

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Effect of Spinomed Orthosis on Effective parameters in Elderly's Balance performance with Hyperkyphosis

Protocol summary

Summary

The first aim of this study is to investigate the effect of orthosis on proprioception, force sense, and muscle endurance. A second aims to verify whether decrease in thoracic curve will be associated with improvement in forward head posture, and in finally investigate the relationship between changes in thoracic proprioception, force sense, extensor muscle endurance, thoracic kyphosis and forward head posture with balance performance. This study is a parallel group randomized controlled trial. The sample size will be 44 subject. Older adults (age \geq 60 years) with thoracic kyphosis angle \geq 50 and capability of walking without assistive devices will be eligible. Subjects with history of cervical, spinal or lower limb fracture and/or trauma, severe spinal pathologies and deformities, cervical and spinal surgery, disease of the central nervous system, neuromuscular disorder, and severe osteoporosis, will be excluded. Furthermore, using of drugs known to affect the central nervous system or equilibrium, and muscle strength will be led to exclusion. Subjects in the experimental group will receive Spinomed. Subject 13 weeks will be instructed to wear Spinomed for 2-4 h daily with keep daily physical activity in the orthosis group and keep daily physical activity in the control group. In this study we will measured thoracic kyphosis with inclinometer, proprioception and force sense with re-position error test, muscle endurance with Ito test, forward head posture with craniovertebral angle and balance with berg balance scale.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017080335480N1**

Registration date: **2017-10-02, 1396/07/10**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-10-02, 1396/07/10

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2017-09-25, 1396/07/03

Expected recruitment end date

2018-01-04, 1396/10/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Spinomed Orthosis on Effective parameters in Elderly's Balance performance with Hyperkyphosis

Public title

spinal orthotic management of the elderly people with hyperkyphosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion: age ≥ 60 years kyphosis angle ≥ 50 capability of walking without assistive devices Exclusion: with history of cervical, spinal or lower limb fracture and/or trauma, severe spinal pathologies and deformities, cervical and spinal surgery, inflammatory diseases such as ankylosing spondylitis, rheumatoid arthritis, disease of the central nervous system, neuromuscular disorder, diabetic neuropathy, vestibular disease, dizziness, uncorrectable visual or vestibular impairments, Severe osteoporosis, foot deformities using of drugs known to affect the central nervous system or equilibrium (i.e., sedatives or anxiolytics), and of drugs known to affect muscle strength (i.e., corticosteroids), back or neck pain at the time of examination reported to be higher than 3 on the Visual Analogue Scale (VAS), and inability to put on Spinomed

Age

From **60 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Next to Milad Tower, Hemmat Highway

City

Tehran

Postal code

Approval date

2017-05-22, 1396/03/01

Ethics committee reference number

IR.IUMS.REC 1396.9411502002

Health conditions studied

1

Description of health condition studied

kyphosis

ICD-10 code

M40.1

ICD-10 code description

Other secondary kyphosis

Primary outcomes

1

Description

Muscle Endurance

Timepoint

Before Intervention,5 weeks After Intervention,9 weeks After Intervention,13 weeks After intervention

Method of measurement

Ito Test and chronometer

2

Description

Forward Head Posture

Timepoint

Before Intervention,5 weeks After Intervention,9 weeks After Intervention,13 weeks After intervention

Method of measurement

Photographic and Craniovertebral Angle

3

Description

proprioception

Timepoint

Before Intervention,5 weeks After Intervention,9 weeks After Intervention,13 weeks After intervention

Method of measurement

Re-position Error Test and Inclinometer

4

Description

Force Sense

Timepoint

Before Intervention,5 weeks After Intervention,9 weeks After Intervention,13 weeks After intervention

Method of measurement

Re-position Error Test and Dynamometer

5

Description

Balance

Timepoint

Before Intervention,5 weeks After Intervention,9 weeks After Intervention,13 weeks After intervention

Method of measurement

Berg Balance Scale and Timed up and Go Test

6

Description

Kyphosis

Timepoint

Before Intervention,5 weeks After Intervention,9 weeks
After Intervention,13 weeks After intervention

Method of measurement

Inclinometer

Secondary outcomes

empty

Intervention groups

1

Description

Spinomed Orthosis, 2 weeks 30 Minutes per Day, 3
Weeks 2 Hour per Day, and 8 Weeks 2-4 Hour per Day

Category

Treatment - Other

2

Description

No treatment

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Nursing Homes

Full name of responsible person

Street address

City

Tehran

2

Recruitment center

Name of recruitment center

Day Care Centers

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Ali Javad Moosavi

Street address

Hemmat Highway, Iran University of Medical Sciences

City

Tehran

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

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

School of Rehabilitation Sciences, Iran University of
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Full name of responsible person

Mostafa Hosseinabadi

Position

Postgraduate Student in Prosthetics & Orthotics

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

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Full name of responsible person
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Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty