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Effects of dry needling intervention on lower limb dysfunction after stroke: study protocol for a randomised controlled trial

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ABSTRACT

Introduction Lower limb dysfunction is among the common sequelae of patients who had a poststroke and often results in the reduction of the quality of life. This study aims to assess the short and interim-term efficacy of dry needling (DN) intervention on lower extremity function, balance and gait in lower limb dysfunction after stroke.

Methods and analysis This protocol entails an assessor and statistician-blinded, single-centre study with a randomised controlled trial. Forty-four patients who had a poststroke will be randomly allocated (1:1) to either the conventional treatment group (n=22) or the DN group (n=22). The conventional treatment group will receive conventional rehabilitation treatment once a day for 40 min each time. The treatment will be performed five times a week for 2 weeks. In the DN group, participants will be treated with DN on the basis of the conventional treatment. The intervention will be performed thrice a week for 2 weeks. The primary outcome that determines the efficacy of lower limb dysfunction will be the change in the Fugl-Meyer Assessment of Lower Extremity scale. The secondary indicators include the range of motion of knee and ankle joints, limits of stability, modified Clinical Test of Sensory Interaction on Balance, Timed Up and Go test, Modified Ashworth Scale and Barthel Index. Results will be evaluated at baseline, at 24 hours after intervention, at 2 weeks after intervention and at 3-month follow-up. Data will be released after the completion of the study. Adverse events will be reported.

Ethics and dissemination The experiment was approved by the Ethical Committee of Shanghai Tong Ren Hospital in October 2021 (approval number: 202105702). The results of this study will be published in peer-reviewed journals.

Trial registration number ChiCTR2000040754.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This study will focus on myofascial trigger points (MTrPs) of the quadriceps, in addition to focusing on MTrPs of the gastrocnemius to examine the efficacy of dry needling on lower limb dysfunction after stroke.
⇒ This study will explore if performing more than one session weekly (current recommendations) may have any potential adverse effects.
⇒ This trial will be the short intervention period because of short hospital stays.
⇒ There will be no sham control group.

INTRODUCTION

Stroke is a serious clinical disease and is the main cause of long-term disability in patients.[1] Stroke results in lower limb motor dysfunction, abnormal posture control, increased muscle tone and decreased balance function.[2 3] Lower limb dysfunction is a factor that directly affects the rehabilitation of patients who had a poststroke and is also the focus of rehabilitation treatment.[4] These clinical manifestations often affect the daily life of patients who had a poststroke, as well as their ability to walk; they reduce the quality of life and increase the economic burden on family and society.

Myofascial trigger points (MTrPs) are hyperirritable painful spots in taut bands of skeletal muscles. 'Spot tenderness', 'referred pain' and 'local twitch response' are the three most popular diagnosis criteria of MTrPs.[5] They have a high prevalence in patients who had a poststroke and are moderately associated with pain and function.[6] MTrPs can cause sensory symptoms and dyskinesias. Sensory symptoms associated with MTrPs include referred pain and hyperalgesia, whereas dyskinesias include increased muscle fatigue or increased synergistic activation of antagonist muscles.[7] Inactivating the hypersensitive points can alleviate the sensory symptoms and dyskinesias.

Dry needling (DN) is a minimally invasive technique that uses a disposable sterile stainless steel needle to penetrate the skin and to directly stimulate MTrPs.[8] It is one of the effective ways to inactivate MTrPs. One study found that regeneration would begin on day 3 after DN caused muscle fibre damage and intramuscular nerve damage. Satellite cells

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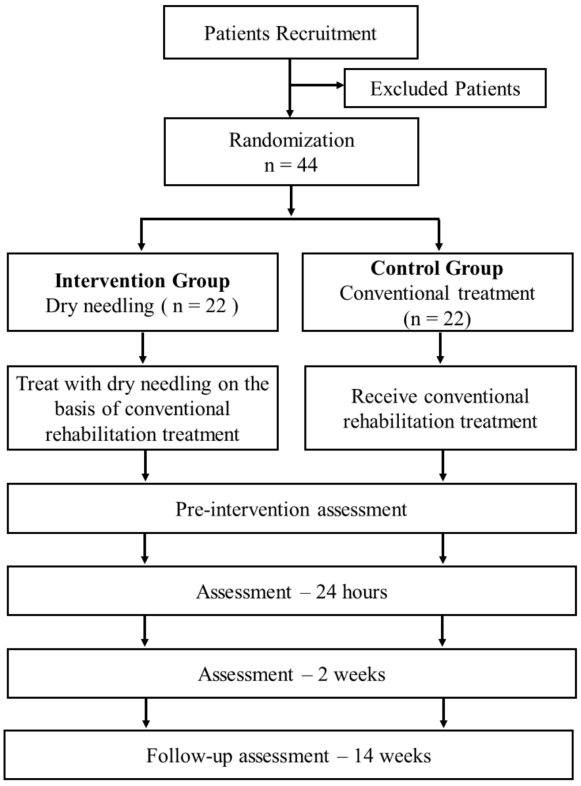

