

# Active self-correction and task-oriented exercises reduce spinal deformity and improve quality of life in subjects with mild adolescent idiopathic scoliosis. Results of a randomised controlled trial

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## Introduction

Adolescent idiopathic scoliosis (AIS) has been defined as a three-dimensional deformity of the spine and trunk occurring in healthy pubertal children [1]. Although its precise aetiology remains unknown, the main causes seem to be genetic predisposition, connective tissue abnormalities, and skeletal, muscular and neurological disturbances during growth [2]. The prevalence of AIS with a Cobb angle of  $>10^\circ$  is approximately 2.5 % in the general population [1, 2].

The risk of the curve progression is higher in the case of females and children aged 10–12 years; in the absence of menarche; in the presence of thoracic curves; with curves size at presentation of more than  $25^\circ$ ; Risser sign 0–1; and residual growth potential [1–4]. Cobb angles at presentation of  $>25^\circ$  when combined with female gender, an age of  $<12$  years, and pre-pubertal status present the highest risk for curve progression at skeletal maturity, while Cobb angles at presentation of  $<25^\circ$  have lower risks for curve progression, especially when combined with male gender,

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post-pubertal status, and an age of  $>12$  [5]. The primary treatment goal for adolescents is therefore to reduce progression in order to decrease the risk of back pain, disability, breathing problems and cosmetic deformities, and improve their health-related quality of life (HRQL) during adulthood [2, 6].

The conservative options for AIS include exercises and bracing [2, 7–10]. Usually, patients with thoracic Cobb angles up to  $25^\circ$  and lumbar or thoraco-lumbar curves up to  $20^\circ$  receive exercises alone; patients between  $25^\circ$  and  $50^\circ$  with thoracic main curves and between  $20^\circ$  and  $40^\circ$  with lumbar or thoraco-lumbar curves additionally receive bracing, and also perform exercises. The use of exercises has evolved to include outpatient physical exercises (e.g. self-correction, strengthening, mobilising, and machine-assisted exercises [11–17]), physiotherapy (e.g. electrical stimulation [18]), and intensive programmes involving breathing and postural exercises during in-hospital stays [19–22], but there are still doubts concerning its indications, effects, characteristics, timing, and long-term results [9].

The aim of this randomised, controlled study was to compare an innovative outpatient programme combining active self-correction, task-oriented exercises and education with a routinely followed programme of traditional exercises to verify whether it could reduce spinal deformities and improve HRQL in adolescents with mild (Cobb angle  $<25^\circ$ ) AIS, including thoracic, lumbar, thoraco-lumbar and S-shaped curves.

## Methods

### Experimental design

A randomised, controlled, parallel-group superiority trial.

### Inclusion and exclusion criteria

In order to be eligible, patients had to have a primary diagnosis of AIS determined by expert clinicians, a Cobb angle of  $10^\circ$ – $25^\circ$ , a Risser sign of  $<2$ , and an age of  $>10$  years. The exclusion criteria were any diagnosable cause of scoliosis, leg-length discrepancy of  $>1$  cm (by means of physical examination of the pelvis and by head femoral comparisons when examining full spine X-rays; full leg X-rays were additionally performed in uncertain cases), lower limb deformities interfering with spinal posture, cardiac and/or respiratory dysfunction (by means of history taking and in uncertain cases through instrumental diagnostic tests, such as echocardiogram or spirometry), systemic illness (by means of history taking), previous spinal surgery, and cognitive impairment (by means of history taking).

### Setting

The study was conducted at the Salvatore Maugeri Foundation's Scientific Institute in Lissone (Italy), a specialised rehabilitation centre that treats about 100 AIS patients every year.

### Patient enrolment

Outpatients consecutively attending the rehabilitation centre between February 2007 and December 2008 were evaluated by two physiatrists coordinated by the principal investigator (PI), and those who satisfied the entry criteria were asked to declare their willingness to comply with whichever treatment option they were randomly assigned to, and to attend all of the follow-up visits. Those who agreed were asked to give their written informed consent, and their demographic and anthropometric data and medical history were recorded using a specific form.

To limit expectation bias and reduce the problems of crossover, the patients were blinded to the study hypothesis by telling them that the trial was intended to compare two common rehabilitation approaches whose efficacy had not yet been established.

