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Research

Combined aerobic and resistance training improves respiratory and exercise outcomes more than aerobic training in adolescents with idiopathic scoliosis: a randomised trial

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KEY WORDS

Exercise Exercise test Resistance training Physical therapy Scoliosis

ABSTRACT

Ouestion: In adolescents with idiopathic scoliosis, does combined aerobic and resistance training improve respiratory function, perceived exertion and functional exercise capacity more than aerobic training only? Design: Randomised controlled trial with concealed allocation, blinded assessors and intention-to-treat analysis. Participants: Forty adolescents with idiopathic scoliosis and formal indication for surgical correction (spinal curvature \geq 45 deg). **Intervention**: Both groups undertook three 60-minute training sessions per week for 12 weeks. The experimental group performed combined aerobic and resistance training and the control group performed only aerobic training. Outcome measures: At baseline and upon completion of treatment, participants completed: a 6-minute walk test with Borg scale (0 to 10) rating of exertion, spirometry, maximal respiratory pressures and peak expiratory flow measurement. Results: After 12 weeks of training, the experimental group improved more than the control group on the 6-minute walk test (MD 22 m, 95% CI 4 to 40), with lower perceived exertion at the end of the test (MD -1.2, 95% CI -1.9 to -0.4). The experimental group also improved more than the control group on several respiratory measures, including: FEV₁ (MD 270 ml, 95% CI 30 to 510), maximal inspiratory pressure (MD 4 cmH₂O, 95% CI 1 to 8) and peak expiratory flow (MD 33 l/minute, 95% CI 7 to 58). Conclusion: In adolescents with idiopathic scoliosis, combined aerobic and resistance training improves functional exercise capacity and several respiratory outcomes more than a similar training regimen with aerobic training only. It is unclear whether the magnitude of the benefits is large enough to be worthwhile. Trial registration: NCT02413788. [Xavier VB, Avanzi O, de Carvalho BDMC, Alves VLS (2019) Combined aerobic and resistance training improves respiratory and exercise outcomes more than aerobic training in adolescents with idiopathic scoliosis: a randomised trial. *Journal of Physiotherapy* ∎:∎-∎]

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Introduction

Adolescent idiopathic scoliosis (AIS), which is also called late-onset idiopathic scoliosis, is a lateral curvature of > 10 deg (as measured by the Cobb angle) that has its onset after 10 years of age.¹ It is often accompanied by a variable degree of rotation of the spinal column. A person with AIS may present with dyspnoea, but even if the patient is asymptomatic, respiratory function tests may reveal impairment. In addition to ventilatory restriction, AIS can lead to respiratory muscle weakness and exercise limitation, thereby altering the physiological responses to activities of daily living and resulting in functional disability in many cases.^{2,3} Lung function testing in these adolescents is typically characterised by decreases in vital capacity and minute ventilation. This is especially true for those whose spinal curvature exceeds 45 deg, probably mainly because the deviation reduces chest compliance.^{1,4–6} Even after corrective surgery, respiratory function can still be reduced when compared with the normal range. 7,8 However, the exact causes of respiratory impairment in AIS patients are not yet completely understood. 9

Despite the impact of AIS on exercise capacity and respiratory function, $^{1,10-12}$ a program of standardised activity for those who have a formal indication for surgical correction (ie, spinal curvature \geq 45 deg) significantly improves cardiorespiratory and musculoskeletal conditioning.^{5,13-19} During exercise, people with scoliosis show appropriate responses in cardiac rate and peripheral vascular resistance but often have ventilatory limitation.^{6,12} Despite this, improvements in a functional exercise test and some aspects of respiratory function were observed after a sustained period of training in an AIS cohort.¹³ High scores of perceived exertion have also been reported during exercise.^{13,16} Although not enough to preclude exercise altogether, the increased perception of exertion may contribute to the reduced exercise capacity. The current study hypothesised that this

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limitation might be mitigated by the use of exercise training that combines aerobic and resistance exercise.

The current study aimed to estimate the average effect of a combined aerobic and resistance training program compared with a program of only aerobic training on respiratory function, perceived exertion and functional exercise capacity in adolescents with idiopathic scoliosis who were awaiting surgical treatment.

Therefore, the research question for this randomised trial was:

In adolescents with idiopathic scoliosis, does combined aerobic and resistance training improve respiratory function, perceived exertion and functional exercise capacity more than aerobic training only?

