Exercises for adolescent idiopathic scoliosis (Protocol)

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[Intervention Protocol]

Exercises for adolescent idiopathic scoliosis

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

The primary aim of this review is to evaluate the effectiveness of exercise in the treatment of adolescent idiopathic scoliosis.

BACKGROUND

Description of the condition

Scoliosis is a complex deformity of the spine that develops in three-dimensions and results in the appearance of frontal curves, fixed vertebral rotations, and a flattening of the sagittal physiological curves. When scoliosis develops between 10 years of age and the end of growth, it is called Adolescent Idiopathic Scoliosis (AIS); idiopathic meaning that there is no known cause. A curvature in the spine can develop at any level of the spine and depending on the vertebrae that are affected, is referred to as either a thoracic, thoracolumber or lumbar scoliosis. While scoliosis can be secondary to other pathologies, in 70% to 80% of cases, the causes are unknown (SRS 2007). Adolescent Idiopathic Scoliosis is the most common diagnosis. Depending on the age of the individual at diagnosis, scoliosis evolves differently. According to the Scoliosis Research Society, the prevalence of AIS is 2% to 3% in the general population, almost 10% of whom require some form of treatment, and up to 0.1% of whom will require surgery (Lonstein 2006). Adolescent Idiopathic Scoliosis is more commonly found in females (female:male ratio is around 7:1). Except for extreme cases, AIS does not typically cause any health problems during growth; however, the resulting surface deformity frequently has a negative impact on adolescents that can give rise to quality of life (QoL) issues and in the worst cases, psychological disturbances (Reichel 2003).

Description of the intervention

Due to the progressive nature of the deformity, adolescent patients are generally treated when the curvature is diagnosed. Furthermore, once the curve progresses, there are no treatments that succeed in fully correcting the spine. Depending on the mobility of the spine, reduction of the deformity can be difficult. The magnitude of scoliotic curves in the frontal plane is generally measured from x-ray and is referred to as the Cobb angle, named after the spinal surgeon who devised the method. The Cobb angle is the angle that measures the curvature of the spine in the frontal plane and measures the angle that includes all of the deformed vertebrae. It is generally agreed that mild curves are curves that measure up to 25° Cobb; moderate curves are considered to be those measuring from 25° to 45° Cobb and severe curves measure over 45° Cobb angle. If scoliosis surpasses a critical threshold, usually considered to be 30° Cobb, at the end of growth, the risk of health problems in adulthood increases significantly (Lonstein 2006). Problems include quality of life and disability, pain, increasing cosmetic deformity, functional limitations, sometimes pulmonary problems, and possible progression during adulthood (Weinstein 2003). Because of this, scoliosis management also includes the prevention of secondary problems associated with the deformity. The main treatment options for the prevention of scoliosis progression include exercises and other forms of physical therapy, bracing and surgery (Lenssink 2005). The use of exercise for the treatment of AIS is controversial. While it is routinely used in France, Germany, Italy, and many other countries in continental Europe, most centers in the UK and USA do not advocate its use.

Exercise therapy for scoliosis includes a series of specific physical movements performed with a therapeutic aim. Exercises work mechanically by changing the musculature and other soft tissues of the spine. It is also believed that exercise can alter the motor control of the spine by affecting neurological changes that interact with each other (Hawes 2003).

The overall primary aims of exercise therapy are the reduction of the progression of the scoliotic deformity and the postponement and possible avoidance of brace prescription. Negrini 2008 and Ducongè 2002 reported that exercises can stabilize and reduce curve magnitude as well as improve respiratory function that may be altered by chest deformity. Exercise has also been reported to reduce the incidence of surgery (Weiss 2003).

How the intervention might work

Exercises in scoliosis treatment can be used in three main clinical scenarios: (i) the sole use of exercise as the primary treatment of AIS for mild curves, (ii) in conjunction with braces for moderate curves, and (iii) during adulthood if the scoliosis curves exceed certain thresholds.

In the treatment of mild scoliosis of less than 25° Cobb, intense three dimensional spine and rib-cage specific exercises are used in order to try and avoid the use of a brace. This critical Cobb angle is generally regarded as the threshold for brace prescription (Lonstein 2006; Weiss 2006). In mild scoliosis cases where exercise is prescribed, exercise is predominantly used according to the recommendations made by the Study group on Scoliosis and Orthopaedic and Rehabilitative Treatment (SOSORT). The key objectives of physical exercise in mild cases of AIS are the stabilisation of the spine combined with three dimensional auto correction of the spine, pelvis and rib-cage.

