

# Preventing uptake of smoking in school-aged children

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| <b>Submission date</b><br>21/11/2012   | <b>Recruitment status</b><br>No longer recruiting             | <input checked="" type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol |
| <b>Registration date</b><br>03/12/2012 | <b>Overall study status</b><br>Completed                      | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>29/09/2020       | <b>Condition category</b><br>Mental and Behavioural Disorders | <input type="checkbox"/> Individual participant data  |

## Plain English summary of protocol

### Background and study aims

Cigarette smoking is the biggest preventable cause of illness and death in the UK. Most smokers start smoking when they are still at secondary (high) school. Smokers who start at this early age are less likely to quit and more likely to be affected by smoking-related illness during their lives. It is therefore important to try to prevent children taking up smoking. Following a period of development work we will investigate a smoking prevention package which combines educational resources for use in schools with materials for use with childrens families or caregivers to reinforce the anti-smoking message.

### Who can participate?

The trial will include 40 schools in the East Midlands area. Approximately 150 students per school (6000 students in total) will take part in the study.

### What does the study involve?

The trial will include 40 schools in the East Midlands area, half of which will receive the smoking prevention package and half of which will not. We will test the effectiveness of a teaching resource called Operation Smoke Storm, developed by Kick It, the Hammersmith and Fulham Stop Smoking Service, in which young people act the role of secret agents working undercover in the tobacco industry. The resource provides information on the health impacts of active and passive smoking along with content not used before in youth smoking prevention in the UK. This includes insights into company tactics, the effect of the tobacco industry on the environment and exploitation of developing country populations. We will trial the use of Operation Smoke Storm with Year 7 students (aged 11-12), along with a booster session when students are in Year 8 (aged 12-13) and additional materials for use with childrens families or caregivers to reinforce the anti-smoking message. The package will be evaluated using data collected from questionnaires and focus groups with students, teachers and family members.

### What are the possible benefits and risks of participating?

Students may benefit from a new way of teaching a topic which is already covered in the curriculum, and if our package is more effective than current practice they will benefit if they do not start smoking. We will provide information for any students, teachers or family members who smoke and who express a desire to quit after receiving the educational package.

There are no risks for students, family members or teachers who receive or teach the educational package.

Where is the study run from?

The study will be run by researchers at the University of Nottingham, in collaboration with the Universities of Stirling, York and Kings College London, and Kick It, the Hammersmith and Fulham Stop Smoking Service.

When is the study starting and how long is it expected to run?

We plan to start the study in January 2013 and it will run until approximately July 2016. However, the early part of the project will focus on designing and testing the package in a limited number of schools, with the larger-scale trial due to commence in January 2015.

Who is funding the study?

The study is funded by the National Institute for Health Research's Public Health programme.

Who is the main contact?

Graeme Docherty  
graeme.docherty@nottingham.ac.uk

## Contact information

### Type(s)

Scientific

### Contact name

Dr Lisa Szatkowski

### Contact details

City Hospital  
Epidemiology & Public Health  
Clinical Sciences Building  
Hucknall Road  
Nottingham  
United Kingdom  
NG5 1PB

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

## Study information

**Scientific Title**

Development and evaluation of a novel intervention providing insight into the tobacco industry to prevent the uptake of smoking in school-aged children

**Study objectives**

To assess whether a multi-component intervention involving education resources for use in schools, alongside family components, is effective and cost-effective in preventing the uptake of smoking in school-aged children.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

University of Nottingham Medical School Research Ethics Committee approval pending

**Study design**

Cluster-randomised controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Other

**Study type(s)**

Prevention

**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**

Tobacco control intervention in schools

**Interventions**

Schools are randomised 1:1 to delivery of the package (intervention) or to control (no intervention). We aim to recruit 40 schools in the East Midlands, with 20 receiving a package based on Operation Smoke Storm, an educational resource highlighting the manipulative tactics of the tobacco industry. 20 schools will act as controls (they will be offered the intervention at the end of the trial if its effectiveness is proven).

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

The proportion of students who are current smokers or susceptible to smoking at the final follow-up point in Year 8 and compare this between those who have and have not received the intervention.

**Secondary outcome measures**

1. Attitudes to smoking including situational self-efficacy
2. Smoking experimentation and uptake; cessation attempts
3. Smoking in students homes
4. Exposure to second hand smoke
5. Perceived acceptability of the intervention
6. Cost-effectiveness

**Overall study start date**

02/01/2013

**Completion date**

31/07/2016

## **Eligibility**

**Key inclusion criteria**

For the cluster-randomised controlled trial we aim to recruit 40 schools in the East Midlands, with 20 receiving the intervention and 20 acting as controls (who will be offered the intervention at the end of the trial if its effectiveness is proven).

1. All mainstream secondary schools (both private and non-private) with students in at least Years 7 to 11
2. In Leicestershire many areas have linked middle (aged 10-14) and high schools (14-18) with students progressing automatically from one to the other. In these areas, schools will only be recruited in linked pairs to ensure longer-term follow up of students is possible.
3. All students in Year 7 at the start of the trial will be eligible for inclusion

**Participant type(s)**

Patient

**Age group**

Child

**Lower age limit**

10 Years

**Upper age limit**

18 Years

**Sex**

Both

**Target number of participants**

Approximately 6000 students in 40 schools (average 150 per school) will be included in the trial.

**Total final enrolment**

1473

**Key exclusion criteria**

Does not meet inclusion criteria

**Date of first enrolment**

02/01/2013

**Date of final enrolment**

31/07/2016

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

England

United Kingdom

**Study participating centre**

**City Hospital**

Nottingham

United Kingdom

NG5 1PB

**Sponsor information****Organisation**

University of Nottingham (UK)

**Sponsor details**

c/o Mr Paul Cartledge

Research & Graduate Services

King's Meadow campus

Lenton Lane

Nottingham

England

United Kingdom

NG7 2NR

**Sponsor type**

University/education

**Website**

<http://www.nottingham.ac.uk/fabs/rgs/home.aspx>

ROR

<https://ror.org/01ee9ar58>

## Funder(s)

**Funder type**

Government

**Funder Name**

National Institute for Health Research [NIHR] - Public Health Research Programme (UK)

## 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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 03/11/2017   | 29/09/2020 | Yes            | No              |