

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 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 divided randomly to Three groups of 20 each.

##### Settings and conduct

Location of research: Hazrate Rasool 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 beginning 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

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##### 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 beginning 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 committee of Iran University of Medical Sciences

**Street address**

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

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**Province**

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**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, muscle endurance and balance

**Timepoint**

At the beginning of the study, after 12 weeks and one year ( At the beginning 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 beginning 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 beginning of the study , after 12 weeks

#### **Method of measurement**

Inclinometer Device and X-ray (X-ray only at the beginning 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 orthosis 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 orthosis 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 Rasool Akram Hospital

**Full name of responsible person**

Haleh Dadgostar

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dadgostar.h@iums.ac.ir

**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****Contact****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

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**Position**

Associate professor , Iran University of Medical Sciences

**Latest degree**

Specialist

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

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**Full name of responsible person**

Samane Ataei

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

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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 strength 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 academic center, it's necessary 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 ataei

**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**