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Braces for idiopathic scoliosis in adolescents.
Cochrane Database of Systematic Reviews 2015, Issue 6. Art. No.: CD006850.
DOI: 10.1002/14651858.CD006850.pub3.

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[Intervention Review]

Braces for idiopathic scoliosis in adolescents

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Editorial group: Cochrane Back and Neck Group.
Publication status and date: New search for studies and content updated (conclusions changed), published in Issue 6, 2015.

Citation: Negrini S, Minozzi S, Bettany-Saltikov J, Chockalingam N, Grivas TB, Kotwicki T, Maruyama T, Romano M, Zaina F. Braces for idiopathic scoliosis in adolescents. *Cochrane Database of Systematic Reviews* 2015, Issue 6. Art. No.: CD006850. DOI: 10.1002/14651858.CD006850.pub3.

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ABSTRACT

Background

Idiopathic scoliosis is a three-dimensional deformity of the spine. The most common form is diagnosed in adolescence. While adolescent idiopathic scoliosis (AIS) can progress during growth and cause a surface deformity, it is usually not symptomatic. However, in adulthood, if the final spinal curvature surpasses a certain critical threshold, the risk of health problems and curve progression is increased.

Objectives

To evaluate the efficacy of bracing for adolescents with AIS versus no treatment or other treatments, on quality of life, disability, pulmonary disorders, progression of the curve, and psychological and cosmetic issues.

Search methods

We searched CENTRAL, MEDLINE, EMBASE, five other databases, and two trials registers up to February 2015 for relevant clinical trials. We also checked the reference lists of relevant articles and conducted an extensive handsearch of grey literature.

Selection criteria

Randomized controlled trials (RCTs) and prospective controlled cohort studies comparing braces with no treatment, other treatment, surgery, and different types of braces for adolescent with AIS.

Data collection and analysis

We used standard methodological procedures expected by The Cochrane Collaboration.

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Main results

We included seven studies (662 participants). Five were planned as RCTs and two as prospective controlled trials. One RCT failed completely, another was continued as an observational study, reporting also the results of the participants that had been randomized.

There was very low quality evidence from one small RCT (111 participants) that quality of life (QoL) during treatment did not differ significantly between rigid bracing and observation (mean difference (MD) -2.10, 95% confidence interval (CI) -7.69 to 3.49). There was very low quality evidence from a subgroup of 77 adolescents from one prospective cohort study showing that QoL, back pain, psychological, and cosmetic issues did not differ significantly between rigid bracing and observation in the long term (16 years).

Results of the secondary outcomes showed that there was low quality evidence that rigid bracing compared with observation significantly increased the success rate in 20° to 40° curves at two years' follow-up (one RCT, 116 participants; risk ratio (RR) 1.79, 95% CI 1.29 to 2.50). There was low quality evidence that elastic bracing increased the success rate in 15° to 30° curves at three years' follow-up (one RCT, 47 participants; RR 1.88, 95% CI 1.11 to 3.20).

There is very low quality evidence from two prospective cohort studies with a control group that rigid bracing increases the success rate (curves not evolving to 50° or above) at two years' follow-up (one study, 242 participants; RR 1.50, 95% CI 1.19 to 1.89) and at three years' follow-up (one study, 240 participants; RR 1.75, 95% CI 1.42 to 2.16). There was very low quality evidence from a prospective cohort study (57 participants) that very rigid bracing increased the success rate (no progression of 5° or more, fusion, or waiting list for fusion) in adolescents with high degree curves (above 45°) (one study, 57 adolescents; RR 1.79, 95% CI 1.04 to 3.07 in the intention-to-treat (ITT) analysis).

There was low quality evidence from one RCT that a rigid brace was more successful than an elastic brace at curbing curve progression when measured in Cobb degrees in low degree curves (20° to 30°), with no significant differences between the two groups in the subjective perception of daily difficulties associated with wearing the brace (43 girls; risk of success at four years' follow-up: RR 1.40, 1.03 to 1.89). Finally, there was very low quality evidence from one RCT (12 participants) that a rigid brace with a pad pressure control system is no better than a standard brace in reducing the risk of progression.

Only one prospective cohort study (236 participants) assessed adverse events: neither the percentage of adolescents with any adverse event (RR 1.27, 95% CI 0.96 to 1.67) nor the percentage of adolescents reporting back pain, the most common adverse event, were different between the groups (RR 0.72, 95% CI 0.47 to 1.10).

Authors' conclusions

Due to the important clinical differences among the studies, it was not possible to perform a meta-analysis. Two studies showed that bracing did not change QoL during treatment (low quality), and QoL, back pain, and psychological and cosmetic issues in the long term (16 years) (very low quality). All included papers consistently showed that bracing prevented curve progression (secondary outcome). However, due to the strength of evidence (from low to very low quality), further research is very likely to have an impact on our confidence in the estimate of effect. The high rate of failure of RCTs demonstrates the huge difficulties in performing RCTs in a field where parents reject randomization of their children. This challenge may prevent us from seeing increases in the quality of the evidence over time. Other designs need to be implemented and included in future reviews, including 'expertise-based' trials, prospective controlled cohort studies, prospective studies conducted according to pre-defined criteria such as the Scoliosis Research Society (SRS) and the international Society on Scoliosis Orthopedic and Rehabilitation Treatment (SOSORT) criteria. Future studies should increase their focus on participant outcomes, adverse effects, methods to increase compliance, and usefulness of physiotherapeutic scoliosis specific exercises added to bracing.

PLAIN LANGUAGE SUMMARY

Braces for idiopathic scoliosis in adolescents

Review question

We reviewed the evidence about the effect of bracing on pulmonary disorders (lung diseases), disability, back pain, quality of life, and psychological and cosmetic issues in adolescent with idiopathic scoliosis. We found seven studies. We looked at randomized controlled trials (RCTs) and prospective controlled cohort studies (CCTs).

Background

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Scoliosis is a condition where the spine is curved in three dimensions (from the back the spine appears to be shaped like an 's' and the trunk is deformed). It is often idiopathic, which means the cause is unknown. The most common type of scoliosis is generally discovered around 10 years of age or older, and is defined as a curve that measures at least 10° (called a Cobb angle; measured on x-ray). Because of the unknown cause and the age of diagnosis, it is called adolescent idiopathic scoliosis (AIS).

While there are usually no symptoms, the appearance of AIS frequently has a negative impact on adolescents. Increased curvature of the spine can present health risks in adulthood and in older people. Braces are one intervention that may stop further progression of the curve. They generally need to be worn full time, with treatment lasting until the end of growth (most frequently, from a minimum of two to four/five years). However, bracing for this condition is still controversial, and questions remain about how effective it is.

Study characteristics

This review included seven studies, with a total of 662 adolescents of both genders. AIS from 15° to more than 45° curves were considered. Elastic, rigid (polyethylene), and very rigid (polycarbonate) braces were studied. The evidence is current to October 2013. Funding sources were not reported or external governmental or scientific agencies.

Key results

We did not find any results on pulmonary disorders and disability. Quality of life was not affected during brace treatment (very low quality evidence); quality of life, back pain, and psychological and cosmetic issues did not change in the long term (very low quality evidence). Rigid bracing seems effective in 20° to 40° curves (low quality evidence), elastic bracing in 15° to 30° curves (low quality evidence), and very rigid bracing in high degree curves above 45° (very low quality evidence); rigid was more successful than an elastic bracing (low quality evidence), and a pad pressure control system did not increase results (very low quality evidence). No specific harms were reported.

Primary outcomes such as pulmonary disorders, disability, back pain, psychological and cosmetic issues, and quality of life should be better evaluated in the future. Side effects, as well as the usefulness of exercises and other adjunctive treatments to bracing should be studied too.

Quality of the evidence

The evidence was moderate to very low quality. Reason for downgrading were evidence coming from few randomized trials with few participants and many lost at follow-up or from observational prospective controlled studies. An issue in the field of AIS is the high rate of failure of RCTs, since parents want to choose with physicians the preferred treatment for their children. Thus, it is challenging to obtain high quality evidence in this field.

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SUMMARY OF FINDINGS FOR THE MAIN COMPARISON [Explanation]

Brace compared with observation (randomized controlled trial) for idiopathic scoliosis in adolescents

Patient or population: adolescents with idiopathic scoliosis
Settings:
Intervention: brace
Comparison: observation

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Observation (RCT)	Brace				
Quality of life PedsQL scores[1] Follow-up: 2 years	The mean quality of life in the control groups was **83.0 ± 13.2 (0-100)**[2]	The mean quality of life in the intervention groups was **2.1 lower** (7.69 lower to 3.49 higher)	-	111 (1 study)	⊕○○○ **very low**[3,4]	Higher scores indicating a better quality of life
Risk of success Curves remaining below 50° Follow-up: 2 years	**Study population**		**RR 1.79** (1.29 to 2.5)	116 (1 study)	⊕⊕○○ **low**[5]	-
	415 per 1000	**744 per 1000** (536 to 1000)				
	Moderate					
	415 per 1000	**743 per 1000** (535 to 1000)				
Pulmonary disorders, disability, back pain, psychological issues, and cosmetic issues Subjective	**Study population**		Not estimable	0 (0)	See comment	None of the included studies assessed these outcomes

	See comment	See comment				
	Moderate					
	-	-				
Any adverse event Number of participants reporting at least 1 adverse event	See comment	See comment	Not estimable	0 (0)	See comment	None of the included studies assessed this outcome

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: confidence interval; **PedsQL:** Pediatric Quality of Life Inventory; **RCT:** randomized controlled trial; **RR:** risk ratio.

GRADE Working Group grades of evidence
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

[1] PedsQL, a generic quality-of-life instrument used in studies of acute and chronic illness (Varni 2001; Varni 2003).[2] Scores range from 0 to 100, with higher scores indicating a better quality of life.
[3] Unclear risk of selection bias for allocation concealment.
[4] Only one study with 111 participants.
[5] Only one study with 116 participants.

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BACKGROUND

Description of the condition

Scoliosis is a three-dimensional deformity of the spine and the trunk (Negrini 2012). The most common form is idiopathic scoliosis (70% to 80% of cases) (Hresko 2013; Negrini 2012). Adolescent idiopathic scoliosis (AIS) is discovered at 10 years of age or older (Hresko 2013), and is defined as a curve of at least 10°, measured on a standing radiograph using the Cobb technique (Negrini 2012). While the prevalence of AIS is 0.9% to 12% in the general population (Grivas 2006), almost 10% of people diagnosed with AIS will require some form of treatment. Furthermore, up to 0.1% of the population is at risk of surgery (Lonstein 2006; Parent 2005). A severe form of AIS is more commonly found in females (80% to 90%). Typically, AIS does not cause any health problems during growth (except for extreme cases). 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 most severe cases, psychological disturbances (Freidel 2002a; Freidel 2002b; MacLean 1989; Reichel 2003). Adolescents are generally treated in an attempt to halt the progressive nature of the deformity. No treatments succeed in full correction to a normal spine, and even reduction of the deformity is difficult (Danielsson 2001a; Lonstein 2006). 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; Negrini 2006a; Weinstein 2003). Problems include reduced QoL, disability, pain, increased cosmetic deformity, functional limitations, pulmonary problems, and possible progression during adulthood (Danielsson 2001a; Danielsson 2003a; Danielsson 2003b; Grivas 2008; Mayo 1994; Negrini 2006a; Pehrsson 1992; Pehrsson 2001; Vasiliadis 2008; Weinstein 2003). Because of this, management of scoliosis also includes the prevention of secondary problems associated with the deformity (Negrini 2006b).

Description of the intervention

Treatment options for the prevention of AIS progression include exercises, bracing, and surgery (Fusco 2011; Lenssinck 2005; Negrini 2003; Negrini 2005; Negrini 2008a; Negrini 2009a; Negrini 2012; Rigo 2006; Romano 2008; Romano 2012; Romano 2013; Rowe 1997). Bracing can be defined as the application of external corrective forces to the trunk. This is usually achieved through rigid supports, but elastic bands are also used (Coillard 2003). Treatment commences when the curve is diagnosed as progressive or exceeds a threshold, which is considered to be above 20° Cobb, usually between 25° and 30° (Lonstein 2006; Negrini 2005; Richards 2005). Braces should generally be worn full-time (at least 20 hours per day) with treatment usually lasting from a minimum of two to four or five years, until the end of bone growth (Katz 2001; Landauer 2003; Rahman 2005; SRS 2006). All this causes a significant impact on the lives of children and adolescents (Climent 1999; Noonan 1997; Odermatt 2003; Ugwonali 2004; Vasiliadis 2006).

How the intervention might work

The mechanical forces and the external and proprioceptive inputs of bracing can reduce unnatural loading and asymmetrical movements and improve neuromuscular control. This facilitates proper spinal growth, neuromotor re-organization, and change of motor behaviours (Castro 2003; Coillard 2002; Grivas 2008; Lupparelli 2002; Negrini 2006c; Odermatt 2003; Smania 2008; Stokes 2006).

Why it is important to do this review

Currently, the bracing of adolescents with AIS is controversial. It is considered standard treatment in continental Europe, but not in many centres of the UK, US, and elsewhere (Altaf 2013; Hresko 2013). Bracing has been widely criticized because there is a paucity of evidence regarding its benefits (Dickson 1999a; Dickson 1999b; Dolan 2007a; Dolan 2007b; Goldberg 1993). Moreover, bracing has been linked to reduced QoL and increased psychological issues (Climent 1999; Fällström 1986; Noonan 1997; Ugwonali 2004; Vasiliadis 2006). To date, reviews on braces have been mainly narrative, have not considered the key issue of evaluating the methodological quality of the studies in the review, and have not included all existing studies (Dolan 2007b; Lenssinck 2005; Rowe 1997). Our previous Cochrane review was based on only two studies and found inconclusive evidence (Negrini 2010a). An update of this review will help clinicians to decide whether the sacrifices required by children to wear braces are indeed worthwhile.

OBJECTIVES

To evaluate the efficacy of bracing for adolescents with AIS versus no treatment or other treatments, on quality of life, disability, pulmonary disorders, progression of the curve, and psychological and cosmetic issues.

METHODS

Criteria for considering studies for this review

Types of studies

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All randomized controlled trials (RCTs) and prospective controlled cohort studies.

Types of participants

We included all participants who were 10 years of age or older (until the end of bone growth) when diagnosed as having AIS. We included only studies in which bone maturity was evaluated by the Risser sign, wrist radiographs, or both. We excluded studies in which participants presented with any type of secondary scoliosis (congenital, neurological, metabolic, post-traumatic, etc.) diagnosed according to the Scoliosis Research Society (SRS) (SRS 2006), and the international Society on Scoliosis Orthopedic and Rehabilitation Treatment (SOSORT) (Negrini 2012), criteria.

Types of interventions

We included all types of rigid, semi-rigid, and elastic braces (defined as devices to apply external corrective forces to the spine and trunk), worn for a specific number of hours per day for a specific number of years. We considered all possible control interventions and comparisons.

Types of outcome measures

Primary outcomes

Pulmonary disorders, disability, back pain, QoL, and psychological and cosmetic issues. We included only validated measures of study outcomes, and we assessed minimal clinically important differences on a case-by-case basis.

