Annals of Physical and Rehabilitation Medicine 62 (2019) 69–76

Available online at ScienceDirect www.sciencedirect.com

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Original article

Specific exercises reduce the need for bracing in adolescents with idiopathic scoliosis: A practical clinical trial

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ARTICLE INFO

Article history:
Received 7 March 2018
Accepted 27 July 2018

Keywords:
Scoliosis
Adolescents
Exercise

ABSTRACT

Background: In an ideal experimental setting, 2 randomized controlled trials recently showed the efficacy of physiotherapeutic scoliosis-specific exercises (PSSEs) for adolescents with idiopathic scoliosis (AIS). Now large observational studies are needed to check the generalizability of these results to everyday clinical life.

Objective: To explore the effectiveness of PSSEs for avoiding bracing or progression of AIS in everyday clinics.

Methods: This was a longitudinal comparative observational multicenter study, nested in a prospective database of outpatient tertiary referral clinics, including 327 consecutive patients. Inclusion criteria were AIS, age $\geq$ 10 years old at first evaluation, Risser sign 0–2, and 11–20°Cobb angle. Exclusion criteria were consultations only and brace prescription at baseline. Groups performed PSSE according to the SEAS (Scientific Exercise Approach to Scoliosis) School, usual physiotherapy (UP) and no therapy (controls [CON]). End of treatment was medical discharge, Risser sign 3, or failure (defined by the need for bracing before the end of growth or Cobb angle > 29°). The probability of failure was estimated by the risk ratio (RR) and 95% confidence interval (CI). The number needed to treat was estimated. Statistical analysis included intent-to-treat analysis, considering all participants (dropouts as failures), and efficacy analysis, considering only end-of-treatment participants. Propensity scores were used to reduce the potential effects of confounders related to the observational design.

Results: We included 293 eligible subjects after propensity score matching (SEAS, $n = 145$; UP, $n = 95$; controls, $n = 53$). The risk of success was increased 1.7-fold ($P = 0.007$) and 1.5-fold ($P = 0.006$) with SEAS versus controls in the efficacy and intent-to-treat analyses, respectively, and the number needed to treat for testing SEAS versus controls was 3.5 (95% CI 3.2–3.7) and 1.8 (95% CI 1.5–2.0), respectively. The success rate was higher with SEAS than UP in the efficacy analysis.

Conclusions: SEAS reduced the bracing rate in AIS and was more effective than UP. PSSEs are additional tools that can be included in the therapeutic toolbox for AIS treatment.

1. Introduction

Adolescent idiopathic scoliosis is a 3-D deformity of the spine and trunk [1] that causes aesthetic deformities during growth. It can be responsible for back pain in adulthood, flexed posture in older people [1,2], and a progressive deformity of the trunk that affects aesthetics as well as quality of life. The related risk of health disorders in adulthood increases as the spinal curvature exceeds the 30°Cobb angle [3]; therefore, the main scientific societies in the field (i.e., the Scoliosis Research Society and the International Society On Scoliosis Orthopedic and Rehabilitation Treatment [SOSORT]) set a 30 °Cobb angle as the best achievable goal for conservative treatment [3]. Conservative treatment includes observation, physiotherapeutic scoliosis-specific exercises (PSSEs), and bracing [1,3].

The effectiveness of bracing for adolescent idiopathic scoliosis was recently confirmed by a high-quality randomized controlled trial (RCT) [4] that confirmed the previous results from a good-quality benchmarking controlled trial [5–7] A brace is recommended with curves 25° to 40° [8,9]; however, how to treat scoliosis with < 25° Cobb angle remains unclear. Is observa-

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https://doi.org/10.1016/j.rehab.2018.07.010
1877-0657/

tion enough? Bracing is challenging and affects quality of life [8–11]; therefore, we need to determine whether the progression of low-degree curves can be reduced and whether use of a brace can be avoided with PSSEs.

Despite the low quality of evidence favouring PSSEs [12], many experts propose PSSEs with bracing (i.e., to increase the brace effectiveness and to compensate for potential adverse effects on the muscles and spine) and also as a stand-alone treatment with milder curves to avoid bracing [1]. PSSEs are based on active self-correction, spinal stabilization, and a cognitive behavioral approach [1]. Two RCTs recently showed the efficacy of PSSEs for adolescents with idiopathic scoliosis (AIS) [10,13]. One, focused on the SEAS (Scientific Exercise Approach to Scoliosis) School, and followed patients until the end of their growth period, thus providing high-quality evidence [10,14]. These studies endorsed the use of PSSEs instead of general exercises [15].

