Effectiveness of dry needling of rectus abdominis trigger points for the treatment of primary dysmenorrhoea: a randomised parallel-group trial

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ABSTRACT

Objective To compare the effectiveness of trigger point dry needling (TrP-DN) versus placebo needling, relative to an untreated control group, on pain and quality of life in primary dysmenorrhoea.

Methods In this randomised, single blind, parallel-group trial, 56 females with primary dysmenorrhoea were randomly allocated to TrP-DN (n=19), placebo needling (n=18) or no treatment (n=19). Patients in both groups were asked to undertake a stretching exercise of the rectus abdominis daily. The needling group received a single session of TrP-DN to trigger points (TrPs) in the rectus abdominis, and the placebo group received placebo needling. The primary outcome was pain intensity (visual analogue scale). Secondary outcomes were quality of life, use of non-steroidal anti-inflammatory drugs, the number of days with pain, and self-perceived improvement, measured using a Global Rate of Change. Outcomes were assessed at baseline, and 1 and 2 months after the treatment.

Results Females receiving TrP-DN exhibited greater decreases (P<0.001) in pain than those receiving placebo (1 month: Δ−19.8 mm, 25.9 to −13.7; 2 months: Δ−26.0 mm, −33.1 to −18.9) or assigned to the untreated control group (1 month: Δ−26.0mm, −32.5 to −19.5; 2 months: Δ−20.1 mm, −26.4 to −13.8). Females in the TrP-DN group also exhibited a greater decrease in the amount of medications (P<0.001). No differences in the number of days with pain or quality of life were found (all P>0.1).

Conclusions This trial suggests that a single session of TrP-DN of the rectus abdominis combined with stretching was more effective than placebo needling and stretching alone at reducing pain and the amount of medication used in primary dysmenorrhoea.

Trial registration number ACTRN12616000170426 .

INTRODUCTION

Primary dysmenorrhoea, defined as pain during menstruation, is one of the most common gynaecological conditions and can occur during the normal ovulatory cycle in the absence of any pelvic pathology. It is extremely common in adolescent and young females and its prevalence ranges between 60 and 93%.[1 2] Primary dysmenorrhoea is characterised by a cramping pain in the lower-half of the abdominal area that can refer to the back, thigh and groin region and may also be accompanied by nausea, vomiting, diarrhoea, headache, fatigue and dizziness.[3] Burnett *et al* found that 60% of females reported moderate to severe pain associated with primary dysmenorrhoea that resulted in numerous functional limitations.[4] The severity of these symptoms often resulted in missed work or school in at least 17% of females suffering from dysmenorrhoea.[4] In fact, 30–50% of females with primary dysmenorrhoea missed school or work at least once per cycle.[1] Additionally, the burden of primary dysmenorrhoea is greater than any other gynaecological complaint.[5] For instance, in Japan, costs have been calculated to be $4.2 billion (USD) a year, resulting in substantial societal and economic burden.[6]

Treatments for primary dysmenorrhoea usually include surgical approaches (nerve ablation), medication, acupuncture, acupressure and physical therapy.[7–9] While all of the aforementioned interventions may be of benefit, a recent systematic review reported that therapists should

consider using transcutaneous nerve stimulation, heat and yoga for the managment of primary dysmenorrhoea.[10] It seems that numerous treatment approaches could be used to manage this condition. An intervention commonly used in clinical practice, which has not been examined in primary dysmenorrhoea, is trigger point dry needling (TrP-DN). Trigger points (TrPs) are defined as hypersensitive spots within taut bands of skeletal muscle that are painful to palpation and usually elicit referred pain.[11] TrPs are classified clinically as active or latent. If they are active, TrPs cause spontaneous pain and the elicited referred pain reproduces the patient's symptoms. If they are latent, TrPs do not reproduce any of the patient's symptoms.[11] TrPs have been found to be involved in chronic pelvic pain syndrome including endometriosis.[12] TrP-DN is widely used for a variety of musculoskeletal chronic pain conditions[13] and it has been shown to be effective for neck-shoulder pain[14] and low back pain,[15] but limited evidence exists to support its use for primary dysmenorrhea. Huang and Liu examined the effects of lidocaine injections for the treatment of primary dysmenorrhoea.[16] In their study, patients received wet needling to TrPs in the abdominal muscles as well as stretching exercises, which were performed at home. This study reported that 63% of patients experienced clinically meaningful improvements following just one session of wet needling at 1 year follow-up. However, no control group was included and therefore cause and effect relationships cannot be inferred.[16] To our knowledge, no study to date has investigated the impact of TrP-DN of abdominal TrPs on symptoms associated with primary dysmenorrhoea. The purpose of the current randomised clinical trial was to compare the effects of TrP-DN versus a placebo needling procedure, relative to an untreated control group, on pain in females with primary dysmenorrhoea. We hypothesised that females in the TrP-DN group would experience greater improvements in their symptoms than those assigned to the placebo needling or untreated control groups.

METHODS

Study design

This randomised, parallel-group controlled clinical trial compared the application of TrP-DN for primary dysmenorrhoea to a placebo needling technique and additionally included an untreated control group. The primary end point was the change in the intensity of pain as assessed by a visual analogue scale (VAS) after 2 months. Secondary outcomes included health-related quality of life (SF-36 questionnaire), use of non-steroidal anti-inflammatory drugs (NSAIDs) to mitigate symptoms, the number of days with pain, and self-perceived improvement with a 4-point Global Rate of Change (GROC). The current trial follows the CONSORT (Consolidated Standards of Reporting Trials) extension for pragmatic clinical trials.[17] The protocol was approved by the Local Ethical Committee of Universidad de Alcalá, Spain (CEIM/HU/2015/22) and it was conducted according to the Declaration of Helsinki. The trial was prospectively registered in the Australian New Zealand Clinical Trials Registry (ACTRN12616000170426) on 10th February 2016.

Participants

Females with dysmenorrhoea attending different healthcare centres in Madrid (Spain) were recruited from February to April 2016 for this randomised clinical trial. To be included, females had to be diagnosed with primary dysmenorrhoea by their gynaecologist, be between 18 and 25 years of age, and have pain >30 mm on a 100 mm VAS. In addition, females also had to exhibit active TrPs in the rectus abdominis reproducing their pain symptoms. They were excluded if they suffered from secondary dysmenorrhoea or any other conditions of the reproductive and urinary systems—for example, endometriosis. Additionally, females with children (previous pregnancy) or previous experiences of abortion were also excluded. Participants were counselled and signed an informed consent form before their inclusion in the study.

Randomisation and masking

Females were randomly assigned to dry needling, placebo-needling or an untreated control group. Concealed allocation was conducted using a computer-generated randomised table of numbers created by an external statistician. Individual and sequentially numbered index cards with the random assignment were prepared. The index cards were folded and placed in sealed opaque envelopes. Another researcher opened the envelope and proceeded with allocation. Treatment allocation was revealed to the participants after collection of baseline outcomes. Clinicians collecting outcomes were blind to group assignment.

Interventions

The day of the intervention was scheduled 2 weeks before the females began their menstrual period. All treatments were applied by two experienced physical therapists with more than 2 years of clinical experience in the treatment of myofascial pain and the use of dry needling for patients with primary dysmenorrhoea.

Females allocated to the TrP-DN group received a single session of dry needling into active TrPs of the rectus abdominis muscle. TrPs were diagnosed when there was a palpable taut band, local pain on palpation of the spot and referred pain reproducing the symptoms of the patient (pain recognition).[18]Patients received TrP-DN using disposable stainless needles (0.25 mm×40 mm, Agupunt, Barcelona, Spain) that were inserted into the skin over the TrP. In this study, the fast-in and fast-out technique described by Hong[19] was applied. Once the active TrP was located, the overlying

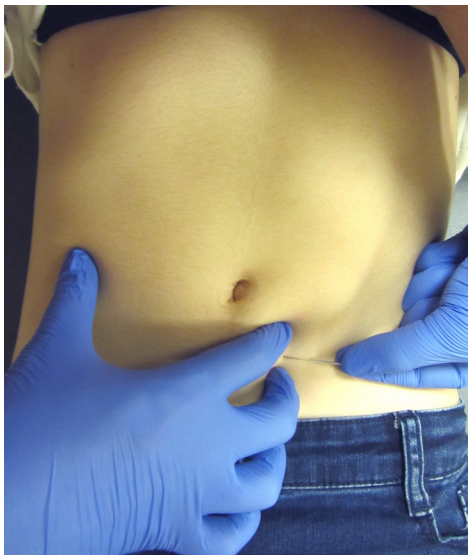

Figure 1 Dry needling applied to trigger points in the rectus abdominis muscle.

skin was cleaned with alcohol. With the patient lying supine, the needle was inserted through the skin and advanced into the TrP horizontal to the lateral edge of the rectus abdominis muscle (figure 1) until the first local-twitch response was obtained. Hong suggested that local twitch responses should be elicited during TrP-DN to constitute a proper and successful technique[19]; however, it should be recognised that there is controversy about the necessity of obtaining local twitch responses in obtaining a positive outcome.[20] Once the first local-twitch response was obtained, the needle was moved in and out of the rectus abdominis muscle (3–5 mm horizontal motions with no rotation) for 25–30 s. This time period usually permits at least 2–3 local-twitch responses. In fact, a recent study has reported that 2–3 local-twitch responses are enough to obtain a positive outcome, at least in patients with neck pain.[21]

No placebo for TrP-DN has been specifically designed. In this study, females assigned to the placebo group received a sham needle procedure using a 'Dong Bang' placebo needle, which is very similar to the Streitberger needle[22] (figure 2). These needles appear to represent an effective placebo technique for the majority of subjects in studies using acupuncture. The therapist performed the same procedure as was done with a real needle in the TrP-DN group in order to blind the subjects. These placebo needles elicit a mechanical stimulus over the tissue without perforating the skin; the patients experienced a sensation of pressure very similar to that of a normal needle.