Secondary outcomes

Clinical and radiographic parameters (Negrini 2006a; Negrini 2012). Very short (any result before the end of bone growth), intermediate (results at the end of bone growth), and long-term (results in adulthood) outcomes. Progression of scoliosis was measured by:

- Cobb angle in degrees (absolute values);
- number of participants who had progressed by more than 5° Cobb (radiographic measurement error, considered as the minimal clinically important difference) (Negrini 2012);
- risk of success, defined in terms of participants that at the end of treatment were neither treated surgically (fused) nor surpassing specific thresholds considered clinically meaningful (45° or 50°, or both) (Negrini 2012; Richards 2005);
- Adverse effects, as outlined in identified trials.

Search methods for identification of studies

Electronic searches

For this update, we searched the following electronic databases to 17 and 18 February 2015 to identify relevant studies:

- the Cochrane Register of Controlled Trials (CENTRAL, *The Cochrane Library,* which includes Cochrane Back Review Group Trials Register; Issue 1 of 12, January 2015);
- MEDLINE (Ovid SP, 1946 to February week 2 2015);
- MEDLINE In-Process & Other Non-Indexed Citations (Ovid SP, 13 February 2015);
- EMBASE (Ovid SP, 1980 to week 7 2015);
- Cumulative Index to Nursing and Allied Health Literature (CINAHL; EBSCO, 1981 to 18 February 2015);
- PsycINFO (Ovid SP, 2002 to February week 2 2015);
- Physiotherapy Evidence Database (PEDro);
- Cochrane Back Review Group Trials Register (Reference Manager and Cochrane Register of Studies (CRS));
- ClinicalTrials.gov;
- World Health Organization (WHO) International Clinical Trials Registry Platform (WHO ICTRP);
- PubMed.

As with the original review, we used the search strategies recommended by the Cochrane Back Review Group for the identification of RCTs (Furlan 2009), and adapted them to include cohort studies. The Cochrane Back Review Group Trials Search Co-ordinator developed the strategies and used a combination of controlled vocabulary terms (e.g. MeSH terms) and keywords to describe methodology, disorders, and treatment. These methods were consistent with the Chapter 6 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). Appendix 1, Appendix 2, and Appendix 3 show the strategies for each database.

Searching other resources

We also included the following strategies:

- reference lists of all relevant papers;
- main electronic sources of ongoing trials (National Research Register, meta-Register of Controlled Trials; Clinical Trials);
- grey literature, including conference proceedings, PhD theses, and unpublished work conducted by manufacturers that were likely to contain trials relevant to the review;
- contacted investigators and authors in this field for information on unpublished or incomplete trials.

All searches included non-English language studies. When considered likely to meet inclusion criteria, we translated studies published in languages other than English.
Appendix 4 and Appendix 5 show the sources handsearched and the years considered.

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Data collection and analysis

Selection of studies

Two review authors (JBS, NC) independently evaluated the search results by reading the titles; two other review authors (TB, TM) independently reviewed the abstracts of the remaining papers. We obtained potentially relevant studies in full text and two review authors (TK, FZ) independently assessed them for inclusion. None of the papers was reviewed by any of the authors who may have written the original papers. At all stages, we resolved disagreements through discussion. The lead review author (SN) solved any persisting disagreements.

Data extraction and management

We prepared a standardized data extraction form, which we used to extract data from the included papers. Two review authors (SM, FZ) independently extracted data on the population, study characteristics, and results added to Review Manager 5.3 (RevMan 2012). We discussed any disagreements, and consulted the lead review author (SN) if disagreements persisted. We summarized key findings in a narrative format and assessed for inclusion in a meta-analysis where possible.

Clinical relevance of results

The review authors assessed each trial for its clinical relevance by using the five questions outlined by Shekelle 1994, and recommended by the Cochrane Back Review Group (Furlan 2009; Appendix 6). We assessed all important outcomes for each comparison. The main conclusions were clinical, because our main aim was to give clinicians state-of-the-art information, according to relevant studies on this issue.

Assessment of risk of bias in included studies

We assessed the risk of bias of RCTs and controlled clinical trials (CCTs) in this review using the 12 criteria recommended by the Cochrane Back Review Group (Furlan 2009; Higgins 2011), as outlined in Appendix 7. We used the Newcastle-Ottawa Scale (NOS scale) to assess the prospective cohort studies with a control group (Wells 2008). The NOS scale assesses three broad areas: selection bias, attrition bias, and detection bias. See Appendix 8 for details. For each included study, each type of bias was rated as high, low, or unclear and entered into the risk of bias table.

Two review authors, one with methodological expertise and one with content expertise, independently assessed the risk of bias of the included studies. The review authors resolved any disagreements by discussion, including input from a third independent review author if required. Risk of bias assessment was not blinded to trial authors, institution, or journal.

Measures of treatment effect

We analysed dichotomous outcomes by calculating the risk ratio (RR) for each trial, with the uncertainty in each result expressed with 95% confidence intervals (CI). We analysed continuous outcomes by calculating the mean difference (MD) or the standardized mean difference (SMD) with 95% CI.

Data synthesis

Meta-analysis was not performed because the retrieved studies were too heterogeneous with regards to the study design, types of comparisons, populations included, and braces applied (elastic, rigid, very rigid). Therefore, we did not perform the pre-planned investigations of heterogeneity, sensitivity analysis excluding studies with high risk of bias, and subgroup analysis for studies at low risk of bias. We assessed the overall quality of the evidence for each outcome. We used an adapted GRADE approach, as recommended by the Cochrane Back Review Group (Furlan 2009).

Factors that may decrease the quality of the evidence are study design and risk of bias, inconsistency of results, indirectness (not generalizable), imprecision (sparse data), and other factors (e.g. reporting bias and publication bias). The quality of the evidence for a specific outcome was downgraded by a level, according to the performance of the studies against these five factors.

- **High quality evidence:** there are consistent findings among at least 75% of RCTs with low risk of bias, consistent, direct, and precise data and no known or suspected publication biases. Further research is unlikely to change either the estimate or our confidence in the results.
- **Moderate quality evidence:** one of the domains is not met. Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
- **Low quality evidence:** two of the domains are not met. Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
- **Very low quality evidence:** three of the domains are not met. We are very uncertain about the results.
- **No evidence:** no RCTs were identified that addressed this outcome.

RESULTS

Description of studies

Results of the search

We found 2479 titles with the electronic search (Figure 1), 13 studies with the handsearch, and 40 titles by searching Conference

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Proceedings and websites. After removing duplicates, we screened 859 titles and excluded 706 based on titles and 10 after reviewing the abstracts. We retrieved 143 full texts. We excluded 135 studies, one of which because we were unable to retrieve the full paper (Wessberg 2011). We wrote to the principal investigators but they did not respond. Both Coillard 2012 and Lusini 2013 agreed to send the final versions of articles that were under review for publication. Lusini 2013 has since been published. This resulted in seven included studies, two of which were reported in the original version of this review. Two studies added to Studies awaiting classification (Guo 2014; Wiemann 2014).

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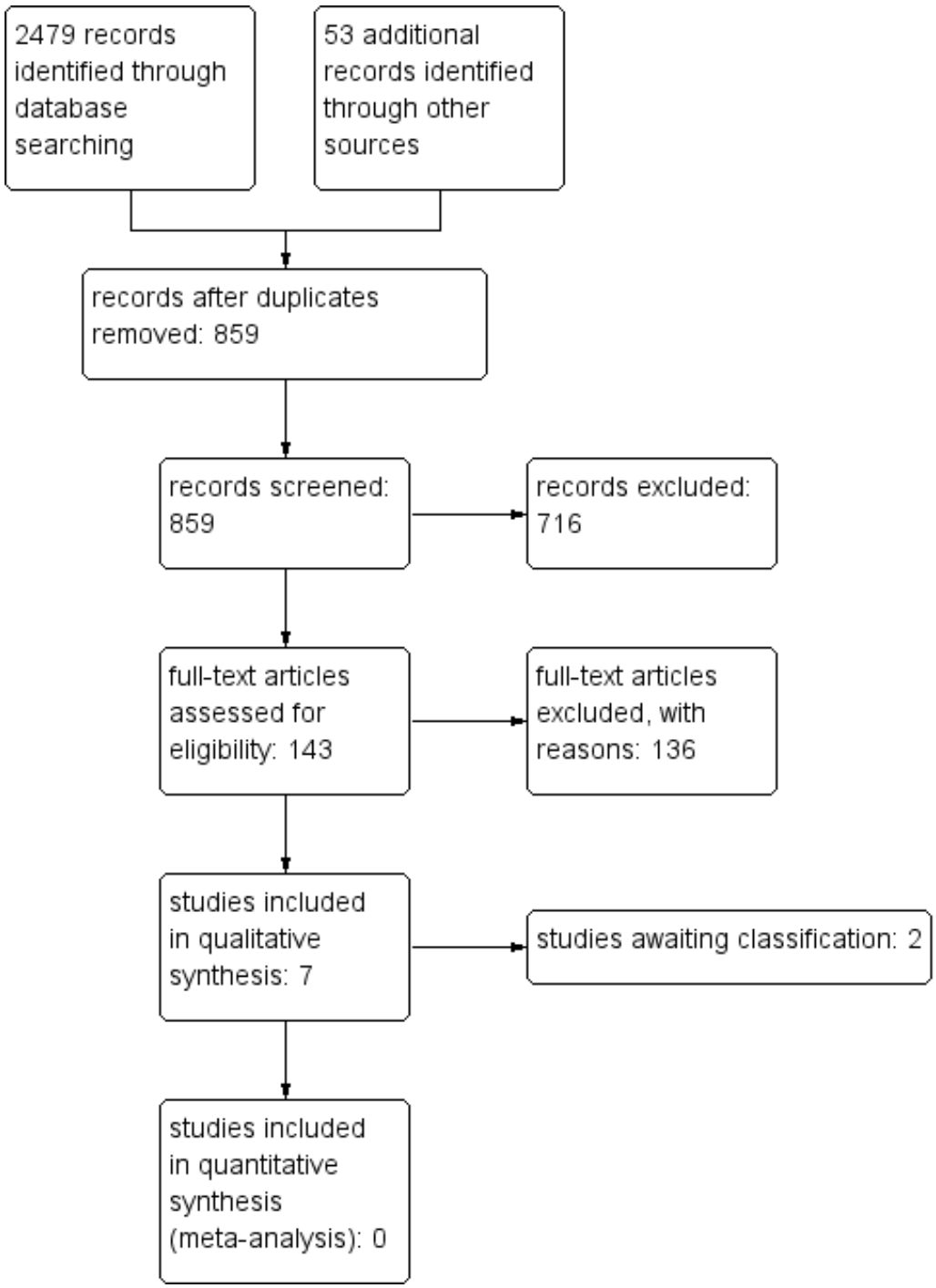
Figure 1. Study flow diagram.



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Included studies

Seven articles met our inclusion criteria: five were planned as RCTs (Bunge 2008; Coillard 2012; Lou 2012; Weinstein 2013a; Wong 2008), and two as prospective controlled trials (Lusini 2013; Nachemson 1995). Two RCTs failed due to very low recruitment of participants (Bunge 2010; Weinstein 2013a).

The RCT by Weinstein 2013a focused on 25° to 40° curves. Unfortunately, 64.7% of adolescents refused to participate and 21% of adolescents and their parents rejected randomization; other adolescents were lost for numerous reasons. The final percentage of participants that could be allocated to the randomized arm was 10.6%, including 0.9% that crossed over groups. Due to this low inclusion rate, the authors extended the inclusion criteria to include adolescents with 20° curves. In addition, they transformed the study into a prospective controlled trial, including a randomized arm. This study was considered both as a prospective non-randomized study with the all sample (Weinstein 2013a), and as randomized trial considering only the sub-sample that was randomized (Weinstein 2013b).

Bunge 2010 aimed to recruit adolescents and compare braces with observation only; the study failed completely during the recruitment phase; so we excluded it from further consideration.

Thus, we included four randomized controlled trials/arms (Coillard 2012; Lou 2012; Weinstein 2013b; Wong 2008), and three prospective controlled trials (Lusini 2013; Nachemson 1995; Weinstein 2013a). One controlled prospective paper had a follow-up at 16 years in a sub-group of adolescents (Nachemson 1995).

Nachemson 1995 was a worldwide collaboration including hospitals from two continents; they observed two groups of clinicians, where the first group believed in the effectiveness of treatment with a brace, and the second group firmly believed that a brace was ineffective and thus managed people with careful observation; two centres of this last group treated adolescents with lateral electrical surface stimulation.

Types of treatments and comparisons: Braces included elastic bands (Coillard 2012; Wong 2008), rigid (polyethylene) (Lou 2012; Nachemson 1995; Weinstein 2013a; Weinstein 2013b; Wong 2008), and very rigid (polycarbonate) thoraco-lumbo-sacral orthosis (Lusini 2013). Two studies compared bracing with observation (Coillard 2012; Weinstein 2013a; Weinstein 2013b), one study compared bracing plus physiotherapeutic-specific scoliosis exercises versus observation (Lusini 2013). One study compared rigid bracing with observation or electrical stimulation (Nachemson 1995). Two studies compared two different types of braces: rigid versus an elastic soft brace (Wong 2008), and two different rigid braces with the same number of hours wearing the brace every day (Lou 2012).

Duration of the trials: the duration was different among all included studies, with the range being between one and five years. Coillard 2012 had a follow-up at five years post-randomization, Lou 2012 had follow-up at three years, and Lusini 2013 had follow-up at two to nine years. In Nachemson 1995, after being treated until maturity (up to four years), a subset of all Swedish adolescents were followed up for 16 years after treatment (range 10.9 to 19.4 years), including a braced (Malmö; 41 participants) and observed (Göteborg; 65 participants) group.

Participants: 662 participants were included, of these 483 were treated with a brace, 133 observed, and 46 were prescribed a control treatment different from bracing (electrical stimulation) (Appendix 9). Studies were not completely homogeneous in terms of population characteristics. The mean age was approximately 12.5 years for all studies except Lusini 2013 (mean age above 14 years). In most studies, Cobb degrees were between 20° and 40°, apart from the studies of Coillard 2012 (15° to 30°) and Lusini 2013 (greater than 45°). The two studies evaluating elastic bracing focused on low degree curves (15° to 30° (Coillard 2012), and 20° to 30° (Wong 2008), while those using very rigid bracing focused on very high degree curves greater than 45° (Lusini 2013). Lou 2012 described neither the Cobb angles nor the age of the participants.

Outcomes: of the primary outcomes considered in this review, only QoL modifications due to bracing were considered by three papers: Weinstein 2013b used the PedsQL score (Varni 2001; Varni 2003), Nachemson 1995 used the SRS22 (Asher 2003a; Asher 2003b) and the 36-item Short Form (SF=36) (Ware 1992; Wiklund 1991), and Wong 2008 used a purpose-designed questionnaire. All the studies focused on the secondary outcome, scoliosis progression.

Countries in which the studies were conducted: one RCT was conducted in Hong Kong (Wong 2008), two in Canada (Coillard 2012; Lou 2012), and one was a multicentre study conducted in the US and Canada (Weinstein 2013b). One prospective cohort study was a multinational study conducted in three centres in the UK, four centres in the US, one centre in Canada, and two centres in Sweden (Nachemson 1995). The other prospective study was performed in Italy (Lusini 2013).

See Characteristics of included studies.