Figure 1 Flow chart of the trial shows the patient recruitment, intervention and assessment.

repair muscle damage by activating muscle fibres and triggering rounds of muscle degeneration followed by regeneration.[9] In previous studies, the effect of DN application on upper limb dysfunction in patients who had a poststroke has been observed.[10 11] Mendigutia-Gómez *et al*[12] found that DN can reduce local pressure pain sensitivity and enlarge the shoulder's range of motion in patients who had a poststroke after 3-week DN application (once per week). Lu *et al* found that DN intervention on the trigger points of the patients' superficial flexor muscle leads to the immediate increase in the active range of motion, the reduction of finger spasticity and the decrease in the frequency of motor unit action potential (MUAP) spikes.[13] In addition, DN application for the upper extremity in patients who had a poststroke appears to be cost-effective.[14 15] DN has benefits on patients' function, quality of life in the treatment of upper limb dysfunction after stroke, which is related to the rationale of lower limbs in this study, but has not been adequately validated.[11]

A meta-analysis suggests a positive effect of DN for decreasing spasticity on lower limb dysfunction after stroke (moderate evidence) while the effect on motor function is inconclusive when DN applied once in one muscle, which may limit the applicability of the results.[16] New randomised controlled trials are needed to investigate the effect of a greater number of DN applications on function, balance and gait in patients with lower limb dysfunction. Previous studies have focused more on the MTrPs in calf muscles of patients who had a poststroke. Salom-Moreno *et al* conducted a DN intervention on the MTrPs of gastrocnemius and tibialis anterior muscle of patients who had a poststroke and found that spasticity decreased in patients with poststroke, and plantar pressure changed, that is, the support surface increased, and the mean pressure decreased.[17] Another research found that after DN intervention on gastrocnemius medialis, lateralis and soleus muscles, the individuals showed short-term effects, that is, reduced spasticity and improved gait.[18] Ghannadi *et al* performed DN intervention on the gastrocnemius of patients after stroke. The passive ankle range of motion, walking speed and activities of daily living significantly improved.[19]

However, no studies have observed the effect of DN intervention performed on the MTrPs of the quadriceps muscle on the lower limb dysfunction of patients who had a poststroke. It has been reported that 40%–68% of patients who had a poststroke have abnormal gait related to knee hyperextension. From the perspective of knee kinematics analysis, the causes of knee hyperextension include knee extensor muscle weakness or spasm, gastrocnemius spasm or proprioception disorder. Simons[20] found that the quadriceps knee extension dysfunction may be related to trigger points.

We hypothesise that DN intervention on MTrPs in quadriceps femoris, gastrocnemius and tibialis anterior muscles may have beneficial effects on lower extremity function, range of motion, balance, gait and activities of daily living in patients who had a poststroke. Moreover, this study will analyse if performing DN sessions in the same MTrPs more than once weekly, which is the recommended practice to respect tissue repair, may have any adverse effects. This present trial aims to assess the short, interim-term efficacy, safety when performing DN more than once weekly on the MTrPs of the quadriceps femoris, gastrocnemius and tibialis anterior muscles on lower extremity function, balance and gait in lower limb dysfunction after stroke.