Females assigned to the control group did not receive any needling intervention. In all groups, participants were asked to perform self-stretching exercises of the external and internal obliques and rectus abdominis muscles (figure 3). They were instructed to perform these stretching exercises 3–5 times per day,

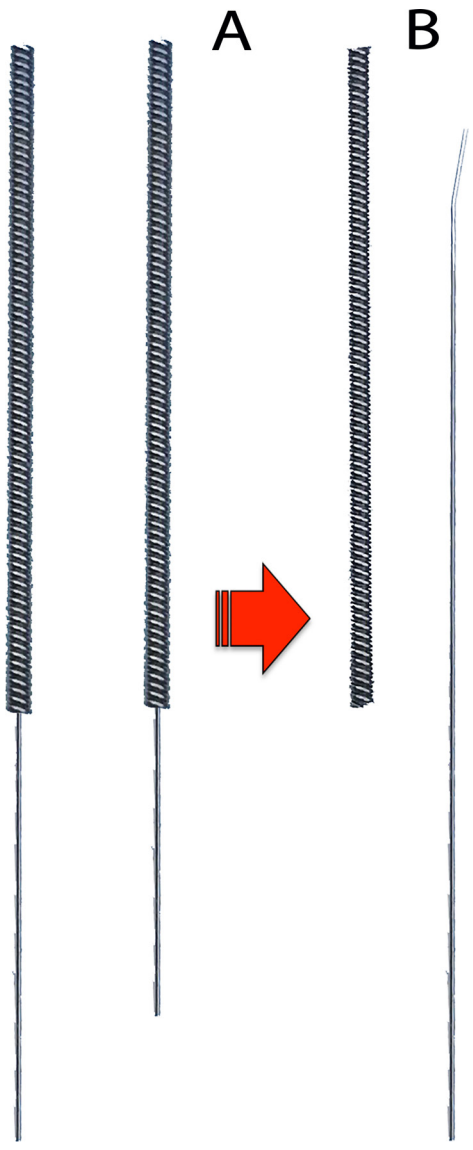

Figure 2 Placebo needling procedure applied.

maintaining the stretching position for 30–60 s every day during the study period. Females were required to complete a daily diary where they documented their adherence to the stretching exercise regimen.

Outcomes

Outcomes were assessed at baseline and at 1 and 2 months after treatment, on the same days of the menstrual cycle. The primary outcome was the mean intensity of pain as assessed by VAS.[23] Participants were asked to mark their intensity of pain on a 100 mm horizontal line, with the ends of the line representing the extreme expressions of pain (no pain to maximum pain).[24] The mean intensity of all days with menstrual pain was used for the analysis. There is no study determining the minimal clinically important difference (MCID) of pain for primary dysmenorrhoea; therefore, we used data from other gynaecological problems such as endometriosis. In fact, it seems that the VAS is the most frequently used scale for

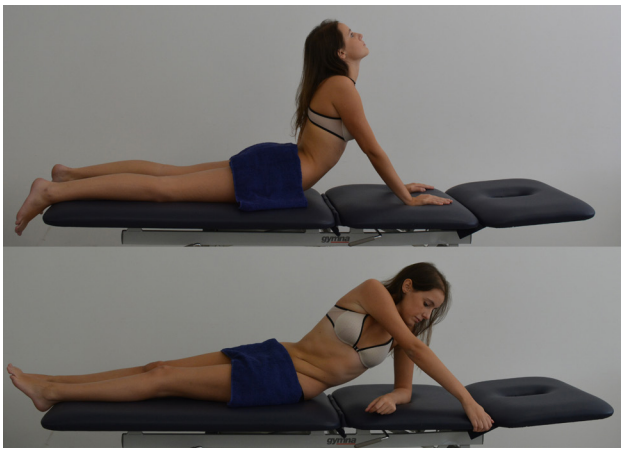

Figure 3 Stretching exercise of the rectus abdominis and oblique musculature.