Method

Design

This was a two-arm, parallel group, randomised controlled trial with concealed allocation, assessor blinding and intention-to-treat analysis. The study was performed in the Department of Orthopedics and Traumatology and the Department of Cardiorespiratory Rehabilitation at Santa Casa de Sao Paulo, São Paulo, Brazil. Adolescents with idiopathic scoliosis were recruited from the hospital's waiting list for surgical correction. Eligible and willing participants were randomised in a 1:1 ratio to either the experimental intervention (aerobic and resistance training) or the control intervention (aerobic training) for 12 weeks. Concealed allocation of the randomisation schedule was achieved using opaque and sealed envelopes containing a computergenerated^a random sequence. One physiotherapist applied the exercise protocols and supervised all participants throughout their allocated exercise. A different professional measured the outcomes in this study. She performed the baseline and post-intervention measurements of all participants during her routine physiotherapy service (as she did for all patients under treatment, including those not in the study). She remained unaware of the study protocol and, therefore, unaware of allocation. The nature of the exercises precluded blinding of the participants and therapist.

Participants

Participants had to be: 10 to 18 years old, candidates for surgical correction of AIS spinal curves \geq 45 deg,²⁰ and without any history of pulmonary, cardiovascular, myo-articular or neurological diseases. Radiographs of the spine on anterior-posterior and lateral views in the standing position were used to assess the spinal curvature using Cobb's method.²⁰ All the radiographic images were analysed by the same orthopaedic spine surgeon to confirm a Cobb angle \geq 45 deg. Exclusion criteria were the known need for urgent or elective surgical intervention of any type during the upcoming planned exercise intervention period, or any history of cognitive and/or physical impairments that would preclude performing the tests of the study's outcome measures.

Intervention

All participants were scheduled to perform three 60-minute sessions of exercise training per week for 12 weeks. The physiotherapist supervised all 36 sessions for each participant.

Control group

Each exercise session for the control group started with 10 minutes of warm-up (stretching exercises and aerobic low-intensity walking) followed by 40 minutes of aerobic exercise on an electric treadmill, and then a 10-minute cool-down and relaxation period (aerobic exercise with low energy expenditure such as slow walking and a relaxation technique performed in supine lying). On the electric treadmill, the intensity of exercise was kept between 60 and 80% of the maximum heart rate, according to a personal heart rate monitor^b. The maximum heart rate was calculated as 220 minus age (in years) for each patient at baseline and maintained throughout the intervention period.²¹

Experimental group

Each exercise session for the experimental group started with 10 minutes of warm-up (stretching exercise and aerobic low-intensity walking) followed by 30 minutes of aerobic exercise on the treadmill at 60 to 80% of maximum heart rate, followed by 10 minutes of resistance training (see below) and 10 minutes of cool-down and relaxation (aerobic exercise with low energy expenditure such as slow walking and a relaxation technique performed in supine lying).

The muscles trained in the resistance training periods were: biceps brachii, triceps brachii, pectoralis (major and minor), latissimus dorsi, quadriceps and triceps surae. See Appendix 1 on the eAddenda for details of the exercises that were used. The amount of resistance was initiated as follows. A one-repetition maximum (1RM) test was performed. The movement was initially performed without load, then the participant performed the same movement using a 0.5 kg anklet or dumbbell (according to the performed test). If there was no compensatory movement during the entire action, another 0.5 kg was added to the anklet or dumbbell, repeatedly. Intervals of 30 seconds of rest were inserted between two attempts at the movement. The test was stopped when any movement adjustment was observed, and the last value, when the activity was completed, was recorded.²² During the 36 training sessions, resistance training was performed using 60% of the load achieved in the most recent 1RM test; this test was repeated weekly.23

Outcome measures

All participants were evaluated before and after the intervention period by the same assessor, using the tests outlined below.

Respiratory function

Spirometry was performed in the sitting position using a commercial spirometer^c and a nose clip. The calculated spirometry measures were forced vital capacity (FVC), forced expiratory volume in 1 second (FEV₁), the ratio of FEV₁/FVC, forced expiratory flow (FEF_{25/75}) and the ratio of FEF_{25/75}/FVC.²⁴ The predicted values were calculated using age, gender and height, according to the equation proposed by Pereira et al.²⁴

Maximum respiratory pressures and flow

Testing of maximum inspiratory and expiratory pressures and peak expiratory flow was performed as recommended by the Respiratory Muscle Testing Statement,²⁵ with three measurements for every variable tested and using the greatest value achieved for the analysis.

