Filter FE

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

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This protocol has been authorised by:

Name	**Role:**	**Signature**	**Date**
Adam Fletcher	Chief Investigator		**27.11.14**

General Information This protocol describes the Filter FE pilot trial and provides information about the procedures for entering participants into the study. Every care has been taken in drafting this protocol; however, corrections or amendments may be necessary. These will be circulated to the known Investigators in the study. Problems relating to the trial should be referred, in the first instance, to DECIPHer.

Compliance This study will adhere to the conditions and principles outlined in the EU Directive 2001/20/EC, EU Directive 2005/28/EC and the ICH Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95). It will be conducted in compliance with the protocol, the Research Governance Framework for Health and Social Care (Welsh Assembly Government November 2001 and Department of Health 2nd July 2005), the Data Protection Act 1998, and other regulatory requirements as appropriate.

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Please contact the Study Manager for general queries and supply of trial documentation

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Glossary of abbreviations

AE	Adverse Event
CF	Consent Form
CTU	Clinical Trials Unit
CU	Cardiff University
FE	Further Education
HE	Health Economics
HTA	Health Technology Assessment
IC	Informed consent
ISRCTN	International Standard Randomised Controlled Trial Number
MSOA	Middle Layer Super Output Area
NICE	National Institute for Clinical Excellence
NIHR	National Institute for Health Research
PI	Principal Investigator
PE	Process Evaluation
R&D	Research and Development
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
SEWTU	South East Wales Trials Unit
SOP	Standard Operating Procedure
TMF	Trial Master File
TMG	Trial Management Group
TSC	Trial Steering Committee

1 Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made
1	2	13.10.14	AF	Trial manager updated (RP)
2	2	13.10.14	AF	Wording of Criterion 1 changed as recommended by TSC (p.26)
3	2	13.10.14	AF	DMC section updated as TSC agreed not required (p.35)
4	3	27.10. 14	AF; RP	Updated details throughout of the post-follow-up saliva testing sample size (n=200 reduced to n=192, 32 per FE setting and methods (cotinine and anabasine tests).
5	3	27.10.14	AF; RP	The methods for monitoring intervention team time spent on the Filter FE Challenge has also been updated (p. 29): "Detailed workload surveys emailed on a weekly basis to the core intervention staff will assess time spent on intervention-related tasks for each FE setting."
6	3.1	2.2.15	JW; AF	The definition of frequent cannabis use has been changed from 3 times to >=4 times in the past 30 days throughout the protocol. Cannabis use in the past 30 days has also been added as a secondary outcome.
7	4	11.2.15	AF; RP; BL	Student focus group numbers amended from 4 focus groups per intervention setting to 2 focus groups for sixth form, 4 focus groups for medium size college and 6 focus groups for large college (p.9; p.20)

