

Pilot trial and process evaluation of a multi-level smoking prevention intervention in further education settings

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Abstract

Background: Preventing smoking uptake among young people is a public health priority. Further education (FE) settings provide access to the majority of 16-18 year olds but few evaluations of smoking prevention interventions have been reported in this context to date.

Aim: To evaluate the feasibility and acceptability of implementing and trialling a new multi-level smoking prevention intervention in FE settings.

Design: Pilot cluster randomised controlled trial (RCT) and process evaluation.

Setting: Six UK FE settings.

Participants: FE students aged 16-18.

Intervention: “The Filter FE” intervention. Staff working on ASH Wales’ *The Filter* youth project applied existing staff training, social media and youth work resources in three intervention settings, compared to three control sites with usual practice. The intervention aimed to prevent smoking uptake via: restricting under-18 sales of tobacco in local shops; implementing tobacco-free campus policies; training FE staff to deliver smoke free messages; publicising *The Filter* youth project’s online advice and support services; and educational youth work activities.

Outcomes: (1) The primary outcome assessed was the feasibility and acceptability of delivering and trialling the intervention; (2) qualitative process data were analysed to explore student, staff and intervention team experiences of implementing and trialling the intervention; and (3) primary, secondary, and intermediate (process) outcomes and economic evaluation methods were piloted.

Data sources: New students at participating FE settings were surveyed in September 2014 and followed up in September 2015. Qualitative process data were collected via: interviews with FE college managers (n=5) and the intervention team (n=6); focus groups with students (n=11) and staff (n=5); and observations of intervention settings. Other data sources were: semi-structured observations of intervention delivery; intervention team records; ‘mystery shopper’ audits of local shops; and college policy documents.

Results: The intervention was not delivered as planned at any of the three intervention settings, with no implementation of some community and college-level components, and low

fidelity of the social media component across sites. Staff training reached 28 staff and youth work activities were attended by 190 students across the three sites (<10% of all eligible staff and students), with low levels of acceptability reported. Implementation was limited by various factors, such as uncertainty about the value of smoking prevention activities in FE colleges, intervention management weaknesses and high turnover of intervention staff. It was feasible to recruit, randomise and retain FE settings. Prevalence of weekly smoking at baseline was 20.6% and 17.2% at follow-up, with low levels of missing data for all pilot outcomes.

Limitations: Only 17% of eligible students participated in baseline and follow-up surveys; the representativeness of student and staff focus groups is uncertain.

Conclusions: In this study, FE settings were not a supportive environment for smoking prevention activities because of their non-interventionist institutional cultures promoting personal responsibility. Weaknesses in intervention management and staff turnover also limited implementation. Managers accept randomisation but methodological work is required to improve student recruitment and retention rates if trials are to be conducted in FE settings.

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Keywords: smoking prevention; tobacco; youth; further education; pilot trial; process evaluation; logic model.

Table of Contents

Abstract	2
Table of contents	4
List of abbreviations	7
Scientific summary	8
Plain English summary	14
1. Introduction	15
1.1 Youth smoking: a public health priority	15
1.2 Health improvement in further education (FE) settings	15
1.3 Effective smoking prevention methods and approaches	16
1.4 “The Filter FE” intervention design and logic model	17
1.5 Public involvement	20
1.6 Study aim, objectives and research questions	20
2. Methods	22
2.1 Study design: overview	22
2.1.1 Intervention components	23
2.2 Sampling and recruitment of FE settings	25
2.3 Randomisation	25
2.4 Progression criteria	26
2.4.1 Data sources	28
2.4.2 Data analysis methods	29
2.5 Evaluating participants’ experiences of the process	29
2.5.1 Qualitative process data	30
2.5.2 Data analysis methods	36
2.6 Pilot outcome measures	38
2.6.1 Pilot primary and secondary outcomes	39
2.6.2 Pilot intermediate outcome measures	39
2.6.3 Data sources	40
2.6.4 Statistical analyses	44
2.7 Economic analysis	45
2.8 Trial registration, governance and ethics	45
3. Results	46
3.1 Description of pilot trial sample	46
3.1.1 Flow of participants in the pilot trial	46
3.1.2 Student characteristics	49
3.2 Progression criteria assessment	56
3.2.1 Intervention feasibility and acceptability	56
3.2.2 Trial feasibility and acceptability	61
3.3 Process evaluation: participants’ experiences	62

3.3.1 Attitudes towards smoking in the FE context	62
3.3.2 Barriers to acceptability and implementation	69
3.3.3 Implementation of intervention components and contextual variation	75
3.3.4 Research methods: feasibility and acceptability	96
3.4 Pilot primary and secondary outcomes	102
3.4.1 Missing data, prevalence and distribution by arm at baseline	102
3.4.2 Missing data, prevalence and distribution by arm at follow-up	107
3.4.3 Feasibility of assessing cost effectiveness	113
3.5 Pilot intermediate outcome measures	123
4. Discussion	130
4.1 Limitations	130
4.2 Key results and generalisability	135
4.3 Implications	138
4.4. Conclusions and recommendations for further research	139
Acknowledgements	142
<i>Authors' contributions</i>	142
<i>Data sharing statement</i>	143
References	144

List of tables and figures

Table 1: Participating FE settings and allocation to trial arm	26
Table 2: Qualitative process data collected by arm and setting	31
Table 3: Participants in semi-structured observations of staff training sessions	32
Table 4: Participants in semi-structured observations of youth work sessions	33
Table 5: Summary of categorical baseline demographic characteristics according to sample eligibility	50
Table 6: Summary of categorical baseline demographic characteristics by trial arm	53
Table 7: Pilot primary outcome and categorical secondary outcomes at baseline	104
Table 8: Numerical secondary outcomes at baseline	105
Table 9: Pilot primary and categorical secondary outcomes at follow-up	110
Table : Numerical secondary outcomes at follow-up	112
Table 11: Categorical EQ-5D-5L items and health service use at baseline	114
Table 12: Numerical EQ-5D-5L items and health service use at baseline	116
Table 13: Categorical EQ-5D-5L items and health service use at follow-up	119
Table 14: Numerical EQ-5D-5L items and health service use at follow-up	121
Table 15: Pilot intermediate outcome measures at baseline	124
Table 16: Pilot intermediate outcome measures at follow-up	125
Box 1: Research questions addressing the agreed criteria for progression	27
Box 2: Research questions to evaluate participant experiences	29
Box 3: Research questions to evaluate outcome measures	38
Figure 1: Intervention logic model	19
Figure 2: Trial CONSORT diagram	48

List of abbreviations

ALPHA	Advice Leading to Public Health Advancement
ASH	Action on Smoking and Health
CCA	Cost-consequence analysis
CTU	Clinical Trials Unit
CUA	Cost utility analysis
DECIPHer	Centre for the Development and Evaluation of Complex Interventions for Public Health Improvement
EMCDDA	European Monitoring Centre for Drugs and Drug Addiction
ESFA	European Smoking Prevention Framework Approach
GLS	General Lifestyle Survey
ICC	Intra-class correlation
km	Kilometre
MRC	Medical Research Council
NETSCC	NIHR Evaluation, Trial and Studies Coordinating Centre
NHS	National Health Service
NICE	National Institute of Health and Clinical Excellence
NIHR	National Institute of Health Research
PHR	Public Health Research
PPI	Patient and Public Involvement
ONS	Office for National Statistics
OR	Odds ratio
RCT	Randomised controlled trial
RQ	Research question(s)
SES	Socioeconomic status
SD	Standard deviation
TSC	Trial steering committee

Scientific summary

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, smoking continues to grow rapidly amongst older youth. 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.). 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. However, research evidence about preventing smoking among FE students is sparse with few evaluations of smoking prevention interventions in FE colleges to date.

To address this gap, "The Filter FE" intervention and logic model was co-designed by ASH Wales and the research team to apply the educational, training and social media resources from ASH Wales' *The Filter* youth project to FE settings in 2014-15. The Filter FE is a novel, multi-level intervention targeting 16, 17 and 18 year-old students in FE settings, delivered by trained staff working on ASH Wales' *The Filter* youth project. Informed by systematic reviews of smoking prevention interventions delivered in schools and other settings, the intervention was designed to integrate the following prevention methods and approaches in FE settings: preventing the sale of tobacco to under 18 year-olds in local shops; implementing tobacco-free campus policies; training FE staff to deliver smoke free messages and support institutional change; publicising *The Filter* youth project's online social marketing campaigns, advice and support services; and on-site youth work activities to provide credible educational messages, address norms, and promote resistance skills, as well as signposting to cessation services. To facilitate scale-ability and sustainability across UK FE settings (including large institutions), the intervention involves standardised processes and activities balanced with opportunities for a local tailoring of activities.

Study aim, objectives and research questions

The aim of the pilot trial was to evaluate the feasibility and acceptability of implementing and trialling the Filter FE intervention. The study had three objectives.

The first objective was to assess whether pre-specified feasibility and acceptability criteria were met prior to progressing to a larger, phase III trial to examine effectiveness. To meet this objective, data were collected and analysed to address these research questions (RQ):

- RQ1. Did the intervention activities occur as planned in (at least) two out of three intervention settings?;
- RQ2. Were the intervention activities delivered with high fidelity across all settings?;
- RQ3. Was the intervention acceptable to the majority of FE managers, staff, students and the intervention delivery team?;
- RQ4. Was randomisation acceptable to FE managers?;
- RQ5. 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?;
- RQ6. 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 second objective was to explore the experiences of FE students, staff and the intervention team regarding the pilot intervention and trial design, including how the logic model, intervention content and data collection methods could be refined. In order to meet this objective data were collected and analysed to address the following RQ:

- RQ7. What are students', staff and intervention team members' experiences of the intervention and views about its potential impacts on health?;
- RQ8. What are the barriers and facilitators to implementation and how do these vary according to college context and/or other factors?;
- RQ9. Were there any unexpected consequences?;
- RQ10. 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?;
- RQ11. What resources and partnerships are necessary for a phase III trial?

The third objective was to pilot primary, secondary and intermediate outcome measures and economic evaluation methods prior to a potential effectiveness trial. It was not an objective of the pilot study to assess intervention effects and the study was not designed or powered to do

so. Data were collected and analysed to address the following RQ:

- RQ12. Does the primary outcome measure (smoking weekly or more) have an acceptable completion rate, adequate validity and minimise floor/ceiling effects?;
- RQ13. Do cotinine concentrations of saliva samples indicate any evidence of response bias between arms in self-reported smoking status?;
- RQ14. Was it feasible and acceptable to measure all the secondary and intermediate outcomes of interest at baseline and follow-up?;
- RQ15. Is it feasible to assess cost effectiveness using a cost utility analysis within a phase III trial?

Methods

A cluster randomised controlled pilot trial and process evaluation was undertaken in six FE settings in Wales (purposively sampled to examine delivery and trial methods in a range of institutional contexts) with allocation to: the Filter FE intervention (three FE settings) or continuation of normal practice (three FE settings). The following criteria were used to purposively sample FE settings and stratify the allocation: large FE college campuses (new intake more than 500) (n=2); small FE college campuses (new intake fewer than 500) (n=2) ‘sixth form’ colleges attached to schools (n=2).

In order to assess the feasibility and acceptability of delivering and trialling the intervention according to pre-specified criteria (objective 1), we collected a range of quantitative and qualitative data via: semi-structured observations of staff training sessions (n=1 per intervention setting), group-based youth work sessions (n=1 per intervention setting) and college websites and social media channels (n=2 per intervention setting); interviews with FE college managers (n=5) and the intervention team (n=6); and documentary evidence (e.g. college policies, intervention team records, etc.). The retention of FE settings and response rates were assessed using student survey data.

To explore participants’ experiences of implementing and trialling the Filter FE intervention (objective 2), qualitative process data were collected via: interviews with FE college managers (n=5) and the intervention team (n=6); focus groups with students (n=11) and staff (n=5), and semi-structured observations of intervention settings. These qualitative data were transcribed verbatim and analysed using techniques associated with thematic content analysis

and grounded theory. The coding framework included both deductive codes, derived from key research questions and relevant progression criteria, and inductive codes, identifying other relevant themes emerging from the data

In addition to examining intervention and trial feasibility and acceptability, primary, secondary, intermediate (process) outcomes and economic evaluation methods were piloted (objective 3). Surveys of new students enrolling at the participating FE settings in September 2014 (baseline) and September 2015 (one year follow-up) were used to examine the pilot primary (self-reported smoking weekly or more) and secondary outcome measures (self-reported lifetime smoking, use of cannabis in the past 30 days; frequent cannabis use, high risk alcohol use, and health-related quality of life). The following additional pilot secondary outcomes for baseline smokers were also examined: cessation; number of cigarettes/week; and, nicotine dependence. Informed by the intervention logic model, multiple sources of data were also collected at baseline and follow-up to pilot intermediate (process) outcomes at multiple levels: the restriction of the availability of tobacco in local shops was assessed via ‘mystery shopper’ audits; changes to the institutional environment and policies were assessed via structured observations and analysis of college policy documents; students’ knowledge, norm and social/situational self-efficacy and resistance skills were assessed via the student survey. Potential economic analyses methods were assessed, including the use of EQ-5D-5L health related quality of life measure. It was not feasible to collect saliva samples from students to assess the validity of self-reported smoking status at follow-up.

Results

The intervention was not delivered in full at any of the three intervention settings, with no implementation of some community and college-level components, and low fidelity of the social media component across sites. The staff training reached a total of 28 staff and youth work activities were attended by 190 students across the three sites (<10% of all staff and students). Lower than intended recruitment to these activities was largely the result of lack of demand from staff at intervention settings and, although those who did attend were observed to be engaged, low levels of acceptability were reported across FE sites. The intervention team reported additional challenges to recruitment due to the short lead-in time prior to implementation and high intervention-team staff turnover during the pilot study. The process evaluation also found that planned institutional policy review activities did not occur at any

of the sites, with limited evidence of changes to smoking policies post-intervention. This was again associated with limited preparation time for intervention delivery as well as issues relating to management of intervention, which also impacted limited community-level activities targeting local shops.

Six colleges were randomised into the two trial arms and all were retained at the one-year follow-up. Recruitment and retention of students was challenging, despite the use of the multiple methods and incentives. In September 2014, 1,320 students out of an estimated total sample of 2,363 participated in the baseline survey. Of these 14.0% (n=185) were ineligible as they were aged under 16 or over 18 and 5 students provided no data, leaving a baseline sample of 1,130 (47.8%). Although this equates to a response rate of less than 50%, the number of potentially eligible students at baseline (n=2,363) was provided by each institution and *over-estimates* the actual number of new students aged 16-18 in that setting and therefore *underestimates the true response rate*, especially in large FE settings, due to: students enrolling in principle prior to September but not registering at the start of term, deferring or dropping out in early September; inclusion of students who study across multiple campuses but whose primary campus is not the study site; and, the inclusion of some students aged over 18 due to incomplete information at enrolment. In September 2015, 412 eligible students completed the follow-up survey (36.5% of baseline respondents; 17.4% of all potentially eligible students at baseline).

The second objective was to explore the experiences of students, staff and the intervention team. Qualitative data indicated that implementation was limited by various factors, including staff and students uncertainty about the need for, and appropriateness of, smoking prevention activities in FE settings, the management of intervention, the high turnover of intervention team staff and the short lead-in time prior to implementation. Although support was expressed for the involvement of external health agencies in the FE setting, the majority of staff and students perceived that FE is 'too late' for smoking prevention activities, with current smokers better served by cessation activities and resistance from non-smokers to educational messages with high degrees of familiarity. Significantly, the act of intervention was itself a source of resistance, with both staff and students suggesting that such approaches contrast with institutional cultures in the FE sector aimed at promoting personal responsibility and developing autonomy in a population transitioning from, more constrained, schools. The emphasis on freedom of choice was expressed via students' right to smoke.

The third objective was to pilot primary, secondary and intermediate outcome measures and economic methods. There were low levels of missing data for all pilot primary and secondary outcomes from the student baseline surveys completed in September 2014 (n=1,130 eligible participants) and one year follow-up surveys completed in September 2015 (n=412 eligible participants). The prevalence of weekly smoking at baseline was 20.6% and 17.2% at follow-up. Of the 336 students who were not a weekly smoker at baseline, only 21 (6.3%) reported being a weekly smoker at follow-up. The trial arms were not well balanced for the indicative primary and secondary outcome measures at baseline or follow up due to the small number of clusters and heterogeneity between clusters (e.g. sixth form and community colleges). It was feasible to assess changes in intermediate (process) outcome (e.g. smoking norms/attitudes, self-efficacy, situational resistance skills, etc.) and economic measures (EQ-5D-5L, health service use) over time. At follow-up, the quantitative process outcomes identified that most students attempting to purchase tobacco were still able to do so. Only 5.1% students were aware of *The Filter* project at follow-up, although the proportion was higher in intervention group (7.1%) than the control group (2.9%).

Conclusion and recommendations

This one-year pilot study is the first reported evaluation of a universal smoking prevention intervention in an FE context to date and the first cluster RCT in FE settings in the UK. It was not feasible to implement the Filter FE intervention as planned and the methods used had low levels of acceptability among students and staff. FE settings do not appear to be a conducive environment for smoking prevention intervention activities, although weaknesses in the management of this intervention also further hindered implementation in this pilot. A larger cluster RCT to examine the effectiveness and cost-effectiveness of this intervention is not recommended. The very low prevalence of smoking uptake suggests that further consideration is needed on whether prevention or cessation activities would be most effective in FE and other educational settings. Findings should be considered in relation to evidence on age of onset for young smokers. It was feasible to recruit, randomise and retain FE settings within a cluster RCT design. FE managers valued the opportunity to be involved in health research and accepted randomisation. However, further methodological work is recommended to improve student recruitment and retention rates if RCTs are to be conducted in this setting.

Plain English summary

Smoking remains the leading cause of ill health and early death in the UK. Preventing young people from taking up smoking is vital to improve public health. More than 1.5 million 16-18 year olds are now enrolled on further education (FE) courses in the UK but there remains very little investment in smoking prevention activities in FE colleges or ‘sixth form’ colleges. Yet this is the time when many people start to smoke, and the transition to FE itself increases the risk of starting smoking for some young people as they make new friends and have more independence from their parents.

This research evaluated a new smoking prevention project for 16-18 year olds that was delivered in both general FE colleges and ‘sixth form’ colleges. The smoking prevention project is called “The Filter FE”. We evaluated this project over one college-year to check if it was delivered as planned and how acceptable (or not) it was with staff and students in different colleges. Three colleges received the project and the other three continued with their normal practice and acted as a ‘control group’.

At the three colleges where the project was delivered, a project manager, staff trainers, social media experts and trained youth workers were deployed to implement a range of new smoking prevention activities. However, prevention activities were not always implemented as intended, such as the planned smoke-free campus policies. Staff training reached a total of 28 staff and youth work activities were attended by 190 students, although many of them felt the messages about the harms of smoking were already well known. It was challenging to integrate existing web-based information, social media campaigns and on-line services with the colleges’ websites and social media. Further evaluation of the Filter FE project is not recommended because of the low levels of acceptability to students and staff.

1. Introduction

1.1 Youth smoking: a public health priority

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 the General Lifestyle Survey (GLS) illustrates that smoking continues to grow rapidly amongst older adolescents.² Although the GLS does not differentiate those in or out of education, with over 1.5 million British 16-18 year olds now enrolled in further education (FE) courses, this suggests 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 may also increase the risk of smoking as young people are exposed to new sources of peer influence and have more independence from their parents.

