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Efficacy of sensorimotor training combined with core strength training for low back pain in adult idiopathic scoliosis: a study protocol for a randomized controlled trial

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ABSTRACT

Introduction Sensorimotor training (SoMT) is a gradual balance training technique employed to treat various chronic musculoskeletal pain. Core strength training (CST) is one of the most commonly used interventions for managing low back pain (LBP). This randomied controlled trial protocol aims to determine whether the combination of SoMT and CST can significantly reduce LBP, and improve scoliosis-related outcomes and overall functional status in adult idiopathic scoliosis (AdIS) patients.

Methods and analysis A total of 300 AdIS patients will be recruited from the outpatient clinic and randomly assigned to one of three groups: CST group, SoMT group or the combined therapy group, using stratified block randomization based on the severity of scoliosis curve. All groups will receive the intervention three times a week for 12 weeks. Sessions will be conducted in the hospital, and no home programme will be provided. Adherence and attendance will be monitored and recorded. The CST group will receive CST therapy, while the SoMT group will receive SoMT therapy, which consists of three progressive phases: static, dynamic and functional. Participants will progress to the next phase on achieving pelvic stability in the current phase. The combined therapy group will receive both CST and SoMT. Assessors and statisticians will remain blinded to participant allocation throughout the study. Assessments will be performed at baseline and at the endpoint, 12 weeks after the initiation of the intervention. The primary outcome will be the self-reported pain level, measured using the visual analogue scale. Secondary outcomes will include pain-related disability (by the Oswestry Disability Index and the Roland-Morris Disability Questionnaire), spinal morphology indicators (including Cobb angle, the angle of trunk rotation and the Sagittal Index), postural control ability (by the Tetrax IBSTM), proprioceptive sensitivity (by the repositioning error test) and health-related quality of life (by the 36-Item Short Form Health Survey). Statistical analysis will adhere to the intention-to-treat principle and will be complemented by per-protocol analysis. To compare the effects of SoMT versus CST and combined therapy versus SoMT on both primary and secondary outcomes, a linear mixed-effects model or generalised linear mixed model will be applied.

Ethics and dissemination The current study received ethical approval from the Xinhua Hospital Ethics Committee Affiliated to Shanghai Jiao Tong University School of Medicine (XHEC-C-2024-080-3). Written informed consent will be obtained from all participants. Any interim analysis and full results will be published in an international peer-reviewed journal.

Trial registration number This protocol was registered in the Chinese Clinical Trial Registry (ChiCTR2400085370).

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The controlled design of this study will ensure scientific rigour and facilitate a comprehensive comparison of the efficacy of each intervention method, both individually and in combination.
⇒ The outcome measures will be multifaceted, providing a thorough evaluation of the diverse effects of the interventions.
⇒ This study will not include a follow-up period to assess the long-term efficacy of the intervention.
⇒ Given the specific nature of the exercise therapy, blinding of participants and therapists will not be feasible.

INTRODUCTION

Idiopathic scoliosis (IS) is a three-dimensional spinal postural asymmetry of no specific aetiology with a Cobb angle greater than 10° in the coronal plane.[1] IS usually occurs in adolescence (age 10–17 years), and the risk of progression of spinal postural asymmetry decreases with age and gradually stabilises in adulthood.[2] However, the severity of the postural asymmetry may still fluctuate in adult idiopathic scoliosis (AdIS) patients and is associated with musculoskeletal pain, such as low back pain (LBP).[3] Previous studies have shown that untreated IS patients have a threefold higher prevalence of LBP and are

approximately 20 times more likely to develop severe LBP compared with IS patients who receive regular interventions, such as brace treatment or Harrington distraction and fusion.[4–6]

Impaired postural control ability may relate to the progression of spine postural asymmetry and the development of LBP in IS patients.[7 8] Postural control refers to the act of maintaining, achieving or restoring a state of balance in any posture or activity.[9] Postural control requires coordinated activation of muscle groups to maintain a standing posture. Impaired postural control ability in IS patients may be associated with deficits at multiple levels of sensory input, central integration and motor output.[10] A meta-analysis of adolescent IS patients demonstrated that their proprioceptive sensitivity was significantly lower compared with non-IS patients.[11] One functional MRI study of cortical and subcortical function in adolescent IS patients revealed abnormal activation patterns in the brain's secondary motor regions during motor execution, suggesting impaired sensorimotor integration in these patients.[12] Abnormalities in sensory input and central integration will induce postural control impairment, which can manifest as spinal malalignment and LBP in IS patients.[7 13] The comorbidity of LBP and scoliosis presents a challenge for rehabilitation interventions. With age, LBP in AdIS patients can be characterised by chronicity due to progressive loss of spinal intersegmental stability.[3 14] When LBP occurs in AdIS patients, persistent pain and spinal postural asymmetry result in a greater likelihood of mental health problems such as anxiety, depression and increased stress.[15] The quality of life in patients declines progressively as pain severity increases, emphasising the urgent need to manage LBP symptoms in AdIS patients.[16 17]

Current therapies for adult scoliosis primarily target localised postural asymmetries and degenerative conditions such as spinal stenosis, vertebral body slippage and disc degeneration, often overlooking LBP symptoms.[18] For persistent LBP (lasting >12 weeks), guidelines recommend physiotherapy as the first-line treatment. Unlike LBP in the general population, interventions for AdIS patients should also focus on re-establishing spinal alignment and balancing the bilateral structures of the spine.[17 19] Core strength training (CST) is a widely used exercise modality for alleviating LBP.[20–22] The concept of CST is to stabilise the spine, relieve pain and improve motor function by restoring the strength of the muscles that control and support the spine.[23–25] While CST has been shown to increase lumbar muscle strength and address neuromuscular imbalances,[26] some studies suggest that its efficacy in alleviating LBP and improving scoliosis remains uncertain.[27–29] Furthermore, CST alone may be inadequate for managing LBP in AdIS patients, given the complexity of the condition's pathogenesis.