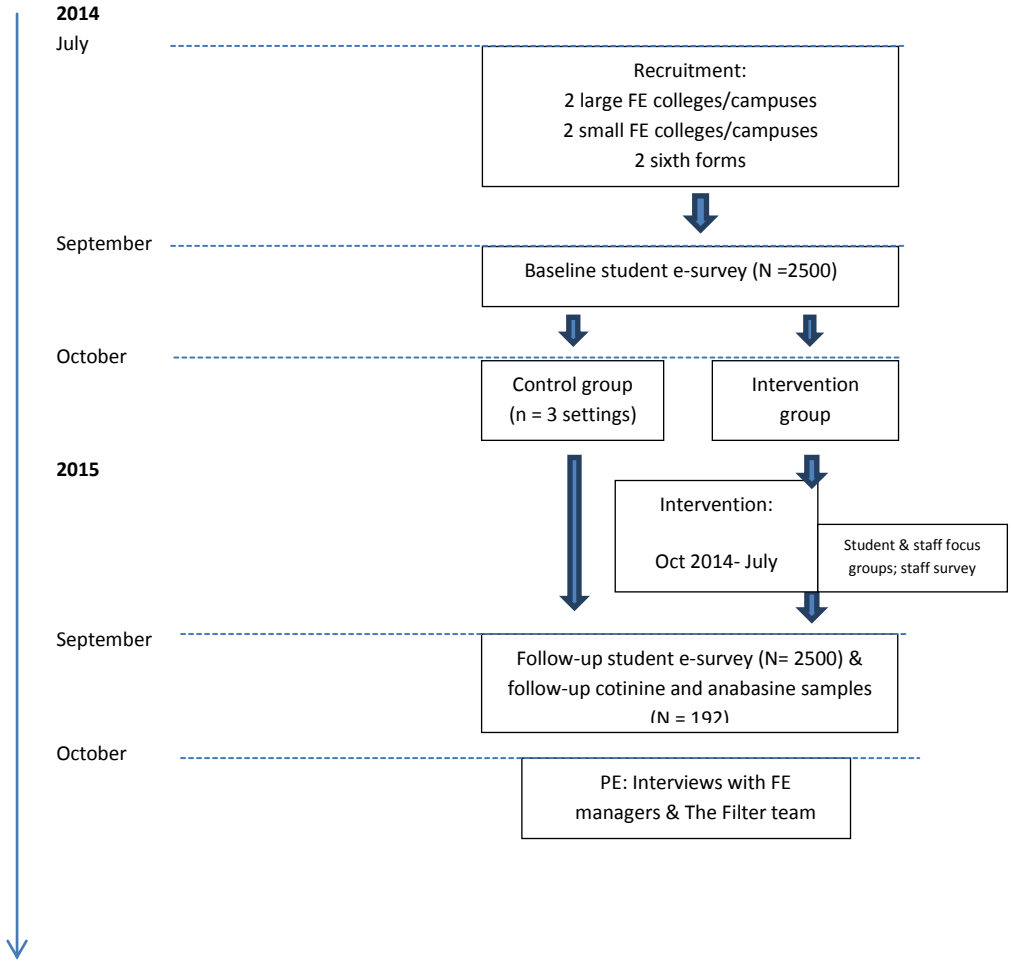
2 Synopsis

Short title	Filter FE pilot trial
Acronym	Filter FE
Trial 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.
Trial participants	The trial will involve six Further Education (FE) settings. New students aged 16-18 enrolling in September 2014 will be recruited to baseline and 1-year follow-up surveys. The process evaluation will include focus groups with students and staff, a brief survey of staff trained by the intervention team, interviews with institutional managers and the intervention team.
Planned sample size	Six FE settings will participate in the trial: 3 intervention group; 3 control group. The following diversity/matching criteria will be used to recruit six FE settings: 'sixth form' colleges attached to schools (n=2); small FE colleges/campuses (new intake fewer than 500) (n=2); large FE colleges/campuses (new intake more than 500) (n=2). New students aged 16-18 enrolling in September 2014 will be recruited to baseline and 1-year follow-up surveys. The estimated sample is 2500. No power calculation has been performed for this pilot trial as our primary aim is to evaluate feasibility and acceptability. A sub-sample of approximately 96 students will also be recruited across the three intervention sites (purposively by socio-economic status, gender, and smoking status) to participate in focus groups (2 focus groups for sixth form, 4 focus groups for medium size college and 6 focus groups for large college). To explore the validity of self-reported smoking measures and if this varies by arm, 192 students will be recruited immediately after the follow-up survey via stratified, random sampling to provide a saliva sample for cotinine and anabasine testing. Staff who participate in the training component will be recruited to take part in a brief post-intervention survey to explore their experiences of the process (approximately 70 in total; 10, 20, 40 per institution depending on size); a sub-sample of approximately 48 intervention college staff will also be recruited (purposively by gender and role) to participate in focus groups (n=2 per college). Two members of the senior management team at each participating FE setting (n=12) will be interviewed.
Follow-up duration	Twelve months
Planned trial period	Twenty-four months
Primary objective	This study aims to evaluate the feasibility and acceptability of implementing and trialling 'The Filter FE Challenge' and assess whether pre-specified feasibility and acceptability criteria are met prior to submission of a potential phase-III trial application.

Secondary objectives	To explore the experiences of FE students, staff and the intervention delivery team to refine the intervention and study design prior to a potential phase-III trial. To pilot primary, secondary and intermediate outcome measures and economic evaluation methods prior to a potential phase-III trial.
Primary endpoint	The intervention phase of the trial is expected to continue until July 2015.
Secondary endpoints	The follow-up survey will take place in September 2015 and the process evaluation will continue until November 2015. The trial will be considered to have ended in July 2016 (month 24) when the final report is submitted.
Interventions	The Filter FE Challenge.

3. Trial summary

3.1 Participant flow diagram



3.2 Trial summary

This study will examine the feasibility and acceptability of delivering and trialling 'The Filter FE Challenge' (a new smoking prevention programme designed for FE settings), including how this this varies according to institutional context; explore student, staff and intervention team experiences; and pilot primary, secondary and intermediate outcome measures and economic evaluation methods prior to a potential phase-III trial.

To facilitate this, researchers will work collaboratively with Action on Smoking and Health (ASH) Wales, who will recruit six FE institutions (four FE colleges and two 'sixth forms' attached to schools) to take part in the study. After institutional recruitment, new students

aged 16-18 enrolling at all participating FE settings for the 2014-15 academic year will complete a survey that will give information about smoking practices and attitudes. Two FE colleges and one school sixth form will be randomised post-baseline survey to the intervention group and will take part in 'The Filter FE Challenge' for the remainder of the 2014-15 college year (i.e. until July 2015). The other three institutions will act as a 'control' group and continue with normal practice. After 12 months a follow up survey will be conducted with the same cohort of students. We will also pilot collecting further information about the institutional and local neighbourhood environments (pre- and post-intervention) via observations, 'mystery shopper' audits of local shops, and an analysis of college policy documents.

At intervention sites, ASH Wales will provide project managers, education officers, social media experts and trained youth workers from The Filter team to help implement five new smoking prevention activities at intervention sites as described below:

1. The project manager will work with local retailers to inform them about the project and trading standard penalties for selling tobacco to under-18s.
2. The project manager will work with college staff to implement smoke-free policies on campus.
3. Education officers will train college staff to teach students about the harms of smoking and how to change their campus environment.
4. Existing web-based information, social media campaigns and on-line services designed for young people will be integrated with the college's website and social media.
5. Youth workers will provide credible messages about the benefits of not smoking and resisting pressure to smoke.

Information about student, staff and intervention team experiences will be collected through interviews with FE college managers, the intervention delivery team and in focus groups with intervention college students and staff.

From students who complete the follow-up survey, a subsample of 192 will be recruited to provide a saliva sample for cotinine and anabasine testing to examine the validity of the self-reported smoking outcome.

4 Introduction

4.1 Background

Smoking is a major cause of preventable illness, premature death and health inequalities in the UK. Preventing young people from taking up smoking is vital to maintain and accelerate recent declines in smoking rates. Although much research has been undertaken to develop and evaluate school-based prevention interventions targeting 11-15 year-olds[1], smoking continues to grow rapidly amongst older adolescents[2]. With over 1.5 million British 16-18 year olds now enrolled in further education (FE) courses, new smoking prevention interventions are required that target FE settings (e.g. general FE colleges, 'sixth form' colleges attached to secondary schools, etc.)[3]. As well as being a period in the life-course when smoking often begins, the transition to FE itself can increase the risk of smoking as young people are exposed to new sources of peer influence and have more independence from their parents.

Research evidence about smoking prevention interventions delivered in FE settings is sparse. Two recent systematic reviews of health improvement interventions in educational sites[4,5] contain no reference to such studies in FE settings. This finding supports recent calls from the National Institute of Health and Care Excellence (NICE)[3] for more evidence regarding smoking prevention interventions in secondary schools and in other youth settings such as FE institutions. Furthermore, the failure of the two reviews[4,5] to identify any cluster randomized controlled trials (RCTs) undertaken within FE settings highlights the lack of rigorous health improvement evaluation in this context to date.

A wider search of literature on smoking prevention in FE identified 14 relevant reports[6-19]. Amongst these, six non-systematic literature and policy reviews reported increasing policy interest in health improvement interventions targeting young people within FE settings but noted the absence of any evidence regarding appropriate or effective interventions in FE settings[6,7,9,10,12,14]. No examples of effective smoking prevention interventions delivered in this context were identified. Three studies evaluated single-session motivational interviewing (MI) interventions in English FE settings[8,11,17] finding that it is feasible to deliver brief interventions within FE settings[11]. These studies also found that MI targeting high-risk students engaged in drug use may reduce their use of cigarettes, alcohol and drug use[8]. However, it was not an effective method for preventing the uptake of smoking among 16-19 year-olds in FE[17]. One quasi-experimental study of a multi-component intervention combining health education, counselling and nicotine therapy in French vocational colleges was found to be effective in supporting smoking cessation[19].

With no evidence of effective smoking prevention methods or approaches in FE settings, five recent systematic reviews of smoking prevention interventions delivered in other educational and/or community contexts were identified and consulted to inform intervention development[20-24]. The reviews suggest the following evidence-based smoking prevention

methods and approaches are effective: reducing the illicit sale of tobacco products to under-18s[20-23]; initiating tobacco-free policies and environmental change[22]; age-appropriate, interactive educational messages delivered via intensive, long-term mass media campaigns[21]; and social competency and skill development interventions to support young people to resist peer influence[24]. A recent systematic review of school effects/environment interventions also found that initiating tobacco-free policies and environmental change is effective, especially in permissive contexts[4] which is likely to be the case in some FE settings.

