Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jul 2026

The effectiveness of bracing with home-based exercise aids on spinal deformity, pulmonary function, trunk muscle endurance and quality of life in adolescents idiopathic scoliosis: A parallel-groups clinical study

Protocol summary

Study aim

The aim of this study was to evaluate the effectiveness of bracing with home-based exercise aids on spinal deformity, pulmonary function, trunk muscle endurance and quality of life in adolescents idiopathic scoliosis in comparison with braces alone.

Design

The study is a single-blind randomized clinical trial with parallel groups. A total of 16 samples are selected using data from previous studies. participants enter each of the study groups through the blocked randomization method.

Settings and conduct

Participants are selected from patients referred to orthopedic centers affiliated to Isfahan University of Medical Sciences through available sampling.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: 1) Diagnosis of idiopathic scoliosis by a specialist. 2) Risser sign 0-2. 3) Thoracolumbar or lumbar curve 20-45 degrees. 4) Single or C-type curves. 5) Ability to use of braces and home-based exercise aids. 6) Physician approval to participate in research. Exclusion Criteria: 1. Existence of shortness and defects in the lower extremities. 2. People with underlying neuromuscular diseases such as cerebral palsy, spina bifida, muscular dystrophy, congenital myopathy and any other disease that is not able to exercise. 3. People with any history of surgery, trauma, fractures and other injuries to the spine. 4. Patients who have not experienced any intervention or practice for at least the past year.

Intervention groups

The test group will receive (a combination of brace and home exercise aids) and control (use of braces and scoliosis exercise program at home).

Main outcome variables

Spine Cobb angle, pulmonary function factors, trunk muscle endurance score, quality of life score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220330054371N1**
Registration date: **2022-05-09, 1401/02/19**
Registration timing: **prospective**

Last update: **2022-05-09, 1401/02/19**
Update count: **0**

Registration date

2022-05-09, 1401/02/19

Registrant information

Name

Zeinab Rezaeian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 4272 1266

Email address

rezaeian.zeinab.236@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-06, 1401/04/15

Expected recruitment end date

2023-01-20, 1401/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effectiveness of bracing with home-based exercise aids on spinal deformity, pulmonary function, trunk muscle endurance and quality of life in adolescents idiopathic scoliosis: A parallel-groups clinical study

Public title
The effectiveness of bracing with home-based exercise aids on spinal deformity of life in adolescents idiopathic scoliosis

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Diagnosis of idiopathic scoliosis by a specialist Risser sign 0-2 Thoracolumbar or lumbar curve 20-45 degrees Single or C-type curves Ability to use of braces and home-based exercise aids Physician approval to participate in research

Exclusion criteria:
Existence of shortness and defects in the lower extremities People with underlying neuromuscular diseases such as cerebral palsy, spina bifida, muscular dystrophy, congenital myopathy and any other disease that is not able to exercise People with any history of surgery, trauma, fractures and other injuries to the spine

Age
From **11 years** old to **17 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **16**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, the samples are placed in a block randomization method with the aim of entering equal samples in each group. The method of random appointment in both groups is that the size of each block is 4 people and based on this and considering the two test groups (T) and control group (C), 6 blocks are obtained. The arrangement of the members of each block is (TTCC), (TCCT), (TCTC), (CCTT), (CTTC) and (CTCT). The blocks are randomly selected and individuals receive the desired treatment based on the order of inclusion criteria in the study.

Blinding (investigator's opinion)
Single blinded

Blinding description
The measurement of curve angle will be carried out using blind assessors. The assessors will measure the curve angle while they are unaware of group allocations and personal details.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences

Street address
Isfahan University of Medical Sciences, Hezar Jerib St., Isfahan

City
Isfahan

Province
Isfehan

Postal code
8174673461

Approval date
2022-04-24, 1401/02/04

Ethics committee reference number
IR.MUI.NUREMA.REC.1401.025

Health conditions studied

1

Description of health condition studied
Lateral spinal deviation with idiopathic cause in adolescents in thoracolumbar and lumbar region

ICD-10 code
M41.125

ICD-10 code description
Adolescent idiopathic scoliosis, thoracolumbar region

Primary outcomes

1

Description
The amount of Cobb angle in the spine

Timepoint
This variable is measured in two sessions. The first time, the measurement is done in the pre-test stage (before the intervention). Then we ask the person to use braces and exercises for three months. After three months, the relevant variable is measured for the second time in the post-test phase.

Method of measurement
To measure the angle of the cobb, the patient's spine with anterior-posterior view is used while standing in a normal position. The calculation is done manually with the help of a pencil and a conveyor. Cobb angle is the angle created between two lines perpendicular to the

upper plateau of the upper vertebra of the scoliotic deviation and the line perpendicular to the lower plateau of the lower vertebra of the scoliotic deviation. On the other hand, because the intersection point is often somewhere off the page, an alternative method is used. Draw a right perpendicular to the two tangent lines and the angle created by the intersection of the two perpendicular lines is the angle of the cobb.

2

Description

Evaluation of pulmonary function

Timepoint

This variable is measured in two sessions. The first time, the measurement is done in the pre-test stage (before the intervention). Then we ask the person to use braces and exercises for three months. After three months, the relevant variable is measured for the second time in the post-test phase.

