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Effects of dry needling on spasticity and motor function in paralympic athletes: a study protocol for a randomised controlled trial

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ABSTRACT

No study has evaluated the effects of dry needling on Paralympic athletes. Therefore, in this study, we will evaluate the effect of dry needling on lower limb spasticity and motor performance, as well as the range of motion of Paralympic athletes. The study will be a triple-blinded, randomised controlled trial. Twenty-four athletes aged 18–45 in T35–T38 groups of the International Paralympic Committee classification will be included in the study. Twelve participants will receive dry needling of the quadriceps and gastrocnemius muscles, and 12 will receive placebo treatment with sham needles at similar points. We will assess the spasticity of the quadriceps and gastrocnemius muscles using the Modified Ashworth Scale, evaluate motor function using the Selective Control Assessment of the Lower Extremity Scale and measure ankle range of motion (ROM) with a goniometer. Considering our hypothesis, the athletes who will undergo the dry needling are supposed to achieve better improvements in spasticity, ROM and motor performance. This study can provide useful information to help better decide on managing complications in Paralympics and its long-term outcomes, to cover the current lack in the literature.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ So far, only one study has evaluated the effectiveness of dry needling in Paralympic athletes, highlighting its positive impact on short-term recovery in Paralympic powerlifting athletes.

WHAT THIS STUDY ADDS

⇒ In this study, we will evaluate the effects of dry needling on lower limb spasticity, motor performance and range of motion of Paralympic athletes.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ This study can provide useful information to help better decisions for managing complications in the Paralympics and its long-term outcomes, to cover the current lack in the literature.

INTRODUCTION

Spasticity is a characteristic of upper motor neuron injuries. It is defined as an increase in tonic stretch reflexes dependent on the stretch's velocity, resulting in excessive tendon jerks due to the hyperexcitability of the stretch reflex.[1 2] Evidence suggests that spasticity can significantly limit the performance capacity of cerebral palsy athletes.[3] Furthermore, lower limb spasticity causes patients to have difficulty walking and maintaining balance and reduces functional independence.[4–6]

International Paralympic Committee functional classification categorises people with increased tone who have enough performance to run and jump into four classes: T35 (moderate diplegia and triplegia), T36 (dystonia, athetosis or ataxia), T37 (hemiplegia) and T38 (mild tone increase, ataxia or athetosis).[7] The relationship between spasticity, lack of control of voluntary movements, muscle strength and range of motion with the performance of Paralympic athletes has been shown.[8] Studies have reported an association between quadriceps muscle spasticity and motor functions, such as walking, in athletes with cerebral palsy.[9 10]

Antispasmodics, botulinum toxin injection and surgery are recommended to improve muscle spasticity.[11 12] However, the application of these interventions may have limitations, such as the necessity for dosage escalation to achieve the desired efficacy, potential non-specific effects leading to reduced function in unaffected muscles, allergic reactions in cases of botulinum toxin injections, and the considerable financial costs associated with these treatments.[13–15]

In recent years, the use of dry needling as a cost-effective and efficient method in patients with upper motor neuron syndrome has

increased.[16–18] In this specialised intervention, the needle is inserted into the muscle and provokes the mechanical disruption of the endplate area, with effects on the nerve, muscle and connective tissues.[19] The efficacy of this method in improving spasticity, range of motion and motor function in patients with damage to the nervous system has been investigated in different populations, such as subacute stroke,[20] chronic stroke,[21 22] cerebral palsy[23] or incomplete spinal cord injuries.[24]

So far, only one study has evaluated the effectiveness of dry needling in Paralympic athletes, highlighting its positive impact on short-term recovery in Paralympic powerlifting athletes.[25] Furthermore, given the findings from previous studies demonstrating the beneficial effects of dry needling for individuals with cerebral palsy[23] and recognising that cerebral palsy is common among Paralympic athletes, particularly within the T35–T38 classification of the International Paralympic Committee,[7] it is reasonable to suggest that dry needling could serve as an effective rehabilitation method to improve function within this group. Therefore, in this study, we will evaluate the effects of dry needling on lower limb spasticity, motor performance, and range of motion of Paralympic athletes.

METHODS

Study design

The study will be a triple-blinded, randomised, controlled trial to evaluate the effects of dry needling on the lower limb spasticity of disabled athletes. This study was registered at the Iranian Registry of Clinical Trials (code: IRCT20210811052141N2).

Participants

According to the International Paralympic Committee, athletes in groups T35–T38 aged 18–45 years will be eligible for inclusion. Exclusion criteria include taking other treatments for spasticity or movement problems and not giving consent to participate in the study.

In coordination with the Iran National Paralympic Committee, we will invite clubs and explain the study's objectives. Those willing to participate in the study will be checked for eligibility criteria, and after completing the consent form, we will enrol those eligible. Participants will be invited to physiotherapy clinics of the School of Rehabilitation, Tehran University of Medical Sciences, to perform the dry needling. Also, they will be asked not to take antispasticity drugs or any other treatment until the end of the study.

Sample size

Using G*Power software and considering P1=0.7, P2=0.1, α equal to 0.05, and power equal to 0.8, the sample size was determined at 24 people (12 people in each group).[26 27] We will divide the participants into two groups, where one group will receive dry needling therapy, and the other group will receive placebo treatment with sham needles at similar points.