Such knowledge highlights the relevance of multi-level smoking prevention interventions and identifies a set of intervention techniques and functions that may underpin intervention efficacy:

1. Restricting the availability of tobacco and opportunities for smoking
2. Restructuring environmental contexts
3. Educating and persuading young people about the harms of smoking and social norms via multiple methods and communication channels
4. Modelling social/situational resistance skills

The intervention, which is to be to be evaluated in the proposed study, has been developed by ASH Wales in collaboration with the investigator team and integrates these evidence-informed techniques and functions within a multi-level smoking prevention for FE settings.

4.2 Rationale for current trial

Preventing youth smoking is a priority for all UK governments and public health agencies. New universal interventions that can deliver further reductions in youth smoking are required to maintain recent decreases in smoking and address social inequalities in health outcomes. However, at present, there are no evidence-based smoking prevention interventions for FE settings and the feasibility and acceptability of using a cluster RCT design in such settings is also uncertain.

Systematic reviews have consistently found that multi-level adolescent health improvement interventions, addressing both individual and environmental determinants of behaviour, are the most effective[20,23,25,26]. Interventions which include 'higher-level' environmental components also tend to be more cost-effective[27] and less likely to generate inequalities than individually focused components alone[22,29]. However, if interventions are to deliver major public health gains they must have sufficient reach and be feasible to deliver and sustain[30].

This study will evaluate a multi-level intervention that balances the need for standardised evidence-informed inputs and processes with some flexibility to allow for local adaption to support universal adoption, institutional ownership and sustainable implementation of multiple activities[31,32]. Informed by the socio-ecological model of health behaviour[33] and recent systematic reviews of effective smoking prevention methods and approaches[20-24], the intervention logic model and design have been co-produced by staff at ASH Wales and the research team in consultation with Public Health Wales, the ALPHA youth group and FE staff.

Prior to undertaking a study to evaluate the effectiveness of this intervention, a pilot trial and process evaluation are required to discover whether the intervention is feasible and acceptable to implement across a range of FE settings [34,35]. Furthermore, there may be challenges to using a trial design and collecting data in FE settings. To address this uncertainty, the proposed study also aims to evaluate the feasibility and acceptability of the trial design and methods across a range of FE settings.

4.3. Risk and Benefits

No participant is likely to be subjected to any physical or psychological risks in relation to the intervention or their participation in the research study.

FE settings participating in the evaluation will facilitate collection of data from students and there will be a very limited degree of disruption for some staff and students. However, we propose to adapt strategies this team has used for collecting data in recent pilot and phase-III cluster RCTs of schools, which have minimised disruption and been successful in ensuring a high response and retention rate[e.g.36,37-39.] For example, the trial manager will work with each participating FE setting to identify the most convenient time and place for students to complete baseline and follow-up e-surveys on-site, and for students and staff to participate in focus groups. It will also be made clear that participation is voluntary and participants can withdraw at any point. Any potential for harmful effects due to the intervention will be explored via the process evaluation.

After the follow-up surveys, saliva samples will be collected for cotinine and anabasine testing from 192 students to examine the validity of self-reported smoking measures, and if under/over-reporting varies by arm, using a non-invasive technique which has been used by the applicants in other studies with children and adolescents (e.g. ASSIST[36]; CHETS [40]; the Strengthening Families Programme RCT).

There is potential for major public health benefits via the prevention of smoking at this key transitional stage in the life-course. We expect participants in the intervention arm to

experience benefits in terms of reduced smoking. A pilot trial and process evaluation are required first to examine acceptability, feasibility and potential impacts prior to any larger, more expensive, phase-III evaluation[34]. By undertaking this pilot trial during the 2014-15 academic year, the intervention costs will be supported entirely by existing Big Lottery funding provided to ASH Wales for The Filter youth project. The research team also benefit from UKCRC centre of excellence funding for the Centre for the Development and Evaluation of Complex Interventions for Public Health Improvement (DECIPHer), including support and knowledge exchange staff.

5 Trial objectives

5.1 Primary objective

This study will evaluate the feasibility and acceptability of implementing and trialling 'The Filter FE Challenge', which is a universal, multi-level smoking prevention intervention for 16-18 year olds in general FE colleges and 'sixth form' colleges attached to secondary schools.

The first objective is to assess whether pre-specified feasibility and acceptability criteria relating to the intervention and trial design are met sufficiently for progression to a larger, phase-III effectiveness trial. To meet this primary objective the following research questions will be addressed:

- Did the intervention activities occur as planned in (at least) two out of three intervention settings?;
- Were the intervention activities delivered with high fidelity across all settings?;
- Was the intervention acceptable to the majority of FE managers, staff, students and the intervention delivery team?;
- Was randomization acceptable to FE managers?;
- Did (at least) two out of three colleges from each of the intervention and control arms continue to participate in the study at 1-year follow-up?;
- Do student survey response rates suggest that we could recruit and retain at least 70% of new students in both arms in a subsequent effectiveness trial?

The specific, detailed 'progression criteria' via which these research questions will be assessed are detailed in **section 14.1**. These criteria will be considered by the TSC. It is important that some discretion is applied in judging whether these criteria have been met, as some of these, such as a college dropping out due to change in management, are not necessarily under the control of the research team.

5.2 Secondary objectives

The second objective is to explore the experiences of FE students, staff and the intervention delivery team, with the aim of aiding refinement of the intervention and study design prior to a potential phase-III trial. With this intent the following questions will be explored:

- What are students, college staff and intervention team members' experiences of the intervention and views about its' potential impacts(s) on health?
- What are the barriers and facilitators to implementation and how do these vary according to college context and/or other factors?
- Were there any unexpected consequences?
- How acceptable were the data collection methods to students and staff and do participants think longer term follow-up via email or phone interview would be feasible?
- What resources and partnerships are necessary for a phase-III trial?

The third objective is to pilot primary, secondary and intermediate outcome measures and economic evaluation methods prior to a potential phase-III trial. With this aim student survey data will be collected and analysed to answer the following questions:

- Does the primary outcome measure (smoking weekly or more) have an acceptable completion rate, adequate validity and minimise floor/ceiling effects?
- Do cotinine concentrations of saliva samples indicate any evidence of response bias between arms in self-reported smoking status?
- Was it feasible and acceptable to measure all the secondary and intermediate outcomes of interest at baseline and follow-up?
- Is it feasible to assess cost effectiveness using a cost utility analysis within a phase III trial?

6 Trial design

The project is a pilot cluster randomised controlled trial with FE institutions as the unit of randomisation. The embedded process evaluation will utilise a quantitative survey, observational and qualitative (focus group and interviews) methods.

7 FE institution selection

Six 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: 'sixth form' colleges attached to schools (n=2); small FE colleges/campuses (new intake fewer than 500) (n=2); large FE colleges/campuses (new intake more than 500) (n=2).

7.1 Exclusion criteria

To avoid contexts where implementation may be less challenging, private institutions, small sites (with fewer than 100 students) and 'sixth forms' at schools where fewer than 10% of students are entitled to free school meals (FSM) will not be included in this study. These studies would be eligible to participate in a subsequent evaluation of effectiveness.