assessing the intensity of pain in females with endometriosis.[25] The MCID of the VAS for endometriosis has been found to be 10 mm.[26] A recent study suggested that in females with endometriosis who exhibit pain of at least 50 mm on a VAS scale at baseline, the suggested MCID should be a 50% decrease.[27]

Secondary outcomes included health-related quality of life (SF-36 questionnaire), use of NSAIDs to mitigate pain symptoms, the number of days with menstrual pain, and self-perceived improvement with a 4-point Global Rate of Change (GROC). The Spanish version of the SF-36 questionnaire was used to determine changes in health-related quality of life.[28] This questionnaire includes eight domains evaluating the repercussion of pain on quality of life. Scores range from 0 (the lowest quality of life) to 100 (the highest quality of life).[29] In the current study, domains were combined into physical component scores (PCS) and mental component scores (MCS).[29] There are no specific data on the MCID for the PCS and MCS of the SF-36 questionnaire, but changes between 3 and 5 points are accepted as clinically relevant[30 31]

The number of NSAID tablets (ibuprofen 600 mg) and the number of days with menstrual pain were monitored using a diary for the duration of the study. Finally, at the 2-month follow-up stage, participants were asked to rate their self-perceived improvement on a 4-point GROC scale with the following possible answers: worse, equal, better, or much better.

Treatment side effects

Females were asked to report any adverse events they had experienced during the study. In the current study, adverse events were defined as sequelae of 1 week's duration with any symptom perceived as distressing and unacceptable to the patient and requiring further treatment.[32] Particular attention was given to the presence of post-dry needling soreness within the group receiving TrP-DN.

Sample size determination

It was estimated that 15 individuals per group would be required to detect a between-group difference of 10 mm in the primary outcome (MCID),[26] assuming an SD of 8 mm, at a two-tailed α level of 0.05 and 90% power. Group sizes were inflated to 17 to account for an anticipated dropout rate of 10%.

Statistical analysis

Statistical analysis was performed using SPSS version 21.0 (Chicago, IL, USA) and it was conducted according to the intention-to-treat principle with all participants analysed in the group to which they were originally allocated. When any data were missing, the multiple imputation method was used.[33] Mean, SD and 95% confidence intervals (95% CI) were calculated for each variable. The Kolmogorov-Smirnov test revealed a normal distribution of the quantitative variables ($P>0.05$). Baseline demographic and clinical variables were compared among the groups using a one-way analysis of variance (ANOVA) for continuous data and χ^2 tests of independence for categorical data. Our evaluation included several 3×3 mixed-model repeated measured analysis of covariance (ANCOVA) with Time (baseline, 1 month and 2 months after) as the within-subjects factor, and Group (dry needling, placebo needling or control) as the between-subjects factor, adjusted for baseline data to evaluate between-group differences in the outcomes. We used χ^2 tests to compare self-perceived improvement at 2 months between all groups. The hypothesis of interest was the Group*Time interaction with a Bonferroni-corrected α level of 0.017 (three time points). To enable comparison of between-group effect sizes, standardised mean score differences (SMDs) were also calculated by dividing mean score differences by the pooled SD.

RESULTS

Between February and April 2016, 80 consecutive females with menstrual pain were screened for eligibility. Fifty-six (70%) females satisfied all the eligibility criteria, agreed to participate, and were randomly allocated into the dry needling group (n=19), the placebo needling group (n=18) or the control group (n=19). Randomisation resulted in similar baseline features (table 1). Four females were lost to follow-up at the end of the study. The reasons for ineligibility are found in figure 4, which provides a flow diagram of patient recruitment and retention. Five females assigned to the TrP-DN group (27%) experienced muscle soreness after dry needling, which resolved spontaneously within 24–36 hours. No other adverse event was reported by any participant during the study. The percentage of adherence to the stretching exercise was 97% during the trial.

Adjusting for baseline outcomes, the mixed-model ANCOVA found significant Group*Time interactions for the mean intensity of menstrual pain (F=8.162;

Table 1 Baseline characteristics by treatment assignment

	Dry needling group (n=19)	Placebo needling group (n=18)	Control group (n=19)
Age (years)	21.4±1.8	21.7±2.1	21.3±2.3
Weight (kg)	56.4±7.5	57.0±9.6	58.8±7.7
Height (cm)	164.1±7.2	163.4±4.6	165.6±4.0
Body mass index (kg/cm^2)	21.0±1.9	21.3±3.2	21.0±2.6
Mean pain intensity (VAS, 0–100)	65.4±19.4	65.5±13.1	62.1±14.3
Days with menstrual pain	2.3±1.1	2.3±1.5	2.5±0.8
Taking NSAIDs (yes/no) n (%)	16 (84%)/3 (16%)	14 (77.5)/4 (22.5%)	15 (78.9)/4 (21.1)
Number of NSAIDs taken	4.7±3.9	4.1±2.9	4.2±5.6
Use of contraceptive (yes/no) n (%)	6 (31.5%)/13 (69.5%)	4 (22.5%)/14 (77.5%)	6 (31.5%)/13 (69.5%)
PCS SF-36 (0–100)	50.7±6.9	52.0±4.5	51.5±6.2
MCS SF-36 (0–100)	51.5±6.0	53.3±4.1	48.1±8.3

MCS, Mental Component Score; NSAIDs, non-steroidal anti-inflammatory drugs; PCS, Physical Component Score; VAS, visual analogue scale.

P<0.001) and the number of NSAIDs (F=6.269; P=0.004). Females receiving TrP-DN exhibited a greater decrease in pain intensity than those receiving placebo needling (1 month: Δ −19.8 mm (−25.9 to −13.7); 2 months: Δ −26.0 mm (−33.1 to −18.9), P<0.001) or only stretching (1 month: Δ −26.0 mm (−32.5 to −19.5); 2 months: Δ −20.1 mm (−26.4 to −13.8), P<0.001, figure 5). Similarly females in the dry needling group exhibited a greater decrease in the number of NSAIDs taken than those in the placebo group (1 month: Δ −2.3 (-4.3 to −0.3); 2 months: Δ −2.5 (-4.3 to −0.7), P<0.001) or the control group (1 month: Δ −2.3 (-4.1 to −0.5); 2 months: Δ −2.5 (-3.7 to −1.3), P<0.001). Between-groups effect sizes were large at all stages of follow-up (1.3>SMD>1.8) in favour of the TrP-DN group.

The ANCOVA did not reveal significant Group*-Time interaction for the number of days with

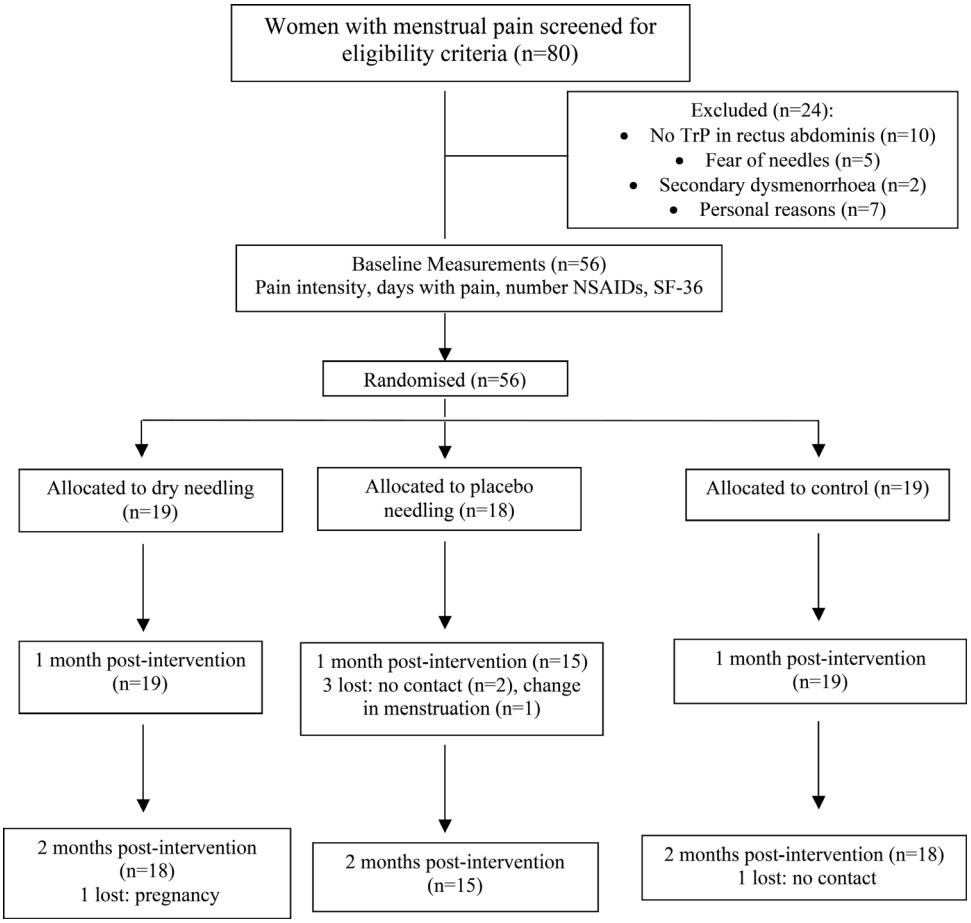

Figure 4 Flow diagram of patients throughout the course of the study. NSAIDs, non-steroidal anti-inflammatory drugs; TrP, trigger point.