6-minute walk test and perceived exertion

The 6-minute walk test (6MWT) was performed as a free walk for 6 minutes, as fast as possible, across a flat 30-m corridor marked out in metres, in accordance with the guidelines of the American Thoracic Society.²⁶ The level of effort at the end of the test was rated by the participant on the Borg scale of perceived exertion.²⁷ At the beginning and end of the test, the assessor recorded the participant's blood pressure in mmHg, heart rate in beats/minute, respiratory rate in breaths/minute and peripheral oxygen saturation (SpO₂). The total distance walked was also recorded.

Note that the primary outcome for the study was a cytokine analysis, which will be reported in another publication.

Data analysis

In the sample size calculation, a smallest worthwhile effect of 32 m was nominated,²⁸ a standard deviation of 30 based on data from the clinic was anticipated, and a significance level of 5% and study power of 80% were used. This indicated that at least 15 participants were required for each group. To allow for possible loss to follow-up, the total sample size was increased to 40 participants.

Baseline characteristics of the participants were summarised with descriptive statistics. Given that the data were normally distributed,



Figure 1. Design and flow of participants through the trial.

estimates of the treatment effect on each outcome were reported as the mean between-group difference with a 95% confidence interval (95% CI). Analyses were conducted according to the principle of intention to treat.

Results

Flow of participants through the study

Starting in September 2015, 63 consecutive adolescents with idiopathic scoliosis on the waiting list for surgery were evaluated for eligibility. Among these, 23 were excluded for the reasons described in Figure 1. The 40 remaining adolescents were considered eligible and enrolled in the study, with 20 randomised to each group. Once all patients had been allocated in the groups, the treatment protocols started. The last evaluation took place in March 2016.

Compliance with the trial protocol

As the waiting time for surgery is long in the public health system in Brazil, none of the participants had to interrupt the exercise intervention for their surgery and all completed the study protocol. There was no loss to follow-up. All participants adhered to the three training sessions per week.

Characteristics of the participants

Baseline characteristics are presented in Table 1 and in the first two columns of data in Tables 2 and 3. There were no important between-group differences in the anthropometric or clinical measures. All study participants presented a single curvature, with a thoracic vertex on radiographic evaluation. There was no important difference in the gender ratio of the groups, with 18 girls in one group and 19 in the other. Similarly, no important between-group differences were observed in their functional capacity or respiratory function at baseline.

Effects of the intervention

Respiratory function

Both groups showed improvements in many aspects of respiratory function by the end of the training period. Combined training was estimated to be more favourable than aerobic training for several measures of respiratory function, including FEV₁, FEF₂₅₋₇₅, FEV₁/FVC, and FEF₂₅₋₇₅/FVC. The result for FVC was unclear, with the confidence interval including estimates that combined training might be more or less favourable than aerobic training. The estimates and their 95% confidence intervals are presented in Table 2.

Maximum respiratory pressures and flow

Both groups showed improvements in maximal respiratory pressures and flow by the end of the training period. Combined training was estimated to be more favourable than aerobic training for maximal inspiratory pressure (MD 4 cmH₂O, 95% Cl 1 to 8). The effect on maximal expiratory pressure was unclear (MD 7 cmH₂O, 95% Cl –2 to 15). Combined training was estimated to be more favourable than aerobic training for peak expiratory flow (MD 33 l/minute, 95% Cl 7 to 58). These results are presented in Table 2.

6-minute walk test and perceived exertion

Both groups showed substantial improvement in the 6MWT by the end of the training period. The improvement was estimated to be 22 m greater in the combined training group (95% CI 4 to 40) than in the control group. This better result on the 6MWT was achieved with less exertion at the end of the 6MWT, with a mean difference on the Borg scale of -1.2 (95% CI -1.9 to -0.4). It was also achieved with a lower respiratory rate at the end of the 6MWT, with a mean difference of -3 breaths/minute (95% CI -4 to -1). The other cardiorespiratory measures taken at the end of the test did not have estimates that clearly favoured one type of training over the other. These results are presented in Table 3.