FE institutions where ASH Wales have developed and piloted educational materials will be excluded from this study and subsequent phases of evaluation.

To minimise the potential for contamination across arms in any subsequent evaluation of effectiveness no more than one FE setting would be recruited from any Middle Layer Super Output Area (MSOA) nor will FE settings be recruited in neighbouring MSOAs. This would ensure a significant 'buffer zone' while not being so restrictive as to constrain recruitment. However, these criteria will not be applied in this study as the aim here is to examine intervention feasibility and acceptability rather than effectiveness.

8 Participant selection

Students are eligible for selection if they are aged between 16 and 18 years old and begin further education studies in one of the participant institutions in September 2014. Students who report being older or younger that 16-18 will be excluded from our analyses. All staff and students at the intervention settings are eligible for (purposive) selection into the focus groups. Staff undertaking the staff training intervention component will be asked to complete brief survey post-training. FE managers and The Filter intervention team will be recruited to post-intervention interviews.

9 Outcome measures

9.1 Primary outcome measure/s

The pilot primary outcome is regular smoking (defined as smoking at least one cigarette weekly or more) and is measured within baseline and follow-up surveys. This study will examine prevalence, completion rate and validity of this measure. A validation sub-study[43] will compare the self-reported smoking measure against the results of cotinine and anabasine testing saliva samples from a sub-sample of students. A subsequent effectiveness trial would compare smoking rates between the intervention and control groups at follow-up, adjusting for baseline values, with additional sub-group analysis conducted by baseline smoking status to assess if there is an intervention effect among baseline non-smokers (intervention prevents uptake) and among baseline smokers (intervention promotes cessation).

9.2. Secondary outcome measure/s

The pilot secondary outcomes are: lifetime smoking (ONS GHS item)[2]; use of cannabis in the past 30 days; frequent cannabis use (4 or more times in last 30 days), using the EMCDDA European Model Questionnaire (EMQ) items[41]; high risk alcohol use, using the Alcohol Use Disorders Identification Test Consumption (AUDIT-C) measure[42]; and, health-related quality of life (HRQoL), using the EQ-5D-5L measure[43].

The following are additional pilot secondary outcomes for baseline smokers: cessation (ONS GHS item); number of cigarettes/week (ONS GHS item); and, nicotine dependence using the Heaviness of Smoking Index (HSI) items[44].

Intermediate outcome variables at the three levels of intervention (community, institutional and individual) will also be piloted.

- At the community-level, the availability of tobacco for under-18s via local retailers will be assessed via: items on the student e-survey (follow-up); a pre- and post-intervention mystery shopper audit of retailers within 1km of intervention and comparison sites.
- At the institutional-level, two measures of change will be piloted. First, progress towards a tobacco free-environment will be determined via an audit of FE college policies and structured observations at both intervention and comparison settings pre- and post-intervention. Second, staff commitment to smoking prevention and delivery of anti-smoking messages will be assessed via the staff (training) evaluation survey and student survey items at follow-up.
- To explore potential mechanisms of action at the individual-level, the student surveys will also assess: awareness of social media campaigns & support services; attitudinal and knowledge-based precursors to smoking, including perceived prevalence of smoking (i.e. perceived norms) adapting NatCen items[45]; and self-reported social/situational self-

efficacy and skills, using the European Smoking Prevention Framework Approach (ESFA) items[46,47].

10. Recruitment

10.1 Number of participants

Institutional recruitment. Six FE settings will be purposively recruited in June-July 2014. The settings will consist of: Sixth form colleges attached to schools (n=2); Small FE colleges/campuses (new intake fewer than 500) (n=2); Large FE colleges/campuses (new intake more than 500) (n=2).

Student recruitment. New students aged 16-18 enrolling in September 2014 will be recruited to baseline and 1-year follow-up surveys. The estimated sample is 2500. No power calculation has been performed for this pilot trial as our primary aim is to evaluate feasibility and acceptability. A sub-sample of approximately 96 students will also be recruited across the three intervention sites (purposively by socio-economic status (SES), gender, and smoking status) to participate in focus groups (2 focus groups for sixth form, 4 focus groups for medium size college and 6 focus groups for large college). To explore the validity of self-reported smoking measures and whether the validity varies by arm, 200 students will be recruited immediately after the follow-up survey via stratified, random sampling to provide a saliva sample for cotinine testing.

Staff recruitment. Staff who participate in the training component will be recruited to take part in a brief post-intervention survey to explore their experiences of the process (approximately 70 in total; 10, 20, 40 per institution depending on size); a sub-sample of approximately 48 intervention college staff will also be recruited (purposively by gender and role) to participate in focus groups (n=2 per college). Two members of the senior management team at each participating FE setting (n=12) will be recruited to take part in interviews.

Intervention team. The intervention delivery team will complete standardised delivery checklists and pro forma, workload surveys, and be interviewed post-intervention implementation**.**

10.2. Recruitment process

The six FE settings will be recruited by ASH Wales. New students aged 16-18 enrolling in September 2014 will be recruited to baseline and 1-year follow-up surveys. The estimated sample is 2500. Student recruitment to the e-questionnaire will involve multiple methods to maximise response rates and retention (see section **10.6 Data collection**).

Researchers will work with college staff to recruit a sub-sample of approximately 96 students will also be recruited across the three intervention sites (purposively by socio-economic status (SES), gender, and smoking status) to participate in focus groups (n=4 per college).

To explore the validity of self-reported smoking measures and if this varies by arm, 192 students will be recruited by fieldworkers immediately after the follow-up survey via stratified, random sampling to provide a saliva sample for cotinine and anabasine testing.

Staff who participate in the training component will be invited to take part in a brief post-intervention survey via email to explore their experiences of the process (approximately 70 in total; 10, 20, 40 per institution depending on size). A sub-sample of approximately 48 intervention college staff will also be recruited (purposively by gender and role) by the trial manager to participate in focus groups (n=2 per college). Two members of the senior management team at each participating FE setting (n=12) will be interviewed. School/College staff and managers will also be invited to participate by trial manager.

The intervention delivery team will complete standardised delivery checklists and pro forma, workload surveys, and after intervention implementation will take part in interviews. The intervention team will be invited by the trial manager.

10.3. Informed consent

During survey recruitment study information will be provided. Staff, managerial and intervention team consent and student consent for focus group will be obtained before participation.

10.4. Randomisation

The study will use a 1:1 allocation ratio. Allocation to intervention and control arms will be conducted by an independent South East Wales Trials Unit (SEWTU) statistician post-baseline and blind to the identity of clusters, which will be stratified according to size/type of institution (see above). To promote compliance, FE managers will sign a letter of agreement prior to baseline assessment and randomisation. To promote retention each institution will be

offered payment of £250 per survey to cover any costs incurred; the trial manager or lead field worker acting as a regular, single point of contact; and feedback of data after study completion.