### Interventional programmes

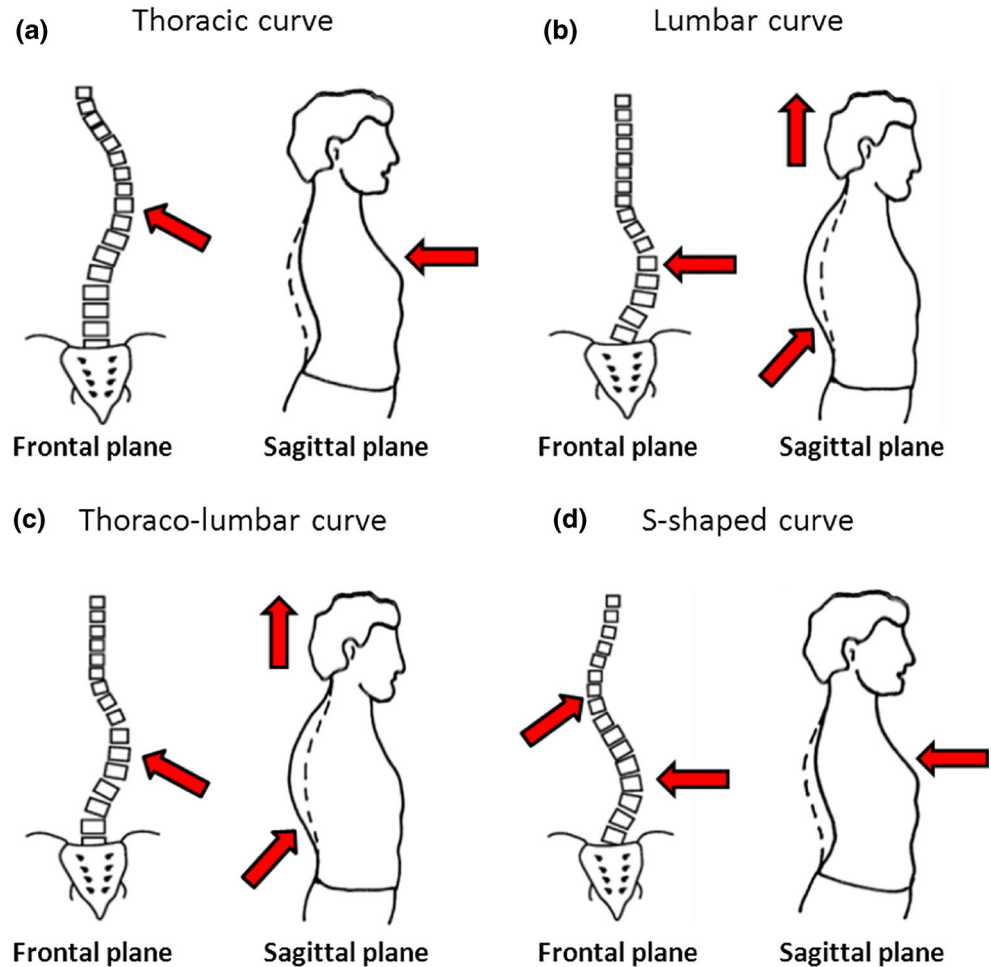
Two physiatrists and six physiotherapists were involved, and the intervention lasted until skeletal maturity had been reached (Risser sign 5). No other treatments at hospital or at home were advised after the end of the intervention. Figure 1 depicts the schedule of both the interventional programmes.

### Experimental group

This programme involved active self-correction (Fig. 2), that is a rehabilitative technique tailored to the type of curve scoliosis: selective vertebrae oblique (bottom-up) deflection and sagittal correction with increased kyphosis and preserved lordosis are required for thoracic curves (panel a); selective vertebrae lateral deflection and sagittal correction with increased lordosis and reduced thoraco-lumbar kyphosis are required for lumbar curves (panel b); selective vertebrae oblique (bottom-up) deflection and sagittal correction with increased lordosis and reduced thoraco-lumbar kyphosis are required for thoraco-lumbar curves (panel c); selective vertebrae oblique (bottom-up) deflection together with selective vertebrae lateral deflection and sagittal correction with increased kyphosis and preserved lordosis are required for S-shaped curves (panel d). Selective vertebrae deflections and sagittal corrections both result in horizontal vertebrae de-rotation. Exercises



**Fig. 2** Self-correction rehabilitative technique. In each panel, the *arrows* indicate the directions of self-correction. The *dashed line* in the sagittal plane indicates the physiological curve pattern



improve the range of motion of thoracic and lumbar segments of the spine), spinal strengthening (mainly devoted to spinal deep muscles) and stretching (mainly devoted to lower limb and back muscles), as well as balancing (by means of proprioceptive training when standing) and walking exercises (mainly devoted to resistance and velocity training).

