# Exploring how the Schroth method impacts sensorimotor control in teens with adolescent idiopathic scoliosis

| Submission date   | Recruitment status       | <ul><li>Prospectively registered</li></ul>    |
|-------------------|--------------------------|---|
| 24/09/2024        | No longer recruiting     | ☐ Protocol                                    |
| Registration date | Overall study status     | Statistical analysis plan                     |
| 26/09/2024        | Completed                | ☐ Results                                     |
| Last Edited       | Condition category       | Individual participant data                   |
| 27/09/2024        | Musculoskeletal Diseases | <ul><li>Record updated in last year</li></ul> |

#### Plain English summary of protocol

Background and study aims

Adolescent idiopathic scoliosis is the most prevalent form of scoliosis, accounting for 80-85% of cases, while other forms include neuromuscular and congenital scoliosis. The consequences of scoliosis can be quite diverse among people, often negatively influencing their physical and mental health. The exact reasons behind idiopathic adolescent scoliosis remain largely unclear. However, various contributing factors are suspected, suggesting it is a multifaceted issue. Furthermore, issues related to the central nervous system are regarded as possible factors in idiopathic scoliosis. People with idiopathic scoliosis could exhibit a changed understanding of their body's spatial orientation. Furthermore, it is suggested that these individuals may have a skewed perception of their body shape and spinal alignment. Research has looked into sensorimotor control deficits in those who suffer from idiopathic scoliosis, but there are conflicting views on whether these issues come before physical deformity, indicating a potential link to the basic causes. Having scoliosis can change both your balance when standing still and moving, as well as how you perceive your spine and peripheral joints. The study goal is to assess the impact of a 10-week Schroth method program on sensorimotor skills in the upper extremities and the spine, including its effects on static and dynamic balance in young individuals suffering from idiopathic scoliosis. Another focus is to examine how this method affects the living standards of these individuals. The study results will inform how effective the treatment is in enhancing sensorimotor control by improving the care of children and adolescents with idiopathic scoliosis.

## Who can participate?

Female adolescent patients aged 10 to 16 years old with a diagnosis of adolescent idiopathic scoliosis

#### What does the study involve?

Participants will be divided into two groups. The study involves bracing as standard treatment for both groups and the intervention group will also receive a 10-week Schroth method program which is a form of physiotherapeutic scoliosis-specific exercises. The study starts immediately after the fitting of the brace and will run for 10 weeks. At the beginning and the end of the 10

weeks, the assessment with four sensorimotor control tests will take place as well as the completion of questionnaires related to the quality of life.

What are the possible benefits and risks of participating?

Both bracing and Schroth methods are safe and there are no risks involved when one follows the safety instructions.

Where is the study run from?

The study will run at the Orthotic Clinic "Scoliosis Spine Laser Center" in which the participants have chosen to manufacture their braces.

When is the study starting and how long is it expected to run for? February 2023 to May 2025

Who is funding the study? Investigator initiated and funded

Who is the main contact?
Alexandros Kastrinis, alexkastrinis@uth.gr

# **Contact information**

#### Type(s)

Public, Scientific, Principal investigator

#### Contact name

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# Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

**ESMSCIAIS 2025** 

# Study information

#### Scientific Title

Effect of the Schroth method on the sensorimotor control of individuals with adolescent idiopathic scoliosis

#### Acronym

**ESMSCIAIS** 

#### **Study objectives**

H0: A 10-week Schroth exercise program will not change the upper extremity proprioception of individuals with Adolescent Idiopathic Scoliosis compared with no exercise program.

H0: A 10-week Schroth exercise program will not change the spine proprioception of individuals with Adolescent Idiopathic Scoliosis compared with no exercise program.

H0: A 10-week Schroth exercise program will not change the static and dynamic balance of individuals with Adolescent Idiopathic Scoliosis compared with no exercise program.

H0: A 10-week Schroth exercise program will not change the quality of life of individuals with Adolescent Idiopathic Scoliosis compared with no exercise program.