1.2 Health improvement in further education (FE) settings

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

A search of bibliographic databases undertaken in 2013 identified a further 14 relevant reports about smoking prevention and other health improvement interventions in FE settings.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.^{6-10,12,14} 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

1.3 Effective smoking prevention methods and approaches

With no evidence of effective smoking prevention methods or approaches in FE settings, the findings of five recent systematic reviews of smoking prevention interventions delivered in other educational and/or community contexts were identified and synthesised to inform the pilot intervention.²⁰⁻²⁴ The reviews suggest the following 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 skills 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 can be effective, especially in permissive contexts,⁴ which is likely to be the case in some FE settings.

This evidence highlights the relevance of multi-level smoking prevention interventions and identifies a set of intervention methods and approaches which may underpin intervention efficacy:

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

Systematic reviews also consistently find that ‘multi-level’ interventions, which address both individual and environmental determinants of behaviour simultaneously, are most effective for improving young people’s health outcomes.^{20,23,25,26} These interventions which include ‘higher-level’ environmental components also tend to be more cost-effective,²⁷ and are less likely to generate inequalities than individually focused components alone.^{28,29} However, if such interventions are to deliver major public health gains they must also be feasible to deliver and sustain.³⁰

1.4 “The Filter FE” intervention design and logic model

“The Filter FE” intervention was co-designed by ASH Wales and the research team following a commissioned call from the National Institute for Health Research (NIHR) Public Health Research (PHR) programme in 2013. It is a smoking prevention intervention managed and delivered by trained staff working on ASH Wales’ *The Filter* youth project who apply existing staff training, social media and youth work resources in FE settings. Informed by the socio-ecological theory of health,³¹ and evidence of effective smoking prevention methods and approaches (summarised above in section **1.3**), the Filter FE aimed to integrate multiple intervention activities within a multi-component, multi-level intervention for FE settings.

The intervention design and hypothesised mechanisms are summarised in the logic model (see **figure 1**) and described in more detail in section **2.1.1** (Intervention components). In summary, five areas of synergistic activity were planned to augment any existing activities already undertaken in FE settings: (1) working with local shops to restrict the sale of tobacco to under 18 year-olds; (2) implementing tobacco-free campus policies; (3) training FE staff to deliver smoke free messages; (4) publicising *The Filter* youth project’s online campaigns, advice and support services via FE websites and social media; and (5) on-site youth work activities to provide credible educational messages and promote social/situational resistance skills, as well as signposting cessation services. As described in the logic model (**figure 1**), it was hypothesised that these components would prevent the uptake of smoking via: the 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 different types of FE settings (including large institutions), as well as sustainability and fidelity, the intervention was designed so that it involved standardised processes and activities balanced with opportunities for a degree of local tailoring of activities. Some flexibility to allow for local adaptation can support universal adoption, institutional ownership and sustainable implementation of multiple activities.^{32,33} The intervention was also designed to allow the ‘dose’ of staff training and youth work activities to vary according to the size of institutions.

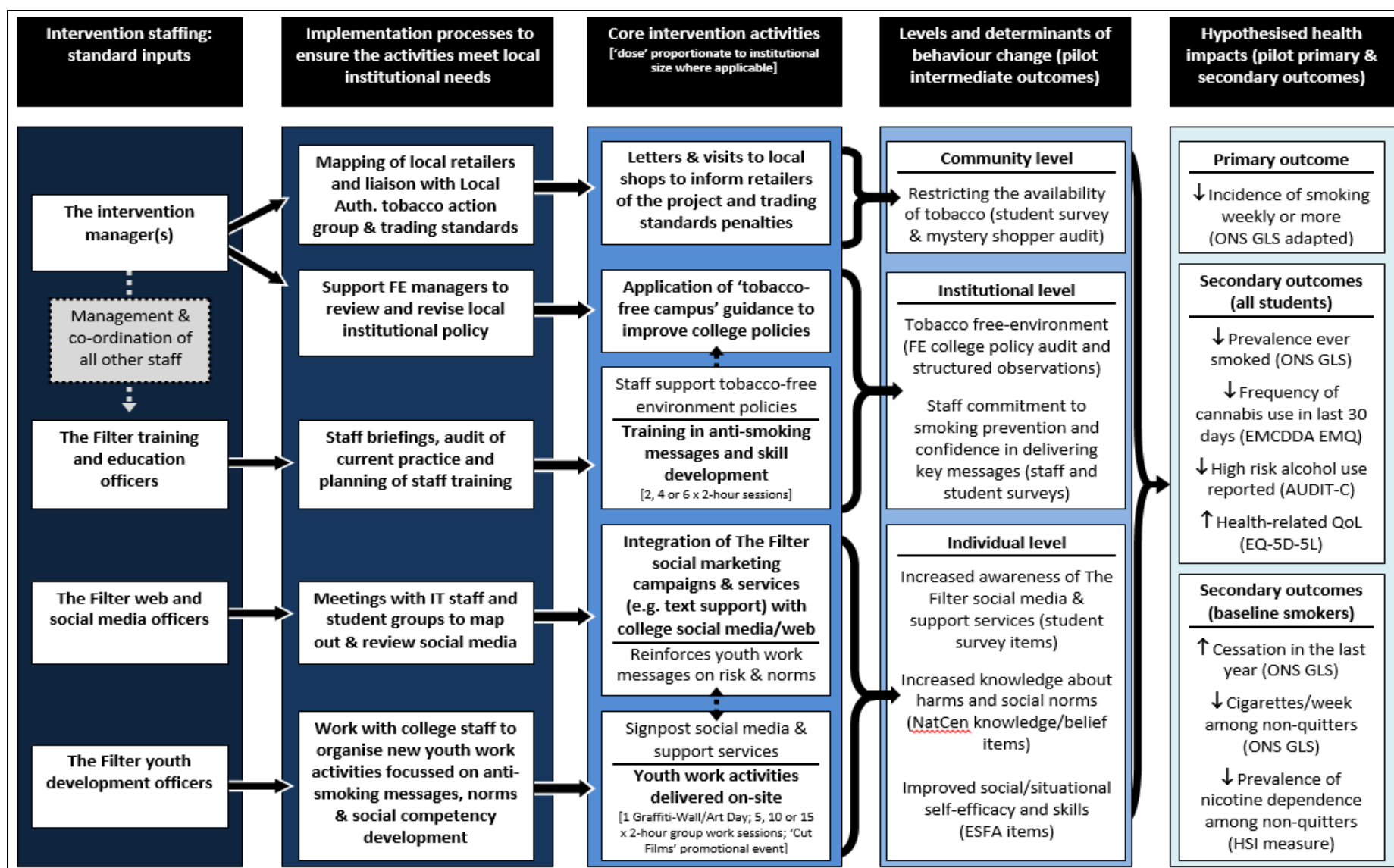


Figure 1: Intervention logic model

1.5 Public involvement

As well as co-designing the pilot intervention, staff working on ASH Wales' *The Filter* youth project were also involved in designing all aspects of the pilot trial and process evaluation prior to bid submission. The research team also worked with the Involving Young People Officer based in the Centre for the Development and Evaluation of Complex Interventions for Public Health Improvement (DECIPHer) to organise two consultations with the Advice Leading to Public Health Advancement (ALPHA) youth group at the project development stage. ALPHA are a group of young people aged 14-21 who advise researchers on intervention design, logic modelling and data collection methods by discussing and debating their views on the proposed research. Staff from Public Health Wales and FE teachers were also consulted on the intervention design, logic model and research strategy.

Three further consultation meetings with the ALPHA group took place post-commissioning to enable the researchers to consult with young people during the project on: recruitment and survey methods (e.g. advice on the design of publicity materials, information sheets, and e-questionnaires); strategies for increasing retention/follow-up; and public engagement and knowledge exchange activities.

1.6 Study aim, objectives and research questions

The aim of the pilot trial was to evaluate the feasibility and acceptability of implementing and trialling a new multi-level smoking prevention intervention in further education (FE) settings. The study had three objectives.

The first objective was to assess whether pre-specified feasibility and acceptability criteria were met, which were agreed with the National Institute of Health Research (NIHR) coordinating centre and trial steering committee (TSC), and deemed necessary conditions for progressing to a phase III trial. The progression criteria are listed in full in section 2.4 of the methods. In order to meet this objective, data were collected and analysed to address the following research questions (RQ):

- RQ1. Did the intervention activities occur as planned in (at least) two out of three intervention settings?;

- RQ2. Were the intervention activities delivered with high fidelity across all settings?;
- RQ3. Was the intervention acceptable to the majority of FE managers, staff, students and the intervention delivery team?;
- RQ4. Was randomisation acceptable to FE managers?;
- RQ5. 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?;
- RQ6. 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 second objective was 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. In order to meet this objective, data were collected and analysed to address the following RQ:

- RQ7. What are students', college staff and intervention team members' experiences of the intervention and views about its potential impacts on health?;
- RQ8. What are the barriers and facilitators to implementation and how do these vary according to college context and/or other factors?;
- RQ9. Were there any unexpected consequences?;
- RQ10. 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?;
- RQ11. What resources and partnerships are necessary for a phase-III trial?

The third objective was to pilot primary, secondary and intermediate outcome measures and economic evaluation methods prior to a potential phase III trial. It was not an objective of the pilot study to assess intervention effects nor was it powered to do so, but data were collected and analysed to address the following RQ:

- RQ12. Does the primary outcome measure (smoking weekly or more) have an acceptable completion rate, adequate validity and minimise floor/ceiling effects?;
- RQ13. Do cotinine concentrations of saliva samples indicate any evidence of response bias between arms in self-reported smoking status?;
- RQ14. Was it feasible and acceptable to measure all the secondary and intermediate outcomes of interest at baseline and follow-up?;
- RQ15. Is it feasible to assess cost effectiveness using a cost utility analysis within a phase III trial?

2. Methods

In this section of the report we provide an overview of the study design (2.1), including the specific intervention components examined. Details are then provided of the sampling and recruitment of the FE settings (2.2) and randomisation (2.3). Sections 2.4–2.6 describe the methods used to assess the ‘progression criteria’ (objective 1), explore participants’ experiences of the process of implementing and trialling the intervention (objective 2), and examine pilot trial outcomes (objective 3) respectively. Details of the pilot economic analysis (2.7) and trial registration, governance and ethics (2.8) are provided at the end of this chapter.

2.1 Study design: overview

A cluster randomised controlled pilot trial was undertaken in six FE settings in south-east Wales with allocation to: the Filter FE intervention (three settings) or continuation of normal practice (three settings). In order to assess the feasibility and acceptability of delivering and trialling the intervention according to pre-specified criteria (objective 1), we collected a range of quantitative and qualitative data via: semi-structured observations of the intervention delivery; interviews with FE college managers and the intervention team; and documentary evidence (e.g. college policies, intervention team records, etc.) The retention of FE settings and response rates were assessed using student survey data.

To explore participants’ experiences of implementing and trialling the Filter FE intervention (objective 2), data were collected via semi-structured interviews with FE managers and the intervention team, focus groups with students and staff, as well as additional process and contextual data via observations of intervention settings, staff training and youth work activities.

Primary, secondary, intermediate (process) outcomes and economic evaluation methods were also piloted in this study (objective 3). Surveys of new students enrolling at the participating FE settings in September 2014 (baseline) and September 2015 (one year follow-up) were used to examine the pilot primary, secondary and economic outcome measures. Informed by the intervention logic model, multiple sources of data were also collected at baseline and follow-up to pilot intermediate (process) outcomes at multiple levels: the restriction of the

availability of tobacco in local shops was assessed via ‘mystery shopper’ audits; changes to the institutional environment and policies were assessed via structured observations and analysis of college policy documents; students’ knowledge, norms and social/situational self-efficacy and resistance skills were assessed via the student survey.

2.1.1 Intervention components

The following section describes how each of the pilot intervention components were *intended* to be delivered, by whom, and their logic.

Prevention of the sale of tobacco to FE students aged under 18. To restrict availability locally, the intervention manager would map and contact all shops selling tobacco within 1 kilometre (km) of the intervention setting (i.e. within a 10 minute walk). Information letters would be distributed to these retailers to inform them that a new project (“The Filter FE”) was taking place at their local FE institution, explain why reducing supply is an important component of prevention and remind them about penalties for selling tobacco to under-18s. The letter focused only on sales of legal tobacco through the retailers. Posters, stickers and other materials would also be supplied for these shops to provide information to their customers about the legal age for purchasing tobacco products and the requirements to produce statutory ID to purchase tobacco.

Institutional 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 would work with FE managers to review institutional policies using the tobacco-free campus guidance developed by ASH Australia.³⁴ 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 using this tool to develop a new whole-campus tobacco-free policy. Second, the revised policies are implemented and launched. Third, policies are monitored, evaluated and updated/refined if required.

FE staff training. To train staff to deliver smoke free educational messages and support institutional change, training officers employed on The Filter youth project (accredited by

YMCA and Agored Cymru) would organise and deliver training sessions on-site using modules and teaching resources developed and piloted by ASH Wales in schools and other youth settings. Interactive, two-hour training workshops would be delivered to approximately 10 staff per session, with FE staff 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 would also be encouraged to champion new tobacco-free policies (above) and intervene to prevent smoking on site. The number of sessions to be delivered would vary depending on the size of the FE setting to ensure resources are distributed appropriately: one session to be delivered at smaller ‘sixth form’ sites (i.e. to reach a total of approx. 10 staff); two to four sessions to be delivered at medium and large FE campuses respectively (to reach up to 20/40 staff).

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 would 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 would 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).

Youth work activities. To educate and persuade students about the harms of smoking and model social/situational resistance skills, qualified youth workers from *The Filter* project would work with college staff and students to plan and deliver a range of youth work activities on-site (e.g. smoke free message film-making, graffiti walls and/or other arts-based activities). Youth workers would 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. As with the staff training, the numbers of sessions delivered would vary according to the FE setting’s size to ensure resources are distributed appropriately. These group-based youth work activities would be provided on-site during college-time and typically last one to two hours. Students

would 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 would also be provided to current smokers where appropriate.

2.2 Sampling and recruitment of FE settings

The following diversity and matching criteria were used to purposively sample six FE settings in south-east Wales: large FE college campuses (new intake more than 500) (n=2); small FE college campuses (new intake fewer than 500) (n=2) ‘sixth form’ colleges attached to schools (n=2).

Purposive sampling ensures a diversity in contexts at the intervention piloting stage so that a realist lens can be applied to address questions regarding not only *what is feasible and acceptable* in general but also *for whom and under what circumstances*, and place much more emphasis on exploring potential mechanisms of action and how these may vary by context prior to large-scale RCTs.³⁵ To avoid contexts where implementation may be less challenging (or atypical in other ways), 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) were not included. To minimise the potential for contamination across arms no more than one FE setting was recruited from any Middle Layer Super Output Area (MSOA), nor were FE settings recruited in neighbouring MSOAs.

The intervention team identified and contacted school and FE managers in the summer term 2014, with recruitment complete by July 2014. A total of 10 FE settings in south and mid Wales were contacted by ASH Wales’ staff in May and June 2014. Those who first expressed an interest were visited by researchers between June and July 2014, until six FE settings had been recruited according to the sampling criteria above. Participating FE settings are listed in **Table 1** (below) according to recruitment strata (pseudonyms).

2.3 Randomisation

Colleges agreed to take part in the study prior to randomisation. This study used a 1:1 allocation ratio. Allocation to intervention and control arms was conducted by the study statistician and stratified by the size and type of further education settings. The three strata

were: large FE college campuses with new intake of over 500 students; small FE college campuses with a new intake of fewer than 500 students; and ‘sixth forms’ within secondary schools. **Table 1** reports the outcome of the random allocation to trial arm by sampling strata, including the size of each FE setting’s new intake.

Table 1. Participating FE settings and allocation to trial arm

Sampling/randomisation strata	FE setting (pseudonyms)	Allocation	Estimated new students aged 16-18
Large FE college campuses (n=2)	Valeside College	Intervention	1027
	Middledale College	Control	760
Small FE college campuses (n=2)	Laurelton College	Intervention	130
	Glynbel College	Control	175
School ‘sixth form’ colleges (n=2)	Athervale ‘sixth form’	Intervention	110
	Afonwood ‘sixth form’	Control	161

It was not possible for colleges, the intervention team and researchers to be blinded to allocation throughout the study. However, colleges were randomised *after* the baseline data collection to ensure that all students, staff and researchers were blind at the time of the recruitment of colleges and baseline data collection.

2.4 Progression criteria

In line with MRC guidance,³⁶ data collection during the pilot trial focused on assessing acceptability and feasibility and allowing us to judge progress against the agreed criteria for progression to a subsequent trial of effectiveness and cost effectiveness. The first objective was specifically to assess whether the criteria deemed necessary in order to progress to a larger cluster RCT were met (see **Box 1**). These were agreed by the investigator team, the NIHR Evaluation, Trial and Studies Coordinating Centre (NETSCC) and the trial steering committee (TSC) prior to commencing the pilot trial as evidence of feasibility and acceptability of the intervention and trial methodology.

Box 1: Research questions addressing the agreed criteria for progression

RQ1. Did the intervention activities occur as planned in (at least) two out of three intervention settings? This will be assessed according to the extent to which the following intervention activities occurred:

- Tobacco retailers within 1km of the FE setting were contacted in writing within three months of the start of the intervention;
- Institutional policies and practices were reviewed, updated using the tobacco-free campus guidance, and changes communicated to staff and students within six months of the start of the intervention;
- A minimum of 1/2/4 staff training sessions were delivered as planned (according to institutional size) with a minimum of five staff attending each session;
- *The Filter* youth project's web-based information, advice and support services were embedded on the FE institution's home page during the intervention 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.); and,
- A minimum of 5/10/15 youth work sessions were delivered as planned (according to institutional size) with a minimum of eight different students attending each session.

RQ2. Were the intervention activities delivered with high fidelity across all settings?

RQ3. Was the intervention acceptable to the majority of FE managers, staff, students and the intervention delivery team?

RQ4. Was randomisation acceptable to FE managers?

RQ5. 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?

RQ6. 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?

2.4.1 Data sources

In order to answer **RQ1** (see **Box 1**, above), multiple sources of quantitative and qualitative data were collected. To assess if tobacco retailers within 1km of the FE setting were contacted in writing within three months of the start of the intervention, data collected via intervention team records were examined and cross-checked through interviews with the intervention team. To assess if institutional policies and practices were reviewed and updated using tobacco-free campus guidance, with changes communicated to staff and students within six months of the start of the intervention, data collected via intervention team checklists were examined and cross-checked with documentary analyses of college policies and structured observations of the FE environments at follow-up. To examine the fidelity and reach of staff training, data collected via intervention team checklists and semi-structured observations of training were examined. Integration of ASH Wales' *The Filter* online resources by intervention setting was assessed using intervention team checklists and cross-checked via semi-structured observations of college websites and social media channels. To examine the implementation of youth work activities, data collected via intervention team checklists were examined and cross-checked in interviews with FE managers.