The patients in both groups were followed individually. Three equally experienced physiotherapists were separately responsible for each group and arranged 60-min outpatient sessions once a week; the patients were asked to continue the exercises at home in 30-min sessions twice a week. To ensure that there was no variability in treatment administration during the course of the study, a fidelity check was made by the physiotherapists at the end of each outpatient session based on a treatment manual for the administration of the exercise training.

#### General recommendations

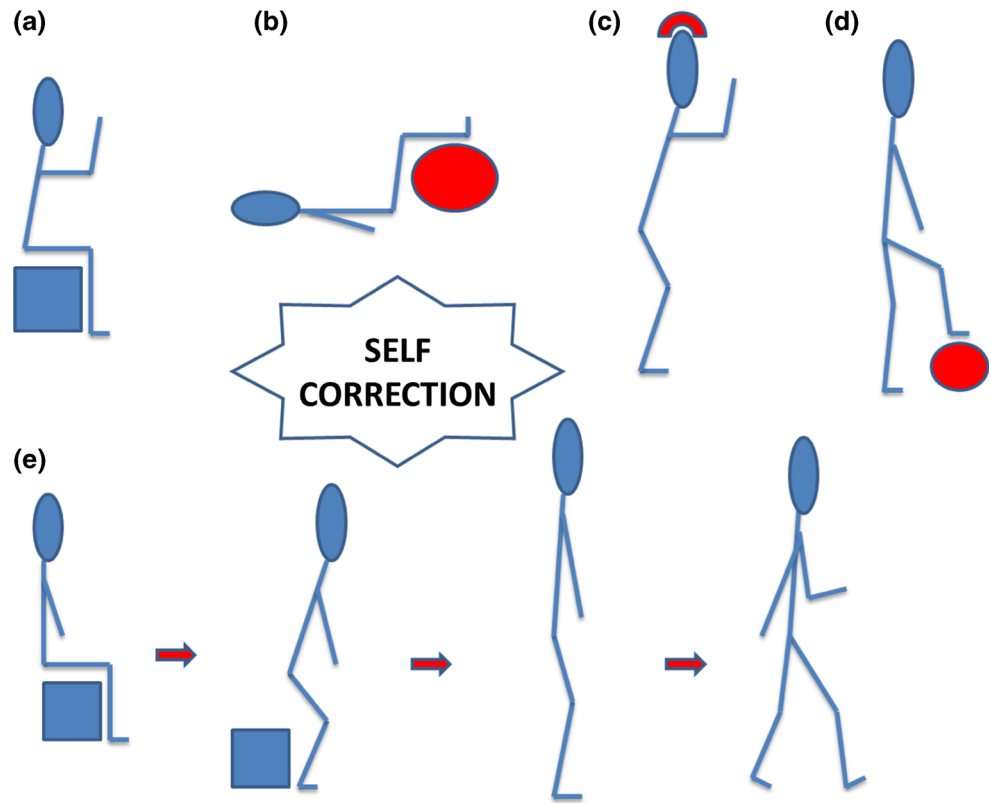
No other treatments (e.g. physical modalities, manual therapies) were offered once the patients had been enrolled.

Mild analgesics were permitted if pain occurred. To enhance compliance, the patients were asked to fill out a diary after each home training session and the physiotherapists checked the diary every week. Parents were encouraged to support the patients' compliance during the study and to inform staff promptly if any difficulty was encountered to strengthen treatment adhesion and minimise dropouts.

#### Randomisation

After signing the written informed consent form, the patients were randomised to one of the two programmes using a previously generated list of blinded treatment codes and an automatic assignment system to conceal the allocation. The list of 110 codes was created using random permuted blocks with a random block length (15 blocks of six and five blocks of four). This method assured that each patient had the same probability of treatment assignment and that the number of patients in the two groups did not differ by more than two; it also minimised selection bias [24].

**Fig. 3** Examples of task-oriented exercises performed while self-correcting: **a** sitting; **b** keeping the supine position with hip and knee flexed at 90°; **c** standing with sandbags on the head with hip and knee partially flexed; **d** climbing obstacles; **e** standing up and walking



### Blinding

The PI obtaining and assessing the outcome data and the biostatistician making the analyses were both blinded to the treatment allocation; the psychiatrists and physiotherapists could not be blinded.

### Outcome measures

The outcome measures were radiological deformities (primary outcome), surface deformities and the HRQL (secondary outcomes).

### Radiological deformities

The patients were examined radiographically for the severity and location of the scoliosis by means of standing anterior–posterior full spine imaging. The degree of curvature in the main curve was assessed by drawing the Cobb angle on each radiograph by hand; ideal measuring conditions were pursued by having the same examiner use narrow-diameter markers, select the same end vertebra and use the same protractor for each measurement. This procedure assured an intra-observer measurement of about 3°–5°, as previously found [25–27]. The location of the scoliosis was defined on the basis of Ponseti’s classification: thoracic, lumbar, thoraco-lumbar and S-shaped [28].

### Surface deformities

Bunnell’s scoliometer was used to measure the angle of trunk rotation (ATR, i.e. the angle between the horizontal plane and a plane across the posterior aspect of the trunk) of the hump in the main curve with the patient bending forward [29]. It has proved to be reliable, sensitive and specific [29, 30].

### HRQL

This was assessed using the region-specific Scoliosis Research Society-22 Patient Questionnaire (SRS-22) [31]. Its 22 questions cover five domains: function (5 items), pain (5 items), mental health (5 items), self-perceived image (5 items), and satisfaction with management (2 items). Five response levels are allowed for each item (scored 1–5, from worst to best), and the results are expressed as the mean score for each domain. We used the Italian version, which has proved to be reliable and valid [32].

The radiological and surface evaluations were made by the PI before treatment (T1), at the end of treatment (T2), and 12 months after the treatment ended (T3). The SRS-22 was administered at the same time points by secretarial staff who checked it and returned any uncompleted part to the patients for completion.

## Adverse effects

The patients were given a specific form on which to record any serious symptoms or events they experienced during the study.

## Statistics

The primary endpoint was the pre- and post-treatment difference (T2–T1) in the Cobb angle. It was calculated that a sample size of 43 patients per group would be capable of detecting a between-group difference of 5° in the primary endpoint with a type I error of 5 % and a power of 95 % [25]. As the interval of Cobb angles at entry was 10–25° and assuming a uniform distribution of Cobb angles in this range (the most unfavourable scenario), a standard deviation of 4.5° was estimated. Fifty-five patients were actually included in each group to allow for a 25 % dropout rate.

Baseline comparability was assessed using Student's *t* test for independent samples. Linear mixed model analyses for repeated measures ( $p < 0.05$ ) were made of each of the outcome measures, with group and time entered as fixed effects. The crossover effect of time and group was entered as an interaction term [33, 34]. Furthermore, since subjects with an age of <13 years are characterised by a higher risk of progression [2], the participants were divided into two subgroups (age <13 and age  $\geq 13$ ) and a linear mixed model analysis for the primary outcome was performed on each subgroup.

The data were analysed using SPSS 21.0 software.

## Institutional review board approval

The study was approved by our hospital's Institutional Review Board, and was conducted in conformity with ethical and humane principles of research.

