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EFFECT OF DRY NEEDLING WITH AND WITHOUT ELECTRICAL STIMULATION IN TREATMENT OF LOWER LIMB IN PATIENTS WITH CHRONIC ISCHEMIC STROKE

EFEITO DO AGULHAMENTO SECO COM E SEM ESTIMULAÇÃO ELÉTRICA NO TRATAMENTO DE MEMBROS INFERIORES EM PACIENTES COM ACIDENTE VASCULAR CEREBRAL ISQUÊMICO CRÔNICO

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Abstract
Lower-limb spasticity after stroke restricts gait and functional independence, and adjunct interventions that reduce hypertonia while modulating segmental excitability may enhance conventional rehabilitation. This assessor-blinded, parallel-group randomized controlled trial tested whether dry needling combined with intramuscular electrical stimulation (DN+ES), integrated within conventional physical therapy (CPT), reduces spasticity, improves lower-limb motor function, and modifies soleus H-reflex indices in adults with chronic ischemic stroke. Sixty-four participants (32 per group) received 6 weeks of treatment (three sessions/week, 60 minutes). The experimental group received DN+ES twice weekly within sessions plus CPT; the control group received CPT only. Outcomes were assessed at baseline, week 3, and week 6.

Resumo
A espasticidade dos membros inferiores após um AVC restringe a marcha e a independência funcional, e intervenções adjuvantes que reduzem a hipertonia enquanto modulam a excitabilidade segmentar podem aprimorar a reabilitação convencional. Este ensaio clínico randomizado controlado, com grupos paralelos e avaliação cega, testou se o agulhamento seco combinado com estimulação elétrica intramuscular (AS+EE), integrado à fisioterapia convencional (FC), reduz a espasticidade, melhora a função motora dos membros inferiores e modifica os índices do reflexo H do sóleo em adultos com AVC isquêmico crônico. Sessenta e quatro participantes (32 por grupo) receberam 6 semanas de tratamento (três sessões/semana, 60 minutos). O grupo experimental recebeu AS+EE

The primary outcome was the Modified Ashworth Scale of the index muscle; secondary outcomes included the Fugl–Meyer Assessment–Lower Extremity, soleus Hmax/Mmax ratio, and H-reflex latency. Compared with CPT, DN+ES+CPT produced larger reductions in spasticity and greater improvements in lower-limb motor function, alongside a greater decrease in Hmax/Mmax, while between-group differences in latency were not detected. These findings support DN+ES as a pragmatic adjunct that may improve the treatability of the limb and strengthen the impact of conventional rehabilitation in post-stroke spasticity.

Keywords: Dry Needling. H-Reflex. Intramuscular Electrical Stimulation. Spasticity. Stroke.

duas vezes por semana durante as sessões, além da FC; o grupo controle recebeu apenas FC. Os desfechos foram avaliados no início do estudo, na 3ª semana e na 6ª semana. O desfecho primário foi a Escala de Ashworth Modificada do músculo avaliado; os desfechos secundários incluíram a Avaliação de Fugl-Meyer para Membros Inferiores, a razão Hmax/Mmax do sóleo e a latência do reflexo H. Em comparação com a Terapia de Preparo Funcional (TPF), a combinação de Agulhamento Seco + Estimulação Elétrica (ASE) e TPF produziu maiores reduções na espasticidade e melhorias mais significativas na função motora dos membros inferiores, juntamente com uma maior diminuição na relação Hmax/Mmax, enquanto não foram detectadas diferenças na latência entre os grupos. Esses achados corroboram a ASE como um adjuvante pragmático que pode melhorar a tratabilidade do membro e fortalecer o impacto da reabilitação convencional na espasticidade pós-AVC.

Palavras-chave: *Agulhamento Seco. Reflexo H. Estimulação Elétrica Intramuscular. Espasticidade. AVC.*

1 INTRODUCTION

Stroke remains a leading cause of long-term disability, and recovery of safe, efficient walking is a central objective of rehabilitation because limitations in gait directly restrict independence and participation. In many individuals living with chronic stroke, lower-limb spasticity, often most evident in the plantarflexors, contributes to resistance against ankle dorsiflexion, impaired tibial progression, reduced toe clearance, and compensatory movement strategies that increase the energetic cost of walking. When excessive tone mechanically constrains movement, the quality, intensity, and specificity of task practice can be compromised, reducing the potential gains from conventional gait training, strengthening, and balance interventions.

Spasticity is increasingly understood as a multifactorial disturbance in motor control rather than a purely local muscle problem. Altered supraspinal drive, dysregulated inhibitory control within spinal circuitry, and impaired selective motor activation can combine to amplify reflex-mediated muscle activity and sustain abnormal limb postures.

From a rehabilitation standpoint, this matters because interventions that merely train function without adequately addressing tone-related mechanical constraints may be less effective, whereas approaches that reduce hypertonia may widen the movement "space" available for motor relearning within the same therapy session.

Adjunct modalities that can rapidly decrease hypertonicity while supporting active retraining are therefore clinically relevant in chronic stroke. Dry needling has been used to reduce hypertonic behavior in affected muscles, potentially improving tissue compliance and reducing resistance to stretch. Electrical stimulation is commonly applied in neurorehabilitation to facilitate muscle activation and reinforce task practice through patterned neuromuscular recruitment. Combining these approaches by delivering electrical stimulation intramuscularly through dry-needling needles may offer a pragmatic strategy to couple local mechanical effects with afferent-driven neuromuscular activation, thereby enhancing the immediate treatability of the limb and improving the efficiency of conventional physical therapy.

This randomized, assessor-blinded trial tested whether integrating dry needling with intramuscular electrical stimulation into a standardized conventional physical therapy program produces greater reductions in lower-limb spasticity and greater improvements in lower-limb motor function than conventional physical therapy alone in adults with chronic ischemic stroke. In addition, the study examined whether clinical changes are accompanied by favorable modulation of segmental excitability indexed by soleus H-reflex measures over the six-week intervention period.

2 THEORETICAL AND SCIENTIFIC BACKGROUND

2.1 Post-stroke lower-limb spasticity and gait impairment

Recovery of walking after stroke is a central goal of rehabilitation, as locomotor performance strongly influences community mobility, independence, and social participation (Winstein et al., 2016). In individuals with chronic hemiparesis, lower-limb spasticity, particularly when predominant in the plantarflexor muscles, is associated with increased stiffness and resistance to stretch that restrict ankle dorsiflexion, impair tibial progression during stance, and compromise foot clearance during swing. These deficits

often lead to compensatory biomechanical strategies and increased energetic cost of walking (Bensoussan et al., 2010). From a neurophysiological perspective, spasticity reflects not only peripheral mechanical changes but also a disruption of motor control characterized by reduced suprasegmental inhibitory drive, reorganization of spinal circuitry, and impaired selective activation. Together, these mechanisms promote co-contraction and dysfunctional synergistic patterns (Sheean, 2002). This combination of mechanical restriction and reflex hyperexcitability may limit the patient's ability to fully benefit from conventional rehabilitation, as task-oriented practice, strengthening, and balance training require functional range of motion and voluntary control with minimal interference from velocity-dependent resistance.

2.2 Neurophysiological rationale: soleus H-reflex indices

To investigate the segmental component of hyperexcitability associated with spasticity, the Hoffmann reflex (H-reflex) is widely used as an indirect and operational measure of Ia afferent–motoneuron responsiveness and of the excitatory–inhibitory balance at the spinal level (Knikou, 2008). In post-stroke populations, modulation of the soleus H-reflex is clinically relevant because it relates to plantarflexor activation patterns and ankle control during postural and gait tasks, and because it is sensitive to joint position and movement conditions (Phadke et al., 2012).

Among commonly reported indices, the Hmax/Mmax ratio is interpreted as a normalized marker of motoneuron pool reflex gain, as it expresses the maximal reflex response (Hmax) relative to the maximal direct motor response (Mmax). This normalization improves longitudinal comparability when stimulation parameters and electrode placement are standardized (Knikou, 2008). In contrast, H-reflex latency is more strongly influenced by peripheral conduction velocity and synaptic transmission time within the monosynaptic reflex arc, and therefore tends to be less responsive to interventions primarily targeting segmental excitability. Consequently, the combined assessment of amplitude-based indices (such as Hmax/Mmax) and latency aids in distinguishing changes attributable to modulation of spinal excitability from those related to conduction properties or methodological artifacts (Knikou, 2008). Mechanistically, a

reduction in Hmax/Mmax accompanied by minimal or no change in latency is commonly interpreted as evidence of decreased reflex gain rather than altered neural conduction.

2.3 Rationale for dry needling combined with intramuscular electrical stimulation

Dry needling has been proposed as an adjunct intervention for neurological conditions characterized by hypertonia and spasticity. Recent syntheses suggest that dry needling may reduce muscle tone in the short term, although findings are heterogeneous due to variability in target muscles, dosing, and methodological quality across studies (Fernández-de-Las-Peñas et al., 2021). Clinically, the plausibility of dry needling in this context is often discussed in terms of local changes in muscle mechanical properties and nociceptive–motor interactions, potentially reducing stiffness and facilitating passive mobility. Such effects may enhance the quality and effectiveness of subsequent active therapeutic interventions (Fernández-de-Las-Peñas et al., 2021).

Neuromuscular electrical stimulation, in contrast, is a well-established modality in neurorehabilitation, used to facilitate muscle recruitment, support strengthening, and increase movement repetition through augmented afferent feedback, particularly in the presence of antagonist weakness and impaired voluntary activation (Sheffler & Chae, 2007). In individuals with hemiparesis, abnormal synergies, co-contraction, and agonist hyperactivity may limit the effectiveness of isolated training approaches. Electrical stimulation may therefore act as a facilitator, increasing both the volume of practice and the quality of motor patterns during therapy sessions (Sheffler & Chae, 2007). Moreover, there is physiological support for the notion that rhythmic afferent input and repeated task practice can influence reflex excitability and spinal control, consistent with experimental observations of H-reflex modulation during stimulation and rhythmic activity in post-stroke populations (Barzi & Zehr, 2008).

The combination of dry needling with intramuscular electrical stimulation, delivered through inserted needles, has been proposed as an integrative strategy that couples a local component, potentially reducing mechanical resistance, with an active neuromuscular component capable of inducing comfortable rhythmic contractions and reinforcing somatosensory afference within the same session (Sheffler & Chae, 2007). Under this framework, an initial reduction in hypertonia may create a therapeutic window

in which gait training, strengthening, and balance exercises can be performed with less resistance and greater motor control, thereby increasing the likelihood of functional gains rather than changes limited to impairment-level outcomes (Fernández-de-Las-Peñas et al., 2021; Sheffler & Chae, 2007). Despite this rationale, clinical evidence remains inconsistent with respect to optimal protocol design, dosage, and mechanistic outcomes, underscoring the need to evaluate interventions that integrate sufficient dosing, explicit coupling with conventional physiotherapy, and concurrent clinical and neurophysiological measures within the same trial (Fernández-de-Las-Peñas et al., 2021; Knikou, 2008).

2.4 Study objective and hypotheses

Against this background, the aim of the present trial was to determine whether integrating dry needling with intramuscular electrical stimulation into a standardized conventional physiotherapy program produces greater reductions in lower-limb spasticity and greater improvements in motor function than conventional physiotherapy alone in adults with chronic ischemic stroke. Additionally, the study sought to examine whether clinical changes are accompanied by favorable modulation of segmental spinal excitability, as assessed by the soleus H-reflex. It was hypothesized that the combined intervention would be associated with a reduction in the Hmax/Mmax ratio, without meaningful changes in H-reflex latency under standardized acquisition conditions (Knikou, 2008; Phadke et al., 2012).

3 METHDS

3.1 Study design, setting, and ethical compliance

This single-center, parallel-group, assessor-blinded randomized controlled trial was conducted at a community rehabilitation center in Lahore, Pakistan, between August 2024 and July 2025. The protocol received institutional ethics approval from the University of Lahore and was prospectively registered (PACTR202411566651896). All participants provided written informed consent prior to any study procedures.

Confidentiality was maintained using coded identifiers, and adverse events were actively monitored and documented at each treatment contact using predefined categories and severity grading.

3.2 Open science statements

Open science statements: The trial protocol was prospectively registered (PACTR202411566651896). Ethical approval was granted by the University of Lahore (Ref No: REC-UOL/435/08/24), and all participants provided written informed consent prior to participation. De-identified participant data and the corresponding analysis code are available from the corresponding author upon reasonable request. The authors declare no conflicts of interest. No specific funding was received for this study.

3.3 Participants: eligibility and recruitment

Adults aged 35–65 years with chronic ischemic stroke of at least 3 months' duration were screened through referrals and outpatient/community outreach. Diagnosis was verified by medical record review and neuroimaging confirmation where available. Eligibility required at least mild-to-moderate lower-limb spasticity in the paretic limb (Modified Ashworth Scale [MAS] ≥1 in one or more clinically relevant muscles) and sufficient capacity to follow instructions (Mini-Mental State Examination [MMSE] ≥18).

Exclusion criteria were designed to reduce foreseeable risk and confounding: severe cognitive impairment (MMSE <18); progressive or active malignancy; uncontrolled cardiovascular disease; major psychiatric illness; botulinum toxin injection, phenol neurolysis, or clinically meaningful medication changes affecting spasticity within the prior 3 months; open wounds or skin infection at intended needling sites; bleeding disorders or anticoagulation not medically optimized; known contraindication/intolerance to electrical stimulation; and pregnancy. Eligibility was confirmed by a study physiatrist prior to randomization.

3.4 Randomization, allocation concealment, and blinding

After baseline assessment (T0), participants were randomized 1:1 to: Experimental: dry needling with intramuscular electrical stimulation integrated within conventional physical therapy (DN+ES+CPT)

3.5 Control: conventional physical therapy alone (CPT)

An independent biostatistician generated the allocation sequence using variable block sizes (4–8), stratified by baseline spasticity severity (MAS 1–1+ vs ≥2) and time since stroke (3–12 months vs >12 months). Allocation concealment used sequentially numbered, opaque, sealed envelopes opened only after baseline testing by a coordinator not involved in outcome measurement. Due to the nature of the interventions, participants and treating therapists were not blinded. Outcome assessors and data analysts were blinded to group assignment, and participants were instructed not to reveal allocation during assessments.

3.6 Interventions

Both groups attended three supervised sessions per week for six weeks (18 sessions total), each lasting 60 minutes to equalize contact time. A standardized home exercise program (flexibility, strengthening, gait practice) was prescribed to both groups; adherence was tracked using daily logs reviewed weekly. Concomitant antispasticity medications were required to be stable for at least four weeks before baseline and throughout the intervention period.

Adherence definition (prespecified): attendance at ≥80% of supervised sessions and completion of ≥75% of the home program. Adherence metrics were recorded to support per-protocol sensitivity analyses.

3.7 Conventional physical therapy (CPT)

CPT (delivered to both groups in all sessions, and comprising the entire session for controls) included: passive stretching and proprioceptive neuromuscular facilitation–based stretching of spastic muscle groups; progressive strengthening emphasizing dorsiflexors, knee extensors, and hip abductors; task-specific gait training (overground walking, step practice, weight shifting drills); and static and dynamic balance training with education and supervised home-program practice.

Progression criteria (prespecified): strengthening exercises were advanced when participants completed two sets of 10–12 repetitions with correct form and without compensatory substitutions; resistance or task complexity was then increased to maintain moderate-to-high effort. Gait training progressed by increasing walking distance, reducing upper-limb support, narrowing base of support, increasing step height, or adding dual-task elements as tolerated, with safety prioritized and excessive fatigue avoided. Therapists documented delivered components and progression using a structured checklist.

3.8 Dry needling plus intramuscular electrical stimulation (DN+ES)

In the experimental group, dry needling was delivered by certified physiotherapists using sterile, single-use filiform needles (0.25–0.30 mm diameter; 30–60 mm length selected by muscle depth). Candidate muscles were selected based on clinical presentation and palpation of taut bands or hypertonic regions contributing to gait-limiting patterns, from: gastrocnemius (medial/lateral head), soleus, tibialis posterior, quadriceps (rectus femoris/vasti), and hamstrings.

