

Randomized Clinical Trials

Adjunctive Dry Needling for Lower Extremity Function, Spasticity, and Muscle Architecture in Post-Stroke Patients: A Single-Blind, Sham-Controlled Randomized Trial

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Abstract: Spasticity significantly limits mobility in over 80% of stroke survivors. This preliminary study evaluated the efficacy of adjunctive dry needling (DN) combined with neurorehabilitation on lower extremity function, mobility, spasticity, and muscle architecture compared with sham treatment. In this single-blind, sham-controlled trial, 24 post-stroke patients were randomized to receive either DN plus neurorehabilitation or sham DN plus neurorehabilitation (n=12 each) over 4 weeks. Outcomes were assessed at baseline, post-treatment, and 1-month follow-up using the Fugl-Meyer Assessment–Lower Extremity (FMA-LE), Timed Up and Go (TUG), Modified Ashworth Scale (MAS), and medial gastrocnemius ultrasonography. The DN group showed significantly greater improvement in lower extremity motor function and mobility than the sham group, demonstrated by larger gains in FMA-LE scores and greater reductions in TUG time (both $p < 0.001$). MAS category distributions also differed significantly between groups immediately after treatment ($p = 0.025$) and at 1-month follow-up ($p = 0.014$). However, these findings should be interpreted cautiously because MAS is an ordinal measure. No meaningful between-group differences were observed in medial gastrocnemius muscle thickness or pennation angle. Adjunctive dry needling with neurorehabilitation yielded greater functional recovery than sham treatment in post-stroke patients. However, this was a small preliminary trial with short follow-up duration, and the findings should be interpreted cautiously. No short-term changes were observed in medial gastrocnemius muscle architecture. Dry needling may represent a useful adjunct in post-stroke rehabilitation, although larger studies with longer follow-up are needed.

Keywords: Stroke, Dry Needling, Spasticity, Lower Extremity, Medical Rehabilitation.

1. Introduction

Stroke is a neurological disorder caused by the interruption of blood flow to the brain, which has a significant impact on global mortality [1–3]. Globally, there are approximately 12.2 million new incident cases of stroke annually [4]. In Indonesia, the incidence of stroke is estimated at 247.79 cases per 100,000 population, with prevalence increasing from 7 per thousand in 2013 to 10.9 per thousand in 2018. At RSUD Dr. Saiful Anwar Malang, stroke has also consistently been one of the top ten most common referral cases [4, 5].

More than 75% of stroke survivors experience disability, and 80% of them suffer from motor dysfunction requiring intensive rehabilitation [6]. One of the most frequently encountered complications is spasticity (reaching a 60% prevalence), which

triggers increased lower extremity muscle tone, contractures, and pain [7–9]. This motor dysfunction leads to impaired balance and gait patterns, significantly limiting patients' activities of daily living (ADL) [10–12]. The decline in lower extremity function necessitates valid evaluation instruments, such as the Fugl-Meyer Assessment-Lower Extremity (FMA-LE) for motor function levels and the Timed Up and Go (TUG) test for functional mobility [13, 14]. Furthermore, post-stroke immobilization causes atrophy and changes in muscle architecture—such as fascicle length, pennation angle, and muscle thickness—which further exacerbate muscle weakness [15, 16].

Conventional neuro-restorative rehabilitation is crucial but often requires a lengthy period [7]. As a novel interventional modality, dry needling (DN) targeting myofascial trigger points has been proposed to reduce spasticity and pain through neurophysiological mechanisms [17, 18]. Several studies have reported the potential of dry needling in improving gait function and muscle structure during subacute and chronic phases [19, 20]. However, current evidence remains limited and heterogeneous, with previous studies showing inconsistent findings regarding the magnitude and durability of DN effects on spasticity and functional outcomes [21–23]. Furthermore, systematic reviews have highlighted methodological limitations, including small sample sizes and short follow-up periods [24–26]. Nevertheless, the integration of dry needling into routine clinical practice in Indonesia remains limited. Therefore, this study aimed to compare the effects of dry needling plus neurorehabilitation with sham dry needling plus neurorehabilitation on FMA-LE scores, TUG time, spasticity, and muscle architecture in post-stroke patients at RSUD Dr. Saiful Anwar Malang, assessed at baseline, post-intervention, and at 1-month follow-up.

