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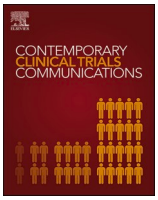

Effects of dry needling and exercise therapy on post-stroke spasticity and motor function– protocol of randomized clinical trial

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ABSTRACT

Background: Spasticity is one of the most common problems after the first stroke. Dry needling (DN) has been presented as a new therapeutic approach used by physiotherapists for the management of post-stroke spasticity. This study aimed to determine whether the addition of exercise therapy to the DN results in better outcomes in wrist flexors spasticity, motor neuron excitability, motor function and range of motion (ROM) in patients with chronic stroke.

Methods: We will use a single-blind randomized controlled trial (RCT) in accordance with the CONSORT guidelines. A total of 24 patients with stroke will be included from the University Rehabilitation Clinics. The outcome measures will include Modified Modified Ashworth Scale, H_{max}/M_{max} ratio, H-reflex latency, Action Research Arm Test, Fugl-Meyer Assessment, and wrist extension active and passive range of motion. Patients in the DN and exercise therapy group will undergo 4 sessions of deep DN in flexor carpi radialis and flexor carpi ulnaris muscles on the affected upper limb and exercise therapy. Participants in the DN group will only receive DN for target muscles. Clinical and neurophysiological tests will be performed at baseline, after four therapy sessions, and at three weeks' follow-up.

Discussion: This study will provide evidence for additional effects of exercise therapy to DN in comparison to DN alone on wrist flexors spasticity, motor neuron excitability, upper-limb motor function, and ROM in patients with chronic stroke.

1. Introduction

Spasticity is one of the most common problems that affects about 43% of patients after the first stroke. It is recognized by muscle stiffness and impairment in neuromuscular control, which may cause limitation of function [1]. Recently spasticity has been defined as a sensory-motor disorder resulting from damage to the upper motor neurons [2]. Spasticity can lead to disability and loss of function in patients with stroke and makes the rehabilitation program difficult [1,3,4]. There are several ways to manage spasticity including physiotherapy, exercises, anti-spasticity drugs, and injection of botulinum toxin [5,6]. Poor recovery of the upper limb after stroke in addition to the direct effect of stroke may be due to insufficient and inappropriate interventions [7]. In fact, due to dissatisfaction with present treatments and the adverse effects of some of these methods, a new treatment protocol has been proposed for achieving a better outcome in post-stroke patients.

Dry needling (DN) has been recently presented as a new therapeutic approach to improve post-stroke spasticity and pain reduction [3,8–13]. However, in most of these trials, the effects of DN have been studied alone [8,9,11,12]. It is recognized that the combining therapeutic techniques would lead to better outcomes than using a single method in the treatment of spasticity after stroke [3,10,14]. There is some evidence

Abbreviations: ARAT, Action Research Arm Test; DN, Dry needling; FCR, Flexor Carpi Radialis; FMA, Fugl-Meyer Assessment; MMAS, Modified Modified Ashworth scale; ROM, Range of Motion.

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that confirms the benefits of using different types of exercises on post-stroke recovery [14–16]. Exercise therapy has been shown to be effective in improving motor function and increasing range of motion (ROM) [14]. There is only a case report that showed the positive effects of DN and exercise therapy on improving spasticity and ROM [17].

We hypothesize that DN and exercise therapy would have further effects on the spasticity and motor function after stroke [9]. Therefore, this single-blinded randomized clinical trial is designed to determine the additional effects of four-session exercise therapy to DN in comparison to DN alone on wrist flexors spasticity, motor neuron excitability, upper-limb motor function, and range of motion (ROM) in patients with chronic stroke.

2. Methods

2.1. Study setting

This study protocol for a single-blind randomized clinical trial (RCT) with parallel groups is registered in the IRCT (https://www.irct.ir/trial/43034) under registration number IRCT20180611040061N1. This study protocol follows the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guideline for quality of clinical trials. The SPIRIT 2013 Checklist used for this prospective study protocol is shown in Fig. 1. Patients will be recruited through an announcement on bulletin boards and referrals by a neurologist from University Clinics and Rehabilitation Departments. The study will be performed at the University Shafa Yahyaian Hospital, Tehran, Iran. Subjects will be recruited in the period from November 2020 to May 2022.

2.2. Informed consent

Written informed consent will be obtained from all participants before beginning the study. Patients will be able to withdraw from the study at any time.