#### Ethics approval required

Ethics approval required

### Ethics approval(s)

approved 07/04/2023, Internal Ethics Committee of the Physiotherapy Department, University of Thessaly (3rd km Old National Road Lamia-Athens, Lamia, 35132, Greece; +30 22310 60176; g-physio@uth.gr), ref: 481

## Study design

Non-randomized controlled study

# Primary study design

Interventional

# Study type(s)

Efficacy

# Health condition(s) or problem(s) studied

Sensorimotor control of individuals with adolescent idiopathic scoliosis

#### **Interventions**

Sixty individuals diagnosed with AIS will be divided into two groups according to the treatment regime prescribed by their physician and their family wishes. The intervention group will follow a 10-week rehabilitation program according to the Schroth method in combination with bracing. The control group will be under bracing treatment alone. Bracing prescription will be for 18-22 hours daily for all participants. Both groups will be given an information leaflet on the importance and effectiveness of scoliosis-specific exercises. The leaflet will contain suggested exercises for scoliosis. The exercises and tests will take place at the Scoliosis Spine Laser Center.

The intervention group will exercise twice a week for one hour under the supervision of a certified Schroth therapist and perform a half-hour program at home five times a week unsupervised. The program according to the Schroth method will include scoliosis mobilization, corrective breathing and three-dimensional scoliosis correction techniques. Schroth method has standardized exercises depending on the classification of scoliosis. All participants will have the right thoracic main curve according to the Schroth Classification, but the final exercise program for each participant will be tailor-made taking into account secondary curves and compensations.

Braces will be of the same type, Scoliosis Brace by SLC, and applied in the same way in both groups. Braces are designed using a CAD/CAM system. A Scoliosis Brace is a 3D asymmetric brace compatible with the Schroth method. Before the start of the measurements, a form will be filled out with demographic and somatometric data. The information collected by this form includes data, in the form of a Likert scale, regarding the level of physical activity of the participants and the level of compliance with the treatment. Then will follow the initial measurements of sensorimotor control and quality of life of people with idiopathic scoliosis. Initially, the GR BSSQ Brace questionnaire will be filled out by the participants. This questionnaire assesses the quality of life in terms of bracing-induced stress. The questionnaire has been cross-culturally adapted and validated in the Greek language.

The first clinical test to be performed will be the Fucuda test. To perform the test, the initial position of the participant while standing upright will be marked. The participant will then be asked to raise both arms to a 90-degree shoulder flexion and keep them there. With eyes closed the participant will be asked to perform steps with a hip flexion angle of approximately 45 degrees trying to hold the same position. After 50 steps, the distance traveled from the starting position will be measured in centimeters as well as the angle of turn of the right leg relative to the starting position. Participants will perform one open-eye familiarity trial and three closed-eye trials.

To determine the sway velocity and the center of gravity elliptic area, the participant will stand shoeless on the force footplate, with his gaze focused on a fixed point in front of him at a distance of one meter. The heels while standing will be 10 cm apart. The test will consist of two consecutive phases. The first trial will be with eyes open and will last 30 seconds. This is for familiarization purposes. Then two closed-eye trials will follow. Data will be obtained with the help of a specific software. A digital inclinometer placed on the seventh cervical vertebra A7 will be used to measure the proprioception of the spine in terms of joint position sense. The participant will be in a sitting position, arms crossed over the chest with palms on opposite shoulders and will be asked to keep the pelvis stable in a neutral position. The participant will be passively guided into a 20-degree lateral flexion with eyes open. They will stay for 5 seconds, be instructed to memorize the position and return to the starting position. The participant will then be asked to repeat the torso movement to reach the predetermined position with eyes closed. The procedure will be repeated 10 times and each time the deviation of the angle placed from the angle originally asked will be noted. The procedure shall then be repeated for the opposite lateral flexion.

