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Schroth versus Postural Restoration Institute (PRI) Exercise Effects on Spinal Alignment, Neuromuscular Activation, and Functional Outcomes in Adolescents with Idiopathic Scoliosis: Protocol for a Three-Arm Randomized Trial

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Study protocol

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Abstract

Background

Adolescent idiopathic scoliosis (AIS) is a three-dimensional spinal deformity associated with neuromuscular control deficits and altered sensorimotor integration. Physiotherapeutic scoliosis-specific exercises (PSSE), including the Schroth method and the Postural Restoration Institute (PRI) approach, are used clinically; however, no randomized controlled trial has directly compared their effects on spinal alignment and functional outcomes in adolescents with AIS.

Methods

This single-center, three-arm, parallel-group, assessor-blinded randomized controlled trial will enroll 90 adolescents aged 15–18 years with mild right thoracic AIS (Cobb angle 10–25°, Risser ≥ 3). Participants will be randomized 1:1:1, stratified by sex and baseline Cobb angle, to a Schroth exercise group, a PRI exercise group, or an active control group (usual activities). The Schroth and PRI groups will receive condition-specific supervised exercise protocols three times weekly for 12 weeks, complemented by home programs and fidelity monitoring; the active control group will continue routine physical activity without structured PSSE. Assessments will occur at baseline (T0), post-intervention (T1, 12 weeks), and follow-up (T2, 24 weeks). The primary outcome is change in photogrammetric Cobb angle from T0 to T1. Secondary outcomes include neuromuscular activation symmetry (sEMG index), angle of trunk rotation (ATR), range of motion (ROM), and Scoliosis Research Society 22r (SRS-22r) quality-of-life scores. Analyses will follow the intention-to-treat principle using linear mixed-effects models to evaluate group×time interactions, with effect sizes, minimal detectable change, and clinically meaningful differences reported. Ethics approval has been obtained from the Research Ethics Committees of University of Guilan, and informed assent/consent will be obtained from participants and guardians.

Discussion

This protocol will provide comparative evidence on the effects of Schroth and PRI exercise programs versus active control on photogrammetric spinal curvature and neuromuscular/functional outcomes in adolescents with mild AIS, informing clinical decision-making and supporting transparent reporting and reproducibility of the trial findings.

Trial registration

Iranian Registry of Clinical Trials (IRCT) IRCT20250729066684N1. Registered on 09 January 2026. URL: https://irct.behdasht.gov.ir/trial/85367.

Background

Epidemiology and Clinical Importance

Adolescent idiopathic scoliosis (AIS) is a three-dimensional spinal deformity of unknown aetiology that arises during adolescence (typically between ages 10 and 18) and accounts for the vast majority of idiopathic scoliosis cases in this age group (1). Prevalence estimates range from approximately 1% to 4% in adolescents worldwide, with a higher risk of progression and greater curve severity observed in females compared to males, roughly 1–4% prevalence (2–4). AIS can lead to back pain, aesthetic concerns, impaired pulmonary function, and reduced quality of life even in mild-to-moderate cases (5–7).

Pathophysiology and Mechanistic Understanding

Although the exact cause of AIS remains unknown, its progression involves complex interactions among genetic, biomechanical, neuromuscular, and sensorimotor control factors (8, 9). AIS diagnosis and severity assessment rely on the Cobb angle measured radiographically in the frontal plane, with thresholds guiding clinical management: curves < 10° are considered normal variants, 10–25° mild, and ≥ 25–40° moderate, with surgery generally considered above 40–50° (1, 10). Contemporary studies suggest that adolescents with AIS demonstrate asymmetric trunk muscle activation and altered neuromuscular control, which may contribute to curve development and persistence (e.g., increased activity of paraspinal muscles on the curve's convex side and sensorimotor integration deficits) (11–13).

Current Evidence for Schroth PSSE

Physiotherapeutic scoliosis-specific exercises (PSSE) aim to improve spinal alignment and neuromuscular control via targeted postural correction, three-dimensional exercises, and breathing techniques (14, 15). Among PSSE protocols, the Schroth method is the most extensively studied and widely implemented internationally, focusing on rotational angular breathing, postural awareness, and curve-specific correction strategies (16, 17). Systematic reviews and meta-analyses report that Schroth-based interventions are associated with improvements in Cobb angle, patient-reported quality of life, and trunk biomechanics in adolescents with idiopathic scoliosis, although effect sizes and clinical significance vary across studies (16, 18, 19). However, the quality and methodological robustness of many Schroth studies remains variable, leading to ongoing debate regarding optimal exercise protocols and dose–response relationships (14, 17).