METHODS

Study design

An assessor and statistician-blinded, single-centre study with a randomised controlled design will be conducted according to Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines at one municipal tertiary hospital (Shanghai Tong Ren Hospital). Forty-four stable patients who had a poststroke will be recruited and randomly assigned to a conventional treatment group or a DN group at a ratio of 1:1. The flow chart of the trial is displayed in figure 1. The experimental process and evaluation are listed in table 1. This trial has used the SPIRIT reporting guidelines.[21] The SPIRIT Checklist is attached as online supplemental file 1. This study commenced in October 2021 at Tong Ren

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Table 1 Study design schedule

Period	Screening	Baseline assessment	Assessment (24 hours)	Assessment (2 weeks)	Assessment (14 weeks)
Inclusion and exclusion criteria	√				
Informed consent	√				
Physical examination	√				
Medical history	√				
Allocation	√				
FMA-LE		√	√	√	√
ROM		√	√	√	√
MMAS		√	√	√	√
mCTSIB		√	√	√	√
LOS		√	√	√	√
TUG		√	√	√	√
BI		√	√	√	√
SAS and SDS		√		√	√
Patient compliance		√	√	√	√
Dropout reasons			√	√	√
Adverse events			√	√	√

BI, Barthel Index; FMA-LE, Fugl-Meyer Assessment of Lower Extremity; LOS, limits of stability; mCTSIB, modified Clinical Test of Sensory Interaction on Balance; MMAS, Modified Modified Ashworth Scale; ROM, range of motion; SAS, Self-rating Anxiety Scale; SDS, Self-rating Depression Scale; TUG, Timed Up and Go test.

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Patient and public involvement

This will be a randomised controlled trial inspired by physical therapist awareness of limited choices for treating patients with MTrPs, and desire by patients for effective treatments. Patients and the public will not further be involved in the design or conduct of the study. Participants will be acknowledged at the end of publication.

Participant recruitment

Participants will be recruited from the Department of Rehabilitation Medicine at Shanghai Tong Ren Hospital. All patients who had a stroke will be screened for eligibility by their physiotherapist. Participants who meet the inclusion criteria and express interest in participating in the trial will be introduced to the trial protocol by the researchers in writing or verbally.

Inclusion criteria

1. Diagnosis of unilateral stroke was made according to neurologists using the WHO stroke diagnostic criteria and combined with neuroimaging data.[22]
2. At least 3 months after stroke.
3. No further deterioration of neurological deficits.
4. Able to walk (auxiliary equipment available).
5. No cognitive impairment with Mini-Mental State Examination score of ≥25.[23]
6. Volunteered to participate in this study and signed the informed consent form.

Exclusion criteria

1. Recurrent stroke (ischaemic and/or haemorrhagic).
2. Botulinum toxin injections to the lower extremities in the past 3 months.
3. Severe cognitive impairment or inability to communicate.
4. Unstable hypertension.
5. Lower extremity fracture.
6. With fear of needles.

Termination criteria

1. Serious adverse events (SAEs).
2. The need for additional treatments.
3. Voluntary withdrawal.
4. Non-compliance.
5. Continued participation in the experiment is inappropriate, as judged by investigators.

Randomisation, concealment of allocation and blinding

Participants who meet the inclusion criteria will sign an informed consent form issued by the researcher and will be randomly assigned to the conventional treatment group or to the DN group (including conventional treatment) in 1:1 ratio through a random sequence. The random sequence will be generated on the random number generator (randomizer.org) by researcher A. Therapists B and C will treat the participants according to their group based on the random sequence. It will not be feasible to maintain the blinding of invention and the therapist because of the particularity of DN. Therapists will not collect or process the data. Data will be collected and maintained by a data manager who has received professional training. Participant retention and follow-up will be collected and recorded truthfully, including any outcome data for participants who discontinue or deviate from intervention protocols. An

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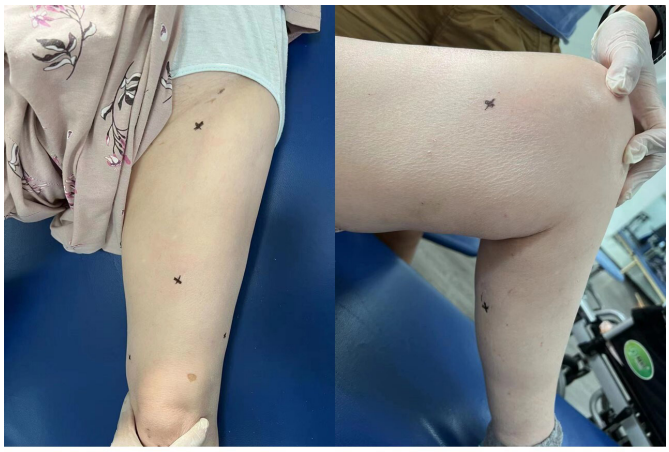

A B

Figure 2 Treatment sites. (A) Myofascial trigger points (MTrPs) on the quadriceps of the lower extremity. (B) MTrPs on the gastrocnemius of the lower extremity.

independent statistician who does not know the allocation will analyse the data.