2. Materials and methods

Study Design and Ethics

This study was designed as a single-blind, parallel-group, sham-controlled randomized controlled trial. Ethical approval was obtained from the Ethics Committee of RSUD Dr. Saiful Anwar Malang, Indonesia (400/001/K.3/102/2026). All participants were informed about the study procedures and provided written informed consent before enrollment. The trial was registered in the Indonesian Clinical Research Registry (INA-E9FFDE0) and conducted in accordance with the CONSORT statement.

Participants

Clinical outcomes were assessed at three time points: baseline, post-intervention (week 4), and 1-month follow-up. The study population consisted of post-stroke patients with lower extremity dysfunction and spasticity treated at the Medical Rehabilitation Installation of RSUD Dr. Saiful Anwar Malang. Twenty-four eligible participants were recruited and randomly assigned in a 1:1 ratio to the intervention or control group using sealed opaque envelopes for concealed allocation.

Inclusion criteria were first-ever hemiplegic patients due to ischemic or hemorrhagic stroke beyond the acute phase, aged 18–60 years, able to walk independently for more than 10 meters with a Functional Ambulation Classification score of at least 3, presenting with ankle plantarflexor spasticity of more than grade 1 on the Modified Ashworth Scale, and not taking antispasmodic medication within the previous 3 months. Exclusion criteria included ankle joint contracture, coagulation disorders, anticoagulant therapy, severe hypertension, neuropathic pain, and local infection at the intervention site.

Intervention

The intervention group received dry needling in combination with neurorehabilitation, whereas the control group received sham dry needling plus the same neurorehabilitation program. Both groups underwent neurorehabilitation twice weekly for 4 weeks. Dry needling was performed by a certified specialist using sterile, single-use filiform needles (0.30 mm × 50 mm, MYONIDEL, Indonesia) applied to the medial and lateral heads of the gastrocnemius muscle with the patient in the prone position and the ankle hanging over the edge of the bed. Needles were inserted to a depth of 15–30 mm using a fast-in, fast-out technique for 1 minute per point during the 1st, 3rd, 5th, and 7th rehabilitation sessions. With respect to the lateral division of the gastrocnemius, a cushion was positioned beneath the participant's limb, and the needle was advanced at an estimated distance of 2 cm lateral from the central locus of the proximal segment of an imaginary trajectory extending from the calcaneal region to the popliteal fold. In relation to the medial division, the insertion locus was identified approximately 2 cm medial to the distal one-third of the identical trajectory (Figure 1).

In the sham group, a needle guide was placed on the skin surface without muscle penetration. Sham procedures were conducted using the same patient positioning, treatment duration, clinical environment, and therapist-patient interaction as the active intervention to help maintain participant blinding. Owing to the nature of the intervention, therapists administering dry needling could not be blinded to treatment allocation.

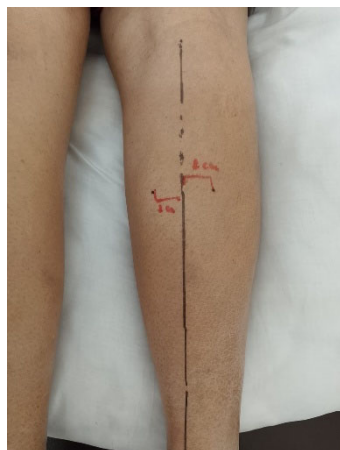


Figure 1. Dry needling application sites

Outcome Measures

The primary clinical measures included FMA-LE for lower extremity motor function, TUG for functional mobility, and MAS for plantarflexor spasticity. Musculoskeletal ultrasonography was used to assess medial gastrocnemius muscle thickness and pennation angle. During ultrasonographic assessment, participants were positioned prone with the feet hanging off the bed and stabilized in maximal plantar flexion using an orthosis. A 5–10 MHz linear transducer was placed at the midpoint of the medial gastrocnemius muscle belly with minimal pressure to avoid tissue compression (Figure 2). All ultrasonographic assessments were performed by the same assessor using a standardized measurement procedure. Each measurement was obtained twice, and the mean value was used for analysis. Muscle thickness was defined as the distance between the superficial and deep aponeuroses, whereas pennation angle was measured at fascicle insertion into the deep aponeurosis.