Method of measurement

Pulmonary function will be assessed by spirometry test using a Japanese CHESTGRAPH HI-301 digital spirometer. After giving personal information to the device and calibrating it, the tests of Total Lung Capacity, Vital Capacity, Forced Vital Capacity, Vital Capacity Inspiratory , Vital Capacity Expiratory, Peak Expiratory Flow and Forced Expiratory Volume In One Second , respectively. This test is performed while sitting on a chair and the patient is asked to remove the brace at least 2 hours before the test. To measure spirometric Indicators, a person is first asked to perform a normal inspiration. The mouthpiece of the device is immediately placed in his mouth and he takes a deep Expiration. The person then takes a deep inspiration, takes a deep Expiration, and then a deep inspiration, and the experiment ends at the end of this deep inspiration. During the test, care will be taken not to separate the input of the device from the mouth. Also, there should be no interruption between her inspiration and Expiration, and the duration of a deep Expiration should last at least 6 seconds. The alarm device alarm will be used for sufficient air.

3

Description

The endurance of the trunk muscles

Timepoint

This variable is measured in two sessions. The first time, the measurement is done in the pre-test stage (before the intervention). Then we ask the person to use braces and exercises for three months. After three months, the relevant variable is measured for the second time in the post-test phase.

Method of measurement

Trunk muscle endurance is assessed by lumbar trunk endurance test or LTMET to assess flexor and extensor trunk endurance and Side-Bridge test to assess lateral trunk flexor endurance. Finally, the Time (s) of Maintain position for each test in both groups can be recorded and compared.

4

Description

Quality of life index

Timepoint

This variable is measured in two sessions. The first time, the measurement is done in the pre-test stage (before the intervention). Then we ask the person to use braces and exercises for three months. After three months, the relevant variable is measured for the second time in the post-test phase.

Method of measurement

Quality of life index is measured by ISYQOL questionnaire which has 13 questions in the field of spinal health. The answers to the questions are based on a 3-point scale (zero to 2) in 3 options (never, sometimes, often). Thus, the score of each question will be between 0 and 2 and the range of total numerical scores will be between 0 and 26 for spinal health. That is, the number zero will be the highest quality of life and the number 26 will be the lowest level of quality of life.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Combination of brace and home-based exercise aid, Cheanue brace: Cheanue is a short piece of thoracolumbosacral brace, made of polypropylene, which opens and closes from the front. By conveying a load on the convex side, the brace directs the spine to the large valves on the wall in all three planes of motion, allowing the patient to perform therapeutic exercises for at least one hour a day. Braces are made specifically by molding the patient's spine. Cantilever Device: A rigid framework consists of levers that increase the mechanical advantage of the device by increasing its length. The corrective mechanism of the system is three points of pressure in which it is done by applying transverse load by pads to the spine to achieve a reduction in deviation. The pads in the device are made of polyurethane and its size depends on the size of the patient. The thoracic pad is fitted on the convex side of the deflection and on the gear that is articulated to the vertex of the deflection and its lower gear. The lumbar pad is also placed between the lower ribs and the upper iliac crest.

Category

Treatment - Devices

2

Description

Control group: Use braces and scoliosis exercise program at home. Cheanue brace: Cheanue is a short piece of thoracolumbosacral brace, made of polypropylene, which opens and closes from the front. By conveying a load on the convex side, the brace directs the spine to the large

valves on the wall in all three planes of motion, allowing the patient to perform therapeutic exercises for at least one hour a day. Braces are made specifically by molding the patient's spine. scoliosis exercise program at home: The exercises in the control group are designed for patients by a therapist and the patient is taught how and when to perform and repeat the exercises orally and in the form of a logbook.

Category
Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Al-Zahra Hospital

Full name of responsible person
Dr. Ali Andalib

Street address
Orthopedic Clinic, Al-Zahra Specialized Hospital, Shohada Soffe Blvd., Isfahan

City
Isfahan

Province
Isfehan

Postal code
8174675731

Phone
+98 31 3620 2020

Email
rezaeian.zeinab.236@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Dr. Mansour Siavash Dastjerdi

Street address
Building No. 3, Isfahan University of Medical Sciences, Hezar Jerib St., Isfahan

City
Isfahan

Province
Isfehan

Postal code
81746-73461

Phone
+98 31 3668 8138

Email
siavash@med.mui.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Esfahan 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
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Dr. Ebrahim Sadeghi Demneh

Position
Associate Professor and Faculty Member of the Department of Orthosis and Prosthesis

Latest degree
Ph.D.

Other areas of specialty/work
Orthosis and Prosthesis

Street address
School of Rehabilitation, Isfahan University of Medical Sciences, Hezar Jerib St., Isfahan

City
Isfahan

Province
Isfehan

Postal code
81746-73461

Phone
+98 31 3792 5053

Email
sadeghi@rehab.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Dr. Ebrahim Sadeghi Demneh

Position
Associate Professor and Faculty Member of the Department of Orthosis and Prosthesis

Latest degree
Ph.D.

Other areas of specialty/work
Orthosis and Prosthesis

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City
Isfahan

Province

Isfehan

Postal code

81746-73461

Phone

+98 31 3792 5053

Email

sadeghi@rehab.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Ebrahim Sadeghi Demneh

Position

Associate Professor and Faculty Member of the Department of Orthosis and Prosthesis

Latest degree

Ph.D.

Other areas of specialty/work

Orthosis and Prosthesis

Street address

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City

Isfahan

Province

Isfehan

Postal code

81746-73461

Phone

+98 31 3792 5053

Email

sadeghi@rehab.mui.ac.ir

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Study information (other than personal information) is shared with other researchers.

When the data will become available and for how long

Information is shared after the results are printed or summarized.

To whom data/document is available

Information will be shared for academic purposes only.

Under which criteria data/document could be used

Information is shared to teach and research applicants. Dr. Sadeghi (Executive Officer) will review the applications.

From where data/document is obtainable

Individuals can request information from the responsible person introduced.

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

Requests must be sent via email (sadeghi@rehab.mui.ac.ir).

Comments