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

Submission date	Recruitment status	[_] Prospectively registered
11/05/2009	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/06/2009	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
06/03/2015	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

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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Child

Lower age limit
11 years

Upper age limit
16 years

Sex
All

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
United Kingdom

England

Study participating centre
The University of Warwick
Warwick
United Kingdom
CV4 7AL

Sponsor information

Organisation
Cancer Research UK (CRUK) (UK)

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, Cancer Research UK (CRUK), CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

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