The exercise training in both groups was well tolerated and there were no adverse events. Individual participant data for all outcomes are presented in Table 4 on the eAddenda.

Xavier et al: Resistance training in adolescent idiopathic scoliosis

Table 1

Characteristics	of participants	at baseline.

Characteristic	Exp (n = 20)	Con (n = 20)
Age (y), mean (SD)	16 (2)	16 (2)
Height (cm), mean (SD)	161 (5)	157 (8)
Weight (kg), mean (SD)	54 (8)	54 (8)
Body mass index (kg/m^2) , mean (SD)	20.6 (2.9)	21.9 (2.4)
Cobb angle (deg), mean (SD)	71 (17)	70 (15)
FVC (l), mean (SD)	2.95 (0.62)	2.75 (0.58)
FEV_1 (1), mean (SD)	2.45 (0.68)	2.36 (0.59)

Con = control group, Exp = experimental group, FVC = forced vital capacity, FEV_1 = forced expiratory volume in 1 second.

Discussion

This study estimated that combined aerobic and resistance training was more beneficial than aerobic training for several outcomes, including most aspects of respiratory function, maximal inspiratory pressure, peak expiratory flow and functional exercise capacity. The greater improvement in functional exercise capacity was achieved with less exertion and a lower respiratory rate. However, it is crucial to recognise that these favourable estimates came with substantial uncertainty. Another important observation to bear in mind when interpreting the results is that both groups showed substantial improvements in most outcomes over the 12 weeks of the study. Although the study did not have a no-intervention control group, it is reasonable to expect that such benefits were due to a simple break in the inactivity cycle that is common among adolescents with idiopathic scoliosis. It is therefore important to consider whether the additional benefits from combined aerobic and resistance training are large enough and certain enough (as reflected in the confidence intervals) to warrant recommending it over aerobic training.

Although several aspects of respiratory function were estimated to improve more in the combined training group than the aerobic training group, these estimates all came with confidence intervals that included trivial benefits. For example, the mean difference in FEV₁ was an extra 270 ml improvement due to using combined training instead of aerobic training. This is arguably worthwhile, but

the lower limit of the confidence interval included a benefit of 30 ml, which could be interpreted as a trivial benefit. Similarly, the lower limits of the confidence intervals for FEF₂₅₋₇₅, FEV₁/FVC and FEF₂₅₋₇₅/ FVC have to be acknowledged as trivial benefits. Even where a 'minimum clinically important difference' has been established for these outcomes, such thresholds generally relate to what would make training (versus not training) worthwhile. However, both groups spent equal amounts of time training in the present study and the only extra imposition from the combined training was some simple extra equipment and the time taken to determine the 1RM. Therefore, the effects on respiratory function might be considered as a 'potential' bonus (ie, combined training can be expected to give greater improvements in respiratory function, but the evidence is not precise about how much greater). The benefits for respiratory function seem roughly consistent with other research, although it was FVC that improved with aerobic exercise in people with scoliosis.^{6,12,13,16} However, no other randomised trial has evaluated the impact of resistance training on respiratory function in AIS.

The extra benefits in respiratory function might be considered worthwhile if they contributed to improved exercise capacity, but here the relationships between respiratory function, strength and exercise capacity are complex. Swallow et al showed reduced quadriceps strength and greater oxidative stress in the muscle in people with restrictive lung disease due to scoliosis and people with chronic obstructive pulmonary disease (COPD), compared with healthy controls.²⁹ The authors state that 'quadriceps weakness is a feature of severe scoliosis; the similarities between patients with scoliosis and patients with COPD suggest a common etiology to quadriceps weakness in both conditions'. Those results inspired the current authors to propose resistance exercises to improve exercise capacity in AIS, perhaps via whole body fitness and/or a possible interaction between limb and thoracic muscles. For example, the limb strengthening exercises may have indirectly strengthened (via their stabilising role in the exercises) muscles in the trunk and shoulder girdle,^{13,22,30,31} which might assist with thoracic expansion. Although strength was not tested, the spirometry results might offer proxy indicators of benefits to the respiratory cage. Also, the greater increase in peak flow with combined training supports the hypothesis of greater conditioning and, consequently, contraction velocity during the expiratory manoeuvre.^{3,4,12,25,32} Again, the estimates of greater

Table 2

Mean (SD) of groups, mean (SD) within-group difference and mean (95% CI) between-group difference for spirometry measures.