Several studies have also shown that bracing (which "binds" the thorax for continuous periods of time) tends to reduce the quality of life of young patients (Kotwicki 2007). Therefore, exercise can help to improve patients' quality of life by keeping the curve and rib hump under control for as long as possible, thus reducing the need for braces.

The second main clinical scenario for exercise use is in conjunction with brace treatment. In this case, the aims are to reduce the side effects of wearing a brace (muscle weakness, rigidity, flat back) and to improve the efficacy of internal brace pads (Romano 2006). Exercises can also be used before a brace is worn to reduce spinal stiffness and improve mobility, thus helping to achieve a better correction (Negrini 2006).

Finally, the third possible clinical scenario is during adulthood. If scoliosis exceeds certain thresholds, significant problems such as

back pain, breathing dysfunction, contractures and progressive deformity can develop. These impairments and consequent disability can be addressed through exercise (Mamyama 2002).

Why it is important to do this review

A scoping literature search identified three systematic reviews on the topic, none of which followed Cochrane methodology (Negrini 2003; Lenssink 2005; Negrini 2008). Therefore, we are planning to examine evidence that has been published since these reviews and follow a more rigourous methodology to answer our clinical question "Is exercise therapy effective in delaying the progression of, or reducing the speed at which the curve progresses? ": Preventing the progression of the disease means avoiding the need for bracing, surgery, or both. We are not going to include studies on bracing, because there is another review (Negrini 2007) that covers it, however, we will consider studies on the effects of exercises added to bracing if compared to bracing alone.

OBJECTIVES

The primary aim of this review is to evaluate the effectiveness of exercise in the treatment of adolescent idiopathic scoliosis.

METHODS

Criteria for considering studies for this review

Types of studies

The primary analysis will combine the results of randomised control trials (RCTs) and quasi-randomised control trials (QRCTs). We will include non-randomised studies (NRS) since it is anticipated that very few RCTs will be found, but they will be pooled in the secondary analysis. Non-randomised studies must be prospective and include a control group.

Types of participants

We will include studies in which all patients were diagnosed as having adolescent idiopathic scoliosis with at least a 10° Cobb angle, and were between the age of 10 years and the end of bone growth (in females, this is approximately between the ages of 15 and 17 years; in males, this usually occurs between 16 and 19 years of age). The end of bone growth can be determined by the Risser sign, which quantifies the ossification of the iliac crest. Stage 4 indicates total ossification of the apophysis, while Stage 5, the Tanner stage, indicates fusion of the apophysis to the iliac crest and the end of further growth. The Greulich-Pyle atlas calculates the maturity of bones by assessing x-rays of the left hand.
Studies in which patients presented with any type of secondary scoliosis (congenital, neurological, metabolic, post-traumatic, etc), diagnosed according to the SRS criteria (SRS 2006), will be excluded.

Types of interventions

Experimental intervention

The experimental interventions in this review will include all types of scoliosis-specific exercises, which are considered to be "specific movements performed with a therapeutic aim of reducing the deformity". Sports and active recreational activities are not considered to be specific exercises for the treatment of scoliosis and studies including these types of activities will be excluded.

Comparison interventions

Comparison interventions will include no treatment; different types, doses or schedules of exercises; or other non-surgical treatments (e.g. braces, electrical stimulation, manual therapy).
Comparisons will include: exercises versus no treatment, exercises plus another treatment versus the other treatment, exercises versus other treatments, different exercises versus each other, or different doses/schedules of exercises versus each other.

Types of outcome measures

Primary outcomes

Progression of scoliosis, as measured by:

- Cobb angle in degrees (absolute values),
- Angle of Trunk Rotation (ATR) in degrees (absolute values),
- Number of patients who have progressed by more than 5° Cobb,
- Number of subjects for whom brace or surgery were prescribed.

Cosmetic issues, as measured by:

- objective surface measurements, including Bunnel degrees or other measurements measures with validated scales or questionnaires (such as the Walter Reed Visual Assessment Scale),
- Topographic measurements e.g. the integrated shape imaging system (ISIS) angles - Quantec, Formetric (Rigo 2006).

Quality of life and disability, as measured by:

- specific validated questionnaires such as SRS-22, SF-36 (Asher 2003), BSSK, BrQ (Vasiliadis 2006).

Back pain, as measured by:

- VAS or other validated measurement tools,

- ·use of drugs.

Psychological issues, as measured by:

- specific questionnaires such as sub-scales of SRS-22 and SF-36, BrQ.

