ISRCTN11717011 https://doi.org/10.1186/ISRCTN11717011

Comparison of the fixed versus the removable functional braces in the treatment of children with sticking out top front teeth

Submission date
01/06/2016

Recruitment status
No longer recruiting

Registration date
03/06/2016

Overall study status
Completed

Last Edited
07/11/2023

Condition category
Oral Health

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Sticking out top front teeth is a very common problem amongst children in the UK, and is caused by the incorrect alignment of the top and bottom jaws (malocclusion). This can result in more injuries to these teeth as a result of accidents. It has also been shown that a child's confidence and the smile can be really affected by this appearance. The alignment of the jaws and the self-esteem of affected children can be improved using a functional appliance, which is a special type of brace that works by holding the bottom jaw in a forward position, to encourage more natural growth of the jaws. Functional braces may be either fixed by glue onto the teeth, or removable. The most popular type of removable functional appliance is called the Twin-Block, and the most popular fixed type is the Herbst. The aim of this study is to compare the effectiveness of fixed and removable functional braces for the treatment of children with sticking-out top front teeth.

Who can participate?
Children aged 10-14 with sticking out top front teeth (class II malocclusion)

What does the study involve?
At the first visit, as in routine practice, the following procedures are undertaken: mouldings of the child's teeth and bite using a putty material, an X-ray of the child's jaws and teeth to check teeth development and jaw alignment, and photographs to assess the child's teeth and face. Taking part in the study also involves the following two additional tasks: children are asked to fill in a questionnaire booklet to help better understand how the appliance and appearance has affected their confidence and quality of life, and they undergo a three-dimensional facial scan, similar to a photograph, to assess the jaw line. At the second visit, the child has further moulds taken to make the functional brace. At the third visit, participants are randomly allocated to be treated with one of two braces: the fixed Herbst brace or the Twin Block brace. The Herbst brace is glued to the teeth and is not possible to take out, whereas the Twin Block is removable, and the child is advised to wear it 24 hours a day (except during swimming and contact sport). The children are then seen every 4-6 weeks (as in normal brace treatment) to check the brace, measure the amount of correction in the top teeth sticking out, and to record their experiences and compliance with the treatment. The treatment with the functional brace ends when the bite

is fully corrected and the top teeth no longer stick out. This may take 6-12 months. At this point, and directly after removing the functional brace, we ask the child to complete the questionnaires and undergo a facial scan again. In addition, in line with routine functional brace care, an x-ray is taken. As with all children receiving functional braces, the child is then assessed to see if they would benefit from having train-track fixed braces. This treatment can last a further 12-18 months depending on the bite and how crooked the teeth are. If the child does not require train track braces, their treatment ends after the functional brace. If the child has the train track brace, he/she completes the questionnaires, facial scan and x-ray again when this treatment is completed.

What are the possible benefits and risks of participating?
The child's sticking-out front teeth and bite problem will be treated by experienced orthodontists. The information we get from this study will help improve the future treatment of children with similar problems. There are no expected risks to the child for taking part in this study. We routinely provide children with these braces and follow-up care detailed above. There is a possibility that this treatment, like all brace treatment, may cause some discomfort and side effects, e.g. breakage, loss of the brace, and mouth sores or ulcers due to brace rubbing. The child will be given all the care instructions to help avoid any of these problems when the brace is fitted.

Where is the study run from?
Barts and the London Health Trust (UK)

When is the study starting and how long is it expected to run for?
October 2016 to July 2023

Who is funding the study?
1. Queen Mary University of London (UK)
2. Barts Health NHS Trust (UK)

Who is the main contact?
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Internal Project Reference of QMUL: DI/PR/16/005

Study information

Scientific Title
A comparison of the effectiveness of fixed versus removable functional appliances in the treatment of Class II malocclusion in children: a randomised clinical trial

Study objectives
Sticking out top front teeth is a very common problem amongst children in the UK, which is associated with deviation of normal occlusion between the top and bottom jaws. This type of malocclusion can result in more injuries to these teeth as a result of accidents. It has also been shown that a child's confidence and the smile can be really affected by this appearance. Treatment is aimed at improving the occlusal outcome and self-esteem of affected children using what is called functional appliance. A functional appliance is a special type of brace to correct the bite and sticking out top front teeth. It works by holding the bottom jaw in a forward

position in growing children, to encourage more natural growth of the jaws. Functional braces may be either a fixed, by glue onto the teeth, or a removable. The most popular type of removable functional appliance is called the Twin-Block, and the most popular fixed type is the Herbst.

The null hypotheses are there will be no significant differences between these appliances with regard to: treatment duration, patient-reported perception and impact of the appliance (quality of life; self-esteem; aesthetics & function), skeletal and dental effects (cephalometric and PAR score) and cost-effectiveness.

Added 01/09/2017: Health Research Authority (HRA) on 4/1/2017

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West - Greater Manchester South Research Ethics Committee, 06/12/2016, ref: 16/NW /0837

Study design
Randomised parallel-group study design with a positive control group

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Class II division 1 malocclusion

Interventions
This trial will compare the effectiveness of an Hanks-Herbst fixed and Twin-Block removable functional appliance in the correction of Class II division 1 malocclusion. Treatment will be provided by four clinicians in a two-centre study in the UK: Bart’s NHS Health Trust and East Kent Hospitals University NHS Foundation Trust. Moreover, an independent data monitoring committee (DMC) will be assigned, and the trial will conform to the recommendations of the UK’ s Medical Research Council for good clinical practice and in line with CONSORT guidelines (Schulz et al., 2010).