In order to answer **RQ2** (see **Box 1**, above): semi-structured observations of staff training sessions (n=1 per intervention setting) and group-based youth work sessions (n=1 per intervention setting) were used to assess fidelity of delivery of those components across settings; and, the fidelity of other intervention components (activities aiming to prevent the sale of tobacco to under-18s in shops near the intervention site; institutional policy review and revision; social media integration) were examined via intervention team checklists and interviews with the intervention team and FE managers. **RQ3** (see **Box 1**, above), intervention acceptability, and whether this was reported by the majority of participants, was assessed via data from semi-structured interviews with FE managers and the intervention team, and student and staff focus groups. Data from semi-structured interviews with FE managers were used to examine **RQ4** (see **Box 1**, above). In order to answer **RQ5** and **RQ6** (see **Box 1**, above), the retention of FE settings and response rates were assessed using student survey data.

2.4.2 Data analysis methods

The quantitative and qualitative data collected to answer RQ1–6 were managed and analysed separately. For example, the standardised checklist data from the mystery shopper, environmental observation and policy audits were collated and analysed in Excel, while data from focus groups and interviews were analysed using NVivo (version 10). The emergent results from each data source were shared and discussed amongst the research team. Individual results were collated according to a framework derived from key research questions and relevant progression criteria to ensure that data from all sources were used where pertinent to answer the research questions, and to facilitate triangulation. Where data from one source contradicted data from another source, this was noted and discussed.

2.5 Evaluating participants' experiences of the process

In addition to examining intervention delivery according to pre-specified criteria (objective 1), a second objective was to explore student, staff and intervention team experiences of implementing and trialling the intervention, and how this varied in different FE contexts, in order to refine the intervention and trial methods. Research questions (RQ) 7-11 addressed this objective (See **Box 2**).

Box 2: Research questions to evaluate participant experiences

RQ7. What are students', college staff and intervention team members' experiences of the intervention and views about its potential impacts on health?

RQ8. What are the barriers and facilitators to implementation and how do these vary according to college context and/or other factors?

RQ9. Were there any unexpected consequences?

RQ10. 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?

RQ11. What resources and partnerships are necessary for a phase III trial?

To answer RQ7-11, multiple sources of qualitative data collected via semi-structured observations, semi-structured interviews, and focus groups were analysed to explore student, staff and intervention delivery team experiences in depth, and how and why these varied.

2.5.1 Qualitative process data

Semi-structured interviews and focus groups were conducted with a range of stakeholders to explore in detail the process of planning, implementing and receiving the intervention. **Table 2** summarises the process evaluation data collected at each FE site. Each method of data collection is described in more detail below.

Table 2: Qualitative process data collected by arm and setting

FE setting	Semi-structured observations of staff training sessions (total delivered)	Semi-structured observations of youth work sessions (total delivered)	Student focus groups	Staff focus groups	FE Manager/ staff interviews
<i>Intervention arm</i>					
Valeside College (Large FE college campus)	1 (1)	1 (10)	5	2	1
Laurelton College (Small FE college campus)	1 (1)	1 (2)	4	2	1
Athervale ‘sixth form’ (School ‘sixth form’ college)	1 (1)	1 (3)	2	1	1
<i>Comparison arm</i>					
Middledale College (Large FE college campus)	N/A (0)	N/A (0)	N/A	N/A	1
Glynbel College (Small FE college campus)	N/A (0)	N/A (0)	N/A	N/A	1
Afonwood ‘sixth form’ (School ‘sixth form’ college)	N/A (0)	N/A (0)	N/A	N/A	0

Semi-structured observations

Semi-structured observations of staff training and youth work sessions were conducted to provide contextual detail on the delivery and receipt of the intervention and to provide data on potential barriers and facilitators to implementation. Observations focused on the way in which sessions were delivered, the content and activities included, and the way in which they were received by staff and young people. Semi-structured observations (of staff training and youth work sessions) were recorded on templates devised *a priori*, documenting the content of sessions, the number and types of participants, and the dynamics amongst the group, allowing for observation of intervention acceptability and fidelity.

The researcher conducting the observations, interviews and focus groups in each FE setting was consistent where possible, and observations of staff training and youth work sessions were carried out before focus groups to maximise the opportunity to respond to issues that arose from observations, and preliminary analyses, in focus groups and interviews. This depth of fieldworker immersion and data triangulation enabled unexpected and emergent issues (e.g. attitudes and beliefs around e-cigarettes) to be tested and clarified.

One staff training session in each of the three intervention sites was observed between April and June 2015. Sessions lasted a maximum of two hours. A total of 28 members of staff attended the three sessions observed (see **table 3**). Participants included both teaching and support staff.

Table 3: Participants in semi-structured observations of staff training sessions

	Participants (n)		
	Total	Teaching staff	Support staff
Valeside College (Large FE college campus)	6	0	6
Laurelton College (Small FE college campus)	9	0	9
Athervale ‘sixth form’ (School ‘sixth form’ college)	13	10	3

Three observations of youth work sessions were undertaken, one in each intervention site, between March and May 2015. The largest observed group had 22 students, the smallest had six participants; a member of teaching staff sat in on each of the observed sessions (see **table 4**). It is not known what proportion of participants identified as smokers as it was not the intention to target students based on smoking status.

Table 4: Participants in semi-structured observations of youth work sessions

Intervention setting	Participants (n)			Teachers present (n)
	Total	Female	Male	
Valeside College (Large FE college campus)	8	4	4	1
Laurelton College (Small FE college campus)	6	0	6	1
Athervale ‘sixth form’ (School ‘sixth form’ college)	22	16	6	1

Focus groups with students and staff

Focus groups were conducted with students and staff at all the intervention settings to explore: their views on student smoking norms and behaviour; their awareness and/or experiences of participation in Filter FE project activities at their college, including their views on how successfully each component was implemented and barriers to implementation; their perceived impact of the intervention activities on student and staff smoking norms and behaviours at their college; and, the acceptability and feasibility of recruiting and collecting multiple waves of e-survey data from students. Focus groups with students were chosen for both pragmatic and methodological reasons. First, focus groups allowed us to quickly capture a range of views from a relatively largely number of students (N=69 in all focus groups). Second, we wished to gain insights into students’ shared (or contested) understandings of the smoking culture within FE settings: focus groups were therefore the most appropriate method.

The number of student focus groups varied according to the size of the college (see **table 2** above). The aim was to recruit six student focus groups (three smokers groups, three non-smokers) at the large FE college campus, four in the medium-sized college campus and two in the ‘sixth form’ college. This was almost achieved: in the large FE college, five student focus groups were taken, with four and two undertaken as planned in the other intervention colleges as planned. FE managers recruited students to attend the focus groups. They were asked to recruit both students who identified as smokers and non-smokers, from a range of courses. In practice, it was difficult to purposively sample and stratify students into groups by smoking status as some young people identified as non-smokers but revealed that they smoke (e.g. ‘social smoking’) during the focus group; other groups were mixed because the students were recruited through friendship groups or through a convenience sample of one tutor group. While managers were briefed about how to recruit students, this mode of recruitment meant there was potential for students to come along without clear understanding of the purpose of the focus groups. We were therefore careful to provide a clear introduction before each focus group started, allowing participants to withdraw if they wished.

Student focus groups took place between April and June 2015. Most were in June 2016, and were conducted only after all intervention activities were completed at the site. A total of 69 students participated in the focus groups, of which 31 were female (45%) and 18 explicitly identified themselves as smokers (26%); some additional participants identified as non-smokers but during the focus group discussion revealed they sometimes smoked. The smallest focus group had two students; the largest 13 participants. The focus groups included part-time and full-time students from a range of courses, including A-level, BTEC and vocational students. Student focus groups lasted between 40 and 80 minutes, were all conducted in private rooms at the intervention college sites, using topic guides. Topic guides covered their views on student smoking norms and behaviours; awareness of and participation in the Filter FE project; how successfully each component was implemented and why implementation may have been limited; perceived impact on student and staff smoking norms behaviours; and the acceptability and feasibility of recruiting and data collection methods piloted. All participants were provided with a £10 ‘love to shop’ voucher for taking part in the focus groups

We conducted two staff focus groups at the two larger intervention sites: one focus group with staff who had received training from *The Filter* team as part of the intervention, one

with staff who had not. Only one staff focus group took place at Athervale 'sixth form' due to the smaller number of students and staff based there. We aimed to include approximately eight staff in each focus group but in practice it was difficult to recruit staff to attend the focus groups, especially those who had not attended the training. In total, 19 staff participated across the five focus groups (including eight staff trained by *The Filter* team); the size of focus groups ranged from two to six participants. Focus groups were conducted in private rooms on each site using semi-structured topic guides that covered the same broad areas as the one used in the student focus group (see above). Participating staff represented a range of teaching, management and support positions within each setting.

Semi-structured interviews with FE managers

Semi-structured interviews were conducted with FE managers at both intervention and control sites to explore: their experiences of participating in a trial, including the acceptability of randomisation and data collection methods; perceived benefits and challenges of the Filter FE intervention on student and/or staff smoking behaviours; and, at intervention sites, managers' experiences of implementation in their college context, including activities completed/not completed and barriers and facilitators to implementation. Interviews were used as FE managers were the person (or in the case of one paired-interview, people) who could offer the best insight into their experience of participating in the research.

A member of the management staff at each of the six participating FE settings was recruited to participate in a semi-structured interview at the end of the intervention. Interviews were conducted with FE managers at both intervention and control sites between June 2015 and February 2016, after the completion of the intervention. One (control) FE manager declined to participate in the interview. One interview was face-to-face with two staff members who had been working jointly as the lead FE manager for the study, four interviews were conducted over the telephone at the participants' request. This may have affected the data collected as the face-to-face interview was longer and the interviewees and interviewer had an established rapport. However, the telephone interviews were conducted by two experienced qualitative researchers (one was the same as conducted the face-to-face interview) and we ensured all data were included in the analysis and contributed to the findings. We were careful to provide prompts to aid the recall of managers who were interviewed. The time between recruitment to the study and the interviews may have affected

some interviewees' accounts and led to difficulties in recall, although two of the interviewees were particularly keen to provide feedback about the recruitment process and the early stages of the study, suggesting the interviewees had had time to reflect on the process even if they could not remember fine details. Interviews lasted between 20 and 60 minutes. Topic guides included questions and prompts regarding our *a priori* progression criteria, their experiences of being involved in the pilot RCT, and of planning, implementing and receiving the intervention (if they were an intervention site).

Semi-structured interviews with the intervention team

Semi-structured interviews were conducted with the intervention team to explore their experiences of: implementing the intervention; facilitators and barriers to implementation; potential changes to be made to the intervention; and their experience of delivering the Filter FE within a trial context. Two of these interviews were conducted before the end of the intervention because the members of staff were leaving the organisation. Recruitment to these interviews was based on whether the individual had been involved in intervention implementation and aimed to encompass a range of different staff roles (project managers, staff trainers, youth workers, and social media team members); researchers recruited these staff directly.

Interviews were conducted with six members of the intervention delivery team between April and September 2015. All interviews were conducted face-to-face, five of the six interviews were conducted in private rooms in the ASH Wales offices, and one was conducted in a private space at an intervention site after a staff training session. Interviews lasted between 30 and 60 minutes. The interview topic guides covered their experiences of: implementing *The Filter* in FE settings; facilitators and barriers to implementation; what they would change about the intervention if they could; and, their experience of delivering the intervention within a trial context.

2.5.2 Data analysis methods

Qualitative data collected via focus groups and semi-structured interviews were transcribed verbatim and entered into NVivo (version 10) software to aid data management and analysis.

Qualitative data were analysed using techniques associated with thematic content analysis and grounded theory. Transcripts were initially divided into four groups to assist manageability: student focus groups, staff focus groups, FE manager interviews and intervention team members. First, one of the research team, MW, read each of the groups of transcripts to familiarise herself with the data. All transcripts for each group were then re-read and coded line by line to identify emergent themes and an initial coding framework was developed to identify key themes and subthemes. The coding framework included both deductive codes, derived from key research questions and relevant progression criteria, and inductive codes, identifying other relevant themes emerging from the data (e.g. e-cigarette use in FE settings). MW and a second researcher (RL) independently applied this coding framework to 3 transcripts and then met to discuss and further refine the coding framework. The final agreed coding framework was applied to all subsequent manuscripts by MW, noting and discussing any substantial additions or modifications with the research team as necessary. The way in which themes inter-related and how they varied between different groups and contexts was carefully scrutinised throughout the analysis process and recorded using detailed memos.

The quotes presented in the report were selected because they best illustrate the common and/or interesting ideas and themes emerging from the data. These were discussed and agreed among the research team. Where contradictory data were identified (e.g. the difference between school sixth forms and colleges, or where some students identified that they felt that they had been bullied into smoking) these are noted in the report.

Observation records of staff training and youth work sessions were analysed separately from interview and focus group data by MW, with NVivo (version 10) used to support cross-checking and data triangulation. Records were coded line-by-line, then grouped according to whether they related to the framework described above or inductive, emergent themes.

Most of the qualitative data collected for the process evaluation were collected by experienced qualitative researchers who were independent of the trial management or baseline data collection. While this added an additional layer of contacts for FE managers to liaise with, it meant the researchers had minimal knowledge or preconceptions about the sites. The researchers were all white professionals (three female, one male) which reflected the predominant ethnicity in FE sites. They had little knowledge of the areas in which the FE

sites are based, and all were English, not Welsh or Welsh speakers, which may have had an impact on how the students and staff responded to them in focus groups. Researchers shared their reflections on data collection to aid analysis and an interpretative approach.

2.6 Pilot outcome measures

The final objective was to pilot primary, secondary and intermediate outcome measures and economic evaluation methods. The pilot cluster RCT design enabled a range of outcome measures and data collection methods (student surveys, policy audits, environmental observations and mystery shopper visits) to be piloted at baseline (September 2014) and one-year follow-up (September 2015) to answer research questions (RQ) 12-15 (see **Box 3**).

Box 3: Research questions to evaluate outcome measures

RQ12. Does the primary outcome measure (smoking weekly or more) have an acceptable completion rate, adequate validity and minimise floor/ceiling effects?

RQ13. Do cotinine concentrations of saliva samples indicate any evidence of response bias between arms in self-reported smoking status?

RQ14. Was it feasible and acceptable to measure all the secondary and intermediate outcomes of interest at baseline and follow-up?

RQ15. Is it feasible to assess cost effectiveness using a cost utility analysis within a phase III trial?

The pilot outcomes are described first in sections 2.6.1 and 2.6.2, followed by a description of the data sources used to operationalize these measures to assess change at the student, college and community levels (2.6.3). These pilot outcomes are also summarised in the intervention logic model (**figure 1**). Finally, the methods for analysing the student survey data and other quantitative data sources are described in section 2.6.4.

2.6.1 Pilot primary and secondary outcome measures

All the pilot primary and secondary outcome measure data were collected via student surveys at baseline and one-year follow-up, which are described in more detail below (2.6.3 Data Sources).

The pilot primary outcome was prevalence of weekly smoking (defined as smoking at least one cigarette weekly or more) at one year follow-up, which was assessed using an item adapted from the GLS.² Students were asked: “Do you smoke cigarettes at all nowadays?” and given four response options: “Yes, every day”; “Yes, at least once a week”; “Yes, occasionally but less than once a week”; and “No, never”. Those who responded “Yes, every day” or “Yes, at least once a week” were considered weekly smokers.

The pilot secondary outcomes were: lifetime smoking, using the Office of National Statistics (ONS) GLS item;² use of cannabis in the past 30 days and frequent cannabis use (4 or more times in last 30 days), past 30 days; frequent cannabis use (4 or more times in last 30 days), using the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) European Model Questionnaire (EMQ) items;³⁷ high risk alcohol use, using the Alcohol Use Disorders Identification Test Consumption (AUDIT-C) measure;³⁸ and, health-related quality of life (HRQoL), using the EQ-5D-5L measure.³⁹

The following three measures were additional pilot secondary outcomes at follow-up *for baseline smokers only*: self-report smoking cessation, using the ONS GLS item;² number of cigarettes smoked per week, using the Office of National Statistics ONS GLS item;² and, nicotine dependence using the Heaviness of Smoking Index (HSI) items.⁴⁰

2.6.2 Pilot intermediate outcome measures

As illustrated in the intervention logic model (**figure 1**), it was hypothesised that the intervention components would prevent the uptake of smoking through triggering changes at the individual (student), college and community levels. For this reason, intermediate outcome variables were piloted at each of these three levels by collecting a range of additional quantitative process data at baseline and one year follow-up via college policy audits,

environmental observations and mystery shopper visits, as well as via the student surveys at each site.

At the individual-level, baseline and follow-up student surveys assessed self-reported changes over time to: attitudinal and knowledge-based precursors to smoking, including perceived prevalence of smoking (i.e. perceived norms), by adapting NatCen items;⁴¹ social and situational self-efficacy and skills, using the European Smoking Prevention Framework Approach (ESFA) items;^{42,43} and awareness of *The Filter* project.

At the institutional-level, two measures of college environmental change were piloted. First, progress towards a tobacco free-environment, 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 smoke free messages, assessed via student survey items at follow-up.

At the community-level, the availability of tobacco to students aged under 18 from local retailers was assessed via: a pre- and post-intervention mystery shopper audit of retailers within 1km of intervention and comparison sites; and, items on the student follow-up survey.

2.6.3 Data sources

Quantitative data were collected at baseline (September 2014) and follow-up (September 2015) via the following methods: student surveys, college policy audits, structured observations of the college environment, and mystery shopper visits. These methods are described in detail in turn below. All baseline data collection was completed prior to randomisation (October 2014). The investigator team was unblinded to allocation at follow-up but all fieldworkers remained blinded throughout the study.

Student surveys

Students were eligible to participate at baseline if they were aged between 16 and 18 years old on 1st September 2014 and had enrolled into further education studies in the 2014-15 academic year (i.e. they were new FE students, aged 16-18). Students who were older or younger than 16-18 years of age and completed the survey were excluded from analyses.

As this was a pilot trial, a power calculation was not required. The estimated sample size at baseline of 2500 students in six FE settings was chosen to provide some information on variability within and between settings at baseline and follow-up. This sample was chosen to indicate the likely response rates, and permit estimates (with 95% confidence intervals) of and intra-cluster correlations (ICCs) of weekly smoking prevalence in advance of a potential effectiveness trial involving a larger number of clusters (colleges) and students.

At baseline and follow-up the consent form and survey was completed using an electronic (e)-questionnaire for ease of delivery and completion in all areas of college, including social spaces without desk access, with paper copies available if necessary (e.g. requested by student, due to technical problems, etc.). Use of incentives is considered fair recompense for time in work with young people.⁴⁴ Here student participation was incentivised via prize draws for an iPad and shopping vouchers at both baseline and follow-up.

In the first week of September 2014 (i.e. the first week of the new term), students at each participating FE setting which used an email system (4/6) were contacted directly via their new email account and asked to complete the baseline survey directly via a weblink; they were also sent a reminder email 3 weeks later. Those students who did not complete the survey online directly via this email link, or who attended an institution without a student email system, were given multiple opportunities to complete the e-questionnaire on-site during September 2014 via: (a) timetabled classroom periods dedicated to survey completion, in which students used either college computers, their own devices (laptop, tablet computer or smart phone) or Google Nexus tablets provided by the fieldworkers; or, (b) informal data collection sessions (using Google Nexus tablet computer and/or QLR codes) in common areas at break periods. Hard copies were available as a backup (e.g. if the internet connection was too slow or could not be accessed temporarily) and were entered online once fieldworkers returned to the office. All baseline collection occurred between 1st and 30th September 2014. Detailed contact information (name, personal email and mobile phone) was collected at baseline to help track students who left or were on work-based placements at follow-up.

The one year follow-up took place when students had begun the next college year in September 2015 and used the same methods (i.e. emails to all students with a college email account, classroom sessions, informal data collection sessions in common areas). To increase

response rates participants were also telephoned up to three times in September 2015 to collect follow-up survey over the phone. All follow-up data collection occurred between 1st and 30th September 2015. Participants who left college or were unable to be contacted were lost to the trial at follow-up.

After the follow-up survey, all students were contacted and asked to provide a saliva sample in order to examine the reliability and validity of the self-reported smoking outcome via cotinine and anabasine testing. However, it was not feasible to recruit sufficient students to provide these samples, despite the use of £10 vouchers as incentives, and we do not report the results of this validation sub-study here.

College policy audits

Institutional policies were obtained in September 2014 (baseline) and September 2015 (follow-up). Researchers requested all relevant tobacco policy documents directly from the management teams at each participating FE setting. Data were extracted into an online pro forma to capture the following information about each setting:

- Whether the institution has a specific tobacco policy in place, or if tobacco use is covered in other institutional policies;
- The date of the policy and how often reviewed;
- Whether students and/or staff are allowed to smoke or use e-cigarettes on site according to current policy;
- Whether college policies make provisions for cessation services and other ‘quit resources’ on site;
- Other details, including whether careers events, funding and financial connections are covered by existing institutional policies.

Structured observations of the college environment

One researcher completed a structured observation of each college environment (n=6) at baseline and follow-up using a tablet computer (‘tablet’). These observations aimed to assess student and staff practices (e.g. smoking outside of designated areas, where e-cigarettes are used, etc.), and the extent to which the physical environment at each site communicated

tobacco-free messages (e.g. through signage) and/or supported institutional policies (e.g. directed people to designated smoking areas off site). Photographs were also taken on the tablets to illustrate the information recorded in the observational schedule.

Mystery shopper visits

Tobacco availability to students aged under 18 was assessed at baseline and follow-up using a mystery shopper audit of all retailers within 1km (i.e. within a 10 minute walk) of all six participating FE sites. These were the shops that were in the target area for intervention. The aim of the visits was to assess whether local shops were compliant with the restriction of tobacco sales to under 18 year-olds at baseline and/or follow-up, and to explore differences over time overall and by arm. The protocol for the mystery shopper activity was developed with input from Caerphilly Trading Standards officers in line with best-practice guidance for test purchasing methods.

Mystery shopper exercises were carried out by two young people aged 17 (one in 2014, one in 2015) who were (i) younger than 18 years and (ii) not students at any of the sites included in the study. At both baseline and follow-up the mystery shoppers were male. The shoppers were accompanied by an adult fieldworker, who remained outside the shops and out of sight. The shopper entered the shop and asked to purchase cigarettes while the fieldworkers waited outside. They then completed an online, standardised checklist with the fieldworkers which covered: type of shop visited; whether they were able to purchase cigarettes and; the presence of age restriction warning posters or materials in the shop. There was one instance at baseline (none at follow-up) where the shopper was unable to recall whether there was additional signage in the store regarding smoking or age restrictions.

A total of 18 shops were followed up at both baseline and follow-up; seven shops were also visited only once (either baseline or follow-up) because of closure or because their identity could not be verified at follow-up (e.g. name changed). In the results section we therefore report the results where data are available for shops at both baseline and follow-up (n=18).

2.6.4 Statistical analyses

The primary aim of the pilot trial was to assess feasibility and acceptability and gather data to plan a future definitive trial. This included estimating rates of eligibility, recruitment, retention at the one-year follow-up, as well as the acceptability, reliability, rates of completion of pilot primary and secondary outcome measures.

The eligibility, recruitment and retention rates for colleges and students are summarised using a Consolidated Standards of Reporting Trials (CONSORT) diagram (**figure 2**). The data collected for trial participants were summarised by trial arm and combined across arms. The aim was to examine the acceptability of potential primary and secondary outcome measures for a future trial, as well as describing the baseline characteristics of participants. The percentage of missing values was reported for all variables. Categorical variables were summarised using the percentage in each category. Numeric variables are summarised with the mean, standard deviation and a five number summary (minimum, 25th centile, median, 75th centile, maximum). We present mean and median values to examine the shape of each distribution. All analyses used intention-to-treat populations.

We used chi-square and t-tests to examine differences between students who did and did not provide data at baseline and follow-up. Cronbach's alpha was calculated to examine the internal consistency of measures. Multilevel logistic regression models adjusting for baseline weekly smoking status, age, gender, residence with an employed adult, ethnicity and educational attainment (\geq five GCSEs A*-C) were used to conduct exploratory effectiveness analyses. All statistical analyses were conducted with Stata v.13.

Data from the mystery shopper, policy audit and environmental observations were collated and analysed using Excel spreadsheets. For the mystery shopper survey, shops visited at both baseline and follow-up were matched in the spreadsheet, and the data for each survey item (e.g. were cigarettes successfully purchased) compared. For each site, items on the policy audit were compared at baseline and follow-up, with differences between intervention and comparison sites scrutinised. Similarly, environmental observation items were compared between intervention and control site, noting any changes between baseline and follow-up.

2.7 Economic analysis

We piloted a brief health service use survey for student completion and the EQ-5D-5L (pilot secondary outcome) to record preference-based HRQoL.³⁹ These measures were piloted because it was anticipated that, if feasible to collect data from students in these settings, they could be used in any subsequent phase-III trial to measure any short term impact of smoking on healthcare use and/or health-related quality of life.

2.8 Trial registration, governance and ethics

The study was funded by the Public Health Research (PHR) programme (PHR project: 13/42/02) at the National Institute for Health Research. The trial protocol was registered with Current Controlled Trials (ISRCTN19563136 <http://www.isrctn.com/ISRCTN19563136>). The study was overseen by a Trial Steering Committee (TSC), comprising an independent chair (Professor Paul Aveyard, University of Oxford) and three other independent members (Professor Angela Harden, University of East London; Professor Rob Anderson, University of Exeter, Dr Julie Bishop, Public Health Wales). The TSC met six-monthly throughout the study (three times in total) to examine the methods proposed and monitor data for quality and completeness. With the agreement of the TSC and NIHR PHR coordinating centre, a separate Data Monitoring and Ethics Committee was *not* established because this was a pilot trial with no interim analysis.

The study was approved by the Cardiff University School of Social Science Research Ethics Committee prior to recruitment and data collection commencing. The validation sub-study (saliva testing) was approved by the School of Medicine Research Ethics Committee, liaising with Cardiff University Human Tissue Act managers as necessary. The pilot trial protocol was approved by the South East Wales Trials Unit (SEWTU) and TSC.

3. Results

In this section of the report, we first describe the student response rates at baseline and follow-up and the characteristics of the students participating in the study (3.1). The findings related to the primary objective are then presented (3.2), which was to assess the pre-specified ‘progression criteria’ considered to represent evidence of feasibility and acceptability of the intervention and trial methodology. We then present student, staff and facilitators’ experiences of the intervention and trial process (3.3). Finally, we report the quantitative data analyses examining the pilot primary and secondary outcomes, including the pilot economic outcome measure (3.4), and the pilot intermediate outcome measures (3.5).

3.1 Description of pilot trial sample

Six colleges were assessed as being eligible to participate in the trial and participated in the study, including random allocation (three intervention, three control; Figure 2). Colleges could not always know or provide exact ages of enrolled students before data collection, which is discussed further in section 4 of the report.

3.1.1 Flow of participants in the pilot trial

Of the target population of 2,363 students at baseline, 1,320 (55.8%) participated in the baseline data collection. Of those 1,320 participants, five students (0.4%) provided consent information but did not answer any questions on the survey and 185 (14.0%) were ineligible due to being either under the age of 16 or over 18. Of those excluded due to age around half (49.7%) were aged 21 or over. The remaining 1130 students, 470 in the control and 660 in the intervention arm, equated to a baseline response rate of 47.8% based on the estimated total population of new students aged 16-18 at these college campuses.

At the one-year follow-up, 472 (35.7%) baseline respondents participated in the repeat survey. Fifty six of these participants (12.0%) were students who were ineligible to take part in this study at baseline because they were either under the age of 16 or over 18. Four participants’ responses were removed due to concerns about the quality of data collected on one day at one site based on fieldworker reports (Laurelton College). Out of the 2,363

potentially eligible students at baseline, 412 (17.4%) students who were eligible to participate provided valid survey data at baseline and one-year follow-up. This comprised 238 students in the intervention arm and 174 students in the control arm.

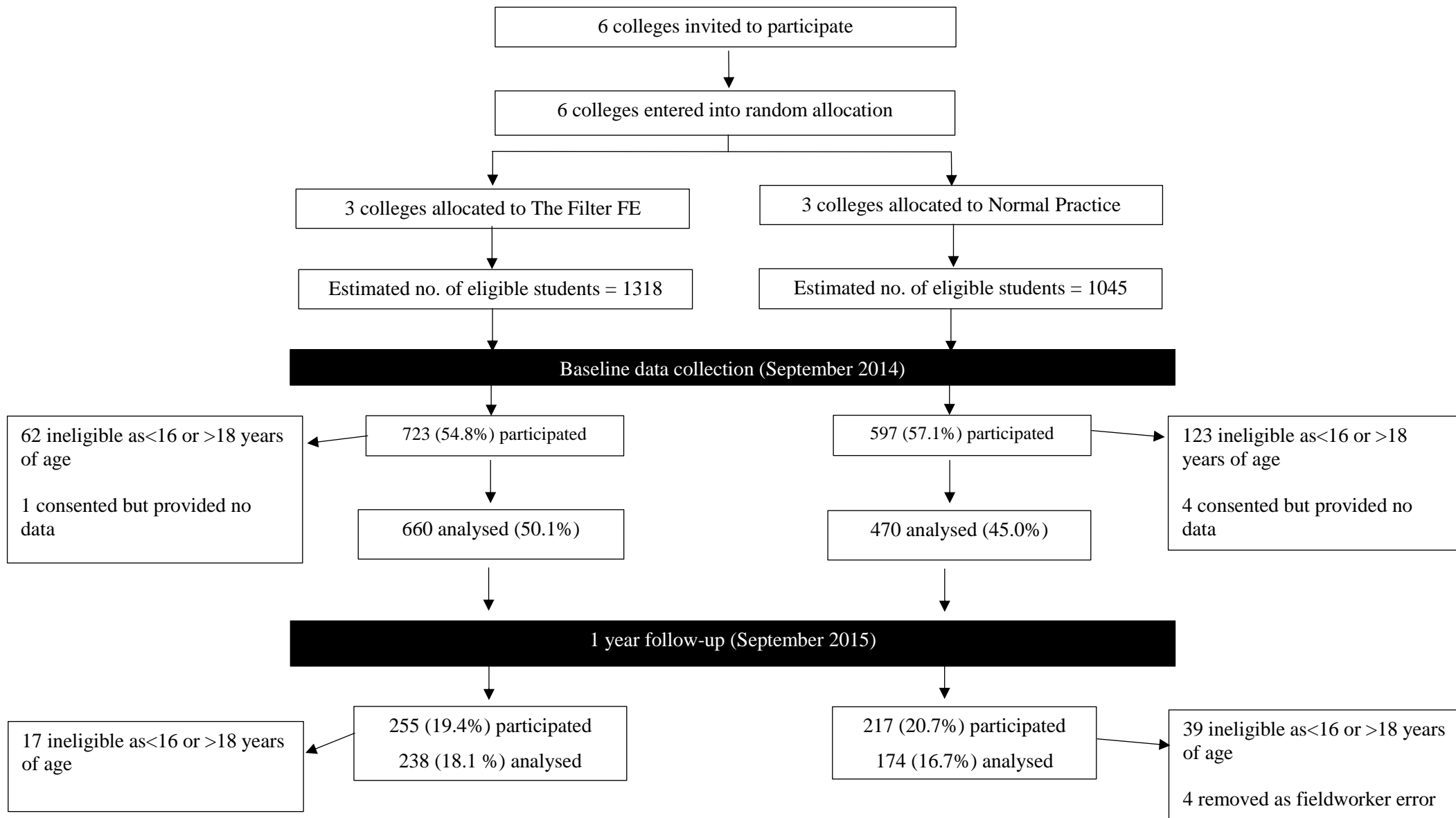


Figure 2: Trial CONSORT diagram

3.1.2 Student characteristics

The categorical baseline characteristics for eligible and non-eligible participants is summarised and compared in **table 5**.

The eligible participants (i.e. those aged 16-18) who completed the baseline survey were predominantly female (62.9%), white British (92.8%), living with an adult in paid work (76.8%), studying full-time (95.3%) and had five or more GCSEs (74%). They were enrolled on a wide range of courses, although the two most common FE pathways reported by participants at baseline were A/AS level courses (34.5%) and BTEC course (32.9%).

The distribution of gender was similar in eligible and non-eligible participants. Ethnic group was evenly distributed across the two groups (eligible and non-eligible participants), with few non-white participants. Non-eligible participants were more likely than eligible participants to study part-time, have a full-time job, be studying for an access level course, but less likely to have five or more GCSEs and study AS/A levels.

The categorical baseline characteristics of eligible participants by trial arm are summarised in **Table 6**. Gender was not evenly distributed across the trial arms: the control group comprised 44.7% males and the intervention group 31.8% males. Participants in the control group were older than intervention group students, with 15.1% of participants at control sites aged 18 compared to just 8.2% at intervention sites. Ethnicity was evenly distributed with very few non-white participants in either arm. Control group participants were more likely to study part-time and live with an adult in paid work, but less likely to have five or more GCSEs, and be studying for AS/A levels than intervention group participants.

Table 5: Summary of categorical baseline demographic characteristics according to sample eligibility

Variable	Baseline data: distribution over categories by eligibility (%)^a	
	Eligible (aged 16-18), n = 1,130	Not eligible (<16 or >18), n = 185
<i>Gender</i>		
Missing	0	0
Male	37.1	38.9
<i>Ethnicity</i>		
Missing	0.1	0
White British	92.8	91.4
White not British	0.9	2.7
Mixed race	3.1	1.1
Asian or Asian British	0.9	1.6
Black or black British	1.2	1.1
Other	1.1	2.2
<i>Is the adult you live with in paid work?</i>		
Missing	2.7	34.5
Yes	76.8	46.0
No	14.2	15.1
Not sure	6.4	4.3
<i>Studying full or part time</i>		
Missing	1.3	2.7

Full-time	95.3	85.4
Part-time	3.5	11.9
<i>Working full or part time</i>		
Missing	1.5	3.2
Full-time	6.7	12.4
Part-time	26.4	27.6
I don't work	65.4	56.8
<i>Do you have five or more GCSEs?</i>		
Missing	0.9	2.2
Yes	74.0	51.9
No	19.0	33.0
Not sure	6.1	13.0
<i>Qualification(s) studying at college</i>		
Missing	1.2	2.7
AS/A level	34.5	8.11
BTEC	32.9	29.7
Access level course	7.4	12.4
GCSE	5.1	7.0
Other vocational award, certificate or diploma	4.1	4.9
Welsh Baccalaureate	0.4	0
Other	5.7	15.1

Apprenticeship	1.4	3.7
Essential skills	2.4	5.4
HNC (Higher National Certificate)	0.2	0.5
HND (Higher National Degree)	0.4	2.3
NVQ (National Vocational Qualification)	4.4	8.2

^a Three participants did not provide their age but provided other data.

Table 6: Summary of categorical baseline demographic characteristics by trial arm

	Baseline data: distribution of categories by trial arm (%)		
Variable	Control, n = 470	Intervention, n = 660	Overall, N = 1,130
<i>Gender</i>			
Missing	0	0	0
Male	44.7	31.8	37.1
<i>Age, in years</i>			
Missing	0	0	0
16	60.4	69.1	65.3
17	24.5	22.7	23.4
18	15.1	8.2	11.0
<i>Ethnicity</i>			
Missing	0.2	0	0.1
White British	91.3	93.9	92.8
White not British	0.4	1.2	0.9
Mixed race	2.6	3.5	3.1
Asian or Asian British	1.5	0.5	0.9
Black or black British	2.6	0.2	1.2
Other	1.5	0.8	1.1
<i>Is the adult you live with in paid work?</i>			
Missing	4.1	1.7	2.7

Yes	68.9	82.4	76.8
No	18.7	10.9	14.2
Not sure	8.3	5.0	6.4
<i>Studying full or part time</i>			
Missing	0.9	1.5	1.3
Full-time	93.4	96.7	95.3
Part-time	5.7	1.8	3.5
<i>Working full or part time</i>			
Missing	1.3	1.7	1.5
Full-time	7.7	6.1	6.7
Part-time	23.8	28.2	26.4
I don't work	67.2	64.1	65.4
<i>Do you have five or more GCSEs?</i>			
Missing	1.1	0.8	0.9
Yes	63.0	81.8	74.0
No	26.4	13.8	19.0
Not sure	9.6	3.6	6.1
<i>Qualification(s) studying at college</i>			
Missing	1.7	0.8	1.2
AS/A level	24.8	41.4	34.5
BTEC	30.4	34.7	32.9

Access level course	7.2	7.6	7.4
GCSE	8.3	2.9	5.1
Other vocational award, certificate or diploma	5.3	3.2	4.1
Welsh Baccalaureate	0.6	0.2	0.4
Other	8.5	3.6	5.7
Apprenticeship	1.5	1.4	1.4
Essential skills	3.8	1.4	2.4
HNC (Higher National Certificate)	0	0.3	0.2
HND (Higher National Degree)	0.2	0.5	0.4
NVQ (National Vocational Qualification)	7.4	2.3	4.4

3.2 Progression criteria assessment

The first objective was to assess whether pre-specified feasibility and acceptability criteria were met to determine whether to progress to a larger, phase III trial to examine effectiveness (RQ 1-6). Section 3.2.1 addresses RQ1-3: 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?; and, was the intervention acceptable to the majority of FE managers, staff, students and the intervention delivery team? The questions regarding the acceptability and feasibility of trial methods (RQ4-6) are then addressed in section 3.2.2.

3.2.1 Intervention feasibility and acceptability

First, each of the five intervention components are considered in turn to understand whether they were delivered as planned (RQ1) and with high fidelity across multiple settings (RQ2). At the end of this section, the question of overall acceptability is addressed briefly (RQ3) prior to presenting participants' views in more detail in section 3.3.

Prevention of the sale of tobacco in local shops

With the aim of restricting the local availability of tobacco at each intervention setting, the Filter FE intervention included a community-level component targeting local retailers. The aim was for the intervention manager to contact all shops selling tobacco within 1 km of the intervention setting (i.e. within a 10 minute walk). This component was intended to be delivered immediately post-randomisation (early October 2014) via letters sent to these retailers to inform them that a new smoking prevention project ("The Filter FE") was taking place at their local FE institution. Posters, stickers and other materials about *The Filter* and ASH Wales were also to be distributed to these shops to provide additional information to them and their customers about the legal age for purchasing tobacco products and the requirements to produce statutory ID to purchase tobacco. Due to the location of the intervention settings in rural and suburban areas, in total there were only five shops within 1 km of all the intervention sites; one rural site had no tobacco retailers within 1 km (Laurelton College).

