ISRCTN79526387 https://doi.org/10.1186/ISRCTN79526387

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

Submission date
16/11/2008

Recruitment status
No longer recruiting

Registration date
30/03/2009

Overall study status
Completed

Last Edited
16/06/2016

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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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United Kingdom
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Other

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
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 measure
Smoking status is measured at 6 and 12 months.

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/02/2009

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

Age group
Child

Lower age limit
11 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
200

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
England

United Kingdom

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)

Sponsor details
c/o Dr Andrew Maines
R & D Directorate
Education & Research Centre
Wythenshawe Hospital
Southmoor Road
Wythenshawe
Manchester
England
United Kingdom
M23 9LT

Sponsor type
Hospital/treatment centre

Website
http://www.uhsm.nhs.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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration