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Investigation of a Smoking Prevention intervention for Young People

Submission date
26/10/2012

Recruitment status
No longer recruiting

Registration date
30/11/2012

Overall study status
Completed

Last Edited
08/03/2019

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Tobacco smoking continues to be an important cause of various diseases and death both in the UK and world wide. The vast majority of smokers take up the habit as adolescents between the ages of 10 and 20 years. This appears to be the case despite the fact that health promotion messages have ensured that awareness of the health consequences of smoking is now widespread, even among the young. The present research focuses on reducing smoking initiation as potentially the most effective way to reduce smoking-related harm. The method in question is the formation of repeated implementation intentions about how to refuse offers of cigarettes. Implementation intentions are simple if-then plans of how to respond to environmental cues in order to help achieve a goal such as not taking up smoking, e.g., if offered a cigarette I will say no thanks, I dont smoke. The aim of the current study is to find out whether the method is effective in preventing smoking initiation among young people.

Who can participate?
Year 7 high school students from the Leeds and Staffordshire area, UK.

What does the study involve?
Participating high schools will be randomly assigned to either an intervention or control group. Year 7 high school students (11-12 years of age) will complete a smoking questionnaire and carbon monoxide (CO) test at the start of the study. In the intervention group, adolescents will form implementation intentions (If-then plans) about how to refuse offers of cigarettes and read simple anti-smoking messages designed to increase motivation not to smoke. In the control group, adolescents will form similar implementation intentions in relation to an unrelated behaviour (i.e., completing all homework) and also read simple motivational messages about that behaviour. The messages and implementation intention task will be presented in the form of a questionnaire. The task will be introduced and led by a trained teacher but completed individually in the classroom and will take a maximum of 30 minutes to complete. Training on how to introduce and conduct the implementation intention method will be undertaken by teachers in the participating schools. Both sets of implementation intentions will be repeated every six months over a four-year time period. Carbon monoxide test and self-reported smoking (questionnaire) will be measured at twelve month intervals over the same four-year time period.

Where is the study run from?
Participating high schools are based in the Leeds and Staffordshire area, UK.

When is the study starting and how long is it expected to run for?
The study starts in September 2012 and is expected to run until December 2016.

What are the possible benefits and risks of participating?
Benefits may involve motivating students to make informed decisions about not smoking. Should the results of the study be positive this could support its widespread use to reduce smoking initiation rates in adolescent groups. Given the relatively simple nature of the intervention this could provide a scalable, cost-effective means of reducing adolescent smoking initiation. Specific benefits for schools include evidence to support the key judgment of Behaviour and Safety of pupils within the OFSTED Inspection Framework, support for schools if they are part of the Healthy Schools programme. four free CPD workshops over 4 years by the researchers, schools are provided with a prestigious certificate for promoting health research. No major risks or discomfort are anticipated.

Who is funding the study?
Medical Research Council (MRC) / National Prevention Research Initiative (NPRI) in the UK.

Who is the main contact?
Professor Mark Conner
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Study website
http://www.psyc.leeds.ac.uk/10/research/hlth/smoking

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Smoking prevention in young people: a cluster randomised controlled trial of implementation intentions

Acronym
SPYP

Study objectives
1. Can repeated implementation intentions related to refusing offers of cigarettes reduce smoking initiation rates in 11-16 year olds relative to a control group of adolescents?
The research question will be addressed using a cluster randomised controlled trial. Participants will be randomised to either an intervention or control condition, and will be compared on objective and self reported smoking outcomes.
Objectively-assessed and self-reported smoking will be measured in data collection sessions at twelve month intervals over a four year time period (i.e., a total of 5 occasions from baseline to 4 years post-baseline). Objectively-assessed smoking at the final time point will be our primary outcome measure, while self-reported smoking will be our secondary outcome measure.

2. What is the cost effectiveness of such an intervention?
Careful recording of the time and costs involved in implementing the intervention will allow us to conduct a full-cost effectiveness (i.e., health economic) analysis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Leeds Research Ethics Committee, 20 September 2012, ref: 12-0155

Study design
Phase III 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
Smoking initiation

Interventions
There are two conditions: intervention and control. The research involves teachers delivering either an intervention OR control session every six months over a period of four years between the ages of 11-12 and 15-16 years (8 occasions).