Results indicate that the criteria for RQ1 and RQ2 were not met for this component at any of the three intervention sites. Despite the low number of retailers, the intervention team checklists were not recorded consistently and intervention team members reported that resources were not sent out to these retailers as planned. Various factors appeared to contribute to this, but the most common factors appeared to be the relatively short time available to identify and work with local community settings as well as poor management of intervention implementation. There was also no evidence of changes in practices from the mystery shopper audit at follow-up in September 2015. In two out of the three shops close to intervention sites that were audited by a mystery shopper at baseline and follow-up, it was possible to buy cigarettes at *follow-up but not at baseline* (i.e. local availability of tobacco to students aged under 18 may have increased; the findings of mystery shopper audit are reported in section 3.5). There was some observational evidence that age restriction signage increased in local shops between baseline and follow-up, although this was consistent across shops in both intervention and control arms.

Policy review to promote a tobacco-free environment

Five policies were audited and recorded at baseline. In one (control) site, Afonwood School, there was no written policy, but if students were caught smoking on site, a letter was sent to their guardian (a copy of the letter was obtained). With the aim of restricting opportunities for smoking and promoting non-smoking as the norm at each intervention setting, it was intended that the intervention manager would develop new whole-campus tobacco-free policies with each intervention setting. This component was intended to be delivered immediately post-randomisation (early October 2014) by the intervention manager who would work with FE managers at each intervention setting to review their institutional policies using the tobacco-free campus guidance developed by ASH Australia.³⁴

Overall, there was little evidence that the intervention delivery team worked with intervention sites to support the introduction or modification of smoking policies. As above, the intervention team checklists were not recorded consistently and intervention team members reported that this intervention component was not implemented as planned, again due to the short run in time and poor management of the intervention implementation. The ASH Australia three-stage tobacco-free campus guidance was not used as intended at any site.

Analysis of institutional policy documents at follow-up found limited evidence of changes made to policies: at one intervention site the smoking policy was amended to include e-cigarettes but both smoking and e-cigarettes were still permitted in designated “smoking areas”; fieldworker notes at one intervention setting recorded that one college had adopted a ‘campus-wide no smoking policy’ between baseline and follow-up but there was no written policy and it was not possible to attribute any changes directly to this intervention component. At the end of the intervention, none of the available school/college policies explicitly addressed issues such as tobacco industry sponsorship, funding and gifts or tobacco advertising and sales on site, which are suggested in the ASH Australia guidance.

FE staff training

It was intended that a minimum of one, two or four staff training sessions would be delivered at the intervention settings, proportionate to institutional size. Staff training was delivered at all intervention sites by experienced training officers employed by ASH Wales on *The Filter* youth project. However, in practice, the number of sessions delivered was driven by demand in each site and only three sessions were delivered in total, one in each site (i.e. lower than intended at the two FE college campuses). All sessions were attended by at least six staff, with a total of 28 staff attending overall, who were observed to be engaged and interested in the topics. At Valeside College, the large FE campus in the intervention arm, attendance was lowest (six people); a second training session had been arranged but was cancelled due to lack of staff interest. ASH Wales staff used their own standard evaluation forms at the end of each staff training. However, these did not collect additional information we required (e.g. staff role, previous training, contact with students etc.) and therefore were not collated or used in the analysis.

The content of the training was agreed between intervention sites and the intervention delivery team as planned, drawing on the different teaching resources developed and piloted by ASH Wales in schools and other youth settings for *The Filter* youth project. All of the FE settings chose the staff training resources developed by ASH Wales on e-cigarettes, and these sessions covered the same topics using the same combination of PowerPoint presentation, group exercises and discussion with high fidelity across all settings.

Social Media

Observations of the college websites provided evidence that links to *The Filter* social marketing campaigns, and their advice and support services (e.g. The Filter text/instant-messaging services), had been publicised on the institutional websites as planned. The intervention team also reported some use of college social media channels to provide more information about *The Filter* services and its smoking prevention messages (e.g. via retweeting on Twitter or sharing on Facebook). However, the intervention team member responsible for social media also reported it was challenging to engage the colleges: they did not have clear systems and structures for using social media, and did not appear to want to publicise smoking prevention messages. None of the three intervention sites embedded information on their home/index webpage, or other frequently-accessed web-pages/micro-sites (e.g. online learning portal, email login page), as intended. Site staff also needed repeated prompting to share information about the intervention on social media.

Youth work activities

It was intended that 5, 10 or 15 groups (depending on institutional size) of 10-20 students would take part in two-hour sessions provided on-site during school/college time. Youth work sessions were delivered in each of the intervention sites, with a total of 15 youth work sessions delivered overall: 10 at the largest college; two at the other college; and three in the school sixth form. A total of 190 students were reached across the three sites. The number of students who participated in each session varied significantly, from four to 40. The number of participants per session was highest in the school sixth form sessions, where 80 students attended in total across the three sessions. Although planned to begin in the autumn term (October – December 2014), all the youth work activities took place in the spring and summer terms 2015.

Sessions were organised and run by facilitators from the intervention delivery team as planned, using *The Filter* youth work resources to educate and persuade students about the harms of smoking and model social/situational resistance skills. Facilitators agreed the content and

length of sessions with staff at each intervention site and there was no evidence young people were consulted at any school/college or involved in the design of activities.

In two of the three observed sessions, students worked in small groups to create smoke free health promotion campaigns, then presented their ideas and voted on them at the end; the other session was a more general workshop which the facilitator said was intended to enable participants to explore how perceptions of smoking have changed over time. Participants did not appear to be engaged in the two sessions where they developed a smoke free message campaign, some students in the other observed session were reported to be engaged by some of the shorter, more interactive activities.

Was the intervention acceptable to the majority of FE managers, staff, students and the intervention delivery team?

In summary, low levels of acceptability were reported by the majority of participants at each pilot setting, meaning criteria for RQ3 were not met. One major barrier to acceptability was the perception among FE staff and students that FE is ‘too late’ for smoking prevention intervention: current smokers reported disengagement and may benefit more from access to cessation services; non-smokers do not want to be ‘bombarded’ with more educational messages about smoking in post-16 settings.

Another key barrier appeared to be the institutional cultures of FE settings, which promotes autonomy and student responsibility which in turn limits the willingness of staff to intervene on issues such as smoking and students’ engagement with such activities. Smoking prevention is not a priority for FE managers and staff, which further limits the acceptability of a multi-component smoking prevention intervention such as this, although they did support external health agencies’ involvement in FE settings. The intervention team also found the proposed smoking prevention activities were significantly less acceptable in college settings than in schools and other youth settings for these reasons (see 3.3.1 below).

Participants’ views are presented in more detail in section 3.3 to explore these sources of unacceptability in more depth, in the wider context of student attitudes towards smoking and institutional culture, and alongside other barriers in implementation.

3.2.2 Trial feasibility and acceptability

This section addresses the progression criteria relating to trial methods and RQs 4-6: Was randomisation 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 we could recruit and retain at least 70% of new students in both arms in a subsequent effectiveness trial?

Interviews identified that randomisation was acceptable to FE managers. Recruitment and baseline surveys took place as planned, with all six FE settings retained at the one-year follow-up. No college manager objected to the use of randomisation to intervention and comparison.

Recruitment and retention of students was challenging, despite the use of the multiple methods and incentives. Student survey response rates in this study did not suggest that it would be feasible to recruit and retain at least 70% of new students to a cluster RCT in FE settings without further methodological work.

The target population of 2,363 enrolled students comprises some ineligible students due to settings having incomplete enrolment data on students over 18, and is therefore the incorrect denominator. In September 2014, 1,320 students out of an estimated total sample of 2,363 participated in the baseline survey. Of these 14.0% (n=185) were ineligible as they were aged under 16 or over 18 and five students provided no data, leaving a baseline sample of 1,130 (47.8%). Although this equates to a response rate of less than 50%, the number of potentially eligible students at baseline (n=2,363) was provided by each institution and *over-estimates* the actual number of new students aged 16-18 in that setting and therefore *underestimates the true response rate*. If data on the number of eligible students were available the correct denominator could be used and the baseline response rate would be higher.

In September 2015, 412 eligible students completed the follow-up survey (36.5% of baseline respondents; 17.4% of all potentially eligible students at baseline), which is significantly below the target response rate of 70%.

3.3 Process evaluation: participants' experiences

Our second objective was to explore participants' experiences of the intervention and pilot trial methods (RQ7-10). We conducted semi-structured observations of staff training sessions and youth work sessions delivered by *The Filter* team, focus groups with students and staff at each intervention site, and interviews with FE managers at intervention and control sites and *The Filter* staff who managed and delivered the intervention to obtain their views on the barriers and facilitators to implementation. This section reports the results of analyses of these data to address RQ7-10. It is divided into four sub-sections: section 3.3.1 reports common student and staff views about smoking and transitions to FE, and how these interrelate, to understand the societal and institutional context in which the Filter FE intervention was being piloted; section 3.3.2 builds on these analyses to report the key barriers to implementation, including the sources of unacceptability, of smoking prevention activities in this context; section 3.3.3 describes participants' experiences of each of the five intervention components separately; and section 3.3.4 reports the acceptability and feasibility of the trial design and research methods.

3.3.1 Attitudes towards smoking in the FE context

During focus groups and interviews, FE students and staff reported their attitudes towards smoking, and the extent to which they perceived the uptake of smoking to be a problem for this age group and/or whether prevention is a priority for FE settings to address. These focus groups therefore provided rich contextual data to understand the environment and systems within which the planned intervention activities were piloted. Through understanding these FE settings, and student and staff norms about smoking, we are able to more fully theorise the sources of unacceptability and other barriers to implementation described in section 3.3.2.

The importance of the principles of freedom, personal responsibility and self-determination in FE settings was a recurring theme emerging across focus groups with both students and staff at all sites. Participants often explained this by contrasting FE settings with more constraining school environments, where staff are considered to be 'stricter'.

Three cross-cutting themes emerged that exemplified this desire for freedom, personal responsibility and self-determination, as well as the power of wider societal norms about smoking, to limit the acceptability and feasibility of smoking prevention activities in the context of FE settings. These cross-cutting themes, described below, are:

- The hegemony of anti-smoking norms;
- The FE transition and liminal identities;
- Smoking as an individual choice in FE.

The hegemony of anti-smoking norms

Anti-smoking attitudes were common among FE students and staff, including college managers. Participants were aware of the health harms of smoking, felt these were universally understood, and agreed with the smoking ban in public places. Reflecting on national trends in smoking rates and attitudes about smoking in public, students realised that smoking was now much less socially acceptable. For example, one student explained:

“Back in the olden days, it’s just everyone used to smoke didn’t they, and they used to think it was normal.” (Athervale School, student focus group)

The minority of students who smoked were typically guarded about their smoking status and felt people made negative judgements about them specifically because they smoked. For example, one student stated:

“I’ve met loads of people that smoke that aren’t as bad as you think they are. [...] People are stereotypical about smokers. Because they think they’re, they’re doing it because they want to look cool and stuff, but it’s nothing to do with that really.” (Laurelton College, student focus group)

Both non-smokers and smokers frequently used words like “dirty”, “smelly”, “stink” and “disgusting” to refer to smoking. One group of non-smoking students at Athervale School said the taste and smell was “disgusting” and “gross”; another non-smoking student from Valeside College said, “I just find it pointless”. A staff member felt that FE students now frequently commented explicitly to each other about the smell, saying that:

“If someone comes in and they’ve been smoking, they’ll pass a comment as well, you know, if it’s other students, they’ll say ‘Oh go away, you stink!’, you know [...] Because there’s less people smoking so it’s more noticeable.”

(Valeside College, staff focus group)

Smokers also reported this process and how they felt judged by some non-smokers at their college:

“I don’t like the, not the snobbiness but the, kind of ‘oh it’s a disgusting, filthy thing’ [...] because it’s an addiction isn’t it? But we don’t force anybody to smoke, we don’t say ‘yeah, oh you should smoke, why not’.” (Valeside College, Student focus group)

Students who smoked occasionally – ‘socially’ – also appeared not to want to identify themselves as “*smokers*” for this reason:

“I don’t know if I’d, like when I fill in forms I don’t know if I consider myself a smoker, because I do when I drink, but I don’t know, about half one [...] My friends always joke and say that I am. Which I guess I am because I do smoke, I suppose, if you do smoke sometimes I guess you are down as being a smoker, so.” (Valeside College, student focus group)

Staff were also aware of the negative connotations of being a ‘smoker’ and described attempting to explain to students on some courses (e.g. health and social care) that this would likely be the case for them in their future workplaces.

The FE transition and liminal identities

Reflecting the power of these social norms about smoking, students also perceived smoking as a behaviour which brings particular responsibilities and requires them to show ‘respect’ for others, particularly children. Through sensitivity to social norms, and in the context of recent bans on smoking in public, the transition into FE enabled some students to demonstrate how

they are responsible adults and thus differentiate themselves from (school) children. For example, one student explained:

“I think everyone just respects the fact that some people don’t smoke and don’t want smoke in their face like, so it’s just that respect. It’s like if I’m walking down the street and there’s a woman and her kid in a pram or something walking by and I’m smoking, I’ll cross the street because I don’t want to blow that in the kid’s face like. It’s just out of respect cos if they don’t smoke then, they shouldn’t have to have second hand smoke.” (Valeside College, student focus group)

While many of the students who identified as smokers (not social smokers) stated they began smoking at a relatively young age, they still emphasised consideration for the welfare of non-smokers, particularly children, and supported bans on smoking in public. This suggests that during transition to FE, attitudes and actions relating to smoking helped to signify students’ co-occurring transition to adulthood and self-determination. This was also demonstrated in several participants’ indications that they would not buy tobacco for younger students, but may sell on to those in year 10 or 11 (age 14-16) – *“if I know them but not people in like year seven and eight [age 11-13] and that”* – reflecting their own experience of commencing smoking in year 10 or 11.

The liminal status resulting from transition was further apparent in the characterisation of children and younger students as *others*. For example, when discussing e-cigarettes, students cited concern over the potential for e-cigarettes to act as a gateway to using tobacco, particularly for children. As one student put it:

“Someone will use e-cigarettes as a start off before actually smoking properly, especially younger children tend to have them and then move on to the actual cigarettes.” (Valeside College, student focus group)

As well as acknowledging their responsibilities to protect younger people, students saw themselves as potential role models to children, typically differentiating themselves from children who have little autonomy and require protection from the effects of smoking.

Staff discussions of student smoking behaviour reflected this perception of students in transition and illustrated a sense of responsibility to help students negotiate this while respecting their personal decision-making and nurturing their autonomy. As one staff member explained:

“It’s their choice to smoke. Now, either we can give them the messages about not smoking, but you know, we’re not, we don’t preach to them about not smoking, our main message to them is if you’re going to smoke, from my point of view, it’s making sure that they do it in the correct way, smoking the correct things, not illegal substances, and they’re in the right places. As long as they’re doing that, we, we’re off their back really.” (Laurelton College, staff focus group).

Both students and staff also discussed smoking as something young people can do to rebel, to assert their autonomy, especially in the face of opposition from authority figures. One student who smoked articulated this as:

“It’s the trying to push people to stop that tends to make them think, no, balls to you.” (Valeside College, student focus group)

This resistance was expected to further limit how receptive students may be to advice and education in this context. As one staff member described:

“I think it’s just, they’ve hit that particular age and, and as I said, the adult in them is trying to come out and they do not, they’re not receptive.” (Laurelton College, staff focus group)

Recognition of the liminal nature of their current status meant that students were also anticipating impending transitions, for example starting higher education or entering work, which affected their views about their future patterns of smoking. When asked, most non-smokers did not think they would start to smoke in the future and most current smokers did not

believe they would continue smoking into their twenties, suggesting associations between smoking and perceived life stage.

Smoking as individual choice in FE

A recurrent theme was that smoking and quitting are *choices* that individuals make. As one student explained, smoking is “*their choice*”, with staff also reflecting this dominant view of autonomy and personal responsibility as embedded in FE. A staff member at Laurelton College explained:

“As long as people are informed of what they’re doing. You know, they’ve got the information. That’s their choice.” (Laurelton College, staff focus group)

This meant that, in recognition of wider societal anti-smoking norms, students typically talked in terms of deciding to smoke as a ‘bad’ *choice*, or not to smoke as a ‘good’ *choice*. For example, one student described with admiration how a friend chose not to smoke even when other friends did:

“He turned round and said he didn’t like it at all. He just didn’t do it. And walked away from them. It’s a good choice isn’t it?” (Valeside College, student focus group)

Consistent with their belief that smoking is a choice, students and staff framed discussions about perceptions and behaviours relating to smoking in the context of rationally weighing up information on risk and deciding whether this information was perceived as reliable and trustworthy. Students (and staff) frequently described what influences their smoking behaviour, including financial considerations, peer and family behaviour.

Reflecting the enhanced autonomy of the life-stage, staff also believed that increased financial independence was significant in student decisions to spend money on smoking if they wanted to:

“There’s an economic factor as well, because if you’re a student who’s suddenly getting your own EMA [Education Maintenance Allowance] and getting thirty quid a week, all of a sudden you can afford to go and buy that packet of cigarettes. It might last you two weeks, it might last you a day, but you’ve actually got the money and the buying power, whereas you might not have had that when you were 15.” (Laurelton College, staff focus group)

This further contributed to the sense that smoking was an individual choice in FE, where decisions to smoke are made through a rational, consumer framework of weighing information about costs, personal preferences and risks to their health and image.

Some students and staff did recognise wider influences beyond the individual’s knowledge and attitudes, particularly peer pressure and the home environment. However, these “*social things*” were seen as influences occurring earlier in the life course:

“[Smoking] it’s a social thing and I don’t know many people who smoke so, I think that’s, I, my parents smoke, my mum and my dad, but I think it’s just, I don’t know, my mates don’t smoke so, I’ve never really got that urge to social smoke with my mates so. I think it’s just who you’ve associated yourself with really.” (Valeside College, student focus group)

Of all the students who smoked, only two perceived they had been bullied into smoking by their peers, contrasting with the presentation of smoking as a personal decision. However, both students explained that this had happened when they were “*younger*”, in secondary school, where other students “*forced*” them to smoke. One explained:

“Truthfully I got bullied into it when I was younger. When I was like 11. I think it was 11 like. Smoking was, you just think you’re cool as well don’t you, in front of your mates and stuff, but no, not really. I don’t like doing it.” (Laurelton College, student focus group)

Students refuted the suggestion they were still subject to such peer pressure in FE and typically perceived they could now resist peer influences. In keeping with the perception of smoking as

a personal choice, students and staff were also firmly convinced that cessation is primarily a matter of self-control. As one student who smoked explained:

“If you want to give up you need will, you need willpower. And I just haven’t got any. At all.” (Valeside College, student focus group).

This viewpoint was also shared by non-smokers:

“Chances are though a lot of people who smoke they have no intention of quitting so you can’t really help them, if they don’t want to help themselves.” (Athervale, student focus group).

Finally, although “stress” was recognised as contributing to smoking and as limiting chances of cessation, students and staff didn’t consider FE environments to be particularly stressful.

Summary

This section has described the key themes arising from the discussions with FE students and staff regarding smoking in the context of transition into FE settings. These analyses illuminate the importance of self-determination for young people at this stage in the life course, particularly in how this manifests and is rehearsed by FE students, and is accommodated in institutional processes during this transitional period. With these themes in mind, the next section describes the barriers to acceptability and implementation of The Filter FE intervention.

3.3.2 Barriers to acceptability and implementation

As described above (3.2.1), the intervention was not implemented as planned. This section describes the key barriers to implementation in two categories; first, the intervention message and aims; second, wider challenges associated implementing interventions in FE settings.

