anterior to the fibula head. Unlike the other 8 needles that were electrically connected in pairs, and for the purpose of standardization, the ninth needle was not paired with 1 of the 4 electrical channels; nevertheless, it was manually manipulated and left in situ for the duration of the treatment (Fig. 1).

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