Sensorimotor training (SoMT) was originally developed by Dr. Vladimir Janda in 1970 as progressive balance training for the therapy of chronic musculoskeletal pain. SoMT is mainly used in the rehabilitation of the lower limbs and spine.[30] SoMT emphasises viewing the motor and sensory systems as a whole by increasing proprioceptive input at three key points, the foot, sacroiliac joints and cervical spine, to stimulate subcortical pathways and improve spontaneity and coordination of movement patterns.[30–32] SoMT treats patients with LBP through three training phases: static, dynamic and functional. In the initial phase, patients are challenged to improve sensory integration and postural stability by challenging their static and dynamic postural stability on different support surfaces. In the functional phase, patients are guided to rebuild postural control in daily life to improve spinal alignment, balance motor function of both lower limbs and ultimately improve the biomechanical characteristics of the low back and reduce pain.[30 31 33] Rather than just strengthening superficial and deep muscle groups (eg, CST), SoMT improves proprioception and postural control, thereby realigning the trunk and controlling LBP symptoms.[31 34–36] It is therefore expected that the improvement of LBP symptoms will also have the potential to improve spinal postural asymmetry. However, there is a lack of scientific research on the effects of applying SoMT to improve LBP symptoms and spinal postural asymmetry in patients with AdIS.

To fill this gap, we designed a ramdomised controlled trial with the primary aim of investigating whether the combined use of CST and SoMT provides superior relief of LBP symptoms in AdIS patients compared with CST or SoMT alone. The secondary aim was to evaluate the effects of the intervention on pain-related disability, spinal morphology, postural control, proprioceptive sensitivity and health-related quality of life. SoMT targets the underlying pathogenesis of IS, potentially contributing to the correction or stabilisation of spinal curvature. We hypothesised that the combined application of CST and SoMT will not only significantly alleviate LBP symptoms but also improve scoliosis-related outcomes and overall functional status in AdIS patients.

METHODS

Study design and setting

This is an assessor and statistician blinded randomised controlled trial with three groups assigned in parallel. AdIS patients who meet the criteria and provide written informed consent will be assigned to one of three treatment groups: CST group, SoMT group and combined therapy group.

No data will be recorded before written informed consent to participate and to publish was given by the participant. The informed consent forms provided to participants are available in the online supplemental material 1 (English version) and online supplemental material 2 (Chinese version). The study protocol will follow the Consolidated Standards of Reporting Trials (CONSORT) statement on randomized trials of non-pharmacological therapy,[37] and Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT)

	STUDY PERIOD		
	Enrolment	Allocation	Post-allocation
TIMEPOINT		T1 (Day0)	T2 (Day84)
ENROLMENT:			
Eligibility screen	✓		
Informed consent	✓		
Allocation		✓	
INTERVENTIONS:			
Core strength training		♦——	——♦
Sensorimotor training		♦——	——♦
Combined therapy		♦——	——♦
ASSESSMENTS:			
Visual Analog Scale		✓	✓
Oswestry Disability Index		✓	✓
Roland-Morris disability Questionnaire		✓	✓
Cobb angle		✓	✓
Angle of Trunk Rotation		✓	✓
Sagittal Index		✓	✓
Fall-risk Index		✓	✓
Repositioning Error Test		✓	✓
36-item Short Form Health Survey Questionnaire		✓	✓

Figure 1 Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) figure.

guidance for protocol reporting.[38] The SPIRIT figure is shown in figure 1, and the SPIRIT checklist is shown in online supplemental material 3. The study will adhere to the Template for Intervention Description and Replication (TIDieR) guide to describe the interventions, and the TIDieR checklist is provided in the online supplemental materials 4 and 5.[39]

Recruitment

We will recruit 300 AdIS patients through responses to a call for volunteers from the outpatient clinic of the Department of Rehabilitation at Xinhua Hospital, Shanghai Jiao Tong University School of Medicine. This department is one of the first scoliosis rehabilitation centres established in Shanghai, and the clinicians have extensive experience in treating IS, especially in exercise therapy. About 1000 IS outpatients are seen annually, of whom about 200 receive outpatient therapy one to three times per week. The above conditions provide a solid foundation for the feasibility of this trial. Patient recruitment is scheduled to start in March 2025 and is scheduled to end in June 2027. Intervention, assessment, data collection and data analysis will be conducted in the same study centre. The CONSORT flow chart is shown in figure 2.

Selection criteria

Participants meeting the following criteria will be included:

- Age is between 18 and 40 years.
- The Cobb angle is 10° or greater, and the aetiology is unknown.
- Participants complain of LBP (located between the 12th rib on the dorsal side of the body and the subgluteal crease) that is severe enough to limit daily activities or alter the daily routine for more than 1one day.
- Participants report experiencing LBP at some point within the last 4four weeks.
- Participants are determined to be without cognitive impairment and able to understand instructions based on an evaluation during the initial clinical interview, which includes a discussion of their medical history and current condition, as well as their ability to express thoughts, answer questions and comprehend the study requirements.

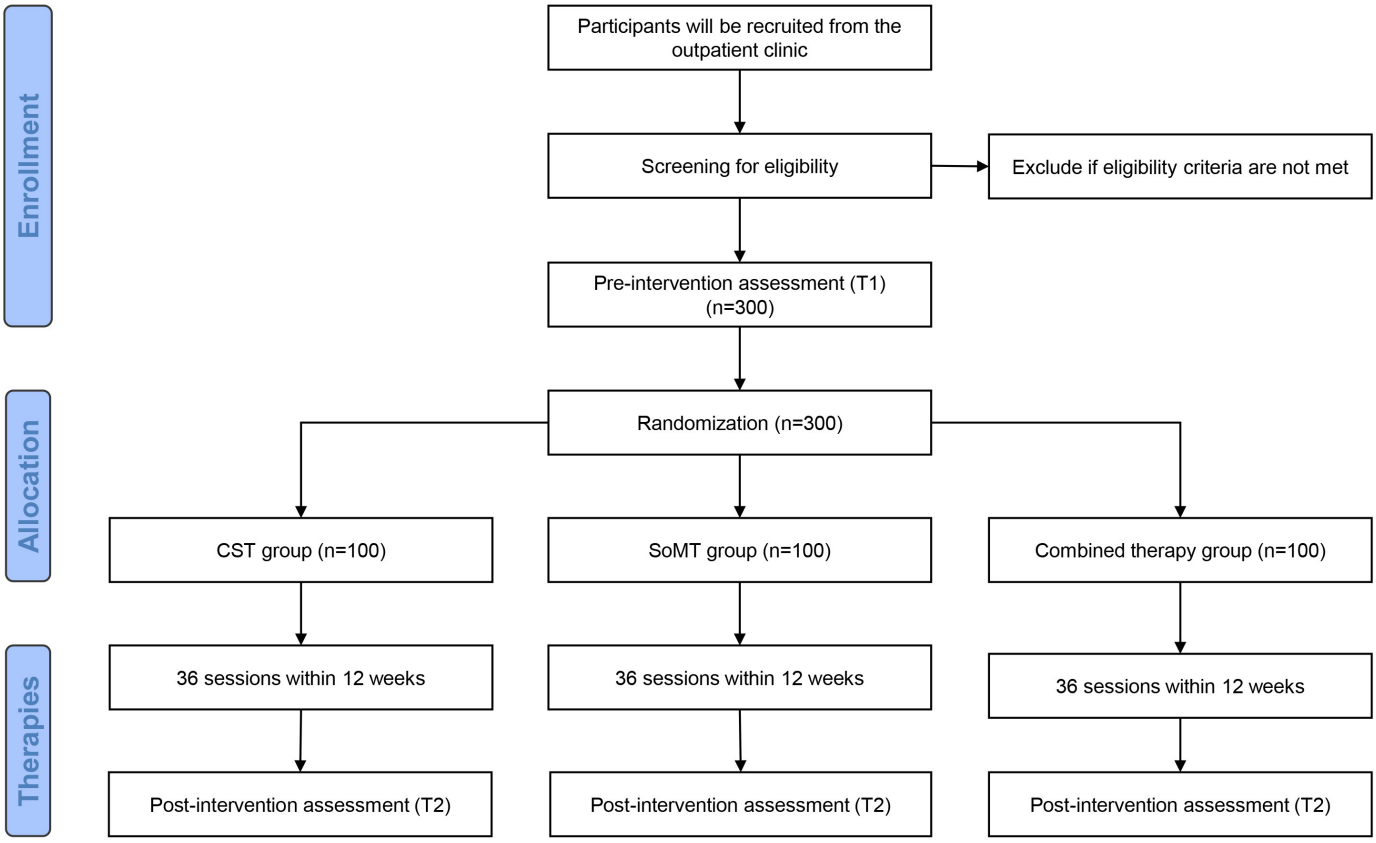

Figure 2 The Consolidated Standards of Reporting Trials (CONSORT) flow chart of study. CST, core strength training; SoMT, sensorimotor training.

- Participants understand the therapy plan and have given written informed consent.

Participants matching any of the following criteria will be excluded:

- Scoliosis with defined aetiologies (eg, neuromuscular disorders, congenital abnormalities or syndromic associations).
- No prior exposure to CST or SoMT.
- History of musculoskeletal/nervous system infections or tumours.
- Current pregnancy or within 3three months postpartum.
- Previous surgical history involving thoracic, abdominal, spinal, pelvic or lower extremity regions, or planned surgical interventions in relevant anatomical regions during the study period.
- Absolute contraindications to physical exercise or documented psychiatric disorders.
- Concurrent participation in alternative scoliosis or LBP therapeutic interventions during the trial.

Withdrawal criteria

- The participant requests to withdraw from the trial.
- Participants are lost to follow-up or die.

Suspension criteria

- Participants are suspended from the trial if the researcher determines that continued participation may compromise their safety or well-being, for example, in the case of serious adverse events or non-compliance with the intervention protocol.
- Participants who receive other interventions that interfered with the study during the trial.
- Participants whose scoliosis progression cannot be controlled by exercise intervention during the trial (the Cobb angle increased ≥5° compared with the baseline).
- Participants with accidental injuries (eg, fractures or trauma) are unable to continue the trial due to various reasons.

All participants who meet either the withdrawal or suspension criteria will be retained in the intention-to-treat (ITT) analysis, in line with the ITT principle.