Intervention message and aims

Key challenges in implementation were rooted in low levels of acceptability of a smoking prevention intervention in FE settings which, as described above, are settings that emphasise personal responsibility, autonomy and individual choice. This institutional culture limits the potential and willingness to implement The Filter FE intervention as planned, as well as limiting students' engagement with the activities that occurred.

Smoking was not a priority issue for staff or the students they worked with. Overall, low levels of acceptability were reported by the majority of students and staff at all sites, including a perception that FE is 'too late' for smoking prevention intervention. It was suggested that current smokers would disengage and may benefit more from access to cessation services, while non-smokers do not want to be 'bombarded' with more educational messages about smoking.

These factors led the intervention team to identify that proposed smoking prevention activities were significantly less acceptable to students in FE settings than schools and other youth settings. Intervention staff also perceived that smoking was not seen as an issue, by staff or students, in FE colleges when compared to schools, potentially relating to differential exposure. One member of *The Filter* team suggested that:

"I think schools do buy into it more because you are there from nine to three, aren't you ... so if you're smoking, it's very present on a school campus. If you're in and out for FE, you can come and go as you choose, can't you? Sixth form, you've got that freedom ... so actually, even if you're a smoker, the FE tutors might not see smoking on campus to be a massive issue because most people might be going down the local café ... park, whatever, to have a fag ... where it's much more present ... even if it's round the shed or whatever ... do you know what I mean? ... It's easier to hide in an FE setting." [ID team member 6]

Data also illustrated staff receptivity to input from an outside agency, particularly on e-cigarettes where they felt they had little knowledge. All students (both smokers and non-smokers) reported having sufficient information about smoking tobacco and its effects on health, leading to some reluctance to engage in further repeated and unnecessary discussion. In

contrast, many staff and students were uncertain how to evaluate e-cigarettes health risks, with discussions about e-cigarettes further illustrating the frames they felt they and others used to make decisions about smoking. For example:

“There’ve been no long term studies [of e-cigarettes]. Nobody knows, you know, and you’re back into a situation of where we were 50 years ago when people thought smoking was fine, you know, and really healthy for you. But, are we going to say in 10 years down the road, oh my gosh, look what e-cigarettes have done to our kids growing up, they shouldn’t have had them for whatever reason.” (Athervale School, staff focus group)

Nevertheless, there were positive aspects of the intervention, including FE managers and staff welcoming the flexibility (e.g. they could choose the topic of the staff training). As one FE manager explained:

“I’m always looking to work, you know with external people and whatever they can bring in to us training wise, we’ll always welcome that.” (Laurelton College FE manager)

It was evident from interviews and focus groups with staff at FE colleges that they, like school staff, have a strong sense of a duty of care, albeit this could manifest in different ways (see section on site policy). As one FE manager explained:

“Post-16 [FE students] get glossed over sometimes on support work, you know, from outside agencies um, and, you know, they’re people and students who you can have a big impact on.” (Athervale School, FE manager)

Implementing interventions in FE settings

While the opportunity to work with outside agencies to deliver an intervention was welcomed (see above), there were several cross-cutting challenges to implementing a complex multi-component intervention which are specific to a FE context. These centre on management and communication systems, intervention timing, timetabling and the nature of courses in FE.

In terms of management and communication, it was difficult for the implementation team to identify who to contact in each institution, with one FE manager commenting that “*every organisation is structured differently*” (Middlesdale College FE manager). This meant that, unlike schools where it might be possible to directly approach the PSHE coordinator, the team found it difficult to identify who to contact as “*they’ve all got different tiers*” (ID Team member 3). However, one intervention team member went on to say that it was easier to identify who is in charge of social media in FE colleges than in schools, due to the presence of dedicated IT staff:

“I think colleges have specific people, whereas [school] sixth forms don’t have like a digital media officer, they have a member of staff who likes tweeting so they kind of tend to put them on it. Whereas in the colleges, they’ll have like one or two people who do the website and the social media, so they’re employed people to do it.” (ID Team member 3)

The intervention delivery team members who required direct contact with students and staff (for youth work and staff training) also struggled to organise convenient times for delivery of sessions as sites required a long lead time to plan such sessions into their timetable. This was compounded by weaknesses in intervention management. For example, a lack of planning and organisation were observed. The intervention manager also had limited experience of working in FE settings and experienced high staff turnover in his own team during this pilot study.

In terms of the youth work sessions, one FE manager explained that, although it might seem an appropriate activity for tutorial time, the “*pressure on our tutors and the timetabling is, is really quite immense now*” (Valeside College FE manager), meaning that existing pastoral sessions with tutors are already struggling to accommodate all requirements. They went on to explain:

“There’s now only going to be group tutorials, there’s going to be only five of those a year, and one of those sessions will be health and wellbeing, that would include smoking, but it also includes things like mental health and other things like that.” (Valeside College FE manager)

Moreover, the nature of courses and timing of exams means that the academic year is quite truncated so the opportunities for intervention are shorter than might be expected. As the Athervale School FE manager explained, there is only a window of opportunity to intervene between “*September to the Easter time, so it’s actually quite a short period of time to do work with students. It’s only 16 weeks.*” They went on to describe their frustration at the organisation of sessions, explaining that with the pressures on students’ timetables, activities needed to be planned at least a term before the start of the intervention.

As a result of the difficulty FE managers experienced in releasing staff and students, intervention team members were sometimes presented with smaller groups than they had anticipated, prompting changes to the delivery style of the session. Lack of prior information on group composition also meant they were also unable to anticipate the appropriate level to pitch the youth work sessions, as one intervention delivery team member described:

“I don’t think the students are a problem, like. But it’s also then tailoring to the right level, because you have, some college students are in college ‘cos they can’t do A levels, but it’s us knowing beforehand what kind of level we’re targeting the work at as well.” (ID team member 3)

Implementation was also problematic in colleges due to the diverse courses offered, with some students absent from campus for extended periods of the academic year when on work placement, or attending college only on day release from their workplace. As one FE manager described:

“Most of our courses will have some kind of placement element to them, so the target that the research was on, we might have, if you got 150 students in that campus, there are probably only 80 students on the campus on that given day.” (Laurelton College FE manager)

Time pressures and competing priorities made it similarly difficult for intervention staff and FE managers to arrange the staff training. Indeed, time restrictions appeared to be a factor in choosing the sessions; staff were interested in e-cigarettes but it was also one of the shorter

training sessions on offer. One of the intervention delivery team members explained the challenges in setting up the staff training:

“It’s been quite hard getting the colleges to organise the sessions [...] we did quite detailed attachments in an email about the different programmes they [FE managers] can pick from, we made it very clear that we can be very flexible on times and how many people we have. Um, and we found, I probably found that part hard, just because the contact was quite sporadic and actually it was, there were issues with the, probably all three colleges, there were issues with getting them to actually, get, take it, take the training up, which we were surprised at because we thought, well, they’d agreed to it and, it’s something for free, for them.” (ID team member 1)

The FE managers also reported time pressures as impacting participation. As one FE manager said: *“it was physically impossible you know, to get all of those staff in there from 9.00 until 5.00”* (Laurelton College FE manager). Another explained they were keen to be involved but that they were incredibly time-poor:

“I think generally students and staff want to be involved, and want to have a go at doing things, it’s just a question of their, their time is split in so many different ways, and their priority and focus has to be on teaching, so if they’re missing another lesson from another subject, they become more hesitant, reticent, to do that, yeah? (Athervale School FE manager)

FE managers suggested potential options for accommodating staff training, for example using inset days, but, as these are planned up to a year in advance, there were some doubts that smoking would be seen as a priority for such events.

Summary

A key challenge to student and staff engagement was a perception that the messages and aim of the intervention were occurring ‘too late’ to address smoking behaviour. This, combined with institutional cultures of FE settings which promote autonomy and student responsibility, meant

the willingness of staff to intervene on issues such as smoking, as well as students' engagement with such activities was further limited. While staff welcomed work with external agencies and perceived a need for interventions targeting FE students, there are significant challenges to implementing interventions in FE settings relating to the heterogeneity of these institutions, the diverse courses and timetables being delivered, and the short windows of opportunity available for intervention.

3.3.3 Implementation of intervention components and contextual variation

As well as considering the acceptability and feasibility of each intervention component, analysis of qualitative data led us to question the *relevance* of the components of the intervention. This primarily related to whether the approach (smoking prevention) was perceived as pertinent in this setting and amongst this population, and whether the five intervention components were all needed. This section discusses the perceived relevance of each intervention component in turn, then describes participants' views about the impact, reach and awareness of the intervention overall. No significant unexpected consequences of the intervention were reported or observed.

Prevention of the sale of tobacco to FE students aged under 18

Shops near to the intervention sites were generally understood by students, staff and FE managers to be strict about sales practices at baseline (i.e. limited potential for this component to trigger changes). However, students had no trouble obtaining tobacco, which suggests that the focus of this component on preventing the supply of tobacco from shops near FE settings was misdirected. Some students did report purchasing from shops on the way to or from school/college but most commonly they would obtain tobacco from friends old enough to legitimately purchase it and/or from family members (particularly parents). One student described their dad buying cigarettes for them because;

“My dad says he'd rather me smoke in front of him than behind his back so that he knows what I'm smoking.” (Laurelton College, student focus group)

Students also reported sharing and selling tobacco products amongst themselves, with one stating that:

“If one of us haven’t got fags, like our, like our friends are like that, come on, you can have one, sort of thing like. So no-one goes without.” (Valeside College, student focus group)

This notion of reciprocity relates to the main reasons cited by students and staff for students smoking: it is a source of identity and social bonding. Most students who smoked said they had been asked to either buy tobacco for younger students or to sell some to them. However, as noted above (section 3.3.1), students developed their own ethical framework for judging whether or not to do this. Where students did go into shops to purchase cigarettes, they indicated they were not deterred now that products are not visible to choose, with one student saying:

“We know all the prices off by heart.” (Athervale, student focus group).

Staff were also aware of alternative access routes to tobacco, with one commenting: *“there’s always loopholes – they can always get it if they want it.”* (Valeside College, staff focus group), with staff most frequently perceiving that student access to tobacco was through their social networks rather than directly from shops. As one staff member said;

“Very, very few students actually go and buy cigarettes or tobacco. It’s, it’s, somebody’s been on holiday or somebody’s selling stuff you know, that grey market...” (Laurelton College, staff focus group)

Indeed, staff and students were aware of various illicit supply modes employed by students, with some suggestion that students were uninterested in the ethics of buying potentially counterfeit products due to more sensitivity to price. For example:

“They don’t care. Because again, it’s this thing, of the relevance to the young people. If they go to a shop and spend, I don’t know, £10, £15 whatever a pouch of tobacco is, but they can go and buy it off him down the road for £5, £6, well

which one are they going to do? They're going for the £5, £6 one." (Laurelton College, staff focus group)

Staff in this focus group were not inclined to report students for using fake products, but might mention to students the potential dangers of using non-regulated products. Similarly, in the school sixth form (but neither of the intervention colleges) staff and students were aware of students selling single cigarettes to others for 50p per cigarette. Staff described this awareness as:

"You overhear things 'do you know who's selling roll ups' or 'so and so's selling'." (Athervale School, staff focus group).

However, this practice was unchallenged because; *"you'd have all the abuse and everything else and then when it went further, nothing would get done"*. This was supported by a colleague, who added that it could also *"impact into your lessons as well if you teach them"*. They rationalised this approach by saying they would only act if they *"actually physically see it"* and:

"You're not allowed to search a child's bag or anything, so it creates a huge commotion doesn't it, if you, it has to involve everybody, it goes like right up the chain. [...] but when you think, you know, it's trivial really isn't it at the end of the day? A cigarette. You know, for all the commotion. I know it isn't, but it is, in a day, if you know what I mean." (Athervale, Staff focus group)

Students were aware that staff were unlikely to try to intervene where sixth form students were selling to younger students, with one stating that it *"would be quite hard to stop"* this trade. This was further discussed:

Student 1: "They have no proof that you did do it anyway, so they can't do anything about it.

Student 2: Unless they're with the cameras, but they can't.

Interviewer: So it's quite hard to stop that kind of like, people passing tobacco

Student 2: No, because if there was more cameras, people would just leave anyway, and they'll just like go somewhere else where there's a blind spot, they will." (Athervale, student focus group)

Policy review to promote a tobacco-free environment

All intervention sites had a policy on smoking before the intervention commenced, reflecting wider societal anti-smoking norms and systemic requirements. Of all the five Filter FE intervention components, the issue of institutional policy on smoking generated most discussion amongst staff and students in focus groups. Below, we first discuss FE managers' perceptions of the relevance of this intervention component and its poor implementation due to weaknesses in intervention management and delivery. Second, we go on to discuss staff and students' responses to institutional policies on smoking, including perceptions of acceptability, as well as strengths and weaknesses of current policies.

There was low awareness of the planned policy review activities but acknowledgement that other intervention activities had influenced institutional policy processes. For example, one FE manager indicated that staff training on e-cigarettes "*led that into the cognisance, oh we need to think about this*", in terms of how to incorporate them in to site policy. The same FE manager also noted that;

"One of the researchers said about no smoking signs not being in schools, and actually it wasn't something that we'd thought about. I can't say that we've had any direct outcome, but it's something that we've [the senior management team] got up for discussion again, and to have a look at." (Athervale School FE manager)

This same manager said it "*definitely*" would have been useful to have feedback about their policy and "*the right way to do it*". Another intervention site manager said they had emailed their policy to the intervention delivery team and described the background to their desire to carry out a review, saying:

“There was consultation done by senior management in this college about five years ago and they wanted to ban smoking on campus altogether, but there was huge backlash to that, so then they obviously introduced designated smoking areas, which has never kind of settled, there is always people for smoking shelters and there are people against, but that’s why I thought to get an external body in, it would be interesting to get view and some extra training on that as well. [...] We haven’t changed the policy, um, we didn’t really come back with anything there from ASH.” (Laurelton College FE manager)

Similarly, a manager at one of the control sites indicated their hope that, if they were part of the intervention, they would have received support on developing a smoking policy:

“We don’t have a smoking policy, that was one of the things that I was hoping, if we did have the intervention, that we might have had a bit of, you know, a bit of input with that, that’s one of the things I was hoping, and that’s why, you know, one of the other reasons why I thought it might be useful to, to get involved.” (Middledale College FE manager)

Knowledge of institutional policies was good among staff and students. The intervention sixth form was part of a school which had a site no smoking policy and, in both the intervention colleges, there were already established policies permitting smoking only in designated smoking areas on campus. Both control colleges had the same rule, although it was only formulated as written policy in one college. In all intervention sites, policies treated e-cigarettes in the same way as tobacco. One control college did not have any institutional rules about e-cigarettes and the other had recently added e-cigarettes to the smoking policy requiring students to vape in designated smoking areas after recognising the issue around the campus. (However, the FE manager indicated this change was unrelated to their participation in the Filter project.) There was evidence that, despite being considered the same as tobacco in policies, the products are considered differently by students who may perceive that it is acceptable to use them indoors as an alternative to smoking outside. As one school staff member said:

“I have caught a few. Like if I go in someone’s classroom, like lunchtimes and stuff, like ‘what are you doing?’ ‘Oh, sorry miss’. So they do try and use them, saves them going outside.” (Athervale, staff focus group).

The college policies of smoking only in designated areas were generally well-accepted amongst staff and students, and attitudes to areas demonstrated the ubiquity of anti-smoking norms (see section 3.3.1), with some students commenting on the unsightliness and smelliness of the shelters. On the whole, college staff perceived that having a designated area was a pragmatic solution because, whether there was provision for them to smoke or not, *“they’d find somewhere. So either it’s controlled to an extent”* (Laurelton College, staff focus group). While staff and students perceived that people mostly adhered to the smoking policy, they also noted that many students smoked just outside of the campus boundaries. One student described how: *“they’ll be like outside the gates, which is quite annoying when you’re walking past and that’s what you can smell.”* (Valeside College, student focus group). A staff member at another college described how:

“You see the buses arriving in the morning, and they don’t walk to the smoking shelter, they’re lighting up as they’re getting off the bus and smoking, walking towards the smoking [shelter], even though they’re not supposed to do it.”
(Laurelton College, staff focus group)

In contrast to the general adherence to, and acceptance of, smoking in designated areas in the colleges, the sixth form policy of prohibiting smoking on site was not well accepted by students. As one student explained, the prohibition of smoking for sixth formers left students who wish to smoke in a difficult position; *“we’re not allowed out of school but then we’re not allowed to smoke in school, so where are we supposed to go?”* (Athervale, student focus group). Students perceived that the school policy did not correspond with their desire for autonomy (see section 3.3.1) and liked the idea of designated smoking areas, saying that; *“Like up the college they’ve got a bus stop which is a smoking area [...] That’s the thing I like about college”* (Athervale student focus group). Staff at the colleges were aware of this and recounted how school students were attracted to college because of the more liberal approach, with the smoking policy being a manifestation of this increased autonomy.

“We used to take school groups around, they’d come for a visit to the college, and, so we’d show them round outside, and that used to be one of the first questions a schoolchild would ask, are you allowed to smoke in college? [laughter] [...] because it’s, we don’t have uniform, they, it was a freer environment” (Valeside College, staff focus group)

School sixth form students who wished to smoke did so wherever they could without getting caught. One non-smoking student smoke said students smoke *“wherever there’s no cameras”* with another qualifying, *“or teachers”* (Athervale, student focus group). It was widely known among school sixth form students that staff have *“like a rota like, certain like, you certain time like an hour where different teachers will go outside and like chase up the smokers.”* (Athervale, student focus group). School sixth form students explained how staff pursue them up the rugby field to move them away from school buildings. When staff were not on duty, students smoked wherever they liked, as one student described, *“if they’re not on duty, we’ll just sit on the steps”* (Athervale, student focus group). The school staff described their response to finding sixth form students smoking and their discomfort in addressing it, saying that:

“You’re not going to stop them, so I think it’s better that they’re in sort of one area, it’s not really a designated, because we don’t have smoking, but, technically we do. And I think we have to acknowledge that we do, and, you know, it, it’s just, a consistent problem and it’s these hardened smokers really, isn’t it?” (Athervale, staff focus group)

Staff and students recognised that informal smoking areas exist on the school campus, despite an established system of sanctions for smoking (letters sent home to parents, followed by exclusion). However, students and staff all said they did not know anyone who had been excluded from school for smoking, *“even though it’s school policy”* (Athervale, staff focus group). Staff and students at the school sixth form stated that the legal status of sixth form students was different to that of younger students, meaning they were sanctioned differently. One (non-smoking) student explained; *“The people in our year and the year above though, the teachers are more laid back about it because, we’re old enough”*, with their fellow student adding; *“And we don’t legally have to be here either, so, that’s why they’re not so concerned*

about us.” (Athervale, student focus group). This differed among some students who smoked, who suggested they are concerned about being caught smoking because, unlike younger students for whom school is compulsory; *“They could just kick us out for good, so I think the younger years are not that like worried, but us, yeah”* (Athervale, student focus group).

