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Original Article

Pilot Evaluation of Dry Needling with Intramuscular Stimulation in Fibromyalgia

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ABSTRACT

Background: Fibromyalgia is a chronic disorder characterized by widespread pain and heightened pain sensitivity, and while dry needling has shown promise, evidence for added intramuscular electrical stimulation remains limited (2,4,5). Objective: To estimate a preliminary pain-related signal and generate sample-size planning parameters for dry needling plus intramuscular electrical stimulation (DN+IMS) versus dry needling alone (DN) in adults with fibromyalgia. Methods: In an assessor-blinded, parallel-group pilot randomized design, 12 participants were allocated 1:1 to DN+IMS or DN (n=6 per group). Pain intensity was measured using the Numeric Pain Rating Scale (NPRS, 0–10) at baseline and end point, and results were summarized descriptively for planning. Results: Baseline NPRS was comparable between groups (DN+IMS: 7.20±1.70; DN: 7.30±1.90), indicating adequate baseline equivalence. At end point, NPRS was lower in DN+IMS (4.55±1.90) than DN (5.90±1.70), yielding a between-group mean difference of 1.35 points with pooled SD≈1.80 and Cohen's d≈0.75. Conclusion: The pilot suggested a moderate-to-large preliminary analgesic signal favoring DN+IMS and provided planning parameters (Δ=1.35; σ=1.80) to inform the sample size of a definitive randomized controlled trial using NPRS as the primary endpoint (12). Keywords: Dry needling; Intramuscular electrical stimulation; Fibromyalgia; Pain; NPRS.

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INTRODUCTION

Fibromyalgia (FM) is a chronic and multifactorial pain disorder characterized by widespread musculoskeletal pain, persistent fatigue, sleep disturbances, and psychological symptoms such as anxiety and depression. The global prevalence of fibromyalgia is estimated to range between 2% and 4%, with a significantly higher incidence among women. The pathophysiology of fibromyalgia is complex and involves central sensitization, dysregulation of nociceptive processing, altered pain modulation pathways, and the presence of myofascial trigger points (MTrPs). These mechanisms collectively contribute to persistent pain perception, functional disability, and reduced quality of life in affected individuals. Despite increasing recognition of fibromyalgia as a major chronic pain condition, its management remains challenging due to the heterogeneous nature of symptoms and variable responses to available treatments.

Current treatment strategies for fibromyalgia include pharmacological interventions, exercise therapy, cognitive behavioral approaches, and patient education. However, pharmacological treatments often provide only modest symptom relief and may be associated with adverse effects, prompting growing interest in non-pharmacological therapies. Among these, dry needling (DN) has emerged as a minimally invasive physiotherapeutic intervention targeting myofascial trigger points to reduce pain and improve functional outcomes. DN is believed to produce therapeutic effects through the mechanical disruption of dysfunctional motor endplates, reduction of peripheral nociceptive input, and modulation of central pain processing mechanisms. Evidence from randomized controlled trials and systematic reviews

suggests that DN can lead to moderate improvements in pain intensity, pressure pain threshold, and quality of life among patients with fibromyalgia.

Recently, adjunctive use of intramuscular electrical stimulation (IMS) with dry needling has been proposed as a strategy to enhance therapeutic outcomes. Electrical stimulation applied through inserted needles may further activate sensory afferent fibers, promote endogenous opioid release, and stimulate descending inhibitory pain pathways. These neurophysiological effects may contribute to improved analgesia and neuromodulation compared with dry needling alone. However, despite the theoretical advantages of combining DN with electrical stimulation, evidence regarding its feasibility and preliminary clinical effects in patients with fibromyalgia remains limited.

Therefore, a pilot study was conducted to evaluate the feasibility, safety, and preliminary therapeutic outcomes of dry needling combined with intramuscular electrical stimulation compared with dry needling alone in individuals with fibromyalgia. The study aimed to explore preliminary changes in pain intensity, pressure pain threshold, fatigue, sleep quality, and psychological symptoms while informing the design and implementation of a larger randomized clinical trial.

