Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Jun 2026

Comparison of the effect of orthosis spinomed and Posture Training Support with exercise therapy on the ability to walk and energy consumption in the elderly with hyperkyphosis

Protocol summary

Study aim

Comparison of the effect of Spinomed orthosis and posture training support orthosis with exercise therapy on the ability to walk and energy consumption in the elderly with hyperkyphosis.

Design

Clinical trial with control group and two intervention groups, with parallel and randomized groups, is performed gradually on a simple type on 39 individuals.

Settings and conduct

Individuals are studied at the Center for the Elderly of the University of Social Welfare and Rehabilitation Sciences. In the first session, basic information (including: gender, height and weight of individuals) and tests related to the ability to walk and energy consumption will be recorded. Individuals in groups will be referred to the center again after 8 weeks of intervention and the tests will be repeated.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 60-80 years, hyperkyphosis with an angle of 50 to 65 degrees, the ability to walk without aids Exclusion criteria: any neuromuscular disease (neurological or myopathic), any sensory muscular dysfunction, joint replacement in the lower limb, history of fracture or surgery of the spine and lower limb in the last 12 months

Intervention groups

The control group received only exercise therapy, the first intervention group received spinal orthosis with exercise therapy and the second intervention group received PTS orthosis with exercise therapy.

Main outcome variables

Thoracic kyphosis angle; Walking efficiency includes: walking ability, traveled distance, walking speed; energy consumption

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210717051913N1**
Registration date: **2021-09-03, 1400/06/12**
Registration timing: **prospective**

Last update: **2021-09-03, 1400/06/12**
Update count: **0**

Registration date

2021-09-03, 1400/06/12

Registrant information

Name

hanie khojasteh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 25 3773 9723

Email address

hani_khojasteh@ymail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-25, 1400/07/03

Expected recruitment end date

2021-12-24, 1400/10/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of the effect of orthosis spinomed and Posture Training Support with exercise therapy on the ability to walk and energy consumption in the elderly with hyperkyphosis

Public title
The effect of spinal braces with exercise therapy in the elderly

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
People are 60-80 years old People have a kyphosis angle of 50-65 degrees People have the ability to walk without auxiliary devices People are able to stand for at least two minutes without assistance Individuals have the ability to score 1 or 2 on the clock drawing test

Exclusion criteria:
People who have any neurological or muscular diseases. People with any sensory-muscular dysfunction. People with scoliosis. People who have had lower limb joint replacement. People with hearing or vision impairment. People with a history of spinal fractures or lower limb surgery in the past 12 months. People who have back or neck pain at the time of evaluation with VAS more than 3.

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: **39**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients are randomly assigned to one of three study groups with the help of a simple gradual random allocation method and receive the intervention of the same group. The randomization unit will be the client. With each patient's visit, one of the envelopes will be randomly selected by the patient and introduced as a study group. There will be no concealment in the study.

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 Social Welfare and Rehabilitation Sciences

Street address
Tehran University of Social Welfare and Rehabilitation Sciences, Evin, Daneshjoo Blvd., Koodkiar dead end

City
tehran

Province
Tehran

Postal code
1985713834

Approval date
2021-07-14, 1400/04/23

Ethics committee reference number
IR.USWR.REC.1400.109

Health conditions studied

1

Description of health condition studied
Hyperkyphosis

ICD-10 code
M40.13

ICD-10 code description
Other secondary kyphosis, cervicothoracic region

Primary outcomes

1

Description
Ability to walk (includes: distance traveled, walking speed and walking efficiency.)

Timepoint
First, the relevant tests are taken from the subjects in the first session before the intervention, and after 8 weeks of the intervention (which includes orthosis with exercise therapy or exercise therapy alone (control group)), individuals are asked to refer to the center again and the tests Will be taken.

Method of measurement
distance traveled (2- MWT) Two minutes of walking The maximum distance traveled is recorded (meters)/Walking speed (10-MWT) 10 meters A person walks. Time will be recorded in this distance. (M / s)/Walking efficiency (EMS) includes 7 functional dimensions that are examined in the person and will be given a score of 20 (score).

2

Description
Energy consumption

Timepoint
Energy consumption of individuals is recorded in the first session before the intervention and after 8 weeks of

intervention (orthosis with exercise therapy or exercise therapy alone (control group)) people are asked to refer to the center and record energy consumption.

Method of measurement

Using the polar electro device, the heart rate at rest and activity is recorded and the amount of energy consumption is calculated in the physiological cost index formula.

3

Description

Thoracic kyphosis angle

Timepoint

The Thoracic kyphosis angle will be recorded in the first session before the intervention. After 8 weeks of intervention (orthosis with therapeutic exercise or exercise therapy alone (control group)) again, individuals are asked to refer to the center and record the angle.