The results from the RCTs proved the efficacy of PSSEs in an ideal experimental setting, but large observational studies are needed to check the generalizability of results to everyday clinical life [16]. In this study, we included a specific sample of participants from a clinical prospective database started in 2003 and investigated whether PSSEs could stop the progression and/or avoid bracing in AIS at high risk for bracing (i.e., 11–20° curves and Risser sign 0–2) as compared with usual physiotherapy or observation only.

2. Material and methods

2.1. Design and setting

This was a longitudinal comparative observational multicenter study nested in a prospective clinical database established in March 2003. The clinical database included all individuals with spinal deformities who visited a tertiary outpatient referral institute that has 26 outpatient centers around Italy; the same doctors moved from centre to centre to visit patients.

The local ethics committee of Milan (Comitato Etico Milano Area B, Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico Palazzo Uffici Via F. Sforza n. 28-20122 Milano) approved the current study (protocol no. 202016_bis). The study included all adolescents who completed their first evaluation between the establishment of the database in 2003 and September 2014 (date of data extraction). Only those who signed an informed consent form to allow the use of their clinical data for research purposes were included in this study.

2.2. Participants

We included all consecutive AIS, age $\geq$ 10 years old, Risser sign 0–2 [17], radiographic Cobb curvature 11–20°, and referred for their first evaluation at this institute. Adolescents were excluded if they were referred to the institute for only consultation (i.e., the institute is a tertiary referral clinic and attracts patients from all over the country; therefore, many attend for only a consultation) or if they had a brace prescribed at the first consultation. Although this immediate prescription is uncommon for this range of curvatures, it can occur with:

- important concomitant hyperkyphosis;
- the physician judging a high risk of disease progression;
- an impaired trunk aesthetic, to be compensated with a brace.

2.3. Interventions

The exercise program tested is the SEAS School, which is based on active self-correction. SEAS has previously been found efficacious for treating scoliosis both during growth and in adulthood [18].

Adolescents were divided into 3 subgroups based on choices made by themselves and their families:

- the SEAS group involved treatment according to SEAS [18–20], an individualized exercise program adaptable to various situations of conservative treatment of scoliosis that aims to improve the stability of the spine in active self-correction. Originally developed by Antonio Negrini and Nevia Verzini, the details of the approach were previously published [18]. The approach continuously adapts its principles to the developing evidence from the field. Consequently, it continuously and slowly changes, even if its main principles described below have remained stable since the 1990s. SEAS is based on a specific active self-correction technique performed without external aids and incorporated in functional exercises. Evaluation tests guide the choice of the exercises most appropriate to the individual patient. SEAS exercises train neuromotor function so as to stimulate by reflex a self-corrected posture during activities of daily life. SEAS has a strong modern neurophysiological basis, to reduce requirements for patients and possibly costs for families by reducing the frequency and intensity of treatment and evaluations. Therefore, SEAS allows for treating a large number of individuals travelling even from far away. Even if SEAS appears simple by requiring less physiotherapist supervision and with fewer home exercises prescribed at a lower dose than some of the other PSSE approaches, real expertise in scoliosis, exercises, and patient and family management is required. The program has no copyrights, and teachers are trained all over the world [18–20]. Individuals are prescribed 4 physiotherapy sessions lasting 1.5 hr per year (one every 3 months). The person is followed by an expert physiotherapist with postgraduate training in SEAS and at least 6 months of supervised practice and who works daily with this program. After evaluation, the physiotherapist chooses and teaches the personalized program of exercise and finally provides material for home practice (i.e., exercise sheets, agendas for adherence, and videos containing the physiotherapist's explanations). We did not provide cognitive behavioural therapy, but the overall approach to treatment by the whole rehabilitation team involved a cognitive-behavioural approach. In fact, the time is spent on a total individual basis (without a pre-specified protocol or time) according to individual needs to explain to patients and families why it is important to treat scoliosis, the consequences of treatment or no-treatment, the role of PSSEs and eventually bracing. Various instruments are used individually for support and problem-solving, including focused colloquia, emails, phone calls, and eventual inclusion in the team of a trainer as a caregiver. The overall aim is to facilitate individuals and parents changing their behaviors and consequently adhering to treatment [21]. The protocol requires exercising for at least 90 min/week, organized in accordance with the patient's preferences and with a wide range of possibilities; for example, the patient can perform the exercises at home or in a gym; unsupervised or supervised by parents, relatives, or external experts (i.e., personal trainers, motor scientists, or physiotherapists); and daily (15–20 min/session) or 2–3 times a week (45 or 30 min/session, respectively). The association with any other kind of scoliosis-specific exercise was strongly discouraged. Only individuals who had used the SEAS approach on regular basis, for at least 45 min/week and who had at least 3 individualized physiotherapy sessions/year, [18–20] were included in the SEAS group;
- the usual physiotherapy (UP) group included all adolescents who did not follow the SEAS protocol and who preferred to

perform general aspecific exercises with independent physiotherapists outside of the institute. Adherence was assessed during each follow-up medical consultation and was self-reported by adolescents and their families;
- the control (CON) group included adolescents who were not prescribed exercises (observation) or who did not regularly exercise (< 15 min/session or 45 min/week).