Interventions

Control group

Participants in the control group will receive conventional rehabilitation treatment, which includes the following: controlling the patient's abnormal posture; strengthening the motor function of the hemiplegic limbs through neurophysiological therapy; and promoting the sensory recovery of the hemiplegic limbs through multisensory stimuli once a day (40 min each time) five times a week for 2 weeks.

Intervention group

Participants in the intervention group will be treated with DN on the basis of conventional rehabilitation treatment. A quiet, single-patient privacy room will be used for DN treatment. A trained therapist who have 10 years of experience will identify a sensitive spot in a taut band of muscles through palpation (figure 2). After cleaning the skin surface, disposable sterile stainless steel needles (size, 0.30 mm × 45 mm; China) will be used on the MTrPs of the lower limb muscles (quadriceps, gastrocnemius and tibialis anterior) on the patient's hemiplegic side with fast-in and fast-out techniques in order to elicit local twitch responses. During treatment, the needle should be kept in a straight track to avoid damage to the muscle fibres as much as possible. The intervention will be performed thrice a week for 2 weeks.[24]

Outcome measures

Primary outcome

Lower limb motor function

The primary outcome that determines the efficacy of the treatment in alleviating lower limb dysfunction will be the change in the Fugl-Meyer Assessment of Lower Extremity (FMA-LE). The scale is a cumulative numerical scoring system divided into four domains, namely motor function, sensory function, balance and joint range of motion; 17 items are included.[25] All items will use a three-level scoring method ranging from 0 to 2 points, with a total score of 34. The higher the score is, the better the lower limb motor function on the hemiplegic side is.Intra-class correlation coefficient (ICC)is the principal measurement of reliability. The FMA-LE has been shown to have excellent intrarater reliability (ICC=0.93) and good test–retest reliability (ICC=0.868) in patients who had a poststroke.[26] The scale will be evaluated at baseline, at 24 hours after treatment, at 2 weeks after treatment and at 3-month follow-up.

Secondary outcomes

Range of motion

Active joint mobility of the lower limbs will be measured by the assessor. This includes the following: hip flexion, extension, abduction, adduction, internal rotation and external rotation; and knee flexion, ankle dorsiflexion and plantar flexion. The scale will be evaluated at baseline, at 24 hours after treatment, at 2 weeks after treatment and at 3-month follow-up.

Muscle spasticity

The Modified Modified Ashworth Scale (MMAS) is a five-grade rating scale for evaluating spasticity. This scale's intrarater reliability was verified to be good and very good for the knee extensors and ankle plantar flexors.[27] In MMAS, the scale will be as follows: 0=no increase in muscle tone; 1=slight increase in muscle tone, manifested by a catch and release or by minimal resistance at the end of the range of motion when the affected part(s) is moved in flexion or extension; 2=marked increase in muscle tone, manifested by a catch in the middle range and resistance throughout the remainder of the range of motion, but affected part(s) easily moved; 3=considerable increase in muscle tone and difficult passive movement; and 4=affected part(s) rigid in flexion or extension.[27] The higher the grade is, the more severe the muscle tone is.

The muscle tones of the quadriceps and gastrocnemius muscles in the affected side will be measured. The scale will be evaluated at baseline, at 24 hours after treatment, at 2 weeks after treatment and at 3-month follow-up.

Sensory interaction on balance

The modified Clinical Test of Sensory Interaction on Balance (mCTSIB) is a test with four different conditions. Previous study has shown that mCTSIB has good test–retest reliability (ICC=0.91) in patients who had a poststroke.[28] It is used to assess how well the participant uses sensory inputs. All participants will be tested while standing with the head in a neutral position. Under condition 1, the participant's somatosensory, visual and vestibular will be available to maintain balance. The participant's eyes will remain open while standing on a firm surface. Under condition 2, the participant will rely on somatosensory and vestibular to maintain balance with eyes closed while standing on a firm surface. Under condition 3, a foam

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cushion as big as the platform will be placed on the force plate, and the participant will stand on this foam cushion. At this time, proprioception will be removed, and the participant will only rely on vision and vestibular perception to maintain balance. Under condition 4, the participant will primarily use vestibular perception to maintain balance with eyes closed and while standing on a foam surface. The test will be evaluated at baseline, at 24 hours after treatment, at 2 weeks after treatment and at 3-month follow-up.

Stability limits

A computerised posturography device (NeuroCom Clinical Research System, USA) is a quantitative method that can be used for assessing individuals' limits of stability (LOS). The device consists of an electronic screen and a force plate. When the participant stands on the plate, the track of centre of gravity (COG) will be displayed on the screen in real time. Before the formal test, all subjects will practise thrice. During the test, the participant will stand barefoot on the plate and will hold the COG in the centre area in a quiet environment. When the signal prompt is given, the participant will move the COG towards the target direction immediately. There are eight directions in this test, namely (1) front, (2) front right, (3) right, (4) rear right, (5) rear, (6) rear left, (7) left, and (8) front left. The movement towards each target direction will be performed in a single trial. The LOS correlates with the Berg Balance Scale in patients who had a stroke.[29]

This parameter includes reaction time (RT; s), movement velocity (MVL; °/s), end-point excursion (EPE; %), maximum excursion (MXE; %) and directional control (DCL; %). RT represents the time from hearing the signal to reacting. MVL is the average speed of COG movement per second in a specific direction. EPE is the distance that the COG travels from the initial position to the target point. MXE is the longest distance the COG travels in the test. DCL is the amount of movement in the predetermined direction minus the amount of the offset direction. DCL scores reflect the subjects' movement coordination. The scale will be evaluated at baseline, at 24 hours after treatment, at 2 weeks after treatment and at 3-month follow-up.

Functional mobility

The Timed Up and Go (TUG) test will be used to evaluate functional mobility in patients with chronic stroke. The test–retest correlation coefficient for TUG scores was 0.95, and correlated well with plantar flexor strength, gait performance and walking endurance in subjects with chronic stroke.[30] The participant will sit on an armchair. The time it takes for a participant to walk 3 m forward, turn around, walk back and sit on the chair will be recorded by the assessor on completion of the test. This test will be evaluated at baseline, at 24 hours after treatment, at 2 weeks after treatment and at 3-month follow-up.

Activities of daily living

The Barthel Index of activities of daily living will be used to assess the participant's dependency in daily life. This scale contains 10 items and has 100 points in total. During the assessment process, questions pertaining to the degree of self-care in terms of feeding, moving from wheelchair to bed, personal toilet (washing, using a shaver or using a comb), using the toilet, bathing, walking on a level surface, ascending and descending the stairs, dressing, controlling bowels and controlling bladder will be asked. The scale will be evaluated at baseline, at 24 hours after treatment, at 2 weeks after treatment and at 3-month follow-up.

Mood

Negative psychology often occurs after a stroke.[31] Thus, it is necessary to monitor mood disorders after a stroke.[32] The Self-rating Anxiety Scale is a self-reported test containing 20 items. Each item is divided into four levels. The total score is 80 points. A score higher than 50 points indicates mild anxiety. The higher the score is, the more severe the anxiety is. The 20-item Self-rating Depression Scale will be used to evaluate participants' affective, psychological and somatic symptoms, which are associated with depression, based on their past week's experience. Each item will be divided into four levels that indicate the frequency of the item as follows: a little of the time, some of the time, a good part of the time and most of the time. The higher the score is, the more severe the depression is. These two scales will be employed at baseline, at 2 weeks after treatment and at 3-month follow-up.

Sample size

G*Power V.3.1.9.7 software was used for sample size calculation. In this trial, participants will be divided into two groups and evaluated at four different time points. Time is the within-subjects variable, and group is the between-subjects variable. Partial eta squared was set to 0.06 as a medium effect size. The estimated sample size was 36 individuals. With this sample size, the 95% statistical value and the 5% significance level are met. The sample size was finally determined to be 44 cases (22 per group) in consideration of the 20% dropout rate.

Data management and monitoring

Electronic data will be input into an encrypted electronic table, whereas the paper data of subjects will be stored in a locked file cabinet. Regular monitoring tests will be performed by the Clinical Research Center of Shanghai Tong Ren Hospital to ensure the integrity and authenticity of all data, including participants' informed consent forms, pathological report forms and possible adverse event (AE) records.

