Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Designing and Developing of Forward Head Rounded Shoulder posture corrective Orthosis (FHRSO) and its Immediate Effect on Craniovertebral and Protraction-Retraction angles in people with Postural deviations in upper body

Protocol summary

Study aim
Designing and Developing of Forward Head Rounded Shoulder posture corrective Orthosis (FHRSO) and its Immediate Effect on Craniovertebral and Protraction-Retraction angles in people with Postural deviations in upper body

Design
A single group with repeated measure design. The participants randomly assigned to the sequence of with orthosis and without orthosis conditions.

Settings and conduct
The measurement was performed with the digital camera, that it was set at a distance of 1.5 meter, on a tripod, all assessments were conducted by a orthotics and prosthesis expert who did not participate in the invention of mentioned orthotics. Photo was recorded in the standing position in the lateral view. after the photography , data entered into the Digimizer software and the angles were evaluated.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age range 18 to 60 years old , and the angle of the craniovertebral less than 42/5 degrees.
exclusion criteria: history of neck surgery, The history of neurological diseases, fractures in cervical vertebrae, scoliosis, rheumatic diseases, torticolli in neck, lack of balance in standing, neck pain, use of assistive device to hearing aids, congenital or bony abnormalities in neck vertebrae, systemic diseases such as arthritis, shoulder surgery history, history of any damage in the scapula and shoulder pain

Intervention groups
a single group with repeated measure design: with and without posture corrective orthosis

Main outcome variables
craniovertebral angle protraction-retraction angle

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200301046657N2**
Registration date: **2020-05-06, 1399/02/17**
Registration timing: **registered_while_recruiting**

Last update: **2020-05-06, 1399/02/17**
Update count: **0**

Registration date
2020-05-06, 1399/02/17

Registrant information

Name
Ali Khaghani

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-01-21, 1398/11/01

Expected recruitment end date
2020-05-19, 1399/02/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Designing and Developing of Forward Head Rounded Shoulder posture corrective Orthosis (FHRSO) and its Immediate Effect on Craniovertebral and Protraction-Retraction angles in people with Postural deviations in upper body

Public title
The effectiveness of corrective posture orthotics on head and neck

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
The age range of 18 to 60 years The angle of the craniovertebral is less than 42.5 degrees.

Exclusion criteria:
history of neck surgery The history of neurological diseases fractures in cervical vertebrae scoliosis rheumatic diseases torticolli in neck lack of balance in standing neck pain , use of assistive device to hearing aids congenital or bony abnormalities in neck vertebrae systemic diseases such as arthritis shoulder surgery history history of any damage in the scapula and shoulder pain

Age
From **18 years** old to **60 years** old

Gender
Male

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Iran University of Medical Sciences

Street address
School of Rehabilitation Sciences, Madadkaran All., Shahnazari St., Madar Sq., Mirdamad Blvd., Tehran

City
Tehran

Province
Tehran

Postal code
1545913487

Approval date
2020-01-03, 1398/10/13

Ethics committee reference number
IR.IUMS.REC.1398.1021

Health conditions studied

1

Description of health condition studied
Forward head posture

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
protraction-retraction angle: the angle between the spinous process of C7 and the middle point of the humeral head and Horizontal line.

Timepoint
immediately effect

Method of measurement
The method of measuring the angles is photography with digital camera(Nikon D7000, Nikon Corporation, Japan) and method of calculating angles is with the Digimizer software(model 5.3.5 MedCalc Software)

2

Description
craniovertebral angle is the angle between ear Targus, the spinous process of C7 and the horizontal line.

Timepoint
immediately effect

Method of measurement
The method of measuring the angles is photography with digital camera(Nikon D7000, Nikon Corporation, Japan) and method of calculating angles is with the Digimizer software(model 5.3.5 MedCalc Software).

Secondary outcomes

empty

Intervention groups

1

Description
In this study, using postural corrective orthosis, which is a assisstive device to adopt the correct posture,

intervention is performed random with orthosis for 10 minutes, and the target angles are measured by phothography method.

Category

Treatment - Devices

2

Description

Intervention group: The target angles are measured by photography method random, without the use of postural corrective orthosis .

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Rehabilitation school of Iran University of Medical Sciences

Full name of responsible person

Reza Hamzelouei

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Ali Khaghani

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Others

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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
Yes - There is a plan to make this available

Informed Consent Form
No - There is not 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
Only the statistical information for variable-identifiable individuals is reported.

When the data will become available and for how long
Six months after printing results

To whom data/document is available
Supervisor in Study

Under which criteria data/document could be used
Do not publish identity information

From where data/document is obtainable
Rehabilitation school of Iran University of Medical sciences, Ali Khaghani

What processes are involved for a request to access data/document
After printing the article

Comments