Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the effect of physical therapy combined with dry needling compared to physical therapy alone on hand muscle strength in people with carpal tunnel syndrome: a randomized clinical trial

Protocol summary

Study aim

Comparison of the effect of physiotherapy treatment alone and physiotherapy combined with dry needling on the components of pain, strength gain, functional status, severity of symptoms and effectiveness of treatment in patients with carpal tunnel syndrome.

Design

Participants in this study will be treated for 12 sessions, 3 sessions per week. In the control group, the standard rehabilitation program includes electrotherapy, ultrasound modality, median nerve mobilization techniques and gliding flexor tendons, and exercises that will be placed in the form of brochures to be performed at the patient's home. In the treatment group, in addition to the standard rehabilitation program that is also performed in the control group, dry needling will be applied in the wrist area by the physiotherapist.

Settings and conduct

Physiotherapy Department of Ghaem Mashhad Hospital

Participants/Inclusion and exclusion criteria

Entry requirements: 65-20 years Clinical diagnosis of CTS based on the presence of at least two criteria proposed by Chang in 2008 Presence of symptoms for at least 4 weeks Confirmation of mild to moderate severity of CTS based on electrodiagnostic findings Non-entry conditions: Clinical conditions that can mimic CTS diabetes Rheumatoid arthritis Hypothyroidism and hyperthyroidism

Intervention groups

In the intervention group, in addition to the standard rehabilitation program that is performed in the control group, at the end of the fifth treatment session, dry needling will be applied based on the FCDN technique. The standard rehabilitation program includes electrotherapy, ultrasound modality, median nerve mobilization techniques and gliding flexor tendons, and exercises that will be available in the form of brochures to be performed at the patient's home. The main outcome evaluated in this study will be pain.

Main outcome variables

Grip strength

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221030056342N3**
Registration date: **2024-10-24, 1403/08/03**
Registration timing: **prospective**

Last update: **2024-10-24, 1403/08/03**
Update count: **0**

Registration date

2024-10-24, 1403/08/03

Registrant information

Name

Afsaneh Zeinalzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-12-02, 1403/09/12

Expected recruitment end date

2025-12-03, 1404/09/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of physical therapy combined with dry needling compared to physical therapy alone on hand muscle strength in people with carpal tunnel syndrome: a randomized clinical trial

Public title

The effect of physical therapy combined with dry needling compared to physical therapy alone on hand muscle strength in people with carpal tunnel syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Clinical diagnosis of CTS based on at least two criteria proposed by Chang Presence of symptoms for at least 4 weeks Confirmation of mild to moderate severity of CTS based on electrodiagnostic findings

Exclusion criteria:

Clinical conditions that can mimic CTS include cervical radiculopathy, brachial plexus injury, proximal median neuropathy, or significant polyneuropathy. Severe CTS with visible muscle atrophy Diabetes Rheumatoid arthritis Hypothyroidism and hyperthyroidism Pregnancy and breastfeeding Alcohol abuse Taking medicine Malignancy

Age

From **20 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **34**

Randomization (investigator's opinion)

Randomized

Randomization description

In the present study, the quadruple randomization block method will be used for randomization. For this method, the volume of each block must be determined first (for example, a quadruple block). Then write the list of blocks and assign numbers to them (AABB(1)- ABAB(2)- ABBA(3)-BBAA(4)- BABA(5)- BAAB(6)) then choose random numbers between 1 and 6 (for example, 1, 4, 5, etc.) and finally specifying the treatment allocation list based on the previous random numbers (...AABB-BBAA-BABA-).}. The website www.sealedenvelope.com will be used to generate the assigned sequences.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients are randomly assigned to two groups of physical therapy alone (control group) and physical therapy with dry needling (treatment group) by the method of quadruple random blocks by a person who is not involved in any of the intervention and evaluation stages.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

Central Organization of Mashhad University of Medical Sciences, Knowledge and Health City, End of Shahid Fakuri Blvd.

City

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Approval date

2024-02-24, 1402/12/05

Ethics committee reference number

IR.MUMS.REC.1403.005

Health conditions studied

1

Description of health condition studied

Carpal tunnel syndrome

ICD-10 code

G56.0

ICD-10 code description

Carpal tunnel syndrome

Primary outcomes

1

Description

Hand grip

Timepoint

Before, immediately after and six weeks after the end of treatment

Method of measurement

Grip strength will be measured in kilograms using a hand-held dynamometer. First, patients are taught how to work with the device. They are then asked to maintain

maximum grip strength and press the handle 3 times with 10 seconds of rest between each test, and the average score of the three presses of the machine will be calculated.

Secondary outcomes

1

Description

Pain severity

Timepoint

Before, immediately after and six weeks after completion

Method of measurement

Visual analog scale (VAS) will be used to evaluate pain intensity at rest (8). VAS is a 10-point scale from 0 to 10, where 0 represents "no pain" and 10 represents "worst possible pain". All participants are instructed to rate pain intensity based on the past 7 days.

