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Original Article

Home-based vibration assisted exercise as a new treatment option for scoliosis - A randomised controlled trial

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Abstract

Objectives: The aim of this study was to evaluate the effect of scoliosis specific exercises (SSE) on a side-alternating whole body vibration platform (sWBV) as a home-training program in girls with adolescent idiopathic scoliosis (AIS). **Methods:** 40 female AIS patients (10-17 years) wearing a brace were randomly assigned to two groups. The intervention was a six months, home-based, SSE program on a sWBV platform five times per week. Exercises included standing, sitting and kneeling. The control group received regular SSE (treatment as usual). The Cobb angle was measured at start and after six months. Onset of menarche was documented for sub-group analysis. **Results:** The major curve in the sWBV group decreased significantly by -2.3° (SD±3.8) (95% CI -4.1 to -0.5; P=0.014) compared to the difference in the control group of 0.3° (SD±3.7) (95% CI -1.5 to 2.2; P=0.682) (P=0.035). In the sWBV group 20% (n=4) improved, 75% (n=15) stabilized and 5% (n=1) deteriorated by ≥5°. In the control group 0% (n=0) improved, 89% (n=16) stabilized and 11% (n=2) deteriorated. The clinically largest change was observed in the 'before-menarche' sub-group. **Conclusions:** Home-based SSE combined with sWBV for six months counteracts the progression of scoliosis in girls with AIS; the results were more obvious before the onset of the menarche.

Keywords: Adolescent Idiopathic Scoliosis, Cobb Angle, Whole Body Vibration, Physical Exercise, Home-training Program

Introduction

Scoliosis is a general term comprising a heterogeneous group of conditions of a torsional deformity of the spine; 80% are idiopathic[1]. If scoliosis develops between the age of ten years and the end of growth it is diagnosed adolescent idiopathic scoliosis (AIS)[2]. According to the Scoliosis Research Society (SRS) the prevalence of AIS is 2-3% in the general population[2]. It is the most common spinal disorder in childhood[3]. Prevalence is higher in girls than in boys[3].

The Cobb angle[4] is commonly used to quantify the amount of spinal curvature[1]. The diagnosis of scoliosis is confirmed at a minimum of 10° Cobb angle and axial rotation[1]. The main treatment options for prevention of scoliosis progression are: scoliosis-specific exercises (SSE) (start from initial diagnosis), bracing (at about 20° Cobb angle)[5] and surgery (>40°)[1,2,6]. It is controversial whether the use of exercise for the treatment of AIS is useful; and once the deformity progresses there are no interventions known counteracting progression[2].

Standard of care for conservative treatment include the "Schroth" method[7] (SSE) and bracing. Schroth exercises facilitate three-dimensional auto-correction of the spinal column through breathing and specific exercise. Various other forms of SSE are used worldwide. Romano et al. (2012) concluded that there is a lack of high quality evidence

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from which recommendations for the use of SSE in AIS can be drawn. A recent study suggests that moderate-quality evidence shows an exercise program may be superior to controls reducing the Cobb angle[8]. The international Scientific Society on Scoliosis Orthopaedic and Rehabilitation Treatment (SOSORT) recommends physical exercise with auto correction[9].

For the use of braces Negrini et al. (2015) concluded that bracing prevents curve progression. However, the included papers were from low to very low quality and future studies should address adverse effects, methods to increase compliance, and the usefulness of SSE in combination with bracing[10].

Recently there has been a trend to incorporate vibration platforms into physical therapy in prevention and rehabilitation. Whole body vibration (WBV) is a reflex-based neuromuscular form of training. Side-alternating WBV (sWBV) is a special form of WBV which uses oscillatory motion around a pivot in the center of the platform[11,12]. Studies examining the effectiveness of sWBV reported increased muscle force and power as well as effects on neural activity[13-15]. Our previous experiences with the combination of six months of home-based sWBV-training with blocks of intensive functional physiotherapy in children with different movement disorders showed an increase in gross motor function and indicated that sWBV might be a safe, feasible and potentially effective home-training program[16-18].

Vibration assisted exercises have the advantage of short training periods with a high number of muscular contractions/ repetitions. A home program has the advantage of possible better compliance compared to frequent visits for supervised therapy programs. The effect of SSE combined with sWBV on the Cobb angle has never been investigated in AIS patients. The aim of this study was to investigate the effect of home-based SSE on a sWBV platform on the progression of the Cobb angle in AIS.

Materials and Methods

The study was a randomised controlled trial (RCT). Assessment was performed at baseline (M0) and after six months (M6). The participants were randomly assigned to either a SSE program on a sWBV platform or “treatment as usual” (TAU, regular SSE “Schroth”). The study was approved by the local ethics committee of the University of Cologne (09-056) and registered at http://www.germanctr.de (DRKS00010657). Written informed consent was obtained from each participant and legal representative prior to inclusion.

Participants

40 participants were recruited through the Paediatric Rehabilitation Centre, UniReha GmbH, University of Cologne, Germany in collaboration with the Department of Orthopaedic and Trauma Surgery, University of Cologne, Germany. Included were girls with moderate AIS (according to the SOSORT criteria[1]) aged 10 to 17 years. Further inclusion criteria were: experience with auto-corrective physiotherapy (SSE, ”Schroth”[7]) and use of a Chêneau brace at least 16 hours per day. Major exclusion criteria were presence of systemic or nervous diseases. Throughout the study period all participants received their regular physical therapy program (TAU).

Training, intervention group

The intervention consisted of a home-based, six months sWBV-training. The platform oscillates around a resting axis between the subject’s feet[19]. The body responds to the lateral oscillation stimulus with spinal reflexes and muscle contractions (Figure 1). The vibration frequency was 10 to 25 Hz depending on the exercise (Figure 2). The amplitude was dependent on the position of the feet on the platform between 0 and ±3.9 mm (peak to peak displacement maximum 7.8 mm). Peak acceleration related to frequency was between 1.57 g (10 Hz) and 9.81 g (25 Hz). Skidding was controlled by barefoot standing.

Participants of the intervention group received an introduction to the sWBV system and the exercises before start of the home-training program. They received an exercise program including four different exercises: standing (16-20 Hz), sitting (18-25 Hz) and two different kneeling positions (10-20 Hz) (Figure 2). Exercises were designed to incorporate auto-correction and stabilising physiotherapy. Each exercise was performed at home for three minutes (4x3 minutes) five times per week.

Each participant received an exercise folder containing photos of the exercises and individual adaptations according to the severity of curvature and a training schedule. Each participant documented the home-training program in a training log. For six weeks the participants received a weekly in-patient check; then the check-up frequency was reduced to bi-weekly. Serious unexpected events were recorded at each visit.

Control group

The participants of the control group were instructed to continue with their usual auto-corrective physiotherapy. This usually contains bi-weekly training under supervision of a physical therapist and a daily home-training program. Schroth exercises focus on strengthening of the spinal musculature and elongating shortened muscles on the concave side of the spinal curvature.

MRI protocol and Cobb angle measurement

MRI was conducted at baseline (M0) and after six months (M6). A 0.6T (Tesla) upright MRI (Fonar Corporation, Melville, NY, USA) imaged the total spine (C1-S2) in two 3D-datasets with patients in standing position (Software Version 8.2.4). Participants removed their brace 24 hours prior to imaging.

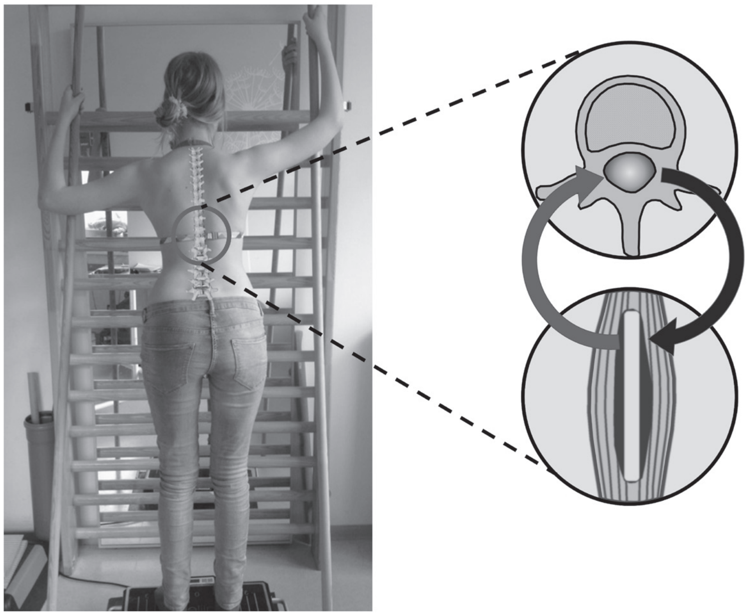

Figure 1. Illustration of the sWBV mechanism.