Figure 2. Ultrasonographic gastrocnemius muscle measurements

Statistical Analysis

Sample size was calculated separately for each dependent variable, and the largest estimate was adopted. The required sample size was 11 participants per group and was increased by 10% to account for possible attrition, yielding a final target of 12 participants per group. The required sample size was determined using the following formula: $n_1 = ((\sigma_1^2 + \sigma_2^2/\kappa)(Z_{1-\alpha/2} + Z_{1-\beta})^2) / \Delta^2$

Continuous outcomes were analyzed using repeated-measures analysis of variance (RM-ANOVA) to assess changes over time. Post hoc pairwise comparisons between time points were performed using Bonferroni correction. Mean change scores were calculated for each measurement period and compared between groups using independent-samples t-tests. MAS, as an ordinal outcome, was summarized as frequencies and percentages at each time point using available cases. Between-group differences at post-intervention (T1) and 1-month follow-up (T2) were analyzed using the Mann–Whitney U test. Because MAS is an ordinal measure, effect sizes for this outcome were not calculated using Cohen's d. Effect sizes for between-group comparisons were interpreted using Cohen's benchmarks: <0.2, no effect; 0.2–0.5, small effect; 0.5–0.8, moderate effect; and >0.8, large effect.

3. Results

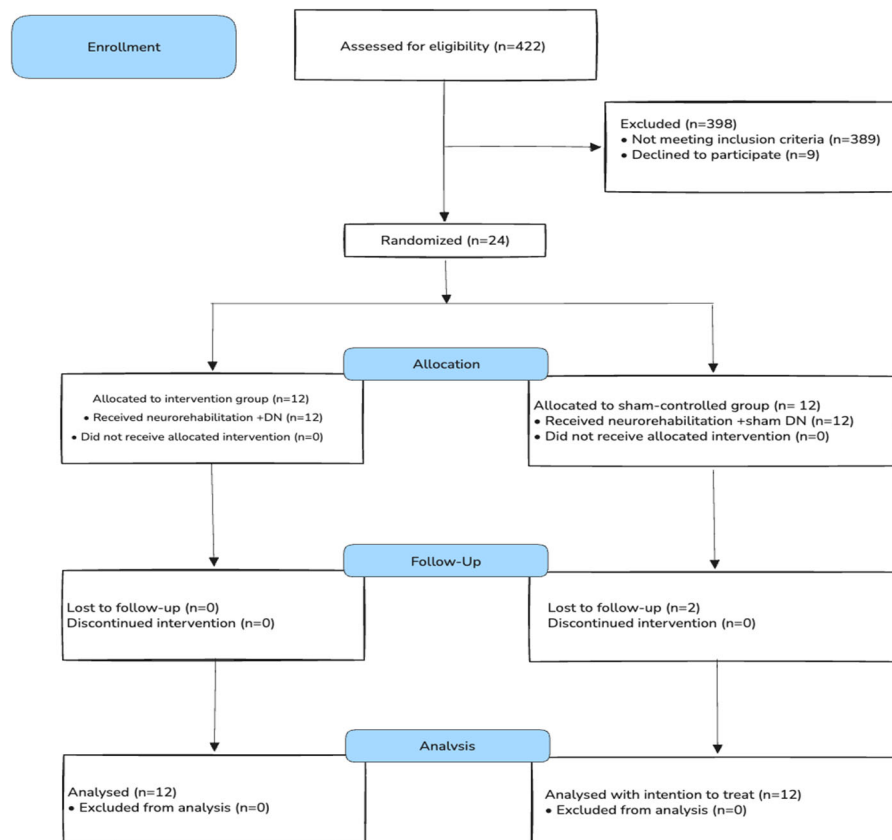
Participant Flow and Baseline Characteristics

Of 422 patients screened, 33 met the eligibility criteria, and 24 consented to participate and were randomized. All participants allocated to the intervention group received dry needling plus neurorehabilitation. All participants in the dry needling group completed the allocated intervention. In the sham group, 10 participants received sham dry needling plus neurorehabilitation as allocated, whereas 2 did not receive the allocated intervention. In the sham group, 10 participants completed all assessments, while 2 did not complete follow-up due to reasons unrelated to the intervention, including inability to attend sessions and unrelated medical hospitalization. No intervention-related adverse events were reported in either group during the study period. All participants who completed the corresponding assessments were included in the analyses of continuous outcomes. Because MAS data at T1 and T2 were unavailable for the two sham participants who did not complete follow-up, MAS category distributions at these time points are presented using available cases only.