Statistical analysis

SPSS V.22.0 statistical software will be used for the statistical analysis. The normality of the distribution of quantitative variables will be determined using the Shapiro-Wilk test. All tests will be bilateral, and $p<0.05$ will be considered

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as statistically significant. Qualitative variables will be described by frequencies and percentages; quantitative variables will be reported by the mean and SD or the median and IQR. Baseline information and demographic characteristics of the 28 participants will be analysed statistically. A two-way repeated measures analysis of variance will be conducted to analyse the data within factors (time: 0, 24 hours, 2 weeks and 3 months) and between factors (conventional rehabilitation treatment and DN intervention) to identify the difference among participants who suffered from stroke.

Adverse events

The AEs will be monitored and recorded throughout the study. Haematoma or muscle soreness at the treatment site after DN will be classified as an AE. Participants' syncope caused by fear of needles and other major medical events will be classified as serious adverse events (SAEs). Medical services will be provided if participants experience these AEs. The intervention will be immediately stopped if participants want to withdraw, and their rights and interests will not be affected.

Ethics and dissemination

The experiment has been approved by the Ethical Committee of Shanghai Tong Ren Hospital in October 2021 (approval number: 202105702). It has been registered in the Chinese Clinical Trial Registry in December 2020 (registration number: ChiCTR2000040754). Any modification of the protocol will be documented at www.chictr.org.cn. This research conforms to the Helsinki Declaration. Demographic data (age, gender, height, weight, type of stroke, affected side and time of stroke) will be gathered and stored properly. The results of this study will be published in peer-reviewed journals.

DISCUSSION

This study will be the first to focus on MTrPs of the quadriceps, in addition to focusing on MTrPs of the gastrocnemius and tibialis anterior. Quadriceps femoris plays an important role in lower limb function. Akbas *et al* found that excessive quadriceps activation may result in the decreased knee flexion in patients with stroke.[33] DN has been shown to decrease MUAP spikes and increase active range of motion. However, previous DN studies focused more on patients' calf. We found that latent trigger points may exist in the quadriceps muscle. Therefore, we wanted to evaluate whether DN intervention on MTrPs of thigh and calf could have a better impact on patients with stroke. DN interventions will be performed by therapists with extensive clinical experience. This study may help analyse the short-term and long-term efficacy of DN intervention on lower limb through the individuals' lower limb motor function, range of motion, balance, gait and mood in patients who had a poststroke. The new treatment site will provide new therapeutic ideas and may improve the efficacy of dry acupuncture in the treatment of lower limb dysfunction after stroke based on previous studies. The limitations of this study are as follows. First, the duration of the intervention in this study will only be 2 weeks due to the limited number of hospital stays. In addition, this study will not include a sham DN group. Lower limb dysfunction after stroke affects the daily life of many patients. This study may provide an efficient and safe method to improve lower limb function. Results may be used to support the development of an evidence-based physical therapy practice in patients who had a poststroke.

Contributors LT and SL conceived and designed the study protocol. YL, Q-MH and FG provided advice and revised the protocol. LT and SL drafted the protocol. LG and HD contributed to data acquisition. All authors read and approved the final manuscript.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Obtained.

Provenance and peer review Not commissioned; externally peer reviewed.

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REFERENCES

1 Kim JS. Stroke in Asia: a global disaster. *Int J Stroke* 2014;9:856–7.
2 Camak DJ. Addressing the burden of stroke caregivers: a literature review. *J Clin Nurs* 2015;24:2376–82.
3 Morgan P, Embry A, Perry L, *et al*. Feasibility of lower-limb muscle power training to enhance locomotor function poststroke. *J Rehabil Res Dev* 2015;52:77–84.
4 Son SM, Park MK, Lee NK. Influence of resistance exercise training to strengthen muscles across multiple joints of the lower limbs on dynamic balance functions of stroke patients. *J Phys Ther Sci* 2014;26:1267–9.
5 Li L, Stoop R, Clijsen R, *et al*. Criteria used for the diagnosis of myofascial trigger points in clinical trials on physical therapy: updated systematic review. *Clin J Pain* 2020;36:955–67.
6 Villafañe JH, Lopez-Royo MP, Herrero P. Prevalence of myofascial trigger points in poststroke patients with painful shoulders: a cross-sectional study. *Pm&r* 2019;11:1077–82. doi:10.1002/pmrj.12123
7 Rahou-El-Bachiri Y, Navarro-Santana MJ, Gómez-Chiguano GF, *et al*. Effects of trigger point dry Needling for the management of knee pain syndromes: a systematic review and meta-analysis. *J Clin Med* 2020;9. doi:10.3390/jcm9072044. [Epub ahead of print: 29 06 2020].
8 Vulfsons S, Ratmansky M, Kalichman L. Trigger point needling: techniques and outcome. *Curr Pain Headache Rep* 2012;16:407–12.