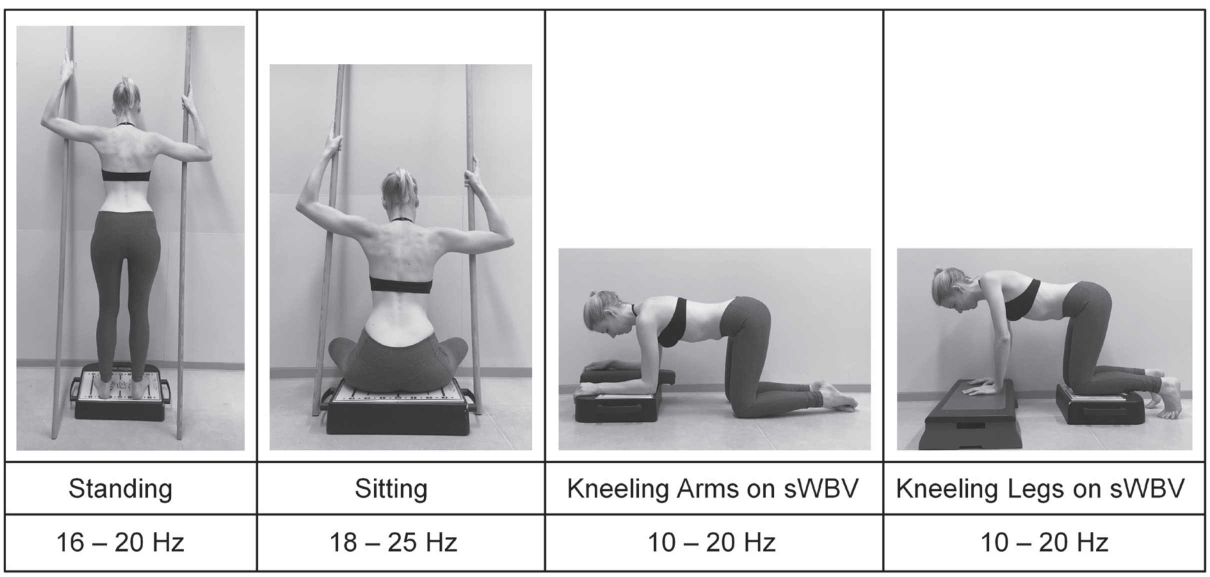

Figure 2. Exercises on the sWBV system.

According to Fonar™ scoliosis specific standard procedures, MRI scans were saved in two 3D-datasets (thoracic and lumbar) and combined. A two dimensional coronar image was calculated with mathematical integration of kyphosis and lordosis; this was used for calculating the Cobb angle.

The Cobb angle was determined digitally. To minimize measurement error, an experienced orthopaedic surgeon marked the neutral vertebrae. A different experienced orthopaedic surgeon and an experienced orthopaedic technician determined the Cobb angle using the previously identified vertebrae independently. We stipulated a measurement discrepancy of ≥5° between the two assessors for re-assessment of the image. Additionally, to increase measurement quality, we used the average of the two

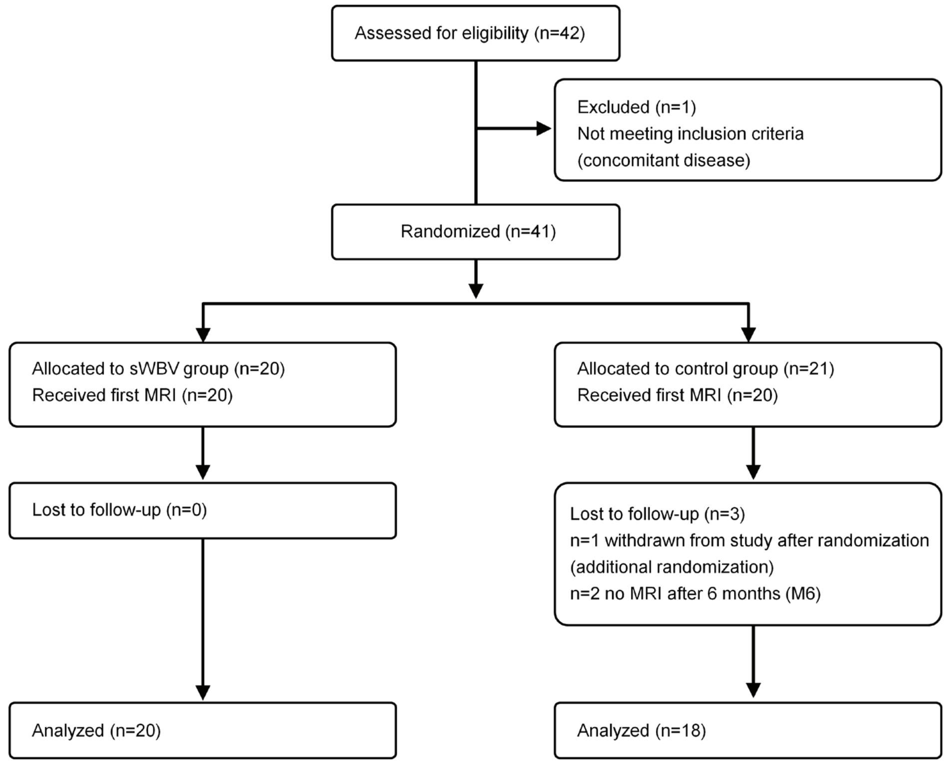

Figure 3. Study Consort Diagram.

assessors. A clinically relevant difference was defined as a Cobb angle of ≥5°; while changes +/-5° were defined as stable.

