Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effects of adding core stability exercises to neck stability exercises and Mulligan's spinal mobilization technique on pain, range of motion and neck disability index in patients with chronic non-specific neck pain.

Protocol summary

Study aim

to determine the effect of adding core stability exercises to cervical stabilization exercises and Mulligan mobilization technique on pain intensity, range of motion, and neck disability index in patients with chronic non-specific neck pain.

Design

A randomized, double-blind, parallel controlled clinical trial will be conducted on 22 patients, using Random Allocation software for randomization.

Settings and conduct

both the assessor and the participants will be blinded to group allocation. Eligible participants will be evaluated at Iranmehr Hospital and the School of Rehabilitation, Tehran University of Medical Sciences, before the intervention, after 24 intervention sessions (post-intervention), and one month after the end of the study by the assessor. The control group will receive CS exercises & Mulligan mobilization, while the intervention group will receive CS exercises, Mulligan mobilization & core stability exercises.

Participants/Inclusion and exclusion criteria

Male and female aged 20 to 55 years with chronic neck pain, with or without radiation to the arms, lasting for at least 3 months, a pain intensity of 4 or higher on the Visual Analogue Scale and a Neck Disability Index score of 10 or higher will be included. Participants with specific causes of neck pain, infection, inflammatory disorders, tumor, osteoporosis, fracture, traumatic injury, cervical disc herniation requiring surgery, pregnancy, recent neck surgery and use of medications affecting pain or inflammation ,history of lumbar spine surgery, dizziness or uncontrolled hypertension will be exclude.

Intervention groups

control group: cervical stability exercise (CS) & neck mulligan mobilization intervention group: CS exercise & neck mulligan mobilization & core stability exercise

Main outcome variables

pain intensity, neck range of motion, functional disability, dynamic balance, patient global impression of change.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251027067790N1**
Registration date: **2025-11-28, 1404/09/07**
Registration timing: **registered_while_recruiting**

Last update: **2025-11-28, 1404/09/07**
Update count: **0**

Registration date

2025-11-28, 1404/09/07

Registrant information

Name
Fatemeh Razmkhah
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

2025-11-10, 1404/08/19

Expected recruitment end date

2026-01-19, 1404/10/29

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effects of adding core stability exercises to neck stability exercises and Mulligan's spinal mobilization technique on pain, range of motion and neck disability index in patients with chronic non-specific neck pain.

Public title
Effects of core stability exercises on neck pain.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Pain intensity should be at least 4 out of 10 The Neck Disability Index score should be at least out of 50 Neck pain that has persisted for at least 3 months, either continuously or recurrently. Non-specific neck pain (pain in the neck region without a pathological cause, with or without radiation to the arm) The ratio of trunk flexor endurance Test to trunk extensor endurance Test is less than 0/5 or greater than 1/5 Men and women aged between 20 and 55 years
Exclusion criteria:
Having a specific cause for neck pain Signs of infection Inflammatory disorder Tumor Osteoporosis Fracture or traumatic injury Disk herniation medically diagnosed as requiring surgical intervention. Pregnancy People who had neck surgery within the last 6 months Use of medications affecting pain, inflammation, or musculoskeletal function—such as NSAIDs, analgesics, muscle relaxants, corticosteroids, or antidepressants—within the week prior to the study. History of lumbar spine surgery, such as discectomy or laminectomy. History of dizziness before enrollment and during the study period. Uncontrolled blood pressure before enrollment and during the study period.
Age
From **20 years** old to **55 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **22**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants will be allocated to the intervention and control groups using a block randomization method with balanced blocks of four and a 1:1 allocation ratio. The random sequence will be generated using Random Allocation Software. The person responsible for generating the random sequence will not be involved in any stage of intervention delivery, participant assessment, or data analysis. After confirming participants' eligibility based on inclusion and exclusion criteria, each set of four participants will form a block, and the software will randomly assign two participants to the intervention group and two to the control group, ensuring balance and randomness throughout the study. To maintain allocation concealment, each participant's random code will be placed in identical, sealed envelopes. These envelopes will be opened in order of participant enrollment by a person not involved in the intervention process, revealing each participant's group assignment.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study will use a double-blind design, meaning that both the participants and the assessor will be unaware of the type of intervention each participant receives (treatment or control group). The intervention will be delivered by a therapist different from the assessor, who will measure the outcomes only before and after the intervention, without access to group allocation.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
ethics committee of tehran university of medical sciences
Street address
School of Rehabilitation, Tehran University of Medical Sciences, corner of Safialishah Street, Enqelab Street, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1148965111
Approval date
2025-10-14, 1404/07/22
Ethics committee reference number
IR.TUMS.FNM.REC.1404.135