Method of measurement

It will be recorded using a kyphometer device.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Posture Training Suport orthosis with exercise therapy ,It is a small orthosis that prevents excessive bending by torque backwards on the spine. The orthosis is prefabricated, consisting of a sac located at the back just below the lower angle of the scapula and measuring 10-20 cm long and 5-10 cm wide. The orthosis will be ordered from Technotan Company in small, medium, large and very large sizes depending on the patient's size and will be covered by the orthotist on the patient's body. The person is asked to wear it for at least 2 hours a day during daily activities. Exercise therapy (exercise therapy) includes exercises (8 exercises) to strengthen the back muscles. These exercises repeat the contraction of the muscles of the dorsal extensor muscles 10 times, reducing the angle of thoracic kyphosis without increasing lumbar lordosis. The person is asked to perform these exercises in home every day as instructed and will be re-evaluated after 8 weeks.

Category

Rehabilitation

2

Description

Intervention group: Spinomed orthosis with exercise therapy, The orthosis is small , creating a backward torque to counteract excessive forward bending. It is a prefabricated orthosis that extends vertically up to the shoulder (1-5 cm below C7) from an abdominal pad, a vertical metal pad on the back, a belt and shoulder straps. The orthosis will be ordered from Technotan Company in small, medium, large and very large sizes depending on the patient's size and will be covered by the orthosis specialist based on the patient's size. The person is required to use at least two hours a day during daily activities. Exercise therapy (exercise therapy) includes exercises (8 exercises) to strengthen the back muscles. These exercises repeat the contraction of the back extensor muscles 10 times, reducing the angle of thoracic kyphosis without increasing lumbar lordosis. The person is asked to do these exercises in home every day as instructed and will be re-evaluated after 8 weeks.

Category

Rehabilitation

3

Description

Control group: exercise therapy, includes exercises (8 exercises) to strengthen the back muscles. These exercises repeat the contraction of the back extensor muscles 10 times, reducing the angle of thoracic kyphosis without increasing lumbar lordosis. The person is asked to do these exercises in home every day as instructed and will be re-evaluated after 8 weeks

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Elderly Center of Tehran University of Social Welfare and Rehabilitation Sciences

Full name of responsible person

zahra mirzaye

Street address

Evin, Daneshjoo Blvd., Koodkiar St., Tehran University of Social Welfare and Rehabilitation Sciences, Aging Research Center

City

tehran

Province

Tehran

Postal code

1985713834

Phone

+98 21 2218 0154

Email

IRCA@USWR.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

Dr. Hamidreza Khorram Khorshid

Street address

Evin, Daneshjoo Blvd., Koodkiar St., University of

Social Welfare and Rehabilitation Sciences, Farabi Building, Second Floor

City
tehran

Province
Tehran

Postal code
1985713871

Phone
+98 21 7173 2832

Email
rd@uswr.ac.ir

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
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
University of social welfare and rehabilitation sciences

Full name of responsible person
hanie khojasteh

Position
master student

Latest degree
Bachelor

Other areas of specialty/work
Orthosis_Prothesis

Street address
Evin, Daneshjoo Blvd., Koodkiar St., University of Social Welfare and Rehabilitation Sciences

City
tehran

Province
Tehran

Postal code
1985713834

Phone
+98 21 2218 0109

Email
hani_khojasteh@ymail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
University of social welfare and rehabilitation sciences

Full name of responsible person
hanie khojasteh

Position
masters student

Latest degree
Bachelor

Other areas of specialty/work
Orthosis_Prothesis

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Postal code
1985713834

Phone
+98 21 2218 0109

Email
hani_khojasteh@ymail.com

Person responsible for updating data

Contact

Name of organization / entity
University of social welfare and rehabilitation sciences

Full name of responsible person
hanie khojasteh

Position
masters student

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Phone
+98 21 2218 0109

Email
hani_khojasteh@ymail.com

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
Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

It is not possible to share all the data and only the demographic information of the participants and the results of the study evaluation variables are shared.

When the data will become available and for how long

Start of data access period 6 months after the publication of the article

To whom data/document is available

Researchers working in academic centers who intend to use these findings in systematic review and meta-analysis

Under which criteria data/document could be used

Other researchers as well as therapists in the field of medicine and rehabilitation can use this study after the publication of the article.

From where data/document is obtainable

University of Social Welfare and Rehabilitation Sciences, Hanie Khojasteh(hani_khojasteh@ymail.com)

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

After requesting the documents, it is necessary for the person in charge of the research project to receive a written permit from the university and send the documents after obtaining the permit. Therefore, it is estimated that about 6 months after the request, this data will be sent.

Comments