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9 Domingo A, Mayoral O, Monterde S, *et al*. Neuromuscular damage and repair after dry needling in mice. *Evid Based Complement Alternat Med* 2013;2013:1–10.
10 Cuenca Zaldívar JN, Calvo S, Bravo-Esteban E, *et al*. Effectiveness of dry needling for upper extremity spasticity, quality of life and function in subacute phase stroke patients. *Acupunct Med* 2021;39:299–308.
11 Calvo S, Brandín-de la Cruz N, Jiménez-Sánchez C, *et al*. Effects of dry needling on function, hypertonia and quality of life in chronic stroke: a randomized clinical trial. *Acupunct Med* 2022;40:312–21.
12 Mendigutia-Gómez A, Martín-Hernández C, Salom-Moreno J, *et al*. Effect of dry needling on spasticity, shoulder range of motion, and pressure pain sensitivity in patients with stroke: a crossover study. *J Manipulative Physiol Ther* 2016;39:348–58.
13 Lu Z, Briley A, Zhou P, *et al*. Are there trigger points in the spastic muscles? Electromyographical evidence of dry Needling effects on spastic finger flexors in chronic stroke. *Front Neurol* 2020;11:78.
14 Fernández Sanchis D, Cuenca Zaldívar JN, Calvo S, *et al*. Cost-Effectiveness of upper extremity dry needling in the rehabilitation of patients with stroke. *Acupunct Med* 2022;40:160–8.
15 Fernández-Sanchis D, Brandín-de la Cruz N, Jiménez-Sánchez C, *et al*. Cost-Effectiveness of upper extremity dry Needling in chronic stroke. *Healthcare* 2022;10. doi:10.3390/healthcare10010160. [Epub ahead of print: 14 01 2022].
16 Fernández-de-Las-Peñas C, Pérez-Bellmunt A, Llurda-Almuzara L, *et al*. Is dry Needling effective for the management of spasticity, pain, and motor function in post-stroke patients? A systematic review and meta-analysis. *Pain Med* 2021;22:131–41.
17 Salom-Moreno J, Sánchez-Mila Z, Ortega-Santiago R, *et al*. Changes in spasticity, widespread pressure pain sensitivity, and baropodometry after the application of dry needling in patients who have had a stroke: a randomized controlled trial. *J Manipulative Physiol Ther* 2014;37:569–79.
18 Hadi S, Khadijeh O, Hadian M, *et al*. The effect of dry needling on spasticity, gait and muscle architecture in patients with chronic stroke: a case series study. *Top Stroke Rehabil* 2018;10:1–7.
19 Ghannadi S, Shariat A, Ansari NN, *et al*. The effect of dry Needling on lower limb dysfunction in poststroke survivors. *J Stroke Cerebrovasc Dis* 2020;29:104814.
20 Travell JG, Simons DG. *Myofascial pain and dysfunction: the trigger point manual: Lippincott Williams & Wilkins*, 1992.
21 Chan A-W, Tetzlaff JM, Gøtzsche PC, *et al*. Spirit 2013 explanation and elaboration: guidance for protocols of clinical trials. *BMJ* 2013;346:e7586.
22 Stroke--1989. Recommendations on stroke prevention, diagnosis, and therapy. Report of the WHO Task Force on Stroke and other Cerebrovascular Disorders. *Stroke* 1989;20:1407–31.
23 Tombaugh TN, McIntyre NJ. The Mini-Mental state examination: a comprehensive review. *J Am Geriatr Soc* 1992;40:922–35.
24 Tang L, Li Y, Huang Q-M, *et al*. Dry needling at myofascial trigger points mitigates chronic post-stroke shoulder spasticity. *Neural Regen Res* 2018;13:673.
25 Gladstone DJ, Danells CJ, Black SE. The fugl-meyer assessment of motor recovery after stroke: a critical review of its measurement properties. *Neurorehabil Neural Repair* 2002;16:232–40.
26 Ng SSM, Liu T-W, Tsoh J, *et al*. Psychometric properties of the TRAIL walking test for people with stroke. *Front Neurol* 2022;13:821670.
27 Ghotbi N, Nakhostin Ansari N, Naghdi S, *et al*. Measurement of lower-limb muscle spasticity: intrarater reliability of modified modified Ashworth scale. *J Rehabil Res Dev* 2011;48:83–8.
28 Pfost GR, Chen A, Farley F. MCTSIB: Modified Clinical Test of Sensory Integration for Balance. *Critical Reviews™ in Physical and Rehabilitation Medicine* 2018;30.
29 P-H K, Chen S-F, Yang Y-R. The effects of AI chi for balance in individuals with chronic stroke: a randomized controlled trial. *Sci Rep* 2020;10.
30 Ng SS, Hui-Chan CW. The timed up & go test: its reliability and association with lower-limb impairments and locomotor capacities in people with chronic stroke. *Arch Phys Med Rehabil* 2005;86:1641–7.
31 Campbell Burton CA, Murray J, Holmes J, *et al*. Frequency of anxiety after stroke: a systematic review and meta-analysis of observational studies. *Int J Stroke* 2013;8:545–59.
32 Lincoln NB, Brinkmann N, Cunningham S, *et al*. Anxiety and depression after stroke: a 5 year follow-up. *Disabil Rehabil* 2013;35:140–5.
33 Akbas T, Kim K, Doyle K, *et al*. Rectus femoris hyperreflexia contributes to Stiff-Knee gait after stroke. *J Neuroeng Rehabil* 2020;17:1–10.