Secondary outcomes

Adverse effects, as outlined in identified trials, will also be reported. All outcomes (primary and secondary) will be measured in the very short-term (any result before the end of bone growth), the short-term (results at the end of bone growth) and long-term (results in adulthood).

Search methods for identification of studies

To faciliate a uniform interpretation of criteria for selecting studies, assessing risk of bias, extracting and analysing data, all forms will be pre-tested by the review team, using two to three studies that will not be included in the review.

Electronic searches

We will undertake a comprehensive search to identify all relevant studies. We will search the following electronic databases:
1) CENTRAL (*The Cochrane Library,* most recent issue), which includes the Cochrane Back Review Group Trials Register,
2) MEDLINE (1966 to present),
3) EMBASE (1980 to present),
4) CINHAL (1982 to present),
5) Pedro (present),
The updated search strategy recommended by the Cochrane Back Review Group for RCTs will be used. This will be adapted for cohort studies (See Furlan 2009). The strategy includes subject headings (MeSH) and text words. These include methodological terms, disorder terms and treatment terms, and are listed in full for MEDLINE, EMBASE and CINAHL (Appendix 1; Appendix 2; Appendix 3). The remaining databases will be searched with the strategy adapted appropriately.

Searching other resources

The following strategies will also be included:
1) screen the reference lists of all relevant papers,
2) search the main electronic sources of ongoing trials (National Research Register, meta-Register of Controlled Trials; Clinical Trials),
3) search the Grey literature, including conference proceedings, PhD theses,
4) contact investigators and authors in this field for information on unpublished or incomplete trials.
All searches will include non-English language literature

Data collection and analysis

Selection of studies

Two review authors will independently screen the search results by reading titles and abstracts. Potentially relevant studies will be obtained in full text and independently assessed for inclusion by two review authors, who will resolve disagreement through discussion. A third review author will be contacted if disagreements persist.

Data extraction and management

A standardized data extraction form will be prepared and used to extract data from the included papers. Data extracted will include: study design (RCT, QRCT, prospective controlled cohort study), study characteristics (country, recruitment modality, study funding, risk of bias), patient characteristics (number of participants, age, sex, severity of scoliosis at baseline), description of the experimental and comparison interventions, co-interventions, adverse effects, duration of follow-up, outcomes assessed and results. Two review authors will independently extract the data. Any disagreement will be discussed and a third review author consulted if disagreements persist. Key findings will be summarized in a narrative format and then assessed for inclusion in a meta-analysis where possible.

Assessment of risk of bias in included studies

The risk of bias for RCTs and QRCTs will be assessed using the 12 criteria recommended by the Cochrane Back Review Group (Furlan 2009; Handbook 5 2008), and outlined in Appendix 4. The Newcastle-Ottawa Scale (NOS scale) (NOS 2000) will be used to assess the observational studies. The NOS scale assesses three broad areas: selection bias, attrition bias, detection bias. See Appendix 5 for details on risk of bias criteria for observational studies. Two review authors will independently assess the internal validity of the included studies. Any disagreement between the review authors will be resolved by discussion; a third independent reviewer will be consulted if disagreements persist. Risk of bias assessment will not be blinded to trial authors, institution or journal since the review team is familiar with the literature.
The criteria recommended and defined by the Cochrane Back Review Group (Furlan 2009; van Tulder 2003) will be scored as 'yes', 'no' or 'unclear' and will be reported in the *Risk of Bias* table. A trial with low risk of bias will be defined as a trial that meets, at a minimum, criteria A (randomisation), B (allocation concealment), C5 (outcome assessor blinding) and any three of the other criteria. Blinding of participants, personnel and outcome assessor (avoidance of performance bias and detection bias) will be considered separately for objective outcomes (brace prescription, progression of the curve, cosmetic issues) and subjective outcomes (back pain, quality of life, disability, psychological issues). It is very

unlikely that trials on the effectiveness of exercises treatments could be blinded for participants and healthcare personnel. Nevertheless, the trials could have a blinded assessment of outcomes. The *Risk of Bias* tables will be ammended so they can be used to report the assessment of RCTs, QRCTs, and observational studies.

Assessment of Clinical relevance

Each trial will be assessed by the review authors for its clinical relevance, using the five questions outlined by Shekelle 1994 (Skekelle 1994; Appendix 6). All outcomes within each comparison will be discussed. Clinical significance (Shekelle question 4) will be defined as a 5° Cobb change, which is the reliability of radiographic examination and the international gold standard for minimum clinically significant change.

