Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

Comparison of the Effect of Types of Orthosis and Back School Program on Physical Fitness and Respiratory Capacity of Elderly with Thoracic Kyphosis

Protocol summary

Study aim
Comparison of the Effect of Spinomed and Elderly Orthoses plus Back School Program and Back School Program on Physical Fitness and Respiratory Capacity of Elderly with Thoracic Kyphosis

Design
A randomized, controlled, Two arm parallel group, single-blinded trial. Randomisation will be done by random digits table and 60 patient will be devided randomly to Three groups of 20 each.

Settings and conduct
Location of research: Hazrate Rasoole Akram Hospital ; Sports Medicine Department ; Patients have been blinded to other groups of study

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 60 years or older;Kyphosis angle 50 degrees or more ;Ability to sit and stand up and walk at least 10 meters independently Non-inclusion criteria: Physical abnormalities other than kyphosis which may need treatment prior to research or impair the research process ; People who had a history of fracture or surgery in the lower extremity or spine 12 months before the begining of the research ; Any illness or disorder that disables one's participation in exercises and group activities

Intervention groups
Intervention Group 1: Spinomed Orthosis plus Back School Program Will use orthosis and exercises for 12 weeks and they will come to hospital every 2 weeks to check and improve exercises and orthoses. Then will use orthosis and exercises for 12 weeks at home. Intervention Group 2: Elderly Orthosis plus Back School Program Will use Elderly orthosis and exercises for 12 weeks and they will come to hospital every 2 weeks to check and improve exercises and orthoses. Then will use orthosis and exercises for 12 weeks at home. Control Group: Back School Program Exercises Will use exercises for 12 weeks and they will come to hospital every 2 weeks to check and improve exercises. Then will use exercises for 12 weeks at home.

Main outcome variables
Physical Fitness and Respiratory Capacity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20100623004251N13**
Registration date: **2020-04-04, 1399/01/16**
Registration timing: **registered_while_recruiting**

Last update: **2020-10-09, 1399/07/18**
Update count: **1**

Registration date
2020-04-04, 1399/01/16

Registrant information

Name
Haleh Dadgostar

Name of organization / entity
Tehran University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 21 2200 4050

Email address
dadgostar.h@iums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-10-23, 1398/08/01

Expected recruitment end date

2020-10-22, 1399/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effect of Types of Orthosis and Back School Program on Physical Fitness and Respiratory Capacity of Elderly with Thoracic Kyphosis

Public title

Comparison of the Effect of Types of Orthosis and Back School Program on Physical Fitness and Respiratory Capacity of Elderly with Thoracic Kyphosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 60 years or older Kyphosis angle 50 degrees or more Ability to sit and stand up and walk at least 10 meters independently

Exclusion criteria:

Physical abnormalities other than kyphosis which may need treatment prior to research or impair the research process People who had a history of fracture or surgery in the lower extremity or spine 12 months before the begining of the research Any illness or disorder that disables one's participation in exercises and group activities

Age

From **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Not randomized

Randomization description

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 committe of Iran University of Medical Sciences

Street address

Sports Medicine Department, Building No. 1, Hazrate Rasoole Akram Hospital, Niayesh Ave, Sattarkhan Ave

City

تهران

Province

Tehran

Postal code

1445613131

Approval date

2019-10-20, 1398/07/28

Ethics committee reference number

IR.IUMS.FMD.REC.1398.311

Health conditions studied

1

Description of health condition studied

Thoracic region postural Kyphosis

ICD-10 code

M40.04

ICD-10 code description

Postural kyphosis, thoracic region

Primary outcomes

1

Description

Physical Fitness consist of muscle strength, mucsle endurance and balance

Timepoint

At the begining of the study, after 12 weeks and one year (At the begining the duration of the follow up was 6 months but after covid 19 pandemic, sampling was incomplete and the time of final assessment was changed from 6 month to one year. According to ethnic principles and to avoid endangering patients to come to Rasool Akram Hospital, which is the center of Corona, final assessments were performed by video call at home and inevitably, unmeasurable variables at home were eliminated in the final evaluation.)

Method of measurement

Muscle Strength by Dynamometer & Weight Machine, Muscle Endurance by 6 MWT(6 minute walk test), Balance by Berg Balance Scale. Senior Fitness Test to Strength, Flexibility, Agility, Cardiopulmonary Fitness, Dynamic Balance

2

Description

Respiratory Capacity

Timepoint

At the begining of the study , after 12 weeks (Inevitably final assessment was eliminated due to covid 19

pandemic)

Method of measurement

Spirometry

Secondary outcomes

1

Description

Kyphosis Angle

Timepoint

At the begining of the study , after 12 weeks

Method of measurement

Inclinometer Device and X-ray (X-ray only at the begining and one year)