Adolescents in all groups were also prescribed sport activities to be performed at least twice a week as a useful approach but non-specific [1]. Group attribution was decided according to the database records of the institute and adherence to treatment, which was assessed during each physiotherapy or follow-up medical consultation. Adolescents and parents were asked how many times per week the adolescent practiced the exercises and how long each session lasted (min). In agreement with current SOSORT guidelines [1], after evaluating all the involved risk factors, the expert physician prescribed the best treatment according to his/her judgement; in some individuals with low risk, the options can be more than one and therefore the adolescent's and family's choices play a role.

2.4. Evaluations

Adolescents underwent a full clinical checkup every 6 months (range: 4–8 months). Standard coronal full-spine standing radiography was performed every 12 months to measure the Cobb degrees for the curves and bone maturity. This radiographic protocol was the same for all included adolescents at all times and strictly follows the SOSORT recommendations for radiography [22] in order to monitor adolescents effectively by reducing as much as possible the radiation exposure. For this reason, the lateral X-ray was taken only at the start and end of treatment. The clinical evaluation every 4 to 6 months allowed for detecting changes and prescribing repeat radiography if needed.

The following clinical data were obtained for all participants at each evaluation [1,23]:

- treatment adherence (i.e., protocol, sessions/week, and time/session);
- age (years and months), weight (kg), and height (cm);
- Bunnell's Angle of Trunk Rotation (ATR) during Adam's test [24] and hump height (mm) [25];
- aesthetic evaluation using the Trunk Aesthetic Clinic Evaluation (TRACE) index (1–12 points) [26];
- sagittal profile according to the plumbline distance (mm) tangent to the apex of kyphosis: L3 for lordosis, the sagittal index (sum of the distances of C7 and L3) for kyphosis, and S1 versus C7 for trunk frontal or sagittal decompensation [27]. Side effects were also recorded.

2.5. Outcome criteria

Adolescents were discharged when they reached a minimum bone age of Risser 3 with stable scoliosis parameters.

The 2 outcome criteria for failure were prescription for a brace [20] or measurement of the principal spinal curve > 29 °Cobb at the end of treatment. Braces were prescribed according to current guidelines for scoliosis treatment [1] and according to the risk factors estimated by the expert physicians; therefore, the prescription usually occurred before the curvature reached 30° to increase the possibility of completing the treatment before reaching this important threshold.

The usual 5° progression thresholds were not used in this study because they are inappropriate for low-degree scoliosis for which the aim is to maintain a < 30°Cobb angle, and thus some progression is acceptable. All other parameters collected during clinical and radiographic evaluations were considered secondary outcomes (Risser score, rib hump height, TRACE score and body mass index).

2.6. Statistical analysis

This was a clinical study focusing on the everyday clinical situation, so the largest possible sample size was included. Descriptive statistics were calculated for baseline demographic, clinical, and radiographic data for the entire sample and for adolescents who dropped out. After checking for normal distribution, parametric and non-parametric tests were used to compare groups as appropriate. Mean (SD) are reported for normally distributed continuous variables, median and ranges for categorical and ordinal variables.

Propensity scores were used to reduce the potential effects of confounders related to the observational design. Propensity scores are useful in the analysis of observational studies. They allow for balancing a large number of covariates between 2 groups (treated and untreated) by balancing a single variable, the propensity score. The main assumption is that every subject has two potential outcomes: one if they were treated, the other if they are not treated. The aim is to compare treated participants to untreated participants with the same potential outcomes, which ensures that the difference between treated and untreated subjects is due to the treatment because the outcomes in both groups would have been the same had the treated subjects not received treatment. To create the propensity score, logit was used with treatment as the outcome variable and potential confounders as the explanatory variables. A stratification analysis was used to estimate the treatment effect and to balance confounders. The variables related to the outcome, as well as to the treatment were age, the TRACE index, ATR and the Cobb angle at the start of the study. After stratification matching, the risk ratio was calculated.