In contrast, college students were unaware of the sanctions that might be applied if they were caught smoking outside of the designated areas. While the FE manager at one control site indicated that: *“there is staff on monitor because our students are quite sneaky [laughs] they will smoke in inappropriate areas”* (Glynbel College FE manager), staff at the intervention colleges reported fewer problems with enforcing the designated smoking area policy. Staff at one college explained that the introduction of this policy had made a big difference:

“I think we used to have a bigger problem last year, where they were smoking just about everywhere, and you know, it was part of our job to tell them, not here, but yeah, we don’t see them smoking in the wrong places so much these days, not in my experience anyway.” (Laurelton College, staff focus group)

At all intervention sites there were a few staff who smoked and it was evident from observations and focus groups that, at college, staff used the designated smoking areas although some reported smoking in their cars to avoid using the shelters because they felt that *“they don’t want to be mingling with students when they’re having a quiet cigarette. They don’t want to socially mix with them.”* (Laurelton College, staff focus group). Similarly, school sixth form students were aware that staff who smoked went off campus in their cars to smoke even though this was forbidden for students. One FE manager suggested that it was not appropriate for staff to use designated smoking areas because:

“Teachers should be like role models I think. You know and be helping to advocate stop smoking and things like that, but yet they are out there with the students.” (Glynbel College FE manager).

Reflecting their sensitivity to the denormalisation of smoking (see section 3.3.1), staff and students were aware that smoking outside campus could detrimentally impact the institution’s reputation. One staff member from the small college indicated that students

smoking just off-premises “*would look quite bad for the college*” and that this had influenced a recent decision not to move to a no smoking campus (Laurelton College, staff focus group), instead maintaining designated shelters on campus where smoking was less visible to the wider community. As one school student explained, concern to keep student smoking out of the public gaze (students were aware that the school declares itself to be a no smoking school) puts staff in a difficult position when enforcing the no smoking policy:

“They try and like get you off the school grounds, [but] they don’t like people smoking at the shop because it still looks bad like a bunch of school girls like smoking at the top.” (Athervale, student focus group)

Staff invoked their professional duty of care to students when discussing the pros and cons of their institution’s smoking policy. For example, staff discussed how the college had considered implementing a no-smoking policy across all campuses but did not because “*they thought the students would then go onto the main road*” (Laurelton College, staff focus group) which would not be safe. Similarly, school sixth form staff justified their attempts to contain sixth form students’ smoking in informal smoking areas, saying:

“We have to usher them [students], sort of, to a certain area, but we can’t send them off the premises, because obviously they’re under our care aren’t they? So it becomes a bit of a problem.” (Athervale, staff focus group).

Few staff or students expressed opposition to designated smoking areas, which seemed to help limit smoking on college campuses by reinforcing the denormalisation of smoking. However, the location of the designated smoking area was important in terms of whether it was used, by whom, and how acceptable it was perceived to be by smokers and non-smokers alike. For example, the FE manager at one of the control colleges described how the smoking shelter was near the campus crèche and that parents were concerned about this (Glynbel College FE manager). Moreover, some staff and students felt they may generate unintended consequences by providing new social spaces and areas where smoking is normalised. For example, some students who did not smoke indicated they sometimes go to the smoking shelter to be with their friends and were equivocal about whether this led to them smoking. However, students who smoked suggested that it might encourage non-smokers, saying:

“They’re taking in second-hand smoke aren’t they? So they’re also getting some sort of nicotine in their system, at the same time.” (Laurelton College, student focus group).

Similarly, staff felt that forcing students to use the smoking shelters may normalise smoking and lead them to increase consumption. As one staff member described:

“What I’ve noticed is, for example, the students before they came to college were having probably one or two fags a day, because they’re mixing with smokers who probably go more regularly, they start picking up the more regular group, so, because it’s like, they go to smoking shelters more often. When they’re in the smoking shelters, oh do you know what, I can smell your cigarette, give me a cigarette please. So, it, they probably, start smoking more.” (Laurelton College, staff focus group)

Staff indicated that the social aspect of designated smoking areas could be problematic for students in other ways, through forcing groups of students together who might not otherwise mix. As one explained:

“The less confident students and they’re being put into a mixed, especially the middle shelter there, there could be 50, 60 students there. And they’re starting to feel anxious about going to the smoking shelter, so what happens then is they stand off themselves in a small little place, or their own little huddle, and then they’re having, you know, the tellings off, the causes for concern, for not using the smoking shelter, but they get more anxious about using the smoking shelter as well.” (Laurelton College, staff focus group)

Indeed, some students indicated avoidance of smoking in the designated areas because they did not want to associate with the groups there, moving to locations just off campus instead. As one group of students described, they smoke in the park because *“it’s the closest”* for them, and even though there is a shelter nearby, *“it’s always full of like... [...] irritating people”*, who are *“childish”* (Valeside College, student focus group).

Staff training

The premise of staff training was to support staff in talking to students about smoking. The content of each session was determined by staff interest and focused on e-cigarettes as this was deemed a priority for staff at each intervention setting. There was no specific training on illegal sales of tobacco although this did come up in discussion. Interviews with FE managers suggest that the aim was not clearly understood, as one manager indicated:

“What’s the aim of the staff training then? So they get trained on, yesterday it was the e-cigs. Is it for them then to go out to students and talk to them and deliver something on that as well then, or?” (Valeside College FE manager)

The same intervention team member delivered all staff sessions, with content broadly the same in each session, although with adaptations according to the numbers in each group (most of the staff training sessions were smaller than the facilitator had anticipated).

Staff who were trained found the sessions very informative and the training acceptable. They particularly enjoyed learning in an interactive way on an issue about which they felt they had a knowledge gap. As one FE manager summarised:

“The training session was really, really useful, and thoroughly of value and, you know, the heads of year still talked about that, and what they’ve learnt from, particularly about e-cigarettes [...] they were thoroughly, enjoyed the way that it was delivered. You know and it was very interactive and hands on, and example, a lot of up to date, factual knowledge, um, and it was also done in a way, you know, that they could test their own knowledge.” (Athervale FE manager)

However, despite being well-received, attendance at the sessions was low, with all sites experiencing difficulties in releasing staff (especially teaching staff) for training. Staff who attended the training were often those in support roles, as they had more flexible timetables

than those with direct teaching or supervisory roles. As the manager at the smaller college noted;

“I think we had about ten in there in the end, about nine or ten, which is a good group and I mean the training was good, don’t get me wrong, but we did struggle to be able to release those ten staff.” (Laurelton College FE manager)

The trainer noted that this is a common issue; *“It’s not just the FE, it’s generally when we do training. It can be a problem get, releasing staff to come along to training.”* (ID Team member 1), further remarking that, in some sites, she was allocated only a one and a half hour slot for the training when the session would ideally be two hours long.

While the training was well-received and perceived as increasing knowledge, it is unclear whether staff expected it to facilitate talking to students about smoking. As one staff member said;

“The training is definitely useful, you know, but it’s more for us about kind of signposting to the professional people, but we do need some knowledge on it.” (Laurelton College, staff focus group).

The FE manager at the same college explained anticipating that staff would use the training *“if a student came in with a particular query on an e-cigarette or a concern, we use that knowledge then”* (Laurelton College FE manager). However, it was clear that while they found it interesting, staff felt there were still a lot of unknown issues around e-cigarettes:

“I’ve got to be honest, I thought the e-cig was, in some ways interesting, to know a little bit more about it, but the message was quite vague because we don’t know enough about it.” (Laurelton College, staff focus group).

Similarly, in discussions about illegal sales of tobacco, staff felt it was not their place to question students about it, saying; *“I don’t think it’s our, our place for us to question”*, with another explaining that:

“If you see a student who’s got illegal tobacco which you would deem to be safe, I’d think, oh fair play, you’re students, you’re getting it cheaper. The same as you wearing a fake t-shirt and carrying a fake handbag. You know, what would you do? Do you report them to the police? I wouldn’t.” (Laurelton College, staff focus group)

Students also questioned the appropriateness of staff talking to them about smoking, reflecting the prevailing culture in FE of fostering self-determination and autonomy (see 3.2.1, above).

Students indicated that it might seem patronising or invasive:

“They’re all, like, they’re older aren’t they, and like most of the people here are over 18 so, like it’s just telling a grown up not to do something. It’s a bit weird isn’t it?” (Valeside College, student focus group).

“I don’t see the point, you know, because if you smoke then they know you smoke already, and then they’re going to come in try and start lecturing you on smoking, and they already know you smoke, then you’re going to get wound up and argue back and that.” (Laurelton College, student focus group)

Staff reported that, as well as reminding students to smoke in designated areas (in sites which have such policies), they tend to talk opportunistically to students about smoking but are wary of 'preaching' to them about smoking and encouraging them to quit. They suggested such messages may be more effective coming from another young person (youth worker or another student). As one staff member suggested:

“They’re used to us just like telling ‘em what to do, you know, reinforcing different things, I mean if it comes from somebody else, it’d be a bit more strong, I suppose. There’s only so much information they can take from a tutor, I suppose...” (Valeside College, staff focus group)

Another staff member explained how staff are concerned to develop and retain trust with students, with concerns that talking about smoking might threaten this, and suggesting that staff perceive smoking as a less serious risk to students than other issues that may present:

“When we’re dealing with students and it’s confidentiality, because that’s a big thing with us, because if, if they don’t get that, that bond with us, they’re not going to interact with us, or trust us, so you know, it’s, I’ve had more than one to say that I didn’t want his or her parents knowing that they smoke. I have to respect that, otherwise I’ve lost that trust, so they won’t come back to you, to iron out anything else, so rightly or wrongly, we, we sort of, don’t mention it to parents.” (Laurelton College, staff focus group)

Students corroborated that staff take the chance to speak informally with them about smoking and did not seem hostile to this, appreciating that the staff were trying to be helpful. As one student described:

“There’s a kid in my class who constantly has to have a fag all the time, every break, doesn’t he, [name]? Every break. So the teachers joke about it, but they never like, obviously, because it’s more of a friendly thing, they’re not, because this is obviously to try and promote them saying anti-smoking. They do say, they don’t like smoking. [...] They do make an effort to make that known that it’s Stoptober and there is help and everything.” (Valeside College, student focus group)

Despite these concerns, staff indicated little time for pastoral work with students and that, while tutorials might seem like a potential opportunity to intervene, they actually presented little opportunity for any discretionary activities. Staff at one college, whose role is to provide support to students, felt that teaching staff might be resistant to training because of existing demands on their time, saying:

“If you said to staff, right, you’ve got to have this training, because you’ve got to deliver this in your personal tutorial, that’s not going to go down very well is it?” (Laurelton College, staff focus group).

Youth work

As the content of the youth work activities were agreed by the intervention delivery team with each site, the content of sessions varied. Two sessions were delivered: one focused on developing a 'no-smoking' campaign; the other looked at the role of advertising in promoting smoking. Neither focused specifically on illegal tobacco supply or use. Activities were delivered by two different facilitators and the same facilitator did not do all the sessions at each site. The quality and style of facilitation between sessions was observed to differ, with observers noting that one of the two facilitators provided little guidance or feedback on the tasks and did not seem to try to engage those students who were not actively participating. The other facilitator had difficulty maintaining the interest of the participants in one of the two sessions they were observed to lead (the smoke free campaign session), but was more successful in generating rapport with students in the other session. The different experiences of facilitators may also reflect participants' disinterest in the content of the sessions on smoke free campaigns.

Students felt that youth work sessions would not change their behaviour and there were issues about who the sessions were targeted at, and why. Both students and staff felt it was difficult to identify a target audience for whom youth work sessions would be relevant and appropriate, as reflected in the observations of these sessions. Participants did not seem engaged in the two sessions where they developed a smoke free message campaign and were heard to make comments such as; '*I don't even want to be here*' and '*Can we go now?*', with the facilitator remarking afterwards that they felt the participants did not want to be there. However, moments of better engagement were reported, for example, during a discussion of the risks of passive smoking and the session on perceptions of smoking over time, with students appearing genuinely interested by some of the photos, videos and adverts the facilitator used to stimulate discussion. They responded well to the facilitator's questions and, with a little encouragement, most were willing to talk as a whole group.

Some students found the youth work repetitive and felt that sessions would be more effective if delivered to younger students (e.g. in year 9). As one explained; "*sometimes they learn, they teach us stuff that we already know.*" (Athervale, student focus group). Students who identified as non-smokers felt the sessions were not relevant to them, while smokers' responses ranged from being quite hostile because they felt that smoking is their choice, to interested but not affected by the content. As one group of students indicated:

Student 1: It was quite effective. It did, does make you think a bit, but unless you're actually thinking about quitting, before doing the training, then I suppose, it won't really make you quit.

Student 2: Yeah, we went out straight away for a fag didn't we?

Student 1: Yeah. [laughs] As soon as the training finished. We all went out for a fag! (Laurelton College, student focus group)

Similarly, a staff member indicated that they were not sure of how generic sessions to both smokers and non-smokers would work, for staff or students. They said:

"If you go into, what is it, year six, primary school, right. There's a, there's a chance that not many of them will smoke, so you're talking mainly to a group of non-smokers so you're catching them early. If you go into tutorial session with us, you could have, you can have smokers and non-smokers. And it would be the same in staff training. In the training we were in we were all non-smokers, so we're all kind of nodding our heads and agreeing, if there was a smoker in there, he'd probably be quite defensive and would be giving bigger arguments. And it would be the same in a tutorial session. You're going to have the non-smokers who would go, yeah, agree, and then you've got the non-smokers who would just be challenging." (Laurelton College, staff focus group)

Unlike the staff training, which did not require much adaption for FE settings, *The Filter* team made some changes to their youth work sessions in anticipation of the slightly older age group in FE. As one member of the intervention said; "[the sessions are] *still all interactive that they can get involved with but it was more like, to try and get discussion as well.*" They went on to contrast their experience in schools with their recent experiences in FE, describing how:

"In an FE setting, if there's less young people then it can... they can be, like steer the session more themselves, like go with like what they're interested in rather than just giving them activities that they don't want to do anyway. So like, a lot of them in [Valeside College] talked about e-cigarettes, So then it was more like tailored towards that." (ID Team member 2).

The youth worker who delivered the sessions at the small college felt the activities based around developing a smoking campaign “got a bit stagnant towards the end”, describing how “It was a new session so it was, you know, you try it out - sometimes it works, sometimes it doesn't” (ID Team member 4).

However, the flexibility of the sessions was problematic for FE managers when trying to recruit staff to engage their students with the sessions. As the manager at the large college noted, “I think the, the aim of it, of the session was a little bit woolly I think” although they were able to describe the content of the sessions, saying:

“The sessions were about marketing wasn't it? And it was about young people's attitudes towards smoking and what it influences them regarding, is it peer pressure, is it what they see in the papers or on television, that kind of thing.” (Valeside College, FE Manager)

The sixth form youth work activities consisted of three consecutive sessions with the same class of students, whereas in the colleges there were one-off sessions with different groups, consisting of between five and 15 students. There were issues of continuity of attendance in the school sixth form, with the youth worker who ran sessions in both the school sixth form and the large college suggesting they might have structured the sessions differently where they had multiple opportunities to engage with the same group of students. The youth worker felt the sessions in the school sixth forms had been more “challenging” (ID Team member 2) compared to those in the large college where students had seemed to be more engaged. They speculated as to the reasons for this, saying it might be because there was a smaller group in the college and also:

“I think [it was] 'cos it was their PSE lesson and I think they'd been told to come for a smoking workshop, so that doesn't really go down well anyway [laughs] and I think a lot of them had, I don't know whether it was the time of the year, a lot of them wanted to do like course work and but the teacher made them come in to the session. But then I guess it was different to their usual classes in the college as well, so don't know, it's hard to tell really.”

She went on to add that the students “*seemed a lot more mature in [Valeside] college as well [laughs].*” The other youth worker also delivered sessions in the large college (n=5) and similarly felt the sessions had been well-received by students. In contrast to the facilitator’s impression, though, the FE manager at the school sixth form felt the training had:

“Made them [students] think about whether they were going to carry on smoking, it was certainly raising their awareness with them. Whether they had actually any impact and they stopped smoking, I really couldn’t say.”

(Athervale, School FE manager)

In the large college there was a teacher present who participated and the youth worker felt this would have also helped the session run more smoothly in the school sixth form.

One control FE manager perceived their participation in the Filter research project had highlighted the issue of student smoking with staff, resulting in additional lessons “*to raise awareness or just discussions and debates with students in the classroom*” (Glynbel College, FE Manager).

Social media

It appeared FE settings were reluctant to give smoking prevention messages prominence online and at one of the sites, the website was not adequate or active enough to be used. The intervention delivery team member responsible for this component of the intervention sent one tweet and a Facebook message to each intervention site each week but very few posts were retweeted or shared without prompting. They stated:

“With Facebook there just wasn’t the engagement there. Um, on Twitter it was a lot better, um, so I think there was probably about 12 posts again, something around that, and the majority of the FEs did retweet the ones that I directly tweeted them.” (Intervention team member)

Most students said although they access social media (e.g. Twitter, Facebook, Instagram), they don't really engage with messages from third parties on these forums and tend to ignore unsolicited/non-personalised messages unless they are already interested in what is being advertised. As one student indicated:

“I just don't think people would really pay attention to it [information]. I think there's more interesting things you'd rather like I think.” (Valeside College, student focus group).

Another student from the same college explained;

“It's got to be your choice that is, some people will just go straight past whereas if you've got it in your head that you want to quit you're going to think, oh yeah, I'll click on that and have a look, so. It depends on the person really.”
(Valeside College, student focus group)

Students reported gathering a lot of information from social media but that it needed to be carefully targeted and age-appropriate. They indicated that unwelcome messages could make them 'switch off' completely. As one staff member said, this was similar to students feeling badgered by their parents:

Staff 1: “If you're using things like Twitter, it's got to be the right message and probably not too often, because I, I've got various twitter accounts and there's certain accounts that keep on popping up and you just, do you know what, I'm bored. So you just unfollow. So if the message is coming constantly, and you're bombarding these messages, just click unfollow and then you've lost them straightaway. So it needs to be relevant and.

Staff 2: Just desensitises you again.

Staff 3: Yeah.

Staff 1: It's just like, oh, whatever, whatever, isn't it? You know.

Staff 2: The more you tell, the more parents tell teenagers what to do.

Staff 3: Yeah.

Staff 2: The less likely they are to do it anyway.” (Laurelton College, staff focus group)

Similarly, FE managers were cautious about inundating students with messages, while also feeling the intervention messages should have been more obvious around campus. As one said; *“people are just inundated with information and it’s just too much, you’ve got to be careful as to what you do get across”* (Valeside College FE manager). The FE manager at one intervention site indicated they had retweeted messages from Filter and ASH Wales a couple of times and some information had been included on the intranet but they had not engaged much with social media. Students had very little awareness of any social media messages from ASH Wales and stated they rarely, if ever, access the school or college website. Those that had seen something online had seen it in the youth work session.

In one discussion amongst college staff, they indicated they thought social media messages needed to be carefully applied as it might prompt students to smoke more. They speculated that:

“It’s done on social media and it’s flashed at them, it makes them think they want a cigarette then? It sorts of brings it to their attention. If you don’t bring it to their attention, they’re fine getting on with things. The moment you bring it to their attention, it’s like ‘Right, I want one now’. So that can have a bit of an adverse effect.” (Valeside College, staff focus group)

Perceived impact and awareness of the intervention

Overall, the intervention had limited reach to staff and students. Very low levels of awareness of The Filter youth project and ASH Wales among staff and students reflect the weaknesses and challenges with implementation described above.