Intervention groups

1

Description

Intervention group 1: Spinomed Orthosis plus Back School Program Exercise Therapy: The spinomode orthosis is made of a dorsal, pelvic belt and ventricle.The main part of the pressure on the spine is the back part, which is made of metal with a soft cover. This orthosis is adjustable and can be used for different sizes. The latest version of Spinomed Orthosis is available in various sizes from the German Medi Company. In the first session, the orthosist will prescribe orthosis according to patients body sizes to use it 2 hours daily for 6 months (which was increased to one year according to the covid 19 pandemic). It will be re-adjusted and improved once every two weeks in first 3 months period. Back School Exercise Therapy .It is a method that includes a training program and a physical exercise that is part of this treatment protocol. Groups of 5 patients will invite to participate in the study, the first session will provide a general description of the study and the effect of the exercise intervention. Exercises will then be taught to individuals based on their ability. The intensity, duration, repetition are individually adjusted and patients are advised to exercise regularly daily for the next two week. They will also share their experiences and problems in groups to a sports medicine specialist once every two weeks. These exercises include back and abdominal muscles , upper and lower limbs strengthening exercises ,and spinal posture correction. These exercises are given to patients in the form containing picture and description of exercises and a logbook for daily recording of the exercises performed. The exercises will be performed for 6 months (which was increased to one year according to the covid 19 pandemic), which will be performed once every two weeks in the first 3 months, and will not come to the hospital in the next 9 months, and will be followed up by phone every month.

Category

Treatment - Devices

2

Description

Intervention group 2: Elderly Orthosis plus Back School Program Exercise Therapy Spinal Elderly Orthosis: This orthosis is made of a dorsal, pelvic belt and ventricle. The main part of the pressure on the spine is the back part, which is made of metal with a soft cover. The latest version of Spinal Elderly Orthosis is produced by the Iranian company Savad Teb. In the first session, the orthosist will prescribe orthosis according to patients body sizes to use it 2 hours daily for 6 months (which was increased to one year according to the covid 19 pandemic) . It will be re-adjusted and improved once every two weeks in first 3 months period. Back School Exercise Therapy .It is a method that includes a training program and a physical exercise that is part of this treatment protocol. Groups of 5 patients will invite to participate in the study, the first session will provide a general description of the study and the effect of the exercise intervention. Exercises will then be taught to individuals based on their ability. The intensity, duration, repetition are individually adjusted and patients are advised to exercise regularly daily for the next two week. They will also share their experiences and problems in groups to a sports medicine specialist once every two weeks. These exercises include back and abdominal muscles , upper and lower limbs strengthening exercises ,and spinal posture correction. These exercises are given to patients in the form containing picture and description of exercises and a logbook for daily recording of the exercises performed. The exercises will be performed for 6 months (which was increased to one year according to the covid 19 pandemic) , which will be performed once every two weeks in the first 3 months, and will not come to the hospital in the next 9 months, and will be followed up by phone every month.

Category

Treatment - Devices

3

Description

Control group: Back School Exercise Therapy .It is a method that includes a training program and a physical exercise that is part of this treatment protocol. Groups of 5 patients will invite to participate in the study, the first session will provide a general description of the study and the effect of the exercise intervention. Exercises will then be taught to individuals based on their ability. The intensity, duration, repetition are individually adjusted and patients are advised to exercise regularly daily for the next two week. They will also share their experiences and problems in groups to a sports medicine specialist once every two weeks. These exercises include back and abdominal muscles , upper and lower limbs strengthening exercises ,and spinal posture correction. These exercises are given to patients in the form containing picture and description of exercises and a logbook for daily recording of the exercises performed.The exercises will be performed for 6 months (which was increased to one year according to the covid 19 pandemic), which will be performed once every two weeks in the first 3 months, and will not come to the hospital in the next 9 months, and will be followed up by phone every month.

Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazrate Rasoole Akram Hospital
Full name of responsible person
Haleh Dadgostar
Street address
Sports Medicine Department, Building No. 1, Hazrate Rasoole Akram Hospital, Niayesh Ave, Sattarkhan Ave
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Seyed Abbas Motevalian
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Iran University of Medical Sciences,next to Milad Tower, Shahid Hemmat Highway
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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
Sponsor: country of origin
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
Haleh Dadgostar
Position
Associate professor , Iran University of Medical Sciences
Latest degree
Specialist
Other areas of specialty/work
Sport Medicine
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Person responsible for scientific inquiries

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Person responsible for updating data

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Resident

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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
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be 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
Changes in physical fitness after the intervention in the three study groups and compared to each other Changes in muscle strenght after the intervention in the three study groups and compared to each other Changes in endurance performance after the intervention in the three study groups and compared to each other Changes in balance status after the intervention in the three study groups and compared to each other Changes in respiratory capacity after the intervention in the three study groups and compared to each other

When the data will become available and for how long
Start of access to data 6 months after publishing the article

To whom data/document is available
Researchers working in academic institutions that want to use these findings in systematic reviews and meta analysis.

Under which criteria data/document could be used
Due to the presence of authors at accademic center, it's nessecary to obtain college written permission for sending data. Therefore, data will be sent no later than 6 months after requesting college written permission.

From where data/document is obtainable
Rasoul Akram Hospital , department of Sports Medicine Dr Haleh dadgostar, Dr Samaneh ataie

What processes are involved for a request to access data/document
Information about who will review requests and criteria for reviewing requests may also be provided.

Comments