Failure was defined as the prescription of bracing or a Cobb angle progressing above 29° and therefore was a categorical variable. Considering the design, the probability of failure in untreated participants (CON group) versus treated participants (SEAS group) was calculated by risk ratios (RRs) and 95% confidence intervals (CIs). The RR is the ratio of incidence rates in the exposed to unexposed groups. The RR is used to compare the measures of disease frequency in 2 different populations, the one exposed to the treatment and the other untreated (unexposed).

Because of the prospective database, data for all dropouts were available for baseline analysis, so to manage in the best possible way these non–at-random missing data and to avoid overestimation of results, the statistical analysis included the following analyses:

- intent-to-treat, considering all consecutive adolescents prospectively included (considering dropouts as failures): this analysis allows for determining the total efficacy to be expected for the treatment at the time of prescription, when physicians do not know yet how many patients will adhere to therapy;
- efficacy, considering only end-of-treatment participants: this analysis reports on the efficacy to be expected when participants decide to adhere to treatment.

The number needed to treat, another relevant parameter that tells how many participants are needed for treatment to observe one good result (in this case, to avoid bracing), was calculated from the RR difference and its 95% CI, and one- and two-sided Fisher's exact tests were calculated for statistical significance. STATACorp 2013 was used for statistical analysis (Stata statistical software release 13, College Station, TX, USA). $P < 0.05$ was considered statistically significant.

3. Results

Among 327 consecutive adolescents prospectively recruited, 34 (10%) were excluded after a brace prescription at the first evaluation (Fig. 1). None was excluded due to lack of data or refusal to participate. In the final study, 240 adolescents performed exercises, including both the SEAS and UP groups (74% females) and 53 did not perform any kind of physiotherapy (CON group; 76% females). Overall, 145 adolescents were in the SEAS group (71% females) and 95 in the UP group (80% females). The distribution of characteristics at baseline are in Tables 1 and 2. All data were collected at the start of the treatment and at the last evaluation before the end of treatment or dropout.

A total of 248 (85%) adolescents reached the end of treatment, which occurred after a mean (SD) of 2.1 (1.3) years. Failure was due to only bracing, because no participant reached the end of treatment with a curvature > 29° without receiving a brace. The mean (SD) Cobb angle (largest curve) at the time of brace prescription was 24.7° (5.2) for the SEAS group, 22.9° (5.6) for the UP group, and 23.6° (5.8) for the CON group, with no differences.

Table 1
Characteristics of adolescents with idiopathic scoliosis before the study by SEAS (Scientific Exercise Approach to Scoliosis) school physiotherapeutic scoliosis specific exercises, usual physiotherapy (UP) and control (CON) groups.

	SEAS $n = 145$	UP $n = 95$	CONT $n = 53$	Braced at start	*P* value
Sex					
Females	71%	80%	75%	85%	NS
Males	29%	20%	25%	15%	
Diagnosis					
Adolescent (age > 10 years)	87%	83%	97%	86%	NS
Juvenile (age 4–9 years)	13%	17%	3%	14%	

NS: not significant.

Rates of failure and dropout in the total sample were 100/293 (34%) and 47/293 (16%), respectively (Table 3).

All 293 eligible participants were included after propensity score matching. Among the variables considered the most influential was age (standardized difference = 0.2), whereas the TRACE index, ATR, hump height and Cobb angle at the start of the study showed lower values (Supplementary data, Table 4). Stratification into quintiles produced a good balance between