Health conditions studied

1

Description of health condition studied
Chronic Non-Specific Neck Pain
ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Pain intensity: Chronic non-specific neck pain, with or without radiation to the arms, lasting at least three months, will be assessed.
Timepoint
Pain intensity will be measured at three time points: before the intervention, after the completion of the intervention (after 24 treatment sessions), and one month post-intervention.
Method of measurement
The Visual Analog Scale (VAS) will be used to evaluate the average pain experienced by participants during the past week. This tool consists of a 10-centimeter horizontal line, with one end representing no pain (score 0) and the other end representing the worst imaginable pain (score 10). Participants will be asked to indicate their pain over the past week by marking a point on the line. The distance from the beginning of the line to the mark will be measured in millimeters, and the final pain intensity score will be reported as a number between 0 and 10.

Secondary outcomes

1

Description
Functional disability
Timepoint
Functional disability will be measured at three time points: before the intervention, after the completion of the intervention (after 24 treatment sessions), and one month post-intervention.
Method of measurement
In this study, the Persian version of the Neck Disability Index (NDI) questionnaire, scored from 0 (no disability) to 50 (severe disability) is used to assess the level of neck disability.

2

Description
Cervical range of motion
Timepoint
Cervical range of motion will be measured at three time points: before the intervention, after the completion of the intervention (after 24 treatment sessions), and one month post-intervention.
Method of measurement
In this study cervical range of motion is measured using a standard goniometer in the direction of flexion, extension, rotation and lateral bending.

3

Description
Dynamic balance (Y-Balance Test)
Timepoint
Dynamic Balance will be measured at three time points: before the intervention, after the completion of the intervention (after 24 treatment sessions), and one month post-intervention.
Method of measurement
In this study, dynamic balance is assessed using the Y-Balance Test in the anterior, posteromedial, and posterolateral directions. The distances reached by the participant's reaching leg in these directions are measured by the examiner using a measuring tape.

4

Description
Patient global impression of change (PGIC)
Timepoint
Patient global impression of change will be measured at two time points: after the completion of the intervention (after 24 treatment sessions), and one month post-intervention.
Method of measurement
In this study, the patient's global impression of change after treatment is evaluated using the Patient Global Impression of Change (PGIC) scale. This instrument is a 7-point scale that asks the patient to subjectively rate the overall changes in their condition compared to the beginning of treatment. The response options range from "very much worse" to "very much improved." Higher scores indicate greater patient satisfaction with the treatment outcome.

Intervention groups

1

Description
Intervention group: This group receives cervical stabilization exercises, Mulligan mobilization (SNAGs) and core stabilization exercises. this intervention is performed 3 sessions per week for 8 weeks, totaling 24 sessions.
Category
Rehabilitation

2

Description
Control group: This group receives cervical stabilization exercises and Mulligan mobilization (SNAGs). this intervention is performed 3 sessions per week for 8 weeks, totaling 24 sessions.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center

Iranmehr hospital

Full name of responsible person
Fatemeh Razmkhah

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

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
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Fatemeh Razmkhah

Position
Master's student

Latest degree
Master

Other areas of specialty/work
Physiotherapy

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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
Some data, such as the mean age and study-related outcome information, can be shared.
When the data will become available and for how long
The access period begin 6 months after publication of the results.
To whom data/document is available
The data will be available to researchers affiliated with academic and scientific instititions.
Under which criteria data/document could be used
The data are only permitted for scientific research analyses, not for commercial or promotional purposes. Analyses must comply with research ethics and maintain data confidentiality. Requests must be submitted formally, along with a research proposal and ethics approval. Data will only be made available after review and approval by the principal research team.
From where data/document is obtainable
Fatemeh Razmkhah fatemeh.razmkhah76@gmail.com
What processes are involved for a request to access data/document
Requestors must submit a formal research proposal along with their ethics approval to the principal research team. After review and approval of the proposal, the de-identified data will be provided in an appropriate format. The review and data delivery process typically takes approximately 4–6 weeks.
Comments