Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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. Existance 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
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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 Tinnel 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
Street address
Golestan Hospital, Golestan Blvd,Ahvaz,Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
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Email
Ahvaz-rehab@ajums.ac.ir
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

Ahvaz University of Medical Sciences

Full name of responsible person

Zarrin Milad

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

Street address

Physical therapy Department, Rehabilitation School, opposite the MRI Building, Jundishapour University of Medical Sciences, Ahvaz

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Saadat Maryam

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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Position

Student

Latest degree

Bachelor

Other areas of specialty/work

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Email

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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