Gaps in Evidence for PRI

The Postural Restoration Institute (PRI) approach is a framework that emphasizes the restoration of symmetrical posture and breathing mechanics by addressing inherent physiological asymmetries and compensatory movement patterns (20). PRI concepts have been applied clinically across various musculoskeletal conditions, including spinal dysfunctions (21, 22). However, despite theoretical relevance to AIS—given the asymmetrical nature of spinal curvature—there is a lack of high-quality, peer-reviewed randomized trials specifically investigating PRI's efficacy in AIS populations. The available PRI literature is largely descriptive or case-based rather than derived from controlled research, highlighting a substantial evidence gap relative to established PSSE modalities like Schroth (23).

Justification for This Study

Current clinical practice guidelines and systematic reviews underscore the need for rigorous comparative effectiveness research among PSSE protocols to inform evidence-based decision-making for AIS management (10, 17). Schroth exercises have demonstrated promise in reducing Cobb angle and improving patient-centric outcomes, whereas PRI's neuromechanical and breathing-focused rationale remains largely untested in controlled trial settings (14, 17, 24). Given this disparity in evidence, a well-designed randomized controlled trial comparing Schroth, PRI, and an active control condition is warranted to determine whether PRI confers similar or superior benefits in spinal alignment, neuromuscular activation symmetry, and functional outcomes in adolescents with mild AIS.

Methods/Design

Study Design

This study is a single-center, three-arm, parallel-group, assessor-blinded randomized controlled trial (RCT) designed with a superiority framework to evaluate the comparative effects of Schroth and Postural Restoration Institute (PRI) exercise protocols against an active control on spinal alignment and functional outcomes in adolescents with idiopathic scoliosis. A superiority design is specified to determine whether either intervention produces superior outcomes relative to control. Participants will be followed for a total of 24 weeks per individual, including a 12-week intervention period and a 12-week post-intervention follow-up evaluation.

Objectives and Hypotheses

Primary Objective

To compare the effect of a 12-week Schroth exercise protocol and a 12-week PRI exercise protocol versus active control on change in photogrammetric Cobb angle in adolescents with idiopathic scoliosis.

Secondary Objectives

To assess the effects of these interventions on neuromuscular activation symmetry, angle of trunk rotation (ATR), range of motion (ROM), and patient-reported quality of life measures.

Hypotheses:

Primary Hypothesis

Schroth and PRI exercise protocols will each produce greater reductions in photogrammetric Cobb angle at 12 weeks compared to active control.

Secondary Hypothesis

Schroth and PRI exercise protocols will each yield larger improvements in neuromuscular activation symmetry, ROM, ATR, and quality of life relative to control.

Planned comparisons

The primary efficacy comparisons will test the superiority of each intervention arm (Schroth and PRI) versus the active control. A direct Schroth-versus-PRI comparison will be conducted as a pre-specified secondary analysis and interpreted cautiously; the trial is powered for superiority comparisons versus control rather than for equivalence or non-inferiority between the two active interventions.

Study Setting

The trial will be conducted at the Department of Sport Injuries and Corrective Exercise, Faculty of Sport Sciences, University of Guilan (Rasht, Iran). The facility is equipped with standardized photogrammetry systems, surface electromyography (sEMG) equipment, and goniometers for outcome assessments. All outcome assessments (photogrammetry, sEMG, ATR, ROM, and questionnaires) will be conducted at this single facility under standardized conditions to minimize measurement variability.

Eligibility Criteria

Inclusion Criteria:

- - Adolescents aged 15–18 years with a diagnosis of adolescent idiopathic scoliosis (AIS) and a mild right thoracic curve.
- - Curve severity confirmed on the most recent standing spinal radiograph obtained as part of routine clinical care (within the past 6 months), showing a Cobb angle of 10–25° and Risser sign ≥ 3 (25, 26).
- - Able and willing to attend supervised sessions three times per week for 12 weeks and to complete all scheduled assessments (T0, T1, T2).
- - Able to understand Persian sufficiently to complete study questionnaires; parent/guardian consent and adolescent assent provided.

Participants will be recruited primarily through school-based scoliosis screening (Adams forward bend test with scoliometer) and referrals from orthopedic and physiotherapy clinics (27, 28).

Exclusion Criteria:

- - Non-idiopathic scoliosis (e.g., congenital, neuromuscular) or prior spinal surgery.
- - Medical or musculoskeletal conditions that contraindicate exercise participation (e.g., uncontrolled cardiovascular or severe pulmonary disease, serious neurological or rheumatologic disorders).
- - Current brace use or brace discontinuation within the past 3 months.

- - Prior participation in a structured physiotherapeutic scoliosis-specific exercise (PSSE) program (e.g., Schroth, PRI, or other scoliosis-specific exercise) within the past 12 months.
- - Concurrent scoliosis-specific physiotherapy, chiropractic treatment, or other active scoliosis interventions at the time of enrollment.
- - Cognitive/communication limitations that preclude valid assent or questionnaire completion, or inability/unwillingness to comply with visit schedules.

No additional radiographs will be required solely for study participation; radiographs used for eligibility confirmation will be those available from routine clinical care.

Table 1 presents the PRO-EDI summary of expected participant characteristics for this trial, informed by local referral patterns and the epidemiology of AIS.

Table 1
PRO-EDI summary of expected participant characteristics (protocol stage)

Characteristic (core)	Planned/expected in this trial	Why (rationale)
Age	**15–18 years** (per eligibility criteria). Baseline age will be reported as mean (SD) and range.	Age is a key determinant of growth stage, neuromuscular control, and response to exercise interventions; reporting supports interpretability and applicability of findings.
Sex	**Male and female** adolescents are eligible and will be enrolled. Based on AIS epidemiology and clinic referral patterns, a higher proportion of females is anticipated. Sex will be recorded at baseline and used for stratified randomization (as specified).	Sex distribution in AIS is often imbalanced and may influence baseline presentation and response; reporting enables assessment of representativeness and subgroup interpretability.
Gender	**Not collected.** Only sex assigned at birth will be recorded.	Gender identity data collection was not feasible within the study timeline and resources. Sex assigned at birth is sufficient for the planned stratification and primary analyses. This limitation will be acknowledged when interpreting generalisability.
Race, ethnicity and ancestry	**Not collected.** Participants will be recruited from the local catchment area (Guilan province, Rasht).	Routine collection of standardised race/ethnicity/ancestry categories is not established in the study setting, and implementing a new classification system was not feasible within the study timeline and resources. Generalisability will be interpreted in light of the recruitment catchment.
Socioeconomic status (SES)	**Not collected.** No individual- or household-level SES indicators (e.g., income, parental education, occupation) will be recorded.	Collecting and verifying individual-level SES indicators was not feasible within the study timeline and resources, and was not essential for the planned analyses. This limitation will be acknowledged when interpreting external validity.
Geographic location	**Guilan province, Rasht (Iran).** Recruitment will occur at the study site(s) in Rasht; the setting (urban catchment) will be described.	Geographic location is a core PRO-EDI element and informs access, service context, and generalisability. Reporting the recruitment region supports interpretation of applicability to similar clinical settings.

Interventions

Interventions are described in accordance with the TIDieR checklist (integrated into SPIRIT 2025) to ensure sufficient detail for replication (29, 30).

Schroth Exercise Group

Participants will undergo a structured Schroth scoliosis-specific exercise regimen emphasizing three-dimensional postural correction and rotational angular breathing. Sessions will be 60 minutes, three times per week for 12 weeks, delivered in person at the university's corrective exercise facility.

PRI Exercise Group

Participants will receive a standardized PRI-based exercise protocol focusing on restoring balanced postural mechanics through integrated breathing strategies and neuromuscular patterning. Frequency and duration will match the Schroth group (60 minutes × 3 sessions/week for 12 weeks).

Active Control Group

Participants in the active control group will continue their usual physical activities (including routine daily activities and school physical education) without any structured scoliosis-specific exercise program. They will be instructed not to initiate any new scoliosis-specific interventions during the trial period (e.g., Schroth/PRI programs or other targeted scoliosis exercise therapies). Control participants will receive a one-time brief educational handout on general adolescent health and physical activity, but no supervised corrective exercise sessions will be provided. Any changes in physical activity patterns or scoliosis-related treatments during follow-up will be documented.

Fidelity monitoring for all intervention arms will utilize standard checklists and attendance logs to document adherence and consistency of delivery. Interventions will be delivered by two trained therapists with ≥ 2 years of experience in exercise-based management of adolescents with scoliosis, following protocol-specific training prior to trial initiation. Delivery will be supervised by a senior faculty member (full professor) with extensive experience teaching scoliosis-specific exercise. To minimize contamination between approaches, therapists will follow arm-specific manuals and will be instructed not to mix components across interventions; adherence and any deviations will be documented.

For per-protocol sensitivity analyses, participants in the Schroth and PRI arms who complete ≥ 80% of prescribed supervised sessions (≥ 29 of 36 sessions) will be classified as adherent. Supervised-session adherence will be documented using attendance logs, and missed sessions and reasons will be recorded. Home-program adherence (where prescribed) will be tracked using participant-completed logs reviewed at supervised visits and summarized descriptively.

Participants will be instructed not to initiate any new scoliosis-specific interventions during the 24-week trial period, including bracing or structured scoliosis-specific exercise therapies (e.g., Schroth, PRI, or similar programs). Participants receiving scoliosis-specific physiotherapy or other active scoliosis interventions at baseline will not be enrolled (per exclusion criteria). Routine daily activities, school physical education, and recreational sports are permitted. Any new musculoskeletal treatments and any substantial changes in physical activity during follow-up will be documented and considered when interpreting outcomes.

Outcomes

All outcomes will be assessed at baseline (T0), post-intervention (T1; 12 weeks, within ± 7 days), and follow-up (T2; 24 weeks, within ± 14 days), unless otherwise specified.

Primary Outcome

Change in spinal curvature, expressed as the photogrammetric Cobb angle in degrees (°), from baseline (T0) to post-intervention (T1 at 12 weeks). Photogrammetry will be performed using a validated protocol with standardized marker placement and image capture settings (28, 31). The T2 photogrammetric Cobb angle will be analysed as a secondary timepoint to explore maintenance of effects; the primary endpoint is defined at T1 (12 weeks).

Secondary Outcomes

(1) Neuromuscular activation symmetry, assessed by surface electromyography (sEMG) recorded bilaterally from pre-specified paraspinal sites during standardized tasks; RMS amplitude will be computed and a pre-specified symmetry index will quantify between-side asymmetry (convex vs concave), with higher values indicating greater asymmetry (32). (2) Angle of trunk rotation (ATR), measured using a scoliometer during the Adams forward bend test and recorded in degrees at the level of maximal trunk rotation. (3) Range of motion (ROM), measured in degrees using a universal goniometer for trunk flexion, extension, and lateral flexion (left/right) according to standardized procedures. (4) Quality of life, assessed using the validated Persian version of the Scoliosis Research Society-22r (SRS-22r) questionnaire, self-completed in paper format under supervision in a quiet testing room (33–35).

Outcome hierarchy and multiplicity

Photogrammetric Cobb angle change from T0 to T1 is the sole primary outcome. All other outcomes and timepoints (including T2) are secondary; multiplicity for secondary outcomes will be addressed as described in the Statistical Methods.

Measurement standardization

Assessments will be conducted by trained assessors using standardized written procedures, and the same blinded assessor will perform repeated assessments for each participant whenever feasible. Photogrammetry and sEMG acquisition and processing will follow standardized protocols (including fixed marker/electrode placement and skin preparation), and measurement consistency will be monitored and reported transparently.

Randomization and Allocation Concealment

Participants will be randomized 1:1:1 to Schroth, PRI, or active control using computer-generated randomization with stratification by sex (male/female) and baseline radiographic Cobb angle category (from the most recent standing radiograph within the past 6 months; 10–15°, 15–20°, and 20–25°),

creating six strata. Within each stratum, permuted blocks of variable sizes (6 and 9) will be used to maintain group balance. The allocation sequence will be generated prior to trial commencement by an independent statistician who is not involved in participant recruitment, intervention delivery, outcome assessment, or data analysis. The generation script and the predefined random seed will be retained in the trial master file to support reproducibility.

Allocation will be concealed using sequentially numbered, opaque, sealed envelopes prepared separately for each stratum. Envelopes will be prepared and sealed by the independent statistician and stored in a locked cabinet with access limited to the designated research coordinator. Envelopes will be opened sequentially only after eligibility is confirmed, written consent/assent is obtained, and all baseline outcome assessments (T0) are completed. The date and time of envelope opening and the envelope number will be recorded to create an audit trail.

A research coordinator (not involved in outcome assessments or data analysis) will screen potential participants, obtain consent/assent, and coordinate baseline assessments. Baseline measurements will be performed by blinded assessors prior to revealing group allocation. After baseline assessments are completed, the coordinator will open the envelope corresponding to the participant's stratum, assign the participant to the allocated group, and inform the intervention team.

The full allocation list (including block sizes) will remain inaccessible to recruiting personnel, outcome assessors, and data analysts until the database is locked and the primary analysis is completed. The allocation list will be stored in a secure, password-protected file separate from the trial database.

Blinding

This is an assessor- and analyst-blinded (single-blind) trial. Outcome assessors (photogrammetry, sEMG, ATR, ROM, and questionnaire administration) and the data analyst will remain blinded to group allocation throughout data collection and the primary analyses. Participants and intervention therapists will not be blinded due to the active, behavioral nature of the exercise interventions. The research coordinator responsible for randomization and trial logistics will not be blinded but will remain separate from outcome assessment activities.

To maintain assessor blinding, assessors will not attend intervention sessions and will not have access to intervention materials, attendance logs, fidelity checklists, or any records that could reveal allocation. Participants will be instructed at baseline and reminded at each follow-up visit not to disclose their allocated group to assessors. Outcome assessments will follow standardized, group-neutral instructions.

To evaluate assessor blinding, after completion of the final (T2) assessment for each participant, the assessor will be asked to indicate their best guess of group allocation using a forced-choice item (Schroth / PRI / active control) and to report their confidence (low/moderate/high). The proportion of correct guesses will be summarized overall and by assessor and interpreted relative to chance (33% in a three-arm trial).

For analyst blinding, the dataset provided for statistical analyses will use generic group labels (e.g., Group A/B/C), with the key linking labels to interventions held by the research coordinator and released only after the primary analysis code and main results are finalized. Any instances of accidental unblinding of an assessor will be documented, and where feasible, subsequent assessments for that participant will be performed by another blinded assessor.

Sample Size Calculation

The sample size was calculated for the primary outcome (change in photogrammetric Cobb angle from baseline [T0] to post-intervention [T1, 12 weeks]) to detect an overall between-group difference across the three trial arms. A moderate effect size (Cohen's $f \approx 0.28$) was assumed based on effect sizes reported in prior PSSE (Schroth-based) trials and meta-analyses in adolescents with idiopathic scoliosis (16, 18, 19). Using a two-sided $\alpha = 0.025$ and 80% power, the required total sample size was approximately 81 participants (27 per group). To account for an anticipated attrition of ~ 10% over the intervention and follow-up period, we plan to enroll 90 participants (30 per group). Sample size calculations were performed using G*Power (36). The study is powered for the primary outcome at T1; the direct Schroth-versus-PRI comparison will be interpreted as a secondary analysis.

Statistical Methods

Primary analyses will follow the intention-to-treat (ITT) principle. Outcomes measured at T0, T1, and T2 will be analyzed using linear mixed-effects models with fixed effects for group (Schroth, PRI, active control), time (categorical: T0, T1, T2), and the group×time interaction, and a random intercept for participant to account for within-participant correlation. The primary endpoint is the change in photogrammetric Cobb angle from T0 to T1; primary treatment effects will be estimated as the between-group difference in mean change from T0 to T1 (group×time contrast) for each intervention versus active control, with 95% confidence intervals.

Multiplicity will be controlled for the two primary comparisons (Schroth vs active control and PRI vs active control at T1) using a Bonferroni-adjusted two-sided significance level of $\alpha = 0.025$ per comparison (family-wise $\alpha = 0.05$); adjusted p-values will be reported. For secondary outcomes, analyses will be interpreted as secondary/exploratory; to aid interpretation, the Benjamini–Hochberg false discovery rate procedure will be applied across secondary outcomes at T1, alongside effect estimates and 95% confidence intervals.

Missing data will be addressed primarily through the mixed-model framework under a missing-at-random assumption. As a sensitivity analysis, multiple imputation by chained equations will be performed ($m = 20$ datasets), including baseline outcome values, stratification factors (sex and Cobb category), group allocation, age, and other baseline characteristics; results will be pooled using Rubin's rules.

A pre-specified per-protocol sensitivity analysis will include participants who completed ≥ 80% of supervised sessions in the Schroth/PRI arms and did not initiate prohibited co-interventions, and who

completed the T1 assessment; the same model specification will be applied. No interim efficacy or futility analyses are planned. Analyses will be conducted using R (version 4.x or later).