Measures of treatment effect

Dichotomous outcomes will be analysed by calculating the relative risk (RR) for each trial, with the uncertainty in each result being expressed by 95% confidence intervals (CI). Continuous outcomes will be analysed calculating the WMD or the SMD with 95%CI.

Assessment of heterogeneity

A P - value of the Chi^2 test less than 0.05 indicates a significant statistical heterogeneity.

Data synthesis

The outcome measures from the individual trials will be combined through meta-analysis where possible (comparability of intervention and outcomes across trials) using a fixed-effect model. If unexplained significant statistical heterogeneity is found, a random-effects model will be used.

Regardless of whether there are sufficient data available to use quantitative analyses to summarize the data, we will assess the overall quality of the evidence for each outcome. To accomplish this, we will use an adapted GRADE approach, as recommended by the Cochrane Back Review Group (Furlan 2009). The quality of the evidence on a specific outcome is based on the study design, risk of bias, consistency and directness of results, precision of the data and non-biased reporting of the results across all studies that measure that particular outcome. The quality starts at high when RCTs with a low risk of bias provide results for the outcome, and reduces by a level for each of the factors not met.

High quality evidence = there are consistent findings among at least two RCTs with low risk of bias that are generalizable to the population in question. There are sufficient data, with narrow confidence intervals. There are no known or suspected reporting biases. Consistency is defined as 75% or more of the studies with similar results.

Moderate quality evidence = one of the factors is not met

Low quality evidence = two of the factors are not met

Very low quality evidence = three of the factors are not met

No evidence = no evidence from RCTs

Subgroup analysis and investigation of heterogeneity

If there is significant statistical heterogeneity, a subgroup analysis will be performed to consider the effects of the following variables: age, bone age, Cobb degrees and type of exercise.

Comparison between primary and secondary analysis

Separate analyses will be performed for randomised (primary analysis) and observational studies (secondary analysis). Results obtained from the two analyses will be compared and contrasted. If there is a difference in results, the conclusions of the review will be based on the results of the primary analysis. However, If there is no difference, conclusions will be based on all available information. Results of observational studies will be added to the GRADE analysis as part of the comparison.

Sensitivity analysis

To incorporate the risk of bias assessment in the review process, we will start by stratifying the intervention effects estimates by risk. If differences in results are seen among studies at different risks of bias, we will go on to perform sensitivity analyses, excluding studies with high risk of bias from the analysis.

ACKNOWLEDGEMENTS

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REFERENCES

Additional references

Asher 2003

Asher M. The reliability and concurrent validity of the Scoliosis Research Society 22-patient questionnaire for idiopathic scoliosis. *Spine* 2003;**28**(1):63–9.

Ducongè 2002

Ducongè PL. [La rèèducation de la scoliose. Mythè ou rèalitè?]. *Résonances Européennes du Rachis* 2002;**10**: 1229–36.

Furlan 2009

Furlan AD, Pennick V, Bombardier C, van Tulder MW on behalf of the Cochrane Back Review Group Editorial Board. 2009 Updated Method Guidelines for Systematic Reviews in the Cochrane Back Review Group. in progress.

Handbook 5 2008

Higgins JPT, Green S (Editors). Cochrane Handbook for Systematic Reviews of Interventions. The Cochrane Collaboration (www.cochrane.org/resources/handbook/index.htm) Version 5.0.0; updated February 2008.

Hawes 2003

Hawes MC. The use of exercises in the treatment of scoliosis: an evidence-based critical review of the literature. *Pediatr Rehabil* 2003 Jul–Dec;**6**(3-4):171–82.

Kotwicki 2007

Kotwicki T, Kinel E, Stry W, Szulc A. Estimation of the stress related to conservative scoliosis therapy: an analysis based on BSSQ questionnaires. *Scoliosis* 2007;**3**(2):1.

Lenssink 2005

Lenssinck ML, Frijlink AC, Berger MY, Bierman-Zeinstra SM, Verkerk K, Verhagen AP. Effect of bracing and other conservative interventions in the treatment of idiopathic scoliosis in adolescents: A systematic review of clinical trials. *Phys Ther* 2005;**85**(12):1329–39.

Lonstein 2006

Lonstein JE. Scoliosis: Surgical versus non-surgical treatment. *Clin Orthop Relat Res* 2006;**443**:284–59.

Mamyama 2002

Mamyama T, Kitagawal T, Takeshita K, Nakainura K. Side shift exercise for idiopathic scoliosis after skeletal maturity. *Stud Health Technol Inform* 2002;**91**:361–4.

