Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluating the Impact of Diaphragm Manual Release Combined with Upper Trapezius Myofascial Release on Mechanical Neck Pain and Active Trigger Points: A Randomized Controlled Trial

Protocol summary

Study aim

To evaluate the effect of adding diaphragm manual release to upper trapezius myofascial release on pain, disability, pressure pain threshold, cervical range of motion, chest expansion, and patient-reported improvement in individuals with chronic mechanical neck pain.

Design

Parallel-group randomized controlled trial with simple randomization. Participants will be allocated equally into two groups. Outcome assessment will be performed by a blinded assessor.

Settings and conduct

Participants will be recruited from physiotherapy and rehabilitation clinics. Eligible participants will provide informed consent before enrollment. Treatments will be delivered by trained physiotherapists over four weeks.

Participants/Inclusion and exclusion criteria

Adults aged 18–55 years with chronic mechanical neck pain (>3 months) and at least one active upper trapezius trigger point will be included. Exclusion criteria include cervical trauma or surgery, neurological or respiratory disorders, radicular pain, pregnancy, and recent participation in other neck pain interventions.

Intervention groups

Group A: Upper trapezius myofascial release only. Group B: Upper trapezius myofascial release combined with diaphragm manual release. Both groups will receive treatment three times weekly for four weeks.

Main outcome variables

Primary outcomes: Pain intensity (NPRS) and Neck Disability Index (NDI). Secondary outcomes: Pain Pressure Threshold (PPT), cervical range of motion, chest expansion, and Patient Global Impression of Change (PGIC). Outcomes will be measured at baseline and after treatment.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260609069722N1**
Registration date: **2026-06-20, 1405/03/30**
Registration timing: **registered_while_recruiting**

Last update: **2026-06-20, 1405/03/30**
Update count: **0**

Registration date

2026-06-20, 1405/03/30

Registrant information

Name

Mohammed Alkhafajy

Name of organization / entity

Country

Iraq

Phone

+964 770 298 4898

Email address

mbmhkh1989@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-06-17, 1405/03/27

Expected recruitment end date

2026-08-17, 1405/05/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluating the Impact of Diaphragm Manual Release Combined with Upper Trapezius Myofascial Release on Mechanical Neck Pain and Active Trigger Points: A Randomized Controlled Trial

Public title
Effect of Diaphragm Manual Release Combined with Upper Trapezius Myofascial Release in Patients with Mechanical Neck Pain

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age 18–55 years. Mechanical neck pain for more than 3 months NPRS between 30–80 mm At least one active upper trapezius trigger point BMI 18.5–29.9. Ability to attend treatment sessions Ability to understand questionnaires.

Exclusion criteria:
Cervical trauma or surgery Neurological disorders Respiratory disorders Radicular pain Pregnancy Recent neck pain intervention Inability to complete assessments

Age
From **18 years** old to **55 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **28**

Randomization (investigator's opinion)
Randomized

Randomization description
Eligible participants will be randomly allocated into two groups in a 1:1 ratio. Randomization will be performed using a computer-generated random sequence with allocation concealment through sequentially numbered opaque sealed envelopes prepared by an independent researcher.

Blinding (investigator's opinion)
Single blinded

Blinding description
Outcome assessments will be performed by an independent physiotherapist who is blinded to group allocation. The assessor will not participate in treatment sessions and will remain unaware of the intervention received by participants.

Placebo
Not used

Assignment
Parallel

Other design features
Two-arm parallel randomized controlled trial comparing upper trapezius myofascial release alone versus upper trapezius myofascial release combined with diaphragm manual release in patients with chronic mechanical neck pain. Treatment will be provided three times per week for four weeks.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Faculty of Nursing and Midwifery and Rehabilitation, Tehran University of Medica

Street address
Tehran, Shahrak Qods (West), between South Flamack and Zarafshan, Simaye Iran Street - Central Headquarters of the Ministry of Health, Treatment and Medical Education, Block A, 13th Floor

City
Tehran

Province
Tehran

Postal code
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Approval date
2026-01-05, 1404/10/15

Ethics committee reference number
IR.TUMS.FNM.REC.1404.225

Health conditions studied

1

Description of health condition studied
Chronic Mechanical Neck Pain

ICD-10 code
M54.2

ICD-10 code description
Cervicalgia

Primary outcomes

1

Description
Pain Intensity

Timepoint
Before intervention and immediately after completion of the 4-week treatment program.

Method of measurement
Numeric Pain Rating Scale (NPRS), 0–10 scale.

2

Description
Neck Disability

Timepoint
Before intervention and immediately after completion of the 4-week treatment program.

Method of measurement
Neck Disability Index (NDI).

Secondary outcomes

1

Description
Pain Pressure Threshold (PPT)
Timepoint
Before intervention and immediately after completion of the 4-week treatment program.
Method of measurement
Measured using a digital pressure algometer over the upper trapezius trigger point (kg/cm²).

2

Description
Cervical Range of Motion (ROM)
Timepoint
Before intervention and immediately after completion of the 4-week treatment program.
Method of measurement
Measured using an inclinometer for cervical flexion, extension, lateral flexion, and rotation (degrees).

3

Description
Chest Expansion
Timepoint
Before intervention and immediately after completion of the 4-week treatment program.
Method of measurement
Measured using a tape measure at the xiphoid level during maximum inspiration and expiration (cm).

4

Description
Patient Global Impression of Change (PGIC)
Timepoint
Immediately after completion of the 4-week treatment program.
Method of measurement
Measured using the 7-point Patient Global Impression of Change (PGIC) scale.

Intervention groups

1

Description
Control group: Participants will receive upper trapezius myofascial release only, three sessions per week for four weeks. Each session will last approximately 15 minutes.
Category
Treatment - Other

2

Description
Intervention group: Participants will receive upper trapezius myofascial release combined with diaphragm manual release, three sessions per week for four weeks. Each session will last approximately 25 minutes.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Medical Rehabilitation and Rheumatology Center
Full name of responsible person
Mohammed Basim Mohammed Alkhafajy
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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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
De-identified participant dataset, study protocol, statistical analysis results, and informed consent template related to the trial evaluating diaphragm manual release combined with upper trapezius myofascial release in patients with chronic mechanical neck pain.
When the data will become available and for how long
Data and supporting documents will be available upon reasonable request beginning 6 months after publication of the study results and will remain available for 5 years.
To whom data/document is available
De-identified data and study documents will be available to qualified researchers, clinicians, and academic investigators conducting scientific research.
Under which criteria data/document could be used
Data may be used for scientific research, secondary analyses, systematic reviews, and meta-analyses following approval of a reasonable research proposal.
From where data/document is obtainable
Requests should be sent by email to the principal

investigator, Mohammed Basim Mohammed Alkhafajy, at the corresponding study email address.

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

Researchers must submit a written request describing the purpose of data use. Requests will be reviewed by the principal investigator, and approved applicants will receive access to de-identified data.

Comments