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

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
16/11/2008	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
30/03/2009	Completed	Results
Last Edited	Condition category	Individual participant data
16/06/2016	Mental and Behavioural Disorders	Record updated in last year

#### Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

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#### 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

#### Study design

Randomised controlled trial

#### Primary study design

Interventional

#### 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

**Study outputs** 

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet Participant information sheet 11/11/2025 No Yes