

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effects of myofascial release on stiffness of thoracolumbar fascia, cervical range of motion, neck disability index and cranio-vertebral angle in women with forward head posture

Protocol summary

Study aim

Assessing the effect of receiving 4 sessions of thoracolumbar release in treating forward posture in women. The effects of this treatment on thoracolumbar fascia stiffness ,craniovertebral angle, neck disability index & active neck range of motion will be assessed as well.

Design

Randomized, control, double-blinded trial with intervention (exercise therapy & myofascial release) & control group(exercise therapy) of 40 patients. Block randomization was done by www.sealedenvelope.com.

Settings and conduct

after checking inclusion & exclusion criteria, candidates will be divided into intervention & control group whom will receive 2 sessions of treatment per week for 2 weeks. Immediately before first session & after last session of treatment assessment will be done.

Participants/Inclusion and exclusion criteria

Inclusion criteria: all females with craniovertebral angle equivalent or less than 48 degrees all females between 18-35 years old Exclusion criteria: (history of surgery in spine/history of backache or neck pain in last 6 months/history of myelopathy or radiculopathy/history of whiplash injury/suffering from fibromyalgia/history of systematic disease/history of neuromuscular disease/ being a professional athlete/having red flags/being pregnant/suffering from headache or dizziness/not willing to finish treatment/start a new treatment for forward head posture/not finishing treatment sessions)

Intervention groups

The intervention group will receive exercise therapy and myofascial release while the control group will receive exercise therapy.

Main outcome variables

thoarcolumbar fascia's shear modulus-craniovertebral angle-neck disability index-neck active range of motion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240307061208N1**

Registration date: **2024-08-05, 1403/05/15**

Registration timing: **registered_while_recruiting**

Last update: **2024-08-05, 1403/05/15**

Update count: **0**

Registration date

2024-08-05, 1403/05/15

Registrant information

Name

Fatemeh Saddeghi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-05-04, 1403/02/15

Expected recruitment end date

2024-08-21, 1403/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of myofascial release on stiffness of thoracolumbar fascia, cervical range of motion, neck disability index and crano-vertebral angle in women with forward head posture

Public title

The effects of myofascial release on forward head posture

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

all females with craniovertebral angle equivalent or less than 48 degrees all females between 18-35 years old

Exclusion criteria:

no history of surgery in spine no history of backache or neck pain in last 6 months no history of myelopathy or radiculopathy no history of whiplash injury not suffering from fibromyalgia no history of systematic disease no history of neuromuscular disease not being a professional athlete not having red flags not pregnant not suffering from headache or dizziness

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be randomly assigned to either the control group (exercise therapy) or the experimental group (exercise therapy + thoracolumbar fascia release) using block randomization method. A computerized random allocation sequence with 4 block sizes will be done using www.sealedenvelope.com website. Envelopes containing group allocations which will be written and opened by an uninvolved party.

Blinding (investigator's opinion)

Double blinded

Blinding description

The study will be conducted in a double-blind manner, in which the assessor and the participants will be blind to participants' group allocation. Envelopes containing participant group allocations will be written and opened by an uninvolved party. Thus, the assessor will be blind to grouping. Also, the participants will visit the clinic at certain intervals. As a result, they will not have a chance to talk to each other.

Placebo

Not used

Assignment

Factorial

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

N0 47, 19th Shahid-Hoseini street, Jahahn-Ara street, Yousef-Abad, Tehran

City

Tehran

Province

Tehran

Postal code

1438914684

Approval date

2023-11-18, 1402/08/27

Ethics committee reference number

IR.TUMS.FNM.REC.1402.161

Health conditions studied

1

Description of health condition studied

forward head posture

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

This index explains the relationship between transverse stress & strain. Also this index is related to shear wave propagation in a homogenous system. Theoretically, shear modulus or tissue elasticity can be calculated by using shear wave speed which gives information about tissue's biomechanic quality.

Timepoint

in first session before intervention and in last session (fourth) after finishing intervention

Method of measurement

shear-wave elastography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

Tehran university of medical sciences

Full name of responsible person

Fateneh Sadeghi

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Tehran university of medical sciences, Enghelab street, Tehran

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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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Web page address<https://tums.ac.ir>**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 Sadeghi

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Person responsible for updating data

Contact

Name of organization / entity

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

The data files include demographic data and data collected from participants during assessment sessions

When the data will become available and for how long

Access to research data will be available after finishing and publishing the research

To whom data/document is available

medical universities researchers

Under which criteria data/document could be used

research and researcher certifications must be available

From where data/document is obtainable

Tehran university of medical sciences- rehabilitation faculty- Fatemeh Sadeghi

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

After consulting with faculty professors, access to data will be available.

Comments