Orthodontic treatment for prominent upper front teeth in children (Review)

Harrison JE, O'Brien KD, Worthington HV

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[Intervention Review]

Orthodontic treatment for prominent upper front teeth in children

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Cochrane Database of Systematic Reviews, Issue 4, 2009 (Status in this issue: *Unchanged*)

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DOI: 10.1002/14651858.CD003452.pub2

This version first published online: 18 July 2007 in Issue 3, 2007.

Last assessed as up-to-date: 14 May 2007. (Help document - [Dates and Statuses](#) explained)

This record should be cited as: Harrison JE, O'Brien KD, Worthington HV. Orthodontic treatment for prominent upper front teeth in children. *Cochrane Database of Systematic Reviews* 2007, Issue 3. Art. No.: CD003452. DOI: 10.1002/14651858.CD003452.pub2.

ABSTRACT

Background

Prominent upper front teeth are an important and potentially harmful type of orthodontic problem. This condition develops when the child's permanent teeth erupt and children are often referred to an orthodontist for treatment with dental braces to reduce the prominence of the teeth. If a child is referred at a young age, the orthodontist is faced with the dilemma of whether to treat the patient early or to wait until the child is older and provide treatment in early adolescence. When treatment is provided during adolescence the orthodontist may provide treatment with various orthodontic braces, but there is currently little evidence of the relative effectiveness of the different braces that can be used.

Objectives

To assess the effectiveness of orthodontic treatment for prominent upper front teeth, when this treatment is provided when the child is 7 to 9 years old or when they are in early adolescence or with different dental braces or both.

Search strategy

The Cochrane Oral Health Group's Trials Register, CENTRAL, MEDLINE and EMBASE were searched. The handsearching of the key international orthodontic journals was updated to December 2006. There were no restrictions in respect to language or status of publication.

Date of most recent searches: February 2007.

Selection criteria

Trials were selected if they met the following criteria:

design - randomised and controlled clinical trials;

participants - children or adolescents (age $\leq$ 16 years) or both receiving orthodontic treatment to correct prominent upper front teeth;

interventions - active: any orthodontic brace or head-brace, control: no or delayed treatment or another active intervention;

primary outcomes - prominence of the upper front teeth, relationship between upper and lower jaws;

secondary outcomes: self esteem, any injury to the upper front teeth, jaw joint problems, patient satisfaction, number of attendances required to complete treatment.

Data collection and analysis

Information regarding methods, participants, interventions, outcome measures and results were extracted independently and in duplicate by two review authors.

The Cochrane Oral Health Group's statistical guidelines were followed and mean differences were calculated using random-effects models. Potential sources of heterogeneity were examined.

Main results

The search strategy identified 185 titles and abstracts. From this we obtained 105 full reports for the review. Eight trials, based on data from 592 patients who presented with Class II Division 1 malocclusion, were included in the review.

Early treatment comparisons: Three trials, involving 432 participants, compared early treatment with a functional appliance with no treatment. There was a significant difference in final overjet of the treatment group compared with the control group of -4.04 mm (95% CI -7.47 to -0.6, Chi^2 117.02, 2 df, $P < 0.00001$, $I^2 = 98.3\%$). There was a significant difference in ANB (-1.35 mm; 95% CI -2.57 to -0.14, Chi^2 9.17, 2 df, $P = 0.01$, $I^2 = 78.2\%$) and change in ANB (-0.55; 95% CI -0.92 to -0.18, Chi^2 5.71, 1 df, $P = 0.06$, $I^2 = 65.0\%$) between the treatment and control groups.

The comparison of the effect of treatment with headgear versus untreated control revealed that there was a small but significant effect of headgear treatment on overjet of -1.07 (95% CI -1.63 to -0.51, Chi^2 0.05, 1 df, $P = 0.82$, $I^2 = 0\%$). Similarly, headgear resulted in a significant reduction in final ANB of -0.72 (95% CI -1.18 to -0.27, Chi^2 0.34, 1 df, $P = 0.56$, $I^2 = 0\%$).

No significant differences, with respect to final overjet, ANB, or ANB change, were found between the effects of early treatment with headgear and the functional appliances.

Adolescent treatment (Phase II): At the end of all treatment we found that there were no significant differences in overjet, final ANB or PAR score between the children who had a course of early treatment, with headgear or a functional appliance, and those who had not received early treatment. Similarly, there were no significant differences in overjet, final ANB or PAR score between children who had received a course of early treatment with headgear or a functional appliance.

One trial found a significant reduction in overjet (-5.22 mm; 95% CI -6.51 to -3.93) and ANB (-2.27 degrees; 95% CI -3.22 to -1.31, Chi^2 1.9, 1 df, $P = 0.17$, $I^2 = 47.3\%$) for adolescents receiving one-phase treatment with a functional appliance versus an untreated control.

A statistically significant reduction of ANB (-0.68 degrees; 95% CI -1.32 to -0.04, Chi^2 0.56, 1 df, $P = 0.46$, $I^2 = 0\%$) with the Twin Block appliance when compared to other functional appliances. However, there was no significant effect of the type of appliance on the final overjet.

Authors' conclusions

The evidence suggests that providing early orthodontic treatment for children with prominent upper front teeth is no more effective than providing one course of orthodontic treatment when the child is in early adolescence.

PLAIN LANGUAGE SUMMARY

Orthodontic treatment for prominent upper front teeth in children

Prominent upper front teeth are an important and potentially harmful type of orthodontic problem. This condition develops when the child's permanent teeth erupt and children are often referred to an orthodontist for treatment with dental braces to reduce the prominence of the teeth. If a child is referred at a young age, the orthodontist is faced with the dilemma of whether to treat the patient early or to wait until the child is older and provide treatment in early adolescence.

The evidence suggests that providing orthodontic treatment, for children with prominent upper front teeth, in two stages does not have any advantages over providing treatment in one stage, when the children are in early adolescence.

BACKGROUND

Orthodontics is the branch of dentistry concerned with the growth of the jaws and face, the development of the teeth and the way the teeth and jaws bite together. It also involves treatment of the teeth and jaws when they are irregular or bite in an abnormal way or both. There are many reasons why the teeth may not bite together correctly. These include the position of the teeth, jaws, lips, tongue, and/or cheeks or may be due to a habit or the way people breath. The need for orthodontic treatment can be decided by looking at the effect any particular tooth position has on the life expectancy of the teeth or the effect that the appearance of the teeth has on how people feel about themselves or both (Shaw 1991).