Based on initial measurements (T0) the numerically largest Cobb angle was defined as major curve (MAC) and the smaller angle as minor curve (MIC). In clinical practice MAC defines further therapy (e.g. brace or surgery); therefore most data is presented for MAC.

Sample size calculation

The study was planned in 2010. At this time no valid between-patient SDs were published; therefore we used inter-observer variability for sample size calculation. Tanure et al. (2010) investigated reliability of measuring the Cobb angle and have found an inter-observer SD of 3.18° in digital measurement[20]. We calculated that a two sided t-test would detect a mean difference in Cobb angle of at least 3.0° in two groups with a SD of 3.18° in 18 participants in each group with 80% power and a significance level of 5%. We expected a drop-out rate of 10% per group for analysis; therefore we added two patients per group (20 patients per group).

Randomization and blinding

Group allocation was performed using sealed envelopes with block randomisation (blocks of four). SL generated the random allocation sequence, enrolled the patients and assigned participants to interventions. If participants dropped out of the study further patients were additionally recruited until n=40 were met. Because of the nature of the intervention, participants and physiotherapists could not be blinded to the treatment, but the investigator calculating the Cobb angle was kept blinded to allocation.

Statistical analysis

Statistical analysis was performed using GraphPad Prism 6.0 (GraphPad Software Inc. USA). Change from M0 to M6 and the difference between groups were analysed using paired t-tests and Mann-Whitney U tests, respectively. Two-sided p values <0.05 were considered statistically significant. Sub-groups were descriptively analysed. Sub-groups for clinical relevance were divided by ≥5° difference in Cobb angle into "improved", "stable", or "progressed". The status of menarche was documented and groups divided: "no menarche at start", "menarche <1 year", and "menarche >1 year".

Results

Forty patients with AIS were included in the study. One girl dropped out of the study after randomization because she was not willing to participate anymore; she did not receive

