Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the effects of 4 weeks exercise with flexible-bar on thoracic kyphosis angle and maximum voluntary contraction of thoracic muscles in postural hyperkyphosis people (18 -35 years old) with and without forward head posture

Protocol summary

Study aim
Evaluation of the effect of flexible-bar exercise on kyphosis angle and maximum voluntary contraction of thoracic muscles in postural hyperkyphosis people with and without forward head posture after 4 weeks treatment session

Design
Randomized trial with control and intervention groups, single blinded on 24 postural hyperkyphosis subjects

Settings and conduct
Twenty subjects with hyperkyphosis and with and without forward head posture will divide random in two groups according to the inclusion and exclusion criteria. The subjects in intervention group will exercise 4 weeks and The control group receives no exercise . The kyphosis angle, the craniovertebral angle, quality of life, thoracic pain and the maximum voluntary contraction in :back extensor,neck extensor ,lower and upper trapezius and levator scapulae muscles will measured befor and after 4 weeks as Pre and post test.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Men and women between18 to 35 years old Having pain less than 3 in thoracic level with numeric pain rating scale(NRS) Having hyperkyphosis angle more than 46 and less than 60 degree Having craniovertebral angle less than 50 degree Exclusion criteria: Having body mass index more than 25 Having kyphosis with bone ,metabolic reason for example tuberculosis and large breast in women Losing any of inclusion criteria Having history of spinal surgery,infection,fracture,rheumatism pregnancy History of professional exercise in upper trunk and shoulder Scoliosis Having respiration and heart problem

Intervention groups
Applying flexible-bar exercise in intervention group and no intervention in control group

Main outcome variables
Kyphosis angle,craniovertebral angle, maximum voluntary contraction,quality of life, thoracic pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20090203001637N11**
Registration date: **2021-03-01, 1399/12/11**
Registration timing: **prospective**

Last update: **2021-03-01, 1399/12/11**
Update count: **0**

Registration date
2021-03-01, 1399/12/11

Registrant information

Name
Sedighe Kahrizi

Name of organization / entity
Tarbiat Modares University

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-04-19, 1400/01/30

Expected recruitment end date

2021-09-22, 1400/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effects of 4 weeks exercise with flexible-bar on thoracic kyphosis angle and maximum voluntary contraction of thoracic muscles in postural hyperkyphosis people (18 -35 years old) with and without forward head posture

Public title
Evaluation of the effects of exercise with flexible-bar on thoracic kyphosis angle in young people (18 -35 years old)

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Men and women between18 to 35 years old Having at least high school diploma education Having pain less than 3 in thoracic level with Numeric Pain Rating Scale(NRS) Having hyperkyphosis angle more than 46 and less than 60 degree Having cranio-vertebral angle less than 50 degree

Exclusion criteria:
Having body mass index more than 25 Having history of spinal surgery,infection,fracture,rheumatism Pregnancy History of professional exercise in upper trunk and shoulder Scoliosis Having respiration and heart problem having Kyphosis with other reasons for example structure deformity, metabolic tuberculosis, and having large breast in women

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

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **24**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization method is performed by randomize table numbers, with due attention to sample size that is 24 people, are given one two digit code to each subject and researcher start by chance from one point of table to selection of subjects and do this work with closed eyes and put finger or pen nib on the table and select the numbers in the direction of row or column and do this work til the end of sample size and thus subjects stay on two intervention and control group by chance

Blinding (investigator's opinion)
Single blinded

Blinding description
Participant subjects are blinded to the kind of the group that they stay on it (intervention and control). Thus subjects of two groups have no meet and assessments are done separately in even and odd days

Placebo
Not used

Assignment
Parallel

Other design features
Intervention group subjects will exercise with flexible bar and control group subjects will not have any exercise

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tarbiat Modares University

Street address
Tarbiat ModaresUuniversity, Nasr bridge, Jalal e al e ahmad street, Tehran

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Tehran

Province
Tehran

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1411713116

Approval date
2020-12-15, 1399/09/25

Ethics committee reference number
IR.MODARES.REC.1399.140

Health conditions studied

1

Description of health condition studied
Subjects with Postural hyper kyphosis

ICD-10 code
M40.0

ICD-10 code description
Postural kyphosis

Primary outcomes

1

Description
Kyphosis angle

Timepoint
Before first exercise session and 24 hours post of last exercise session

Method of measurement
Flexicurve ruler

2

Description
Craniovertebral(CVA) angle
Timepoint
Before first exercise session and 24 hours post of last exercise session
Method of measurement
Goniameter

3

Description
Maximum Voluntary Contraction(MVC) of back extensor, lower trapezius, upper trapezius, neck extensor, levator scapulae muscles
Timepoint
Before first exercise session and 24 hours post of last exercise session
Method of measurement
Recording with Electromyography system

Secondary outcomes

1

Description
score of the Quality of life questionnaire
Timepoint
Before first exercise session and 24 hours post of last exercise session
Method of measurement
Persian version of the Sf36 Questionnaire

2

Description
Pain of the back region
Timepoint
Before first exercise session and 24 hours post of last exercise session
Method of measurement
Numeric Pain Rating Scale

Intervention groups

1

Description
Intervention group: exercise with flexible-bar 6 days in 4 weeks (24 session) and 3 sets in each session. number (adding one set) and time (adding 5 seconds) of doing sets increase progressively each weak. to prevent from fatigue, allocated 30 seconds rest between each set
Category
Rehabilitation

2

Description
Control group: No intervention
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Tarbiat Modares University
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Sponsors / Funding sources

1

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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
Research Deputy of Tarbiat Modares University
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
Tarbiat Modares University
Full name of responsible person
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Position
Student of M.sc in physical therapy
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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
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
File of intervention program protocol and statistical analysis plan through publication of thesis and writingan article
When the data will become available and for how long
Starting 6 months after publication of results
To whom data/document is available
The research team of this study and other clinical academic researchers who are studying in favor of these patients
Under which criteria data/document could be used
Researchers who intend to write a meta-analysis or systematic review articles are allowed to access document
From where data/document is obtainable

Dr.sedighe kahrizi , Zohreh vaseghi fard

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

The request will be responded after getting the approval of university or the academic institution

Comments