

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The effects of conventional physical therapy with and without neck manual therapy on clinical outcomes in people with carpal tunnel syndrome

Protocol summary

Study aim

The effects of conventional physical therapy with and without neck manual therapy on clinical outcomes in people with carpal tunnel syndrome

Design

Randomized control trial with 2 group of control and treatment design of 40 patients, double-blind, with a parallel group.

Settings and conduct

Patients are randomly assigned to either intervention or treatment groups at Golestan hospital in Ahvaz. In this study, patients and assessors are blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Tingling, numbness, burning or pain in at least 2 of digits 1, 2 or 3. Ages range between 18 to 60. Positive result Phalen or Tinnel sign or Carpal compression test. Existence CTS symptoms for greater than twelve weeks. Pain intensity at least a 4/10 on a Visual Analog Scale over the past 24 h. Electrodiagnostic findings indicate mild to moderate damage to the median nerve. Exclusion criteria: Any sensory or motor deficit in either the ulnar or radial nerve. History of surgery or injection in the wrist area. Presence of systemic diseases such as rheumatoid arthritis, fibromyalgia, diabetes mellitus, hyperthyroidism or hypothyroidism. The presence of conditions that might cause numbness in the hand, including cervical radiculopathy, cervical ribs, plexopathy, and polyneuropathy. Pregnancy. History of neck, shoulder or upper extremity trauma.

Intervention groups

Intervention group: Combined conventional physiotherapy including wrist splints, electrical stimulation, phonophoresis, and wrist manual therapy and neck manual therapies. Control group: Conventional physiotherapy including wrist splints, electrical stimulation, phonophoresis, and wrist manual therapy

Main outcome variables

Pain, upper limb level of function, symptoms and functional status of patients, median sensory nerve conduction velocity, median nerve motor distal latency

General information

Reason for update

Due to the continuation of the COVID-19 pandemic condition and the lack of patient referrals and patient follow-up, the end date was increased.

Acronym

IRCT registration information

IRCT registration number: **IRCT20201201049565N1**

Registration date: **2020-12-15, 1399/09/25**

Registration timing: **prospective**

Last update: **2022-04-18, 1401/01/29**

Update count: **2**

Registration date

2020-12-15, 1399/09/25

Registrant information

Name

Milad Zarrin

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-20, 1399/09/30

Expected recruitment end date

2021-08-22, 1400/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of conventional physical therapy with and without neck manual therapy on clinical outcomes in people with carpal tunnel syndrome

Public title

The effects of neck manual therapy on the carpal tunnel syndrome

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Tingling, numbness, burning or pain in at least 2 of digits 1, 2 or 3 Ages 18-60 years Positive Phalen sign or Tinel sign over the carpal tunnel or carpal compression test CTS symptoms present for greater than twelve weeks Pain intensity at least a 4/10 on a Visual Analog Scale scale over the past 24 h Electrodiagnostic findings indicate mild to moderate damage to the median nerve

Exclusion criteria:

Any sensory or motor deficit in either the ulnar or radial nerve History of surgery or injection in the wrist area Presence of systemic diseases such as rheumatoid arthritis, fibromyalgia A history of systemic disease associated with carpal tunnel syndrome (such as diabetes mellitus or hyperthyroidism or hypothyroidism) The presence of conditions that might cause numbness in the hand, including cervical radiculopathy, cervical ribs, plexopathy, and polyneuropathy Pregnancy History of neck, shoulder or upper extremity trauma

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Individuals who met the inclusion criteria were randomly allocated to Group A (conventional physiotherapy) or Group B (combination of conventional physiotherapy treatments with neck manual therapy) using Block randomization (size: 4 and 6) prepare by an independent statistician with no clinical involvement in the trial. The allocation will be concealed in opaque, sealed envelope. A research assistant opens the envelopes to reveal group

allocation before starting the intervention

Blinding (investigator's opinion)

Double blinded

Blinding description

This is a double-blind clinical trial in which patients are evaluated by another physiotherapist who is unaware of assigning individuals to groups. Patients and data analysts will also be unaware of group assignments.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Ahvaz University of Medical Sciences

Street address

Deputy of Research and Technology, Jundishapur University of Medical Sciences, Ahvaz

City

Ahvaz

Province

Khouzestan

Postal code

61357-33133

Approval date

2020-12-01, 1399/09/11

Ethics committee reference number

IR.AJUMS.REC.1399.727

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**

pain

Timepoint

One day before first session of treatment, two or three days after end of treatment

Method of measurement

Visual Analog Scale

2

Description

Upper limb level of function

Timepoint

One day before first session of treatment, two or three days after end of treatment

Method of measurement

Disabilities of the arm, shoulder and hand (DASH) questionnaire

3

Description

Symptoms and functional status of patients

Timepoint

One day before first session of treatment, two or three days after end of treatment

Method of measurement

Boston Carpal Tunnel(BCTQ) Questionnaire

4

Description

Median sensory nerve conduction velocity

Timepoint

One day before first session of treatment, two or three days after end of treatment

Method of measurement

Tru trace 4 EMG system DEYMED electromyography device

5

Description

Median nerve motor distal latency

Timepoint

One day before first session of treatment, two or three days after end of treatment

Method of measurement

Tru trace 4 EMG system DEYMED electromyography device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Combined conventional physical therapy including wrist splints, electrical stimulation, phonophoresis, and wrist manual therapy and neck manual therapies.

Category

Rehabilitation

2

Description

Control group: Conventional physical therapy including

wrist splints, electrical stimulation, phonophoresis

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan hospital

Full name of responsible person

Saadat Maryam

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Sponsors / Funding sources

1

Sponsor

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Web page address

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahvaz 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
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Zarrin Milad
Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

The person's information will be confidential and the results will be as collective statistics

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

This clinical trial will be an research article and its protocol, results report and statistical analysis will be published to be used by therapists.

When the data will become available and for how long

If the journal has requested access to the data at any time, the data will be provided.

To whom data/document is available

Journal editors and Reviewers

Under which criteria data/document could be used

Sometimes for re-analysis or for use in meta-analysis studies

From where data/document is obtainable

Project manager

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

It should be send email to project manager and after reviewing the reason for requesting the data, they will be send

Comments