Randomisation, blinding and allocation concealment

The assigned interventions (12 dry needling and 12 placeboes) will be written on paper, and the papers will be placed in opaque envelopes. We will use stratified randomisation methods to allocate the treatments. We will enrol 12 females and 12 males, and the participants will be stratified based on their gender. Within each stratum, three blocks will be used to allocate the interventions. Each block comprises an equal number of intervention and placebo treatments, which are randomly assigned. The researchers will be unaware of the sequence of interventions within the blocks. Each participant will be assigned to a treatment or control group by staff out of the research team, and participants will need to be made aware of the assigned group. The patients will go to the therapist with the envelopes and receive the assigned treatment. In addition, assessments will be performed by a physiotherapist who needs to be made aware of the treatment received by patients. The data analyst will also be blinded to the interventions.

Interventions

Before dry needling, the diagnosis of myofascial trigger points will be performed in the gastrocnemius, rectus femoris, vastus medialis, vastus lateralis and vastus intermedius muscles, following the essential diagnostic criteria published for patients with neurological impairments[28] : Within the group of taut bands, (1) the one that displays the highest degree of tension (in muscles that are accessible); (2) the nodular zone within the band or the more sensitive area, if this exists. An expert physiotherapist will perform the dry needling procedure with solid non-bevelled steel needles (0.25×0.30; DongBang AcuPrime, Korea) using the fast-in and fast-out cone shape technique on the myofascial trigger points of these muscles. For the gastrocnemius, the patients will be asked to lie in the prone position, straighten their legs and hang their feet from the edge of the bed. We will assume a line from the popliteal fossa to the middle of the heel and will divide this line into three segments. Two centimetres lateral and medial from this vertical line in the proximal segment (first third) will be the points where the dry needling will be applied for the lateral and medial heads of the gastrocnemius muscle, respectively. To perform needling in the rectus femoris, vastus intermedius, and vastus medialis muscles, the patient will be positioned supine, and the needle will be inserted perpendicular to the taut band on palpation. For the vastus lateralis muscle, if a taut band is palpated in the anterior part of the muscle, the patient will be asked to lie in the supine position with their leg extended. If a taut band is present in the posterior part, covered by the iliotibial band, the individual will lie on their side. The control group will receive placebo treatment with sham needles at similar points. The application followed the criteria described for patients with a central nervous system lesion[28]: (1) place the muscle to be treated in a position of submaximal stretch; (2) perform explorations of myofascial

trigger points using the needle while controlling the stability of the segment until a significant cessation in the excessive muscular activity occurs.

Primary and secondary outcomes

Demographic information such as age, gender, body mass index, related diseases, type of sport and exercise frequency will be collected before intervention. We will assess the spasticity of the quadriceps and gastrocnemius muscles using the Modified Ashworth Scale (MAS), evaluate motor function using the Selective Control Assessment of the Lower Extremity Scale (SCALE) and measure ankle range of motion with a goniometer. Assessments will be performed by an independent examiner three times (before treatment, immediately after treatment and 1 week after treatment). The examiner will be a physiotherapist who is blinded to the interventions.

Selective Control Assessment of the Lower Extremity Scale

SCALE will be used to assess participants' motor function. This scale is designed to assess the motor function of the lower extremities.[29] The subject will be asked to perform specific movements in the hip, knee, ankle, subtalar and toes, and each movement will be scored on three sequential scales: two points will be dedicated when a person can do the movement in at least 50% of the range without moving other joints. One point will be given to slower movements or when the movements happen in less than 50% of the range of motion or slight motions in other joints. Finally, no point will be given when movement is impossible or the pattern is fully displayed. Studies have demonstrated the reliability and validity of SCALE.[29 30]

Modified Ashworth Scale

The spasticity of the quadriceps and gastrocnemius muscles will be assessed using the MAS. A score will be dedicated on a Likert scale from 0, when there is no increase in tone, to 4, when the limb is fixed at flexion or extension. The participants will be evaluated once. For assessment of gastrocnemius spasticity, the assessor will ask the participants to lie in the supine position, and the ankle will be moved from maximum plantar flexion to maximum possible dorsiflexion by the assessor. For the assessment of quadriceps spasticity, participants will be asked to lie on their side with their hip and knee fully extended. Subsequently, their knee will be flexed from maximum extension to the maximum possible flexion. Studies have demonstrated the reliability and validity of MAS.[31–35]

Range of motion

A standard goniometer will measure the ankle's range of motion. The maximum range of extension, flexion and dorsiflexion of the ankle with a bent knee will be evaluated.[36] Studies have shown that a goniometer is reliable for evaluating the range of motion.[37]

Statistical analysis

We will report mean and standard deviation (SD) for continuous variables and number and percentage for categorical ones. We will use χ^2 or Fisher exact tests to compare the categorical variables between groups. As the sample size is small and most outcome measures are ordinal variables, we will use non-parametric tests to make within-group and between-group comparisons. P values less than 0.05 will be considered significant. The data analyst will also be blind to the intervention received by participants.

DISCUSSION

Spasticity is a common complication in paralympic athletes following training and intense physical exercises, which requires the athlete to have a proper recovery.[3 8] Despite the increasing use of dry needling in the management of different neurological populations, there are no studies analysing this technique's effectiveness in improving the Paralympians' complications. Therefore, this trial aims to evaluate the effectiveness of dry needling on lower limb spasticity, range of motion and the overall performance of Paralympic athletes. Considering our hypothesis, the athletes who will undergo the dry needling are supposed to achieve better improvements in muscle spasticity, ROM and motor performance.

Regarding the wide-spreading use of dry needling in managing musculoskeletal complications, further studies are required to support or reject the method's effectiveness in this field. Likewise, this study can provide useful information to help better decisions for managing complications in the Paralympics and its long-term outcomes to cover the current lack in the literature.

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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.

Patient consent for publication Not applicable.

Ethics approval The study protocol is approved by Neuroscience Institute, TUMS (Ethical code: IR.TUMS.NI.REC.1400.025).

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