Excluded studies

We excluded 136 papers for the following main reasons: 45 were retrospective, 37 were prospective but without concurrent controls, and 53 were excluded for other reasons. Bunge 2008 was an RCT, but was excluded from the final analysis because of the low numbers of participants that agreed to participate and be randomized.

See Characteristics of excluded studies.

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Risk of bias in included studies

See Figure 2 and Figure 3

Figure 2. Methodological quality summary: review authors' judgements about each methodological quality item for each included study.

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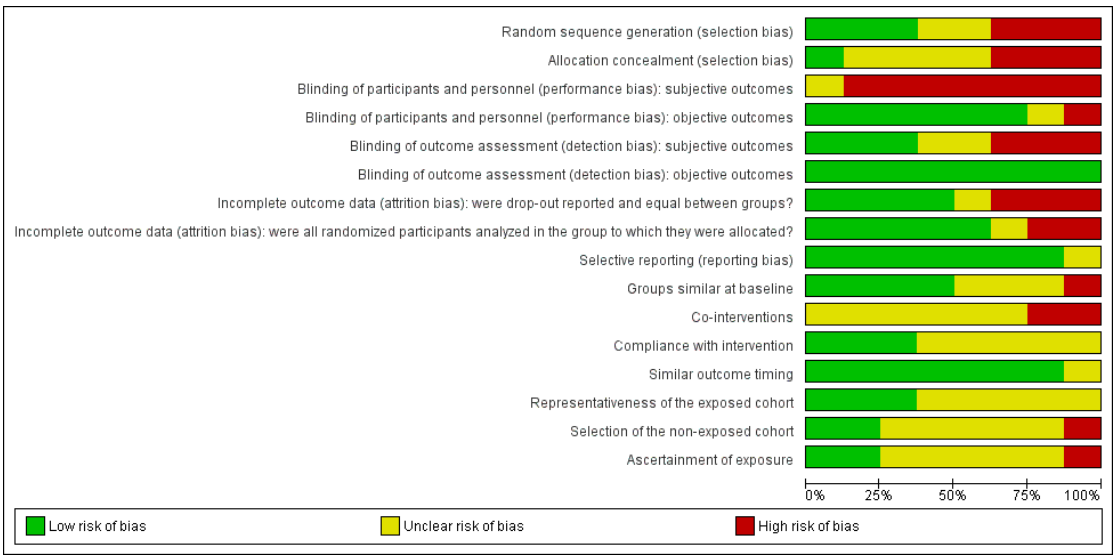
Figure 3. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.



Allocation

We judged the method of random sequence generation as low risk of bias in two RCTs (Coillard 2012; Weinstein 2013b). Random sequence generation was unclear in the other two RCTs (Lou 2012; Wong 2008). The allocation concealment was at low risk of bias in one RCT (Coillard 2012), and unclear in the remaining studies. It was at high risk of bias in the observational studies.

Blinding

Neither the RCTs nor the prospective cohort studies could be blinded for participants and providers because of the type of intervention assessed (brace). The risk of detection bias was high for all the studies for subjective outcomes (e.g. QoL or disability) and low for objective outcomes (e.g. Cobb degrees or scoliosis progression). The outcome assessor was not blinded in Coillard 2012, and was blinded in Weinstein 2013a, whereas blinding of the assessor was not reported in all other studies. Consequently, for subjective outcomes (e.g. self reported pain), we judged the risk of detection bias to be high for Coillard 2012, low for Weinstein 2013a, and unclear in the other studies, For objective outcomes, we rated detection bias as low because they are unlikely to be biased by lack of blinding.

Incomplete outcome data

Three RCTs reported no drop-outs (Lou 2012; Weinstein 2013b; Wong 2008). We judged Coillard 2012 at high risk of attrition bias because there was a high rate of drop-outs and this was unbalanced between groups. In two of the prospective cohort studies, the percentage of loss at follow-up was unbalanced between groups (21% in the experimental group and 7% in the control group in Nachemson 1995; 7.7% in the experimental group and 44% in the control group in Lusini 2013). However, Lusini 2013 performed an intention-to-treat (ITT) analysis with worst-case analysis considering loss at follow-up as a failure for the outcome 'improvement', and as a success for the outcome 'scoliosis progression/fusion'. Consequently, we judged this study to be at low risk of attrition bias. We judged the Weinstein 2013a paper at low risk of bias because there was no loss at follow-up.

Selective reporting

All studies were free of selective reporting.

Other potential sources of bias

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In terms of group similarity at baseline, in two RCTs, groups were similar for the main prognostic factors (Coillard 2012; Wong 2008), in one RCT, no information was reported about the baseline characteristics of participants (Lou 2012). In one prospective cohort study, the brace group had more participants with severe scoliosis, fewer participants with imbalance, and fewer participants with menarche at baseline compared with the electrical stimulation or observation-only groups (Nachemson 1995). Bunge 2010, Lusini 2013, and Weinstein 2013a reported no information about the similarity or differences of participants at baseline.

Two of the observational studies did not adjust for the most important confounding factors. Weinstein 2013a used propensity scores to reduce the effect of treatment selection bias, so we judged this study at low risk of bias due to confounding. Two studies did not report information on compliance and co-interventions. Weinstein 2013a assessed compliance by temperature monitor data and self reported diary, so we judged it as being at low risk of bias due to non-compliance. The timing of outcome assessment was similar across groups in all studies.

Effects of interventions

See: **Summary of findings for the main comparison** Brace compared with observation (randomized controlled trial) for idiopathic scoliosis in adolescents; **Summary of findings 2** Bracing compared with observation (cohort studies) for idiopathic scoliosis in adolescents; **Summary of findings 3** Brace and exercise compared with observation in high degree curves (cohort study) for idiopathic scoliosis in adolescents; **Summary of findings 4** Rigid versus elastic brace (randomized controlled trial) for idiopathic scoliosis in adolescents

1. Brace versus observation (randomized controlled trials)

Primary outcome measures

Pulmonary disorders, disability, back pain, psychological issues, and cosmetic issues

No studies assessed pulmonary disorders, disability, back pain, psychological issues, and cosmetic issues.

Quality of life

Two years' follow-up: Weinstein 2013b (111 participants) found that the mean PedsQL did not differ significantly between bracing and observation (MD -2.10, 95% CI -7.69 to 3.49; Analysis 1.1).

Secondary outcome measures

Progression of scoliosis

Two years' follow-up: Weinstein 2013b found the rate of success (curves remaining below 50°) was 38/51 in the brace group and 27/65 in the observation group (RR 1.79, 95% CI 1.29 to 2.50; Analysis 1.2). The results were in favour of brace.

Three years' follow-up: Coillard 2012 reported the rate of success (correction or stabilization, i.e. 5° or less curve progression) as 21/26 in the brace group and 9/21 in the control group(RR 1.88, 95% CI 1.11 to 3.20; Analysis 1.3). The results were in favour of brace.

Five years' follow-up: Coillard 2012 found the rate of success was 19/26 in the brace group and 12/21 in the control group (RR 1.28, 95% CI 0.83 to 1.98; Analysis 1.4). There was no significant difference between groups.

Participants with curves exceeding 45° at maturity: Coillard 2012 found that 3/21 (14.3%) participants in the control group and 3/26 (11.5%) participants in the treated group had Cobb angles that exceeded 45° at the end of study. Weinstein 2013b found that 13/51 participants in the brace group and 38/65 in the observation group reached 50° or more at the end of growth.

Participants who had undergone surgery or received a recommendation for surgery: Coillard 2012 reported that 3/21 (14.3%) immature participants required surgical fusion while in the trial. The mean curve magnitude at the beginning of the treatment in this particular group was 27° (range 20° to 30°) and they all had a Risser sign of 0. In the treated group, 2/26 (7.7%) immature participants were recommended surgery during the study and 1/26 treated participant was recommended surgery after three years following the end of treatment.

Adverse events

No studies assessed adverse events.

2. Brace versus observation or electrical stimulation (prospective cohort studies)

Primary outcome measures

Pulmonary disorders and disability

No studies assessed pulmonary disorders, and disability.

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Quality of life, back pain, and psychological and cosmetic issues

Two years' follow-up: Weinstein 2013a (236 participants) reported that the mean PedsQL for all participants included in the study did not differ significantly between bracing and observation (MD 0.10, 95% CI -3.90 to 4.10; Analysis 2.1).

Long-term (16 years) follow-up: the Swedish cohort of Nachemson 1995 reported 16 years' follow-up with 40 participants in the observation group and 37 participants in the brace group. Using the SRS22, they found no differences between groups for each of the sub-scales and the total score (mean (SD); pain: 4.3 (0.7) with observation versus 4.4 (0.6) with brace; P value = 0.94; self image/appearance: 3.9 (0.8) with observation versus 3.9 (0.7) with brace; P value = 0.98; function/activity: 4.5 (0.5) with observation versus 4.5 (0.5) with brace; P value = 0.60; mental health: 4.1 (0.7) with observation versus 4.1 (0.7) with brace; P value = 0.93; satisfaction with management: 3.7 (1.0) with observation versus 3.8 (0.9) with brace; P value = 0.45; total score: 4.1 (0.5) with observation versus 4.2 (0.4) with brace; P value = 0.91).

Similarly, there were no differences using the SF-36 (mean observation versus brace; physical functioning 94.5 (95% CI 91.9 to 97.1) versus 94.9 (95% CI 92.1 to 97.1); P value = 0.80; role physical: 93.1 (95% CI 87.3 to 98.9) versus 91.9 (95% CI 84.8 to 97.7); P value = 0.94; bodily pain: 75.0 (95% CI 67.4 to 82.5) versus 68.1 (95% CI 60.2 to 74.5); P value = 0.19; general health: 83.7 (95% CI 74.6 to 88.2) versus 79.8 (95% CI 75.1 to 83.6); P value = 0.15; vitality: 69.9 (95% CI 63.3 to 76.1) versus 68.2 (95% CI 61.6 to 73.7); P value = 0.78; social functioning: 91.9 (95% CI 86.7 to 97.0) versus 89.5 (95% CI 83.3 to 94.6); P value = 0.34; emotional aspects: 90.0 (95% CI 82.5 to 97.5) versus 86.5 (95% CI 76.5 to 94.6); P value = 0.79; mental health: 83.5 (95% CI 78.9 to 88.1) versus 81.3 (95% CI 76.2-85.4); P value = 0.51).

Secondary outcome measures

Progression of scoliosis

Two years' follow-up: Weinstein 2013a examined rate of success (curves not evolving to 50° or above) among 146 braced and 96 observed participants. The rate of success was in favour of the bracing group (RR 1.50, 95% CI 1.19 to 1.89; Analysis 2.2).

Three years' follow-up: Nachemson 1995 reported that the success rates (defined as less than 6° increase of the curve) were 80% (95% CI 66% to 88%) for bracing, 46% (95% CI 25% to 56%) for observation, and 39% (95% CI 19% to 59%) for electrical stimulation. When comparing brace with observation, the results favoured the brace group (240 participants; RR 1.75, 95% CI 1.42 to 2.16; Analysis 2.3).

Four years' follow-up: Nachemson 1995 reported that the success rates were 74% (95% CI 52% to 84%) for bracing, 34% (95% CI 16% to 49%) for observation, and 33% (95% CI 12% to 60%) for electrical stimulation (log-rank test P value < 0.0001). When comparing brace with observation, the results favoured the brace group (240 participants; RR 2.22, 95% CI 1.70 to 2.90; Analysis 2.4). A worst-case analysis for the bracing group in which the 23 participants who dropped out from the brace arm were considered to have had failed treatment, maintained a highly significant success in preventing progression of 6° or more until skeletal maturity (log-rank test P value < 0.0005).

Long-term (16 years) follow-up: Nachemson 1995 found that participants braced or observed progressed more than 5° (range 5° to 21°). This progression meant that braced participants returned to the pre-treatment levels (31.9° now versus 33.0° at start). Observed participants (excluding 11 who were braced and six who were fused during growth because of failure) showed an overall progression from the start of treatment of 6.4° (range 5° to 14°).

Adverse events

Two years' follow-up: Weinstein 2013a found no difference between groups in the percentage of participants with any adverse event (RR 1.27, 95% CI 0.96 to 1.67; Analysis 2.5) and in the percentage of participants reporting back pain (which was the most common adverse event) (RR 0.72, 95% CI 0.47 to 1.10; Analysis 2.6). One serious adverse event, a hospitalization for anxiety and depression, was reported in one participant who wore a brace. Adverse events involving the skin under the brace were reported in 12/146 (8%) participants who wore a brace.

3. Brace and exercise versus observation in high-degree curves (prospective cohort study)

Primary outcome measures

Pulmonary disorders, disability, back pain, psychological issues, cosmetic issues, and quality of life

The study did not assess pulmonary disorders, disability, back pain, psychological issues, cosmetic issues, and QoL.

Secondary outcome measures

Progression of scoliosis

Two to nine years' follow up: Lusini 2013 reported that the rate of success (no progression of 5° or more, no fusion, or no waiting list for fusion) was 25/33 in the brace group and 0/10 in observation group in the per-protocol analysis (RR 15.21, 95% CI 1.00 to 230.23; Analysis 3.2) and 31/39 in the brace group and 8/18 in the observation group in the ITT analysis (RR 1.79, 95% CI 1.04 to 3.07; Analysis 3.3). The results were in favour of brace.

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Adverse events

The study did not assess adverse events.

4. Smart brace versus standard rigid brace (randomized controlled trial)

Primary outcome measures

Pulmonary disorders, disability, back pain, psychological issues, cosmetic issues, and quality of life

The study did not assess pulmonary disorders, disability, back pain, psychological issues, cosmetic issues, and QoL.

Secondary outcome measures

Progression of scoliosis

Lou 2012 (12 participants) found no significant difference between the Smart brace and the standard rigid brace. The Cobb angles (mean ± SD) were: pre-brace 33 ± 6° with Smart brace versus 33 ± 6° with standard rigid brace; in brace: 20 ± 5° with Smart brace versus 21 ± 4° with standard rigid brace; three years after: 35 ± 7° with Smart brace versus 38 ± 9° with standard rigid brace. The in-brace correction (% of initial Cobb angle) was 38 ± 3% with Smart brace versus 36 ± 5% with standard rigid brace.
Five years' follow-up: risk of progression (mean ± SD): 60.2 ± 27% with Smart versus 63.4 ± 27% with standard rigid brace. At the end of treatment, the Cobb angle progressed by (mean ± SD) 2.2 ± 1.2° with Smartbrace versus 4.8 ± 8° with standard rigid brace.

Adverse events

The study did not assess adverse events.

Compliance

The participants in the Smart brace group were more likely to wear their brace at the prescribed level during day time activity compared with the standard rigid group (67% with Smart brace versus 54% with standard rigid brace).

5. Rigid brace versus elastic brace (randomized controlled trial)

Primary outcome measures

Pulmonary disorders, disability, back pain, psychological issues, and cosmetic issues

The study did not assess pulmonary disorders, disability, back pain, psychological issues, and cosmetic issues.

Quality of life

While the rigid brace caused significantly more problems with heat (85% with rigid brace versus 27% with elastic brace), as well as difficulties with donning and doffing, the participants using the elastic braces had difficulties with toileting (Wong 2008).