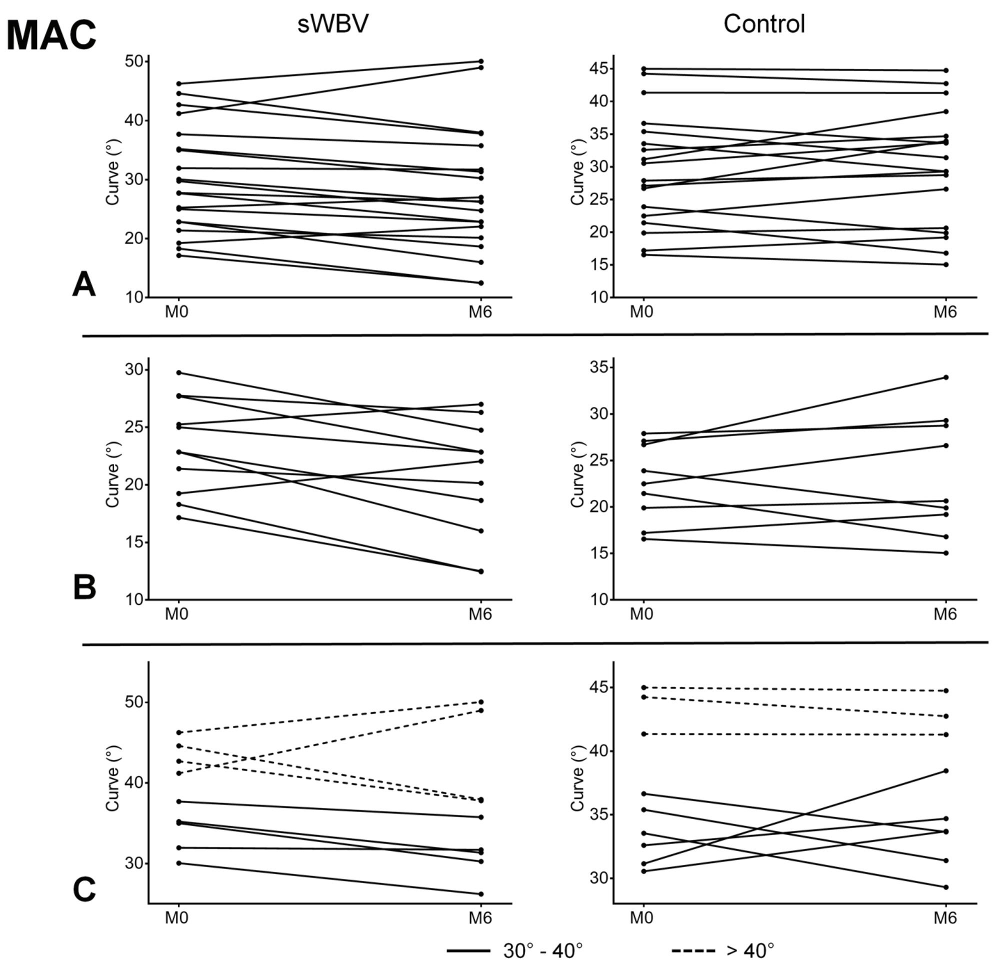

Figure 4. Individual changes for sWBV and control group, major curve (MAC). A, all patients; B, Cobb angle ≤30°; C, Cobb angle >30°.

Table 1. Clinical characteristics at baseline (MO).

	Total		sWBV		Control	
	Mean (±SD)	n	Mean (±SD)	n	Mean (±SD)	n
Age [years]	13.8 (1.3)	38	13.6 (1.6)	20	14.0 (0.9)	18
Height [cm]	163.2 (7.3)	36	163.1 (6.7)	19	163.3 (8.0)	17
Weight [kg]	52.9 (8.6)	36	51.9 (8.1)	19	54.1 (9.2)	17
BMI [kg/mÇ]	19.9 (2.7)	35	19.6 (3.1)	18	20.2 (2.3)	17
MAC [°]	29.9 (8.7)	38	30.1 (9.0)	20	29.7 (8.7)	18
MIC [°]	22.5 (9.9)	38	21.5 (11.4)	20	23.6 (8.2)	18

Abbreviations: MAC, major curve; MIC, minor curve, sWBV, side-alternating Whole Body Vibration.
No significant differences between groups.

Table 2. Effect of training on Cobb angle.

		sWBV			Control		
		MO	M6	P Value	MO	M6	P Value
MAC	Mean (±SD)	30.1 (9.0)	27.8 (10.5)	0.014	29.65* (8.7)	30.01* (9.0)	0.682
MIC	Mean (±SD)	21.46* (11.4)	21.14* (11.7)	0.723	23.6 (8.2)	25.0 (7.2)	0.066

Abbreviations: MAC, major curve; MIC, minor curve, sWBV, side-alternating Whole Body Vibration.
**Hundredth to avoid round-off error*

