ISRCTN24501159 https://doi.org/10.1186/ISRCTN24501159

A study of a modified brace and manual therapy for teenagers with sideways curvature of the spine

Submission date
25/05/2026

Recruitment status
Recruiting

Registration date
27/05/2026

Overall study status
Ongoing

Last Edited
26/05/2026

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Adolescent idiopathic scoliosis is a sideways curvature of the spine that occurs during growth. It can affect posture, appearance, comfort, daily activity and quality of life. Bracing and manual therapy are used as conservative treatments for adolescents who do not need surgery, but long-term brace wearing can be uncomfortable and some patients find it difficult to continue. This study aims to find out whether a modified airbag Cheneau brace combined with balance-restoring bone-setting therapy can improve spinal curvature, posture and quality of life in teenagers with adolescent idiopathic scoliosis.

Who can participate?
Teenagers aged 10 to 18 years with adolescent idiopathic scoliosis who are suitable for conservative treatment, meet the study criteria, and whose legal guardian or representative provides written informed consent.

What does the study involve?
Participants are randomly assigned to one of three groups. One group receives conventional Chinese massage technique, tuina. A second group receives balance-restoring bone-setting therapy combined with tuina. A third group receives the same balance-restoring bone-setting therapy and also wears a modified airbag Cheneau brace. Treatment lasts for 12 weeks. The brace group has a short adaptation period and is then asked to wear the brace for most of the day, except during treatment, personal hygiene and exercise. Participants have spinal imaging, posture assessment and questionnaires before and after treatment, and are followed for 1 month after the treatment course.

What are the possible benefits and risks of participating?
Possible benefits include improvement in spinal alignment, posture, symptoms, comfort and quality of life. These benefits cannot be guaranteed. Possible risks include temporary soreness after manual therapy, local discomfort, skin redness or pressure discomfort from brace wearing, and inconvenience from repeated follow-up and imaging. The study team monitors participants and adjusts treatment if discomfort or adverse events occur.

Where is the study run from?
The study is run at Hangzhou Hospital of Traditional Chinese Medicine, Hangzhou, Zhejiang, China.

When is the study starting and how long is it expected to run for?
The project period is from January 2025 to December 2027. Participant recruitment is planned from July 2025 to December 2026, with treatment lasting 12 weeks and follow-up for 1 month after the treatment course.

Who is funding the study?
The study is supported by the Zhejiang Provincial Traditional Chinese Medicine Science and Technology Program and institutional matching funds from Hangzhou Hospital of Traditional Chinese Medicine.

Who is the main contact?
Yan Chen, Hangzhou Hospital of Traditional Chinese Medicine, chenyan000fox@163.com.

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Ms Yan Chen

ORCID ID
https://orcid.org/0009-0009-6931-9582

Contact details
No. 453 Tiyuchang Road, Xihu District
Hangzhou
China
310007
+86 571 85827896
87406360@qq.com

Additional identifiers

Zhejiang Provincial Traditional Chinese Medicine Science and Technology Program project number
2025ZL410

Study information

Scientific Title
A single-centre randomized parallel-group clinical study of a modified airbag Cheneau orthosis combined with balance-restoring bone-setting therapy compared with balance-restoring bone-setting therapy and conventional tuina for adolescent idiopathic scoliosis

Acronym

PINGMI-AIS

Study objectives
1. To evaluate whether a modified airbag Cheneau orthosis combined with balance-restoring bone-setting therapy improves spinal curvature in adolescents with idiopathic scoliosis compared with balance-restoring bone-setting therapy alone and conventional tuina.
2. To assess the effects of the combined treatment on posture, health-related quality of life, treatment satisfaction and clinical effectiveness indicators.
3. To assess the safety and feasibility of applying a Pingmi theory-based integrated conservative treatment pathway for adolescent idiopathic scoliosis.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 30/06/2025, Scientific Research Ethics Committee of Hangzhou Hospital of Traditional Chinese Medicine (No. 453 Tiyuchang Road, Xihu District, Hangzhou, Hangzhou, China; +86 571 85827896; 2057874175@qq.com), ref: 2025KLL168

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Adolescent idiopathic scoliosis (AIS)

Interventions
This is a single-centre, randomized, three-arm, parallel-group clinical study. Approximately 96 adolescents with adolescent idiopathic scoliosis are randomized in a 1:1:1 ratio using a digital /computer-generated random number method to one of the following groups, with approximately 32 participants in each group. Outcome data are collected by personnel who do not participate in patient treatment.

Group 1: Conventional tuina control group. Participants receive conventional tuina once weekly for 12 weeks. The treatment is performed with the participant in the prone position and includes

rolling and kneading along both sides of the spine and the Bladder meridian, focused treatment at the curved spinal segment, pressing and kneading at related acupoints such as Xinshu, Feishu, Ganshu, Shenshu and Dachangshu, thumb muscle-relaxing techniques to the erector spinae, spinal pressing and oblique-pulling manipulation, followed by rolling and kneading along the paraspinal region.