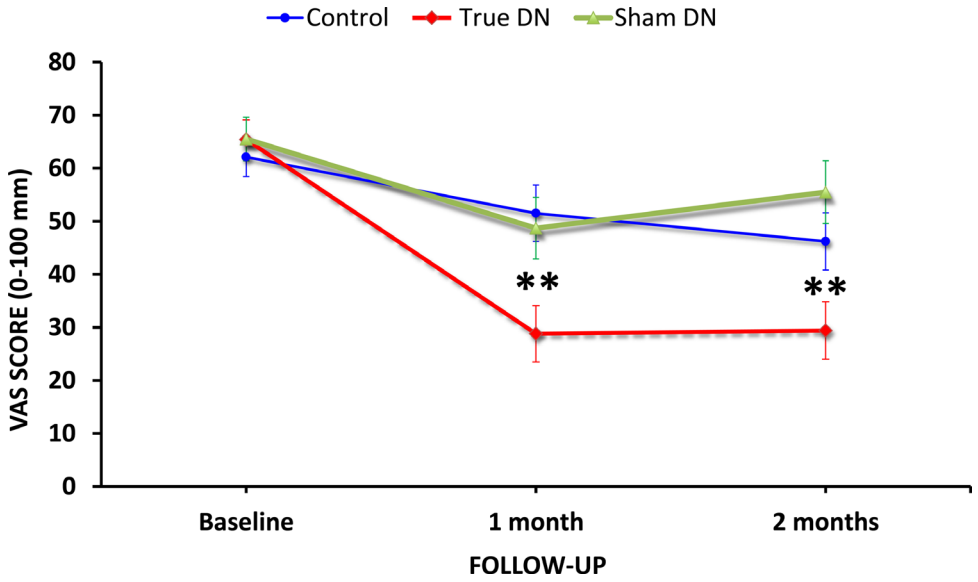

Figure 5 Evolution of the intensity of menstrual pain intensity throughout the course of the study stratified by randomised treatment assignment. Data are presented as mean (SE). VAS, visual analoque scale. ** indicates significant differences between groups (ANOVA, P<0.001).

menstrual pain (F=1.306, P=0.280), PCS (F=2.184; P=0.124) and MCS (F=0.158; P=0.855). No significant changes were observed at any stage of follow-up in either group (P>0.32) (table 2).

No change was found in the distribution of females using NSAIDs at any stage of follow-up (P>0.215). A greater number of females receiving dry needling described a self-reported improvement categorised as better (n=10, 55%) or much better (n=6, 33%) compared with those receiving placebo needling (better: n=2, 14%) or control (better: n=3, 16%) as assessed by the GROC (χ^2=28.277; P<0.001).

DISCUSSION

This randomised clinical trial found that a single session of dry needling directed at active TrPs of the rectus abdominis muscle combined with a stretching exercise was more effective than placebo needling and stretching alone at reducing pain intensity and the number of NSAID tablets used in females with primary dysmenorrhoea. No significant differences in health-related quality of life were observed.

Current evidence suggests the use of medication, acupuncture, acupressure, heat or nerve stimulation for the management of females with primary dysmenorrhoea.[7–9] Previous trials have not identified TrP-DN as a potentially effective intervention, not because there is scientific evidence against this approach but rather because there is a lack of studies investigating the effectiveness of this intervention in this population. To our knowledge, the current controlled trial is the first to combine Tr-DN and stretching in females with primary dysmenorrhoea. We observed that females receiving TrP-DN exhibited better outcomes in terms of pain than those who received placebo needling or stretching only. In fact, between-group change scores and their 95% CIs surpassed the MCID of 10 mm for the VAS[26] in favour of the TrP-DN, supporting a clinically relevant effect of this intervention. In addition, within-group score changes of the TrP-DN group also surpassed the restrictive MCID of 50% of reduction of baseline scores.[27] Our results are similar to those previously reported by Huang and Liu, in their quasi-experimental study, who also demonstrated that TrP injection of abdominal muscles was effective at reducing menstrual pain.[16]

Current literature supports the use of NSAIDs as first-line therapy, or oral contraceptive pills as second-line, for pain relief in primary dysmenorrhoea.[34] We did not find changes in the number of females taking NSAIDs for pain relief; however, those females receiving TrP-DN reduced the number of tablets taken for management of their pain. This would be expected since a reduction in pain intensity during their menstrual cycles might lead to the need for fewer NSAID tablets. Females receiving placebo needling or stretching only did not experience significant change in the number of tablets. It should also be noted that 30% of our females were taking contraceptive pills by medical prescription, and, obviously, no change in this proportion was observed after treatment. There were no differences in results in this small subgroup of females (data not shown).

To determine the mechanisms of TrP treatment in order to explain the results of this trial is beyond the scope of this paper; however, some hypotheses can be proposed. Simons *et al* suggested that rectus abdominis muscle TrPs could refer pain to the hypogastrium, mimicking menstrual pain symptoms.[11] We selected a sample of females with primary dysmenorrhoea where the referred pain elicited by active TrPs in the rectus abdominis reproduced their symptoms. The current

Table 2 Primary and secondary outcomes at baseline, 1 month and 2 months after as well as within-group mean scores by randomised treatment assignment

	Timeline scores and within-group change scores: mean±SD (95% CI)		
Outcomes	**Dry needling**	**Placebo needling**	**Control**
Mean intensity of menstrual pain (VAS, 0–100)*			
Baseline	65.4±19.4 (57.9 to 72.9)	65.5±13.1 (57.2 to 73.8)	62.1±14.3 (54.5 to 69.7)
One month after	28.8±21.9 (18.1 to 39.5	48.7±26.5 (37.1 to 60.3)	51.5±19.5 (40.8 to 62.2)
Change baseline → 1 month	−36.6±20.1 (-47.1 to 26.1)	−16.8±22.3 (-29.1 to 4.4)	−10.6±16.0 (−18.6 to −2.6)
Two months after	29.4±22.5 (18.4 to 40.4)	55.5±22.6 (43.5 to 67.5)	46.2±24.1 (35.3 to 56.9)
Change baseline → 2 months	−36.0±14.2 (-43.2 to 28.8)	−10.0±22.1 (-22.3 to 2.3)	−15.9±22.1 (−26.9 to−4.9)
Number of days with menstrual pain			
Baseline	2.3±1.1 (1.7 to 2.9)	2.3±1.5 (1.7 to 2.9)	2.5±0.8 (2.0 to 3.0)
One month after	1.8±0.7 (1.4 to 2.2)	2.0±3.0 (1.4 to 2.6)	2.2±0.9 (1.8 to 2.6)
Change baseline → 1 month	−0.5±0.7 (−0.7 to 0.3)	−0.3±1.5 (-1.1 to 0.5)	−0.3±0.8 (-0.6 to 0.0)
Two months after	1.8±1.1 (1.2 to 2.4)	2.0±1.5 (1.6 to 2.4)	2.4±0.8 (1.8 to 3.0)
Change baseline → 2 months	−0.5±1.0 (−0.8 to 0.2)	−0.3±0.9 (−0.9, 0.3)	−0.1±0.7 (−0.2 to 0.0)
Number of non-steroidal anti-inflammatory drugs*			
Baseline	4.7±3.9 (3.0 to 6.5)	4.1±2.9 (2.6 to 5.6)	4.2±2.6 (3.1 to 5.1)
One month after	1.4±1.8 (0.4 to 2.4)	3.1±1.8 (2.0 to 4.2)	3.2±3.3 (1.9 to 4.5)
Change baseline → 1 month	−3.3±1.5 (−4.1 to 2.5)	−1.0±2.3 (−2.3 to 0.3)	−1.0±2.0 (−2.5 to 0.5)
Two months after	1.1±1.5 (0.2 to 2.0)	3.0±3.1 (1.5 to 4.5)	3.1±3.3 (1.8 to 4.4)
Change baseline → 2 months	−3.6±2.1 (−4.7 to 2.5)	−1.1±1.5 (−2.5 to 0.3)	−1.1±2.0 (−2.6 to 0.4)
Physical Component Score SF-36 (0–100)			
Baseline	50.7±6.9 (47.7 to 53.7)	52.0±4.5 (48.7 to 55.3)	51.5±6.2 (48.6 to 54.4)
One month after	53.7±5.4 (51.0 to 56.4)	51.8±7.3 (48.8 to 54.8)	53.7±4.1 (51.1 to 56.3)
Change baseline → 1 month	3.0±6.3 (−0.2 to 6.2)	−0.2±5.2 (-3.3 to 2.9)	2.2±5.9 (−0.7 to 5,1)
Two months after	54.9±4.6 (52.3 to 57.5)	51.5±8.2 (48.5 to 54.5)	54.6±2.6 (52.0 to 57.2)
Change baseline → 2 months	4.2±5.8 (1.2 to 7.2)	−0.5±5.2 (−3.6 to 2.6)	3.1±7.4 (−0.5 to 6.7)
Mental Component Score SF-36 (0–100)			
Baseline	51.5±6.0 (48.3 to 54.7)	53.3±4.1 (49.6 to 57.0)	48.1±8.3 (44.9 to 51.3)
One month after	49.6±7.4 (46.0 to 53.2)	54.3±3.0 (50.2 to 58.4)	47.8±9.4 (44.3 to 51.3)
Change baseline → 1 month	−1.9±6.0 (−4.9 to 1.1)	1.0±4.0 (-1.3 to 3.3)	−0.3±10.6 (−5.4 to 5.0)
Two months after	51.1±7.6 (47.6 to 54.6)	54.2±4.6 (50.3 to 58.1)	47.8±7.8 (44.5 to 51.1)
Change baseline → 2 months	−0.4±7.1 (−4.0 to 3.2)	0.9±6.5 (−3.0 to 4.8)	−0.3±6.5 (−3.6 to 3.0)