2

Description

Functional status and symptom severity

Timepoint

Before, immediately after and six weeks after completion

Method of measurement

Functional status and severity of self-reported symptoms will be measured using the self-reported Boston Carpal Tunnel Questionnaire (BCTQ). This is a CTS-specific questionnaire that refers to a typical 24-hour period in the past two weeks. It consists of two different scales: Symptom Severity Scale (SSS) and Functional Status Scale (FSS). The SSS consists of 11 questions about symptom severity, while the FSS consists of 8 daily activities that are rated by severity. These two scales will be rated on a 5-point scale, where greater impairment is indicated by higher scores, and finally, the average of each section is calculated, and the higher the average, the greater the severity of the patient's symptoms and disability. The BCTQ is responsive to clinically relevant changes and is therefore an appropriate measure of treatment outcome. This questionnaire was Persianized by Mashhad University of Medical Sciences and its reliability and validity have been reported before.

3

Description

The effectiveness of treatment

Timepoint

Before, immediately after and six weeks after completion

Method of measurement

Global rating of change (GRC) will be used to evaluate the effectiveness of the treatment, which evaluates the patient's current health status compared to the patient's status at the beginning of the treatment. It is an 11-point Likert scale ranging from +5 (much better) to -5 (much worse).

Intervention groups

1

Description

Intervention group: In the treatment group, in addition to the standard rehabilitation program that is also performed in the control group, dry needling will be applied in the wrist region based on the Four Pole Carpal Dry Needling technique by the physiotherapist. In this method, needles with dimensions of 25*0.30 mm are placed in their position in all patients according to anatomical references. The highest needles are at the scaphoid (proximal-radial: P-R) and pisiform (proximal-ulnar: P-U) bones, while the lowest ones are at the level of the trapezium (distal-radial: D-R) and hamate (distal-ulnar: D-U) bones.) are placed. 4 oblique directional needles (45 degrees in both cranio-caudal and internal-external directions), slightly inclined to the back and at the same time follow the midline. Each needle is inserted into the tissue until an elastic state is felt, which in the absence of ultrasound confirmation is attributed to the transverse carpal ligament. Fascial winding technique (FWT) is then applied to each needle, which involves twisting them in one direction until reaching the final threshold of "Needle grasp". The rotation of the needles is limited due to their adhesion to the tissue, which means that by applying force to remove the needles, the tissue will be exposed to tension. This force is along the longitudinal axis of the needles, but it is not enough to pull them out of the tissue and it must be done simultaneously on each pair of opposite needles that are two by two miles together (i.e. P-R with D-U and P-U with D-R). At this moment, we consider the FWT complete. This method leads to continuous tension on the transverse carpal ligament, which is stronger and more effective. In the treatment group, dry needling will be performed at the beginning of the first, fifth and ninth sessions before routine physiotherapy, and patients will be advised to refrain from taking NSAIDs 24 hours before and after the dry needling treatment.

Category

Rehabilitation

2

Description

Control group: In the control group, the standard rehabilitation program includes electrotherapy, ultrasound modality, median nerve mobilization techniques and gliding flexor tendons, and exercises that will be placed in the form of brochures to be performed at the patient's home. The mobilization technique of the median nerve, which is performed by the physiotherapist, and the gliding of the flexor tendons will be explained in detail, and the patient will be taught how to do the exercise at home. The treatment duration of the standard rehabilitation program is 45 to 60 minutes per session. And it is as follows: 20 minutes of electrotherapy in the form of tennis with a frequency of 80 Hz and a pulse width of 60 microseconds - 5 minutes of interrupted ultrasound on the carpal tunnel area of the

wrist with a frequency of 1 MHz and an intensity of 1 watt per square centimeter - mobilization of the median nerve in 3 sets with 15 repetitions in Each session - Glide the flexor tendons of the hand so that each exercise is repeated 1 to 3 times for 10 times and each position is maintained for 5 seconds. Teaching exercises to stretch the transverse carpal ligament and glide the median nerve and flexor tendons to be done at home as follows: 1) Stretching the transverse carpal ligament by the patient: the patient is asked to bend his wrist upwards at a 90 degree angle. and connect his palm to the opposite wall, and with his opposite hand, slowly pull the thenar ridge towards him so that the transverse carpal ligament is stretched. Participants are asked to hold each stretch for 30 seconds and do it 4 times a day during their treatment period. Participants in this study will be treated for 12 sessions, 3 sessions per week.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Special clinic of physical therapy of Ghaem Hospital

Full name of responsible person

Mohammad Javad Zarandi

Street address

Narjes building, first floor, Physiotherapy Department, Qaem Hospital, Nurse Street.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Shayeste Jan Alizadeh

Position

MSc Colleague

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

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Faculty of Paramedical and Rehabilitation Sciences, Kharazmi Building, University Campus, East Door of Mashhad University of Medical Sciences, Azadi Square

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Associate Professor of Mashhad University of Medical Sciences

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data will be reported in the form of a research article. Raw data will be delivered to researchers for meta analysis.

When the data will become available and for how long

6 months after publication

To whom data/document is available

For researchers only

Under which criteria data/document could be used

For meta-analysis Only

From where data/document is obtainable

zeinalzadehAF@mums.ac.ir

What processes are involved for a request to access data/document

The response will be sent 3 within months after considering the researcher's request.

Comments