Randomisation, blinding and allocation concealment

The statisticians will apply SPSS (IBM SPSS Statistics for Windows, V.26.0. Armonk, NY: IBM Corp) software to generate random numbers for participant coding. Participants will be randomly assigned to one of three groups in a 1:1:1 ratio: either (1) the CST group, (2) the SoMT group or (3) the combined therapy group. Participants will be allocated using stratified block randomization according to curve severity, with three strata defined by Cobb angle: mild (≥10° to ≤20°), moderate (>20° to ≤40°) and severe (>40°). The allocation results will be placed

in sealed opaque envelopes. After the baseline assessment and participant consent, sealed envelopes will be randomly assigned to therapists. Statisticians will not be involved in the recruitment, intervention or evaluation. Due to the nature of the exercise intervention, blinding of both participants and therapists is not feasible. Therefore, blinding will be applied to assessors and statisticians, and participants will be asked not to disclose their treatment assignments to ensure assessors remain unaware of group allocation.

To evaluate the success of blinding, assessors will be asked after data collection whether they were able to determine the group to which the participant was assigned or if they had made a guess. This will allow for documentation of blinding effectiveness and help assess whether any biases may have influenced the outcomes. Any reported blinding failure will be noted and taken into consideration during the analysis.

Compliance supervision

To evaluate adherence and attendance to the training, researchers will interview participants every 4four weeks starting from the initiation of the intervention. Communication will occur via phone, during which researchers will record attendance and provide any relevant medical consultation related to LBP and AdIS, aiming to reduce poor compliance and absenteeism. Participant adherence will be assessed using the Chinese version of the Exercise Adherence Scale (EXAS) at each phone interview.[40] EXAS is a valid and reliable tool for measuring exercise adherence in LBP patients.[41] Attendance will be calculated as the percentage of prescribed visits attended. Scores from EXAS and attendance data will be recorded in a dedicated notebook.

Intervention

All participating patients will receive 12 weeks of sessions, with a frequency of three sessions/week. All interventions will be provided during the scheduled supervised sessions, and participants will not be instructed to engage in the home programme. The supervising therapists will receive specific training in delivering SoMT and CST prior to the trial. Each therapy group (SoMT group, CST group and combined therapy group) will be supervised by the same therapist, ensuring consistency in the delivery of treatments across all groups. The therapists involved in the study hold Master's in physiotherapy, and each has obtained relevant certifications, including certified physical therapist. All therapists involved in the study have more than 5five years of clinical experience, specialising in the treatment of IS patients, including providing comprehensive spinal correction rehabilitation, as described in the previous study.[42] The exercise therapy programme is described in figure 3.

Core strength training group

The CST group will receive CST therapy, and the design of the training content will follow the proven *Core Stability Exercise Principles*.[43] Each training session will begin with a 5-min warm-up and end with a 5-min relaxation exercise, and the formal training session will last 30 min per session. CST is progressive and phased, and the training consists of two phases in total. The first phase will aim to activate the core muscles and improve proprioception and muscle coordination in the spinal region. This phase will specifically activate the transversus abdominis through abdominal drawing-in exercises. Once the transversus abdominis is 'activated', the training will progress to the second phase, which will involve higher intensity exercises. The second phase will target the core muscles of the trunk, including the unilateral internal and external abdominal obliques, anterior transversus abdominis, posterior gluteus maximus and gluteus medius, in order to enhance muscle stability and endurance. The formal training positions will include six movements: side plank support, plank support, single-leg hip bridge, clam opener, Swiss ball seated knee extension and single-leg stance. The number of repetitions for each movement will be adjusted based on the participant's exercise tolerance, with a range of 10 to 30 repetitions per session, determined based on the participant's heart rate, reaching 180 beats per minute, indicating severe exhaustion and exceeding the participant's exercise tolerance.[44] The warm-up exercise will involve the 'cat-camel pose' stretch, while the relaxation exercise will include stretching of the anterior abdominal muscles, lateral abdominal muscles and gluteus maximus muscles. The therapist will encourage participants to maintain a neutral pelvic and spinal position and to breathe rhythmically and normally.

Sensorimotor training group

The SoMT group will receive SoMT therapy, which will begin each session with a 5-min warm-up and end with a 5-min relaxation exercise, with each formal training session lasting 30 min. The warm-up and relaxation exercises will follow the same protocol as those used in the CST group intervention. In SoMT, pelvic stability will be a key factor in phase progression. Pelvic stability refers to the ability to achieve and maintain optimal alignment of body segments in both static and dynamic positions. The body segments involved in this assessment include the lumbar and thoracic spine, pelvis and thighs. Pelvic stability will be considered achieved when these body segments are aligned and maintained in a neutral posture.[45] All assessments of pelvic stability in this study will be conducted by the same therapist.

The modified SoMT in this study will consist of three phases (static, dynamic and functional). The static phase of the training will require participants to maintain pelvic stability across four progressively challenging surfaces: firm surface, foam surface, balance mat and wobble board. The therapist will instruct participants to maintain a two-legged standing position and a single-leg standing position for 20 s each. Participants will practise on each surface until they can demonstrate sustained pelvic stability, after which the training will progress to