Secondary outcome measures

Progression of scoliosis

Four years' follow-up: Wong 2008 found that, in participants with 20° to 30° Cobb angle before skeletal maturity, a rigid brace showed better results than an elastic brace (SpineCor) (risk of success defined as no progression more than 5°: RR 1.40, 95% CI 1.03 to 1.89; Analysis 4.2).

Adverse events

Wong 2008 did not assess adverse events.

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ADDITIONAL SUMMARY OF FINDINGS *[Explanation]*

Brace compared with observation (cohort studies) for idiopathic scoliosis in adolescents

Patient or population: adolescents with idiopathic scoliosis
Settings:
Intervention: brace
Comparison: observation (cohort studies)

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Observation (cohort studies)	Brace				
Quality of life PedsQL score[1] Follow-up: 2 years	The mean quality of life in the control groups was **83.3 ± 13.3 (0-100)**[2]	The mean quality of life in the intervention groups was **0.1 higher** (3.9 lower to 4.1 higher)	-	236 (1 study)	⊕○○○ **very low**[3]	Higher scores indicating a better quality of life
Risk of success curves remaining below 50° Follow-up: 2 years	**479 per 1000**	**719 per 1000** (570 to 906)	**RR 1.5** (1.19 to 1.89)	242 (1 study)	⊕○○○ **very low**[4]	Highly clinically relevant
Any adverse event number of participants with at least 1 adverse event Follow-up: 2 years	**427 per 1000**	**542 per 1000** (410 to 713)	**RR 1.27** (0.96 to 1.67)	242 (1 study)	⊕○○○ **very low**[4]	-

Pulmonary disorders, disability, back pain, psychological issues, and cosmetic issues subjective or objective	See comment	See comment	Not estimable	0 (0)	See comment	None of the included studies assessed these outcomes

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: confidence interval; **PedsQL:** Pediatric Quality of Life Inventory; **RR:** risk ratio.

GRADE Working Group grades of evidence
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

[1] PedsQL, a generic quality-of-life instrument used in studies of acute and chronic illness (Varni 2001; Varni 2003).
[2] Scores range from 0 to 100, with higher scores indicating a better quality of life.
[3] Only one observational study with 236 participants.[4] Only one observational study with 242 participants.

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Brace and exercise compared with observation in high degree curves (cohort study) for idiopathic scoliosis in adolescents

Patient or population: adolescents with idiopathic scoliosis
Settings:
Intervention: brace and exercise
Comparison: observation in high degree curves (cohort study)

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Observation in high degree curves (Cohort study)	Brace and exercise				
Quality of life	See comment	See comment	Not estimable	0 (0)	See comment	None of the included studies assessed this outcome
Risk of success no progression over 50°, no fusion, no waiting list for fusion	**Study population**		**RR 1.79** (1.04 to 3.07)	57 (1 study)	⊕◯◯◯ **very low**[1,2]	-
	444 per 1000	**796 per 1000** (462 to 1000)				
	Moderate					
	444 per 1000	**795 per 1000** (462 to 1000)				
Any adverse event number of participants with at least 1 adverse event	See comment	See comment	Not estimable	0 (0)	See comment	None of the included studies assessed this outcome

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Pulmonary disorders, disability, back pain, psychological issues, and cosmetic issues subjective or objective	**Study population**		Not estimable	0 (0)	See comment	None of the included studies assessed these outcomes
	See comment	See comment				
	Moderate					
	-	-				

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: confidence interval; **RR:** risk ratio.

GRADE Working Group grades of evidence
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

[1] Lost at follow-up (19.3%), unbalanced between groups: 7.7% in the experimental group, 44.4% in the control group.
[2] Only one study with 57 participants.

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Rigid versus elastic brace (randomized controlled trial) for idiopathic scoliosis in adolescents

Patient or population: adolescents with idiopathic scoliosis
Settings:
Intervention 1: rigid brace
Intervention 2: elastic brace

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Control	Rigid versus elastic brace (RCT)				
Quality of life	See comment	See comment	Not estimable	0 (0)	See comment	None of the included studies assessed this outcome
Risk of success curves remaining below 50° Follow-up: 4 years	**682 per 1000**	**955 per 1000** (702 to 1000)	**RR 1.4** (1.03 to 1.89)	43 (1 study)	⊕⊕◯◯ **low**[1]	-
Any adverse event number of participants with at least 1 adverse event	See comment	See comment	Not estimable	0 (0)	See comment	None of the included studies assessed this outcome
Pulmonary disorders, disability, back pain, psychological issues, and cosmetic issues subjective or objective	See comment	See comment	Not estimable	0 (0)	See comment	None of the included studies assessed these outcomes

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: confidence interval; **RR:** risk ratio.

GRADE Working Group grades of evidence
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

[1] only one study with 43 participants.

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DISCUSSION

Summary of main results

Despite a comprehensive search of published and unpublished literature, we found only seven studies (one failed), which included 662 participants.

We did not find any results on pulmonary disorders and disability. There was moderate quality evidence from one small RCT (111 participants) that QoL did not differ significantly between rigid bracing and observation (Weinstein 2013b); QoL, back pain, and psychological and cosmetic issues did not change in the long term (16 years) (very low quality evidence) (Nachemson 1995). All included papers were consistent in showing that bracing prevented progression (secondary outcome): rigid bracing in 20° 40° curves (moderate quality evidence) (Nachemson 1995; Weinstein 2013a; Weinstein 2013b), elastic bracing in 15° to 30° curves (low quality evidence) (Coillard 2012), very rigid bracing in high degree curves above 45° (very low quality evidence) (Lusini 2013); rigid was more successful than elastic bracing (low quality evidence) (Wong 2008), and a pad pressure control system did not increase results (very low quality evidence) (Lou 2012). Nevertheless, due to the strength of evidence (from low to very low quality), further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate. No specific harms have been reported. The high rate of failure of RCTs demonstrated the huge difficulties in performing RCTs in a field where parents reject randomization of their children: this questions the possibility of consistently increasing the strength of the actual evidence.

Overall completeness and applicability of evidence

The current evidence about brace treatment for AIS is of low to very low quality. Until now, four RCTs have been performed, two comparing two types of braces (Wong 2008; Lou 2012), and two comparing braces versus observation (Coillard 2012; Weinstein 2013b). In Coillard 2012 and Wong 2008, participants had a range of pathology below the most frequent indications for bracing (Negrini 2012), 15-30° (Coillard 2012), and 20° to 30° (Wong 2008). On the contrary, in the classical range of 25° to 40° curves (Negrini 2012; Richards 2005), the implementation of RCTs is challenging. The members of one of the main scientific societies in the field, the SRS, which consists mainly of orthopaedic surgeons, were found to be in equipoise on bracing (Dolan 2007b), and were able to plan an RCT (Weinstein 2013b); conversely, members of the second main society, the conservative experts of SOSORT, rejected the possibility of performing an RCT (Negrini 2009b; Negrini 2012; Negrini 2014); they found this possibility comparable to an RCT on parachutes (Smith 2003). Despite these professional positions, the strongest argument against the possibility of performing RCTs comes from the reality that most parents (70% to 80% of cases) will not allow their children to be randomized. This was the main reason for failure of the two best efforts performed in recent years (Bunge 2008; Negrini 2014; Weinstein 2013a). In fact, while the Dutch RCT failed completely (Bunge 2010), the US trial (Weinstein 2013a), financed with more than USD 5 million by the US Government through the 'National Institute of Arthritis and Musculoskeletal and Skin Diseases', has finally been changed from an RCT to a CCT (Weinstein 2013a). In 2013, the ethical committee requested that the study be stopped due to the evident success of bracing (Weinstein 2013a), and for this reason, it was also possible to report the RCT data. Therefore, the probability of new, future RCTs of bracing versus observation is low. Clinicians in this field will rely on the current low quality evidence for many years to come. Bunge, the main Dutch researcher (an epidemiologist) concluded, "it is harder to perform a RCT that abolishes or postpones a treatment than a RCT that adds a new treatment" (Bunge 2010). Nevertheless, RCTs comparing different types or designs of braces (Lou 2012; Wong 2008), or different approaches have already been done and will presumably be performed in the future.

Apart from the research design used by Alf Nachemson (Nachemson 1995), the SRS Bracing Committee proposed another possible study design to address the methodological criteria for bracing studies (Richards 2005). Compliance and the standard of bracing should also be considered (Grivas 2012; Negrini 2009b). In fact, the wide range of results in brace studies (Dolan 2007a) usually leads to a discussion on the methodology of the study and the type of brace used, but the quality of bracing and participants' management should also be considered (Grivas 2012; Negrini 2009b). These have been addressed by the Society on Scoliosis Orthopaedic and Rehabilitation Treatment (SOSORT) with the Guidelines on "Standards of management of idiopathic scoliosis with corrective braces in daily clinics and in clinical research" (Negrini 2009b). The SRS and SOSORT criteria for bracing should be considered for the methodological and management standards to be followed in future research studies, and will allow meta-analysis to be performed on solid methodological criteria.

Other fields to be explored are the importance of compliance and methods to increase compliance (Donzelli 2012; Katz 2010); the possible usefulness of physiotherapeutic scoliosis (specific or not) exercises (Negrini 2012; Zaina 2009); means to reduce the impact of bracing on participants, even if according to our results there is low quality evidence that it is not different from observation alone (Weinstein 2013a).

Clinical relevance

All included studies strongly mimic the clinical reality (high ecological and external validity). Two studies included only females, which reflects the fact that the majority (80% to 90%) of people with AIS are female (Nachemson 1995; Wong 2008). In fact, the

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limit of the current evidence comes from the difficulty previously discussed in performing a classical RCT (high internal, but usually low external validity).

Generally in the literature, and specifically in the retrieved studies within this review, outcomes other than Cobb degrees are barely considered. This reflects physicians' attitudes that during growth, their focus is on avoiding or at least curbing curve progression (secondary aim) to prevent future problems of QoL, disability, back pain, etc. (primary aims). This approach comes from the fact that scoliosis is progressive during growth, and if the curves surpass 30° Cobb at the end of growth, the risk of health problems in adulthood increases. Consequently, results reported in this review are clinically relevant, according to the current focus in the literature on Cobb degrees as the primary outcome. Nevertheless, the lack of focus on secondary adverse effects of treatment, as well as the absence of long-term, primary outcome results (QoL, disability, pain) must be stressed and addressed in future studies.

No major risks of the intervention have been reported in the literature, apart from skin problems and anxiety (Weinstein 2013a), hot during summer with rigid bracing and difficulties in toileting with the elastic braces, that is, minor adverse effects (Wong 2008).

Quality of the evidence

Overall, the quality of evidence in favour of bracing alone or bracing plus exercise compared to observation or electrical stimulation is from low to very low quality. The included studies for these comparisons were two RCTs with only 47 and 116 participants. One RCT was at high risk of attrition bias, the other trial was at unclear risk of selection bias. The other included studies were three prospective cohort studies, two of which had a high attrition rate and no adjustment for potential confounding factors. In addition, the evidence for comparisons of different types of braces is low: only two RCTs with very small sample size and a high or unclear risk of bias across all domains of bias.

Note that since 80% to 90% of people with AIS are female, the inclusion of one study of only females was not considered to be a source of indirectness (Nachemson 1995; Wong 2008).

Potential biases in the review process

The strength of the review is the extensive and comprehensive searches conducted, including many different sources in many languages. Another strength is its high ecological validity, due to the real-life situations considered in the studies. The main weakness of the review is the absence of strong studies in this field that do not make it possible to reach firm conclusions. Nevertheless, results among the studies included are fairly coherent. Two authors of this review were also authors of one of the primary studies (Lusini 2013); this paper was evaluated by the other review authors.

Agreements and disagreements with other studies or reviews

The previous Cochrane review was based on two studies only (Negrini 2010a; Negrini 2010b). In recent years, a number of well-designed studies have been conducted, and as a whole, the current evidence is much stronger than that presented in the original review.

One "evidence-based review" looked at entirely different outcomes from those considered here: the "rate of surgery" (failure of treatment) in braced groups ranged between 1.4% and 41% (Dolan 2007a). This paper was based on retrospective comparative studies, and on retrospective and prospective case series results, all of which we excluded from the current review. Furthermore, only papers in English were considered, while those adding exercises to bracing were excluded. It was not possible to obtain a good uniformity of methods and outcomes among papers, even if subgroup analysis was attempted. These problems could be overcome following the SRS criteria for bracing studies (Richards 2005). Moreover, excluding papers that add exercises to bracing should not be done in the future, because, according to SOSORT criteria (Negrini 2009b), this is a management criterion to increase compliance. In fact, papers including exercises report very low surgery rates (2% to 7% for efficacy analysis, 10% to 14% for worst - case analysis), comparable to the best results in the bracing papers reported above (Maruyama 2003; Negrini 2008b; Negrini 2009a; Rigo 2003; Weiss 2003).

AUTHORS' CONCLUSIONS

Implications for practice

Due to the important clinical differences among the studies, it was not possible to perform a meta-analysis. We found no studies reporting pulmonary disorders and disability; one study showed that bracing did not change quality of life (QoL) during treatment (moderate quality evidence); QoL, back pain, and psychological and cosmetic issues did not change in the long term (16 years) (very low quality). All included papers were consistent in showing that bracing avoided progression (secondary outcome). Due to the strength of evidence (from moderate to very low, owing to the methodological quality of the studies), a good estimate of the effect remains uncertain. The high rate of failure of randomized controlled trials (RCTs) demonstrates the huge difficulties in performing RCTs in a field where parents reject randomization of their children: this questions the possibility of consistently increasing the strength of the actual evidence.

Implications for research

Due to the difficulties in performing RCTs in this field, "expertise-based" trials, where people are randomized to centres acting

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according to their preferred protocols, are a possible option. Together with controlled prospective trials, another option is studies conducted according to the SRS (Richards 2005) and SOSORT (Negrini 2009b) criteria for bracing to allow comparability, such as prospective multicentre cohort studies or prospective case series of participants treated and not treated. Other similar criteria for different populations would be important to allow future meta-studies to be performed.

Moreover, any future study should significantly widen their focus on participant outcomes (not just radiographic outcomes of scoliosis progression) as well as adverse effects, so that balanced conclusions may be generated. Other fields to be explored are the importance of compliance and methods to increase compliance; the possible usefulness of physiotherapeutic exercises as well as means to reduce the impact of bracing on participants.

ACKNOWLEDGEMENTS

We wish to thank all the Cochrane Back Group Editors, and particularly Vicki Pennick (first edition), Teresa Marin (second edition), and Rachel Couban, for their work and continuous help. Specifically, Rachel Couban who performed all the electronic searches.

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* *Indicates the major publication for the study*

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CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Bunge 2010

Methods	Multicentre randomized controlled trial
Participants	Girls and boys aged 8-15 years whose diagnosis of AIS has been established by an orthopaedic surgeon, who have not yet been treated by bracing or surgery, and for whom further growth of physical height is still expected based on medical examination and maturation characteristics (Risser sign) established by X-ray
Interventions	**Experimental:** Boston brace worn every day 12-23 hours. Participants are usually advised to attend physiotherapy for muscle training and to correct body posture. Physiotherapy alone is not expected to prevent further progression of the curvature. Therefore, participants were free to choose whether they would attend physiotherapy. Although some orthopaedic surgeons prefer to keep people in the hospital for a few days to allow them to become used to wearing the brace, others do not. The orthopaedic surgeons were allowed to apply their own protocol concerning this hospital admission **Control:** people in the control group were not initially braced during the 2-year study, unless their curvature shows more than 10° progression compared with the Cobb angle at inclusion. In this case, the orthopaedic surgeon, participants, and their parents could decide to start brace treatment. The participants in the control group were allowed to attend physiotherapy if they want to, because physiotherapy alone would not prevent further progression of the curvature
Outcomes	Progression in Cobb angle Health-related quality of life
Notes	Study failed in the recruitment phase

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated random numbers
Allocation concealment (selection bias)	Unclear risk	Information not reported
Blinding of participants and personnel (performance bias) subjective outcomes	High risk	Blinding of participants and orthopaedic surgeons for treatment was not possible for the type of intervention
Blinding of participants and personnel (performance bias) objective outcomes	Low risk	Blinding of participants and orthopaedic surgeons for treatment was not possible for the type of intervention but outcome were unlikely to be biased by lack of blinding

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Bunge 2010 (*Continued*)

Blinding of outcome assessment (detection bias) subjective outcomes	Low risk	Quote: "to ensure blinding of the primary outcome, the randomization status of the participants will not be disclosed to these two orthopedic surgeons, who judge the patient's Xrays"
Blinding of outcome assessment (detection bias) objective outcomes	Low risk	Quote: "To ensure blinding of the primary outcome, the randomization status of the participants will not be disclosed to these two orthopedic surgeons, who judge the patient's Xrays"
Incomplete outcome data (attrition bias) were drop-out reported and equal between groups?	Unclear risk	Not applicable. Study failed in the recruitment phase
Incomplete outcome data (attrition bias) were all randomized participants analyzed in the group to which they were allocated?	Unclear risk	Not applicable. Study failed in the recruitment phase
Selective reporting (reporting bias)	Unclear risk	Not applicable. Study failed in the recruitment phase
Groups similar at baseline	Unclear risk	Not applicable. Study failed in the recruitment phase
Co-interventions	High risk	The participants in the control group were allowed to attend physiotherapy if they want to
Compliance with intervention	Unclear risk	Not applicable. Study failed in the recruitment phase
Similar outcome timing	Low risk	Every 4 months for both groups
Representativeness of the exposed cohort	Unclear risk	Not applicable
Selection of the non-exposed cohort	Unclear risk	Not applicable
Ascertainment of exposure	Unclear risk	Not applicable

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Coillard 2012

Methods	Randomized controlled trial
Participants	68 participants diagnosed with AIS and with a Cobb angle 15-30°. Mean age: 12.2 years Radiological confirmation of absence of significant pathological malformation of the spine. All participants had no prior treatment for scoliosis All participants had a suspected high risk of progression: 1. family history of scoliosis or other well knows prognostic factors (Risser, age, menstruation status, etc.) or 2) confirmed progression (Cobb angle increase of 5° in the last 6 months), or both
Interventions	**Experimental:** Dynamic SpineCor brace orthosis, which uses a specific Corrective Movement dependant of the type of the curve. The curve specific Corrective Movement is performed and the orthosis is applied according to definitions contained in the SpineCor Assistant Software. All the health providers need to complete a 2-phase training course before fitting the SpineCor orthosis In order to obtain the neuromuscular integration, the orthosis must maintain and amplify the corrective movement over time. The orthosis must be worn 20 hours a day for a minimum of 18 months to create a neuromuscular integration of the Corrective Movement through active bio-feedback (36 participants) **Control:** no treatment (32 participants)
Outcomes	Percentage of participants who had ≤ 5° curve progression and the percentage of participants who had ≥ 6° progression Percentage of participants who had surgery recommendation/under gone before skeletal maturity Percentage of participants with curves > 45º at maturity
Notes	Follow-up: 5 years post randomization

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Quote: "an independent controller based in Sainte-Justine Hospital in Montreal assigned the patients to the control and treated group based on a random computer generated number table"
Allocation concealment (selection bias)	Low risk	Quote: "an independent controller based in Sainte-Justine Hospital in Montreal assigned the patients to the control and treated group based on a random computer generated number table"
Blinding of participants and personnel (performance bias) subjective outcomes	High risk	Blinding of participants not possible for the type of interventions compared (brace vs. no treatment)
Blinding of participants and personnel (performance bias) objective outcomes	Low risk	Blinding of participants not possible for the type of interventions compared (brace vs. no treatment), but outcomes unlikely to be influenced by lack of blinding

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Coillard 2012 (*Continued*)

Blinding of outcome assessment (detection bias) subjective outcomes	High risk	Quote: "the measurements were done without being blinded to the treatment or control group status"
Blinding of outcome assessment (detection bias) objective outcomes	Low risk	Outcomes unlikely to be influenced by lack of blinding
Incomplete outcome data (attrition bias) were drop-out reported and equal between groups?	High risk	21 (15 (47%) from the control group and 6 (17%) from the brace group) participants were lost due to withdrawal from the study
Incomplete outcome data (attrition bias) were all randomized participants analyzed in the group to which they were allocated?	High risk	Only per-protocol analysis performed
Selective reporting (reporting bias)	Low risk	Results from all pre-specified outcomes were adequately reported
Groups similar at baseline	Low risk	No significant difference at baseline
Co-interventions	Unclear risk	Information not reported
Compliance with intervention	Unclear risk	Information not reported
Similar outcome timing	Low risk	
Representativeness of the exposed cohort	Unclear risk	Not applicable
Selection of the non-exposed cohort	Unclear risk	Not applicable
Ascertainment of exposure	Unclear risk	Not applicable

Lou 2012

Methods	Randomized controlled trial
Participants	12 participants, 10 girls, mean age 12.5 ± 1.7 years, no further description
Interventions	**Experimental:** Smart brace for 12 months and then rigid standard brace for 12 months. Smart brace was a standard brace with a microcomputer system, a force transducer, and an air-bladder control system. The force transducer and air bladder were embedded at the main pressure pad area to control the interface pressure. When the mean pad pressure was less than the target range over a period of 15 minutes the microcomputer system directed air to be pumped into the bladder. Similarly, when the mean pad pressure was greater than the target range over a period of 15 minutes, the microcomputer system caused air to be released from the bladder. The pressure control was to maintain the

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	interface pressure at the prescribed level during daily activities (6 participants) **Control:** standard rigid brace for 24 months (6 participants)
Outcomes	Cobb angle Risk of progression Brace wear time Quality of brace wear
Notes	Follow-up: 3 years after the brace treatment was finished

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	No information reported
Allocation concealment (selection bias)	Unclear risk	No information reported
Blinding of participants and personnel (performance bias) subjective outcomes	Unclear risk	No information reported
Blinding of participants and personnel (performance bias) objective outcomes	Unclear risk	No information reported
Blinding of outcome assessment (detection bias) subjective outcomes	Unclear risk	No information reported
Blinding of outcome assessment (detection bias) objective outcomes	Low risk	No information reported; outcomes unlikely to be influenced by lack of blinding
Incomplete outcome data (attrition bias) were drop-out reported and equal between groups?	Low risk	No lost at follow-up
Incomplete outcome data (attrition bias) were all randomized participants analyzed in the group to which they were allocated?	Low risk	No information reported
Selective reporting (reporting bias)	Low risk	Results from all pre-specified outcomes were adequately reported
Groups similar at baseline	Unclear risk	No information reported

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Lou 2012 (*Continued*)

Co-interventions	Unclear risk	No information reported
Compliance with intervention	Low risk	No significant difference between groups
Similar outcome timing	Low risk	
Representativeness of the exposed cohort	Unclear risk	Not applicable
Selection of the non-exposed cohort	Unclear risk	Not applicable
Ascertainment of exposure	Unclear risk	Not applicable

Lusini 2013

Methods	Prospective controlled cohort study
Participants	57 participants with AIS, at least 1 curve of ≥ 45°, Risser stage 0-4, aged >above 10 years, first evaluation between 1 March 2003 and 31 December 2010, surgical intervention refused
Interventions	**Experimental:** full-time brace treatment. Participants who arrived in the institute for the first time in 2003 and 2004 were treated with either a Risser cast followed by the Lyon brace, or only the Lyon brace if they refused a cast; from 2005, participants were treated with the Sforzesco brace. Braces had to be worn full-time (24 hours per day for the Risser cast, 23 hours for the Lyon/Sforzesco brace for the first year, followed by a 1-hour reduction for 6 months, and then a weaning of 2 hours every 6 months. Physiotherapy-specific exercises were prescribed systematically to all participants, which were to be performed twice a week. Participants were prescribed Scientific Exercises Approach to Scoliosis exercises to be followed up and updated regularly in the institute (every 3 months - exercised then performed autonomously at home or followed by a trainer) (39 participants) **Control:** treatment not accepted or came for a second opinion only (18 participants)
Outcomes	Percentage of participants to have radiographically improved above the measurement error (5°). We considered the main curve (if there was > 1 curve, both were considered main curves if their difference was less than 11° Cobb) and the maximum curve. Treatment success (improvement of ≥ 5°) Treatment failure (either progression of ≥ 5°, or fusion) Clinical and radiographic results: TRACE for aesthetics, Cobb degrees, angle of trunk rotation, and plumb-line distances for the sagittal plane Compliance
Notes	Both per-protocol (treatment completers) and ITT analysis (all participants enrolled, including drop-outs) performed length of follow-up: 2-9 years
Risk of bias	

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Lusini 2013 (*Continued*)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Prospective cohort study
Allocation concealment (selection bias)	High risk	Prospective cohort study
Blinding of participants and personnel (performance bias) subjective outcomes	High risk	Blinding of participants not possible for the type of interventions compared (brace vs. no treatment)
Blinding of participants and personnel (performance bias) objective outcomes	Low risk	Blinding of participants not possible for the type of interventions compared (brace vs. no treatment) but outcomes unlikely to be influenced by lack of blinding
Blinding of outcome assessment (detection bias) subjective outcomes	High risk	Information about blinding of outcome assessor not reported but he was probably not blinded
Blinding of outcome assessment (detection bias) objective outcomes	Low risk	Information about blinding of outcome assessor not reported but he was probably not blinded; but outcomes unlikely to be influenced by lack of blinding
Incomplete outcome data (attrition bias) were drop-out reported and equal between groups?	High risk	11 participants lost at follow-up (19.3%), unbalanced between groups: 7.7% in the experimental group, 44.4% in the control group
Incomplete outcome data (attrition bias) were all randomized participants analyzed in the group to which they were allocated?	Low risk	ITT analysis with worst-case analysis considering lost at follow-up as failure when the outcome "improvement" was addressed and as success when the outcome "scoliosis progression/fusion" was addressed
Selective reporting (reporting bias)	Low risk	Results from all pre-specified outcomes have been adequately reported
Groups similar at baseline	Unclear risk	Data not reported
Co-interventions	High risk	Physiotherapy prescribed only to the experimental group
Compliance with intervention	Unclear risk	Information not reported
Similar outcome timing	Unclear risk	Information not reported

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Lusini 2013 (*Continued*)

Representativeness of the exposed cohort	Low risk	Sample representative of the mean population with scoliosis
Selection of the non-exposed cohort	Low risk	Drawn from the same cohort
Ascertainment of exposure	Low risk	Clinical records

Nachemson 1995

Methods	Multicentre multinational prospective cohort trial. 8 centres enrolled; included only physicians who firmly believed in effectiveness of bracing or who firmly believed that bracing was ineffective. Each physician consecutively enrolled all participants who met the inclusion criteria and prescribed only 1 treatment
Participants	240 girls with AIS; mean age 12.7 years; Cobb angle 30-35°: 42% in the observation group and 65% in the brace group; Cobb angle 20-29°: 58% in the observation group and 35% in the brace group; menarche at baseline: 57% in the observation group and 41% in the brace group; imbalance: 46% in the observational group and 25% in the brace group
Interventions	**Experimental:** plastic brace worn for at least 16 hours per day (111 girls) **Control:** observation only (who received the electrical stimulation referred to in the text) (129 girls)
Outcomes	Failure of treatment as measured by an increase of the curve of ≥ 6°, noted on 2 consecutive roentgenograms performed every 4 months before menarche and every 6 months after menarche
Notes	Length of follow-up: 16 years after maturity

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	High risk	Prospective cohort study
Allocation concealment (selection bias)	High risk	Prospective cohort study
Blinding of participants and personnel (performance bias) subjective outcomes	High risk	Blinding of participants not possible for the type of interventions compared (brace vs. no treatment)
Blinding of participants and personnel (performance bias) objective outcomes	Low risk	Blinding of participants not possible for the type of interventions compared (brace vs. no treatment) but outcomes unlikely to be influenced by lack of blinding

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Blinding of outcome assessment (detection bias) subjective outcomes	Unclear risk	No subjective outcomes measured
Blinding of outcome assessment (detection bias) objective outcomes	Low risk	Roentgenograms read by providers, but objective outcomes unlikely to be influenced by lack of blinding
Incomplete outcome data (attrition bias) were drop-out reported and equal between groups?	High risk	7% lost at follow-up in the control group; 21% lost at follow-up in the experimental group Comment: percentage unbalanced between groups, but worst-case analysis performed
Incomplete outcome data (attrition bias) were all randomized participants analyzed in the group to which they were allocated?	High risk	Quote: "the patients lost at follow-up were included in the survivorship analysis for the time they were in the study" Quote: "the 23 patients who dropped out from the brace group were analysed in the worst-case analysis and considered as treatment failure" Comment: only the participants who dropped out from the experimental group were included in the worst-case analysis
Selective reporting (reporting bias)	Low risk	Results from all pre-specified outcomes have been adequately reported
Groups similar at baseline	High risk	Comparability of cohorts on the basis of the design or analysis: more participants with severe scoliosis (30-35° in the brace group (65% with brace vs. 42% with observation) ; fewer participants with imbalance in the brace group (25% with brace vs. 46% with observation); menarche at baseline: 41% with brace vs. 57% with observation No adjustment for most important confounding factors Comment: differences at the baseline were in favour of the control group
Co-interventions	Unclear risk	Not reported
Compliance with intervention	Unclear risk	Not reported
Similar outcome timing	Low risk	All participants received a roentgenogram every 4 months before menarche and every

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Nachemson 1995 (*Continued*)

		6 months after menarche
Representativeness of the exposed cohort	Low risk	Truly representative of the average adolescents with scoliosis
Selection of the non-exposed cohort	High risk	Drawn from a different source
Ascertainment of exposure	Low risk	Secure record (e.g. clinical records)

Weinstein 2013a

Methods	Multicentre study with a randomized cohort and a preference cohort
Participants	242 adolescents at high risk of AIS progression. 116 adolescents (48%) in the randomized cohort and 126 (52%) adolescents in the preference cohort. The 2 cohorts differed significantly at baseline with respect to sex distribution, the interval between the diagnosis of scoliosis and trial enrolment, the person who first noticed the scoliosis, and the largest degree of apical vertebral rotation Mean age: 12.7 ± 1 years; girls: 91.3%; Cobb angle: 30.4 ± 6.0°; Risser grade 0: 69.2%, 1: 26.7%, 2: 11.2%, 3: 2.1%, 4-5: 0.8%. Thoracic curve: 24.6%, thoracolumbar 13.2%, lumbar 3.7, double major 28.5%, double thoracic 9.1%, thoracic and thoracolumbar 13.6%, triple 7.5%
Interventions	**Experimental:** brace: rigid thoracolumbosacral orthosis, prescribed to be worn for a minimum of 18 hours per day. Participating centres prescribed the type of brace used in their normal clinical practice (146 adolescents) **Control:** observation, no specific treatment (96 adolescents)
Outcomes	Curve progression of ≥ 50°Treatment failure Skeletal maturity without this degree Treatment success (skeletal maturity defined as a Risser grade of 4 for girls or 5 for boys) Quality of life (Pediatric Quality of Live Inventory: PedsQL)
Notes	Length of follow-up: mean 23 months