Group 2: Balance-restoring bone-setting therapy group. Participants receive balance-restoring bone-setting therapy combined with tuina once weekly for 12 weeks. With the participant in the prone position, the practitioner palpates along the Du meridian, Jiaji points and Bladder meridian on both sides of the spine to identify abnormal tender, tense or nodular points. These points are treated using pressing, plucking-kneading and one-finger Zen manipulation for approximately 10 minutes. Region-specific low-force bone-setting techniques are selected according to the affected spinal region, including head-lifting correction for cervical involvement, prone thoracic impulse correction for thoracic involvement and Long's traction-based lumbar bone-setting technique for lumbar involvement.

Group 3: Combined therapy group. Participants receive the same balance-restoring bone-setting therapy as Group 2 and additionally wear an individualized modified airbag Cheneau orthosis. The orthosis consists of a Cheneau-type brace and adjustable airbag components. The brace is customized according to each participant's spinal curvature model. During the adaptation period in the first 5 days, participants wear the brace for at least 4 hours per day. After the adaptation period, participants are instructed to wear the brace for approximately 23 hours per day, removing it only for treatment, personal hygiene and exercise. Airbag inflation is adjusted according to Cobb angle and clinical assessment. Participants are instructed to perform deep-breathing pulmonary exercises.

All groups receive study-related communication, rehabilitation education, guidance on posture, home exercise, diet and daily activities, follow-up reminders, imaging review arrangements and safety monitoring. Participants are followed during the 12-week treatment period and for 1 month after completion of the treatment course.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Modified airbag Cheneau orthosis

Primary outcome(s)
1. Change in Cobb angle measured using standing full-length posteroanterior spinal radiographs (degrees). The change is calculated as the absolute difference between the value at follow-up and the value at baseline; at baseline (before randomisation) and 1 month after completion of the 12-week treatment course

Key secondary outcome(s))
1. Spinal posture measured using clinical posture assessment including plumb line alignment, shoulder balance, scapular symmetry, waist angle and pelvic tilt, at baseline, week 6, week 12, and 1 month after completion of the 12-week treatment course

2. Health-related quality of life measured using the Scoliosis Research Society-22 questionnaire (SRS-22) at baseline, week 12, and 1 month after completion of the 12-week treatment course

3. Treatment satisfaction measured using a treatment satisfaction questionnaire developed for this study, with items rated on a 5-point Likert scale at week 12 and 1 month after completion of the 12-week treatment course

4. Clinical treatment response measured using prespecified clinical effectiveness indicators including: (1) improvement in angle of trunk rotation measured using a scoliometer; (2) improvement in waist-angle difference; and (3) overall clinical effectiveness rating (significant improvement, moderate improvement, no change, or deterioration) assessed by the treating physician, at week 12 and 1 month after completion of the 12-week treatment course.

5. Safety and adverse events from enrolment (baseline) to 1 month after completion of the 12-week treatment course, measured using the type, frequency, severity and relatedness of adverse events recorded from enrolment to study completion. Severity is graded as mild, moderate or severe. Relatedness to study interventions is assessed by the investigator as unlikely, possible, probable or definite, at one data collection time point

Completion date
31/12/2027

Eligibility

Key inclusion criteria
1. Adolescents aged 10 to 18 years
2. Diagnosis of adolescent idiopathic scoliosis
3. Cobb angle less than 40 degrees and considered suitable for conservative treatment
4. Outpatients or inpatients treated at Hangzhou Hospital of Traditional Chinese Medicine who meet the study diagnostic, inclusion and exclusion criteria
5. Able to complete the planned 12-week treatment and follow-up assessments
6. The participant and his/her legal guardian or representative provide written informed consent according to the approved consent process

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
10 years

Upper age limit
18 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Scoliosis requiring surgical treatment, including Cobb angle greater than 40 degrees, progressive worsening with clear surgical indication, obvious back pain requiring surgical evaluation, or neurological compression symptoms
2. Congenital, neuromuscular, syndromic, degenerative or other non-idiopathic scoliosis
3. Previous spinal surgery or other treatment that, in the investigator's judgment, would interfere with evaluation of the study interventions
4. Severe cardiopulmonary, neurological, infectious, metabolic bone, tumour-related or other systemic disease that makes participation unsafe
5. Contraindication to tuina, bone-setting manipulation, brace wearing or radiographic follow-up
6. Skin ulceration, severe skin disease or local condition preventing safe brace wearing
7. Inability to complete study treatment or follow-up assessments
8. Refusal of informed consent by the participant or legal guardian/representative

Date of first enrolment
01/07/2025

Date of final enrolment
31/12/2026

Locations

Countries of recruitment
China

Study participating centre
Hangzhou Hospital of Traditional Chinese Medicine
Tuina Department / Orthopedics Department, No. 453 Tiyuchang Road, Xihu District
Tuina Department / Orthopedics Department, No. 453 Tiyuchang Road, Xihu District
China
310007

Sponsor information

Organisation
Hangzhou Hospital of Traditional Chinese Medicine

ROR
https://ror.org/03a8g0p38

Funder(s)

Funder type

Funder Name
Zhejiang Provincial Traditional Chinese Medicine Science and Technology Program

Funder Name
Hangzhou Hospital of Traditional Chinese Medicine

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			26/05/2026	No	Yes