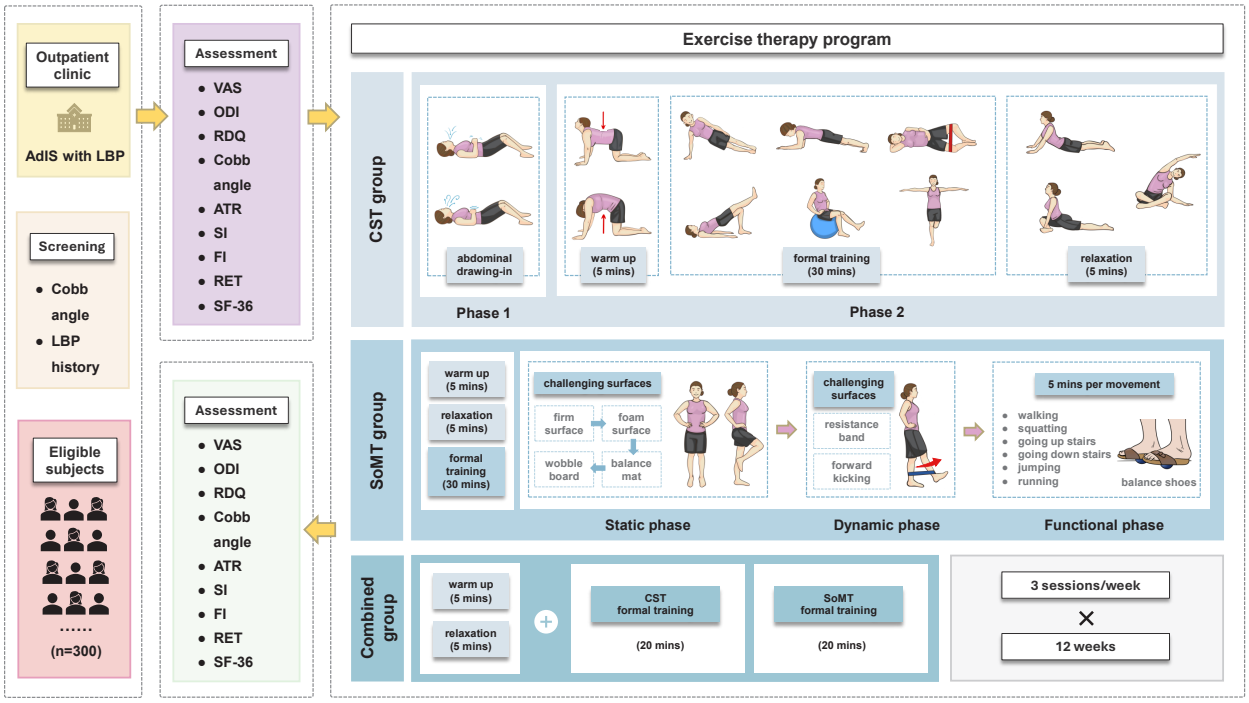

Figure 3 The exercise therapy programme. AdIS, adult idiopathic scoliosis; ATR, the angle of trunk rotation; CST, core strength training; FI, fall-risk Index; LBP, low back pain; ODI, the Oswestry disability index; RDQ, the Roland-Morris disability questionnaire; RET, repositioning error test; SF-36, 36-item short form health survey questionnaire; SI, sagittal index; SoMT, sensorimotor Training; VAS, visual analogue scale.

the next surface. The dynamic phase of training will also be performed on the four surfaces mentioned above. In this phase, participants will first be asked to stand upright on the surface with both legs, wearing a resistance band around the calves. The addition of the resistance band aims to further challenge participants to maintain stability and balance under more difficult conditions. Participants will then lift one leg and perform a forward kicking motion, maintaining both the one-legged stance and the forward kicking position for 20 s. Participants will alternate kicking their legs forward, repeating the exercise until they can sustain pelvic stability on the surface. As in the first phase, the next surface will be introduced only after the participant has successfully stabilised the pelvis. Once participants can maintain pelvic stability during training on all four surfaces in the second phase, they will progress to the functional phase. The final phase of SoMT focuses on achieving functional postural control through limb movements while maintaining pelvic stability. Training in this phase will be conducted using balance shoes, which have a hard rubber ball cut in half in the middle of the sole, increasing the challenge of maintaining balance. The exercises will include six movements: walking, squatting, going up stairs, going down stairs, jumping and running. During each training session, each movement will be practiced for 5 min, with an emphasis on avoiding any lateral or vertical pelvic movement throughout the exercises.

SoMT will be personalised, as participants will not be required to complete all three phases of training. While the study design includes three training phases, each participant's progression will be determined by their individual capabilities. Throughout the 12-week training period, the therapists will monitor and record each participant's progress in these phases on a weekly basis. For example, participant 1 entered the static phase with foam surface training in week 3, and participant 2 entered the functional phase in week 10 (a phase that did not include challenges from different surfaces and thus was not recorded). This personalised approach will allow each participant to progress at a pace suited to their individual abilities.

Combined therapy group

The combined therapy group will receive both CST and SoMT therapy. Each session will begin with a 5-min warm-up and conclude with a 5-min relaxation exercise, with the formal training lasting 40 min in total. The warm-up and relaxation exercises will follow the same protocol as those used in the CST group intervention. During each training session, participants will first receive CST. The training content is the same as the CST group,

but the formal training time of each CST session will be shortened to 20 min. Following the CST session, participants will receive SoMT, which will include the same exercises as the SoMT group, with each SoMT session lasting no more than 20 min. The difference is that in the third phase of SoMT, the training time for the six movements of the training in the balance shoes will be shortened to 3–4 min. Therapists will make sure that all six movements will be practiced in each session of the third phase and that the total duration will not exceed 20 min.