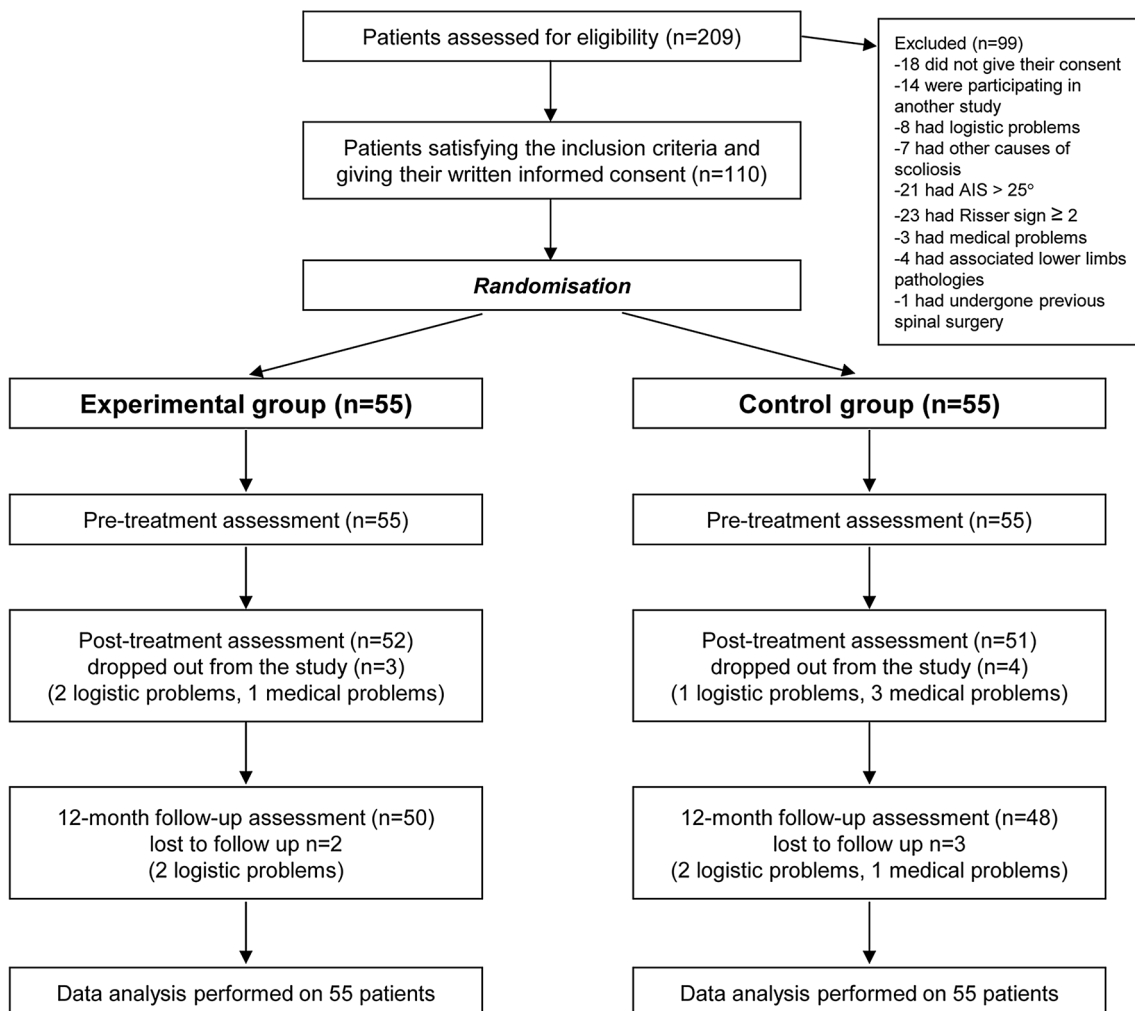


Fig. 4 Study flow chart



## Results

### Study timing

The study lasted about 80 months: the participants enrolled in the experimental and control groups completed the interventions after a mean treatment duration of, respectively,  $42.76 \pm 9.09$  and  $42.36 \pm 7.66$  months, and then entered a 1-year observational phase.

### Participants

Of the 209 screened patients, 110 agreed to participate and were randomised. The programmes were completed by 52 patients in the experimental group and 51 in the control group, and a further five patients were lost to follow-up (two in the experimental group, and three in the control group). Figure 4 shows the study flow chart. No crossover problems arose as no patient asked to swap groups.

The two groups were comparable at baseline (Table 1).

### Effects of the interventions

After training, the spinal deformity improved in 69 % of the patients in the experimental group (Cobb angle decreases of  $<3^\circ$ ), worsened in 8 % (Cobb angle increases of  $>3^\circ$ ), and remained stable in 23 %. In the control group, 6 % improved, 39 % worsened, and 55 % remained stable.

Table 2 shows the changes over time in the two groups.

The Cobb angle showed a significant effect of time ( $p < 0.001$ ), group ( $p < 0.001$ ), and time by group interaction ( $p < 0.001$ ), with a mean change after training of  $-5.3^\circ$  in the experimental group and  $1.7^\circ$  in the control group. The improvements in the experimental group were maintained at follow-up.

