

# The effectiveness of an orthodontic brace for a receding chin

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<b>Registration date</b> 12/06/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 23/06/2021	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Children with small lower jaws and prominent upper front teeth represent about one third of the workload of British Orthodontists. The braces aim to reduce the prominence of the teeth by bringing the lower jaw forward to 'catch up' with the upper jaw. This treatment reduces the risk of damage to the upper teeth and improves the bite (eating) in some cases. The orthodontic brace used to correct the small lower jaw and prominent upper teeth is called a 'twinblock'. This brace has been in use for over 30 years and is used widely on growing children between around 10 1/2 and 15 years old. If an orthodontist was asked whether the twinblock works best on a 10.5 year old or a 15 year old they would be unsure of the correct answer. This is because there is no research to help with the decision. Therefore, this study has two groups, an earlier and a later group where the earlier group starts treatment straight away and the later group waits until they are 18 months older. The aim of the treatment is to assess how well the twinblock brace works comparing the earlier and later groups. We will measure jaw and tooth improvements and also self esteem and how patients feel about their teeth.

### Who can participate?

Boy or a girl, age 10.5 - 13.5 years. You can take part if you have a small lower jaw and top front teeth that 'stick out'. You will need to be happy to wear the brace.

### What does the study involve?

The treatment is with a twinblock brace. It is plastic two part top and bottom brace that clips over your teeth. You would wear the brace for 18 months. All the people taking part will have the same design of twinblock brace. You will be randomly allocated to two groups. The difference is when you have your treatment, group 1 means you have the brace straight away, group 2 means that you wait 18 months until you are a little older.

### What are the possible benefits and risks of participating?

The quality of your brace treatment is the same whether you enrol in study or not. Usually for the twinblock brace there is a waiting list of 18 months or longer. So if you are in the later treatment group there is no difference in the time you wait. You may be in the immediate

treatment group and start your brace quicker. There are no side effects to the treatment except some mild discomfort that you normally have with the twinblock braces. Paracetamol or headache tablets will take away any tooth or jaw ache.

Where is the study run from?

The study is run from Tameside Hospital NHS, Foundation Trust, Manchester UK, and this is the lead centre. There are two other hospitals taking part these are St Lukes Hospital Bradford UK and University Hospital of NorthStaffordshire UK.

When is the study starting and how long is it expected to run for?

The study has started at the lead centre in December 2011. The duration of the trial is 6 years. When the additional two hospitals sites are recruiting it is expected that the recruitment will be completed by December 2014.

Who is funding the study?

Tameside Hospital NHS Foundation Trust (UK)

Who is the main contact?

Dr Nicky Mandall

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## Contact information

**Type(s)**

Scientific

**Contact name**

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## Additional identifiers

**Protocol serial number**

version 1 Date 26.4.2011

## Study information

**Scientific Title**

A randomised controlled trial to compare the effect of a twinblock brace to correct a receding chin with a delayed treatment/control group

## **Acronym**

C2C

## **Study objectives**

There is no difference in the effectiveness of a twinblock functional appliance compared with a delayed treatment control in terms of:

1. Skeletal and dental improvement
2. Self esteem, psycho-social impact of malocclusion and oral health quality of life

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Multicentre Research Ethics Committee (MREC); 11/NW/0312

## **Study design**

Randomised controlled trial

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Orthodontic Myofunctional Braces, Skeletal / malocclusion Class II div (i), Sub speciality of dentistry

## **Interventions**

The intervention is an orthodontic brace used to correct the small lower jaw and prominent upper teeth which is called a 'twinblock'. This brace has been in use for over 30 years and is used widely on growing children between 10.5 and 15 years old.

All children wear the brace for 18 months. The difference is when you have your treatment

Group 1: wears the brace straight away

Group 2: has to wait 18 months to become a little older

## **Intervention Type**

Device

## **Primary outcome(s)**

1. Facial and dental movements
2. Study models plaster casts to measure tooth movements
3. X-ray to measure facial/jaw growth

## **Key secondary outcome(s)**

1. Self esteem - Piers Harris 2002 questionnaire
2. Psychosocial impact OASIS (Mandall et al 200) validated questionnaire
3. Oral health quality of life questionnaire (Jokovic et al 2002)

## **Completion date**

29/12/2017

## Eligibility

### Key inclusion criteria

1. Girls who are nearing their 11th birthday
2. Boys who are nearing their 12th birthday
3. Overjet (upper teeth prominence) of 7mm or more
4. Skeletal class II jaw pattern (a lower jaw which is set back)
5. White Caucasian children only
6. Written parent and child consent

### Participant type(s)

Patient

### Healthy volunteers allowed

No

### Age group

Child

### Lower age limit

10 years

### Upper age limit

11 years

### Sex

All

### Key exclusion criteria

1. Girls older than 12.5 years
2. Boys older than 13.5 years
3. Cleft lip or palate or craniofacial syndrome
4. Lower jaw asymmetry
5. Muscular dystrophy
6. General health precludes treatment
7. Presence of medically diagnosed growth excess or deficiency
8. Not dentally fit - presence of tooth decay or gum disease
9. Previous orthodontic treatment

### Date of first enrolment

29/12/2011

### Date of final enrolment

01/12/2014

## Locations

### Countries of recruitment

United Kingdom

England

**Study participating centre**

**Tameside Hospital NHS Foundation Trust**

Greater Manchester

United Kingdom

OL6 9RW

## Sponsor information

**Organisation**

Tameside Hospital NHS Foundation Trust (UK)

**ROR**

<https://ror.org/04d713p41>

## Funder(s)

**Funder type**

Hospital/treatment centre

**Funder Name**

Tameside Hospital NHS Foundation Trust (UK)

## Results and Publications

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are not expected to be made available as there is no participant consent to share data

**IPD sharing plan summary**

Not expected to be made available