Outcome

Primary outcome: self-reported level of pain

The pain level of LBP will be assessed using the visual analogue scale (VAS), a widely used and internationally recognised tool for pain assessment in IS patients.[46] The VAS consists of a 100 mm horizontal line, with the leftmost end representing 'no pain' and the rightmost end indicating 'the most severe pain imaginable'. The assessor will ask participants to recall the most severe LBP they have experienced over the past 4four weeks, with the region of LBP defined as extending from the 12th rib to the ilium.[47] The assessor will then instruct the participant to mark a point on the line that corresponds to the intensity of pain experienced, and the distance of the marked point from the leftmost end will be used as the assessment result.[48] The minimal detectable change (MDC) for the VAS is 13 mm,[49] and the minimal clinically important difference (MCID) is 18 mm.[50]

Secondary outcomes

Pain-related disability: Pain-related disability will be assessed using the Chinese version of the Oswestry Disability Index (ODI) and the Roland-Morris Disability Questionnaire (RDQ).[51 52] Both the ODI and RDQ are highly reliable, valid and responsive,[53] making them suitable for use with AdIS patients.[54 55]

- The ODI evaluates disability across 10 daily activity domains: pain, body hygiene, lifting objects, walking, sitting, standing, sleeping, sexual behaviour, social life and travelling. Items are scored on a 6-point scale, where 0 indicates 'no activity-related pain or symptom exacerbation' and 5 represents complete functional inability ('requires full assistance'). Final scores are calculated by converting the sum of all items (maximum 50 points) into percentage values. Disability levels are classified as follows: 0%–20% indicates minimal disability, 21%–40% moderate disability, 41%–60% severe disability, 61%–80% represents crippling back pain and 81%–100% indicates either bed-bound status or exaggeration of symptoms.[56] The MDC value for ODI is 13 scores,[57] and the MCID is a reduction of <30% from baseline ODI scores.[58]
- The RDQ takes approximately 5 min to complete and can be completed without the assistance of the assessor. The RDQ consists of 24 items that represent the ability to perform daily physical activities and functions that can be affected by LBP, such as difficulty with housework, sleep, activity, dressing, requiring help-seeking, limited appetite, having irritability and experiencing pain. Items are selected as 'yes' if the patients experienced pain-related disability and 'no' otherwise. Points are scored according to the options selected by the participant, with one point for each 'yes' choice, and the total score ranges from 0 (no disability) to 24 (most severe disability), with higher scores representing more severe disabilities. The total score will be taken as the result of the assessment.[59] The MDC value for RDQ is 5.5 points,[57] and the MCID is <30% reduction from baseline RDQ scores.[60]

Indicators of spine morphology: Indicators of spine morphology will include the Cobb angle, the angle of trunk rotation (ATR) and Sagittal Index (SI).

- Cobb angle: Participants will undergo a full spine radiograph in a standing position, fists on clavicles. The measurement of Cobb angle demonstrates excellent validity and reliability, with intraobserver and interobserver intraclass correlation coefficient(ICC) exceeding 0.864, and the average interobserver variability for Cobb angle is 3°.[61] The vertebrae with the greatest inclination on the cephalic and caudal sides of the spinal curvature are designated as the upper and lower vertebrae, respectively. A straight line is drawn along the upper endplate of the upper vertebra and the lower endplate of the lower vertebra, and the angle between these two lines is defined as the Cobb angle.[62] The primary curvature will be used as the assessment results. The severity of the curve will be classified based on the Cobb angle as follows: 10°–20° for mild, 20°–40° for moderate and >40° for severe.[1] The MCID for Cobb angle is 5°.[63]
- ATR: ATR is a key parameter for assessing vertebral rotation and lateral rib hump abnormality. The magnitude of ATR can be quantitatively measured using the Scoliometer, which has 53% specificity and 85% sensitivity when detecting scoliosis with a Cobb angle greater than 10° on a frontal radiograph, using an ATR threshold of 5°.[64] The Scoliometer demonstrates high intrarater and inter-rater reliability (0.92 and 0.89, respectively).[65] ATR will be assessed based on the Adams forward bend test, during which the participant's hands will be placed palms together, the legs and feet will be straightened and the torso will be flexed forward until parallel to the floor. The arms will be lowered and kept parallel to the legs, and the participant will maintain this position. The assessor will then hold the instrument perpendicular to the spine, place the centre above the spinous process and measure ATR in the thoracic, thoracolumbar and lumbar segments sequentially.[66] The ATR values from these three regions will be used as the assessment results. The MCID for ATR is 5°.[65]
- SI: The spinal SI will be measured using a plumb line, which has demonstrated excellent inter-rater reliability (ICC>0.90) across all measurement points.[67] The plumb line will be fixed to the ceiling, and the

assessor will instruct the participant to stand with his/her back to the plumb line and remain stationary. The assessor will then measure the horizontal distance from the plumb line to three marked points: C7, the last convexity of the thoracic vertebrae (T5-T6), and L3. Finally, the distance from the point T5-T6 to the plumb line will be subtracted from the distance from C7 or L3 to the plumb line, which will be used to minimise the measurement error. The sum of the corrected distances from C7 and L3 to the plumb line will be used as the assessment results. A sum of <60 mm will be considered flat back, 60–90 mm will be within the normal range and >90 mm will be considered kyphosis.[68] The MDC for SI is a change exceeding 10 mm.[67]

Postural control: Postural control will be assessed using the Tetrax IBSTM (Sunlight Medical Ltd., Tel Aviv, Israel), a balance testing device that includes specific software installed on a computer, foam rubber pads and a force platform with handrails. The force platform consists of four independent, integrated force plates labelled A, B, C and D, mounted on a level, carpet-free floor. Participants, in a barefoot state, will position their toes and heels over a guiding design, with arms extended along their bodies. They will be instructed to remain silent and maintain an upright, stable and static posture for 32 s in each of the eight sensory conditions evaluated. The eight sensory conditions will be as follows: eyes open while standing on foam rubber pads, eyes closed while standing on foam rubber pads, eyes closed with the head turned to the right, eyes closed with the head turned to the left, eyes closed with the head tilted back 30° and eyes closed with the head tilted forward 30°. The duration of the entire test will be approximately 5 min. The Tetrax system will assess postural control ability under eight sensory conditions. For each, it will record postural sway parameters from four force plates (toes and heels bilaterally). Based on the variability and distribution of pressure signals across these conditions, the software will integrate and standardise these data to produce a single Fall-risk Index (FI) score. The FI ranges from 0% to 100%, with values ≤36% indicating low risk, 37% to 58% indicating moderate risk and ≥59% indicating high risk.[69] The FI will serve as the outcome measure, with higher FI scores reflecting poorer postural control.