Data Management, Monitoring, and Safety

Data management

All study data will be recorded using coded IDs and stored in a secure, password-protected electronic database with role-based access controls and audit trails. Personal identifiers collected for screening, scheduling, or follow-up will be stored separately from research data in a password-protected file accessible only to the principal investigator and the designated study coordinator. Data capture will utilize standardized electronic case report forms with built-in logic checks (where feasible) to reduce entry errors. Regular backups will be implemented to ensure data integrity throughout the trial. Any paper records (e.g., signed consent forms) will be kept in locked cabinets within secure university facilities. Study records will be retained for 10 years after study completion, in line with institutional policy and regulatory requirements, after which they will be securely destroyed or archived. Data sharing procedures are described in the “Open Science and Data Sharing” section, and handling of photogrammetric images is described in the “Confidentiality” section.

Monitoring and safety oversight

Given the low-risk, exercise-based nature of the interventions, the single-center setting, and the short intervention duration, an independent Data Monitoring Committee/Data Safety Monitoring Board is not planned. Safety oversight will be conducted internally by the principal investigator. Adverse events (AEs) will be actively solicited and recorded at each supervised session and at each assessment visit using a standardized form documenting onset date, description, severity (mild/moderate/severe), relatedness to the intervention (unlikely/possible/probable/definite), actions taken, and outcome.

Harms and reporting

An AE is defined as any unfavorable sign, symptom, or injury occurring during the trial, whether or not related to the intervention. A serious adverse event (SAE) is any event resulting in hospitalization, life-threatening condition, persistent/significant disability, or death, or requiring urgent medical intervention to prevent these outcomes. SAEs will be reported to the institutional ethics committee within the committee-required timeframe (initial notification within 72 hrs of awareness), with follow-up information provided as available. Participants will discontinue the intervention if they experience an SAE judged at least possibly related to the intervention, an acute injury requiring medical care that prevents participation, or persistent pain ≥ 6/10 that does not resolve within one week despite modification/rest. Participants may withdraw at any time; those discontinuing the intervention will be encouraged to complete follow-up assessments for ITT analyses. Any accidental unblinding and safety-relevant protocol deviations will be documented in a deviation log and reviewed by the principal investigator; any substantive changes to the protocol will be handled as described in the “Protocol

amendments” section. Incidental findings requiring clinical attention will be communicated to the participant and parent/guardian, and appropriate referral will be made.

Open Science and Data Sharing

The full trial protocol (versioned) and the statistical analysis plan will be publicly accessible through the published protocol and any protocol updates. After publication of the primary results, de-identified individual participant data underlying the reported outcomes (photogrammetric Cobb angle in degrees, sEMG-derived symmetry indices, ATR, ROM, and SRS-22r at T0/T1/T2), together with a data dictionary and the analysis code, will be made available within 6 months. Analysis code and de-identified study materials (e.g., scoring templates, fidelity checklists, and blank logs) will be deposited in an open repository with a DOI (e.g., Zenodo). Because participants are minors and raw photogrammetric images may carry a risk of re-identification, raw images and any direct identifiers will not be shared; only derived quantitative measurements will be shared. The repository record (metadata, data dictionary, analysis code, and de-identified study materials) will be publicly available with a DOI.Due to the inclusion of minors and the risk of re-identification, access to the de-identified participant-level dataset will be provided under controlled access upon reasonable request (brief proposal, intended analyses, and confirmation of appropriate ethical and data-protection safeguards). Requests will be handled by the corresponding author, and a data-use agreement may be required where applicable.

Patient and Public Involvement

No patients, adolescents with scoliosis, parents/guardians, or public representatives were formally involved in the design of this trial (e.g., defining the research question, selecting outcomes, or shaping recruitment and intervention procedures). This was primarily due to time and resource constraints during protocol development and the lack of an established local patient/public advisory structure at the time of planning. We acknowledge this as a limitation, as stakeholder input could have further informed outcome prioritization and the acceptability of study procedures.

To incorporate patient-centred perspectives, we included the SRS-22r as a secondary outcome to capture domains relevant to adolescents and families (e.g., pain, self-image/cosmesis, and function) in addition to clinician- and performance-based measures.

After completion of the primary analyses, a plain-language summary of the findings will be prepared in Persian and offered to all participants and their parents/guardians (via email or a printed summary, according to preference). Summary results will also be posted in the IRCT trial registry record. In addition, brief structured feedback on participant experience and procedure acceptability will be solicited from participants (and, where feasible, parents/guardians) after the final follow-up assessment to inform future research and implementation.