10.5. Screening logs

A screening log of participants who refused participation will be kept to allow detection of any recruitment bias

10.6. Data collection

The pilot primary and secondary outcomes will be measured at baseline and follow-up via self-report student surveys using an electronic(e)-questionnaire. All eligible students will be contacted where possible via college email accounts, or through college websites, at the start of September 2014 when they enrol (and again 2-3 weeks later). Those students who do not complete the survey online after receiving this email, or who attend institutions without a student email system will be able to complete the e-questionnaire on-site during: (a) timetabled classroom periods dedicated to survey completion, in which students can use either college computers, their own devices (laptop, tablet or smart phones) or Google Nexus tablets provided by the fieldworkers; or, (b) informal data collection sessions (using Google Nexus tablets and/or QLR codes) in common areas at break periods, which will aim to recruit any students who have not yet responded. Hard copies will be available as a backup (e.g. if the internet connection is too slow) and the information will submitted online once they are returned to the office. We will track non-completion via the SEWTU IT data collection and management system. These methods will be repeated at follow-up. Detailed contact information (name, personal email and mobile phone) will also be collected at baseline to help track students who have left or are on work-based placements at follow-up. Student participation will be incentivised via prize draws at both time-points.

Other quantitative (process) data will be collected via: structured observations (intervention delivery, smoking on site and on-line observations of institutional websites); intervention team delivery checklists and pro forma; 'mystery shopper' audits of local shops; analyses of college policy documents; and a staff training evaluation survey.

Qualitative process data will be collected on-site via interviews and focus groups to explore the feasibility, acceptability, and potential mechanisms of action from the perspective of young people, staff and the intervention team.

To explore whether under/over-reporting of smoking occurs and varies by arm, 192 students will provide a saliva sample on-site after follow-up for cotinine testing.

11. Withdrawal & loss to follow-up

Participants have the right to withdraw consent for participation in any aspect of the trial at any time. Participants will not be affected at any time by declining to participate or withdrawing from the trial/study.

12. The Intervention

Institutions will be randomised into intervention and control groups.

Intervention group

Intervention colleges will sign up to 'The Filter FE Challenge' and work with ASH Wales staff to implement this intervention. ASH Wales have worked with the investigator team to develop the intervention logic model and design. Informed by systematic reviews of smoking prevention interventions delivered in schools and other contexts[20-24] and Michie and colleagues typology[48], this multi-level intervention targets 16-18 year-olds in FE settings and integrates the following evidence-informed smoking prevention techniques and functions: restriction of the availability of tobacco; restructuring the institutional context to prevent smoking on-site and promote non-smoking behaviour as normative; education and persuasion of young people regarding the harms of smoking and social norms via multiple interactive methods and channels of communications; modelling social/situational self-efficacy and resistance skills. In order to enable scale-ability across all UK FE settings (including large institutions) as well as sustainability and fidelity, the intervention involves standardised core processes and activities balanced with opportunities for a degree of local tailoring of activities.

Five areas of synergistic activity and implementation will begin immediately post-randomisation in September 2014 augmenting any existing activities taking place at the intervention sites:

1. Prevention of the sale of tobacco to FE students aged under 18. To restrict availability, the intervention manager will map and contact all shops selling tobacco within 1 km of the intervention setting (i.e. within a 10 minute walk). Information letters will be distributed to these retailers to inform them that a new project (The Filter FE Challenge) is taking place at

their local FE institution and explain why reducing illicit supply is an important component of prevention. The letter will also remind them about penalties for selling tobacco to under-18s and that they will be particularly in the spotlight due to the intervention. Posters, stickers and other materials for shops will be supplied regarding the legal age for purchasing tobacco products and the requirements to produce statutory ID to purchase tobacco.

2. Policy review to promote a tobacco-free environment. To restrict opportunities for smoking and promote non-smoking as the norm via modifying the institutional context, the intervention manager will work with FE managers to review institutional policies using the tobacco-free campus guidance developed by ASH Australia. This tool uses a three-stage process to promote a tobacco-free environment, including advice on advertising, the supply of tobacco and support services, as well as information on maintaining smoke-free public areas, buildings and vehicles. First, current policies and practices are reviewed and a new whole-campus tobacco-free policy developed. The intervention team will support FE managers to communicate the policy changes locally. Second, the policy will be implemented and launched. Third, the intervention and FE managers monitor, evaluate and update/refine the policy if required.

3. Staff training. To train staff to deliver anti-smoking educational messages and support institutional change, training and education officers employed on The Filter youth project (accredited by YMCA and Agored Cymru) will organise and deliver training sessions on-site using modules and teaching resources developed and piloted by ASH Wales in FE and other youth settings. Interactive, two-hour training workshops will be delivered to approximately 10 staff per session. Staff will be trained to integrate activities about smoking into their lesson-plans and other routine work (e.g. via body mapping the health harms of smoking, exercises on how tobacco companies recruit young smokers). All staff attending these sessions will also be encouraged to champion new tobacco-free policies (above) and trainers will aim to deliver and reinforce their skills for intervening effectively to prevent smoking on site. The number of sessions delivered will vary depending on the size of the FE setting to ensure resources are distributed appropriately: one session will be delivered at 'sixth form' sites (i.e. to reach a total of approx. 10 staff); two and four sessions will be delivered at medium and large general FE settings respectively (to reach up to 20/40 staff).

4. Social media. To educate and persuade students about the harms of smoking, social norms and the relevance of support services, The Filter youth project's web and social media officers will work with staff and students to integrate their online social marketing campaigns, advice and support services (e.g. The Filter text/instant-messaging services) with institutional websites and social media channels maintained by staff and/or students (e.g. the college Facebook page, institutional twitter feeds, Instagram, etc.). As well as embedding

information on each intervention setting's home/index webpage, the web and social media officers will work with the college IT staff and consult students to identify opportunities for publicising key information and messages via frequently-accessed web-pages/micro-sites (e.g. online learning portal, email login page).

5. Youth work activities. To educate and persuade students about the harms of smoking and model social/situational resistance skills, qualified youth workers will work with college staff and students to plan and deliver a range of youth work activities on-site. Youth workers will launch the project in the autumn term, and then work with staff and/or student groups to identify 5, 10 or 15 groups (depending on institutional size) of 10-20 students to take part in locally tailored group-based activities. These group-based youth work activities will be provided on-site during college-time. As with the staff training, the numbers of sessions delivered varies according to the FE setting's size to ensure resources are distributed appropriately: five two-hour sessions will be provided at smaller 'sixth form' sites; ten and fifteen two-hour sessions will be provided at the medium and large general FE settings respectively. Students will not be targeted based on their smoking status or any other characteristics as the aim is to recruit as many newly enrolled students as possible. Information about online support/advice services will also be provided to current smokers. Youth workers are trained to use 'graffiti walls' and/or other arts-based activities where appropriate and will also publicise the annual Cut Films competition (an anti-tobacco short films competition for young people).