*Statistically significant differences among the groups (ANCOVA, P<0.001).

results are similar to those previously reported for females with chronic pelvic pain where active TrPs in the rectus abdominis muscle were the most prevalent.[35] It is interesting to note that, in females with primary dysmenorrhoea, pain appears only for a few days per month, usually the menstrual days, which does not seem commensurate with TrP normal behaviour.[11] Increased uterine prostaglandin F2α (PGF2α) production in the weeks before menstruation could be transported in the blood and settle in rectus abdominis muscle taut bands, leading to irritation and activation, as Huang and Liu also suggested.[16] After menstruation, with the falling concentration of prostaglandins, the TrP could return to latency (asymptomatic), and the symptoms may therefore decrease or disappear for a period of time. This is the reason why TrP-DN was conducted 2 weeks before menstruation in the current study. We believe that if dry needling was carried out during menstruation, post-needling induced soreness might have increased symptoms; however, we do not currently know what would happen if TrP-DN was performed at another time during the menstrual cycle. Finally, it is also possible that needling therapies—for example, acupuncture or dry needling—regulate nitric oxide levels,[36] which are elevated in females with primary dysmenorrhoea.[37]

Another potential explanation could be related to somatovisceral convergence between the rectus abdominis muscle and the uterus. It seems that lamina I of the spinal cord is the first site in the central nervous system where somatic and visceral pathways converge onto individual projection and local circuit neurons.[38] Therefore, nociceptive stimulation of one structure, for example, somatic tissue, could refer to the other, that is, the viscera, and vice versa. In such a way, the area of pain could be amplified by these mechanisms of convergence, overlapping visceral and somatic stimuli. Since the uterus and the rectus

abdominis muscle share common pain fibre pathways and are both innervated by the lower thoracic nerves (T10 to T12), a nociceptive stimuli in either structure can stimulate the other. By reducing muscle nociception from active TrPs in the rectus abdominis with TrP-DN, we may have been able to reduce nociceptive thresholds from the uterus, explaining our results. In such a scenario, TrP-DN could act as a counter-irritant somatic stimulus to reduce visceral pain.[38]

It is also important to consider that all the groups also received a stretching exercise of the rectus abdominis muscle as described by Huang and Liu.[16] In fact, all the groups exhibited some decrease in the intensity of menstrual pain, probably associated with the stretching of the rectus abdominis. These findings are similar to Ortiz *et al*, who found that a general stretching programme was effective at decreasing menstrual pain.[39] It is possible that part of the decrease in pain observed in our study could be related to the effects of the stretching exercise. We do not currently know the potential effects of the application of TrP-DN combined with a general stretching and/or strengthening exercise programme. Future studies should investigate which combination of therapeutic programmes provides the best pain relief in females with primary dysmenorrhoea.

The results of this randomised controlled trial should be considered in light of some potential limitations. First, we cannot be confident that our placebo needling was truly inert, since the mechanical feeling of the needle entering into the tissue could also exert an analgesic effect. Second, only the rectus abdominis muscle was needled; however, the referred pain elicited by TrPs in other musculature could also be related to symptoms in primary dysmenorrhoea. Third, we only included a follow-up period of two menstrual cycles, so we are unable to comment on the longer-term effects of treatment or the natural history of the underlying condition. Fourth, we just applied a single session of TrP-DN. It is possible that a greater number of sessions could lead to better outcomes; however, this assumption remains to be tested. Additionally, it should be considered that we applied a stretching exercise just to the rectus abdominis muscle. Finally, we used a general questionnaire (the SF-36) to assess health-related quality of life. It is possible that this questionnaire does not represent the best outcome for assessing quality of life in females with primary dysmenorrhoea, explaining the lack of effect of the interventions. Future trials including a sample of females with a broader age range and longer follow-up periods are now needed.

CONCLUSIONS

The results of this randomised clinical trial found that a single session of dry needling into active TrPs of the rectus abdominis muscle combined with a stretching exercise was more effective than placebo needling and stretching alone at reducing pain intensity and the number of NSAIDs used in females with primary dysmenorrhoea. No changes in health-related quality of life were observed in either group.

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