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	High risk	Observational study: participants chose the preferred treatment
Allocation concealment (selection bias)	High risk	Observational study: participants chose the preferred treatment
Blinding of participants and personnel (performance bias) subjective outcomes	High risk	Blinding of participants and providers not possible for the type of the interventions compared (brace vs. no intervention)

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Blinding of participants and personnel (performance bias) objective outcomes	Low risk	Blinding of participants and providers not possible for the type of the interventions compared (brace vs. no intervention) but outcomes unlikely to be influenced by lack of blinding
Blinding of outcome assessment (detection bias) subjective outcomes	Low risk	Quote: "all radiographic evaluations and outcome determinations were made at the central coordinating centre by two readers who were unaware of the treatment assignment and the treatment received"
Blinding of outcome assessment (detection bias) objective outcomes	Low risk	Quote: "all radiographic evaluations and outcome determinations were made at the central coordinating centre by two readers who were unaware of the treatment assignment and the treatment received"
Incomplete outcome data (attrition bias) were drop-out reported and equal between groups?	Low risk	No lost at follow-up
Incomplete outcome data (attrition bias) were all randomized participants analyzed in the group to which they were allocated?	Low risk	No lost at follow-up
Selective reporting (reporting bias)	Low risk	Results from all pre-specified outcomes have been adequately reported
Groups similar at baseline	Low risk	Quote: "propensity scores will be used to reduce the effect of treatment selection bias (due to nonrandomized treatment assignment and/or crossover) in the estimation of the treatment effect"
Co-interventions	Unclear risk	Information not reported
Compliance with intervention	Low risk	There were no significant between-group differences at baseline, except for the comparisons of sex in the 2 study cohorts (P value = 0.02) Quote: "patients in the bracing arm completed a 2-week brace wear diary between each follow-up visit. Moreover temperature monitor data (date, time stamps, and temperature) were downloaded at least every 6 months by the research coordinator. Temperatures 82.4° or greater 72 indicated that

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Weinstein 2013a (*Continued*)

		the brace was being worn“
Similar outcome timing	Low risk	Every 6 months
Representativeness of the exposed cohort	Low risk	The sample was truly representative of the average adolescents with scoliosis
Selection of the non-exposed cohort	Low risk	The sample has been drawn from the same community as the exposed cohort
Ascertainment of exposure	High risk	Self report data

Weinstein 2013b

Methods	Randomized cohort of a multicentre study including also a preference cohort
Participants	116 adolescents at high risk of AIS progression; mean age: 12.7 ± 1; girls: 87%; Cobb angle: 30.5 ± 6.0°; Risser grade 0: 61%, 1: 22%, 2: 15%, 3: 2%, 4: 1%. Thoracic curve 22%, thoracolumbar 15%, lumbar 3%, double major 33%, double thoracic 5%, thoracic and thoracolumbar 17%, triple 6%
Interventions	**Experimental:** brace: rigid thoracolumbosacral orthosis, prescribed to be worn for a minimum of 18 hours per day. Participating centres prescribed the type of brace used in their normal clinical practice (51 participants) **Control:** observation: no specific treatment (65 participants)
Outcomes	Curve progression of ≥ 50° Treatment failure Skeletal maturity without this degree Treatment success (skeletal maturity defined as a Risser grade of 4 for girls or 5 for boys) Quality of life (Pediatric Quality of Live Inventory: PedsQL)
Notes	Length of follow-up: mean 23 months

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Computer-generated assignment stratified according to curve type (thoracic vs. all others)
Allocation concealment (selection bias)	Unclear risk	No information reported
Blinding of participants and personnel (performance bias) subjective outcomes	High risk	Blinding of participants and providers not possible for the type of the interventions compared (brace vs. no intervention)

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Blinding of participants and personnel (performance bias) objective outcomes	Low risk	Blinding of participants and providers not possible for the type of the interventions compared (brace vs. no intervention) but outcomes unlikely to be influenced by lack of blinding
Blinding of outcome assessment (detection bias) subjective outcomes	Low risk	Quote: "all radiographic evaluations and outcome determinations were made at the central coordinating centre by two readers who were unaware of the treatment assignment and the treatment received"
Blinding of outcome assessment (detection bias) objective outcomes	Low risk	Quote: "all radiographic evaluations and outcome determinations were made at the central coordinating centre by two readers who were unaware of the treatment assignment and the treatment received"
Incomplete outcome data (attrition bias) were drop-out reported and equal between groups?	Low risk	No lost at follow-up
Incomplete outcome data (attrition bias) were all randomized participants analyzed in the group to which they were allocated?	Low risk	No lost at follow-up
Selective reporting (reporting bias)	Low risk	Results from all pre-specified outcomes have been adequately reported
Groups similar at baseline	Low risk	There were no significant between-group differences at baseline
Co-interventions	Unclear risk	Information not reported
Compliance with intervention	Low risk	Quote: "patients in the bracing arm completed a 2-week brace wear diary between each follow-up visit. Moreover temperature monitor data (date, time stamps, and temperature) were downloaded at least every 6 months by the research coordinator. Temperatures 82.4 ° or greater 72 indicated that the brace was being worn"
Similar outcome timing	Low risk	Every six months
Representativeness of the exposed cohort	Unclear risk	Not applicable
Selection of the non-exposed cohort	Unclear risk	Not applicable

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Weinstein 2013b (*Continued*)

Ascertainment of exposure	Unclear risk	Not applicable

Wong 2008

Methods	Randomized controlled trial	
Participants	43 female adolescents diagnosed with progressive scoliosis. Mean age 12.5 years; mean menarche at 12.7 years. Mean Risser's sign 0.4; mean AP Cobb angle: 24.3°	
Interventions	**Experimental:** dynamic orthosis named 'SpineCor' worn for 23 hours per day (22 adolescents) **Control:** conventional rigid spinal orthosis worn 23 hours per day (21 adolescents)	
Outcomes	Adolescents acceptance assessed by feedback questionnaire with 16 questions in visual analogue scale Progression of scoliosis as measured by percentage of participants without documented progression and still managed with the original treatment	
Notes	Length of follow-up: 18 months	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Sequence generation not reported Quote: "Forty-three subjects were recruited and randomly assigned to two groups"
Allocation concealment (selection bias)	Unclear risk	Not stated
Blinding of participants and personnel (performance bias) subjective outcomes	High risk	Blinding of providers not possible for the type of interventions compared (rigid brace vs. dynamic SpineCor brace)
Blinding of participants and personnel (performance bias) objective outcomes	High risk	Blinding of providers not possible for the type of interventions compared (rigid brace vs. dynamic SpineCor brace)
Blinding of outcome assessment (detection bias) subjective outcomes	High risk	No blinding
Blinding of outcome assessment (detection bias) objective outcomes	Low risk	Information not reported; probably not blinded; outcomes unlikely to be influenced by lack of blinding

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Wong 2008 (*Continued*)

Incomplete outcome data (attrition bias) were drop-out reported and equal between groups?	Low risk	No drop-outs
Incomplete outcome data (attrition bias) were all randomized participants analyzed in the group to which they were allocated?	Low risk	No drop-outs
Selective reporting (reporting bias)	Low risk	Results from all pre-specified outcomes have been adequately reported
Groups similar at baseline	Low risk	Groups comparable for mean age, age at menarche, Risser's sign, AP Cobb angle, apical vertebral r otation degrees, Trunk listing
Co-interventions	Unclear risk	Information about co-intervention not reported
Compliance with intervention	Unclear risk	Information about compliance not reported
Similar outcome timing	Low risk	All participants received radiographs after the first month and then every 3 months; all participants completed a feedback questionnaire at 3rd, 9th and 18th months of intervention
Representativeness of the exposed cohort	Unclear risk	Not applicable
Selection of the non-exposed cohort	Unclear risk	Not applicable
Ascertainment of exposure	Unclear risk	Not applicable

AIS: adolescent idiopathic scoliosis; ITT: intention to treat.

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Allington 1996	Retrospective
Andersen 2006	Follow-up retrospective non-controlled study
Avellanet 2006	Case report
Bassett 1986	Retrospective

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(*Continued*)

Bassett 1987	Retrospective
Becchetti 1990	Not controlled
Bernard 2005	Retrospective
Bowen 2001	Prospective with retrospective control group
Brox 2012	Prospective uncontrolled study
Bullmann 2004	Prospective no control group
Bunge 2007	Retrospective
Bunnell 1980	Prospective without control group
Carman 1985	Retrospective
Carr 1980	Follow-up retrospective not controlled study
Cassella 1991	Review
Castro 2003	Not controlled
Charlopain 1998	Retrospective
Cheung 2007	Retrospective
Coillard 1999	Not controlled
Coillard 2003	Not controlled
Coillard 2007	Not controlled
Cottalorda 2005	No end growth results
D'Amato 2001	Prospective with literature control group
Danielsson 2001a	Follow-up with healthy control group
Danielsson 2001b	Follow-up of retrospective study
Danielsson 2006	Follow-up with no relevant data
Den Boer 1999	Prospective controlled with historical cohort
Dickson 1999a	Review

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(*Continued*)

Dobosiewicz 2006	Not controlled
Durham 1990	Retrospective not controlled
Dziri 1991	Retrospective not controlled
Ebenbichler 1994	Review
Edmonsson 1977	Follow-up not controlled
El Sayyad 1994	Randomized controlled trial including juvenile and adolescent idiopathic scoliosis (6-16 years)
Emans 1986	Retrospective not controlled
Feise 2005	Not relevant topic
Fernandez-Feliberti 1995	Prospective controlled including both juvenile and adolescent idiopathic scoliosis (8-15 years old)
Fisher 1987	Prospective with retrospective control group. Controls were matched to pa rticipants
Fällström 1986	Follow-up with no relevant data
Gabos 2004	Retrospective
Gammon 2010	Retrospective study
Geissele 1991	Not relevant topic
Gepstein 2002	Retrospective controlled study
Goldberg 1981	Retrospective
Gore 1981	Screening, not controlled
Green 1986	Retrospective, not controlled
Griffet 1996	Not controlled
Griffet 2000	Not relevant topic
Grivas 2003	Retrospective with literature control group. Included also 2 participants < 10 years
Haefeli 2006	Retrospective follow up
Hanks 1998	Retrospective
Hassan 1983	Not controlled

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(*Continued*)

Hensinger 2007	Editorial
Hopf 1985	Case series
Howard 1998	Retrospective
Janicki 2007	Retrospective
Kahanovitz 1982	Not controlled
Karol 2001	Not controlled
Katz 1997	Retrospective
Keiser 1976	Retrospective
Kohashi 1996	Not relevant topic
Korovessis 2000	Prospective not controlled
Kotwicki 2002	Retrospective not controlled
Kumano 1992	Not controlled
Little 2000	Retrospective
Lonstein 1994	Retrospective
Lou 2004	Not controlled
Lou 2005	Not controlled
Mellencamp 1977	Retrospective
Miller 1984	Retrospective
Minami 1982	Not controlled
Miyasaki 1980	Not controlled
Moe 1970	Retrospective
Mollon 1984	No primary research paper
Montgomery 1989	Retrospective controlled
Montgomery 1990	Retrospective

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(*Continued*)

Mouilleseaux 1984	No primary research paper
Mounier 1984	No primary research paper
Negrini 2007	Prospective with retrospective control group
Noonan 1996	Juvenile participants
O'Donnell 1988	Retrospective
O'Neill 2005	Retrospective
Park 1977	Retrospective
Peltonen 1988	Not controlled
Peterson 1995	Prospective not relevant
Pham 2007	Retrospective
Piazza 1990	Retrospective
Price 1990	Prospective not controlled
Price 1997	Not controlled
Rahman 2005	Prospective not controlled
Rigo 2003	Literature control group
Roach 1998	Retrospective
Robinson 1996	Juvenile scoliosis
Rosso 1998	Not controlled
Rowe 1997	Meta-analysis
Schmitt 1987	Juvenile and adolescent idiopathic scoliosis (7-16 years old)
Schraudebach 1974	Juvenile and adolescent idiopathic scoliosis
Scoloveno 1990	Retrospective
Shirado 1995	Not relevant topic
Skaggs 1996	Letter to the editor

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(*Continued*)

Spoonamore 2004	Retrospective
Tonseth 2005	Retrospective
Trivedi 2001	Retrospective not controlled
Upadhyay 1995	Not controlled
Van Rhijn 2002	Not controlled
Van Rhijn 2003	Retrospective
Veldhuizen 2002	Not controlled
Vijvermans 2004	Retrospective
Watanabe 2005	Not relevant topic
Weigert 2006	Retrospective
Weiss 2003	Retrospective
Weiss 2005	Case series
Weiss 2006	No brace treatment
Wessberg 2011	Incomplete data, only congress abstract
Wever 2002	Not controlled
Wiley 2000	Retrospective
Willers 1993	Follow-up not controlled
Yamauchi 1986	Retrospective follow-up
Ylikoski 1989	Not controlled
Yrjonen 2006	Prospective with retrospective control group

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Characteristics of studies awaiting assessment *[ordered by study ID]*

Guo 2014

Methods	Randomized Controlled Trial according to SRS standardized criteria
Participants	34 females, 10-14 years of age
Interventions	SpineCor elastic brace versus rigid brace
Outcomes	35.0% progressed in SpineCor versus 5.6% in Rigid brace (P = 0.026) At the 4 years follow-up after skeletally maturity, 29.4% of successfully treated by rigid brace showed progression, versus 38.5% in SpineCor (P > 0.05) For both groups, the primary curves were slightly improved at the time of brace weaning, but additionally increased at the latest follow-up
Notes	

Wiemann 2014

Methods	Randomized (by location) Controlled Trial
Participants	37 females, Risser 0, Codd degrees 15-25
Interventions	nighttime Charleston bending brace versus observation
Outcomes	All patients in the observation group progressed to fulltime bracing threshold. In the nighttime bracing group, 29% of the patients did not progress to 25 degrees primary curve magnitude. Rate of progression to surgical magnitude was similar in the 2 groups
Notes	

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DATA AND ANALYSES

Comparison 1. Brace versus observation (RCT)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Quality of life (PedsQL scores)	1	111	Mean Difference (IV, Fixed, 95% CI)	-2.10 [-7.69, 3.49]
2 Risk of success at 2 years	1	116	Risk Ratio (M-H, Fixed, 95% CI)	1.79 [1.29, 2.50]
3 Risk of success at 3 years	1	47	Risk Ratio (M-H, Fixed, 95% CI)	1.88 [1.11, 3.20]
4 Risk of success at 5 years	1	47	Risk Ratio (M-H, Fixed, 95% CI)	1.28 [0.83, 1.98]
5 Any adverse event	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]

Comparison 2. Brace versus observation (cohort studies)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Quality of life (PedsQL score)	1	236	Mean Difference (IV, Fixed, 95% CI)	0.10 [-3.90, 4.10]
2 Risk of success at 2 years	1	242	Risk Ratio (M-H, Fixed, 95% CI)	1.50 [1.19, 1.89]
3 Risk of success at 3 years	1	240	Risk Ratio (M-H, Fixed, 95% CI)	1.75 [1.42, 2.16]
4 Risk of success at 4 years	1	240	Risk Ratio (M-H, Fixed, 95% CI)	2.22 [1.70, 2.90]
5 Any adverse event	1	242	Risk Ratio (M-H, Fixed, 95% CI)	1.27 [0.96, 1.67]
6 Adverse event back pain	1	242	Risk Ratio (M-H, Fixed, 95% CI)	0.72 [0.47, 1.10]

Comparison 3. Brace and exercise versus observation in high degree curves (cohort study)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Quality of life	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
2 Risk of success per protocol at 2-9 years	1	43	Risk Ratio (M-H, Fixed, 95% CI)	15.21 [1.00, 230.23]
3 Risk of success intention to treat at 2-9 years	1	57	Risk Ratio (M-H, Fixed, 95% CI)	1.79 [1.04, 3.07]
4 Any adverse event	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]

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Comparison 4. Rigid versus elastic brace (RCT)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Quality of life	0	0	Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
2 Risk of success at 4 years	1	43	Risk Ratio (M-H, Fixed, 95% CI)	1.40 [1.03, 1.89]
3 Any adverse event	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]

Analysis 1.1. Comparison 1 Brace versus observation (RCT), Outcome 1 Quality of life (PedsQL scores).