In this study, the intervention will be managed and delivered directly by the ASH Wales in-house staff team working on The Filter youth project.

Control group

FE settings in the comparison arm (n=3) will continue with their usual activities. Our scoping of current practices in FE settings, and consultation with young people, FE staff and policy and practice partners, suggests that this may include some tobacco-free policies at control sites but all the other 'core' intervention activities (targeting local retailers to restrict supply, staff training on smoking prevention, integrated social media inputs, and youth work activities focused on smoking) are not likely to be operating as standard, and will certainly not be delivered systematically and in combination. The process evaluation will assess standard practice (via policy-document analyses, interviews with management staff, and control group student survey reports of policies/practices). Students at comparison settings may also be aware of The Filter youth project via its social media and/or youth work outreach. Any such contamination will be assessed via the process evaluation.

13. Adverse Events

The occurrence of adverse events or harm as a result of the trial is unlikely. This study is not powered to examine intervention effects (positive or adverse) but qualitative data will be collected as part of the process evaluation to explore any potentially harmful effects. However, should any adverse events occur these will be recorded and reported to the PI and dealt with appropriately. These will also be reported in the final report.

14. Trial procedures

14.1 Progression criteria

The primary aim of this study is to examine whether the intervention and trial methods are feasible and acceptable prior to a potential phase-III effectiveness study. This will be assessed according to the following pre-specified 'progression criteria' and data sources:

Criterion 1. Did the intervention activities occur as planned? This will be assessed according to the extent to which the following intervention activities occurred:

- Tobacco retailers within 1 km of the FE setting were contacted in writing with 3 months of the start of the intervention (assessed using the data collected via intervention team checklists and cross-checked through interviews);
- Institutional policies and practices were reviewed, updated using the tobacco-free campus guidance, and changes communicated to staff and students within 6 months of the start of the intervention (assessed using intervention team checklists/pro forma and cross-checked via documentary analyses of college policies and structured observations);
- A minimum of 1/2/4 staff training sessions were delivered as planned (according to institutional size) with a minimum of 5 staff attending each session (assessed using intervention team checklists/pro forma and cross-checked via staff surveys);
- The Filter youth project's web-based information, advice and support services were embedded on the FE institution's home page during the intervention (assessed using intervention team checklists/pro forma and cross-checked via structured, on-line observations) and on-line information, advice and support services are promoted through at least one local social media channel maintained by staff and/or students (e.g. the college Facebook page, twitter feed, etc.) (assessed as above); and,
- A minimum of 5/10/15 youth work sessions were delivered as planned (according to institutional size) with a minimum of 8 (different) students attending each session (assessed using intervention team checklists/pro forma and cross-checked in interviews with FE managers).

Criterion 2. Were the intervention activities delivered with high fidelity across all settings? Structured observations of staff training sessions (n=2 per intervention setting) and group-based youth work sessions (n=2 per intervention setting) will be used to assess fidelity of delivery of those components. The fidelity of other intervention processes (prevention of the sale of tobacco to under-18s; policy review and revision; social media integration) will be examined via intervention team standardised checklists/pro forma.

Criterion 3. Was the intervention acceptable to the majority of FE managers, staff, students and the intervention team? Intervention acceptability, and whether this was reported by the majority of participants, will be assessed via data from semi-structured interviews with FE managers and intervention staff, and student and staff surveys.

Criterion 4. Was randomisation acceptable to FE managers? Data from semi-structured interviews with FE managers will be used to examine this.

Criterion 5. Did (at least) two out of three colleges from each of the intervention and control arms continue to participate in the study at 1-year follow-up? Student baseline and follow-up survey data will evidence if at least two out of three colleges from each arm were retained.

Criterion 6. Do student survey response rates suggest that we could recruit and retain at least 70% of new students in both arms in a subsequent effectiveness trial? Student baseline and follow-up survey data will be analysed by the trial statistician to assess student survey response rates in both arms at baseline and follow-up.

14.2 Pilot outcome measures:

The study will examine the prevalence, completion rate, and validity of the pilot primary outcome: a measure of regular smoking (defined as smoking at least one cigarette weekly or more) based on the Office for National Statistics (ONS) General Lifestyle Survey (GLS) items[2]. A validation sub-study will compare the self-reported smoking measure against the results of cotinine testing saliva samples from a sub-sample of students.

The study will also pilot a number of secondary outcomes of interest via an e-survey with this population:

- lifetime smoking (ONS GHS item)[2];
- use of cannabis in the past 30 days;

- frequent cannabis use (4 or more times in last 30 days), using the EMCDDA European Model Questionnaire (EMQ) items[41];
- high risk alcohol use, using the Alcohol Use Disorders Identification Test Consumption (AUDIT-C) measure[42];
- and, health-related quality of life (HRQoL), using the EQ-5D-5L measure[43].

The following are additional pilot secondary outcomes for baseline smokers: cessation (ONS GHS item); number of cigarettes/week (ONS GHS item); and, nicotine dependence using the Heaviness of Smoking Index (HSI) items[44].

Intermediate outcome variables at the three levels of intervention (community, institutional and individual) will also be piloted.

- At the community-level, the availability of tobacco for under-18s via local retailers will be assessed via: items on the student e-survey (follow-up); a pre- and post-intervention mystery shopper audit of retailers within 1km of intervention and comparison sites.
- At the institutional-level, two measures of change will be piloted. First, progress towards a tobacco free-environment will be determined via an audit of FE college policies and structured observations at both intervention and comparison settings pre- and post-intervention. Second, staff commitment to smoking prevention and delivery of anti-smoking messages will be assessed via the staff (training) evaluation survey and student survey items at follow-up.
- To explore potential mechanisms of action at the individual-level, the student surveys will also assess: awareness of social media campaigns & support services; attitudinal and knowledge-based precursors to smoking, including perceived prevalence of smoking (i.e. perceived norms) adapting NatCen items[45]; and self-reported social/situational self-efficacy and skills, using the European Smoking Prevention Framework Approach (ESFA) items[46,47].

14.3 Assessment and follow-up

a. Piloting assessment of effectiveness

All newly-enrolled students in each participating FE settings aged 16-18 will be asked to complete a baseline e-questionnaire in September 2014, prior to randomisation. Multiple opportunities to complete this survey will be given to support recruitment and maximise response rates. All students completing the baseline survey will be asked to complete a follow-up e-questionnaire one year later (September 2015) using the same methods of data collection. E-mail addresses and mobile phone numbers will be collected at baseline to allow fieldworkers to contact students and survey them via the telephone if they have left or are on

work placement by follow-up. These contacts will also be used to contact students who are still at college/school but fail to respond to other methods.

Analyses of response rates, along with student and staff focus groups, will help to refine survey methods prior to a potential phase-III study.