Index muscle definition (primary outcome standardization): at baseline, the index muscle was defined as the single muscle among ankle plantarflexors (gastrocnemius–soleus complex) and tibialis posterior with the highest MAS score judged most relevant to impaired ankle dorsiflexion during stance and swing. If tied, the gastrocnemius–soleus complex was prioritized. The same index muscle designation was retained across all follow-up assessments.

Needling used deep insertion into the identified taut band with a fast in/fast out pistoning technique, targeting 3–5 local twitch responses per muscle where feasible, with a maximum of six muscles treated per session. Needle retention was limited to the time required to elicit twitch responses and deliver intramuscular stimulation to reduce variability due to dwell time.

Intramuscular electrical stimulation (ES): immediately following needling, ES was delivered through the inserted needles using a biphasic symmetrical waveform for 10–15 minutes during two of the three weekly sessions. Stimulation parameters followed a prespecified algorithm:

frequency default 4 Hz (allowable adjustment 3–6 Hz for comfort or to achieve a visible but comfortable contraction), pulse duration fixed at 250 μs (allowable 200–250 μs if needed for comfort), intensity titrated upward until a visible, rhythmic, comfortable local twitch was observed without pain, then maintained. In each of those two weekly sessions, DN+ES was delivered in the first 15 minutes of the 60-minute visit, followed by 45 minutes of CPT. The third weekly session consisted of 60 minutes of CPT without DN+ES, ensuring identical total contact time.

3.9 Treatment fidelity and safety monitoring

Fidelity and safety were documented across sessions using structured forms. For the DN+ES group, therapists recorded muscles treated per session, number of insertions, local twitch response counts per muscle, stimulation frequency, pulse width, duration, and peak intensity achieved using the visible-twitch criterion. Fidelity targets were defined a priori: needling of at least three clinically relevant muscles per DN session unless limited by tolerance; attainment of at least three twitch responses in most targeted muscles when feasible; and completion of at least 10 minutes of stimulation under the parameter algorithm. For both groups, checklists captured CPT components delivered and progression steps. Adverse events were solicited and recorded at each contact, including post-needling soreness, bruising/hematoma, vasovagal symptoms, and stimulation-related discomfort, each graded by severity (mild/moderate/severe) and relatedness (related/possibly related/unrelated).

3.10 Outcomes and assessment schedule

Outcomes were assessed at baseline (T0), week 3 (Post1), and week 6 (Post2) by trained physiotherapists blinded to allocation. Primary outcome: spasticity of the index muscle measured using the Modified Ashworth Scale (MAS), operationalized as the average of three passive, velocity-dependent stretches using a standardized procedure to reduce rater variability.

3.11 Secondary outcomes

lower-limb motor function measured with the Fugl–Meyer Assessment–Lower Extremity (FMA-LE; range 0–34); soleus H-reflex indices: Hmax/Mmax ratio and H-reflex latency.

3.12 H-reflex acquisition and processing

H-reflex testing was performed with participants prone and the knee flexed approximately 20 degrees to reduce reflex variability attributable to joint position. After skin preparation, surface electrodes were placed with the active electrode over the soleus belly, the reference electrode over the Achilles tendon, and a ground electrode on the posterior calf. The posterior tibial nerve was stimulated at the popliteal fossa using square-wave pulses (1 ms) delivered at low frequency to minimize habituation. Stimulation intensity was progressively increased to identify maximal H-reflex amplitude (Hmax) and maximal direct motor response (Mmax). The Hmax/Mmax ratio was computed as the normalized excitability index.

EMG acquisition used standard physiological band-pass filtering, and artifact-free traces were repeated and averaged to enhance reliability. Electrode placement landmarks were templated for repeat visits, participants were instructed to remain relaxed to minimize background EMG contamination, and testing conditions were held constant across time points.

Latency definition H-reflex latency was defined as the time (ms) from the stimulation artifact to the onset of the H-wave, using a consistent onset criterion across all visits as exported by the acquisition software.

3.13 Sample size

Sample size was calculated for the primary endpoint as the between-group difference in change in MAS from baseline to week 6. Assuming a clinically meaningful difference of 0.6 MAS points (SD 0.8), 80% power, two-sided alpha 0.05, and within-subject correlation 0.50 across three time points, 58 participants were required under a repeated-measures mixed-design approximation. The target enrollment was set at 64 to allow approximately 10% attrition.

3.14 Statistical analysis

Analyses followed a modified intention-to-treat framework including all randomized participants who contributed at least one post-baseline outcome measurement. Mixed-effects models were estimated using maximum likelihood or restricted maximum likelihood as appropriate, accommodating incomplete repeated measures under a missing-at-random assumption without single imputation. The prespecified primary inference was the between-group contrast in change from baseline to week 6 (T0→Post2) for MAS.

To control multiplicity, a hierarchical testing strategy was prespecified: the primary endpoint at Post2 was tested first at alpha 0.05; only if significant were key secondary outcomes (FMA-LE and Hmax/Mmax at Post2) evaluated, followed by Post1 contrasts and within-group interval changes, with Holm–Bonferroni adjustment applied within each family of secondary contrasts.

MAS, as an ordinal outcome, was analyzed using a cumulative link mixed model with logit link, fixed effects for group, time, and group-by-time interaction, and a random intercept for participant. Effects were reported as adjusted odds ratios with 95% confidence intervals, supplemented by model-derived probabilities for clinically interpretable thresholds when needed. Continuous outcomes (FMA-LE and H-reflex

indices) were analyzed using linear mixed-effects models with fixed effects for group, time, and group-by-time interaction and random intercepts for participant, with prespecified covariate adjustment for baseline outcome value, age, sex, BMI, affected side, and time since stroke. For Hmax/Mmax, a logit transformation was planned to respect the bounded nature of the ratio, with back-transformed estimated marginal means reported for interpretation. Model assumptions were evaluated using residual diagnostics. Sensitivity analyses included unadjusted models and per-protocol analyses restricted to participants meeting adherence criteria. Analyses were conducted in R (v4.2.1) using established mixed-model packages, with CONSORT-aligned reporting planned for flow, missingness, and analysis denominators.