After training, the mean change in ATR in the experimental group was  $-3.5^\circ$ , whereas it remained stable in the control group. The results were maintained at follow-up and showed significant differences (time, group, and time by group interaction).

For all of the SRS-22 domains, high scores were achieved by both groups already at baseline (values ranged between 3.4 and 3.9 out of 5). Further significant improvements were obtained by the experimental group (post-training change  $>0.75$  for all of the domains), while no significant changes were highlighted for the control group.

Table 3 reports the results of the subgroup analysis on the Cobb angle. Significant effects of time, group and time by group interaction were found in both subgroups. Within the experimental group, the subgroup with the higher risk of progression (age  $<13$  years) exhibited a mean change after training of  $-4.9$ , whereas a mean change of  $-5.8$  was

**Table 1** Patients' baseline characteristics ( $n = 110$ )

	Experimental group	Control group	<i>p</i> value
Age (years)	12.5 (1.1)	12.4 (1.1)	0.672
Males/females	16/39	14/41	
Height (cm)	146.3 (7.5)	147.0 (5.7)	0.569
Weight (kg)	44.1 (5.7)	45.3 (5.5)	0.242
Risser sign (0/1)	25/30	25/30	
Menarche (females only), yes/no	28/11	29/12	
Family history of scoliosis, yes/no	34/21	36/19	
Type of scoliosis			
Thoracic	8	8	
Lumbar	13	14	
Thoraco-lumbar	21	20	
S-shaped	13	13	
Sport activities, yes/no	30/25	29/26	
Soccer	7	8	
Volleyball	18	16	
Tennis	2	4	
Basketball	3	1	
Back pain, yes/no	16/39	14/41	
Education			
Primary school	13	14	
Middle school	40	39	
High school	2	2	
Cobb angle ( $^\circ$ )	19.3 (3.9)	19.2 (2.5)	0.861
Angle of trunk rotation ( $^\circ$ )	7.1 (1.4)	6.9 (1.3)	0.403
SRS-22 <sup>a</sup>			
Function (0–5)	3.8 (0.5)	3.9 (0.5)	0.404
Pain (0–5)	3.8 (0.4)	3.9 (0.5)	0.383
Self-perceived image (0–5)	3.6 (0.6)	3.4 (0.6)	0.094
Mental health (0–5)	3.8 (0.6)	3.9 (0.6)	0.433

Mean values (SD)

<sup>a</sup> Scoliosis Research Society-22 Patient Questionnaire

found for subjects with an age of  $\geq 13$  years. A slight increase of the Cobb angle was instead observed in both subgroups within the control group (mean change of 1.2 and 2.3 for age  $<13$  and  $\geq 13$ , respectively). In Table 4, the number of improved, deteriorated, and stable subjects for each subgroup is reported.

### Adverse effects

The minor adverse effects of transient pain worsening ( $n = 11$  in the experimental group, and  $n = 14$  in the control group) were easily managed by means of symptomatic drugs and brief periods of rest.