Participant Timeline

The schedule of enrollment, interventions, and assessments is presented in Fig. 1 in accordance with SPIRIT recommendations.

Limitations

This trial has anticipated limitations inherent to non-pharmacological interventions. First, the single-center design in Rasht (Guilan province, Iran) may limit generalisability to other settings and health systems. Second, participant and therapist blinding is not feasible for exercise-based interventions, which may introduce performance and expectancy effects, particularly for self-reported outcomes; to mitigate this, outcome assessors and the data analyst will remain blinded, standardized instructions will be used, and blinding integrity will be evaluated. Third, the primary outcome is based on radiation-free photogrammetry, which—despite validation—may not fully capture the three-dimensional nature of scoliosis compared with radiography; therefore, results will be interpreted in this context and reported with transparent measurement procedures. Fourth, the 24-week follow-up captures short- to mid-term effects and may not reflect longer-term maintenance or curve progression. Finally, although powered for the primary endpoint at 12 weeks, subgroup and exploratory comparisons may be underpowered; effect sizes and confidence intervals will be prioritised, and all secondary analyses will be interpreted cautiously.

Attachments (Additional Files):

- - Ethics approval certificate (English)
- - SPIRIT 2025 checklist (with page and line numbers)

Abbreviations

AIS
Adolescent idiopathic scoliosis
ATR
Angle of trunk rotation
IRCT
Iranian Registry of Clinical Trials
ITT
Intention-to-treat
PRI
Postural Restoration Institute
PSSE
Physiotherapeutic scoliosis-specific exercises
RCT
Randomized controlled trial
ROM

Range of motion
SAE
Serious adverse event
sEMG
Surface electromyography
SPIRIT
Standard Protocol Items:Recommendations for Interventional Trials
SRS-22r
Scoliosis Research Society 22-Item Questionnaire (revised)
T0
Baseline (pre-intervention) timepoint
T1
Post-intervention timepoint (12 weeks)
T2
Follow-up timepoint (24 weeks).

Declarations

Ethics approval and consent to participate

Ethical approval for this trial was obtained from the Research Ethics Committees of University of Guilan (Approval No. IR.GUILAN.REC.1404.138). Approval date: 03 November 2025. The study will be conducted in accordance with national regulations and the Declaration of Helsinki and its later amendments (37). Written informed consent will be obtained from a parent or legal guardian prior to any study-specific procedures, and written informed assent will be obtained from each adolescent participant. Both guardian consent and adolescent assent are required for enrolment; if either is not provided, the participant will not be enrolled. Consent/assent will be obtained by a trained research team member not involved in outcome assessment, and families will be given adequate time to ask questions and consider participation. Participants will be informed that participation is voluntary and that they may withdraw at any time without consequences for medical care or school activities. If a participant reaches 18 years of age during follow-up, consent will be re-confirmed with the participant as an adult at the next study contact, in accordance with institutional requirements. Any substantial protocol amendments will be submitted for ethics review and approval prior to implementation and updated in the trial registry, as described under “Protocol amendments”.

Consent for publication

Not applicable. No identifiable individual data will be published. Photographic images collected for photogrammetry will not be used in publications.

Availability of data and materials

Data sharing (including timing, repository deposition, and access conditions) is described in the “Open Science and Data Sharing” section. Raw photogrammetric images and direct identifiers will not be shared due to re-identification risk; only derived quantitative measurements and de-identified datasets will be shared under the stated conditions.

Protocol amendments

Any important modifications to the protocol that may affect participant safety, study conduct, or scientific integrity (e.g., eligibility criteria, interventions, outcomes, sample size, or analysis plans) will be documented in a formal protocol amendment with a new version number and date, including a description and rationale for the change. Substantial amendments will be submitted to the ethics committee for review and approval prior to implementation (except where immediate change is required to eliminate an unforeseen hazard, in which case it will be enacted promptly and reported to the ethics committee as soon as feasible). All approved amendments will be communicated to the IRCT registry and reflected in the public trial record, and an amendment log (audit trail) will be maintained by the principal investigator.