Outcome	Groups			Difference within groups		Difference between groups	
	Week 0		Week 12		Week 12 minus Week 0		Week 12 minus Week 0
	Exp (n = 20)	Con (n = 20)	Exp (n = 20)	Con (n = 20)	Exp	Con	Exp minus Con
FVC (1), mean (SD)	2.95 (0.62)	2.75 (0.58)	3.23 (0.53)	2.88 (0.47)	0.28 (0.36)	0.13 (0.26)	0.15 (-0.05 to 0.35)
FVC (% pred), mean (SD)	90 (18)	90 (14)	99 (18)	94 (18)	9 (12)	5 (11)	4 (-3 to 12)
FEV ₁ (<i>l</i>), mean (SD)	2.45 (0.68)	2.36 (0.59)	2.83 (0.51)	2.47 (0.45)	0.38 (0.47)	0.11 (0.25)	0.27 (0.03 to 0.51)
FEV_1 (% pred), mean (SD)	83 (22)	85 (19)	96 (18)	89 (20)	13 (16)	4 (11)	9 (0 to 18)
FEF ₂₅₋₇₅ (<i>l/second</i>), mean (SD)	2.77	2.72	3.72	2.96	0.95	0.24	0.71 (0.11 to 1.32)
FEV ₁ /FVC (%), mean (SD)	87	90 (11)	96 (6)	91 (8)	9 (13)	1 (5)	(0.11 to 1.52) 8 (2 to 14)
FEV ₂₅₋₇₅ /FVC (%), mean (SD)	73	79	98 (19)	84	25	6 (14)	(2 to 11) 20 (3 to 36)
Maximal inspiratory pressure	42	44	49	47	7	3	(3 to 30) 4 (1 to 8)
Maximal expiratory pressure	64	67	(9) 79	(8)	(5)	(6)	(1108)
(<i>cmH</i> ₂ O), mean (SD) Peak expiratory flow (<i>l/min</i>),	(11) 324	(13) 333	(12) 400	(17) 377	(8) 76	(16) 44	(-2 to 15) 33
mean (SD)	(44)	(42)	(28)	(33)	(48)	(29)	(7 to 58)

Small anomalies in subtraction are due to the effects of rounding.

Con = control group, Exp = experimental group, FEV₁ = forced expiratory volume in 1 second, FEF₂₅₋₇₅ = forced expiratory flow at 25 to 75% of the expiratory volume, FVC = forced vital capacity.

Research

Mean (SD) of groups, mean (SD) within-group difference and mean (95% CI) between-group difference for outcomes measured at the end of the 6-minute walk test.

Six-minute walk test outcomes	Groups				Difference within groups		Difference between groups
	Week 0		Week 12		Week 12 minus Week 0		Week 12 minus Week 0
	Exp (n = 20)	Con (n = 20)	Exp (n = 20)	Con (n = 20)	Exp	Con	Exp minus Con
Distance (m), mean (SD)	406 (26)	406 (29)	524 (32)	501 (30)	118 (29)	96 (28)	22 (4 to 40)
Systolic BP (mmHg),	118	121	118	121	-1	٥́	-1
mean (SD)	(8)	(8)	(4)	(4)	(7)	(6)	(-5 to 4)
Diastolic BP (mmHg),	80	82	79	82	-1	0	-1
mean (SD)	(8)	(7)	(4)	(5)	(6)	(6)	(-5 to 3)
Heart rate (beats/min),	122	122	115	118	-7	-4	-3
mean (SD)	(8)	(9)	(5)	(4)	(6)	(8)	(-8 to 2)
Respiratory rate	25	25	21	24	-4	-1	-3
(breaths/min), mean (SD)	(4)	(4)	(2)	(3)	(3)	(3)	(-4 to -1)
SpO ₂ (%), mean (SD)	96.7	96.9	97.9	97.8	1.2	0.9	0.3
	(1.1)	(0.7)	(0.8)	(0.8)	(0.7)	(0.7)	(-0.2 to 0.7)
Exertion on Borg scale	6.0	6.3	3.5	5.0	-2.5	-1.3	-1.2
(0 to 10), mean (SD)	(1.1)	(1.2)	(0.9)	(1.3)	(1.2)	(1.1)	(-1.9 to -0.4)

Small anomalies in subtraction are due to the effects of rounding.