Intervention - Smoking Prevention Condition
The intervention involves of asking adolescents to read simple anti-smoking messages and then forming an implementation intention by planning how, where, and when to resist smoking (i.e., refuse the offer of a cigarette).

The anti-smoking messages focus on simple to understand negative consequences of starting smoking and the positive consequences of remaining a never smoker. The implementation intervention is designed to give adolescents simple responses for how to refuse a cigarette. It is also designed to link this simple response to likely situations where a cigarette might be offered. Five options will be provided for how they could refuse the offer of a cigarette or resist the temptation to smoke (e.g., No thanks, I dont want to smoke; No thanks, I dont want the habit; No cancer sticks for me; No thanks, smoking makes you smell bad; No, its bad for your health). Participants are required to check the options they plan to use or to write in an additional response. Similarly participants will be required to check where they would not smoke (e.g., I will not smoke at school; I will not smoke at home; I will not smoke at a party; I will not smoke with my friends; I will not smoke if offered a cigarette) and when they would not smoke (e.g., I think I can make sure I dont smoke) and to agree to their plan.

Control - Homework Condition
The design is similar to the intervention condition except the control condition involves asking adolescents to read simple pro-homework messages and then forming an implementation intention by planning how, where, and when to compete homework.

The pro-homework messages focus on simple techniques used to help students feel more positive about completing homework. The implementation intervention is designed to give adolescents simple responses on how to complete homework. Five options will be provided for how they could complete their homework (e.g., Do the homework when it is given to me; Do the homework in a quiet place without distractions; Do homework with friends; Do the homework and ask for help if it is difficult; Do the homework in stages by
planning it out). Participants are required to check the options they plan to use or to write in an additional response. Similarly participants will be required to check where they would complete homework (e.g., When I get up in the morning; When I get home from school; After Ive had my tea; Last thing at night; At lunchtime at school.) and when they would complete homework (e.g., I think I can get all my homework done) and to agree to their plan.

Both conditions
Students in both conditions (intervention and control) will complete a smoking questionnaire and carbon monoxide (CO) test at one year intervals over a four year period (baseline and four separate time points: 12, 24, 36 and 48 months post baseline).

Intervention Type
Other

Phase
Phase III

Primary outcome measure
Smoking initiation based on objective measures: carbon monoxide (CO) test. CO will be assessed at baseline and at 12, 24, 36 and 48 months post baseline in order to explore the time periods over which the intervention might be best targeted. The primary outcome will be the data from the final time point.

Our objective measure of smoking will be obtained from breath carbon monoxide monitors (Micro+ Smokerlyzer® CO Monitor, Bedfont Scientific Limited, Kent, England). This instrument gives a measure of carbon monoxide in the breath in parts per million (ppm) accurate to within 2% based upon exhaling one breath into the device and has been adapted for use in adolescent samples.

Secondary outcome measures
Self-reported smoking is our secondary outcome measure. Self-reported smoking and measures of cognitions will be collected via questionnaire completed individually but in a classroom setting (assessed at baseline, 12, 24, 36, and 48 months post baseline). The key secondary outcome measure will be self-reported smoking at the final time point.

Self-reported smoking will be assessed by standard measures (as used in national surveys and our previous research; Conner & Higgins, 2010; Jarvis, 1997). We will also measure smoking cognitions (e.g., beliefs about smoking, attitudes to smoking, intentions to resist smoking, self-efficacy over resisting, family smoking and friends smoking).

Overall study start date
01/10/2012

Completion date
31/12/2016

Eligibility

Key inclusion criteria
1. Year 7 female and male high school students (starting high school in October 2012) from the Leeds and Staffordshire area.
2. At baseline students will be aged between 11-12 years. At the end of the study participants will be aged between 15-16 years.

Participant type(s)
Patient

Age group
Child

Lower age limit

11 Years

Upper age limit
12 Years

Sex
Both

Target number of participants
4320

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/10/2012

Date of final enrolment
31/12/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Professor of Applied Social Psychology
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Sponsor information

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Sponsor type
University/education

Website
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ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) - National Prevention Research Initiative (NPRI) Phase 4 (UK) ref: MR/J000264/1

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date
30/04/2019

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	19/01/2013		Yes	No
Results article	results	01/05/2019	08/03/2019	Yes	No