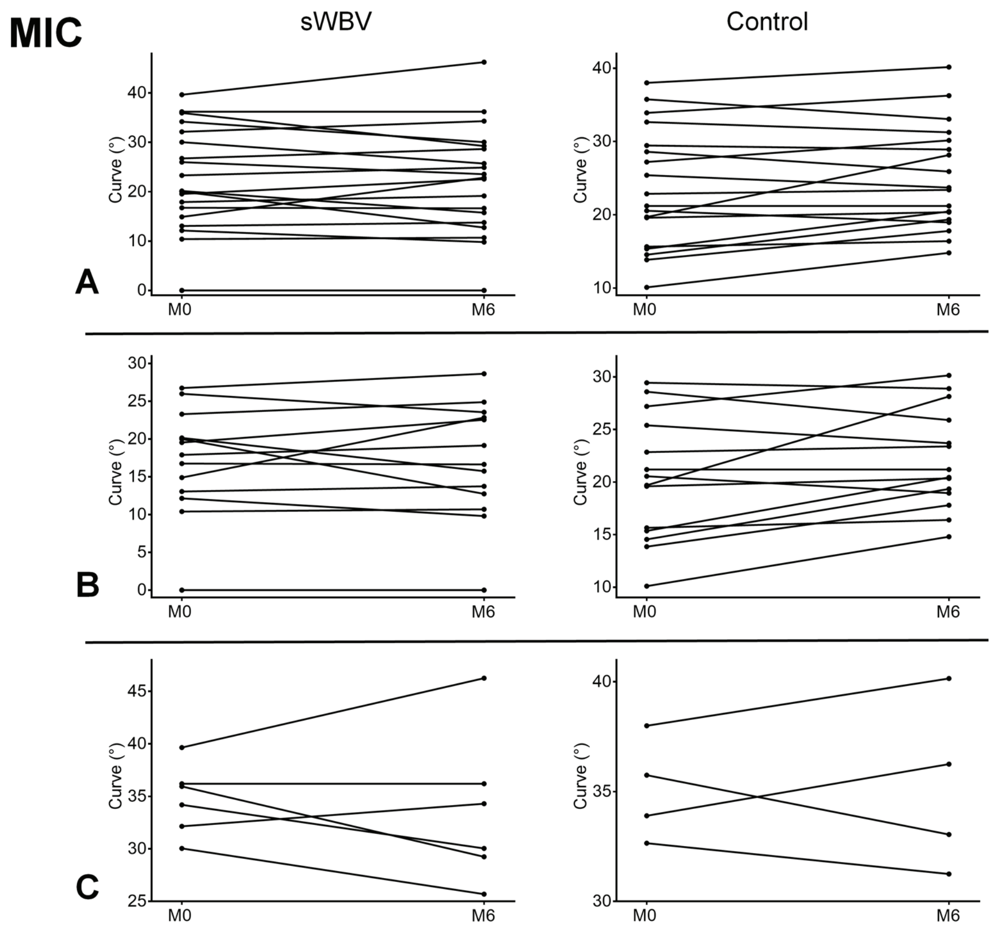

Figure 5. Individual changes for sWBV and control group, minor curve (MIC). A, all patients; B, Cobb angle ≤30°; C, Cobb angle >30°.

the first MRI. Therefore one more girl had to be additionally recruited, so in total 41 patients were randomized (Figure 3). Two girls of the control group did not perform the MRI after six months and were lost to follow up for analysis (Figure 3). No MRI examinations required re-assessment due to inter-observer discrepancy. Study enrolment took place from December 2010 to May 2013.

Baseline characteristics of data analysed (n=38) are depicted in Table 1 with 18 girls in the control group (mean age 14.0 years SD± 0.9), and 20 girls in the sWBV group (mean age 13.6 years SD± 1.6). Some values for height and weight were missing and therefore could not be included in analysis. In the sWBV group mean MAC Cobb angle prior to intervention was 30.1° (SD± 9.0) and MIC was 21.5° (SD± 11.4). In the control group mean MAC Cobb angle was 29.7° (SD± 8.7) and MIC 23.6° (SD± 8.2). Clinical characteristics and severity of curves did not differ significantly at baseline between groups.

After six months of training, the mean MAC in the sWBV group decreased significantly by -2.3° (SD± 3.8) (95% CI -4.1 to -0.5; P=0.014) from 30.1° (SD± 9.0) to 27.8° (SD± 10.5) compared to the difference in the control group of 0.36° (SD±3.7) (95% CI -1.5 to 2.2; P=0.682) from 29.65° (SD± 8.7) to 30.01° (SD± 9.0) (Table 2, Figure 4 A-C). Differences between groups were significant (P=0.035).

In the sWBV group, the MIC difference was -0.32° (SD± 3.9) (95% CI -2.2 to 1.5; P=0.723) from 21.46° (SD± 11.4) to 21.14° (SD± 11.7). In the control group, the Cobb angle difference was 1.4° (SD± 3.1) (95% CI 0.1 to 3.0; P=0.066) from 23.6° (SD± 8.2) to 25.0° (SD± 7.2) (Table 2, Figure 5 A-C). Differences between groups were not significant (P=0.138).

Individual changes stratified by initial severity of the Cobb angle (more or less than 30°) are displayed in Figures 4 and 5 (B and C).

Clinical relevance: In the sWBV group 20% (n=4) improved by ≥5° in the MAC, 75% (n=15) stabilized and 5% (n=1) deteriorated. In the control group 0% (n=0) improved in the MAC by ≥5°, 89% (n=16) stabilized and 11% (n=2) deteriorated (Table 3). Changes for the MIC are displayed in Table 3.

Analysing the clinical relevant (≥5°) MAC differences according to onset of menarche, 22% (n=2) of the WBV group

