

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Sep 2026

design and construction of Postural Forward Head and Hyperkyphosis corrective Orthosis (FHKO) in youth people and evaluation of its 2-month effect with exercise training on craniovertebral angle of head and neck, thoracic kyphosis angle and electrical activity level of target muscles

Protocol summary

Study aim

- Design and construction of progressive postural corrective orthosis and thoracic hyperkyphosis in young people
- The effect of two-month orthosis with exercise training on the intensity of electrical activity of target muscles (anterior serratus, inferior trapezius, upper trapezius and sternocleidomastoid) and protruding postural correction and thoracic hyperkyphosis

Design

In this study, firstly, orthosis modifying the forward head and thoracic hyperkyphosis (FHKO) for young people will be developed and then evaluated in a single-blind, randomized clinical trial (RCT) study, the effectiveness of orthosis with exercise training. Non-probability sampling and available sampling will be done on 36 patients. .

Settings and conduct

To randomize the samples, random block method is used. For example, in the event of the ABBA sequence, the character A represents the assignment of the person to the exercise group, and character B represents the assignment of the person to the exercise group with orthotics Patients living in Arak city are evaluated in three stages, in the first then one month and then two months and variables are studied in them

Participants/Inclusion and exclusion criteria

inclusion criteria: 18 to 45 years old The angle of kyphosis is greater than 42 degrees Craniovertebral angle less than 48° exclusion criteria: No Neuromuscular Diseases

Intervention groups

Subjects will be divided into two groups of control and test, the control group will receive corrective exercises and the test group will receive the designed orthosis along with corrective exercises.

Main outcome variables

Craniovertebral angle, Thoracic kyphosis angle , Intensity

of the electrical activity of the muscles.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231002059590N1**

Registration date: **2023-10-14, 1402/07/22**

Registration timing: **prospective**

Last update: **2023-10-14, 1402/07/22**

Update count: **0**

Registration date

2023-10-14, 1402/07/22

Registrant information

Name

reza hamzelloui

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 86 4633 9228

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rezarh777@yahoo.com.sg

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-22, 1402/09/01

Expected recruitment end date

2024-08-22, 1403/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

design and construction of Postural Forward Head and Hyperkyphosis corrective Orthosis (FHKO) in youth people and evaluation of its 2-month effect with exercise training on craniovertebral angle of head and neck, thoracic kyphosis angle and electrical activity level of target muscles

Public title

design and construction of Postural Forward Head and Hyperkyphosis corrective Orthosis (FHKO) in youth people and evaluation of its 2-month effect with exercise training on craniovertebral angle of head and neck, thoracic kyphosis angle and electrical activity level of target muscles

Purpose

Diagnostic

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 18 to 45 years Kyphosis angle greater than 42°
Craniovertebral angle less than 48°

Exclusion criteria:

History of cervical vertebral surgery A history of fracture, surgery or trauma in the spine and lower extremity within the past year according to the individual's report
Inflammatory diseases such as Ankylosing spondylitis and rheumatoid arthritis based on the individual's report
History of neurological diseases Fracture in cervical vertebrae Scoliosis above ten degrees. Rheumatic diseases Torticollis Use of hearing aids. Systemic diseases such as arthritis. History of surgery or injury to the shoulder during the past year BMI less than 18.5 and more than 25 kg/m².

AgeFrom **18 years** old to **45 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

No information

Sample sizeTarget sample size: **36****Randomization (investigator's opinion)**

Randomized

Randomization description

Sampling will be non-probability and available sampling. To randomize the samples, random block method with R software is used. For example, in the sequence event of ABBA, the character A represents the assignment of the individual to the group of exercises, and character B represents the assignment of the individual to the group of exercises with orthotics.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of University of Rehabilitation Sciences and Social Health

Street address

University of Rehabilitation Sciences and Social Health, Koodakyar St., Daneshjoo Blvd., Evin, Iran.

City

arak

Province

Markazi

Postal code

3881917558

Approval date

2023-10-02, 1402/07/10

Ethics committee reference number

<https://ethics.research.ac.ir/IR.USWR.REC.1402.149>

Health conditions studied**1****Description of health condition studied**

thoracic hyper kyphosis

ICD-10 code

M40.04

ICD-10 code description

Postural kyphosis, thoracic region

2**Description of health condition studied**

forward head posture

ICD-10 code

M40.03

ICD-10 code description

Postural kyphosis, cervicothoracic region

Primary outcomes**1****Description**

Craniovertebral angle

Timepoint

At the beginning of the study, one month and then two months after the start of the study

Method of measurement

Digital imaging to measure angles

2

Description

Thoracic kyphosis angle

Timepoint

At the beginning of the study, one month and then two months after the start of the study

Method of measurement

Digital imaging to measure angles

3

Description

Intensity of the electrical activity of the muscles

Timepoint

At the beginning of the study, one month and then two months after the start of the study

Method of measurement

electromyography to check the intensity of electrical activity

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group receive Designed kyphotic orthosis with corrective exercises for kyphosis and forward head posture (Three times a week) for two months.

Category

Rehabilitation

2

Description

The control group received only kyphotic postural correction exercises three times a week for two months.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Rabiei Occupational Therapy Clinic

Full name of responsible person

reza hamzeloie

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

hamidreza khankeh

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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

University of social welfare and rehabilitation sciences

Proportion provided by this source

10

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

University of social welfare and rehabilitation sciences

Full name of responsible person

reza hamzeloie

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Orthopedics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Ethical issues

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available