Prominent upper front teeth (Class II malocclusion) may be due to any combination of the jaw, tooth and/or lip position. The upper jaw (maxilla) can be too far forward or, more usually, the lower jaw (mandible) is too far back. The upper front teeth (incisors) may stick out if the lower lip catches behind them or due to a habit e.g. thumb sucking. This gives the patient an appearance that may be a target for teasing (Shaw 1980). When front teeth stick out (more than 3 mm) they are twice as likely to be injured (Nguyen 1999). Prominent upper front teeth (Class II malocclusion) is one of the most common problems seen by orthodontists and affects about a quarter of 12 year old children in the UK (Holmes 1992). However, there are racial differences. Prominent upper front teeth (Class II malocclusion) are most common in whites of Northern European origin and least common in black and oriental races and some Scandinavian populations (El-Mangoury 1990; Proffit 1993; Silva 2001).

Several dental brace (orthodontic) treatments have been suggested to correct prominent upper front teeth (Class II malocclusions). Some treatments aim to move the upper front teeth backwards whilst others aim to modify the growth of the upper or lower jaw or both to reduce the prominence of the upper front teeth. Treatment can involve the use of one or more types of orthodontic brace. Some braces apply a force directly to the teeth and can either be removed from the mouth or fixed to the teeth, with special glue, during treatment. Other types of brace are attached, via the teeth, to devices (headgear) that allow a force to be applied to the teeth and jaws from the back of the head. Treatment is usually carried out either early (early treatment), when the patients have a mixture of their baby and adult teeth present (around 7 to 11 years of age) or later (adolescent treatment) when all the adult teeth have come into the mouth (around 12 to 16 years of age). In severe cases and some adult patients, orthodontic treatment may need to be combined with jaw surgery to correct the position of one or both jaws.

OBJECTIVES

To assess the effectiveness of orthodontic treatment for prominent upper front teeth, when this treatment is provided when the child is 7 to 9 years old or when they are in early adolescence or with different dental braces or both.

To test the null hypotheses that there are no differences in outcomes between:

- the age at which orthodontic treatment for prominent upper front teeth is carried out;
- different orthodontic interventions for correcting prominent upper front teeth against the alternative that there are.

METHODS

Criteria for considering studies for this review

Types of studies

All randomised and controlled clinical trials of orthodontic treatments to correct prominent upper front teeth.

Types of participants

Children or adolescents (age 16 years or less) or both receiving orthodontic treatment to correct prominent upper front teeth. Trials including patients with a cleft lip or palate or both, or other craniofacial deformity/syndrome were excluded as were trials that had recruited less than 80% children or adolescents or patients who had previously received surgical treatment for their Class II malocclusion.

Types of interventions

- Active interventions: Orthodontic braces (removable, fixed, functional) or head-braces.
- Control: No treatment, delayed treatment or another active intervention.

Types of outcome measures

- Primary: Prominence of the upper front teeth (overjet measured in mm or by any index of malocclusion).
- Secondary: Relationship between upper and lower jaws, self esteem, patient satisfaction, any injury to the upper front teeth, jaw joint problems, number of attendances required to complete treatment.
- Harms: Health of the gums, damage to the teeth e.g. tooth decay.

We recorded these outcomes at all ages and the most common endpoints that were reported. If we identified harms these were recorded and reported in descriptive terms.

Search methods for identification of studies

We developed detailed search strategies for the identification of studies for each database searched. These were initially based on the search strategy developed for MEDLINE and then revised appropriately for each database. Our subject search strategy used a combination of controlled vocabulary and free text terms based on the search strategy for MEDLINE, in conjunction with phases 1 and 2 of the Cochrane Sensitive Search Strategy for Randomised Controlled Trials (RCTs) as published in the *Cochrane Handbook for Systematic Reviews of Interventions* 4.2.6, Appendix 5b. See [Appendix 1](#).

Databases searched

We searched the following databases:

Cochrane Oral Health Group's Trials Register (to February 2007)
Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library* 2007, Issue 1)
MEDLINE (1966 to February 2007)
EMBASE (1980 to February 2007).

Handsearching

We obtained articles that were identified as part of the Cochrane Oral Health Group's handsearching programme, from the following journals: *American Journal of Orthodontics and Dentofacial Orthopedics*, *The Angle Orthodontist*, *European Journal of Orthodontics*, and *Journal of Orthodontics*. In addition, we handsearched the following journals from their inception to December 2006: *Seminars in Orthodontics* (from 1995 to December 2006), *Clinical Orthodontics and Research* (from 1998 to December 2006) and *Australian Journal of Orthodontics* (from 1956 to December 2006). The bibliographies of the clinical trials that we identified were checked for references to trials published outside the handsearched journals, including personal references.

Language

Databases were searched to include all languages and we would have attempted translated any non-English language papers that we found.

Unpublished studies

The first named authors of all trial reports were contacted in an attempt to identify unpublished studies and to obtain any further information about the trials.

Data collection and analysis

Study selection

Two review authors (Jayne Harrison (JH) and Kevin O'Brien (KOB)) independently and in duplicate assessed the eligibility of all reports that we identified by the search strategy as being potentially relevant to the review. We were not blind to author(s), institution or site of publication. Agreement was assessed using

the kappa statistic ([Landis 1977](#)). Disagreements were resolved by discussion or following clarification from authors.

Data extraction

Two review authors (JH and KOB) then independently and in duplicate extracted data using a specially designed data extraction form. We recorded the year of publication, interventions assessed, outcomes, sample size and age of subjects.

The primary outcome was prominence of the upper front teeth and the secondary outcomes were relationship of upper and lower jaws, self esteem, patient satisfaction, jaw joint problems, number of attendances and any injury to the upper front teeth. Harms e.g. health of the gums, damage to the teeth.

We grouped the outcome data into those measured at the end of early treatment and following adolescent treatment.

Quality assessment

The quality assessment was undertaken independently and in duplicate by two review authors (JH and KOB) as part of the data extraction process. The methodological quality of [UK \(11-14\)](#); [UK \(Mixed\)](#) were assessed independently by Helen Worthington (HW).