Confidentiality

Each participant will be assigned a unique study identification code. Personal identifiers (e.g., name and contact information) collected for screening and scheduling will be stored separately from research data in a password-protected file accessible only to the principal investigator and designated study coordinator. All research data (including photogrammetry measurements, sEMG data, clinical evaluations, and questionnaire responses) will be recorded using coded IDs and stored in a secure electronic database with role-based access controls and audit trails; paper records (e.g., signed consent/assent forms) will be stored in locked cabinets within secure university facilities. Digital photographs used for photogrammetry will be coded and stored on secure institutional servers with access limited to the research team; photographs will be taken and stored in a manner that excludes participant faces to minimize re-identification risk. Records will be retained for 10 years after study completion in line with institutional policy and regulatory requirements, after which they will be securely destroyed or archived as permitted. In the unlikely event of unauthorized access or accidental disclosure, the incident will be documented, the ethics committee will be notified promptly, affected participants/guardians will be informed as required, and corrective actions will be implemented to prevent recurrence.

Dissemination policy (publication plan)

The results of this trial will be disseminated regardless of the magnitude or direction of findings. We plan to publish the primary and relevant secondary outcomes in peer-reviewed journals and present findings at national and international scientific conferences. Summary results will be posted on the IRCT trial

registry in accordance with registry requirements and applicable reporting guidance. A plain-language summary of the results will be prepared in Persian and offered to all participants and their families after the primary analysis is completed (via email or printed copy according to preference); it will also be available upon request.

Competing interests

The authors declare no competing interests.

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Authorship

Authorship of resulting publications will be determined according to ICMJE criteria. All individuals meeting authorship criteria will approve the final manuscript and take responsibility for the integrity of the work. Contributor roles will be documented transparently (e.g., using a CRediT-style description) and contributors who do not meet authorship criteria will be acknowledged appropriately.

Authors’ contributions

HD conceptualized the study, led the trial design, and oversaw development of the protocol. MK and SS contributed to study design refinements and developed the statistical analysis plan. SS assisted in creating detailed intervention protocols for both the Schroth and PRI groups. All authors read, provided critical revisions, and approved the final manuscript.

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Ancillary and Post-Trial Care

During the trial, participants will have access to ancillary clinical support for any new symptoms or adverse events occurring in the context of study participation. At each supervised session and assessment visit, therapists/assessors will screen for pain, musculoskeletal complaints, or other health changes and will document and manage events according to best clinical practice. Where indicated, the intervention will be modified or paused, and the participant will be referred to an appropriate healthcare provider (e.g., orthopedist or physiotherapist). Participants and parents/guardians will also be provided with study contact details to report concerns between scheduled visits.

Although the risk of serious harm from exercise-based interventions is expected to be low, any adverse event assessed as possibly, probably, or definitely related to the intervention will be managed promptly, with referral and follow-up care facilitated by the research team. The trial does not provide financial compensation or insurance coverage for medical treatment of intervention-related injuries. Participants will be referred to appropriate healthcare providers, and any related costs will be borne by the participant and/or their health insurance, in accordance with standard care pathways in Iran. This information will be explained during the consent process.

After completion of the primary analysis, participants and families will be informed of the results. If either Schroth or PRI demonstrates clinically relevant superiority over the active control for the primary outcome, participants allocated to the active control (and, if applicable, the less effective intervention arm) will be offered the option to receive the superior intervention through the university corrective exercise clinic, free of charge, for up to 12 weeks after trial completion (subject to therapist capacity and scheduling). Uptake is voluntary and will not be considered part of the trial outcomes.

Trial status

Protocol version 1.0 (09 January 2026). Recruitment has not started at the time of manuscript submission. Recruitment is expected to begin in February 2026 and to be completed by April 2026. The intervention period is 12 weeks, with follow-up assessments planned at 24 weeks after baseline.

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Figures

Timepoint	Screening	Baseline (T0)	Intervention (Weeks 1–12)	Post-Intervention (T1, Week 12)	Follow-up (T2, Week 24)
Enrollment					
Eligibility screen	X				
Informed consent/assent		X			
Baseline radiograph (one-time)		X			
Randomization		X			
Interventions					
Schroth exercise (Group 1)			X		
PRI exercise (Group 2)			X		
Active control (Group 3)			X	X	X
Outcomes					
Photogrammetric Cobb angle		X		X	X
sEMG assessment		X		X	X
SRS-22r questionnaire		X		X	X
Angle of trunk rotation (ATR)		X		X	X
Shoulder & trunk ROM		X		X	X
Postural alignment indices		X		X	X
Adherence logs			X	X	X
Adverse events monitoring			X	X	X

Figure 1

Schedule of Enrollment, Interventions, and Assessments (SPIRIT schematic).

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- PRIprotocol.docx
- SPIRIT2025checklist.docx
- Schrothprotocol.docx