

Evaluation of QUIT's Break Free smoking cessation intervention for young people

Submission date 11/05/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 04/06/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 06/03/2015	Condition category Mental and Behavioural Disorders	<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
Dr Wolf Markham

Contact details
School of Health and Social Studies
The University of Warwick
Warwick
United Kingdom
CV4 7AL
-
wolf.markham@warwick.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Evaluation of QUIT's Break Free smoking cessation intervention for young people: a cluster-randomised controlled trial

Study objectives

1. A stop smoking support group, run by the national charity QUIT, will help more young people to stop smoking than getting advice on how to do so on their own
2. The running of a smoking cessation group will have an effect on the whole school smoking prevalence (a population effect)

Ethics approval required

Old ethics approval format

Ethics approval(s)

London MREC, 09/08/2007, ref: 07/H0718/45

Study design

Cluster-randomised single-centre controlled trial

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

School

Study type(s)

Treatment

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 prevalence and cessation

Interventions

The intervention will consist of QUIT's Break Free smoking cessation programme for groups of young people. The intervention will occur on the school premises and will be administered by the staff of QUIT. It will take place over 7 weeks with each session lasting approximately 30 - 50 minutes. The control will consist of one-to-one advice given to young people over the same period of time.

Intervention Type

Behavioural

Primary outcome measure

Success of quitting smoking four weeks post quit day (the standard used by the NHS). This will be defined as self declared abstinence from smoking on days 21 - 28, confirmed by an exhaled carbon monoxide concentration of less than 10 parts per million.

Secondary outcome measures

1. Seven-day point prevalence abstinence at four weeks and six months
2. Sustained abstinence at six months, measured according to the Russell Standard
3. Young people's evaluations of the value of the QUIT's Break Free smoking cessation course

Overall study start date

01/06/2006

Completion date

31/05/2008

Eligibility**Key inclusion criteria**

1. Pupils (aged 11 - 16 years) of schools who agree to participate in the study will be offered access to either the intervention or control
2. Pupils of participating schools will be judged as competent to make their own decisions as to whether they wish to participate in the programme; no parental consent is required

Participant type(s)

Other

Age group

Child

Lower age limit

11 Years

Upper age limit

16 Years

Sex

Both

Target number of participants

200 (100 intervention/100 control)

Key exclusion criteria

1. Schools who only agree to participate if they are offered either the control or intervention will be excluded
2. Pupils of participating school whose parents object to their participation will be excluded from the programme

Date of first enrolment

01/06/2006

Date of final enrolment

31/05/2008

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

The University of Warwick

Warwick

United Kingdom

CV4 7AL

Sponsor information

Organisation

Cancer Research UK (CRUK) (UK)

Sponsor details

PO Box 123

London

United Kingdom

WC2A 3PX

Sponsor type

Charity

Website

<http://www.cancerresearchuk.org>

ROR

<https://ror.org/054225q67>

Funder(s)

Funder type

Charity

Funder Name

Cancer Research UK (CRUK) (UK) (ref: A7201)

Alternative Name(s)

CR_UK, Cancer Research UK - London, CRUK

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol and preliminary results	14/12/2010		Yes	No