Four main quality criteria were examined:

- (1) Allocation concealment, recorded as:
 - (A) Adequate
 - (B) Unclear
 - (C) Inadequate as described in the *Cochrane Handbook for Systematic Reviews on Interventions* 4.2.6.
- (2) Blind outcome assessment
- (3) Completeness of follow up
- (4) Intention-to-treat analysis.

Data analysis

For dichotomous outcomes, the estimates of effect of an intervention were expressed as odds ratios together with 95% confidence intervals (CIs). For continuous outcomes, mean differences and standard deviations were used to summarise the data for each group.

Only if there were studies of similar comparisons reporting the same outcome measures was meta-analysis to be attempted. Odds ratios were to be combined for dichotomous data, and mean differences for continuous data, using random-effects models.

The significance of any discrepancies in the estimates of the treatment effects from the different trials was to be assessed by means of Cochran's test for heterogeneity and the I^2 statistic, which describes the percentage total variation across studies that is due to heterogeneity rather than chance. Clinical heterogeneity was to be assessed by examining the types of participants and interventions for all outcomes in each study. It was planned to undertake sensitivity analyses to examine the effect of the study quality assessment on the overall estimates of effect. In addition, the effect of including unpublished literature on the review's findings was also to be examined, but there were insufficient trials to undertake this.

RESULTS

Description of studies

See: [Characteristics of included studies](#); [Characteristics of excluded studies](#).

Results of the search

Electronic searches identified 185 titles and abstracts. From this we obtained 105 full reports for the review. Eight trials, involving data from 592 participants, were included in the review. This included contemporary unpublished data from the [Florida](#); [UK \(11-14\)](#) studies.

Included studies

See [Characteristics of included studies](#) table.

Characteristics of the trial settings and investigators

Of the included trials, three were conducted in the United Kingdom ([London](#); [UK \(11-14\)](#); [UK \(Mixed\)](#)), two were carried out in North America ([Florida](#); [North Carolina](#)), one was conducted in China ([Mao 1997](#)), one in New Zealand ([New Zealand](#)) and one in Turkey ([Cura 1997](#)). All trials had a parallel group design. Two were multicentre studies ([UK \(11-14\)](#); [UK \(Mixed\)](#)). Five of the trials had more than one publication. Four of the trials received external funding. The percentage of patients lost to follow up varied from 0% to 26%. The providers and assessors were dental staff.

Characteristics of the participants

Four trials provided treatment for children aged between 8 and 11 years old ([Florida](#); [New Zealand](#); [North Carolina](#); [UK \(Mixed\)](#)). Four provided treatment for children who were 10 to 15 years old ([Cura 1997](#); [London](#); [Mao 1997](#); [UK \(11-14\)](#)). Two of the trials had an active recruitment strategy that involved screening school children and providing incentives, such as reduced fees, for participation ([Florida](#); [North Carolina](#)).

Characteristics of the interventions

All of the trials provided a clear description of the treatment protocols. Three trials included an untreated control group ([Cura 1997](#);

[Mao 1997](#); [New Zealand](#)), three used a delayed treatment control group ([Florida](#); [North Carolina](#); [UK \(Mixed\)](#)) and two compared two or more types of orthodontic appliances ([London](#); [UK \(11-14\)](#)). Three evaluated the effects of early treatment and followed the children through to the completion of all treatment in adolescence ([Florida](#); [New Zealand](#); [North Carolina](#)). One had a similar design, but is not yet complete ([UK \(Mixed\)](#)).

The interventions for the treatment of Class II malocclusion could be classified as:

- Early treatment followed by adolescent treatment ([Florida](#); [New Zealand](#); [North Carolina](#); [UK \(Mixed\)](#))
- Adolescent treatment only ([Cura 1997](#); [London](#); [Mao 1997](#)).

Excluded studies

See [Characteristics of excluded studies](#) table.

Of the 65 studies that were excluded:

- 21 were not a controlled or a randomised clinical trial (CCT/RCT);
- 25 had unclear methods;
- 6 were review articles that yield no extra references;
- 5 did not involve treatment of patients with a Class II malocclusion;
- 6 reported outcomes that were not of interest; and
- 2 were excluded for other reasons.

Risk of bias in included studies

Allocation concealment was adequate for four of the trials but it was unclear for the remaining (Additional [Table 1](#)). The outcome assessor was blinded for three trials, but this was not clear for the others. Withdrawals were adequately reported in all of the eight trials. The kappa scores between the two raters were 1.0 for allocation concealment, 1.0 for blinding of outcome assessment and 0.9 for clear information on withdrawals.

Table 1. Quality assessment of included trials

Trial	Allocation concealment	Blinded outcome	Clear withdrawals	Risk of bias
Cura 1997	Unclear	Unclear	Yes	Moderate
Florida	Yes	Yes	Yes	Low
London	Unclear	No	Yes	Moderate

Table 1. Quality assessment of included trials (Continued)

Mao 1997	Unclear	Unclear	Yes	Moderate
New Zealand	Unclear	Yes	Yes	Moderate
North Carolina	Yes	Yes	Yes	Low
UK (11-14)	Yes	Yes	Yes	Low
UK (Mixed)	Yes	Yes	Yes	Low

Four trials were assessed as low risk of bias (Florida; North Carolina; UK (11-14); UK (Mixed)) and four were thought to have moderate risk bias (Cura 1997; London; Mao 1997; New Zealand). The methodological quality of UK (Mixed) and UK (11-14) were assessed independently by Helen Worthington.

Effects of interventions

Electronic searches identified 185 titles and abstracts. From these 105 full papers were retrieved for further assessment. Of these, 71 references to 65 trials were excluded. Thirty-four references to eight trials met the defined criteria for trial design, participants, interventions and outcomes.

For the eight trials included in the review the results are based on data from 592 patients who presented with Class II Division 1 malocclusion. The number of participants in each treatment/control group ranged from 15 to 95.

We divided the trials into two main groups:

- (i) those that reported the effects of early treatment (Phase I treatment) at either the end of Phase I or follow up to the end of Phase II and
- (ii) those that reported the effects of treatment that was provided as one phase in adolescence.