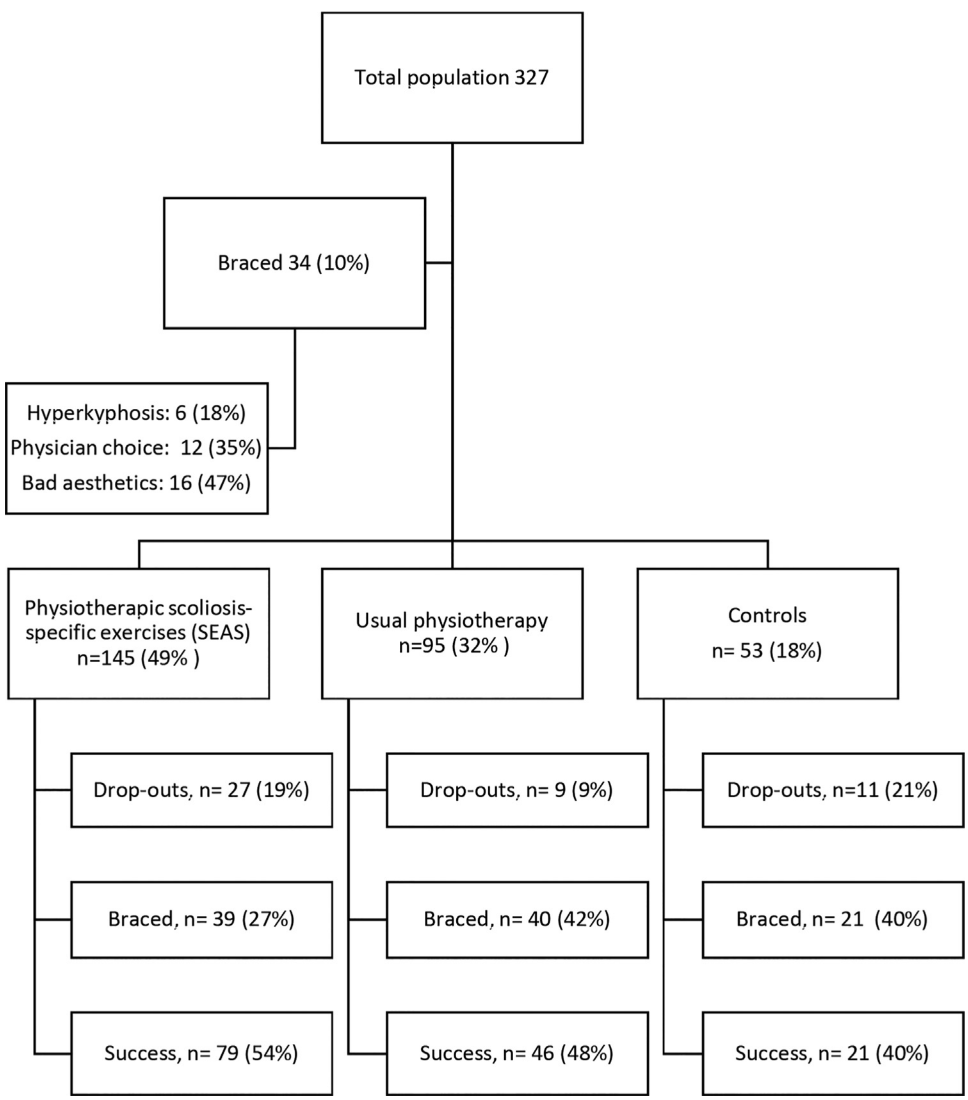

Fig. 1. Flow of participants in the study.

Table 2
Comparison of groups by all considered clinical parameters at the start of the study.

	SEAS $n = 145$	UP $n = 95$	CON $n = 53$	Braced at start $n = 34$	*P* value	
					SEAS vs. UP vs. CON	Braced vs. others
Time exercising (years:months)	2:04 (1:04)	1:12 (1:01)	1:10 (1:05)	NA		NA
Age (years:months)	12:07 (1:05)	12:07 (1:07)	12:03 (1:03)	13:0 (1.0)	NS	< 0.01
Risser sign (0–5), median (range)	0 (0–2)	0 (0–2)	0 (0–2)	0 (0–2)	NS	NS
Maximum Cobb angle (degrees)	15.4 (2.7)	15.4 (2.6)	15.3 (3.1)	17.9 (2.2)	NS	< 0.01
Weight (kg)	45.1 (13.0)	44.7 (9.1)	44.2 (7.7)	47.7 (20.9)	NS	NS
Height (cm)	155.7 (14.3)	155.5 (10.7)	155.2 (9.0)	153.0 (22.7)	NS	NS
Maximum ATR (degrees)	5.9 (2.6)	6.0 (2.5)	6.3 (3.2)	8.7 (3.7)	NS	< 0.01
Maximum hump height (mm)	7.0 (3.8)	7.1 (3.9)	7.0 (5.4)	12.1 (4.6)	NS	< 0.01
Aesthetics (TRACE: 1–12 points), median (range)	5 (3–7)	5 (3–7)	5 (3–7)	7 (4–9)	NS	< 0.01
PD C7–L3 (mm)	71.2 (19.6)	70.2 (19.5)	72.5 (20.3)	71.2 (21.3)	NS	NS
PD L3 (mm)	36.7 (12.8)	36.4 (13.4)	35.8 (13.4)	36.3 (16.4)	NS	NS
PD S1 (mm)	19.5 (16.1)	18.9 (14.5)	19.1 (16.7)	12.3 (14.4)	NS	< 0.05

Data are mean (SD) unless indicated. ATR: angle of trunk rotation; TRACE: trunk aesthetic clinical evaluation; PD: plumbline distance; NS: not significant

Table 3
Rates of failure and dropout.