BP = blood pressure, Con = control group, Exp = experimental group, SpO₂ = peripheral oxyhaemoglobin saturation measured via pulse oximetry.

benefit in maximal inspiratory pressure and peak expiratory flow come with substantial uncertainty, so the effects may be trivial but perhaps these were contributors to the improved functional exercise capacity.

On the 6MWT, the estimate of 22 m greater improvement with combined training when compared with aerobic training did not reach the 32-m minimum clinically important difference that was used in the sample size calculation. As discussed above, however, that threshold may not be relevant when comparing two very similar training regimens. The lower end of the confidence interval was a benefit of 4 m, which must be considered trivial, and the upper end exceeded 32 m. Overall, the study estimated greater improvement in functional exercise capacity if resistance exercise is incorporated into an otherwise aerobic training regimen, but how much extra benefit cannot be precisely estimated from the available data. The greater distance on the 6MWT was achieved with a lower respiratory rate and less exertion. When these three benefits are combined, perhaps it suggests a worthwhile synergy.

The results should also be interpreted remembering that participants in the present study were fairly homogeneous: all of them with high angles of curvature, all with single curvatures with a thoracic vertex and all otherwise healthy. AIS is a three-dimensional deformity, with the degree of progression and prognosis related to the characteristics of the spinal torsion.^{33,34} Possibly, the respiratory changes that are seen in AIS are related to this three-dimensional torsion.^{1,3,4,35–37} In contrast, other studies about respiratory impairment in scoliosis usually deal with patients with severe impairment of respiratory function.^{1,3,4,35}

Although the effects observed in this study are potentially small, it is worth speculating further on their relationships. The increase in lung capacity and volumes may have contributed to the achievement of greater exercise with less increase in respiratory rate. This could be physiologically explained by the greater ventilation achieved with the increase in volume, which directly affects the relationship between ventilation and perfusion.^{3,4} Possibly, there was an optimisation of the ventilation perfusion ratio if the oxygen uptake and transport were optimised with the training.

One limitation of the present study is that the long-term effects of exercise were not measured. Long-lasting benefits for adolescents with idiopathic scoliosis have already been demonstrated from aerobic exercise.³⁸ Long-term resistance training has not been examined, but the current results suggest that this should be explored further. Future studies could adjust for potential confounders in the analysis. Another limitation of the study is the uncertainty in the estimates of the benefits. Given that the combined training regimen requires only some simple extra equipment and similar time and effort, it could be recommended over aerobic exercise to adolescents with idiopathic scoliosis, with the caveat that the extra benefits obtained may be very small. Given that uncertainty, other issues (eg, a patient may prefer and be more compliant with aerobic training) should also be taken into consideration in clinical decision-making.

In conclusion, adolescents with idiopathic scoliosis respond more positively to combined aerobic and resistance training than to aerobic training only. The benefits were evident in several measures of respiratory function, maximal inspiratory pressure, peak expiratory flow and functional exercise capacity. The magnitude of the benefits was fairly uncertain, with the estimates for all benefits not excluding the possibility of trivial effects, but some of the estimates included the possibility of arguably worthwhile benefits.

What was already known on this topic: Adolescents with idiopathic scoliosis may have respiratory impairment, muscle weakness and exercise limitation. Regular aerobic training improves quality of life in adolescents with idiopathic scoliosis. What this study adds: In adolescents whose idiopathic scoliosis has progressed enough to warrant surgery, combined aerobic and resistance training improves functional exercise capacity more than a similar training regimen with aerobic training only. The greater functional exercise capacity may be contributed to by some of the other benefits, such as respiratory function, maximal respiratory pressure and peak expiratory flow. However, it is unclear whether the magnitude of each benefit is trivial or worthwhile.

Footnotes: ^a Java.util, OracleCorporation, Redwood Shores, USA. ^b RS800, Polar, Kempele, Finland. ^c Koko spirometer, nSpire Health, Longmont, USA.

eAddenda: Table 4 and Appendix 1 can be found online at https://doi.org/10.1016/j.jphys.2019.11.012.

Ethics approval: This study was previously approved by the local Research Ethics Committee (protocol number 16710613.5.0000.5479). Patients and their legal guardians signed informed consent forms to participate in the study and adolescents an assent term.

Competing interests: Nil.

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Xavier et al: Resistance training in adolescent idiopathic scoliosis

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