2.3. Eligibility criteria

The inclusion criteria will be: 1) age≥40; 2) the first-ever stroke resulted in hemiplegia; 3) history of disease at least 6 months; 4) wrist flexor Modified Modified Ashworth Scale (MMAS) spasticity score ≥1; 5) taking no anti-spastic drugs, and 6) ability to understand and follow the instructions. The exclusion criteria will be: 1) fixed muscle contractures at the wrist joint; 2) DN contraindications (e.g. needle phobia; lymphedema; presence of vascular disease, and diabetes mellitus); 3) any other neurological disorder; 4) currently receiving other treatment protocols, and 5) non-willing to participate in the study.

2.4. Outcome measures

The primary outcome measures in this study will include MMAS, Hmax/Mmax ratio, and H-reflex latency. The secondary outcome measures will include the Action Research Arm Test (ARAT), Fugl-Meyer Assessment (FMA), and wrist extension active and passive ROM. All patients will be asked to empty their bladder before testing and then rest on the bed for about 5 min in a room with about 25 °C temperature. The order of the tests will be determined at random.

2.4.1. Primary outcome measures

2.4.1.1. MMAS. In this study, wrist flexor spasticity will be quantified using the Persian version of the MMAS that is a reliable and valid measure in assessing spasticity after stroke which scores muscle spasticity from "0" to "4" [18]. To perform the test, the patient will be supine, with the affected arm at slight abduction and forearm in mid position. The assessor will move the wrist passively from maximum possible flexion to maximum possible extension by counting one thousand one [8,18]. The assessor will make one passive extension to avoid varying in spasticity [19].

Time point	Enrolment	Allocation	Post-allocation		
	$-T_1$	T_0	T_1	T_2	T_3
Enrolment:					
Eligibility screen	✖				
Informed consent		✖			
Demographic Questionnaire		✖			
Allocation		✖			
Interventions:					
DN			✖		
DN+ET			✖		
Assessments:					
MMAS		✖		✖	✖
H-reflex		✖		✖	✖
ARAT		✖		✖	✖
FMA		✖		✖	✖
ROM		✖		✖	✖
SPIRIT standard protocol items: recommendations for intervention trials;					

Fig. 1. The SPIRIT schematic diagram of study schedule. SPIRIT standard protocol items: recommendations for intervention trials; DN, dry needling; ET, exercise therapy; MMAS, Modified Modified Ashworth Scale; ARAT, Action Research Arm Test; FMA, Fugl-Meyer Assessment; ROM, range of motion; $-T_1$: Pre-study, Screening/Consent; T_0: Pre-study/Baseline Randomization; T_1: Study/Intervention; T_2: Study, after 4 sessions intervention T_3: 3-week follow-up.

2.4.1.2. H-reflex. Hmax/Mmax ratio and H-reflex latency are reliable indices to measure α motor neuron excitability [20]. For doing the tests, the patient will be in a supine position, with the forearm in supination. We will use an EMG machine (MytoII, Italy) set with a band-pass filter, 5 Hz to 3 kHz; sensitivity at 200–500 V/div, and sweep speed, 5 msec/div. For stimulation of the median nerve, the assessor will place the surface stimulating electrode consisting of two felt pads just medial to the tendon of the biceps brachii in the cubital fossa. To prevent anodal block, the cathode will be set in the proximal and the anode in the distal in line with the median nerve. The stimulator will deliver a rectangular pulse, duration 1 msec, every 5 s. The recording electrodes will be placed over the Flexor Carpi Radialis (FCR) belly, at the point between the upper and middle third of a distance from the medial epicondyle of the humerus to the radius styloid process [8,9]. The ground electrode will be placed between the recording and stimulating electrodes on the forearm. The stimulation intensity will be increased gradually until maximum H-reflex amplitude is recorded. Then, by increasing the intensity of the stimulation, the maximum amplitude of the M wave will be obtained (Mmax). The Hmax/Mmax ratio will be calculated by dividing the Hmax by the Mmax. Finally, the H-reflex latency in msec will be calculated from the beginning of the stimulation to the start of the initial deflection [8,9].

2.4.2. Secondary outcome measures

2.4.2.1. ARAT. The ARAT is a 19 item reliable and valid measure that assesses the upper extremity performance after stroke. The ARAT items are scored according to an ordinal from "0" (no movement) to "3" (normal movement) with higher values indicating better arm motor status. The ARAT total score is 57 [21,22].

2.4.2.2. FMA. The FMA is a quantitative stroke-specific scale that is used to assess motor function, balance, sensations, and joint function in hemiplegic patients. This scale has been found to have good validity and reliability in the stroke population. The items are evaluated and scored according to a 3-point ordinal scale; 0 = not able to perform, 1 = partially performance, and 2 = normal performance. In this study, an upper limb motor section will be used which includes 33 sections with scores from "0" to "66" [23].

2.4.2.3. ROM. To measure the wrist extension active and passive ROM, a standard goniometer will be used. To measure the ROM, the patient will be in a sitting position on a chair with a comfortable back. The forearm and hand will be positioned comfortably in a neutral position with the elbow in 90° flexion. The goniometer axis will be at the snuff box, the fixed arm parallel to the longitudinal axis of the forearm, and the movable arm parallel to the second metacarpal long axis. To measure the active wrist extension ROM, the patients will be asked to voluntarily extend the wrist. To measure the passive ROM, the assessor will move the patient's hand to extension to the maximum possible extension range [9]. Measurements will be performed three times and the average will be recorded for analysis [10].

2.5. Procedure

Patients in the DN + exercise therapy group will undergo 4-session

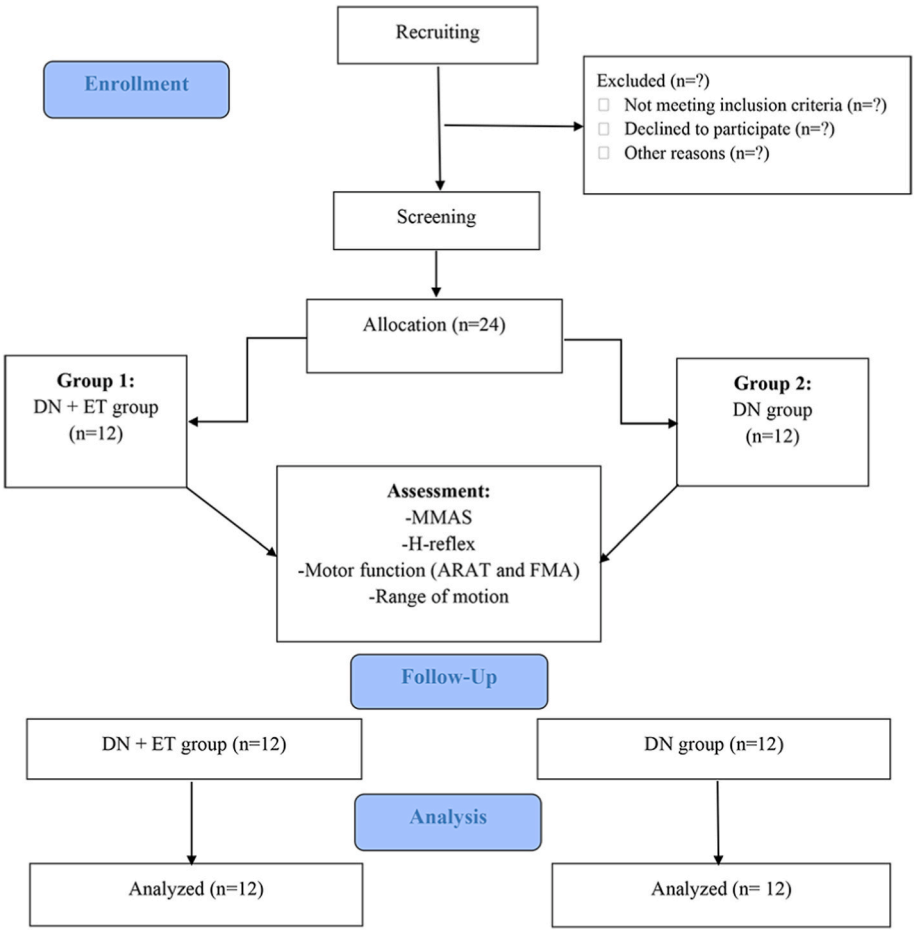

Fig. 2. Flow diagram of study protocol. DN, Dry needing; ET, exercise therapy; Modified Modified Ashworth Scale; H-reflex, Hoffmann reflex; ARAT, Action Research Arm Test; FMA, Fugl-Meyer Assessment.

deep DN in the affected upper limb plus exercise therapy. Participants in the DN group will only receive DN for target muscles. Clinical and neurophysiological tests will be performed at baseline (T1), after four-session treatment (T2), and three-week follow-up (T3). Patients are not permitted to receive any other treatments or using spasticity drugs during the study. The Flow diagram of study protocol will be presented in Fig. 2.