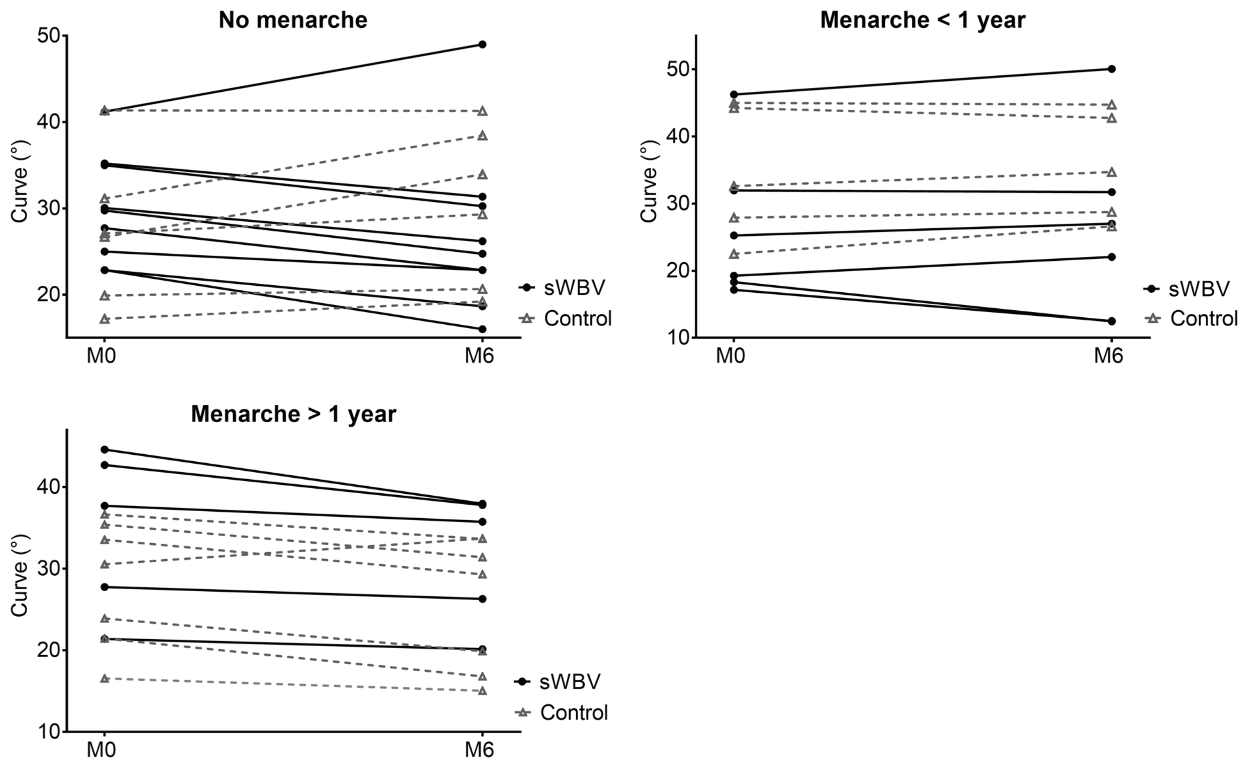

Figure 6. Individual changes for subgroups, onset of menarche, major curve (MAC).

Table 3. Effect of training in subgroups, minimal Cobb angle difference of ≥5° and onset of menarche, major curve (MAC).

	No menarche at start			Menarche < 1 year			Menarche > 1 year		
	Total	sWBV	Control	Total	sWBV	Control	Total	sWBV	Control
Total, n (%)	15 (100)	9 (100)	6 (100)	11 (100)	6 (100)	5 (100)	12 (100)	5 (100)	7 (100)
Improved, n (%)	2 (13)	2 (22)	0 (0)	1 (9)	1 (17)	0 (0)	1 (8)	1 (20)	0 (0)
Stable, n (%)	10 (67)	6 (67)	4 (67)	10 (91)	5 (83)	5 (100)	11 (92)	4 (80)	7 (100)
Progressed n (%)	3 (20)	1 (11)	2 (33)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

Abbreviations: sWBV, side-alternating Whole Body Vibration.

Table 4. Effect of training in subgroups, minimal Cobb angle difference of ≥5°.

	MAC			MIC		
	Total	sWBV	Control	Total	sWBV	Control
Total, n (%)	38 (100)	20 (100)	18 (100)	38 (100)	20 (100)	18 (100)
Improved, n (%)	4 (10)	4 (20)	0 (0)	2 (6)	2 (10)	0 (0)
Stable, n (%)	31 (82)	15 (75)	16 (89)	32 (83)	16 (80)	16 (89)
Progressed, n (%)	3 (8)	1 (5)	2 (11)	4 (11)	2 (10)	2 (11)

Abbreviations: MAC, major curve; MIC, minor curve, sWBV, side-alternating Whole Body Vibration.

improved in the group “no menarche at start”, 17% (n=1) in the group “menarche <1 year” and 20% (n=1) in the group “menarche >1 year”. Progression occurred in 11% (n=1) of the “no menarche at start” group and in neither of the other two groups (Table 3). The control group did not clinically improve in the group “no menarche at start” (0%, n=0), but progressed in 33% (n=2); in the group “menarche <1 year” and “no menarche at start” no clinical changes were observed for the control group (Table 4). Individual differences for the subgroup “onset of menarche“ are displayed in Figure 6.

No serious unexpected events were reported.