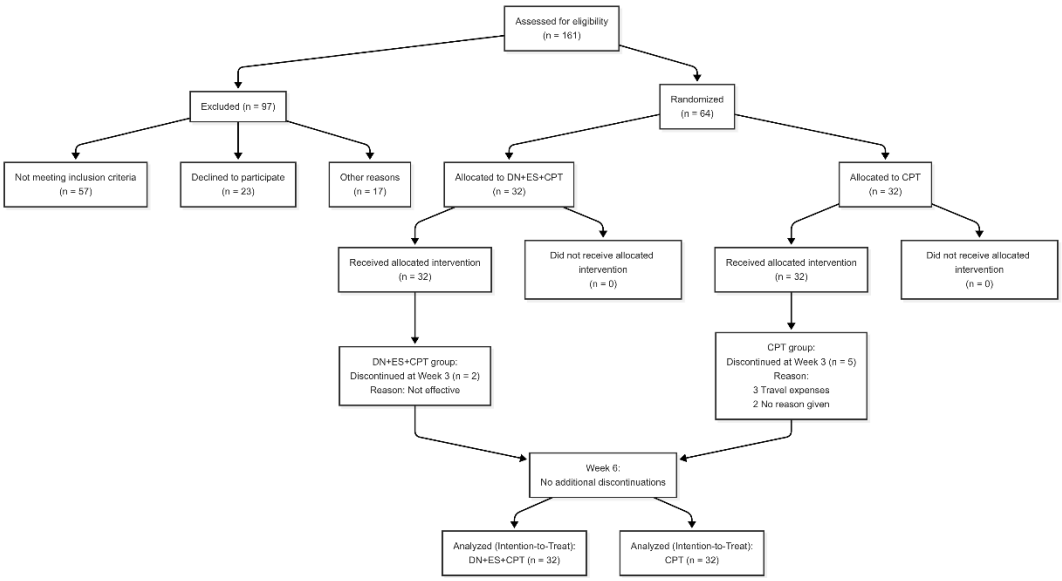
4 RESULTS

4.1 Participant flow and retention

A total of 161 individuals were assessed for eligibility; 97 were excluded (57 did not meet inclusion criteria, 23 declined participation, and 17 were excluded for other reasons). Sixty-four participants were randomized (32 to DN+ES+CPT and 32 to CPT), and all randomized participants received the allocated intervention (Figure 1). At week 3, discontinuations occurred in both groups: DN+ES+CPT (n = 2; reason: perceived lack of effectiveness) and CPT (n = 5; reasons: travel expenses [n = 3] and no reason given [n = 2]). No additional discontinuations occurred between week 3 and week 6. All participants were included in the intention-to-treat analysis as specified (Figure 1).

Figure 1

CONSORT flow diagram of participant recruitment, allocation, follow-up, and analysis.



4.2 Baseline comparability

Baseline demographic and clinical characteristics were comparable between groups, with no statistically significant between-group differences in age, anthropometrics, sex distribution, hand dominance, socioeconomic status, or education level (Table 1). Baseline outcome values were also closely aligned (Table 2), including MAS (CPT 2.754 vs DN+ES+CPT 2.803), FMA-LE (20.012 vs 19.979), and soleus Hmax/Mmax (0.580 vs 0.574), indicating adequate baseline balance for the prespecified endpoints.

Table 1

Baseline Demographic and Clinical Characteristics (n = 64)

Variable	Category	DN+ES+CPT (n = 32) Mean ± SD or n (%)	CPT (n = 32) Mean ± SD or n (%)	p-value
Age (years)		49.51 ± 6.44	50.87 ± 6.69	0.411
Height (cm)		170.73 ± 8.81	171.06 ± 9.63	0.886
Weight (kg)		78.73 ± 14.12	80.68 ± 14.28	0.584
BMI (kg/m²)		26.50 ± 5.26	27.85 ± 4.86	0.290
Sex	Female	23 (71.9%)	18 (56.2%)	0.297
	Male	9 (28.1%)	14 (43.8%)	
Hand dominance	Left	3 (9.4%)	6 (18.8%)	0.474
	Right	29 (90.6%)	26 (81.2%)	
Socioeconomic status	High	3 (9.4%)	7 (21.9%)	0.161
	Low	11 (34.4%)	14 (43.8%)	
	Middle	18 (56.2%)	11 (34.4%)	
Education level	Higher	11 (34.4%)	10 (31.2%)	0.743
	No formal	1 (3.1%)	1 (3.1%)	
	Primary	10 (31.2%)	14 (43.8%)	
	Secondary	10 (31.2%)	7 (21.9%)	

Note: Values are mean ± SD or n (%). p-values are from independent-samples t-tests (continuous variables) or chi-square tests (categorical variables), as appropriate.