	Total $n = 293$		SEAS $n = 145$		UP $n = 95$		CON $n = 53$	
Dropouts	47	16%	27	19%	9	9%	11	21%
End of treatment								
Total	246	84%	118	81%	86	90%	42	79%
Braced	100	41%	39	33%	40	46%	21	50%
Medical prescription	113	46%	56	47%	36	42%	21	50%
Risser sign 3	33	13%	23	19%	10	12%	0	0

covariates and thus removed possible confounders (Supplementary data, Table 4).

The risk of success was 1.7-fold ($P = 0.007$) and 1.5-fold ($P = 0.006$) higher with SEAS than controls in the efficacy and intent-to-treat analyses, respectively, and the number needed to treat for SEAS versus CON was 3.5 (95% CI: 3.2–3.7) and 1.8 (1.5–2.0), respectively (Table 4). The success rate of SEAS versus UP was significantly increased in the efficacy analysis (1.4; 95% CI: 1.0–2.0) but not in the intent-to-treat analysis.

Significant differences were also found for Cobb angles in all groups between the start and end of treatment but were still within the measurement error range (5°) (Table 5). For the SEAS group, significant differences were found between the start and end of treatment for hump height and plumbline distance although not clinically significant. Aesthetics (i.e., TRACE Index) improved significantly and clinically in the SEAS group (1.8/12 points) and UP group (1.5/12 points) but not in the CON group. Only the SEAS improvement was significantly better than the CON group improvement.

No side effects were reported in all groups.

4. Discussion

This observational study of AIS involved data from everyday clinical practice in a multicenter prospective clinical database. It has shown the effectiveness of PSSEs (i.e., the SEAS) in avoiding failure (i.e., the need for bracing or spinal curvature exceeding a Cobb angle of 29° at the end of treatment) in a wide cohort of AIS at high risk of progression (i.e., those with curves of 11–20° at the start of puberty).

In a previously published observational prospective trial, 1 year of SEAS improved the largest curvature by 0.3° and all curves by a mean of 0.7°. Conversely, UP worsened the largest curve by 1.1° and all curves by a mean of 1.4 [20]. This previous study provided low-quality evidence to support the SOSORT recommendation that PSSE was more effective than general exercises. The Monticone et al. RCT [10] presented the first high-level of evidence to support the use of SEAS-based PSSEs in AIS. The sample included girls with mean (SD) age 12.5 (1.1) years, mean Cobb angle 19.3° (3.9), and Risser sign 0–2. Scoliosis-specific active self-correction and task-oriented exercises consistent with the SEAS approach improved Cobb angle by 5.3° at skeletal maturity, and traditional exercises were associated with stable curves. The curves remained stable at 1 year after the end of the study [10]. In the last years, results of further RCTs of PSSEs also using the Schroth method have been published [13,28].

Despite evidence from previously published RCTs, in many countries, exercises are not prescribed and their effectiveness is still debated [2,29,30] perhaps because of feasibility; however, this study shows that adolescents can perform exercises on a regular basis. In the UP group, participants performed different types of exercises in various facilities throughout the country and these were more effective than no treatment. Experts recommended PSSEs (SEAS) instead of general exercises and this study shows their superiority over UP.

Table 5 shows that the SEAS group performed a mean (SD) of 92 (26) min of exercise per week and the UP group a mean of 105 (90) min/week, which was higher for the UP than SEAS group although not significantly. This finding was related to the classical UP protocols in which participants are required to perform exercises twice a week for 60 to 90 min in the physiotherapy lab or gym, whereas the SEAS protocol requires home exercises for 90 min/

Table 4
Comparison of groups by efficacy and intent-to-treat analyses and number needed to treat.

	Efficacy analysis			Intent-to-treat analysis		
	SEAS vs. CON	SEAS vs. UP	UP vs. CON	SEAS vs. CON	SEAS vs. UP	UP vs. CON
Risk ratio (95% CI)	1.7 (1.7–2.5)	1.4 (1.0–2.0)	1.2 (0.8–1.7)	1.5 (1.1–2.0)	1.1 (0.9–1.5)	1.3 (1.00–1.7)
Fisher exact test	0.0053	0.04	0.17 NS	0.004	0.21 NS	0.04
Risk difference	0.24	0.13	0.1	0.22	0.06	0.16
Number needed to treat (95% CI)	3.5 (3.2–3.7)	3.5 (3.2–3.7)	0.7 (0.4–0.9)	1.8 (1.5–2.0)	1.4 (1.1–1.7)	0.8 (0.5–1.0)

95% CI: 95% confidence interval.