Discussion

This is the first randomised controlled trial comparing home-based, vibration assisted SSE with SSE (Schroth). Our results yield statistical and clinical differences in favour of the sWBV group on scoliosis progression in comparison to the control group. The sWBV group showed improvements, or at least lack of progression, regardless of menarche stage.

The positive changes in the sWBV group regarding the Cobb angle reduction may be due to improved neural activity, including the stimulation of sensory receptors resulting in an improvement of neuro-muscular function, as described in the literature[15]. However, this can only be hypothesised because the exact working mechanism of sWBV is still unknown. “Most authors hypothesize that vibrations stimulate muscle spindles and alpha-motoneurons, which then initiate a muscle contraction”[21].

When calculating sample size in 2010 no valid between-patient SDs was published; therefore we used inter-observer variability of 3.18° for sample size calculation. Meanwhile we know from published results and from our own data that between-patient SDs in this population are about 9°[22]. Therefore a type II error cannot be disregarded. For future studies and interpretation of results this should to be taken into account.

We decided to use upright MRI as imaging method. Most Cobb angles are calculated on x-rays or lying MRI. Lying MRI has the disadvantage of missing gravity influence. X-ray has the disadvantage that girls, once wearing a brace, are only re-assessed by x-ray wearing the brace in Germany. We wanted to evaluate the effect of training in standing without brace. Therefore we decided to use upright standing MRI. A limitation of this method is that participants were included based on measurements taken on routine x-ray wearing the brace. Baseline assessments for the study were re-assessed using a standing MRI without brace. Sometimes there was a difference in the Cobb Angle between the two measures, which e.g. lead to the inclusion of one girl in the sWBV group “No menarche” in Figure 6, who did not exceed 40° Cobb angle (indication for surgery) at inclusion (x-ray in the brace), but did exceed 40° without the brace in the MRI. Therefore she was probably at a “point of no return” where it was very likely that she deteriorates regardless of the therapeutic intervention and therefore would have been a candidate for surgery as recommended by the SOSORT guidelines[1].

Kuru et al. (2016) investigated in their RCT (n=45) 24 weeks of supervised versus non-supervised Schroth training versus no intervention. The Cobb angle in the supervised group improved by 2.5°, and deteriorated by 3.3° and 3.1° in the home exercise group and the control group respectively; differences were significant[23]. Schreiber et al. (2016) could show significant reduction of the Cobb angle in the major curve of 3.5° with 30-45 minutes of daily home-based Schroth training and weekly supervised Schroth sessions (RCT, n=50)[22]. Negrini et al. (2008) found in their retrospective study on SSE according to the Scientific Exercise Approach to Scoliosis (SEAS) improvement of the major curve of 0.33° with deterioration in the control group “usual” therapy by 1.12°. In this group only girls not needing a brace were included[24]. All studies are variable in their intensities, content of training, measurement procedures, samples regarding severity of curvature, bracing status, measurement technique etc. and therefore difficult to compare.

The strength of this present study is that for the first time it addressed a combination home-based SSE program with sWBV. In addition, it may be regarded another strength that the measurement procedure was highly standardized and blind assessors carried out the Cobb angle assessment. Another strength can be regarded the fact that braces were removed prior to imaging in order to evaluate the effect of training under gravity influence. Home-based vibration assisted training has the advantage of short training periods compared to “normal” SSE without vibration assistance. One session vibration assisted therapy is only 4x3 minutes long, compared to 30 to 45 minutes[22] minimum supervised training in the above mentioned studies.

However, the study also has a number of limitations: The frequency of conventional therapy sessions (TAU) was not recorded. Stratification by age and onset of menarche and not by Risser sign is certainly a limitation of the study. Although the Cobb angle change is certainly the most important measure in scoliosis patients, additional endpoints such as quality of life and aesthetic improvements should be included in further studies. In order to better understand the effect of training in general on progression of the Cobb angle in AIS, it would be useful to investigate larger cohorts stratified by Risser sign.

In conclusion home-based SSE performed on a sWBV platform for six months counteracted the progression of scoliosis measured by Cobb angle in girls with AIS. Our results suggest that sWBV assisted physical therapy in girls with AIS should be considered as an additional therapeutic option (especially before onset of menarche).

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Author contributions

SL, OS and ES conceived the idea and designed the project; SL, CS, RS, OS, JF, MS, JS, ES and PE were responsible for acquisition, analysis, or interpretation of data; SL, CS and JF analyzed the data; SL and CS had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis; SL, CS and OS drafted the manuscript; all authors interpreted the results and critically revised the manuscript for important intellectual content; technical support (MRI) was provided by MS; all authors approved the final version of the manuscript for publication.

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