2.5.1. Randomization and blinding

The subjects will randomly assign into DN + exercise therapy or DN groups using opaque, sealed envelopes containing either the assigned "DN" group label or "DN + exercise therapy" group label. The use of opaque envelopes ensures the concealment of randomization. The secretary of the clinic who is not involved in the study will randomly draw out the envelope from a bowl to hand it over to the physiotherapist for treatment.

This is a single-blind randomized clinical trial (RCT) in which an experienced and blinded physiotherapist will apply the clinical tests randomly (assessor blinded to group assignments). All treatment procedures will be performed by another trained physiotherapist who will be unaware of the tests results.

2.5.2. Dry needling

Patients in the DN + exercise therapy group will receive four sessions of deep DN (once a week) in Flexor Carpi Radialis (FCR) and Flexor Carpi Ulnaris (FCU) muscles on the affected upper limb and exercise therapy. Since the FCR and FCU are commonly affected by spasticity after stroke and needled in previous studies [8,9,17], DN will be used for these muscles. Participants in the DN group will only receive DN in target muscles for four sessions (once a week). For the application of DN, patients will be in a supine position, arm away from the trunk and forearm in supination. The fast-in and fast-out cone shape deep DN technique will be adopted, and each muscle will be needled using one needle for 1 min [9]. The depth of needle insertion will be at least 15 mm depending on the forearm morphology. The acupuncture needles, 0.25 × 20 mm; Dong Bang, Korea, will be used. The FCR will be needled on a point in the medial of the forearm, 1 cm medial to the midpoint of the elbow crease, 4 cm below this point. The FCU will be needled on a point in the middle of the proximal third of a line from the medial epicondyle of the humerus to ulnar styloid process [9].

2.5.3. Exercise therapy

Exercises will be done in three levels of structure, function, and activity, based on the international classification of functioning, disability, and health (ICF) [24] to affect the patient's ROM and active motor function. The exercises take about 30–45 min each session. Patients will do exercises daily at home with the help of another person if necessary, and once a week in the clinic after DN under the supervision of the physiotherapist (Appendix 1) [25–28].

To ensure the adherence to home exercises, the physiotherapist will call each patient regularly to remember them of exercises emphasizing the importance and usefulness of exercises in the outcomes.

2.5.4. Adverse effects

DN is a safe treatment, however muscle soreness and local bleeding may occur [29]. Any discomforts and symptoms will be assessed and recorded. The standard procedure with a trained physiotherapist involved in DN and using single-wrapped-sterilized needles will greatly reduce the occurrences of adverse events. The adverse effects associated with DN is not usually serious. Interventions in the form cold or heat compress will be applied for the muscle soreness, if needed.

2.5.5. Sample size

We used G*Power 3.1.3 by repeated-measures ANOVA, within factors test with three measurements. Considering α level of 0.05 and a power of 0.8 with between group medium effect size (0.5) with MMAS as a primary outcome measure, 24 participants (12 in each group) will be required. Accounting for a 10% dropout rate, we will recruit 26 participants.

2.5.6. Statistical analysis

In this study we will use the intention-to-treat analysis to process the missing data. The data gathered will be coded and stored in files. If any patient or participant fails to complete the follow-up session, his/her data will be removed and will not be included in the analysis. Data analysis will be performed using the SPSS, version 25.0. Before analyses, the Kolmogorov Smirnov test will be performed to assess if the data have a normal distribution. For data analysis, we will use the Repeated Measure ANOVA test to evaluate the effect of treatment on the outcome variables with a normal distribution. Friedman test will be used for the ordinal variable of MMAS (primary outcome) and variables with no normal distribution. Post-hoc analyses will be performed using Bonferroni Correction and Wilcoxon Signed Rank test. The Kruskal Wallis test will be used to compare the differences between the two groups on MMAS spasticity scores. The effect size will be calculated using Cohen's *d*. The significance level will be set at $p \leq 0.05$.

2.5.7. Monitoring

An independent data monitoring committee (DMC) with four members, all expert in the clinical trials well published, will supervise the study to ensure the protocol design is followed. Any possible changes in the study protocol will be applied after d approval of the Review Board as well as the Ethics Committee and receiving the written notice by the research team. Any interim analyses will be performed by the research manager who will have access to the data and interim results and will make the final decision to terminate the trial.