Table 5
Comparison of groups by all considered clinical parameters at the start and end of the study.

	SEAS n = 145							UP n = 95							CON n = 53							SEAS vs. UP vs. CON
	Start		End		Result		P value	Start		End		Result		P value	Start		End		Result		P value	P value*
	Mean	SD	Mean	SD	Mean	SD		Mean	SD	Mean	SD	Mean	SD		Mean	SD	Mean	SD	Mean	SD		
Treatment min/week			91.84	25.68						105.35	89.55						34.87	44.09				
Treatment years:months			02:04	01:04						01:12	01:01						01:10	01:05				
Age (years:months)	12:07	01:05	14:10	01:09				12:07	01:07	14:06	01:09				12:03	01:03	14:01	01:06				
Risser sign (0–5)	0.48	0.76	2.39	1.46				0.59	0.82	2.15	1.40				0.43	0.72	1.60	1.55				
Maximum Cobb angle (degrees)	15.36	2.67	17.07	7.29	1.70	7.24	< 0.01	15.38	2.62	17.70	7.33	2.08	7.36	< 0.01	15.36	3.13	17.75	6.90	2.20	6.25	< 0.01	NS
Weight (kg)	45.14	13.04	52.27	8.82	7.46	11.02	< 0.01	44.67	9.08	52.88	9.78	7.07	5.59	< 0.01	44.24	7.72	52.34	9.01	7.89	5.69	< 0.01	NS
Height (cm)	155.69	14.27	165.21	8.23	9.88	11.70	< 0.01	155.54	10.74	163.58	8.53	7.08	6.13	< 0.01	155.22	9.02	164.27	8.74	9.68	8.56	< 0.01	NS
Maximum ATR (degrees)	5.92	2.56	5.94	2.95	0.03	2.52	NS	6.05	2.48	6.00	3.20	−0.05	2.35	NS	6.26	3.21	5.98	4.77	−0.28	3.38	NS	NS
Maximum hump height (mm)	7.02	3.77	7.93	4.87	0.91	4.40	< 0.05	7.08	3.89	7.91	5.47	0.82	4.61	NS	6.96	5.39	7.40	6.56	0.43	4.65	NS	NS
Aesthetics (TRACE 1 – 12 points)	4.98	1.61	3.56	2.07	−1.41	2.22	< 0.01	4.91	1.67	4.00	1.87	−0.91	2.37	< 0.01	4.67	1.68	4.28	1.97	−0.40	2.39	NS	PSSE vs. CON < 0.01
PD (mm) C7 + L3	71.24	19.65	66.83	22.95	−4.42	21.74	< 0.01	70.21	19.51	67.90	17.97	−2.42	19.30	NS	72.55	20.32	70.50	22.11	−1.70	19.32	NS	NS
PD (mm) L3	36.72	12.85	37.03	13.92	0.30	13.83	NS	36.42	13.42	35.74	11.80	−0.74	12.66	NS	35.85	13.51	34.70	12.39	−0.50	12.01	NS	NS
PD (mm) S1	19.47	16.14	17.07	16.38	−4.81	14.91	< 0.05	18.90	14.54	18.03	13.35	−1.88	15.90	NS	19.09	16.74	14.50	15.33	−6.00	14.92	NS	NS

Data are mean (SD). ATR: angle of trunk rotation; TRACE: trunk aesthetic clinic evaluation; PD: plumbline distance; NS: not significant.
* Anova (+ post-hoc).

week. PSSEs (SEAS) require less time than general exercises (UP) to obtain better results, which is a value for patients.

One of the main characteristics of this study was that 10% of patients were immediately excluded due to the physician prescribing braces at the patient's first evaluation. This is a typical everyday clinical study, and grouping was according to the physician's choice (i.e., based on their expertise) and patient preference. This finding increases the study's generalizability; however, patients may have been self-selected according to other confounding factors. The outcome of bracing could be considered subjective, but it was previously used (20) and is typical of the field (e.g., surgery when bracing fails [31–33]. Stratification by propensity score matching allowed for better control of possible confounders in the treated and untreated groups. Brace prescription always agreed with current guidelines [1,32,33].

The rate of dropout was quite high (16%), which is typical for the field and reflects how demanding AIS treatments are. The dropout rate was higher for the SEAS than UP group (19% vs. 9%), which accounts for the reduced efficacy of SEAS in the intent-to-treat analysis. This finding was related to the SEAS protocol, which requires regular home exercises and 4 physiotherapy sessions per year in one expert center. For some families, the journey every 3 months may have become too difficult and thus enhanced the dropout rate. In addition, home exercise requires strong motivation that can be lost after years of therapy and commitment. UP is generally provided at centers near a patient's home and offers AIS regular exercise (i.e., generally twice a week) in small groups. This situation may lead to a reduced dropout rate due to the higher supervision and care than for the other groups. The dropout rate in the control group was the highest (21%); however, this group included all participants who autonomously decided not to adhere to the prescription.