**Table 2** Changes over time within and between control and experimental group ( $n = 110$ )

	Group	Pre-training <sup>a</sup>	Post-training <sup>a</sup>	Follow-up <sup>a</sup>	Change post-training <sup>b</sup>	Change at follow-up <sup>b</sup>	$F$ ( $p$ value) time effect	$F$ ( $p$ value) group effect	$F$ ( $p$ value) interaction effect
Primary outcome									
Cobb angle (°)	Experimental	19.3 (3.9)	14.0 (2.4)	14.3 (2.3)	-5.3 (0.6)	-4.9 (0.4)	15.874 ( $<0.001$ )	149.293 ( $<0.001$ )	91.841 ( $<0.001$ )
	Control	19.2 (2.5)	20.9 (2.2)	22.0 (1.6)	1.7 (0.3)	2.8 (0.4)			
Secondary outcomes									
Angle of trunk rotation (°)	Experimental	7.1 (1.4)	3.6 (1.1)	3.3 (1.1)	-3.5 (0.2)	-3.7 (0.2)	160.872 ( $<0.001$ )	94.785 ( $<0.001$ )	120.186 ( $<0.001$ )
	Control	6.9 (1.3)	6.6 (1.2)	6.5 (1.1)	-0.2 (0.1)	-0.4 (0.1)			
SRS-22 <sup>c</sup>									
Function (0-5)	Experimental	3.8 (0.5)	4.7 (0.2)	4.8 (0.2)	0.89 (0.07)	1.00 (0.07)	79.24 ( $<0.001$ )	59.38 ( $<0.001$ )	71.50 ( $<0.001$ )
	Control	3.9 (0.5)	4.0 (0.4)	3.9 (0.4)	0.09 (0.03)	0.01 (0.04)			
Pain (0-5)	Experimental	3.8 (0.4)	4.6 (0.3)	4.7 (0.2)	0.82 (0.05)	0.89 (0.06)	138.684 ( $<0.001$ )	14.304 ( $<0.001$ )	26.463 ( $<0.001$ )
	Control	3.9 (0.5)	4.3 (0.3)	4.2 (0.4)	0.45 (0.06)	0.33 (0.06)			
Self-perceived image (0-5)	Experimental	3.6 (0.6)	4.4 (0.3)	4.6 (0.3)	0.82 (0.07)	1.00 (0.08)	111.559 ( $<0.001$ )	65.764 ( $<0.001$ )	41.852 ( $<0.001$ )
	Control	3.4 (0.6)	3.7 (0.5)	3.6 (0.4)	0.30 (0.03)	0.21 (0.04)			
Mental health (0-5)	Experimental	3.8 (0.6)	4.5 (0.3)	4.7 (0.2)	0.75 (0.07)	0.95 (0.08)	61.964 ( $<0.001$ )	34.862 ( $<0.001$ )	60.674 ( $<0.001$ )
	Control	3.9 (0.6)	3.9 (0.5)	3.8 (0.4)	0.11 (0.03)	-0.01 (0.04)			
Satisfaction with management (0-5)	Experimental	NA	4.8 (0.3)	4.9 (0.3)	NA	NA	23.257 ( $<0.001$ )	93.796 ( $<0.001$ )	1.191 (0.278)
	Control	NA	4.0 (0.5)	4.2 (0.5)	NA	NA			

<sup>a</sup> Mean values (SD)<sup>b</sup> Mean change in score (SE)<sup>c</sup> Scoliosis Research Society-22 Patient Questionnaire**Table 3** Sub-group analysis on the Cobb angle (primary outcome measure)

Group	Group	Pre-training <sup>a</sup>	Post-training <sup>a</sup>	Follow-up <sup>a</sup>	Change post-training <sup>b</sup>	Change at follow-up <sup>b</sup>	$F$ ( $p$ value) time effect	$F$ ( $p$ value) group effect	$F$ ( $p$ value) interaction effect
Age <13 years ( $N = 32$ experimental group; $N = 35$ control group)	Experimental	18.9 (4.1)	14.1 (2.5)	14.2 (2.3)	-4.9 (0.8)	-4.7 (0.6)	9.351 ( $<0.001$ )	89.711 ( $<0.001$ )	47.625 ( $<0.001$ )
	Control	19.3 (2.4)	20.7 (2.5)	21.9 (1.6)	1.2 (0.4)	2.5 (0.5)			
Age $\geq$ 13 years ( $N = 23$ experimental group; $N = 20$ control group)	Experimental	19.9 (3.6)	14.0 (2.4)	14.5 (2.4)	-5.8 (0.9)	-5.3 (0.7)	6.253 (0.004)	58.667 ( $<0.001$ )	45.135 ( $<0.001$ )
	Control	19 (2.7)	21.4 (1.8)	22.1 (1.5)	2.3 (0.5)	3.1 (0.6)			

<sup>a</sup> Mean values (SD)<sup>b</sup> Mean change in score (SE)

## Discussion

The findings of this study show that a rehabilitation programme including specific and task-oriented exercises is superior to a programme including traditional exercises in

reducing spinal deformities and enhancing the HRQL in patients with mild AIS. The effects lasted for at least 1 year after the intervention had ended.

Radiological deformities remained stable in the control group and improved in the experimental group at the end of



**Table 4** Number of improved, deteriorated, and stable subjects for each subgroup at post assessment

Group	Improved no. (%)	Deteriorated no. (%)	Stable no. (%)
Age <13 years ( <i>N</i> = 63)			
Experimental	22 (71.0)	3 (9.7)	6 (19.3)
Control	3 (9.4)	10 (31.2)	19 (59.4)
Age ≥13 years ( <i>N</i> = 40)			
Experimental	14 (66.7)	1 (4.8)	6 (28.5)
Control	0 (0)	10 (52.6)	9 (47.4)

treatment (a 5° decrease in the Cobb angle); there was a slight worsening in the control group at follow-up, whereas the experimental group remained stable. The superiority of the experimental training programme was observed regardless of the risk of progression at admission, as highlighted by the subgroup analysis (Table 3).

