

# A randomised controlled trial to assess whether smoking cessation instruction provided by orthodontists to teenage orthodontic patients is beneficial

|                                        |                                                               |                                                      |
|----------------------------------------|---------------------------------------------------------------|------------------------------------------------------|
| <b>Submission date</b><br>16/11/2008   | <b>Recruitment status</b><br>No longer recruiting             | <input type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>30/03/2009 | <b>Overall study status</b><br>Completed                      | <input type="checkbox"/> Protocol                    |
| <b>Last Edited</b><br>16/06/2016       | <b>Condition category</b><br>Mental and Behavioural Disorders | <input type="checkbox"/> Statistical analysis plan   |
|                                        |                                                               | <input type="checkbox"/> Results                     |
|                                        |                                                               | <input type="checkbox"/> Individual participant data |
|                                        |                                                               | <input type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Mrs Susi Caldwell

### Contact details

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## Additional identifiers

### Protocol serial number

Sponsor/protocol No.: 20080D001

## Study information

**Scientific Title**

A randomised controlled trial of smoking cessation instruction in teenage orthodontic patients

**Study objectives**

Null hypothesis:

Smoking cessation instruction provided to teenage orthodontic patients will have no impact on quit rates of smoking patients, nor smoking uptake rates of non-smoking patients.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Oldham Research Ethics Committee, 18/02/2009, ref: 09/H1011/1

**Primary study design**

Interventional

**Study design**

Randomised controlled trial

**Study type(s)**

Other

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

Smoking, malocclusion

**Interventions**

The smoking cessation instruction will be verbal from the orthodontist along with pictorial information. The orthodontist will discuss with the patient an information sheet containing facts regarding the effects of smoking on the mouth, face and teeth, as well pictures of such effects.

The control group of participants will receive their orthodontic treatment only (no interventions).

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome(s)**

Smoking status is measured at 6 and 12 months.

**Key secondary outcome(s)**

No secondary outcome measures

**Completion date**

30/06/2010

**Eligibility**

**Key inclusion criteria**

1. Orthodontic patients (both males and females) 11-18 years at start of study
2. About to start or undergoing orthodontic treatment with fixed or removable orthodontic appliances
3. Parental agreement to the child's participation in the study and that the child has full confidentiality regarding their smoking status (if child under 16)

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Child

**Lower age limit**

11 Years

**Upper age limit**

18 Years

**Sex**

All

**Key exclusion criteria**

Lack of consent - parental or child

**Date of first enrolment**

01/02/2009

**Date of final enrolment**

30/06/2010

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre**

Department of Orthodontics & Oral Surgery

Manchester

United Kingdom

M23 9LT

# Sponsor information

## Organisation

University Hospital of South Manchester NHS Foundation Trust (UK)

## ROR

<https://ror.org/00he80998>

# Funder(s)

## Funder type

Hospital/treatment centre

## Funder Name

University Hospital of South Manchester NHS Foundation Trust

## Funder Name

Burnley General Hospital

## Funder Name

Trafford General Hospital

## Funder Name

Tameside General Hospital

## Funder Name

Salford Royal Hospital

# Results and Publications

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