A total of 47% of patients in the CON group received braces because of scoliosis evolution. This rate of progression was higher than previously reported in long-term follow-up studies. The same results were found in a RCT of bracing by Dolan and Weinstein [4], in which the rate of surgery in the untreated group was 52% and was much worse for participants with Risser sign 0–2 at the start of treatment than experts used to think. For curves measuring 11° to 20° and treated with PSSEs only, the failure (bracing) rate was almost 50%, whereas for curves measuring 20° to 40° and treated with bracing, the failure rate (reaching 50°/surgery) was 58%. These data are useful because they provide a better understanding of the natural history of scoliosis, as shown in a recently published systematic review and metanalysis by Di Felice et al. [34].

5. Strengths and limitations

The everyday clinic observational design may have introduced some biases. The selection bias due to a prescription for bracing at the first evaluation was investigated, in that excluded patients had the least desirable clinical situation and the prescription was performed for other reasons (Table 1).

To provide a better control of the possible confounders due to the nonexperimental design, we selected all variables involved in treatment choices (age, TRACE, rib hump height, ATR, and Cobb angle), and propensity score matching stratification was applied. The propensity score stratification enhanced the power of the results by providing better control of potential confounders related to the nonexperimental design and better control of selection bias.

Data for each patient were always collected by the same physician who was unaware of the study and who was clinically obligated to give the best possible treatment to their patient. A possible confounder was identified in the outcome "brace prescription." This term was used by analogy to the outcome "surgery prescription,'' which is a standard in the literature [3,31,32]. In fact, avoiding more demanding treatment is an important aim from a patient's perspective. Nevertheless, these aims could be due to the treating physicians' preference, so we verified that braces were prescribed to patients with the same characteristics in the 3 groups.

Because of the high drop-out rate in the SEAS groups, theoretically only adolescents with no or little evolution of scoliosis may have remained in the SEAS group. Nevertheless, we verified that among the patients classified as dropouts, the mean (SD) Cobb angle at their last radiography evaluation was 13.4 (4.6): for this reason, we cannot hypothesize that only those with minor curves remained in the study. However, since we cannot be sure, we performed an efficacy analysis.

Sports activities were not chosen as an influencing covariate. Sport activities have a positive influence on adolescents in general but are not considered a treatment by the SOSORT recommendations [1]. Considering that we were testing a treatment that demonstrated a small effect size [10], the outcome measure showed a large measurement error and we used some categorical variables, we decided to include only those variables with already demonstrated significant impact on results to avoid loss of power in the analysis. In fact, when creating a regression model, it is strongly recommend to include only the most significant variables and not too many [35,36].

To be as inclusive as possible, we considered different situations at the end of treatment that typically occur in everyday clinical activity: (1) medical discharge, (2) brace prescription, and (3) Risser sign > 3. The last end-point could be criticized because it does not necessarily correspond to the end of growth. Nevertheless, this endpoint has been proposed as significant for bracing studies by the Scoliosis Research Society [32] and has become a gold standard in the literature [4,37,38]. The risk of progression significantly decreases with Risser sign 3 [30,39,40], and in this study, we dealt with minor curves ($< 25^\circ$) with the risk of progression lower than in patients with braces, who usually have higher curve degrees.

6. Conclusions

The results of the present study of AIS were obtained from a prospective clinical database, which allows for better generalizability of the results and confirms previous RCT findings, and from a population at high risk of bracing; therefore, both intent-to-treat and efficacy analyses were performed to limit the effects of bias. The results were obtained from the long-term follow-up of adolescents until they had finished growing. In light of data from RCTs regarding exercise, further RCTs become less feasible because of ethical reasons and the high rate of individuals not accepting randomization to a nontreatment arm of the trial. Therefore good-quality observational studies are needed to confirm and further understand the effects of PSSE. This study provides an important contribution to this field of research. According to the present findings, SEAS reduced failure in AIS who were at high risk of brace prescription. Provided the patients accepted the treatment, SEAS was more effective than UP. PSSEs are additional tools that can be included in the therapeutic toolbox for AIS treatment.

Disclosure of interest

SN, AN and MR have stocks in the ISICO (Italian Scientific Spine Institute).

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at https://doi.org/10.1016/j.rehab.2018.07.010.

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