2.6. Ethical approve

This study has been approved by the Research Council, School of Rehabilitation, Tehran University of Medical Sciences (TUMS) and ethics approval has been obtained from the Ethics Committee of TUMS (Code: IR. TUMS.FNM.REC.1399.008; Version 1 on Feb. 12.2020). The present study will be performed in accordance with the principles of the Helsinki Declaration.

2.6.1. Access to data

The data will be secured in the Lab computer and will be available through the corresponding author.

2.6.2. Participants and public involvement

Participants and public will not be involved in the preparation of the study protocol. We will disseminate the study results in a peer-reviewed journal and present it at national as well as international congresses.

3. Anticipated results

This study will provide the effects of DN and exercise therapy compared to the DN alone on wrist flexor spasticity, motor neuron excitability, upper-limb motor function, and active and passive ROM in post-stroke patients.

4. Anticipated discussion

The attempt for presenting effective interventions to promote recovery and improve outcomes is a priority for hemiparesis after stroke. DN is a cost-effective therapeutic method [30,31], and physiotherapists use DN for various conditions, especially for pain and disability. The results of this study will assist in providing further evidence on the combined effects of DN with exercise therapy on neurological outcomes of spasticity and active motor function after stroke. The effectiveness of DN in conjunction with exercise therapy can have theoretical and

clinical implications if confirmed in this study. The findings of this study will produce new knowledge about DN with exercise therapy that will extend the existing literature on rehabilitation practice in stroke.

Muscle spasticity and impairments in motor function of the affected arm in patients after stroke are major challenges to both patients and physiotherapists. Impairments in motor function of the affected arm after stroke is difficult to treat as it either does not improve or partially improve with the current rehabilitation strategies. DN has been shown to be one useful intervention that could lead to increases in brain activity [32], significant reduction of spasticity and consequent improvement in active movements after stroke [8–12,33,34]. We hypothesized that the DN when used in combination with the exercise therapy would lead to further reduction of spasticity and enhanced outcomes in active motor function. As a consequence, we anticipate the significant decrease in wrist flexor spasticity following DN and exercise therapy and improvements in patients' active performance and functional ability [34].

In the neurophysiotherapy clinics, patients' spasticity limits their ability to participate in active exercise programs. As DN appears to have a significant effect on reducing spasticity and improving active movements after stroke [8,9,35,36], we would expect that the DN in conjunction with exercise therapy may further facilitate voluntary movements of the affected arm. Therefore, the aim of this trial is to determine whether the addition of exercise therapy to DN will further reduce spasticity and improve voluntary motor function in post-stroke patients with wrist flexor spasticity as compared to DN alone. The strength of this study protocol is that the methodology adopted is RCT with assessor blinded.

We acknowledge the potential challenges to the present study in the era of pandemic COVID-19 in particular difficulty with patient recruitment, patient compliance with four-session treatment, and a three-week follow-up schedule. To address these challenges and to enroll stroke patients in a timely manner, we will utilize the physical medicine and rehabilitation department of a large university hospital in Tehran, and will be keeping in touch with other large university hospitals and rehabilitation clinics to refer eligible cases. We will provide treatment at no cost and financial reimbursement of transportation to and from clinic as strategies to increase the recruitment of patients and reduce the drop-outs. We recognize the short-term follow-up period of 3-week as a study limitation. Therefore, future investigations should consider a longer follow-up period to assess the maintenance of the beneficial effects after DN interventions, alone or in conjunction with exercise therapy.

Author contributions

SSBZ: Critical intellectual input, read and approval of the final submission, study concept and design, methodology, writing manuscript draft.

NNA: Critical intellectual input, read and approval of the final submission, study concept and design, methodology, revision for critically intellectual content, study supervision.

NGH: Critical intellectual input, read and approval of the final submission, study concept and design, methodology, study supervision.

SN: Critical intellectual input, read and approval of the final submission, study concept and design, methodology.

SMJH: Critical intellectual input, read and approval of the final submission, writing manuscript draft.

BSS: Critical intellectual input, read and approval of the final submission, revision for critically intellectual content.

IS: Critical intellectual input, read and approval of the final submission, revision for critically intellectual content.

NNA and **SN** are member of data monitoring committee (DMC).

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Declaration of interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.conctc.2022.100921.

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