

# 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](http://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)

##### Phone

+98 21 8833 1733

##### Email address

fa-sadeghi@razi.tums.ac.ir

##### 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 crano-vertebral 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

**Street address**

Tehran university of medical sciences, Enghelab street, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1416753955

**Phone**

+98 21 81613

**Email**

tumspr@tums.ac.ir

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Ali Akbari Sari

**Street address**

Tehran university of medical sciences, Enghelab street, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1416753955

**Phone**

+98 21 81613

**Email**

tumspr@tums.ac.ir

**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

**Street address**

No 47, 19th street, Jahan-Ara, Yousef-Abad, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1438914684

**Phone**

+98 21 8833 1733

**Email**

fatemehsadeghi333@gmail.com

**Person responsible for scientific 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

**Street address**

No47, 19th street, Jahan-Ara, Yousef-Abad, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1438914684

**Phone**

+98 21 8833 1733

**Email**

fatemehsadeghi333@gmail.com

## Person responsible for updating data

### 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

**Street address**

No47, 19th street, Jahan-Ara, Yousef-Abad, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1438914684

**Phone**

+98 21 8833 1733

**Email**

fatemehsadeghi333@gmail.com

## 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**