Early treatment comparisons

Comparisons with early treatment appliance versus untreated control (Comparison 1; Outcomes 1.1-1.4)

Three trials, involving 432 participants, compared early treatment, using a functional appliance, with no treatment. The meta-analysis showed that there was a statistically significant difference in final overjet of the treatment group compared with the control group (-4.04 mm; 95% confidence interval (CI) -7.47 to -0.6, Chi^2 117.02, 2 degrees of freedom (df), $P < 0.00001$, $I^2 = 98.3\%$).

When we evaluated the effect of treatment on the final ANB, we found that there was a significant difference between the treatment and control groups (-1.35 mm; 95% CI -2.57 to -0.14, Chi^2 9.17, 2 df, $P < 0.01$, $I^2 = 78.2\%$). Similarly, there was a statistically significant difference (-0.55 degrees; 95% CI -0.92 to -0.18, Chi^2

5.71, 2 df, $P = 0.06$, $I^2 = 65.0\%$) in the change in ANB between the treatment and control groups.

Early treatment also had a statistically significant effect on the PAR score with the early treatment groups having a PAR score that was 12.63 PAR points (95% CI -22.8 to -2.99, Chi^2 56.53, 2 df, $P < 0.00001$, $I^2 = 96.5\%$) lower than the control groups.

Comparisons of early treatment with headgear versus untreated control (Comparison 2; Outcomes 2.1-2.2)

The comparison of the effect of treatment with headgear, compared with untreated control, revealed that there was a small, but statistically significant, effect of headgear treatment on the overjet (-1.07 mm; 95% CI -1.63 to -0.51, Chi^2 0.05, 1 df, $P = < 0.82$, $I^2 = 0\%$). Similarly, headgear resulted in a significant reduction of -0.72 degrees (95% CI -1.18 to -0.27, $\text{Chi}^2 = 0.34$, 1 df, $P = 0.56$, $I^2 = 0\%$) in final ANB.

Comparisons of early treatment with headgear versus functional appliance (Comparison 3; Outcomes 3.1-3.3)

When we compared the effects of early treatment between headgear and the functional appliances we found no statistically significant differences with respect to final overjet, ANB, or ANB change.

Effects of early treatment at the end of adolescent treatment (two-phase treatment)

Comparisons with early treatment versus untreated control (Comparison 4; Outcomes 4.1-4.3)

When we evaluated the effects of a course of early treatment, with headgear or a functional appliance, at the end of all orthodontic treatment, we found that there were no statistically significant differences in the overjet, final ANB or PAR score compared with an untreated control.

Comparisons of early treatment with headgear versus control (Comparison 5; Outcomes 5.1-5.3)

Similarly, there were no statistically significant effects of an early course of headgear treatment at the end of Phase II treatment with respect to overjet, final ANB or PAR score compared with an untreated control.

Comparisons of early treatment with headgear versus functional appliance (Comparison 6; Outcomes 6.1-6.3)

An evaluation of the effect of early treatment between headgear and functional appliance revealed that there were no significant differences in overjet, final ANB or PAR score.

One-phase adolescent treatment comparisons

Comparisons of one-phase adolescent treatment functional appliance versus untreated control (Comparison 7; Outcome 7.1)

We only found one trial addressing this outcome (Cura 1997). There was a statistically significant reduction in overjet of -5.22 mm (95% CI -6.51 to -3.93, $P < 0.0001$) for the treatment group compared with an untreated control.

Comparisons of one-phase adolescent treatment functional appliance versus untreated control (Comparison 7; Outcome 7.2)

The evaluation of the effect of functional appliance on ANB revealed a statistically significant reduction in ANB of -2.27 degrees (95% CI -3.22 to -1.31, Chi^2 1.9, 1 df, $P = 0.17$, $I^2 = 47.3\%$) compared with an untreated control.

Comparisons of one-phase adolescent treatment with the Twin Block functional appliance versus other functional appliances (Comparison 8; Outcomes 8.1-8.2)

This comparison revealed that there was statistically significant reduction on ANB with the Twin Block when compared to other functional appliances. This was only -0.68 degrees (95% CI -1.32 to -0.04, Chi^2 0.56, 1 df, $P = 0.46$, $I^2 = 0\%$). However, there was no statistically significant effect of the type of appliance on final overjet.

DISCUSSION

Two-phase versus one-phase treatment

We have found evidence that when orthodontic treatment is provided for children with prominent upper front teeth, when they are aged 7 to 9 years old (early treatment), this results in clinically and statistically significant reduction in incisor prominence.

This effect occurs if the child received treatment with a functional appliance or headgear. This treatment also resulted in some changes in the relationship of the upper and lower jaws. However, while these changes or differences were statistically significant they were unlikely to be clinically significant. As these studies were of high/moderate quality, carried out in several different countries, using different functional appliances on children who were representative of the population, we can conclude that the results of this review are generalisable.

When we considered the final outcome of treatment at the end of a second phase of treatment when the child was in early adolescence, we found that the treatment was effective, in that incisor prominence had been reduced. Nevertheless, there were no differences in treatment outcome between the groups of children who had received one or two phases of treatment. As a result, it appears that two-phase treatment does not have any advantages over one-phase treatment.

Treatment provided in one phase in early adolescence

We found two studies that measured the effect of treatment with functional appliance versus an untreated control. The analysis revealed that the treatment resulted in a reduction of overjet and a change in skeletal pattern, but again this change was so small that it may not be of clinical significance.

We also found that several investigators had compared the effect of the Twin Block functional appliance against other similar appliances, for example, the Bionator and Herbst appliances. We found that while there was a statistically significant difference in ANB however, this was so small that it was unlikely to be of clinical significance. We did not find any other significant differences.

One important finding from this review was that while we identified eight randomised controlled trials, they had been published in 34 different papers. Furthermore, several of the investigators had not only reported outcomes at the end of early treatment but they had produced several papers that were confined to analysis of subsets of subjects, to form interim reports or 'updates'. While they may have had good reasons to follow this publication strategy, in terms of having to compete for the renewal of grant funding, this did result in difficulty interpreting the results of these studies. We approached this problem by identifying the most relevant outcomes and data points and then produced composite data extraction for these studies. We would like to suggest that studies are not reported until they are completed. The registration of trials will come some way to addressing some of these issues, where each trial has a unique identity number which will appear on all publications. The quality of the trials in this review was fair with 50% being considered at low risk of bias, the remainder at moderate risk. This was mainly due to the lack of blinding of the outcome assessors. Finally, there was great variation in the outcome measures that were adopted by the investigators. This was particularly marked with

the use of cephalometric analyses and is not surprising when we consider that there are many different types of analysis. We would suggest that when future studies are planned uniformly applied cephalometric analyses are utilised, so that adequate comparisons between trials can be achieved.