Review: Braces for idiopathic scoliosis in adolescents

Comparison: 1 Brace versus observation (RCT)

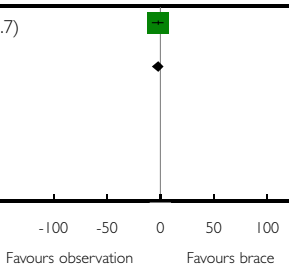
Outcome: 1 Quality of life (PedsQL scores)

Study or subgroup	Brace N	Brace Mean(SD)	Observation N	Observation Mean(SD)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
Weinstein 2013b	50	79.1 (15.9)	61	81.2 (13.7)		100.0 %	-2.10 [-7.69, 3.49]
Total (95% CI)	**50**		**61**			**100.0 %**	**-2.10 [-7.69, 3.49]**

Heterogeneity: not applicable

Test for overall effect: Z = 0.74 (P = 0.46)

Test for subgroup differences: Not applicable



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Analysis 1.2. Comparison 1 Brace versus observation (RCT), Outcome 2 Risk of success at 2 years.

Review: Braces for idiopathic scoliosis in adolescents

Comparison: 1 Brace versus observation (RCT)

Outcome: 2 Risk of success at 2 years

Study or subgroup	Brace n/N	Observation n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Weinstein 2013b	38/51	27/65		100.0 %	1.79 [1.29, 2.50]
Total (95% CI)	**51**	**65**		**100.0 %**	**1.79 [1.29, 2.50]**
Total events: 38 (Brace), 27 (Observation)					
Heterogeneity: not applicable					
Test for overall effect: Z = 3.47 (P = 0.00052)					
Test for subgroup differences: Not applicable					

Analysis 1.3. Comparison 1 Brace versus observation (RCT), Outcome 3 Risk of success at 3 years.

Review: Braces for idiopathic scoliosis in adolescents

Comparison: 1 Brace versus observation (RCT)

Outcome: 3 Risk of success at 3 years

Study or subgroup	Brace n/N	Observation n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Coillard 2012	21/26	9/21		100.0 %	1.88 [1.11, 3.20]
Total (95% CI)	**26**	**21**		**100.0 %**	**1.88 [1.11, 3.20]**
Total events: 21 (Brace), 9 (Observation)					
Heterogeneity: not applicable					
Test for overall effect: Z = 2.35 (P = 0.019)					
Test for subgroup differences: Not applicable					

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Analysis 1.4. Comparison 1 Brace versus observation (RCT), Outcome 4 Risk of success at 5 years.

Review: Braces for idiopathic scoliosis in adolescents

Comparison: 1 Brace versus observation (RCT)

Outcome: 4 Risk of success at 5 years

Study or subgroup	Brace n/N	Observation n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Coillard 2012	19/26	12/21		100.0 %	1.28 [0.83, 1.98]
Total (95% CI)	**26**	**21**		**100.0 %**	**1.28 [0.83, 1.98]**

Total events: 19 (Brace), 12 (Observation)

Heterogeneity: not applicable

Test for overall effect: Z = 1.10 (P = 0.27)

Test for subgroup differences: Not applicable

Analysis 2.1. Comparison 2 Brace versus observation (cohort studies), Outcome 1 Quality of life (PedsQL score).

Review: Braces for idiopathic scoliosis in adolescents

Comparison: 2 Brace versus observation (cohort studies)

Outcome: 1 Quality of life (PedsQL score)

Study or subgroup	Brace N	Mean(SD)	Observation N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
Weinstein 2013a	144	82 (17)	92	81.9 (14.1)		100.0 %	0.10 [-3.90, 4.10]
Total (95% CI)	**144**		**92**			**100.0 %**	**0.10 [-3.90, 4.10]**

Heterogeneity: not applicable

Test for overall effect: Z = 0.05 (P = 0.96)

Test for subgroup differences: Not applicable

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Analysis 2.2. Comparison 2 Brace versus observation (cohort studies), Outcome 2 Risk of success at 2 years.

Review: Braces for idiopathic scoliosis in adolescents

Comparison: 2 Brace versus observation (cohort studies)

Outcome: 2 Risk of success at 2 years

Study or subgroup	Brace n/N	Observation n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Weinstein 2013a	105/146	46/96		100.0 %	1.50 [1.19, 1.89]
Total (95% CI)	**146**	**96**		**100.0 %**	**1.50 [1.19, 1.89]**
Total events: 105 (Brace), 46 (Observation)					
Heterogeneity: not applicable					
Test for overall effect: Z = 3.43 (P = 0.00060)					
Test for subgroup differences: Not applicable					

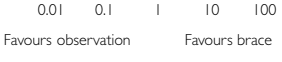
Analysis 2.3. Comparison 2 Brace versus observation (cohort studies), Outcome 3 Risk of success at 3 years.

Review: Braces for idiopathic scoliosis in adolescents

Comparison: 2 Brace versus observation (cohort studies)

Outcome: 3 Risk of success at 3 years

Study or subgroup	Brace n/N	Observation n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Nachemson 1995	89/111	59/129		100.0 %	1.75 [1.42, 2.16]
Total (95% CI)	**111**	**129**		**100.0 %**	**1.75 [1.42, 2.16]**
Total events: 89 (Brace), 59 (Observation)					
Heterogeneity: not applicable					
Test for overall effect: Z = 5.25 (P < 0.00001)					
Test for subgroup differences: Not applicable					



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Analysis 2.4. Comparison 2 Brace versus observation (cohort studies), Outcome 4 Risk of success at 4 years.

Review: Braces for idiopathic scoliosis in adolescents

Comparison: 2 Brace versus observation (cohort studies)

Outcome: 4 Risk of success at 4 years

Study or subgroup	Brace n/N	Observation n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Nachemson 1995	82/111	43/129		100.0 %	2.22 [1.70, 2.90]
Total (95% CI)	**111**	**129**		**100.0 %**	**2.22 [1.70, 2.90]**
Total events: 82 (Brace), 43 (Observation)					
Heterogeneity: not applicable					
Test for overall effect: Z = 5.82 (P < 0.00001)					
Test for subgroup differences: Not applicable					

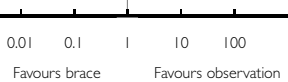
Analysis 2.5. Comparison 2 Brace versus observation (cohort studies), Outcome 5 Any adverse event.

Review: Braces for idiopathic scoliosis in adolescents

Comparison: 2 Brace versus observation (cohort studies)

Outcome: 5 Any adverse event

Study or subgroup	Brace n/N	Observation n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Weinstein 2013a	79/146	41/96		100.0 %	1.27 [0.96, 1.67]
Total (95% CI)	**146**	**96**		**100.0 %**	**1.27 [0.96, 1.67]**
Total events: 79 (Brace), 41 (Observation)					
Heterogeneity: not applicable					
Test for overall effect: Z = 1.68 (P = 0.093)					
Test for subgroup differences: Not applicable					



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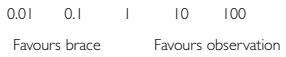
Analysis 2.6. Comparison 2 Brace versus observation (cohort studies), Outcome 6 Adverse event back pain.

Review: Braces for idiopathic scoliosis in adolescents

Comparison: 2 Brace versus observation (cohort studies)

Outcome: 6 Adverse event back pain

Study or subgroup	Brace n/N	Observation n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Weinstein 2013a	33/146	30/96		100.0 %	0.72 [0.47, 1.10]
Total (95% CI)	**146**	**96**		**100.0 %**	**0.72 [0.47, 1.10]**
Total events: 33 (Brace), 30 (Observation)					
Heterogeneity: not applicable					
Test for overall effect: Z = 1.50 (P = 0.13)					
Test for subgroup differences: Not applicable					



Analysis 3.2. Comparison 3 Brace and exercise versus observation in high degree curves (cohort study), Outcome 2 Risk of success per protocol at 2-9 years.

Review: Braces for idiopathic scoliosis in adolescents

Comparison: 3 Brace and exercise versus observation in high degree curves (cohort study)

Outcome: 2 Risk of success per protocol at 2-9 years

Study or subgroup	Brace n/N	Observation n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Lusini 2013	23/33	0/10		100.0 %	15.21 [1.00, 230.23]
Total (95% CI)	**33**	**10**		**100.0 %**	**15.21 [1.00, 230.23]**
Total events: 23 (Brace), 0 (Observation)					
Heterogeneity: not applicable					
Test for overall effect: Z = 1.96 (P = 0.050)					
Test for subgroup differences: Not applicable					

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Analysis 3.3. Comparison 3 Brace and exercise versus observation in high degree curves (cohort study), Outcome 3 Risk of success intention to treat at 2-9 years.

Review: Braces for idiopathic scoliosis in adolescents

Comparison: 3 Brace and exercise versus observation in high degree curves (cohort study)

Outcome: 3 Risk of success intention to treat at 2-9 years

Study or subgroup	Brace n/N	Observation n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Lusini 2013	31/39	8/18		100.0 %	1.79 [1.04, 3.07]
Total (95% CI)	**39**	**18**		**100.0 %**	**1.79 [1.04, 3.07]**
Total events: 31 (Brace), 8 (Observation)					
Heterogeneity: not applicable					
Test for overall effect: Z = 2.11 (P = 0.035)					
Test for subgroup differences: Not applicable					

Analysis 4.2. Comparison 4 Rigid versus elastic brace (RCT), Outcome 2 Risk of success at 4 years.

Review: Braces for idiopathic scoliosis in adolescents

Comparison: 4 Rigid versus elastic brace (RCT)

Outcome: 2 Risk of success at 4 years

Study or subgroup	Rigid brace n/N	Elastic brace n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Wong 2008	20/21	15/22		100.0 %	1.40 [1.03, 1.89]
Total (95% CI)	**21**	**22**		**100.0 %**	**1.40 [1.03, 1.89]**
Total events: 20 (Rigid brace), 15 (Elastic brace)					
Heterogeneity: not applicable					
Test for overall effect: Z = 2.18 (P = 0.030)					
Test for subgroup differences: Not applicable					

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APPENDICES

Appendix 1. MEDLINE and EMBASE search strategies

MEDLINE and MEDLINE Non-Indexed and In-Process Citations

Last searched 17 February 2015
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.
11 cohort analy$.mp.
12 (follow up adj (study or studies)).mp.
13 (observational adj (study or studies)).mp.
14 longitudinal.mp.
15 retrospective.mp.
16 cross sectional.mp.
17 control$.mp.
18 prospective$.mp.
19 volunteer.mp.
20 or/1-19
21 randomized controlled trial.pt.
22 controlled clinical trial.pt.
23 randomized.ab,ti.
24 placebo.ab,ti.
25 drug therapy.fs.
26 randomly.ab,ti.
27 trial.ab,ti.
28 groups.ab,ti.
29 or/21-27
30 (animals not (humans and animals)).sh.
31 29 not 30
32 Animals/
33 Humans/
34 32 not (32 and 33)
35 29 not 34
36 20 not 34
37 35 or 36 or 31
38 exp Spinal Diseases/
39 exp Scoliosis/
40 scoliosis.mp.
41 or/38-40
42 exp Braces/
43 brace$.mp.
44 bracing.mp.
45 exp Orthotic Devices/

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46 exp Orthopedic Equipment/
47 limit 46 to yr="1902 - 1975"
48 or/42-45
49 47 or 48 (
50 exp Adolescent/
51 adolescen$.mp.
52 50 or 51
53 41 and 48 and 52
54 37 and 53
55 limit 54 to yr=2013-2015
56 limit 54 to ed=20131009-20150217
57 55 or 56

EMBASE

Last searched 17 February 2015. For this search, the animal study filter was updated and line 51 was changed from 34 and 51 to 34 or 51. See previous strategy below.
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, device trade name, keyword]
9 (case control adj (study or studies)).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]
10 (follow up adj (study or studies)).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]
11 (observational adj (study or studies)).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]
12 (epidemiologic$ adj (study or studies)).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]
13 (cross sectional adj (study or studies)).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]
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/

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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$)).mp.
48 trial.mp.
49 (versus or vs).mp.
50 or/35-49
51 34 or 50
52 20 or 51
53 exp animals/ or exp invertebrate/ or animal experiment/ or animal model/ or animal tissue/ or animal cell/ or nonhuman/
54 human/ or normal human/ or human cell/
55 53 and 54
56 53 not 55
57 52 not 56
58 exp SPINE/
59 exp Spine Disease/
60 exp SCOLIOSIS/
61 exp Idiopathic Scoliosis/
62 scoliosis.mp.
63 or/58-62
64 exp Brace/
65 brace$.mp.
66 bracing.mp.
67 exp ORTHOTICS/
68 exp orthopedic equipment/
69 or/64-68
70 Adolescent/
71 adolescen#.mp.
72 70 or 71
73 63 and 69 and 72
74 57 and 73
75 limit 74 to yr=2013-2015
76 limit 74 to em=201340-201507
77 75 or 76
Previous search strategy for 2012 and 2013
1 exp Clinical Study/
2 exp Case Control Study/
3 exp Family Study/
4 exp Longitudinal Study/
5 exp Retrospective Study/

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6 exp Prospective Study/
7 exp Cohort Analysis/
8 (cohort adj (study or studies)).mp.
9 (case control adj (study or studies)).mp.
10 (follow up adj (study or studies)).mp.
11 (observational adj (study or studies)).mp.
12 (epidemiologic$ adj (study or studies)).mp.
13 (cross sectional adj (study or studies)).mp.
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

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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 52 and 76

Appendix 2. CENTRAL and CINAHL search strategies

CENTRAL

Last searched 17 February 2015.
#1 MeSH descriptor: [Scoliosis] this term only
#2 scoliosis
#3 #1 or #2
#4 MeSH descriptor: [Braces] this term only
#5 braces in Trials
#6 bracing in Trials
#7 #4 or #5 or #6
#8 #3 and #7
#9 #8 Publication Year from 2013 to 2015, in Trials

CINAHL

Last searched 18 February 2015.
S14 S13 Limiters - Published Date: 20131001-20150231
S13 S12 and S9 and S5
S12 S11 or S10
S11 adolescen*
S10 (MH "Adolescence+")
S9 S8 or S7 or S6
S8 "bracing*"
S7 "brace*"
S6 (MH "Orthoses+")
S5 S4 or S3 or S2 or S1
S4 "scoliosis"
S3 (MH "Scoliosis")
S2 (MH "Spinal Diseases+")

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S1 (MH ”Spine+“)

Appendix 3. PsycINFO, PEDro, Back Group Trials Register, clinical trials registries, and PubMed search strategies

PsycINFO

Last searched 17 February 2015.

1. scoliosis.mp.
2. braces.mp.
3. bracing.mp.
4. 2 or 3
5. 1 and 4
6. limit 5 to yr=2013-2015

PEDro

Last searched 17 February 2015. For this search, the method section was left blank. In the previous searches in 2012 and 2013, the method section was limited to clinical trial.
Abstract & Title: scoliosis
AND
Method: left blank
AND
Published since: 2013

Back Group's Trials Register

Cochrane Register of Studies (CRS)
Last searched 18 February 2015. The purpose of this search was to identify studies not in CENTRAL, therefore only studies not in CENTRAL and dated 2013 and onward were selected.
#1 (scoliosis AND brac*) AND (INREGISTER)
Reference Manager
2012: All non-indexed text fields: (scoliosis AND brac*), published since 2008

ClinicalTrials.gov

Last searched 17 February 2015.
Search term: scoliosis
AND
Intervention: brace or bracing
AND received from 10/10/2013 to 02/17/2015

WHO ICTRP

Last searched 17 February 2015.
Title: brace or bracing
AND
Condition: scoliosis
Date of registration is between 01/10/2013-17/02/2015

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PubMed

Last searched 17 February 2015.
((((braces or bracing))) AND scoliosis) AND ("2013/10/01"[Date - Publication] : "3000"[Date - Publication])

Appendix 4. Journals handsearched

Journal	Language	From	To
Acta Orthopaedica and Traumatologica Hellenica	Greek	1948	2013
Annales Academiae Medicae Silesiensis	Polish	1997	2013
Annales de Kinésithérapie	French	1978	2007
Cahiers de Kinésithérapie	French	1978	1997
Chinesiologia Scientifica	Italian	1978	2013
Chirurgia Narzadow Ruchu i Ortopedia Polska	Polish	1997	2013
Fizjoterapia	Polish	1993	2013
Fizjoterapia Polska	Polish	2001	2013
Ginnastica Medica, Medicina Fisica e Riabilitazione	Italian	1953	2013
Journal of Japanese Orthopaedic Association	Japanese	1963	1995
Journal of Japanese Scoliosis Research Society	Japanese	1988	2006
Journal of Japanese Spine Society	Japanese	1990	2007
Kinésithérapie Scientifique	French	1978	2007
Kultura Fizyczna	Polish	1997	2013
Kwartalnik Ortopedyczny	Polish	1991	2013
Medycyna Manualna	Polish	1997	2013

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(*Continued*)

Ortopedia Traumatologia Rehabilitacja	Polish	1999	2013
Postepy Rehabilitacji	Polish	1997	2013
Rehabilitacja Medyczna	Polish	1997	2013
Rehabilitacja w Praktyce	Polish	2006	2013
Résonances Européennes Du Rachis	French	1994	2010

Appendix 5. Conference proceedings handsearched

Society	Language	From	To	Single years
American Physical Therapy Association	English	-	-	1991; 1992
Back Pain Society	English	-	-	1990
British Scoliosis Society	English	-	-	1992; 1999; 2000; 2006
Chartered Society of Physiotherapists	English	-	-	1994; 1999; 2000; 2006
European Spinal Defomities Society	English	-	-	1994
Groupe Europeen Kinesitherapique de travail de scoliose	French	-	-	1991; 1992
International Research Society of Spinal Deformities published in the research into spinal deformities series	English	1996	2013	-
Phillip Zorab Symposium	English	-	-	1979

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(*Continued*)

Polskie Towarzystwo Ortopedyczne i Traumatologiczne (Polish Orthopedic and Traumatologic Society)	Polish	1978	2006	-
Quebec Scoliosis Society	French/English	-	-	1994
Scoliosis Research Society - SRS Meeting abstracts	English	2001	2012	-
Società Italiana di chirurgia vertebrale - GIS	Italian	1978	2012	-
Society on Scoliosis Orthoapedic and Rehabilitation Treatment - SOSORT Meeting abstracts	English	2003	2013	-
Surface Topography and Spinal Deformity meetings	English	1980	1994	-
World Confederation of Physical Therapy	English	-	-	1991; 1995

Appendix 6. Assessment of clinical 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?

Appendix 7. Criteria for risk of bias assessment for randomized controlled trials (RCTs) and controlled clinical trials (CCTs)

Random sequence generation (selection bias)

Selection bias (biased allocation to interventions) due to inadequate generation of a randomized sequence

There is a low risk of selection bias if the investigators describe a random component in the sequence generation process such as: referring to a random number table, using a computer random number generator, coin tossing, shuffling cards or envelopes, throwing dice,

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drawing of lots, minimization (minimization may be implemented without a random element, and this is considered to be equivalent to being random).

There is a high risk of selection bias if the investigators describe a non-random component in the sequence generation process, such as: sequence generated by odd or even date of birth, date (or day) of admission, hospital or clinic record number; or allocation by judgement of the clinician, preference of the participant, results of a laboratory test or a series of tests, or availability of the intervention.

Allocation concealment (selection bias)

Selection bias (biased allocation to interventions) due to inadequate concealment of allocations prior to assignment

There is a low risk of selection bias if the participants and investigators enrolling participants could not foresee assignment because one of the following, or an equivalent method, was used to conceal allocation: central allocation (including telephone, web-based, and pharmacy-controlled randomization); sequentially numbered drug containers of identical appearance; or sequentially numbered, opaque, sealed envelopes.

There is a high risk of bias if participants or investigators enrolling participants could possibly foresee assignments and thus introduce selection bias, such as allocation based on: using an open random allocation schedule (e.g. a list of random numbers), assignment envelopes were used without appropriate safeguards (e.g. if envelopes were unsealed or non-opaque or not sequentially numbered), alternation or rotation, date of birth, case record number, or other explicitly unconcealed procedures.

Blinding of participants

Performance bias due to knowledge of the allocated interventions by participants during the study

There is a low risk of performance bias if blinding of participants was ensured and it was unlikely that the blinding could have been broken; or if there was no blinding or incomplete blinding, but the review authors judge that the outcome is not likely to be influenced by lack of blinding.

Blinding of personnel/care providers (performance bias)

Performance bias due to knowledge of the allocated interventions by personnel/care providers during the study

There is a low risk of performance bias if blinding of personnel was ensured and it was unlikely that the blinding could have been broken; or if there was no blinding or incomplete blinding, but the review authors judge that the outcome is not likely to be influenced by lack of blinding.

Blinding of outcome assessor (detection bias)

Detection bias due to knowledge of the allocated interventions by outcome assessors

There is low risk of detection bias if the blinding of the outcome assessment was ensured and it was unlikely that the blinding could have been broken; or if there was no blinding or incomplete blinding, but the review authors judge that the outcome is not likely to be influenced by lack of blinding, or:

- for participant-reported outcomes in which the particpant was the outcome assessor (e.g. pain, disability): there is a low risk of bias for outcome assessors if there is a low risk of bias for participant blinding (Boutron 2005);
- for outcome criteria that are clinical or therapeutic events that will be determined by the interaction between participants and care providers (e.g. co-interventions, length of hospitalization, treatment failure), in which the care provider is the outcome assessor: there is a low risk of bias for outcome assessors if there is a low risk of bias for care providers (Boutron 2005);
- for outcome criteria that are assessed from data from medical forms: there is a low risk of bias if the treatment or adverse effects of the treatment could not be noticed in the extracted data (Boutron 2005).

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Incomplete outcome data (attrition bias)

Attrition bias due to amount, nature, or handling of incomplete outcome data

There is a low risk of attrition bias if there were no missing outcome data; reasons for missing outcome data were unlikely to be related to the true outcome (for survival data, censoring unlikely to be introducing bias); missing outcome data were balanced in numbers, with similar reasons for missing data across groups; for dichotomous outcome data, the proportion of missing outcomes compared with the observed event risk was not enough to have a clinically relevant impact on the intervention effect estimate; for continuous outcome data, the plausible effect size (difference in means or standardized difference in means) among missing outcomes was not enough to have a clinically relevant impact on observed effect size, or missing data were imputed using appropriate methods (if drop-outs are very large, imputation using even 'acceptable' methods may still suggest a high risk of bias) (van Tulder 2003). The percentage of withdrawals and drop-outs should not exceed 20% for short-term follow-up and 30% for long-term follow-up and should not lead to substantial bias (these percentages are commonly used but arbitrary, not supported by literature) (van Tulder 2003).

Selective reporting (reporting bias)

Reporting bias due to selective outcome reporting

There is low risk of reporting bias if the study protocol is available and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way, or if the study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified (convincing text of this nature may be uncommon).

There is a high risk of reporting bias if not all of the study's pre-specified primary outcomes have been reported; one or more primary outcomes is reported using measurements, analysis methods or subsets of the data (e.g. subscales) that were not pre-specified; one or more reported primary outcomes were not pre-specified (unless clear justification for their reporting is provided, such as an unexpected adverse effect); one or more outcomes of interest in the review are reported incompletely so that they cannot be entered in a meta-analysis; the study report fails to include results for a key outcome that would be expected to have been reported for such a study.

Group similarity at baseline (selection bias)

Bias due to dissimilarity at baseline for the most important prognostic indicators.

There is low risk of bia*s* if groups are similar at baseline for demographic factors, value of main outcome measure(s), and important prognostic factors (examples in the field of back and neck pain are duration and severity of complaints, vocational status, percentage of people with neurological symptoms) (van Tulder 2003).

Co-interventions (performance bias)

Bias because co-interventions were different across groups

There is low risk of bias if there were no co-interventions or they were similar between the index and control groups (van Tulder 2003).

Compliance (performance bias)

Bias due to inappropriate compliance with interventions across groups

There is low risk of bias if compliance with the interventions was acceptable, based on the reported intensity/dosage, duration, number and frequency for both the index and control intervention(s). For single-session interventions (e.g. surgery), this item is irrelevant (van Tulder 2003).

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Intention-to-treat-analysis

There is low risk of bias if all randomized participants were reported/analysed in the group to which they were allocated by randomization.

Timing of outcome assessments (detection bias)

Bias because important outcomes were not measured at the same time across groups

There is low risk of bias if all important outcome assessments for all intervention groups were measured at the same time (van Tulder 2003).

Other bias

Bias due to problems not covered elsewhere in the table

There is a low risk of bias if the study appears to be free of other sources of bias not addressed elsewhere (e.g. study funding).

Appendix 8. Criteria for the risk of bias assessment of observational studies

Selection bias

Representativeness of the exposed cohort: assess whether the sample is truly representative of the average adolescents with scoliosis; somewhat representative of the average adolescents with scoliosis; selected group of adolescents with scoliosis; no description of the derivation of the cohort. This item was added in the 'Risk of bias' table as 'other source of bias'.
Selection of the non-exposed cohort: assess whether the sample has been drawn from the same community as the exposed cohort; drawn from a different source/community, "no description of the derivation of the non exposed cohort'. This item was added in the 'Risk of bias' table as 'other source of bias'.
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 was added in the 'Risk of bias' table as 'other source of bias'.
Comparability of cohorts on the basis of the design or analysis: either exposed and non-exposed participants must be matched in the design or confounders (or both) 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 risk ratio 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 was assessed in the 'Risk of bias' table under the item 'group similar at baseline'.

Attrition bias

Complete follow-up: assess if: all participants accounted for; participants lost to follow-up unlikely to introduce bias (lost to follow-up 5%); participants lost to follow-up greater than 5% and description provided of those lost. This item was assessed in the 'Risk of bias' table under the item 'incomplete outcome data'.

Detection bias

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 was assessed in the 'Risk of bias' table under the item 'blinding of outcome assessor'.

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Appendix 9. Clinical characteristics of the included studies

	Coillard	Lou	Lusini	Nachemson	Weinstein*		Wong	Total
Type of study	RCT	RCT	QRCT	QRCT	QRCT	(RCT arm)	RCT	-
Population	68	12	57	240	242	116	43	662
Total braced	36	12	39	111	242	51	43	483
Brace active	36	6	39	111	146	51	22	360
Brace control	-	6	-	-	96	-	21	123
Observation	32	-	18	83	-	65	-	133
Electrical stimulation	-	-	-	46	-	-	--	46
Gender								
Males	7	2	11	0	24	15	0	44
Females	40	10	46	240	221	101	43	600
Age								
Mean	12.02	12.05	15.03	12.07	12.07	12.07	12.05	-
SD	02.02	01.07	01.10		01.01	01.01	00.08	-
Min	10	10	10	10	10	10	10.06	-
Max	ND	ND	ND	15	15	15	13.08	-
Bone age								
Risser min	0	NR	0	0	0	0	0	-
Risser max	2	NR	4	4	2	2	2	-
Cobb degrees								
Mean	21	33	52.5	-	30.4	30.5	24.3	-
SD	4.5	6	NR	-	6	6	2.7	-
Min	15	NR	45	20	20	20	20	-

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(*Continued*)

Max	30	NR	93	35	40	40	30	-

max: maximum; min: minimum; ND: not defined; NR: information not retrievable in the study; QRCT: Quasi RCT, i.e. prospective controlled trial; RCT: randomized controlled trial; SD: standard deviation

* The entire study by Weinstein is a QRCT, since it includes 2 arms, 1 RCT, the other QRCT

WHAT'S NEW

Date	Event	Description
19 February 2015	New search has been performed	The literature search has been updated. 5 more studies incorporated and 2 studies added to Studies awaiting classification (Guo 2014; Wiemann 2014).
27 February 2014	New citation required and conclusions have changed	5 new papers have been added: 3 RCTs (Bunge 2008, Lou 2012, Coillard 2012) and two prospective controlled trials (Lusini 2013, Weinstein 2013b). Weinstein 2013b also included a randomized arm (Weinstein 2013a). Since the last version of the review was published the quality of the evidence increased from very low to a range from moderate to very low. It was concluded that results were consistently in favour of bracing

CONTRIBUTIONS OF AUTHORS

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DECLARATIONS OF INTEREST

Negrini S and Romano M are stakeholders of ISICO (Italian Scientific Spine Institute), Milan, Italy.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

We changed the criteria to assess methodological quality of included studies from that described in the protocol to conform to the recommended methods outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011), and to the requirements of Review Manager 5 (RevMan 2012).

INDEX TERMS

Medical Subject Headings (MeSH)

*Braces [adverse effects]; Cohort Studies; Disease Progression; Prospective Studies; Quality of Life; Randomized Controlled Trials as Topic; Scoliosis [*therapy]

MeSH check words

Adolescent; Child; Female; Humans; Male

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