

# The long-term effects of orthodontic growth modification for severe Class II anomalies

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| <b>Submission date</b><br>19/01/2001   | <b>Recruitment status</b><br>No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol |
| <b>Registration date</b><br>19/01/2001 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>07/09/2009       | <b>Condition category</b><br>Oral Health          | <input type="checkbox"/> Individual participant data  |

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
G9901331

## Study information

**Scientific Title**

**Study objectives**

The proposed study is a follow-up to an existing MRC funded study into orthodontic growth modification treatment for Class II skeletal malocclusion, which:

1. Investigated early orthodontic intervention compared to a control group
2. Compared two orthodontic appliances in later intervention

The proposed study aims to

1. Compare early treatment patients and controls after any subsequent treatment received, to evaluate the long-term benefits/drawbacks of treatment timing
2. Evaluate the long-term effects of the appliances in the existing study
3. Start a new trial to compare the effect of two types of post-treatment retention on Class II patients who have finished orthodontic growth modification treatment

ISRCTN61138858 - grant G9410454 preceded this trial.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Not provided at time of registration.

### **Study design**

Randomised controlled trial

### **Primary study design**

Interventional

### **Study type(s)**

Not Specified

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

Dental

### **Interventions**

Study 1: Early orthodontic treatment with Twin Block or untreated control

Study 2: Orthodontic treatment with a Twin Block or a Herbst appliance

Study 3: Orthodontic treatment with a Twin Block appliance randomised to fixed or removable orthodontic retention

ISRCTN61138858 - grant G9410454 preceded this trial.

### **Intervention Type**

Other

### **Phase**

Not Specified

### **Primary outcome(s)**

Study 1

Children in the early group, already randomised to treatment or control, will be treated where necessary according to the protocol of the consultant. Records will be taken at the end of all treatment or after 5 years if there has been no treatment. The outcomes will be:

- Whether further treatment was needed.
- If treatment was needed.
- Duration of treatment.
- Did the treatment involve jaw surgery?
- The number of visits required to complete treatment.
- Dental change, recorded from study model analysis with the PAR index.
- Skeletal and Dental change, measured with cephalometric analysis.
- Change in patient perceptions with Piers Harris self-esteem measure.
- The cost of the treatment
- Trauma to the incisors?

### Study 2

Patients already randomised to treatment with a Herbst or a Twin Block appliance (treatment now completed) will be followed up for a period of 5 years and the following outcome measures will be collected:

- Skeletal and dental change, measured with cephalometric analysis.
- Dental change, recorded from study model analysis with the PAR index.
- Change in patient perceptions with Piers Harris self-esteem measure.

### Study 3

Patients finishing growth modification treatment with a Twin Block appliance will be randomised to two groups. One group will be given upper and lower removable retaining appliances, the other will have fixed retaining appliances fitted to the inside of their anterior teeth. Outcomes:

- Skeletal and dental change, measured with cephalometric analysis.
- Dental change, recorded from study model analysis with the PAR index.
- Change in patient perceptions with Piers Harris self-esteem measure.

### Key secondary outcome(s)

Not provided at time of registration.

### Completion date

30/09/2006

## Eligibility

### Key inclusion criteria

Studies 1 and 2 : Initial Dental overjet of greater than 7 mm; enrolment in the original Class II study.

Study 3: The patient has received Twin Block treatment followed by upper and lower fixed appliances; the original overjet was greater than or equal to 7 mm; any operator in the department provided treatment.

### Participant type(s)

Patient

### Healthy volunteers allowed

No

### Age group

Child

**Sex**

Not Specified

**Key exclusion criteria**

Studies 1 and 2: Initial dental overjet of less than 7 mm; enrolment in the original Class II Study.

Study 3: Individuals with clefts of the lip and/or palate or any other suspected identifiable syndromes; people with midline diastema not caused by incisor proclination; people with hypodontia; treatment discontinued early/poor oral hygiene.

**Date of first enrolment**

01/04/2001

**Date of final enrolment**

30/09/2006

**Locations**

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Department of Dental Medicine and Surgery**

Manchester

United Kingdom

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**Sponsor information**

**Organisation**

University of Manchester (UK)

**ROR**

<https://ror.org/027m9bs27>

**Funder(s)**

**Funder type**

Research council

**Funder Name**

Medical Research Council (MRC) (UK)

**Alternative Name(s)**

Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

## Results and Publications

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

Not provided at time of registration

**Study outputs**

| Output type                     | Details            | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|--------------------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results of Study 1 | 01/09/2003   |            | Yes            | No              |