Negrini 2003

Negrini S, Antonini G, Carabalona R, Minozzi S. Physical exercises as a treatment for adolescent idiopathic scoliosis. A systematic review. *Pediatr Rehabil* 2003 Jul–Dec;**6**(3-4): 227–35.

Negrini 2006

Negrini S, Negrini A, Romano M, Verzini N, Negrini A, Parzini S. A controlled prospective study on the efficacy of SEAS.02 exercises in preparation to bracing for idiopathic scoliosis. *Stud Health Technol Inform* 2006;**123**:519–22.

Negrini 2007

Negrini S, Minozzi S, Bettany-Saltikov J, Zaina F, Chockalingam N, Grivas TB, et al.Braces for idiopathic scoliosis in adolescents (Protocol). *Cochrane Database of Systematic Reviews* 2007, Issue 4. [DOI: CD006850. DOI: 10.1002/14651858.CD006850]

Negrini 2008

Negrini S, Fusco C, Minozzi S, Atanasio S, Zaina F, Romano M. Exercises reduce the progression rate of adolescent idiopathic scoliosis: Results of a comprehensive systematic review of the literature. *Disabil Rehabil* 2008;**30** (10):772–85.

NOS 2000

Wells GA, Shea B, O'Connell D, Peterson J, Welch V, Losos M, et al.The Newcastle-Ottawa Scale (NOS) for assessing the quality of nonrandomised studies in meta-analyses. www.ohri.ca/programs/clinical_epidemiology/oxford.htm (accessed December 2008) 2000.

Reichel 2003

Reichel D, Schanz J. Developmental psychological aspects of scoliosis treatment. *Pediatr Rehabil* 2003;**6**(3-4):221–5.

Rigo 2006

Rigo M, Quera-Salva G, Villagrasa M. Sagittal configuration of the spine in girls with idiopathic scoliosis: Progressing rather than initiating factor. *Stud Health Technol Inform* 2006;**123**:90–4.

Romano 2006

Romano M, Carabalona S, Petrilli S, Sibilla P, Negrini S. Forces exerted during exercises by patients with adolescent idiopathic scoliosis wearing fiberglass braces. *Scoliosis* 2006; **21**:1–12.

Skekelle 1994

Shekelle PG, Andersson G, Bombardier C, Cherkin D, Deyo R, Keller R. A brief introduction to the critical reading of the clinical literature. *Spine* 1994;**19**:2028s–31s.

SRS 2006

Scoliosis Resarch Society. Brace Wear Compliance.. *http://www.srs.org/professionals/bracing_manuals/section3.pdf* 2006.

SRS 2007

Scoliosis Research Society. The Scoliosis Research Society Brace Manual. Introduction. *http://www.srs.org/professionals/bracing_manuals/section1.pdf* 2007.

van Tulder 2003

van Tulder M, Furlan A, Bombardier C, Bouter L, Editorial Board of the Cochrane Collaboration Back Review Group. Updated method guidelines for systematic reviews in the Cochrane Collaboration Back Group. *Spine* 2003;**28**(12): 1290–9.

Vasiliadis 2006

Vasiliadis E, Grivas TB, Gkoltsiou K. Development and preliminary validation of Brace Questionnaire (BrQ): a new instrument for measuring quality of life of brace treated scoliotics. *Scoliosis* 2006;**1**:7. [DOI: 10.1186/1748-7161-1-7]

Weinstein 2003
Weinstein SL, Dolan LA, Spratt KF, Peterson KK, Spoonamore MJ, Ponseti IV. Health and function of patients with untreated idiopathic scoliosis: A 50-year natural history study. *JAMA* 2003;**289**(5):559–67.

Weiss 2003
Weiss HR, Weiss G, Schaar HJ. Incidence of surgery in conservatively treated patients with scoliosis. *Pediatric Rehabilitation* 2003;**6**:209–14.

Weiss 2006
Weiss HR, Negrini S, Hawes MC, Rigo M, Kotwicki T, Members of the SOSORT. Physical exercises in the treatment of idiopathic scoliosis at risk of brace treatment - SOSORT consensus paper 2005. *Scoliosis* 2006;**1**:6.