Proprioceptive sensitivity: Positional awareness of the lumbar spine will be assessed using the repositioning error test (RET). The RET has demonstrated good intrarater (ICC=0.78–0.92) and inter-rater (ICC=0.78–0.93) reliability.[70] The iPhone 11 (Apple Inc, Cupertino, CA, USA) will be used as a measuring instrument with an inclinometer application (iHandy level).[71] The testing process will be as follows: (1) The participant will sit in a chair with the trunk upright. (2) An iPhone will be secured by a belt in an upright position, positioned above the participant's iliac crest, at the midpoint between the anterior and posterior iliac spines. (3) The participant will then be instructed to bend the trunk forward to the maximum range of motion, and the assessor will record the angle of the participant's maximum range of motion. (4) The 0° position will be set as the initial position, while 50% of the maximum range of motion will be designated as the target position.[72] (5) The assessor will instruct the participant to voluntarily contract the trunk muscles to move from the initial position to the target position, with the angle between these two positions designated as T (°). (6) The participant will remain in the target position for 10 s to familiarise himself/herself with the position and then returns to the initial position. (7) Finally, the participant will be asked to actively move to the target position again, at which point the actual reset position will be recorded. The angle between the actual reset position and the initial position will be labelled as the actual reset angle X (°). The assessor will then measure both T and X to calculate the absolute error (AE) angle: AE = |X - T|.[73] Larger AE values indicate poorer proprioceptive sensitivity. Each participant will perform three times, with the average AE angle taken as the assessment result. The MDC for the AE angle is 4°.[74]

Level of quality of life: Health-related quality of life will be assessed using the Chinese version of the 36-Item Short Form Health Survey (SF-36), which has established construct validity.[75] The SF-36 is appropriate for assessing the impact of LBP symptoms on the health-related quality of life in AdIS patients.[76] The SF-36 assesses participants across eight dimensions. The Physical Component Summary (PCS) assesses physical health, encompassing four dimensions: physical functioning, role-physical, bodily pain and general health. In contrast, the Mental Component Summary (MCS) assesses mental health, including four dimensions: vitality, social functioning, role-emotional and mental health. The scores reflect an individual's health status, with higher scores indicating better functional status and a higher quality of life in that domain.[77] Scores on the two summary scales (ie, PCS and MCS) will be used as assessment outcomes. The MDC values are 6.09 for the PCS and 6.14 for the MCS.[78]

Safety assessment and adverse event reporting

A detailed history of scoliosis, LBP, falls, cardiac disease, pulmonary disease and surgery will be recorded prior to the start of therapy, and exclusion criteria will exclude participants with any contraindications to protect participant safety. After the initial six training sessions, the intervention will be discontinued if either of the following predefined criteria is met: (1) an increase of ≥13 mm in LBP symptoms, as measured by the VAS, or (2) a deterioration of ≥13 points in functional status, as evaluated by the ODI. In such cases, two independent therapists will systematically review the case to assess the relationship to the intervention before finalising the discontinuation decision.

Collection of adverse events will begin after participants provide informed consent and are enrolled in the study. Adverse events will be reported by the participant and recorded by the therapist at the beginning of each

therapy session; reported adverse events or perceived potential risks will be recorded. The therapist will inquire about any adverse events experienced by the participant during the training. Each query will consist of items from a checklist, supplemented by an open-ended option. The checklist will include worsening pain, muscle strain, ligament tears, subperiosteal soft tissue damage, psychological deterioration, pain induced by muscle fatigue and a decline in muscle strength. If an adverse event occurs after a participant has signed informed consent (enrolment) but has not yet begun receiving the study intervention, the event will be reported as unrelated to the study intervention.

Sample size calculation

The sample size was calculated using a power analysis based on a standard design.[79] The effect size was set at 0.40, as reported in previous studies.[80] Engel *et al* evaluated the efficacy of SoMT for LBP. After 12 weeks of SoMT, the experimental group had a mean VAS score of 35 mm, while the control group had a mean score of 27 mm, with a pooled SD of 20 mm. Considering twice comparisons, type I error was set to be two-tailed α=0.05/2. Under the statistical power (1-β) of 0.90, the estimated sample size of each treatment group is 80. Considering the dropout rate of 20%, a total of 300 participants will be needed. The sample size was calculated with R software (V.4.1.2; R Core Team, Vienna, Austria) and package 'sjstats' (V.0.19.0.1, by Daniel Lüdecke).

Statistical analysis

All statistical analyses will be performed using R software (V.4.1.2; R Core Team, Vienna, Austria). The significance level (α) will be adjusted using the Bonferroni correction. All participants who will be randomised will be included in the ITT analysis, while those who will complete the intervention according to the protocol will be included in the per-protocol (PP) analysis. The safety set (SS) dataset will include all participants who received at least one training. The ITT dataset will be used for both primary and secondary outcomes, supplemented by the PP dataset. Multiple imputation approach will be used to deal with missing data.

The Shapiro-Wilk test will be used to assess the normality of variables, and the Levene test will be used to test for the equality of variances. If normality is violated, appropriate data transformations (eg, log or square root transformations) will be considered. To examine the effect of SoMT versus CST and combined therapy versus SoMT on the primary outcome and secondary outcomes, the linear mixed-effects model or generalised linear mixed model will be used. The time is used as the within-subjects variable (preintervention and postintervention), and treatment group is applied as the between-subjects variable (SoMT, CST, combined therapy).

