

The Filter FE Challenge: pilot trial and process evaluation of a multi-level smoking prevention intervention in further education settings

Submission date 27/09/2014	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 12/12/2014	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 09/11/2017	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Smoking remains the leading cause of ill health and early death in the UK. Preventing young people from taking up smoking is vital to improving public health. More than 1.5 million 16-18 year olds now attend further education (FE) courses in the UK, typically in sixth form colleges and general FE colleges. For many young people, this is the time in their lives when they begin smoking as they make new friends and become more independent from their parents; over 40% of adult smokers say that they started the habit when aged between 16-19 years old. Despite this, there has been little investment in smoking prevention activities in either general FE colleges or sixth form colleges. Here, we will test the Filter FE Challenge, a new smoking prevention project for 16-18 year olds that has been designed to be run in the FE college environment. To do this, we will work with Action on Smoking and Health (ASH) Wales and six colleges (including large FE colleges and smaller sixth form colleges) in Wales. At the moment we don't know if it will be possible to carry out all of the activities of the Filter FE Challenge in full in different types of FE colleges, or if these activities will prove acceptable to staff and students. There may even be unintended consequences that no-one has anticipated and the project may need to be revised. We will therefore assess if the activities were run as intended, if and how this varied in different colleges, and find out people's views about the process and consequences of this. We also don't know whether colleges will be willing to be allocated to a control group at random, so we will assess this, and also how many young people are willing to take part in the study. We will also try to estimate the costs of these smoking prevention activities prior to any further research. If the project activities and research are delivered as planned then we intend to proceed to a much larger evaluation to see if the project reduces the uptake of smoking among 16-18 year-olds, by how much, and at what cost.

Who can participate?

Students aged between 16-18 attending one of the FE colleges taking part in the study

What does the study involve?

The colleges taking part in the study are randomly allocated into one of two groups. Those in group 1 run the the Filter FE Challenge project. Those in group 2 continue as usual and act as a

control group. At the three colleges where the project is run, ASH Wales provide project managers, education officers, social media experts and trained youth workers to help these colleges to put in place a range of new smoking prevention activities. This includes ensuring those under age 18 cannot buy tobacco products in local shops, implement smoke-free policies and teaching college staff to teach students about the harms of smoking. Existing web-based information, social media campaigns and online services designed for young people are also integrated with the college's website and social media. Youth workers also provide credible messages about smoking and resisting peer pressure, and signpost support services.

What are the possible benefits and risks of participating?

Not provided at time of registration

Where is the study run from?

Cardiff University (UK)

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

September 2014 to October 2015

Who is funding the study?

National Institute for Health Research (UK)

Who is the main contact?

Dr Adam Fletcher

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Study website

<http://www.nets.nihr.ac.uk/projects/phr/134202>

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

PHR 13/42/02

Study information

Scientific Title

The Filter FE Challenge: pilot trial and process evaluation of a multi-level smoking prevention intervention in further education settings: a pilot clustered randomised controlled trial

Study objectives

This study aims to evaluate the feasibility and acceptability of implementing and trialling The Filter FE Challenge (a new smoking prevention intervention).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Cardiff University School of Social Sciences Research Ethics Committee, July 2014, ref: SREC /1271

Study design

A pilot clustered randomised controlled trial (RCT) and embedded process evaluation of The Filter FE Challenge to evaluate intervention and trial feasibility and acceptability.

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

School

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Smoking prevention

Interventions

The Filter FE Challenge is a universal, multi-level smoking prevention intervention that is intended to be adaptable for use in all FE settings (i.e. general FE colleges/campuses, sixth form colleges, etc.), delivered by trained staff, using resources developed by ASH Wales for The Filter youth project. Informed by evidence of effective smoking prevention methods and approaches,

the intervention aims to prevent the uptake of smoking among FE students aged 16-18 at multiple levels via:

1. Restricting the sale of tobacco to under 18 year-olds
2. Implementing tobacco-free campus policies
3. Training FE staff to deliver anti-smoking messages and support institutional change
4. Publicising The Filter youth project's online social marketing campaigns, advice and support services
5. Youth work activities to provide credible educational messages, modify perceived norms, and promote social/situational resistance skills, as well signposting cessation services if necessary

Intervention Type

Behavioural

Primary outcome measure

The pilot primary outcome is regular smoking (defined as smoking at least one cigarette weekly or more). Collected September 2014 (baseline) and September 2015 (follow-up)

Secondary outcome measures

1. Lifetime smoking (ONS GHS item)
2. Frequent cannabis use (3 or more times in last 30 days), using the EMCDDA European Model Questionnaire (EMQ) items
3. High risk alcohol use, using the Alcohol Use Disorders Identification Test Consumption (AUDIT-C) measure
4. Health-related quality of life (HRQoL), using the EQ-5D-5L measure.

The following are additional pilot secondary outcomes for baseline smokers:

1. Cessation (ONS GHS item)
2. Number of cigarettes/week (ONS GHS item)
3. Nicotine dependence using the Heaviness of Smoking Index (HSI) items

Collected September 2014 (baseline) and September 2015 (follow-up)

Overall study start date

01/09/2014

Completion date

31/10/2015

Eligibility

Key inclusion criteria

Six further education (FE) settings in south Wales will be purposively sampled for a pilot trial to examine delivery and trial methods in a range of institutional contexts. The following diversity/matching criteria will be used to recruit six FE Settings:

1. Sixth form colleges attached to schools (n=2)
2. Small FE colleges/campuses (new intake fewer than 500) (n=2)
3. Large FE colleges/campuses (new intake more than 500) (n=2)

Students are eligible for selection if:

1. They are aged between 16 and 18 years old
2. They begin further education studies in one of the participant institutions in September 2014

Participant type(s)

Other

Age group

Child

Lower age limit

16 Years

Upper age limit

18 Years

Sex

Both

Target number of participants

Six FE settings will participate in the trial: 3 intervention group; 3 control group. The estimated sample is 2500.

Key exclusion criteria

1. Private institutions
2. Small sites (with fewer than 100 students)
3. Sixth forms at schools where fewer than 10% of students are entitled to free school meals (FSM)
4. Students who report being older or younger than 16-18

Date of first enrolment

01/09/2014

Date of final enrolment

31/10/2015

Locations**Countries of recruitment**

United Kingdom

Wales

Study participating centre

Cardiff University

Cardiff

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CF10 3BD

Sponsor information

Organisation

Cardiff University Research & Commercial Division (UK)

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Sponsor type

University/education

ROR

<https://ror.org/03kk7td41>

Funder(s)**Funder type**

Government

Funder Name

Public Health Research Programme (PHR 13/42/02)

Alternative Name(s)

NIHR Public Health Research Programme, PHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

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?
Results article	results	01/10/2017		Yes	No