* *Indicates the major publication for the study*

APPENDICES

Appendix 1. MEDLINE search strategy

1 Comparative Study/
2 exp Evaluation Studies/
3 exp Follow-Up Studies/
4 exp Prospective Studies/
5 exp Cross-Over Studies/
6 exp Epidemiologic Studies/
7 exp Case-Control Studies/
8 exp Cohort Studies/
9 exp Cross-Sectional Studies/
10 (cohort adj (study or studies)).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
11 cohort analy$.mp. [mp=title, original title, abstract, name of substance word, subject heading word]
12 (follow up adj (study or studies)).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
13 (observational adj (study or studies)).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
14 longitudinal.mp. [mp=title, original title, abstract, name of substance word, subject heading word]
15 retrospective.mp. [mp=title, original title, abstract, name of substance word, subject heading word]
16 cross sectional.mp. [mp=title, original title, abstract, name of substance word, subject heading word]
17 control$.mp. [mp=title, original title, abstract, name of substance word, subject heading word]
18 prospective$.mp. [mp=title, original title, abstract, name of substance word, subject heading word]
19 volunteer.mp. [mp=title, original title, abstract, name of substance word, subject heading word]
20 or/1-19
21 exp “Clinical Trial [Publication Type]”/
22 randomized.ab,ti.
23 placebo.ab,ti.
24 dt.fs.
25 randomly.ab,ti.
26 trial.ab,ti.
27 groups.ab,ti.
28 or/21-27
29 Animals/

30 Humans/
31 29 not (29 and 30)
32 28 not 31
33 20 not 31
34 32 or 33
35 exp Spinal Diseases/
36 exp Scoliosis/
37 scoliosis.mp.
38 or/35-37
39 exp Braces/
40 brace$.mp.
41 bracing.mp.
42 exp Orthotic Devices/
43 exp Orthopedic Equipment/
44 limit 43 to yr="1902 - 1975"
45 or/39-42
46 44 or 45
47 exp Adolescent/
48 adolescen$.mp.
49 47 or 48
50 38 and 45 and 49
51 34 and 50

Appendix 2. EMBASE search strategy

1 exp Clinical Study/
2 exp Case Control Study/
3 exp Family Study/
4 exp Longitudinal Study/
5 exp Retrospective Study/
6 exp Prospective Study/
7 exp Cohort Analysis/
8 (cohort adj (study or studies)).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name]
9 (case control adj (study or studies)).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name]
10 (follow up adj (study or studies)).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name]
11 (observational adj (study or studies)).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name]
12 (epidemiologic$ adj (study or studies)).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name]
13 (cross sectional adj (study or studies)).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name]
14 exp Comparative Study/
15 evaluation study.mp.
16 follow-up study.mp. or exp Follow Up/
17 Crossover Procedure/
18 prospective$.mp.
19 exp VOLUNTEER/
20 or/1-19
21 Clinical Article/

22 exp Clinical Study/
23 Clinical Trial/
24 Controlled Study/
25 Randomized Controlled Trial/
26 Major Clinical Study/
27 Double Blind Procedure/
28 Multicenter Study/
29 Single Blind Procedure/
30 Phase 3 Clinical Trial/
31 Phase 4 Clinical Trial/
32 crossover procedure/
33 placebo/
34 or/21-33
35 allocat$.mp.
36 assign$.mp.
37 blind$.mp.
38 (clinic$ adj25 (study or trial)).mp.
39 compar$.mp.
40 control$.mp.
41 cross?over.mp.
42 factorial$.mp.
43 follow?up.mp.
44 placebo$.mp.
45 prospectiv$.mp.
46 random$.mp.
47 ((singl$ or doubl$ or trebl$ or tripl$) adj25 (blind$ or mask$)).mp.
48 trial.mp.
49 (versus or vs).mp.
50 or/35-49
51 34 and 50
52 20 or 51
53 Human/
54 Nonhuman/
55 exp ANIMAL/
56 Animal Experiment/
57 54 or 55 or 56
58 53 not 57
59 52 not 57
60 58 or 59
61 exp SPINE/
62 exp Spine Disease/
63 exp SCOLIOSIS/
64 exp Idiopathic Scoliosis/
65 scoliosis.mp.
66 or/61-65
67 exp Brace/
68 brace$.mp.
69 bracing.mp.
70 exp ORTHOTICS/
71 exp orthopedic equipment/
72 or/67-71
73 Adolescent/
74 adolescen#.mp.