Quality control and quality assurance

All researchers involved in this study hold relevant academic qualifications, including a Master's degree in physiotherapy, rehabilitation or a related field. The assessors possess a minimum of two years of clinical experience in assessing patients with musculoskeletal disorders, particularly those related to scoliosis and LBP. Prior to the study, the assessors will undergo specialised training to ensure consistency and accuracy in assessing both primary and secondary outcomes. During the training, assessors will perform practice assessments on test participants to ensure inter-rater reliability and minimise potential bias. Regular calibration sessions will be held to further standardise the assessment process, and the lead investigator will oversee the assessors throughout the study.

A three-tiered quality control system will be used: self-checks by researchers, monthly checks by team inspectors and quarterly monitoring by the study leader. A Clinical Research Unit (CRU) will be established in this study before the study is formally conducted to ensure the safety and validity of the data in this study. The CRU may terminate the trial early if a significant number of adverse events occur or if the data prove to be invalid.

Trial status

The current version of the research protocol is 2.0 and was registered on 6 June 2024.

Patient and public involvement

Patients or the public will not be involved in the design, conduct, reporting or dissemination plans of our research. On the conclusion of the study, participants will be provided with written feedback regarding their test and assessment results throughout the course of the therapy.

Ethics and dissemination

The current study received ethical approval from the Xinhua Hospital Ethics Committee Affiliated to Shanghai Jiao Tong University School of Medicine (study protocol number XHEC-C-2024-080-3). Written informed consent will be obtained from all participants. Any necessary modifications to the protocol will be reported to the same ethics committee. Any interim analysis and full results will be published in an international peer-reviewed journal. Before submission, all manuscripts will be submitted to all authors, who will review the manuscript for appropriateness and scientific merit.

DISCUSSION

The core objective of this randomised controlled trial protocol is to explore whether the combined application of CST and SoMT is more effective than either of them alone in the therapy of LBP symptoms and spinal postural asymmetry in AdIS patients. According to the most recent International Society on Scoliosis Orthopaedic and Rehabilitation Treatment (SOSORT) guidelines, the overall goal of conservative treatment of IS should include alleviating or treating spinal pain syndromes as well as stopping or slowing down the progression of scoliosis.[1]

Although the SOSORT guidelines primarily endorse physiotherapeutic scoliosis-specific exercises (PSSE) for scoliosis management, CST represents a more general physiotherapeutic strategy that may complement PSSE or be used independently to enhance trunk control and reduce LBP.[81–83] Previous research has demonstrated the benefits of CST for IS patients: a recent meta-analysis suggested improvements in the Cobb angle, ATR and quality of life.[84] Park *et al* further reported that individuals under 40 with abnormal spinal range of motion may respond particularly well to CST.[85] However, several studies have observed that CST has limited effectiveness in alleviating LBP in IS patients and may not outperform other therapeutic exercise regimens.[27–29] These limitations may reflect the multifactorial nature of LBP in AdIS, the severity of postural asymmetry and the duration of exercise intervention. Notably, interventions extending beyond 8eight weeks have shown greater potential for improving the Cobb angle.[86] Based on these insights, we designed a 12-week, phased and progressive CST programme.

SoMT is a programme geared towards musculoskeletal disorders to promote mobility with augmentation of sensory input for remodelling movement patterns in AdIS patients.[30] The neuroplasticity of LBP offers the possibility of resolving or ameliorating LBP, and the integration of sensory and motor processes increases the likelihood of eliminating LBP symptoms.[87] By repeatedly correcting movement patterns, SoMT therapy relieves LBP due to abnormal sensorimotor control.[35] At the same time, SoMT can also correct the alignment of the spine by improving postural control. However, there are no specific recommendations on its dosage, frequency or intensity to anticipate training effects. Due to the lack of standardised recommendations for SoMT implementation, existing SoMT studies show significant practice heterogeneity, and there are relatively few high-quality studies. A meta-analysis showed that the most effective relief of LBP occurred when patients were guided and actively encouraged to move and exercise in a progressive manner. Stabilisation/motor control exercise training is one of the most effective interventions for LBP.[88] It is hypothesised that combining SoMT with CST will further enhance paravertebral muscle strength and lumbar spine stability, thereby alleviating LBP, improving the correction of spinal postural asymmetry and preventing its progression.

Based on these considerations, we hypothesised that the combination of CST and SoMT would be more effective in improving LBP symptoms and spinal postural asymmetry in AdIS patients. The results of this protocol may reveal the additive effect of the combination of CST and SoMT. If the use of SoMT proves to be feasible and effective in the AdIS population, this study will inform the use of SoMT in the AdIS population for future implementation in large-scale studies.

Limitations

This study has several limitations. First, the study design does not include a follow-up period to assess the long-term efficacy of the intervention, which may leave the sustainability of its effects uncertain. Future research with extended follow-up would be necessary to evaluate the durability of the intervention's benefits. Second, due to the nature of exercise therapy, blinding will not be feasible for either the participants or the therapists. This lack of blinding could introduce a risk of bias in outcome assessment and reporting. Thirdly, there is currently a lack of authoritative literature validating the measurement properties—such as reliability and validity—of the Tetrax IBSTM. As a result, the data concerning the Tetrax IBSTM in this study will primarily rely on the manufacturer's specifications, which may limit the interpretation of the findings. Finally, LBP symptoms may be influenced by various factors, including biophysical, psychosocial, pain processing and comorbid conditions.[89] However, this study will not explore these factors in depth, which could limit the generalisability of the findings.

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