AUTHORS' CONCLUSIONS

Implications for practice

Early orthodontic treatment (Phase I), followed by a later phase of treatment (Phase II) when the child is in early adolescence, does not appear to have any advantages over treatment that is provided in one phase when the child is in early adolescence.

When functional appliance treatment is provided in early adolescence it appears that there are minor beneficial changes in skeletal pattern, however, these are probably not clinically significant. Similarly, the choice of functional appliance when compared to the Twin Block does not result in any advantageous effects.

Implications for research

Consideration needs to be given to forming a consensus on the type of measures that are used in orthodontic trials, this is particularly relevant for cephalometric measurement and analysis. In addition, studies should be carried out at the same time points and reported according to the Consolidated Standards of Reporting Trials (CONSORT) guidelines.

ACKNOWLEDGEMENTS

Thanks to Sylvia Bickley (Cochrane Oral Health Group) for her help in conducting the searches, and to Luisa Fernandez Mauleffinch (Cochrane Oral Health Group) for editorial management of the review. Thanks to Bill Shaw for his initial advice, Bill Proffit, Kitty Tulloch (University of North Carolina), Tim Wheeler, Sue McGorry (University of Florida), David Morris; Danny Op Heij and Urban Hagg for providing additional data for this review; John Scholey for undertaking some of the hand-searching and Sue Pender for retrieving, copying and collating the full papers. We would also like to thank all those who have provided comments and editorial input into this review.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Cura 1997

Methods	Randomised parallel group study carried out in Turkey. Treatment duration 6 months. Unclear on blind assessment. Unclear information on withdrawals. Drop outs: 21%.	
Participants	Children in clinic with Class II Division 1 malocclusion, defined by class II molar relationship and ANB difference of 5 degrees. 60 enrolled and 47 completed.	
Interventions	2 groups (i) Bass functional appliance (ii) untreated control.	
Outcomes	(i) Skeletal discrepancy measured by ANB.	
Notes		
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Florida

Methods	Randomised parallel group study over 10 years. Assessor blind. Clear information on withdrawals. Drop outs: 24%.	
Participants	Screened child population then referred to clinic for treatment. 276 enrolled and 68 dropped out.	
Interventions	3 groups (i) delayed treatment control (ii) Bionator appliance (ii) cervical pull headgear with removable biteplane.	
Outcomes	(i) Overjet (ii) skeletal discrepancy (iii) dental alignment measured with the PAR index.	
Notes		
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

London

Methods	Randomised parallel group study over 9 months conducted in the UK. Assessor not blinded. Clear information on withdrawals. Drop outs: 21%.	
Participants	Children aged 8-15 years old with Class II Division 1 malocclusion and an overjet greater than 7mm. 39 enrolled and 31 completed.	
Interventions	3 groups (i) Bass appliance (ii) Bionator appliance (iii) Twin Block appliance.	
Outcomes	(i) Overjet (ii) skeletal discrepancy - ANB method unclear (iii) soft tissue variables.	
Notes		
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Mao 1997

Methods	Randomised parallel group study carried out in China over 18 months of treatment. Unclear on blinding. Drop outs: 0%.	
Participants	Children aged 8-11 years old with Class II Division 1 malocclusion. 54 enrolled and 54 completed.	
Interventions	2 groups (i) Bionator/headgear appliance (ii) no treatment control.	
Outcomes	Skeletal discrepancy measured by ANB.	
Notes		
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

New Zealand

Methods	Randomised parallel group study carried out in New Zealand over 18 months of treatment. Assessor blind. Unclear reporting on withdrawals. Drop outs: 23%. 18-month follow up of 3 parallel groups with 50 children in total.	
Participants	Children in clinic with Class II Division 1 malocclusion. 54 enrolled and 42 completed.	

New Zealand (Continued)

Interventions	3 groups (i) Harvold functional appliance (ii) Frankel functional appliance (iii) untreated control group.	
Outcomes	(i) Change in skeletal pattern represented by ANB (ii) change in overjet (iii) PAR score.	
Notes		
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

North Carolina

Methods	Randomised parallel group study carried out the in the USA. Treatment provided for 15 months. Assessor blind. Clear information on withdrawals. Drop outs: 21%.	
Participants	Children in the mixed dentition with overjet greater than 7 mm. 175 children enrolled and 137 completed.	
Interventions	3 groups (i) Bionator appliance (ii) cervical pull headgear (iii) delayed treatment control.	
Outcomes	(i) Overjet (ii) skeletal discrepancy measured by ANB (iii) dental alignment measured with the PAR index (iv) treatment duration (v) incidence of incisal trauma.	
Notes		
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

UK (11-14)

Methods	Randomised parallel group multicentre study carried out in the UK. Assessor blind. Clear information on withdrawals. Drop outs: 25%. Included 215 children in 2 groups. 32 dropped out.	
Participants	Children aged 11-14 with overjets greater than 7 mm. 215 enrolled and 151 completed.	
Interventions	2 groups (i) Herbst appliance (ii) Twin Block appliance. Followed by fixed appliance treatment, if necessary.	
Outcomes	(i) Overjet (ii) skeletal discrepancy measured by Pancherz analysis (iii) dental alignment measured with the PAR index and (iv) duration of treatment.	