75 73 or 74
76 66 and 72 and 75
77 60 and 76

Appendix 3. CINHAL search strategy

1 exp Prospective Studies/
2 exp Case Control Studies/
3 exp Correlational Studies/
4 exp Nonconcurrent Prospective Studies/
5 exp Cross Sectional Studies/
6 (cohort adj (study or studies)).mp. [mp=title, subject heading word, abstract, instrumentation]
7 (observational adj (study or studies)).mp. [mp=title, subject heading word, abstract, instrumentation]
8 Randomized Controlled Trials.mp.
9 clinical trial.pt.
10 exp Clinical Trials/
11 (clin$ adj25 trial$).tw.
12 ((singl$ or doubl$ or trebl$ or tripl$) adj25 (blind$ or mask$)).tw.
13 exp PLACEBOS/
14 placebo$.tw.
15 random$.tw.
16 exp Study Design/
17 (latin adj square).tw.
18 exp Comparative Studies/
19 exp Evaluation Research/
20 Follow-Up Studies.mp.
21 exp Prospective Studies/
22 (control$ or prospectiv$ or volunteer$).tw.
23 Animals/
24 or/1-22
25 24 not 23
26 Randomized Controlled Trials.mp.
27 clinical trial.pt.
28 exp Clinical Trials/
29 (clin$ adj25 trial$).tw.
30 ((singl$ or doubl$ or trebl$ or tripl$) adj25 (blind$ or mask$)).tw.
31 exp PLACEBOS/
32 placebo$.tw.
33 random$.tw.
34 exp Study Design/
35 (latin adj square).tw.
36 exp Comparative Studies/
37 exp Evaluation Research/
38 Follow-Up Studies.mp.
39 exp Prospective Studies/
40 (control$ or prospectiv$ or volunteer$).tw.
41 Animals/
42 or/26-40
43 42 not 41
44 exp SPINE/
45 exp Spinal Diseases/
46 exp SCOLIOSIS/

47 scoliosis.mp.
48 or/44-47
49 exp Orthoses/
50 brace$.mp.
51 bracing.mp.
52 or/49-51
53 exp Adolescence/
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Appendix 4. Criteria for risk of bias assessment for RCTs and CCTs

1. Was the method of randomization adequate? A random (unpredictable) assignment sequence. Examples of adequate methods are coin toss (for studies with two groups), rolling a dice (for studies with two or more groups), drawing of balls of different colours, drawing of ballots with the study group labels from a dark bag, computer-generated random sequence, pre-ordered sealed envelops, sequentially-ordered vials, telephone call to a central office, and pre-ordered list of treatment assignments
Examples of inadequate methods are: alternation, birth date, social insurance/security number, date in which they are invited to participate in the study, and hospital registration number
2. Was the treatment allocation concealed? Assignment generated by an independent person not responsible for determining the eligibility of the patients. This person has no information about the persons included in the trial and has no influence on the assignment sequence or on the decision about eligibility of the patient.
Was knowledge of the allocated interventions adequately prevented during the study?
3. Was the patient blinded to the intervention?
This item should be scored "yes" if the index and control groups are indistinguishable for the patients or if the success of blinding was tested among the patients and it was successful.
4. Was the care provider blinded to the intervention? This item should be scored "yes" if the index and control groups are indistinguishable for the care providers or if the success of blinding was tested among the care providers and it was successful
5. Was the outcome assessor blinded to the intervention? Adequacy of blinding should be assessed for the primary outcomes. This item should be scored "yes" if the success of blinding was tested among the outcome assessors and it was successful or:

- **for patient-reported outcomes** in which the patient is the outcome assessor (e.g., pain, disability): the blinding procedure is adequate for outcome assessors if participant blinding is scored "yes"

- **for outcome criteria assessed during scheduled visit and that supposes a contact between participants and outcome assessors** (e.g., clinical examination): the blinding procedure is adequate if patients are blinded, and the treatment or adverse effects of the treatment cannot be noticed during clinical examination

- **for outcome criteria that do not suppose a contact with participants** (e.g., radiography, magnetic resonance imaging): the blinding procedure is adequate if the treatment or adverse effects of the treatment cannot be noticed when assessing the main outcome

- **for outcome criteria that are clinical or therapeutic events** that will be determined by the interaction between patients and care providers (e.g., co-interventions, hospitalization length, treatment failure), in which the care provider is the outcome assessor: the blinding procedure is adequate for outcome assessors if item "4" is scored "yes"

- **for outcome criteria that are assessed from data of the medical forms**: the blinding procedure is adequate if the treatment or adverse effects of the treatment cannot be noticed on the extracted data

Were incomplete outcome data adequately addressed?
6. Was the drop-out rate described and acceptable? The number of participants who were included in the study but did not complete the observation period or were not included in the analysis must be described and reasons given. If the percentage of withdrawals and drop-outs does not exceed 20% for short-term follow-up and 30% for long-term follow-up and does not lead to substantial bias a 'yes' is scored. (N.B. these percentages are arbitrary, not supported by literature).