4.3 Primary outcome: spasticity (MAS)

Model-based estimates showed improvement in spasticity over time in both groups, with a substantially steeper reduction in the DN+ES+CPT group (Table 2). In the CPT group, MAS decreased from 2.754 at baseline to 2.441 at week 3 and 1.707 at week 6 (ΔPost2–T0 = −1.047). In contrast, DN+ES+CPT decreased from 2.803 at baseline to 1.578 at week 3 and 0.890 at week 6 (ΔPost2–T0 = −1.913) (Table 2). Between-group contrasts confirmed statistically significant advantages for DN+ES+CPT at both follow-up time points (Table 3). The largest separation was evident by week 3 (Post1 $\beta = -0.863$, 95% CI −1.106 to −0.620, $p<0.001$) and remained significant at week 6 (Post2 $\beta = -0.816$, 95% CI −1.036 to −0.597, $p<0.001$). On the odds ratio scale derived from the ordinal mixed model, these estimates corresponded to substantially lower odds of being in higher MAS categories in the DN+ES+CPT group at week 3 (OR 0.42, 95% CI 0.33 to 0.54) and week 6 (OR 0.44, 95% CI 0.36 to 0.55) relative to CPT (Table 3). Standardized effects were large at both time points ($d \approx -1.63$ at week 3; $d \approx -1.54$ at week 6) (Table 3).

4.4 Secondary outcome: lower-limb motor function (FMA-LE)

Lower-limb motor function improved over time in both groups, with earlier and larger gains in DN+ES+CPT (Table 2). In the CPT group, FMA-LE was essentially unchanged from baseline to week 3 (20.012 to 19.979; ΔPost1–T0 = −0.033) and increased by week 6 (22.619; ΔPost2–T0 = 2.607). In the DN+ES+CPT group, FMA-LE increased from 19.979 at baseline to 22.296 at week 3 (ΔPost1–T0 = 2.317) and to 25.725 at week 6 (ΔPost2–T0 = 5.745) (Table 2). Between-group contrasts favored DN+ES+CPT at week 3 (β = 2.317, 95% CI 1.805 to 2.829, $p<0.001$; d ≈ 0.77) and increased further by week 6 (β = 3.106, 95% CI 2.280 to 3.931, $p<0.001$; d ≈ 1.03) (Table 3).

4.5 Secondary outcomes: soleus H-reflex indices

4.5.1 Reflex excitability (Hmax/Mmax)

The soleus Hmax/Mmax ratio decreased over time in both groups, with larger reductions in DN+ES+CPT at both follow-up assessments (Table 2). The CPT group decreased from 0.580 at baseline to 0.392 at week 3 and 0.371 at week 6 (ΔPost2–T0 = −0.209). DN+ES+CPT decreased from 0.574 at baseline to 0.330 at week 3 and 0.283 at week 6 (ΔPost2–T0 = −0.291) (Table 2).

Between-group contrasts showed a significant difference at week 3 (β = −0.062, 95% CI −0.093 to −0.032, $p<0.001$; d ≈ −0.36) and a smaller but statistically significant difference at week 6 (β = −0.088, 95% CI −0.165 to −0.010, $p<0.05$; d ≈ −0.51) (Table 3), consistent with a greater reduction in reflex excitability in the DN+ES+CPT arm.

4.6 H-reflex latency (timing index)

The exported H-reflex latency values decreased from baseline to week 3 in both groups and then changed minimally between week 3 and week 6 (Table 2). Between-group contrasts were not statistically significant at baseline, week 3, or week 6 (all $p\geq0.05$), with confidence intervals spanning zero at each time point (Table 3). This

outcome is therefore reported as a timing index; the current inference remains consistent with no detectable between-group timing difference attributable to DN+ES (Tables 2–3).

4.7 Adverse effects

No serious adverse events were reported during the intervention period. Minor adverse effects, specifically transient soreness and mild bruising at the needling site, were reported by four participants in the DN+ES+CPT group and resolved spontaneously. No participants discontinued treatment due to adverse events.

Table 2

Model-Based Estimated Marginal Means by Group and Time, Within-Group Change Scores

Outcome	Group	T0 Baseline	Post1 (Week 3)	Post2 (Week 6)	Δ(Post1–T0)	Δ(Post2–T0)	Δ(Post2–Post1)
MAS (ordinal)	CPT	2.754	2.441	1.707	−0.313	−1.047	−0.734
	DN+ES+CPT	2.803	1.578	0.890	−1.225	−1.913	−0.687
FMA-LE (0–34)	CPT	20.012	19.979	22.619	−0.033	2.607	2.640
	DN+ES+CPT	19.979	22.296	25.725	2.317	5.745	3.428
Soleus Hmax/Mmax (ratio)	CPT	0.580	0.392	0.371	−0.188	−0.209	−0.021
	DN+ES+CPT	0.574	0.330	0.283	−0.244	−0.291	−0.047
H-reflex latency (ms)	CPT	31.398	15.300	16.017	−16.098	−15.381	0.717
	DN+ES+CPT	31.998	16.038	16.545	−15.960	−15.453	0.507

Notes: (1) Values are model-based estimated marginal means at each time point. (2) MAS values are model derived from the ordinal mixed model and are presented for descriptive interpretation. (3) H-reflex latency was analyzed in milliseconds as exported by the acquisition software and interpreted as a timing measure; between-group differences were not detected across time points.