For the assessment of proprioceptive function in the upper extremities, a transparent plexiglas panel featuring dome-shaped holes at specified intervals will be utilized, positioned at the level of the patient's shoulder. The subject will be seated with their eyes closed, and one index finger, which will be encased in a thimble with an opening at the apex, will remain free adjacent to the subject's body. The other index finger will be inserted and fixed from beneath the panel into one of the holes. The assessor will pick the holes in a random order and will guide the index finger of the participant. Then the participant will try to identify the corresponding position with their free hand from the superior surface of the Plexiglas panel. The upper surface of the panel

remains intact and no contact between the two indexes is allowed. Each instance in which the participant believes they have located their other index finger will prompt the evaluator to extract the finger from the thimble and mark the location on the surface with a marker, using the hole in the thimble as a reference point. Consequently, the distance between each index will be documented. This evaluation will be conducted in eight positions with the eyes closed and subsequently repeated with the roles of the hands reversed. Each hole in the transparent surface will be subjected to three trials for data collection. Before the commencement of measurements, a familiarization session will be conducted with the eyes open for each hand.

All tests will be performed at baseline and after the treatment program at week 10 of treatment for both groups. Measurements will be performed by a therapist specialized in idiopathic scoliosis and appropriately trained in assessment procedures. This person will not know which group each participant has joined and will not be involved in the treatment sessions. At the end of the treatment, the GR BSSQ Brace quality of life questionnaire will be completed again, as well as the satisfaction subdomain of the Scoliosis Research Society questionnaire (SRS22).

#### Intervention Type

Procedure/Surgery

#### Primary outcome(s)

The following primary outcome measures are assessed at baseline and after completing 10 weeks of treatment:

- 1. Dynamic balance measured using the Fukuda test
- 2. Static Balance measured using a force footplate device that measures, Mean of sway velocity (mm/sec) and Center of Gravity Ellipse Area (mm2)
- 3. Right and left side spine lateral flexion at 20 degrees measured using the Spine Joint Position Sense Test
- 4. Upper limb functional proprioception measured using a spatial orientation test

# Key secondary outcome(s))

Quality of life measured using the GR-BSSQ Brace questionnaire at baseline and after completing 10 weeks of treatment

# Completion date

30/05/2025

# **Eligibility**

#### Key inclusion criteria

- 1. A diagnosis of adolescent idiopathic scoliosis
- 2. Female
- 3. Aged between 10 and 16 years old
- 4. Risser Sign: 0-4
- 5. Cobb Angle: 20-45 degrees
- 6. Main Curve: Right Thoracic according to Schroth Classification
- 7. Brace treatment: Yes. With "Scoliosis Brace by SLC"
- 8. Appropriate cognitive level and knowledge for both participants and their parents

## Participant type(s)

Patient

# Healthy volunteers allowed

No

#### Age group

Child

#### Lower age limit

10 years

# Upper age limit

16 years

#### Sex

Female

#### Key exclusion criteria

- 1. Other types of scoliosis treatment in the past in the form of exercise or other orthotic means
- 2. Suffering from diseases that can affect motor control
- 3. Conditions or injuries that can affect balance
- 4. Cognitive problems
- 5. Spondylolisthesis
- 6. Other forms of scoliosis besides idiopathic adolescent scoliosis
- 7. Mental, neurological, and other musculoskeletal diseases
- 8. Vestibular problems not related to scoliosis

#### Date of first enrolment

15/01/2024

#### Date of final enrolment

20/03/2025

# Locations

#### Countries of recruitment

Greece

# Study participating centre Scoliosis Spine Laser Center

Thessalonikis 2 Moschato Greece 18345

# Sponsor information

#### Organisation

University of Thessaly

#### **ROR**

https://ror.org/04v4g9h31

# Funder(s)

#### Funder type

Other

#### **Funder Name**

Investigator initiated and funded

# **Results and Publications**

#### Individual participant data (IPD) sharing plan

The datasets generated during and/or analyzed during the current study are not expected to be made available. Sharing IPD would be a risk to patient confidentiality. The consent forms signed by the participants do not contain the information that raw data will be shared. There is also the danger of misinterpretation of this data leading to conclusions that would be inaccurate and harmful to the credibility of the study.

# 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 Participant information sheet 11/11/2025 No Yes