UK (11-14) (Continued)

Notes	Quality assessed independently by Helen Worthington.	
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

UK (Mixed)

Methods	Randomised parallel group multicentre trial carried out in the UK over 15 months. Assessor blinded to outcomes. Clear information on withdrawals. Drop outs < 1%.	
Participants	Children in the mixed dentition with overjets greater than 7 mm. 176 patients enrolled and 173 completed.	
Interventions	2 groups (i) Twin Block (ii) delayed treatment.	
Outcomes	(i) Overjet (ii) skeletal discrepancy measured by Pancherz analysis (iii) dental alignment measured with the PAR index (iv) socio-psychological effects of treatment.	
Notes	Quality assessed independently by Helen Worthington.	
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

Characteristics of excluded studies [ordered by study ID]

Ackerman 2004	Not CCT/RCT
Aelbers 1996	Literature review. No extra references
Aknin 2000	Method unclear
Ashmore 2002	Not CCT/RCT
Banks 2004	No suitable outcomes

(Continued)

Bishara 1995	Not CCT/RCT
Boecler 1989	Not CCT/RCT
Cevdanes 2003	No extractable data
Chen 2002	Systematic review. No extra references
Chintakanon 2000	Not outcome of interest
Collett 2000	Not CCT/RCT
Cura 1996	Method unclear
Dahan 1989	Not CCT/RCT
De Almeida 2002	Method unclear
DeVincenzo 1989	Method unclear
Du 2002	Method unclear
Erverdi 1995	Not CCT/RCT Contacted authors. No response was received
Falck 1989	Method unclear
Firouz 1992	Method unclear
Franco 2002	Not outcome of interest
Ghafari 1995	Not outcome of interest
Ghiglione 2000	Method unclear
Gianelly 1983	Not CCT/RCT
Guner 2003	Method unclear
Hagg 2002	Method unclear
Harvold 1971	Not CCT/RCT
Hiyama 2002	Not CCT/RCT
Ingervall 1991	Method unclear

(Continued)

Iscan 1997	Not Class II
Jacobs 2002	Systematic review. No extra references
Janson 2003	Not CCT/RCT
Jarrell 2001	Method unclear
Kalra 1989	Method unclear
Keski-Nisula 2003	Not CCT/RCT
Kiliaridis 1990	Not Class II
Kluemper 2000	Review. No extra references
Kumar 1996	Method unclear
Lange 1995	Not CCT/RCT
Lund 1998	Not CCT/RCT
Malmgren 1987	Not CCT/RCT
Mantysaari 2004	Not Class II
Meral 2004	Not Class II
Muniandy 2000	Not Class II
Nelson 2000	Method unclear
Op Heij 1989	Not CCT/RCT
Ozturk 1994	Method unclear
Pangrazio 1999	Method unclear
Pangrazio 2003	Not CCT/RCT
Parkin 2001	Not CCT/RCT
Pennsylvania	Not outcome of interest
Petrovic 1982	Method unclear

(Continued)

Pirttiniemi 2005	RCT outcomes not relevant to this review
Popowich 2003	Systematic review. No extra references
Reukers 1998	Method unclear
Sari 2003	Method unclear
Schaefer 2004	Not CCT/RCT
Shannon 2004	Not CCT/RCT
Taner 2003	Not outcome of interest
Thuer 1989	Method unclear
Tulloch 1990	Literature review. No extra references
Tumer 1999	Method unclear
Ucem 1998	Method unclear
Ucuncu 2001	Method unclear
Wieslander 1984	Not CCT/RCT
Witt 1999	Method unclear

CCT = controlled clinical trial

RCT = randomised controlled trial

DATA AND ANALYSES

Comparison 1. Early treatment at the end of Phase I: functional versus control

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Final overjet	3	432	Mean Difference (IV, Random, 95% CI)	-4.04 [-7.47, -0.60]
2 Final ANB	3	419	Mean Difference (IV, Random, 95% CI)	-1.35 [-2.57, -0.14]
3 PAR score	3	380	Mean Difference (IV, Random, 95% CI)	-12.63 [-22.28, -2.99]
4 ANB change	3	318	Mean Difference (IV, Random, 95% CI)	-0.55 [-0.92, -0.18]
5 Self concept	1	135	Mean Difference (IV, Fixed, 95% CI)	3.63 [-0.40, 7.66]
6 Incidence of incisal trauma during Phase I treatment	1	113	Odds Ratio (M-H, Random, 95% CI)	0.31 [0.11, 0.86]

Comparison 2. Early treatment at the end of Phase I: headgear versus control

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Final overjet	2	278	Mean Difference (IV, Random, 95% CI)	-1.07 [-1.63, -0.51]
2 Final ANB	2	277	Mean Difference (IV, Random, 95% CI)	-0.72 [-1.18, -0.27]
3 Incidence of incisal trauma during Phase I treatment	1	111	Odds Ratio (M-H, Random, 95% CI)	0.52 [0.21, 1.30]

Comparison 3. Early treatment at the end of Phase I: headgear versus functional

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Final overjet	2	271	Mean Difference (IV, Random, 95% CI)	1.26 [-0.92, 3.44]
2 Final ANB	2	271	Mean Difference (IV, Random, 95% CI)	-0.04 [-0.49, 0.41]
3 ANB change	2	284	Mean Difference (IV, Random, 95% CI)	0.01 [-0.28, 0.29]
4 Incidence of incisal trauma during Phase I treatment	1	102	Odds Ratio (M-H, Fixed, 95% CI)	1.68 [0.55, 5.13]

Comparison 4. Early treatment at the end of Phase II: functional versus control

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Final overjet	3	343	Mean Difference (IV, Random, 95% CI)	0.24 [-0.32, 0.80]
2 Final ANB	3	347	Mean Difference (IV, Random, 95% CI)	-0.03 [-0.55, 0.48]
3 PAR score	3	360	Mean Difference (IV, Random, 95% CI)	0.96 [-1.68, 3.61]
4 New incisal trauma during Phase II treatment	1	93	Odds Ratio (M-H, Random, 95% CI)	0.40 [0.17, 0.94]

Comparison 5. Early treatment at the end of Phase II: headgear versus control

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Final overjet	2	238	Mean Difference (IV, Random, 95% CI)	-0.24 [-0.63, 0.16]
2 Final ANB	2	231	Mean Difference (IV, Random, 95% CI)	-0.27 [-0.80, 0.26]
3 PAR score	2	177	Mean Difference (IV, Random, 95% CI)	-1.55 [-3.70, 0.60]
4 New incisal trauma during Phase II treatment	1	97	Odds Ratio (M-H, Random, 95% CI)	0.25 [0.10, 0.60]

Comparison 6. Early treatment at the end of Phase II: headgear versus functional

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Final overjet	2	225	Mean Difference (IV, Random, 95% CI)	-0.21 [-0.57, 0.15]
2 Final ANB	2	222	Mean Difference (IV, Random, 95% CI)	-0.13 [-0.78, 0.53]
3 PAR score	2	224	Mean Difference (IV, Random, 95% CI)	-0.81 [-2.21, 0.58]
4 New incisal trauma during Phase II treatment	1	88	Odds Ratio (M-H, Random, 95% CI)	0.62 [0.24, 1.62]

Comparison 7. Adolescent treatment: functional versus control

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Final overjet	1	47	Mean Difference (IV, Random, 95% CI)	-5.22 [-6.51, -3.93]
2 Final ANB	2	99	Mean Difference (IV, Random, 95% CI)	-2.27 [-3.22, -1.31]

Comparison 8. Adolescent treatment: Twin Block versus other functional appliances

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Final ANB	2	155	Mean Difference (IV, Random, 95% CI)	-0.68 [-1.32, -0.04]
2 Final overjet	2	164	Mean Difference (IV, Random, 95% CI)	0.47 [-0.12, 1.06]

Analysis 1.1. Comparison 1 Early treatment at the end of Phase I: functional versus control, Outcome 1 Final overjet.

Review: Orthodontic treatment for prominent upper front teeth in children

Comparison: 1 Early treatment at the end of Phase I: functional versus control

Outcome: 1 Final overjet

Analysis 1.2. Comparison 1 Early treatment at the end of Phase I: functional versus control, Outcome 2 Final ANB.

Review: Orthodontic treatment for prominent upper front teeth in children

Comparison: 1 Early treatment at the end of Phase I: functional versus control

Outcome: 2 Final ANB

Analysis 1.3. Comparison 1 Early treatment at the end of Phase I: functional versus control, Outcome 3 PAR score.

Review: Orthodontic treatment for prominent upper front teeth in children

Comparison: 1 Early treatment at the end of Phase I: functional versus control

Outcome: 3 PAR score

Analysis 1.4. Comparison 1 Early treatment at the end of Phase I: functional versus control, Outcome 4 ANB change.

Review: Orthodontic treatment for prominent upper front teeth in children

Comparison: 1 Early treatment at the end of Phase I: functional versus control

Outcome: 4 ANB change

Analysis 1.5. Comparison 1 Early treatment at the end of Phase I: functional versus control, Outcome 5 Self concept.

Review: Orthodontic treatment for prominent upper front teeth in children

Comparison: 1 Early treatment at the end of Phase I: functional versus control

Outcome: 5 Self concept

Analysis 1.6. Comparison 1 Early treatment at the end of Phase I: functional versus control, Outcome 6 Incidence of incisal trauma during Phase I treatment.

Review: Orthodontic treatment for prominent upper front teeth in children

Comparison: 1 Early treatment at the end of Phase I: functional versus control

Outcome: 6 Incidence of incisal trauma during Phase I treatment

Analysis 2.1. Comparison 2 Early treatment at the end of Phase I: headgear versus control, Outcome 1 Final overjet.

Review: Orthodontic treatment for prominent upper front teeth in children

Comparison: 2 Early treatment at the end of Phase I: headgear versus control

Outcome: 1 Final overjet

Analysis 2.2. Comparison 2 Early treatment at the end of Phase I: headgear versus control, Outcome 2 Final ANB.

Review: Orthodontic treatment for prominent upper front teeth in children

Comparison: 2 Early treatment at the end of Phase I: headgear versus control

Outcome: 2 Final ANB

Analysis 2.3. Comparison 2 Early treatment at the end of Phase I: headgear versus control, Outcome 3 Incidence of incisal trauma during Phase I treatment.

Review: Orthodontic treatment for prominent upper front teeth in children

Comparison: 2 Early treatment at the end of Phase I: headgear versus control

Outcome: 3 Incidence of incisal trauma during Phase I treatment

Analysis 3.1. Comparison 3 Early treatment at the end of Phase I: headgear versus functional, Outcome 1 Final overjet.

Review: Orthodontic treatment for prominent upper front teeth in children

Comparison: 3 Early treatment at the end of Phase I: headgear versus functional

Outcome: 1 Final overjet

Analysis 3.2. Comparison 3 Early treatment at the end of Phase I: headgear versus functional, Outcome 2 Final ANB.

Review: Orthodontic treatment for prominent upper front teeth in children

Comparison: 3 Early treatment at the end of Phase I: headgear versus functional

Outcome: 2 Final ANB

Analysis 3.3. Comparison 3 Early treatment at the end of Phase I: headgear versus functional, Outcome 3 ANB change.

Review: Orthodontic treatment for prominent upper front teeth in children

Comparison: 3 Early treatment at the end of Phase I: headgear versus functional

Outcome: 3 ANB change

Analysis 3.4. Comparison 3 Early treatment at the end of Phase I: headgear versus functional, Outcome 4 Incidence of incisal trauma during Phase I treatment.

Review: Orthodontic treatment for prominent upper front teeth in children

Comparison: 3 Early treatment at the end of Phase I: headgear versus functional

Outcome: 4 Incidence of incisal trauma during Phase I treatment

Analysis 4.1. Comparison 4 Early treatment at the end of Phase II: functional versus control, Outcome 1 Final overjet.

Review: Orthodontic treatment for prominent upper front teeth in children

Comparison: 4 Early treatment at the end of Phase II: functional versus control

Outcome: 1 Final overjet

Analysis 4.2. Comparison 4 Early treatment at the end of Phase II: functional versus control, Outcome 2 Final ANB.

Review: Orthodontic treatment for prominent upper front teeth in children

Comparison: 4 Early treatment at the end of Phase II: functional versus control

Outcome: 2 Final ANB

Analysis 4.3. Comparison 4 Early treatment at the end of Phase II: functional versus control, Outcome 3 PAR score.

Review: Orthodontic treatment for prominent upper front teeth in children

Comparison: 4 Early treatment at the end of Phase II: functional versus control

Outcome: 3 PAR score

Analysis 4.4. Comparison 4 Early treatment at the end of Phase II: functional versus control, Outcome 4 New incisal trauma during Phase II treatment.

Review: Orthodontic treatment for prominent upper front teeth in children

Comparison: 4 Early treatment at the end of Phase II: functional versus control

Outcome: 4 New incisal trauma during Phase II treatment

Analysis 5.1. Comparison 5 Early treatment at the end of Phase II: headgear versus control, Outcome 1 Final overjet.

