Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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≥60 years) with thoracic kyphosis angle ≥ 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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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 Medical Sciences
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Person responsible for scientific inquiries

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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