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Preventing uptake of smoking in school-aged children

Submission date
21/11/2012

Recruitment status
No longer recruiting

Registration date
03/12/2012

Overall study status
Completed

Last Edited
29/09/2020

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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 Researchs Public Health programme.

Who is the main contact?
Graeme Docherty
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

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

Primary study design
Interventional

Study design
Cluster-randomised controlled trial

Study type(s)
Prevention

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 acting 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(s)
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.

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Child

Lower age limit
10 Years

Upper age limit
18 Years

Sex
All

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
United Kingdom

England

Study participating centre

City Hospital
Nottingham
United Kingdom
NG5 1PB

Sponsor information

Organisation
University of Nottingham (UK)

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

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?
Results article	results	03/11/2017	29/09/2020	Yes	No