Patients who fulfil the selection criteria and are willing to participate will be asked to complete an assent form and their parents a consent form, after reading a participant information leaflet. Treatment allocation will be performed centrally at Queen Mary University. The duration of participants in the trial will be 12-36 months. This includes the length of functional treatment phase (6-12 months) followed by the second phase of FA treatment (12-18 months) if the clinician decides that it is necessary to achieve an optimal occlusal relationship.

Participants will randomly (like tossing a coin) be allocated to one of the two different functional brace options: Fixed Herbst brace OR Twin Block brace. To improve the quality of the study neither the child or the researcher will decide or know which brace the child will receive.

At the first visit, and in the line of routine orthodontic practice, the following procedures will be undertaken in order to best help decide on child treatment:
1. Mouldings of child's teeth and bite, using a putty material (5 minutes to complete)
2. An X-ray for child's jaws and teeth, to check teeth development and jaws alignment (10 minutes to complete)
3. Photographs to assess child's teeth and face (5 minutes to complete)
Taking part in the study will involve the following two additional tasks:
4. Questionnaires. Children will be asked to fill and answer a questionnaire booklet independently in the hospital, to help better understand how the bite/appearance have affected child's confidence and their quality of life (15 minutes to complete)
5. Three-dimensional facial scan, similar to undergoing a photographs, to assess the jaw line (1 minute to complete)

At the second visit, the child will have further moulds done to fabricate the functional brace.

At the third visit, the child will receive either the Herbst or Twin Block brace. The Herbst brace will be glued to the teeth, and will not be possible to take it out, whereas the Twin Block is removable, and the child will be advised to wear it 24 hours a day (except during swimming and contact sport).

Follow-up visits, the child will then be seen every 4-6 weeks (as in normal brace treatment), to check the brace, measure the amount of correction in the top teeth sticking out, and to record his/her experiences and compliance with the treatment. The treatment with functional brace will end when the bite is fully corrected and the top teeth no longer stick out. This may take 6-12 months to be completed. At this point, and directly after removing the functional brace, we will request the child to complete the questionnaires and a facial scan again. In addition, in line with routine functional brace care, an x-ray will be taken.

Train track brace: as with all children receiving functional braces, the child will then be assessed if would benefit from having train-track fixed braces. This treatment can last a further 12-18 months depending on the bite and how crooked the teeth are. If the child does not require train track braces, their treatment will be ended after the functional brace. If the child has the train track brace, he will complete the questionnaires, facial scan and x-ray again when this treatment is completed.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
-

Primary outcome measure
1. The effectiveness in terms of morphological changes (skeletal, soft tissue and dento-alveolar)
2. The duration of functional treatment until the full reduction of the overjet (0-2mm)

The measurements will be undertaken at the following points:
1. T0, at the baseline and before commence treatment
2. T1, at the end of functional phase of treatment and directly after removal the functional brace (6-12 months), when the sticking out teeth (the overjet) is a full reduced to within normal value (0-2 mm)
3. T2, if the children is assessed to have a second phase of treatment using train-track brace, then a third measurements will be undertaken after achieving an ideal occlusion relationship (18-30 months)

Secondary outcome measures
1. The impact on patient-reported perception (function; compliance; harms; quality of life; self-esteem; and function)
2. Cost-effectiveness

The measurements will be undertaken at the following points:
1. T0, at the baseline and before commence treatment
2. T1, at the end of functional phase of treatment and directly after removal the functional brace (6-12 months), when the sticking out teeth (the overjet) is a full reduced to within normal value (0-2 mm)
3. T2, if the children is assessed to have a second phase of treatment using train-track brace, then a third measurements will be undertaken after achieving an ideal occlusion relationship (18-30 months)

Overall study start date
01/10/2016

Completion date
31/07/2023

Eligibility

Key inclusion criteria
1. Patients medically and dentally fit
2. Adolescent patients aged 10-14 years
3. Class II malocclusion, with overjet of ≥ 7mm
4. Neutral or hypo-divergent facial type, with mandibular plane angle (ML/NSL) ≤39 (Pancherz, 1982)

Participant type(s)
Patient

Age group
Child

Lower age limit
10 Years

Upper age limit
14 Years

Sex
Both

Target number of participants
80: A sample size calculation was performed. On the basis of which a 4-month (SD 4.61) difference in treatment duration is regarded as a clinically relevant difference in treatment duration between these two modalities. This provides a sample size of 40 patients in each group, allowing for a non-compliance rate of 30% with a power of 85% and an alpha of 0.05.

Total final enrolment
74

Key exclusion criteria
1. Associated craniofacial syndrome
2. Serious or compromised medical conditions
3. Previous orthodontic treatment
4. Dental extractions or missing permanent teeth, except the third molars

Date of first enrolment
01/02/2017

Date of final enrolment
01/10/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Barts and the London Health Trust
The Royal London Dental Hospital
Turner Street
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E1 2AD

Study participating centre

East Kent Hospitals University NHS Foundation Trust
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00b31g692

Funder(s)

Funder type
University/education

Funder Name
Queen Mary University of London

Alternative Name(s)
Queen Mary Uni of London, Queen Mary, Queen Mary and Westfield College, QMUL, QM

Funding Body Type
Government organisation

Funding Body Subtype

Universities (academic only)

Location
United Kingdom

Funder Name
Barts Health NHS Trust

Results and Publications

Publication and dissemination plan
The results of the study will be disseminated in peer-reviewed dental journals and submitted for oral presentation at the specialty conferences.

Intention to publish date
30/11/2023

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Results article		04/07/2023	07/07/2023	Yes	No
Results article		31/10/2023	07/11/2023	Yes	No