The participant flow is presented in Figure 3. Baseline analysis showed no statistically significant differences between groups in demographic or clinical variables, including age, sex, stroke onset, body mass index, baseline muscle strength, hemiplegic side, stroke type, FMA-LE score, TUG time, MAS category, muscle thickness, and pennation angle (**Table 1**). These findings indicate that randomization achieved comparable baseline conditions between groups.

Table 1. Baseline Characteristics of Research Subjects

Variable	Category / Unit	Dry Needling (n = 12)	Sham (n = 12)	p-value
Age	Mean (SD) Years	52.5 (7.52)	52.33 (5.77)	0.952 ^a
Gender	Male n (%)	6 (50.0%)	6 (50.0%)	1.000 ^b
	Female n (%)	6 (50.0%)	6 (50.0%)	
Stroke Onset	Mean (SD) Months	7.67 (9.16)	6.00 (6.54)	0.613 ^a
BMI	Mean (SD) kg/m ²	22.70 (2.68)	24.67 (4.74)	0.223 ^a
MMT	Grade 2 n (%)	1 (8.3%)	0 (0.0%)	0.665 ^b
	Grade 3 n (%)	1 (8.3%)	1 (8.3%)	
	Grade 4 n (%)	3 (25.0%)	5 (41.7%)	
	Grade 5 n (%)	7 (58.3%)	6 (50.0%)	
Hemiplegic Side	Left n (%)	6 (50.0%)	6 (50.0%)	1.000 ^b
	Right n (%)	6 (50.0%)	6 (50.0%)	
Stroke Type	Ischemic n (%)	9 (75.0%)	8 (66.7%)	0.653 ^b
	Hemorrhagic n (%)	3 (25.0%)	4 (33.3%)	
FMA Score	Mean (SD)	23.00 (1.59)	22.00 (1.41)	0.118 ^a
TUG Time	Mean (SD) Seconds	33.26 (10.99)	31.01 (14.39)	0.671 ^a
MAS Score	Grade 2 n (%)	5 (41.7%)	6 (50.0%)	0.865 ^b
	Grade 3 n (%)	4 (33.3%)	4 (33.3%)	
	Grade 4 n (%)	3 (25.0%)	2 (16.7%)	
Muscle Thick- ness	Mean (SD) mm	11.53 (2.67)	12.15 (4.12)	0.671 ^a
Pennation Angle	Mean (SD) Degrees	18.41 (3.23)	16.16 (2.55)	0.072 ^a

(Note: ^a = Independent t-test; ^b = Chi-square test)**Figure 3.** CONSORT flow diagram of participant progress through the trial

Lower Extremity Motor Function

Both groups demonstrated improvement in FMA-LE scores over time; however, gains were significantly greater in the dry needling group than in the sham group (Table 2). This difference was evident both immediately after the intervention and at 1-month follow-up ($p < 0.001$). The total change from baseline to follow-up in the dry needling group corresponded to moderate-to-large effect sizes (Cohen's $d = 0.64$ – 1.43). Figure 4 shows changes in motor performance over time in each group.

Table 2. Comparison of FMA-LE Score Changes Between Groups

Measurement Period	Dry Needling		Sham Mean Change (SD)	Sham p-value (Within)	p-value (Between Groups)	Effect Size (Cohen's d)
	Mean Change (SD)	p-value (Within)				
T1 - T0	3.583 (0.379)	<0.001	3.000 (0.447)	<0.001	<0.001	1.43
T2 - T1	3.417 (0.288)	<0.001	3.200 (0.467)	<0.001	<0.001	0.64
T2 - T0	7.000 (0.590)	<0.001	6.200 (0.573)	<0.001	<0.001	1.41

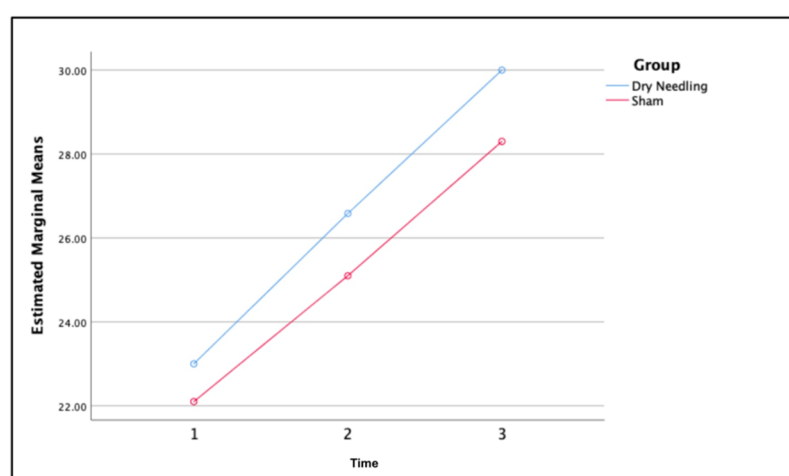


Figure 4. Changes in FMA-LE scores over time.

Functional Mobility

Functional mobility, assessed using the TUG test, also improved in both groups, with a greater reduction in completion time in the dry needling group (Table 3). From baseline to follow-up, the average TUG reduction was 12.49 seconds in the dry needling group compared with 10.49 seconds in the sham group. Between-group differences were significant across all observation periods, with a large overall effect size. In addition to statistical significance, the magnitude of TUG improvement suggests potentially meaningful enhancement in functional mobility during post-stroke rehabilitation.

Table 3. Comparison of TUG Time Changes Between Groups

Measurement Period	Dry Needling Mean Change (SD)	Dry Needling p-value (Within)	Sham Mean Change (SD)	Sham p-value (Within)	p-value (Between Groups)	Effect Size (Cohen's d)
T1 - T0	-7.665 (0.975)	<0.001	-6.390 (0.703)	<0.001	<0.001	1.46
T2 - T1	-4.833 (0.706)	<0.001	-4.100 (1.749)	<0.001	<0.001	0.54
T2 - T0	-12.498 (0.838)	<0.001	-10.490 (2.188)	<0.001	<0.001	1.16

Spasticity

Spasticity severity was assessed using MAS as an ordinal outcome. Significant between-group differences in MAS category distribution were observed at post-intervention ($U = 26.500$, $p = 0.025$) and at 1-month follow-up ($U = 23.000$, $p = 0.014$) (**Table 4**). However, because MAS is an ordinal measure, the direction and magnitude of the effect should be interpreted cautiously.

Table 4. Comparison of MAS Scores Between Groups at T1 and T2

Measurement Time	MAS Category	Dry Needling n (%)	Sham n (%)	Mann-Whitney U Value	p-value
T1 (Post-intervention)	Grade 0	0 (0.0)	1 (10.0)	26.500	0.025
	Grade 1	1 (8.3)	3 (30.0)		
	Grade 1+	2 (16.7)	4 (40.0)		
	Grade 2	5 (41.7)	1 (10.0)		
	Grade 3	4 (33.3)	1 (10.0)		
	Grade 4	0 (0.0)	0 (0.0)		
T2 (1-Month Follow-Up)	Grade 0	1 (8.3)	4 (40.0)	23.000	0.014
	Grade 1	2 (16.7)	4 (40.0)		
	Grade 1+	3 (25.0)	1 (10.0)		
	Grade 2	1 (8.3)	1 (10.0)		
	Grade 3	1 (8.3)	0 (0.0)		
	Grade 4	0 (0.0)	0 (0.0)		

(Note: Two participants in the sham group were lost to follow-up at T1 and T2; percentages for the sham group were calculated using the number of observed cases at each time point ($n = 10$). Higher MAS grades indicate greater spasticity. Between-group comparisons at each time point were performed using the Mann-Whitney U test.)

Muscle Architecture

In contrast to the functional outcomes, ultrasonographic measures of medial gastrocnemius structure did not demonstrate significant remodeling. No statistically significant differences were found in muscle thickness or pennation angle either within or between groups over time ($p > 0.017$ after Bonferroni correction), with effect sizes only ranging from small to medium (0.26 to 0.76) (**Table 5**).

Table 5. Comparison of Muscle Thickness Changes Between Groups

Measurement Period	Dry Needling Mean Change (SD)	Dry Needling p-value (Within)	Sham Mean Change (SD)	Sham p-value (Within)	p-value (Between Groups)	Effect Size (Cohen's d)
T1 - T0	-0.575 (0.693)	1.000	-0.240 (1.652)	1.000	1.000	0.26
T2 - T1	0.208 (0.679)	1.000	-1.030 (1.765)	1.000	1.000	0.53
T2 - T0	-0.367 (0.757)	1.000	-1.270 (1.492)	1.000	0.947	0.76

A similar phenomenon was also observed in the pennation angle parameter, where the intervention did not trigger significant changes ($p > 0.017$) (**Table 6**). Although mean pennation angle values fluctuated, the large standard deviations suggested substantial inter-individual variability. Overall, the clinical improvements observed in this study were not accompanied by measurable short-term structural changes in the gastrocnemius muscle.

Table 6. Comparison of Pennation Angle Changes Between Groups

Measurement Period	Dry Needling Mean Change (SD)	Dry Needling p-value (Within)	Sham Mean Change (SD)	Sham p-value (Within)	p-value (Between Groups)	Effect Size (Cohen's d)
T1 - T0	13.333 (12.266)	0.901	0.200 (0.573)	1.000	0.985	1.35
T2 - T1	-12.917 (12.297)	0.948	0.500 (0.671)	1.000	1.000	1.19

T2 - T0	0.417 (1.048)	1.000	0.700 (0.496)	0.574	1.000	0.65
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4. Discussion

This study showed that adjunctive dry needling combined with neurorehabilitation produced greater improvements in lower extremity motor function and functional mobility than sham dry needling plus neurorehabilitation in post-stroke patients. Because there were no significant baseline differences between groups, the observed post-treatment differences are more likely attributable to the intervention rather than to confounding clinical characteristics [24, 25, 27, 28]. Participants were generally in the late subacute to chronic phase after stroke, when spontaneous neurological recovery is typically limited; therefore, the observed improvements are more plausibly related to the therapeutic effects of neurorehabilitation and dry needling [26, 29].

The superior gains in FMA-LE and TUG outcomes in the dry needling group are consistent with previous studies suggesting that dry needling may enhance motor performance, walking ability, and functional outcomes after stroke [24, 25, 27, 30]. A plausible explanation is that reduced spasticity lowers passive soft-tissue resistance and improves afferent input to the central nervous system, thereby facilitating more efficient motor control and better ankle mechanics during gait. The persistence of motor gains at 1-month follow-up may reflect the combined effect of repeated dry needling and concurrent neurorehabilitation, which may have supported retention of newly acquired motor function. However, a recent study by Okhravi et al. reported limited or mainly acute effects, suggesting that treatment dosage, protocol characteristics, and study methodology may influence the extent of benefit observed across studies [28].

This study also identified significant between-group differences in MAS category distribution after the intervention and at follow-up. These findings suggest that dry needling may influence plantarflexor spasticity when delivered as an adjunct to conventional neurorehabilitation, which is broadly in line with previous reports on post-stroke spasticity and motor outcomes [29, 31]. Mechanistically, dry needling may alter peripheral nociceptive input and spinal motor neuron excitability, thereby reducing resistance to passive stretch and facilitating more efficient movement during rehabilitation [30]. In addition, the sustained difference observed at follow-up may indicate that dry needling-related neuromodulatory effects are better maintained when combined with ongoing therapeutic exercise and stretching [27, 30, 32]. Support for this proposed mechanism comes from previous studies (e.g., Al Amin 2024, 2026; Fakhari et al. 2017), which reported reductions in spasticity accompanied by changes in H-reflex parameters, suggesting decreased spinal motor neuron excitability following dry needling interventions. However, these mechanistic interpretations remain theoretical in the present study, as no direct neurophysiological measures (e.g., H-reflex, EMG, or corticospinal excitability) were collected to confirm changes in neural activity [21, 33, 34]. Nevertheless, because MAS is an ordinal clinical scale and MAS data at T1 and T2 were unavailable for 2 participants in the sham group, the magnitude and direction of this effect should be interpreted cautiously and in accordance with the final verified category distribution [29, 31].

From a rehabilitation perspective, these findings suggest that dry needling may serve as a useful adjunct to multidisciplinary post-stroke rehabilitation programs. The observed improvements in plantarflexor spasticity, lower extremity motor function, and functional mobility may facilitate participation in gait training and task-oriented rehabilitation by reducing movement limitations and improving motor performance. Because lower-limb spasticity is a common barrier to mobility and func-

tional independence after stroke, interventions that enhance walking-related function may contribute to broader rehabilitation goals, including improved activity, participation, and quality of life. Therefore, dry needling may be considered as a complementary intervention within comprehensive neurorehabilitation programs rather than as a stand-alone treatment.

Despite clear clinical improvement, no significant changes were detected in gastrocnemius muscle thickness or pennation angle. This discrepancy suggests that short-term functional gains may primarily reflect neuromodulation and improved motor control rather than rapid morphological remodeling of chronically spastic muscle [24, 25]. In long-standing spastic muscle, fibrosis and extracellular matrix changes may already be established and may require a longer intervention period before measurable architectural adaptation becomes apparent. The high variability in ultrasonographic parameters further suggests considerable inter-individual differences in biomechanical response and may also indicate limited measurement precision and reduced statistical power due to the modest sample size. Furthermore, the marked fluctuation in pennation angle values over time, including the apparent increase followed by near-complete reversal, may reflect a combination of measurement variability inherent to ultrasonographic assessment, biological variability among participants, the limited sample size, and the relatively short follow-up duration. Therefore, these findings should be interpreted cautiously and require confirmation in larger studies with longer observation periods.

Several limitations should be acknowledged. First, both the intervention period and the follow-up duration were relatively short, which may have limited the ability to detect longer-term structural adaptation. Second, the sample size was modest, potentially reducing statistical power, particularly for ultrasonographic outcomes. In addition, MAS data were missing for two participants in the sham group at follow-up, which may have affected the interpretation of spasticity outcomes. Third, complete double blinding was not feasible because the therapist administering dry needling was aware of treatment allocation and participant blinding may not have been fully achieved due to potential differences in sensory perception between real and sham dry needling. Finally, variability in stroke chronicity among participants may have contributed to heterogeneity in fibrosis severity and neuroplasticity potential. No direct neurophysiological measures were collected to confirm the proposed mechanisms of action (e.g., H-reflex or EMG changes). Overall, the present findings support the potential role of dry needling as an adjunctive intervention in post-stroke neurorehabilitation, particularly for improving lower extremity function, mobility, and spasticity, although larger studies with longer follow-up are still required to confirm the durability of these effects [24–32].

5. Conclusions

In this randomized, sham-controlled trial, adding dry needling to a neurorehabilitation program was associated with greater improvement in lower extremity motor function and functional mobility than sham treatment in subacute to chronic post-stroke patients. Significant between-group differences were also observed in spasticity status as measured by MAS. However, no significant short-term changes were detected in gastrocnemius muscle thickness or pennation angle. These findings provide preliminary evidence for dry needling as an adjunct to post-stroke rehabilitation, but should be interpreted cautiously given the small sample size and short follow-up, and require confirmation in larger trials.

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original draft preparation, F.S.; writing—review and editing, D.I.L., V.P.A., H.H., I.D., A.Z. and R.S. All authors have read and agreed to the published version of the manuscript.

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Institutional Review Board Statement: This study obtained ethical approval (Ethical Clearance) from the Ethics Committee of RSUD Dr. Saiful Anwar Malang (Ethical Approval No. 400/001/K.3/102/2026) and was conducted in accordance with the Declaration of Helsinki.

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study. Written informed consent has been obtained from the patients to publish this paper.

Data Availability Statement: The data presented in this study are not publicly available due to ethical and privacy restrictions involving patient data but are available from the corresponding author on reasonable request.

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

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