Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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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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 cranio-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. Theoratically, 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Ali Akbari Sari
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Phone
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Email
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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
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Other areas of specialty/work
Physiotherapy
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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
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