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SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Page and Line Number	Reason if not applicable
Administrative information				
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	Page 1 Line 1-2	
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	Page 2 Line 37	
	2b	All items from the World Health Organization Trial Registration Data Set		n/a
Protocol version	3	Date and version identifier		n/a
Funding	4	Sources and types of financial, material, and other support	Page 17 Line 356-359	
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Page 17 Line 351-354	
	5b	Name and contact information for the trial sponsor		n/a This is a project of hospital, so no contact information is written.
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	Page 17 Line 356-359	
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)		n/a
Introduction				

Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	Page 3-4 Line 46-88	
	6b	Explanation for choice of comparators	Page 3-4 Line 62-81	
Objectives	7	Specific objectives or hypotheses	Page 5 Line 89-92	
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	Page 5 Line 96-99	
Methods: Participants, interventions, and outcomes				
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	Page 5 Line98-99	
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	Page 6-7 Line 121-136	
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	Page 8-9 Line 160-174	
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	Page 7 Line 139-144	
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)		n/a
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	Page 8 Line 166-167 Page 9	

			Line 175-176
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	Page 9-14 Line 179-280
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Page 5-6 Line 103-112
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	Page 14 Line 283-289
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	Page 6 Line 115-119
Methods: Assignment of interventions (for controlled trials)			
Allocation: sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	Page7-8 Line 147-150
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any	Page 7-8 Line 147-151

		steps to conceal the sequence until interventions are assigned		
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	Page 8 Line 149-151	
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	Page 8 Line 151-158	
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial		n/a
Methods: Data collection, management, and analysis				
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	Page 14 Line 292-296	
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols		n/a
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	Page 14 Line 292-293	
Statistics: methods	20a	Statistical methods for analysing primary and secondary	Page 14 Line 299-308	

		outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol		
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)		n/a
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)		n/a
Methods: Monitoring				
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	Page 14 Line 293-296	
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial		n/a
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	Page 15 Line 311-316	
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor		n/a
Ethics and dissemination				
Research ethics approval	24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	Page 15 Line 319-320	
Protocol amendments	25	Plans for communicating important protocol modifications	Page 15 Line 320-323	

		(eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)		
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	Page 7 Line 147-148	
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable		n/a This study does not collect biological specimens.
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	Page 14 Line 292-293	
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	Page 17 Line 364	
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators		n/a
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation		n/a
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	Page 16 Line 325-326	
	31b	Authorship eligibility guidelines and any intended use of professional writers		n/a
	31c	Plans, if any, for granting public access to the full protocol,		n/a

		participant-level dataset, and statistical code		
Appendices				
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	The patient consent form as a 'Supplemental Material' file has been upload in ScholarOne.	
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable		n/a This study does not collect biological specimens.

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.