MATERIAL AND METHODS

A randomized, parallel-group, assessor-blinded pilot trial was conducted in an outpatient tertiary physiotherapy service at the University of Lahore Teaching Hospital, Lahore, Pakistan, from November 2023 to January 2024 to compare dry needling combined with intramuscular electrical stimulation (DN+IMS) versus dry needling alone (DN) in adults with fibromyalgia. Adults aged 18–60 years were eligible if they met fibromyalgia diagnostic criteria consistent with the 2010 framework (generalized pain for ≥3 months with required WPI/SS thresholds) and reported clinically meaningful baseline pain (Numeric Pain Rating Scale [NPRS] ≥4/10). Exclusion criteria included pregnancy, severe psychiatric illness limiting participation, active malignancy, recent surgery, or contraindications to needling/electrostimulation (e.g., bleeding disorders, clinically relevant anticoagulant use, local infection, or needle phobia). Potential participants were screened at the clinic and provided written informed consent prior to enrollment.

Participants were allocated 1:1 to DN+IMS or DN using a computer-generated random sequence with concealed allocation (sealed opaque envelopes). Owing to the nature of the interventions, therapists and participants were not blinded; however, outcome assessors and the statistician remained blinded to minimize detection and analysis bias. Both groups received four weekly sessions. Dry needling was applied to clinically relevant active myofascial trigger points identified through standardized palpation (taut band, hypersensitive point, and reproduction of recognizable pain), using sterile disposable filiform needles (0.25 mm diameter; 25–40 mm length). In the DN+IMS arm, intramuscular electrical stimulation was delivered after needle placement using a biphasic square-wave current at 2–4 Hz with a pulse width of 120 μs for 20 minutes, with intensity titrated to tolerance; the DN arm received identical needling without stimulation. Both groups received standardized co-interventions comprising education, stretching, and moderate-intensity aerobic exercise guidance.

The prespecified primary outcome was pain intensity measured using NPRS (0–10), assessed at baseline and end point by trained blinded assessors. Adverse events and tolerability were monitored throughout. Given the pilot objective, the sample size was constrained to support feasibility and to generate planning parameters for a definitive trial; the primary analysis summarized the between-group difference in end-point NPRS and the pooled standard deviation to support subsequent sample size estimation. Data were analyzed using Python (version 3.10). Baseline comparability was summarized descriptively and with standardized mean differences, and end-point between-group NPRS differences were reported with corresponding standardized effect size estimates for planning. The study followed internationally accepted ethical principles; participants provided informed consent, and data were de-identified with restricted access and prespecified analysis scripts to support integrity and reproducibility.

RESULTS

Twelve participants with fibromyalgia were enrolled and randomized equally into two intervention arms: dry needling combined with intramuscular electrical stimulation (DN+IMS, n = 6) and dry needling alone (DN, n = 6). All participants completed baseline and end-point assessments, resulting in a follow-up completion rate of 100% for the pilot phase. No serious adverse events were observed during the intervention period. Mild post-needling soreness was occasionally reported but resolved spontaneously without treatment discontinuation.

Baseline demographic and clinical characteristics were comparable between the two groups. The mean age of participants was similar between the DN+IMS group (49.8 ± 7.6 years) and the DN group (50.3 ± 8.1 years). The majority of participants were female in both groups, consistent with the epidemiology of fibromyalgia. Baseline pain intensity measured using the Numeric Pain Rating Scale (NPRS) demonstrated comparable values between groups (7.20 ± 1.70 vs 7.30 ± 1.90), indicating adequate baseline equivalence.

Following the intervention period, both groups demonstrated reductions in pain intensity; however, greater improvement was observed in the DN+IMS group. At the end point, the DN+IMS group demonstrated a mean NPRS score of 4.55 ± 1.90 compared with 5.90 ± 1.70 in the DN group. The mean reduction in pain from baseline was −2.65 points in the DN+IMS group and −1.40 points in the DN group. The between-group difference at the end point was 1.35 NPRS points favoring DN+IMS. The pooled standard deviation was approximately 1.80, corresponding to a standardized effect size of Cohen's d ≈ 0.75, suggesting a moderate-to-large preliminary treatment effect.

Given the exploratory nature of the pilot study, the principal purpose of these findings was to generate planning parameters for the definitive randomized controlled trial. The pilot-derived mean between-group difference (Δ = 1.35 NPRS points) and pooled standard deviation (σ = 1.80) were therefore identified as the primary estimates for future sample size calculation.

Table 1. Baseline Demographic Characteristics and Pilot Pain Outcomes

Variable	DN+IMS (n=6) Mean ± SD / n (%)	DN (n=6) Mean ± SD / n (%)	P value	Extended Statistics
Age (years)	49.8 ± 7.6	50.3 ± 8.1	0.91	SMD = 0.06
Female sex	5 (83.3%)	5 (83.3%)	1.00	—
BMI (kg/m²)	27.9 ± 4.8	28.4 ± 5.1	0.86	SMD = 0.10
Pain duration (months)	98.6 ± 41.3	101.4 ± 44.6	0.88	SMD = 0.07
Baseline NPRS	7.20 ± 1.70	7.30 ± 1.90	0.92	Cohen's d = 0.06
End-Point NPRS	4.55 ± 1.90	5.90 ± 1.70	0.21	Mean difference = −1.35
Change in NPRS	−2.65 ± 1.40	−1.40 ± 1.20	—	Pooled SD = 1.80
Effect size (Cohen's d)	—	—	—	0.75

Abbreviations: BMI = Body Mass Index; NPRS = Numeric Pain Rating Scale; SD = Standard Deviation; SMD = Standardized Mean Difference

DISCUSSION

In this pilot randomized study, participants receiving dry needling plus intramuscular electrical stimulation (DN+IMS) demonstrated a larger reduction in pain intensity than those receiving dry needling alone, with closely comparable baseline NPRS values and a moderate-to-large standardized between-group separation at the end point. Although the pilot was not designed to make definitive efficacy claims, the direction and magnitude of the signal were clinically plausible in the context of fibromyalgia, a condition strongly linked to altered central pain processing and impaired endogenous analgesia (2,3). Contemporary guidance emphasizes multimodal, non-pharmacological care, and needling-based interventions have been increasingly evaluated as adjuncts to exercise and education pathways (4,5).

The observed incremental analgesic signal with the addition of electrical stimulation is biologically coherent. Dry needling is proposed to reduce nociceptive input from myofascial trigger points and modulate pain sensitivity, which has been supported by systematic evidence in fibromyalgia populations (5,6). Layering low-frequency electrical stimulation through needles may further amplify

neuromodulatory effects by enhancing afferent stimulation and engaging segmental and descending inhibitory mechanisms, consistent with broader evidence on electrical neuromodulation approaches in fibromyalgia and chronic pain (7,8). Prior controlled electroacupuncture work in fibromyalgia also supports the plausibility that electrically mediated stimulation can improve pain-related outcomes in this population, albeit with substantial protocol heterogeneity across studies (9).

Several methodological considerations are important for the definitive trial design. First, the small pilot sample increases uncertainty in effect estimation; therefore, the primary value of these data is to provide planning parameters rather than confirm treatment superiority. Second, therapist and participant blinding was not feasible; expectancy effects may influence pain reporting in centrally mediated pain syndromes, reinforcing the importance of assessor blinding and standardized scripts to minimize differential contextual effects between arms (2,5). Third, the definitive trial should prespecify the primary endpoint timing explicitly and implement a transparent approach to multiplicity if secondary outcomes (sleep, mood, fatigue) are included, to protect interpretability and reduce selective emphasis across domains (4,5). Finally, while no serious adverse events were observed, tolerability should be systematically captured using standardized adverse-event definitions because needling-related soreness can influence adherence and follow-up completion.

Overall, the pilot results support feasibility and yielded sample-size planning parameters based on NPRS, with an observed between-group difference and pooled variability that can be carried forward into a fully powered randomized controlled trial. A definitive study using the same core protocol, clear endpoint specification, and sensitivity analyses for missing data would clarify whether DN+IMS provides clinically durable analgesic benefit beyond dry needling alone in adults with fibromyalgia (4,5,12).

CONCLUSION

In this pilot randomized study, dry needling combined with intramuscular electrical stimulation showed a larger reduction in pain intensity than dry needling alone, and the observed between-group difference and pooled variability provide pragmatic planning parameters for calculating the sample size of a definitive, adequately powered randomized controlled trial using NPRS as the primary endpoint.

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