Saliva samples will be collected from a sub-sample of students in order to validate self-reported smoking measures and assess reporting bias by trial status (i.e. whether under/over-reporting is greater in the intervention arm) prior to a larger trial.

b. Economic costs and outcomes

A phase-III trial would require a 'lifetime decision analysis model' capable of extrapolating short-term smoking status to later positions: longer term smoking behaviour; NHS and other sector costs; health and quality adjusted life years (QALYs), to establish intervention cost-effectiveness[51]. Within this, study methods to measure the incremental cost of 'The Filter FE Challenge' in a phase-III trial study will be developed and piloted. With use of a broad public and third sector perspective resources measured will include: resources used by ASH Wales, FE colleges and the NHS. Within this, key interventional resources will include intervention staff time (intervention manager, training and education officers, web & social media officers, youth workers), training events/workshops and consumables. Measures will include:

- Standardised sessional checklists and pro-formas to monitor and document attendance, preparation and delivery time for key training and youth work events
- Detailed workload surveys emailed on a weekly basis to the core intervention staff will assess time spent on intervention related tasks for each FE setting.
- All intervention staff travel and other consumer expenses relating to this intervention will be charged to a specific project grant code and be documented to support the estimates of delivery costs.

A brief health service use survey and the EQ-5D-5L (pilot secondary outcome) to record preference-based HRQoL[46] will be emailed for student completion. It is anticipated that these measures would be used in a phase-III trial to measure any short term impact of smoking on healthcare use and/or health-related quality of life.

14.4 Process evaluation

The process evaluation will seek to examine intervention feasibility and acceptability (and if/how this varies in different contexts), reach and potential contamination, and potential mechanisms of action. Data will be collected through analysis of institutional smoking policies

at baseline and follow-up; baseline and follow-up observations of FE settings; electronic surveys of staff and students; staff check-lists and proformas; and semi-structured interviews with the intervention team and FE managers and focus groups with FE staff and students which will take place after the intervention ends.

Intervention feasibility, fidelity and acceptability. Semi-structured interviews with the intervention team and FE managers and focus groups with FE staff and students will assess phase-III trial 'progression criteria' relating to intervention feasibility, fidelity and acceptability and contextual barriers and facilitators to implementation.

Intervention reach and potential contamination. Focus groups with students at each intervention setting will explore students' views of the study intervention and their levels of involvement. As findings are likely to be unrepresentative of the wider student body, the reach of the social media and youth work activities will be further explored in follow up e-questionnaire surveys. Additional survey information (socio-demographic, educational and neighbourhood characteristics) will be used to explore reach according to these measures and how it varies by institutional setting. The potential reach and 'added value' of staff training activities will be explored by use of checklists/pro forma to record the number of staff attending each session. An evaluation survey completed by staff attending training will provide additional information on staff role, the number of students they are in routine contact with, and their previous training. The intervention's 'added value' will also be assessed through analysis of control group student reports of contact with ASH Wales' 'The Filter project in other settings (e.g. youth centres) and/or online. Contamination across arms will be explored in: student follow-up surveys; interviews with FE managers; interviews with the intervention team. The aim is to ensure contamination is not a threat to internal validity in an effectiveness trial and explore whether additional sampling exclusion criteria needed.

Mechanisms of action. Contextual qualitative data collected in focus groups and interviews will analysed to explore the hypothesised mechanisms of action at each of the three intervention levels (community, institutional and individual). Findings will be used to refine and optimise the intervention logic model and design. Interest will be in: variations according to institutional context, students' socio-demographic characteristics and/or other factors; the key behaviour techniques and functions via which the intervention is hypothesised to work (restriction, environmental change, education, persuasion and modelling) will be explored[25,49]. Qualitative data and field-notes will be analysed to explore any unintended and potentially harmful consequences.

15 Statistical considerations

The statistical analyses will be primarily descriptive, providing a realistic estimate of eligibility, recruitment and retention rates, intervention reach, and the completion rates, reliability and validity of the pilot outcome measures. To help estimate ICCs and potential effect sizes prior to an effectiveness trial, analyses of the pilot primary outcome (weekly smoking incidence) will be carried out at the participant level using multi-level regression models, with the FE college fitted as a random effect to account for the effects of clustering within FE settings. Models will adjust for the following pre-hypothesised baseline covariates: baseline smoking status, age, gender, parental SES, ethnicity and educational attainment (five GSCEs A*-C). Between-group comparisons will be made using regression models with the focus on 95% confidence intervals to estimate possible effect sizes.

As a pilot trial, the proposed study is not powered to provide a definitive comparison between intervention and control groups and as such p-values will not be presented. The reliability and validity of the pilot primary, secondary and immediate outcome measures will be assessed via: analyses of completion rates for each measure (total score and each item), overall and by gender and SES; calculating mean scores, standard deviations and response distributions to examine potential 'floor'/'ceiling' effects; calculating intra-class correlations for each measure to examine the stability of measures over time; and, Cronbach's alpha statistics (baseline and follow-up) to assess the internal consistency of measures. Self-reported smoking will be validated though cotinine and anabasine testing of saliva samples to examine reporting bias and assess variation across arms. We will assess this by estimating the mean difference and 95% confidence interval (CI) for the difference in cotinine values between self-reported smokers and non-smokers in the intervention and control arms. If these 95% CI overlap this would suggest that levels of misreporting did not differ significantly between arms.

Estimating attrition is important as it will inform the degree to which any sample size calculation needs to be increased to account for attrition in a subsequent larger trial. At an individual-level, we will firstly compare the baseline characteristics of those who remain in the study and provide primary outcome data to those who drop-out. To do this we will examine levels of attrition by study arm, gender, ethnicity, socio-economic status, baseline smoking status (overall and by arm) and whether participants were still registered as attending the college at the 1-year follow-up. Following guidance issued on how to deal with missing data in clinical trials[50-52] and the strategy implemented in a highly-cited smoking cessation trial[53], we will then run a series of sensitivity analyses to estimate the potential effects of missing data. For the primary analysis we will use multiple imputation to attempt to correct for any potential bias caused by missing data[54,55]. This will include the observed predictors of smoking status and loss to follow-up to impute missing outcome data. At a minimum, 20 imputed datasets will initially be generated, and point estimates combined with

Rubin's rules[55]. We will then carry out three sensitivity analyses: we will impute missing smoking status data by assuming that all participants had started smoking[51,53]; we will repeat this imputation by then assuming all participants did not start smoking; then carry out a complete case analysis in which participants with missing outcome data will be excluded.

15.1 Randomisation

This study will use a 1:1 allocation ratio. Allocation to intervention and control arms will be conducted by an independent South East Wales Trials Unit (SEWTU) statistician post-baseline and blind to the identity of clusters, which will be stratified according to size/type of institution (see above). To promote compliance, FE principals and governors will sign a letter of agreement prior to baseline assessment and randomisation. Our experience from trials in schools is that retention of control-group institutions is enhanced by: randomisation post-baseline; payment of £250 per survey to cover any costs incurred; the trial manager acting as a regular, single point of contact; and feedback of data after study completion.