Review: Orthodontic treatment for prominent upper front teeth in children

Comparison: 5 Early treatment at the end of Phase II: headgear versus control

Outcome: 1 Final overjet

Analysis 5.2. Comparison 5 Early treatment at the end of Phase II: headgear versus control, Outcome 2 Final ANB.

Review: Orthodontic treatment for prominent upper front teeth in children

Comparison: 5 Early treatment at the end of Phase II: headgear versus control

Outcome: 2 Final ANB

Analysis 5.3. Comparison 5 Early treatment at the end of Phase II: headgear versus control, Outcome 3 PAR score.

Review: Orthodontic treatment for prominent upper front teeth in children

Comparison: 5 Early treatment at the end of Phase II: headgear versus control

Outcome: 3 PAR score

Analysis 5.4. Comparison 5 Early treatment at the end of Phase II: headgear versus control, Outcome 4 New incisal trauma during Phase II treatment.

Review: Orthodontic treatment for prominent upper front teeth in children

Comparison: 5 Early treatment at the end of Phase II: headgear versus control

Outcome: 4 New incisal trauma during Phase II treatment

Analysis 6.1. Comparison 6 Early treatment at the end of Phase II: headgear versus functional, Outcome 1 Final overjet.

Review: Orthodontic treatment for prominent upper front teeth in children

Comparison: 6 Early treatment at the end of Phase II: headgear versus functional

Outcome: 1 Final overjet

Analysis 6.2. Comparison 6 Early treatment at the end of Phase II: headgear versus functional, Outcome 2 Final ANB.

Review: Orthodontic treatment for prominent upper front teeth in children

Comparison: 6 Early treatment at the end of Phase II: headgear versus functional

Outcome: 2 Final ANB

Analysis 6.3. Comparison 6 Early treatment at the end of Phase II: headgear versus functional, Outcome 3 PAR score.

Review: Orthodontic treatment for prominent upper front teeth in children

Comparison: 6 Early treatment at the end of Phase II: headgear versus functional

Outcome: 3 PAR score

Analysis 6.4. Comparison 6 Early treatment at the end of Phase II: headgear versus functional, Outcome 4 New incisal trauma during Phase II treatment.

Review: Orthodontic treatment for prominent upper front teeth in children

Comparison: 6 Early treatment at the end of Phase II: headgear versus functional

Outcome: 4 New incisal trauma during Phase II treatment

Analysis 7.1. Comparison 7 Adolescent treatment: functional versus control, Outcome 1 Final overjet.

Review: Orthodontic treatment for prominent upper front teeth in children

Comparison: 7 Adolescent treatment: functional versus control

Outcome: 1 Final overjet

Analysis 7.2. Comparison 7 Adolescent treatment: functional versus control, Outcome 2 Final ANB.

Review: Orthodontic treatment for prominent upper front teeth in children

Comparison: 7 Adolescent treatment: functional versus control

Outcome: 2 Final ANB

Analysis 8.1. Comparison 8 Adolescent treatment: Twin Block versus other functional appliances, Outcome 1 Final ANB.

Review: Orthodontic treatment for prominent upper front teeth in children

Comparison: 8 Adolescent treatment: Twin Block versus other functional appliances

Outcome: 1 Final ANB

Analysis 8.2. Comparison 8 Adolescent treatment: Twin Block versus other functional appliances, Outcome 2 Final overjet.

Review: Orthodontic treatment for prominent upper front teeth in children

Comparison: 8 Adolescent treatment: Twin Block versus other functional appliances

Outcome: 2 Final overjet

APPENDICES

Appendix I. MEDLINE search strategy

#1 MALOCCLUSION-ANGLE-CLASS-II (ME)
#2 ("Class II" AND ((Angle OR Angle's) OR malocclusion OR bite))
#3 (Explode) ORTHODONTIC-APPLIANCES-FUNCTIONAL (ME)
#4 (Explode) ORTHODONTIC-APPLIANCES-REMOVABLE (ME)
#5 "Frankel" OR "Twin*block" OR "Fixed appliance"
#6 ((Extraoral OR "extra oral" OR extra-oral) AND appliance*)
#7 ("growth modif*" AND (jaw OR maxilla* OR mandible))
#8 ("head gear" OR headgear)
#9 ((two-phase (treatment OR therapy)) AND (orthodontic* OR malocclusion))
#10 ((orthopedic* OR orthopaedic*) AND (dental OR orthodontic* OR facial))
#11 #1 OR #2
#12 #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10
#13 #11 AND #12

WHAT'S NEW

Last assessed as up-to-date: 14 May 2007.

23 June 2008	Amended	Converted to new review format.
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HISTORY

Protocol first published: Issue 1, 2002

Review first published: Issue 3, 2007

CONTRIBUTIONS OF AUTHORS

The review was conceived by Jayne Harrison (JH), Kevin O'Brien (KOB) and Bill Shaw (Cochrane Oral Health Group). Previous work, that was the foundation of current study, was undertaken by JH and KOB. The protocol was written by JH, Helen Worthington (HW) and KOB.

The review was co-ordinated by JH and KOB. Sylvia Bickley (Cochrane Oral Health Group) developed the search strategy and undertook the electronic searches. JH undertook the handsearching. JH and KOB screened the search results and retrieved papers, appraised the quality of the papers and extracted data from them. HW checked the data extraction, analysed the data and assisted in the interpretation of the data. JH, KOB and HW wrote the review.

DECLARATIONS OF INTEREST

Kevin O'Brien was involved in acquiring funding, running and reporting of the UK (11-14) and UK (Mixed) trials.

SOURCES OF SUPPORT

Internal sources

- The Royal Liverpool and Broadgreen University Hospitals NHS Trust, UK.
- The University of Manchester, UK.
- Cochrane Oral Health Group, UK.

External sources

- NHS National Primary Dental Care R&D programme PCD97-303, UK.

INDEX TERMS

Medical Subject Headings (MeSH)

Adolescent; Age Factors; Malocclusion, Angle Class II [*therapy]; Orthodontic Appliances, Functional; Orthodontic Retainers; Orthodontics, Corrective [*methods]; Randomized Controlled Trials as Topic; Treatment Outcome

MeSH check words

Child; Humans