The ATR measurements of the patients in the experimental group decreased to below the threshold of 5°–7°, the referral criterion for medical evaluations during screening at schools [29, 30]; the improvements were maintained at follow-up. The patients in the control group remained stable over time.

Our findings support the use of active self-correction and task-oriented exercises until skeletal maturity as the spinal deformities worsened in only 8 % of the experimental group, less than the estimated 20–60 % risk of progression in this population and age [35]. The exercises had distinctive characteristics in comparison with traditional training as they were based on selective movements designed to achieve the maximum possible correction of the deformity, and their postural effectiveness was strengthened by the development of neuromotor abilities during everyday activities. Education also helped the patients to adopting supportive attitudes and appropriate behaviours, thus enhancing their compliance with exercises and long-lasting interventions.

The effect of the treatment on the SRS-22 domains confirms the benefits of specific and task-oriented exercises and education. The greatest improvements were observed in the function domain because the treatment was targeted at improving functional abilities; pain diminished as a result of the exercises and interventions concerning modifiable risk factors such as lifestyle, and physical and school-related factors [36]; self-image and mental health also showed evidence of the synergistic effects of developing patients' awareness of a disease which, in mild cases, can be managed without any negative aesthetic or mental health effects. The higher rates of satisfaction with management in the experimental group indicate the superiority of the experimental treatment, probably because enhancing self-management skills helps to improve patients' self-

efficacy and is perceived as a better means of responding to concerns about scoliosis. However, caution is required when interpreting these findings because the physiotherapists could not be blinded to the study hypothesis and, consequently, may have influenced the patients' expectations.

The positive effects of reducing curve patterns and improving spinal abilities by the end of adolescence, providing correct information and graded exposure to physical exercise, and teaching appropriate behaviours are important when it comes to preserving a healthier spine for as long as possible [36, 37].

Other studies have investigated the effects of exercise therapy on AIS, but these are not comparable with ours because of differences in the patients' characteristics and selection, and differences in the procedures and settings [9]. One prospective study compared the effects of exercises based on active self-correction with those of usual physiotherapy by having consecutive outpatients undergone individual sessions every 2–3 months at the institute and continuing the treatment by themselves twice a week; however, the small improvement in Cobb angle, the doubt about which treatment group the patients were to be assigned to, and the absence of a compliance assessment make it impossible to draw any firm conclusions [11]. Our programme developed active self-correction also by means of task-oriented exercises, which made a distinctive contribution to the training, and education contributed to developing the patients' knowledge of the disease and their self-management skills, thus strengthening their motivation and providing assistance in the case of difficulties. It was also characterised by more frequent and intensive sessions of supervised exercises to assure they were correctly carried out at home.

This trial had a high level of internal validity, was capable of distinguishing the effects obtained in the two groups, was adequately sized, and involved concealed randomisation, blinded data collection, and the effective masking of assessors and analysts. The support of relatives and staff helped to create a protected situation, thus limiting the dropout rate and minimising adverse effects.

The sample was representative of the general population undergoing conservative treatment for mild AIS in Europe [11, 15, 19–22], but the data cannot be generalised to rehabilitation during bracing or after surgical correction.

The study has some limitations. Treatment expectations were not addressed, and this confounding factor was only partially limited by telling the patients during enrolment that the efficacy of both treatments had not yet been established, and that both approaches might contribute to improving their deformity. Secondly, exercise compliance and adherence to treatment could not be fully guaranteed, although the patients' diaries were checked every week.

Thirdly, mixing rib humps with lumbar humps may lead to an incorrect interpretation of the results and future studies are recommended to keep the measurement of thoracic humps separated from the measurement of ATR lumbar humps.

## Conclusions

Our findings suggest that a rehabilitation programme including active self-correction, task-oriented exercises and education carried out until skeletal maturity is useful in reducing the course of spinal deformity and improving HRQL in adolescents with mild AIS. We recommend its use in secondary care settings in which the staff are adequately trained in managing AIS.

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**Conflict of interest** None.

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