7. Were all randomized participants analysed in the group to which they were allocated? All randomized patients are reported/ analyzed in the group they were allocated to by randomization for the most important moments of effect measurement (minus missing values) irrespective of non-compliance and co-interventions.
8. Are reports of the study free of suggestion of selective outcome reporting? In order to receive a 'yes', the review author determines if all the results from all pre-specified outcomes have been adequately reported in the published report of the trial. This information is either obtained by comparing the protocol and the report, or in the absence of the protocol, assessing that the published report includes enough information to make this judgment.
Other sources of potential bias:
9. Were the groups similar at baseline regarding the most important prognostic indicators? In order to receive a "yes", groups have to be similar at baseline regarding demographic factors, duration and severity of complaints, percentage of patients with neurological symptoms, and value of main outcome measure(s).
10. Were co-interventions avoided or similar? This item should be scored "yes" if there were no co-interventions or they were similar between the index and control groups.
11. Was the compliance acceptable in all groups? The reviewer determines if the compliance with the interventions is acceptable, based on the reported intensity, duration, number and frequency of sessions for both the index intervention and control intervention(s). For example, physiotherapy treatment is usually administered over several sessions; therefore it is necessary to assess how many sessions each patient attended. For single-session interventions (for ex: surgery), this item is irrelevant.
12. Was the timing of the outcome assessment similar in all groups? Timing of outcome assessment should be identical for all intervention groups and for all important outcome assessments.

Appendix 5. Criteria for risk of bias assessment for observational studies

Selection bias:
1. Representativeness of the exposed cohort: Item is assessing the representativeness of exposed individuals in the community, not the representativeness of the sample of adolescents from a general population. Assess whether the sample is truly representative of the average adolescent with scoliosis; somewhat representative of the average adolescent with scoliosis; selected group of adolescents with scoliosis; no description of the derivation of the cohort. This item will be added in the Risk of bias table as "other source of bias".
2. Selection of the non exposed cohort: Item is assessing the representativeness of non-exposed individuals in the same community as the exposed cohort that have been included in the study during the study period. Assess whether the sample has been drawn from the same community as the exposed cohort; drawn from a different source "no description of the derivation of the non-exposed cohort'. This item will be added in the Risk of bias table as "other source of bias".
3. Ascertainment of exposure: Information in the study was obtained from a secure record (e.g. clinical records); structured interview; written self report; no description. This item will be added in the Risk of bias table as "other source of bias".
4. Comparability of cohorts on the basis of the design or analysis: Either exposed and non-exposed individuals must be matched in the design and/or confounders must be adjusted for in the analysis. Statements of no differences between groups or that differences were not statistically significant are not sufficient for establishing comparability. If the relative risk for the exposure of interest is adjusted for the confounders listed, then the groups will be considered to be comparable on each variable used in the adjustment. Were most important prognostic factors matched? Yes/No. Were unmatched important prognostic factors adjusted for? Yes/No. This item will be assessed in the Risk of Bias table under the item "group similar at baseline".
Attrition bias:
5. Complete follow up: Assess if: all subjects are accounted for; subjects lost to follow up unlikely to introduce bias (lost to follow-up < 5%); subjects lost to follow up > 5% and description provided of those lost. This item will be assessed in the Risk of Bias table under the item "incomplete outcome data".
Detection bias:
6. Independent blind assessment: Independent or blind assessment stated in the paper, or confirmation of the outcome by reference to secure records (x-rays, medical records, etc.), record linkage, or self report; or no blinding; no description. This item will be assessed in the Risk of Bias table under the item "blinding of outcome assessor"

Appendix 6. Assessment of Clinial Relevance

1. Are the patients described in detail so that you can decide whether they are comparable to those that you see in your practice?
2. Are the interventions and treatment settings described well enough so that you can provide the same for your patients?
3. Were all clinically relevant outcomes measured and reported?
4. Is the size of the effect clinically important?
5. Are the likely treatment benefits worth the potential harms?

WHAT'S NEW

Date	Event	Description
23 November 2009	Amended	Contact details updated.

HISTORY

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DECLARATIONS OF INTEREST

Many members of the review team have published widely in the field of scoliosis. Whenever a paper authored by a review author is considered, all decisions about the paper will be made by the other reviewer authors.

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