Table 3

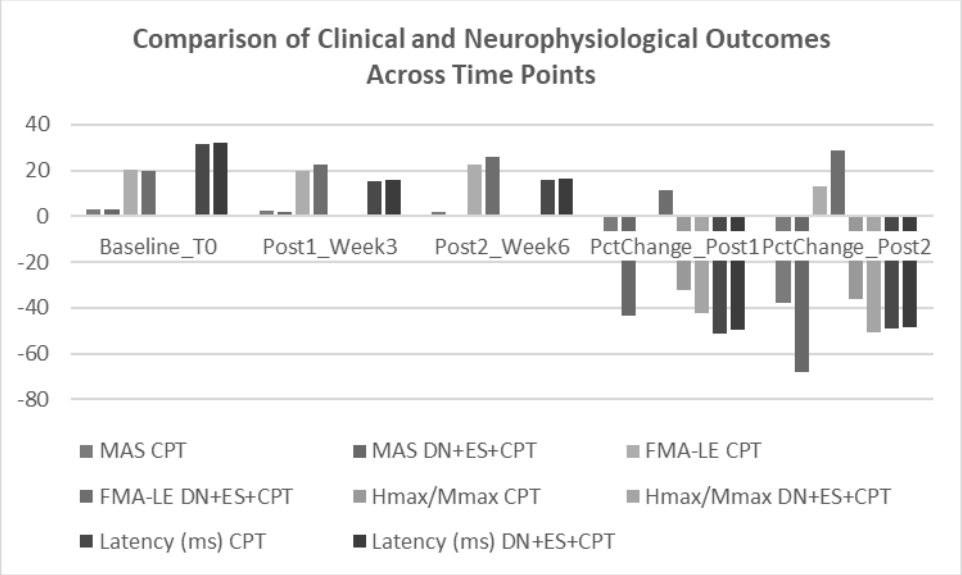
Between-Group Contrasts (DN+ES+CPT − CPT) at Each Time Point With 95% Confidence Intervals, p-Values, and Effect Sizes

Outcome	Time point	Contrast (β) (95% CI)	SE	p-value	Effect size (d)
MAS (CLMM; log-odds scale)	Baseline	0.049 (−0.046, 0.145)	0.049	ns	0.093
	Post1 (Week 3)	−0.863 (−1.106, −0.620)	0.124	<0.001	−1.633
	Post2 (Week 6)	−0.816 (−1.036, −0.597)	0.112	<0.001	−1.544
MAS (derived OR from CLMM)	Baseline	OR 1.05 (0.96, 1.16)	,	ns	,
	Post1 (Week 3)	OR 0.42 (0.33, 0.54)	,	<0.001	,
	Post2 (Week 6)	OR 0.44 (0.36, 0.55)	,	<0.001	,
FMA-LE (LMM)	Baseline	−0.033 (−0.125, 0.060)	0.047	ns	−0.011
	Post1 (Week 3)	2.317 (1.805, 2.829)	0.261	<0.001	0.772
	Post2 (Week 6)	3.106 (2.280, 3.931)	0.421	<0.001	1.034
Soleus Hmax/Mmax (LMM; contrast on ratio scale)	Baseline	−0.006 (−0.040, 0.028)	0.018	ns	−0.034
	Post1 (Week 3)	−0.062 (−0.093, −0.032)	0.015	<0.001	−0.358
	Post2 (Week 6)	−0.088 (−0.165, −0.010)	0.040	<0.05	−0.505
H-reflex latency (timing index; LMM)	Baseline	0.600 (−0.211, 1.412)	0.414	ns	0.361
	Post1 (Week 3)	0.738 (−0.070, 1.546)	0.412	ns	0.444
	Post2 (Week 6)	0.528 (−0.246, 1.301)	0.395	ns	0.318

Notes: (1) Contrasts are DN+ES+CPT − CPT. For MAS, β is the log-odds from the cumulative link mixed model (CLMM); ORs are derived from β. (2) “ns” indicates $p \geq 0.05$. Where only thresholds are available from the current output, p-values are reported as <0.001 or <0.05. (3) (3) H-reflex latency was analyzed as a timing measure (ms) as exported by the acquisition software; no statistically significant between-group differences were observed..

Figure 2

Clustered bar chart showing mean values of Modified Ashworth Scale (MAS), Fugl–Meyer Assessment–Lower Extremity (FMA-LE), Hmax/Mmax ratio, and H-reflex latency (ms) at baseline (T0), Week 3 (Post1), and Week 6 (Post2) for the CPT group and the DN+ES+CPT group. Percentage change from baseline is also presented for Post1 and Post2, illustrating greater reductions in MAS and more favorable neurophysiological changes over time, particularly in the combined intervention group.



5 DISCUSSION

5.1 Principal findings

This assessor-blinded randomized controlled trial evaluated whether integrating dry needling with intramuscular electrical stimulation into a standardized conventional physical therapy program provides incremental benefit over conventional therapy alone for chronic post-stroke lower-limb spasticity. The principal finding was that DN+ES+CPT produced substantially larger reductions in spasticity than CPT, with clear separation by week 3 and sustained through week 6. These effects were not only statistically robust but large in magnitude on standardized metrics, suggesting that DN+ES functioned as a clinically meaningful adjunct rather than a marginal add-on. In parallel, lower-limb motor function improved to a greater extent in the DN+ES arm, with

gains emerging early and continuing across the intervention period. Neurophysiologically, the DN+ES group demonstrated larger reductions in the soleus Hmax/Mmax ratio, consistent with greater down-modulation of reflex excitability under standardized testing conditions, while the exported H-reflex timing metric did not show detectable between-group differences.

5.2 Interpretation and mechanistic plausibility

The magnitude and temporal profile of the spasticity response support the interpretation that DN+ES may operate as an early "primer" within the treatment session. In practical terms, lowering tone early in the visit likely reduces mechanical resistance to dorsiflexion and tibial progression, enabling more effective delivery of the downstream active components of rehabilitation, including strengthening, balance retraining, and task-specific gait practice. This sequencing is coherent with contemporary views that spasticity reflects a multilevel disturbance in sensorimotor control rather than an isolated peripheral muscle phenomenon, and that reducing hypertonia can improve the quality of voluntary practice, particularly when plantarflexor dominance constrains stance and swing mechanics.