15.2 Sample size

Six FE settings will participate in the trial: 3 intervention group; 3 control group. New students aged 16-18 enrolling in September 2014 will be recruited to baseline and 1-year follow-up surveys. The estimated sample is 2500. No power calculation has been performed for this pilot trial as our primary aim is to evaluate feasibility and acceptability.

16 Analysis

16.1 Main analysis

The primary outcome of interest in this study is whether the intervention and trial methods are feasible and acceptable prior to a potential phase-III effectiveness study. We will assess this according to pre-specified 'progression criteria' by cross-checking multiple data sources (see above, section 14.1).

16.2 Qualitative analysis

Qualitative data collected via interviews and focus groups will be transcribed verbatim and analysed in NVivo 10 software to aid data management and analysis. Techniques associated with thematic content analysis and grounded theory will be used. First, a priori codes will be applied to transcripts, according to the type of participant and institution, and any progression criteria relevant to the transcript will be assessed. Second, to identify key

emerging themes, and how these inter-relate, each transcript will be coded thematically to explore different groups' experiences and to compare processes across different contexts/groups. Further analyses will use techniques associated with grounded theory to build and refine hypotheses regarding the potential mechanisms of action via which effects may occur, as well to explore unanticipated effects reported by participants. Further quantitative data analyses may then be undertaken to test these hypotheses if possible (e.g. analyses of variation in reach by hypothesised sub-group).

16.3 Data storage & retention

Data will be stored securely in paper and/or electronic format, as appropriate. Data stored in paper format will be held securely at CU, in a locked room, in a locked cupboard or cabinet. Electronic data will be held securely in folders on CU servers and be accessed via username and password with access restricted to members of the research team. Digital recordings of interviews and focus groups will be stored securely, and will be held separately from transcripts and information on participant identities. Anonymised interviews will be transcribed, and entered into password-protected university files.

Identifiable data (paper-based and electronic) will be stored separately from non-identifiable source data. Access to identifiable data will be restricted to certain members of the research team. Those researchers with access to identifiable data will be responsible for anonymising the data before sharing with other members of the research team. Access to trial data will be limited to the trial researchers, sponsor's designee and inspection by relevant regulatory authorities.

All data will be kept for a period of no less than 5 years or at least 2 years post-publication (as appropriate) to allow for further analysis and review, and aid any future queries or disputes regarding intellectual property, research conduct or the actual results of the research. The study documents held by the PI on behalf of the Sponsor shall be finally archived at secure archive facilities at CU.

17 Trial closure

The recruitment of FE colleges and schools to the trial (intervention period) will take place in July 2014 (month 1). The follow-up will take place in September 2015 (month 15). The trial will be considered to have ended in June 2016 (month 24).

18 Regulatory issues

18.1 Ethical and research governance approval

The study will not be initiated before the protocol and trial documents have received approval from the CU School of Social Science Research Ethics Committee. Should a protocol amendment be made that requires ethical approval, the changes in the protocol will not be instituted until the amendment and revised informed consent forms and study information leaflets have been reviewed and received approval from the Research Ethics Committee. Minor protocol amendments for logistical or administrative purposes only, may be implemented immediately and the Research Ethics Committee informed.

The study will be conducted in accordance with the ethical principles that have their origin in the 2008 Declaration of Helsinki. We will obtain ethical approval for the validation sub-study (saliva testing) from the School of Medicine Research Ethics Committee; liaising with Cardiff University Human Tissue Act managers as necessary.

18.2 Confidentiality

The PI and the research team will preserve the confidentiality of participants in accordance with the Data Protection Act 1998.

18.3 Indemnity

CU will provide indemnity and compensation in the event of a claim by, or on behalf of participants, for negligent harm as a result of the trial design and/or in respect of the protocol authors/research team. Cardiff University does not provide compensation for non-negligent harm.

18.4 Trial sponsorship

The study does not require Cardiff University to act as Sponsor as it does not fall under the Research Governance Framework for Health and Social Care in Wales. This is due to the absence of any NHS involvement in the study. However, Cardiff University will provide Public Liability and Professional Negligence indemnity policies, as standard.

18.5 Funding

The trial is funded by a National Institute for Health Research (NIHR) Public Health Research (PHR) programme grant awarded to Dr Adam Fletcher, the PI.

18.6 Audits & inspections

The trial will be subject to inspection by NIHR PHR (funding organisation) to source data/documents as necessary.

19 Trial management

The management of the study will be undertaken by a Trial Management Group (TMG) consisting of PI, co-applicants and employed staff. The PI (Dr Adam Fletcher) will have overall responsibility for the conduct of the trial. The Project Manager (PM; Dr Ria Poole) will be responsible for the day to day management of the trial. The PI, PM, co-applicants and employed staff will review study progress, adherence to the protocol, standard operating procedures (SOP), quality assurance, research governance and financial management. This group will meet monthly through the initial six months, then bi-monthly.

20 Data monitoring & quality assurance

20.1 TSC (Trial Steering Committee)

An independent TSC will be established and meet three times throughout the life of the project to advise on the conduct and progress of the trial, and relevant practice and policy issues. Professor Paul Aveyard (Oxford), an expert in RCTs of tobacco control interventions, has agreed to chair the TSC. Other members of the TSC are Professor Rob Anderson (Exeter), Professor Angela Harden (UEL) and Dr. Julie Bishop, a consultant in public health and academic-policy collaboration lead at Public Health Wales. The protocols and pre-specified progression criteria will be agreed and monitored by the TSC.

20.2 DMC (Data Monitoring Committee)

Given the nature of this study it is not considered necessary by either the study team or the TSC to have a Data Monitoring Committee.

21 Publication policy

It is anticipated that a number of papers will emerge from the pilot study. The main criteria for associated authorship is that it should reflect the work undertaken in producing an article suitable for peer review and named authors accept responsibility for the final published

article. In order to meet the criteria for authorship each author must have made a substantial contribution to the conception and design, or acquisition of data, or analysis and interpretation of data; drafted the article or revised it critically for important intellectual content; and given final approval of the version to be published. Acquisition of funding, collection of data, or general supervision of the research group, alone, does not constitute authorship. Furthermore, guest (honorary, courtesy, or prestige), gift and ghost authorship undermines this process, it misleads and there are currently efforts to have guest authorship classified as legal fraud[56]. Guest, gift, and ghost authorship are all inconsistent with the definition of authorship, and therefore constitute a violation of this policy. This policy therefore aims to clearly and unambiguously outline the criteria used in determining authorship. While this policy attempts to distil usual practice in behavioural and medical journals it is also informed by a template published by Kosslyn[57].

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