The observed reduction in Hmax/Mmax in the DN+ES group provides mechanistic support that the clinical tone reduction was accompanied by a favorable shift in segmental reflex gain rather than being solely attributable to altered perception of resistance. Because Hmax/Mmax is a normalized marker of the excitability of the motoneuron pool to Ia afferent input, a greater decline in this ratio is consistent with reduced responsiveness of the spinal reflex pathway that contributes to plantarflexor hyperactivity. Although reflex indices cannot fully partition neural from mechanical contributions to hypertonia, the convergence of a large MAS reduction with a directionally concordant decrease in Hmax/Mmax strengthens the plausibility of a segmental component to the observed clinical change. The absence of a detectable between-group effect on the exported H-reflex timing metric is consistent with the expectation that amplitude-based indices are more sensitive to excitability modulation than timing measures, while also highlighting the importance of verifying the definition and units used in the exported latency/timing variable prior to final submission.

5.3 Comparison with previous literature

The present pattern of findings aligns with prior work indicating that dry needling can reduce spasticity in neurological populations, with effects often most evident in the short term. However, existing evidence has frequently been limited by smaller sample sizes, heterogeneous needling protocols, inconsistent integration within structured rehabilitation, and variable reporting of functional outcomes. In that context, the current trial adds value by applying a defined six-week dose, embedding DN+ES within a standardized CPT program with equalized therapist contact time, and measuring both impairment-level and neurophysiological outcomes at multiple time points. The observation that functional improvement in FMA-LE paralleled spasticity reduction is particularly clinically relevant, as tone reduction does not necessarily translate into better motor control unless paired with sufficient task practice, progressive strengthening, and gait-focused training. Electrical stimulation is widely used in neurorehabilitation to facilitate activation and augment repetition; delivering stimulation intramuscularly through the needling needles may have amplified neuromuscular recruitment and afferent input in a way that complements the local effects of needling, contributing to a more favorable motor recovery trajectory than CPT alone.

5.4 Clinical implications and implementation considerations

From a pragmatic rehabilitation perspective, these findings support positioning DN+ES as an adjunct delivered early within the session, immediately followed by high-quality task-specific training. Such sequencing is consistent with the concept that reducing tone and reflex gain can create a therapeutic window for practicing dorsiflexor activation, weight acceptance, and controlled tibial advancement with less mechanical interference. The protocol used in this trial also has implementation advantages in resource-constrained settings: it relies on skills and equipment commonly available in outpatient rehabilitation, provided that clinicians are appropriately trained in needling techniques, screening for contraindications is rigorous, and session documentation is standardized to preserve fidelity. Importantly, benefits were achieved without serious

adverse events, and minor needling-related effects were transient and self-limited, supporting feasibility when basic safety procedures are followed.

5.6 Limitations

Several limitations should temper interpretation. First, MAS is an ordinal, rater-dependent measure and does not fully distinguish neural from non-neural components of resistance; future studies could incorporate instrumented assessments of velocity-dependent stretch responses and passive stiffness to strengthen inference. Second, participant and therapist blinding was not possible, raising the possibility of performance or expectation effects, although assessor and analyst blinding mitigated detection bias. Third, the study was single-center and followed participants for six weeks, so durability of benefit, optimal maintenance dosing, and effects on real-world mobility outcomes remain uncertain. Fourth, although the DN+ES protocol was structured, individualized muscle targeting introduces potential variability; detailed reporting of fidelity metrics (e.g., number of muscles treated, local twitch response counts, stimulation intensity achieved) is essential for replication and for exploring dose–response relationships. Finally, the H-reflex timing metric should be interpreted cautiously until the acquisition/export definition and units are confirmed, even though between-group inferences were consistently non-significant.

5.7 Future directions

Future multicenter trials with longer follow-up should evaluate whether the improvements observed here persist beyond the intervention period, whether booster sessions enhance durability, and whether changes translate into broader activity and participation outcomes such as gait speed, endurance, community ambulation, and fall risk. Mechanistic work could expand neurophysiological profiling by adding measures of reciprocal inhibition, presynaptic inhibition, and voluntary activation capacity to better characterize how DN+ES influences inhibitory control and motor output. In addition, phenotyping approaches may help identify subgroups most likely to benefit, such as

individuals with prominent plantarflexor spasticity limiting dorsiflexion, higher baseline reflex gain, or specific gait-compensation profiles.

6 CONCLUSION

In adults with chronic ischemic stroke and lower-limb spasticity, integrating dry needling with intramuscular electrical stimulation into a standardized conventional physical therapy program produced substantially greater reductions in spasticity than conventional therapy alone, with effects evident by week 3 and maintained through week 6. These clinical improvements were accompanied by greater reductions in the soleus Hmax/Mmax ratio, supporting a concurrent decrease in segmental reflex excitability, while no detectable between-group differences were observed in the exported H-reflex timing metric. The overall pattern suggests that DN+ES may pragmatically "prime" the limb for more effective task-specific practice and strengthening within routine stroke rehabilitation. Confirmation in larger multicenter trials with longer follow-up and rigorously verified neurophysiological measurement definitions is needed to establish durability, optimize dosing, and clarify which patient profiles derive the greatest functional benefit.

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Authors' Contribution

All authors contributed equally to the development of this article.

Data availability

All datasets relevant to this study's findings are fully available within the article.

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