As the manager at Valeside College commented; *“I don’t think they would have been aware of the project, because we, you know, we haven’t been, pushing it, pushing it, pushing it.”* A few students in the intervention school sixth form had heard of *The Filter* through having received other outreach youth work the previous year. FE managers could not recall all the intervention

components, with one saying: *“I’m going to struggle to answer questions about the intervention”* (Laurelton College FE manager).

Some students participating in focus groups could recall participating in youth work sessions, and staff recalled receiving training. All students and staff were already aware of their site smoking policy, reflecting awareness of changing social norms around smoking and non-smoking normalised in practice (see Section 3.3.1). As one student put it:

“Obviously [I’ve] seen the signs and that obviously that’s a normal thing. And obviously that’s our generation, and I’m sure back in the day they wouldn’t have had those signs. Um, there are smoke-free signs in college isn’t there? That say no smoking?” (Valeside College, student focus group)

Staff and students seemed most engaged when discussing issues relating to the site policy on tobacco, although there was little input from the intervention delivery team on this. Staff who received training seemed to enjoy the sessions, and found them informative. Student reactions to the youth work were mixed, although staff felt they may have appreciated the sessions *“because they do enjoy that kind of tutorial stuff. It gets them out of their own boring lessons.”*, however, they doubted the impact of the sessions, saying; *“I don’t think it would have put anyone off smoking”* (Laurelton College FE manager). Another FE manager concurred, stating that:

“The youth work sessions, you know. With, without a doubt, um, you know, I think are really, really important [...] in an ideal world I would have liked to have done more youth work sessions. [...] just to get the message, just to get, just to get more students, and make them aware of the project, and make them aware of what you’re trying to achieve.” (Valeside College FE manager).

The core message of the intervention (smoking prevention) was not clearly communicated; some students assumed the intervention was ‘anti-smoking’ and smokers were not receptive to this. Similarly, students who were non-smokers felt it was not necessary for them to be bombarded with this message. Students and staff felt smoking prevention messages might be

too late for this population group, but that improved smoking cessation support could be helpful. As one FE manager summarised:

“To be honest, if by 16 they haven’t started yet, I don’t, I know they come to college then, I suppose they see, they may get new friends who do smoke, but they’re probably going to be trying it a lot younger than 16. Um, but maybe to prevent smoking but to also assist with quitting as well.” (Valeside College FE manager).

Summary

This section has described in detail how each of the intervention components was received by staff and students. It shows that, despite a willingness to engage in an intervention in FE, including via policy change at the institutional level (as reported in 3.3.2), the reach and impact on students and staff in terms awareness of the intervention was very limited. In light of the analyses presented in 3.2.1, which indicate that smoking is largely denormalised among the FE population and that students and staff value freedom, personal responsibility and self-determination, it is perhaps unsurprising that core components of this intervention such as staff training and youth working were not perceived as relevant and necessary in the FE setting.

3.3.4 Research methods: feasibility and acceptability

This section focusses on RQ10: 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? First, we present FE managers’ perceptions of the randomisation and recruitment processes. Then we describe the acceptability and feasibility of the survey data collection methods used at baseline and follow-up in this pilot study.

Randomisation and recruitment

FE managers stated they were satisfied with the trial recruitment process (most were approached by email by the intervention delivery team). Agreement to participate had usually

been contingent on senior management approval, although one manager noted it had been delegated to them, saying:

“This just sort of fell into my lap a bit, but it’s not, it’s not, you know, I guess I was the nearest person to, you know, to sort of pick it up.” (Middledale College FE manager).

In the smaller control college, students were involved in the decision whether to participate, and according to the FE manager they had *“a good input from the students, they were all excited about it”* (Glynbel College FE manager).

FE managers perceived the randomisation process as fair and acceptable. Some expressed disappointment they were not in the intervention arm but said this possibility did not affect their decision to join the trial. A manager from a control site summarised the tenor of managers’ feelings about randomisation saying:

“Our students could only benefit and if they, if we weren’t chosen then things sort of stayed more or less, that’s what I thought at the time anyway, I thought that, you know, there was no harm done then.” (Middledale College FE manager).

FE managers had few reservations about getting involved in the study although some had been concerned about the time commitment required. One manager described their reservations about which campus of the college was selected for randomisation and, after being asked to suggest a small campus, stated they *“didn’t think that we chose the right campus in all honesty”* because they knew there were not many smokers on the small campus and also because the campus was located in a very rural area. There were no shops *“within a three mile radius”* which they felt would therefore render redundant any intervention with shopkeepers about access to tobacco. (Laurelton College FE manager).

FE managers reported several motivations for participating in the study. Primarily, managers were keen to work with other organisations, and for some it was part of their role to foster links

with external agencies. One manager suggested the reputation of these organisations was important:

“When you got professional bodies like the Filter team and ASH, if they can come in and offer something different, we’ll always take that.” (Laurelton College FE manager).

The same manager indicated they had felt that it would be good for students to see the University at work, saying:

“We are happy to support the University, it was good to work with the Uni and us. You know, it created awareness of the University as well for our students.” (Laurelton College FE manager).

Managers were also motivated by potential benefits for students, with most perceiving that smoking was an issue amongst their students:

“My interest was in, you know, providing support um, and information to our staff and students about smoking. Because it is an issue.” (Valeside College FE manager).

Another reason for participating in the study was that they might learn as an organisation. As one manager explained; *“I thought it would benefit the students in the school, and that we might get some feedback from it that would allow us to um, further support the students.”* (Athervale FE manager). One of the managers at a control site indicated they were disappointed not to be involved because they thought it might help them to develop their site policy on smoking.

Acceptability of the survey data collection methods

On the whole, surveys were an acceptable form of data collection and while longer term follow-up by phone or email was perceived as acceptable, both students and staff felt it was

unlikely to be feasible. There was some indication of fatigue amongst students about completing surveys though, particularly on smoking. For example one student said that:

“People ain’t going to be willing because the smokers then probably find it offensive, and then they’re not willing to help people like yourselves like this then are they? Because they think ah, they’re just trying to offend us. So why should we help.” (Laurelton College, student focus group)

There was no strong preference amongst students for completing the surveys online or on paper, although online (including via mobile phone) was perceived as most convenient.

Accessing students to complete surveys was challenging. FE managers had concerns about data protection and it was not possible to share student email addresses so that the surveys could be sent directly to them, so students were asked to complete the survey at Freshers’ Fairs. This was acceptable to both students and staff although as one FE manager put it; *“The timing probably wasn’t brilliant for us because September/October is people really settling into their courses.”* (Laurelton College FE manager). Moreover, this system made it harder to trace students for the follow-up survey as they were approached at random. Indeed, after an initial registration period at the start of each academic year, students may move to different campuses or courses, or may only attend the site sporadically or on particular days (e.g. they may have started a work placement). As one FE manager explained:

“Our learners tend, full-time learners tend to be in three days a week, and they could be any three days of five, so, you know, come in on a Monday, not everybody’s going to be in on a Monday, not everybody, do you see what I mean? So it’s from that sort of point of view, it’s a very flexible provision, and um, and therefore you may not always get, you know, the responses, and it might, it just might mean that researchers need to come a bit more often to those sort of organisations or campuses really.” (Middlesdale College FE manager)

For the follow-up survey, students were approached in public spaces on campuses. A few students indicated they did not like being disturbed on their breaks to complete the follow-up

survey (e.g. Valeside College, student focus group). Staff and students suggested students might be asked to complete the survey in their tutor groups, although students indicated they might then feel obliged to complete it. For example one sixth form student said; *“if you’re told to do it in a lesson like fill out this questionnaire please, you will.”* (Athervale, student focus group). However, students did not seem to mind this, saying; *“It’s less of a chore then do you know what I mean?”* (Valeside College, student focus group).

Students and staff felt using personal emails would be the best way to follow-up with students, but all acknowledged that few students check emails. Many students said using phone or text message to contact them would be acceptable. For example, one student said:

“I’m fine with anything. I’m easy, but obviously you’ve got to think as well. Phone numbers might change in a year or two. Because my phone number’s changed three times last year, because I was upgrading my contract.” (Valeside College, student focus group)

However, one FE manager indicated that even now, when they try to contact students via telephone, *“they won’t answer if it’s a withheld [number].”* (Glynbel College FE manager). Another FE manager reiterated the difficulty in following up with students over time, stating that:

“To be honest at the start at the year they were all very keen and they want to do that, but doing the follow up and doing the evaluation they were less keen” (Athervale FE manager).

Students had mixed views on the use of incentives (win an ipad, ‘Love to Shop vouchers’) to encourage them to complete the survey. While they didn’t believe it undermined the credibility of the survey, they had differing views about whether it would be an effective inducement. One student said; *“it was that they offered prizes, that’s the only reason I did it really.”* (Laurelton College, student focus group). Staff also seemed to think that incentives would be helpful, as one staff member said; *“They’re not going to do it for nothing.”* (Laurelton College, staff focus group). On the other hand, some students felt that if the researcher was friendly, introduced

themselves and made you feel comfortable, then *“that would be fine”* (Valeside College, student focus group). A student at a different site indicated that:

“I don’t think you should offer anything. To be quite honest. It’s like, if they want to fill it out, they will, and then if they don’t, then don’t it.” (Laurelton College, student focus group)

The shopping vouchers in particular were seen as acceptable and appropriate incentives. Some students felt the iPad was too valuable a prize to be seen as having a realistic chance of winning and more, smaller prizes such as shopping vouchers, were preferable. Students were cynical about their chances of winning prizes, comparing it with incentives they see on TV and online. They felt that incentives did not motivate them to participate because:

“Everybody thinks it’s a fix though when people, say like oh, take this survey and you’re going to get a prize. Everyone thinks it’s a fix, so you don’t actually think you’re going to win.” (Athervale, student focus group)

Students needed to feel they had a chance of winning for incentives to work and were sceptical about the incentives because they had not heard who had won the iPad at baseline. One group of students suggested it should be clear that there would be one prize per site so they would know who had won. Alternative incentives suggested included smoking cessation advice; *“free help stopping stuff”* (Valeside College, student focus group).

Summary

Overall, the FE managers were supportive of the research, including the use of randomisation, and they were keen to engage with external agencies to deliver interventions to students. However, FE settings are not often engaged in trials and may therefore require additional support and information to ensure that the research process is clear. Digital survey methods and use of incentives are likely to be the most effective methods for surveying students at multiple time points in this context but more methodological work is required to understand how to work with organisational settings where barriers to identification of appropriate sampling

frames exist. More effective approaches to initial organisational process mapping would improve recruitment and retention rates if further research is to be conducted in this setting.

3.4. Pilot primary and secondary outcomes

The third objective of this study was to pilot primary, secondary and intermediate outcome measures and economic evaluation methods and measures. It was not an objective of the pilot study to assess intervention effects and the study was not designed or powered to do so. The response rates, prevalence and distribution by arm is reported for the pilot primary and secondary outcomes at baseline (3.4.1) and follow-up (3.4.2). This section concludes by assessing the feasibility of assessing cost effectiveness using a cost utility analysis based on the EQ-5D-5L (3.4.3)

3.4.1 Missing data, prevalence and distribution by arm at baseline

The characteristics of eligible and non-eligible participants according to the pilot primary and secondary outcome measures at baseline are reported in tables 5 (categorical data) and 6 (numeric data), by arm and overall.

Missing data

There were few missing values with the percentage of missing responses under two percent for all but four questions: living with an adult in paid work, spending money each week, number of cigarettes a day and the heaviness of smoking HSI. Across these variables there were more missing data for control than intervention arm participants. For living with an adult in paid work, the percentage of missing responses in the control arm was 4.1% and in the intervention arm was 1.7%. The percentage of missing data for spending money each week was not equally distributed across arms (control: 11.3%; intervention: 5.9%). For the number of cigarettes a day and the HSI, the percentage of missing data was 7.2% in the control and 2.5% in the intervention arm.

Prevalence and distribution by arm

The indicative primary outcome in this study was the prevalence of weekly smoking which was 20.6% (n = 233) for all participants (95 % confidence interval [CI] = 18.4 to 23.1%). There was a greater percentage of weekly smokers in the control than intervention arms (23.6%, n = 111 vs 18.5% n = 122) (Table 9). This compares with 20.0 % of 16 to 19 year olds in the 2010 General Lifestyle Survey.² Twenty one percent of control arm and 14.9% of intervention arm participants smoked every day. Around a quarter of participants in each arm had ever smoked cannabis. Out of those who had ever tried cannabis, 43.1% of control and 40.9% intervention group participants had smoked cannabis in the past 30 days. There were more control group participants who had smoked cannabis on four or more of the last 30 days (control: 60.4%, intervention: 48.7%). The majority of participants screened positive for hazardous levels of alcohol consumption using the ≥ 2 cut point on the AUDIT-C validated in adolescents,⁴⁵ (overall 68.2%); slightly more screened positive in the intervention than control group (70.9% vs. 64.5%). The percentage screening positive using the ≥ 5 cut point validated in adults,³⁸ was evenly distributed across arms (control: 36.4%, intervention: 38.5%).

The intra cluster correlation (ICC) suggested there was a moderate level of clustering at baseline in weekly smoking status (ICC = 0.03, 95% CI = 0.00 to 0.08), lifetime smoking status (ICC = 0.02, 95% CI = 0.00 to 0.10), and screening positive for hazardous levels of alcohol consumption using the ≥ 2 cut point on the AUDIT-C (ICC = 0.02, 95% CI = 0.00 to 0.21). The ICCs for the use of cannabis in the last 30 days (ICC = 0.12, 95% CI = 0.03 to 0.39), and more than four times in the last 30 days (ICC = 0.12, 95% CI = 0.02 to 0.54) were larger. In contrast, there was very little clustering in lifetime cannabis use (ICC <0.00001). There was a moderate level of internal consistency across items in the HSI ($\alpha = 0.50$) and AUDIT ($\alpha = 0.65$).

The distribution of numeric baseline variables for control and intervention group participants are summarised in Table 8. The five number summaries show a wide range of values reported on the AUDIT-C, for the number of cigarettes a day and the HSI, with little difference across study arms. Median scores on the AUDIT-C (control: 3.0, intervention: 4.0), number of cigarettes a day (control: 10.0, intervention: 10.0) and HSI (control: 2.0, intervention: 1.0) were very similar across arms.

Table 7: Pilot primary outcome and categorical secondary outcomes at baseline

Variable	Baseline data: distribution over categories by trial arm (%)		
	Control, n = 470	Intervention, n = 660	Overall, N = 1,130
<i>Ever tried smoking, even if a puff?</i>			
Missing	1.1	1.4	1.2
Yes	54.0	52.3	53.2
<i>Do you smoke at all nowadays?</i>			
Missing	1.1	1.4	1.2
Yes, every day	20.6	14.9	17.3
Yes, at least once a week	3.0	3.6	3.4
Yes, occasionally but not once a week	6.8	8.8	8.0
No, never	68.5	71.4	70.2
<i>Weekly smoking status</i>			
Missing	1.1	1.4	1.2
Weekly smoker	23.6	18.5	20.6
<i>Ever smoked cannabis?</i>			
Missing	1.5	1.8	1.7
Yes	26.2	28.2	27.4
<i>Smoked cannabis in past 30 days? ^a</i>			
Missing	0	0	0

Yes	43.1	40.9	41.8
<i>Smoked cannabis ≥4 days in last 30 days?</i> ^b			
Missing	0	0	0
Yes	60.4	48.7	53.5
<i>AUDIT-C</i>			
Missing	1.1	2.0	1.6
Hazardous drinker (scoring ≥2) ^c	64.5	70.9	68.2
Hazardous drinker (scoring ≥5) ^c	36.4	38.5	37.6

^a Percentages calculated only in those who reported ever smoking cannabis; ^b Percentages calculated only in those who reported smoking cannabis in last 30 days; ^c AUDIT-C: cut-point validated in adolescents is ≥2; in adults ≥5

Table 8: Numerical secondary outcomes at baseline

Variable (potential scale range)	Baseline data: demographic characteristics and outcomes by trial arm (%)									
	Trial arm	N	Missing	Minimum	25 th	Median	75 th centile	Maximum	Mean	SD
<i>AUDIT-C (0-12)</i>	Control	465	1.1	0.0	0.0	3.0	6.0	11.0	3.4	2.9
	Intervention	647	2.0	0.0	1.0	4.0	6.0	11.0	3.6	2.7
	Overall	1112	1.6	0.0	1.0	3.0	6.0	11.0	3.5	2.8
<i>Number of cigarettes a day</i> ^a (0-100)	Control	111	7.2	0.0	5.0	10.0	16.0	50.0	12.1	8.4
	Intervention	122	2.5	0.0	5.0	10.0	15.0	35.0	10.5	6.5
	Overall	233	4.7	0.0	5.0	10.0	15.0	50.0	10.7	7.6

<i>Heaviness of smoking index</i> ^a (0-6)	Control	111	7.2	0.0	0.0	2.0	3.0	5.0	1.8	1.6
	Intervention	122	2.5	0.0	0.0	1.0	3.0	5.0	1.6	1.5
	Overall	233	4.7	0.0	0.0	2.0	3.0	5.0	1.7	1.5

^a Information only recorded on weekly smokers.

3.4.2 Missing data, prevalence and distribution by arm at follow-up

The characteristics of eligible and non-eligible participants according to the pilot primary and secondary outcome measures at follow-up are reported in tables 7 (categorical data) and 8 (numeric data), by arm and overall.

Missing data

As at baseline, there were few missing values, with the percentage of missing responses for the pilot primary and secondary outcome item typically only 1-2%. Students who provided data at baseline and follow-up had a slightly lower prevalence of weekly smoking (16.7% vs. 22.8%, $p = 0.03$) and lifetime cannabis use (23.5% vs 29.5%, $p = 0.02$) than students who only provided data at baseline. No meaningful difference was found on any demographic characteristic or other secondary outcomes.

Prevalence and distribution by arm

Across all participants the prevalence of weekly smoking was 17.2% (95% CI = 13.9 to 21.2%). There was imbalance in prevalence, with more weekly smokers in the control (21.3%) than intervention arm (14.3%). There was a slightly higher percentage of control than intervention group participants who smoked every day (control: 16.7%, intervention: 13.0%) and at least once a week (control: 4.6%, intervention: 1.3%).

Around a quarter of participants had ever smoked cannabis, slightly more in the intervention (26.1%) than control group (21.8%). Out of those who had ever tried cannabis, 44.7% of control and 32.3% of intervention group participants had smoked cannabis in the past 30 days. The percentage of control and intervention group participants who had smoked cannabis on four or more of the last 30 days was similar (control: 88.2%, intervention: 85.0%). Seventy five percent of participants screened positive for hazardous levels of alcohol consumption at follow up using the ≥ 2 cut point on the AUDIT-C with slightly more screening positive in the intervention than control group (77.3% vs. 71.3%). The percentage screening positive using the ≥ 5 cut point validated in adults was evenly distributed across arms (control: 36.2%, intervention: 37.4%).

The distribution of numeric outcomes for control and intervention group participants are summarised in Table 8. Across groups the median AUDIT-C score was 4.0, number of cigarettes a week was 10.0 and HSI score 2.0. The five number summaries suggest that there was a large range of scores on the AUDIT-C (0-11), number of cigarettes (0-30 a day) and HSI (0-5), and all had relatively large standard deviations. There was little variation across the intervention and control arms for medians on the AUDIT-C (control: 3.5, intervention: 4.0) and HSI (control: 2.0, intervention: 2.0), and participants in the intervention arm smoked slightly more cigarettes than those in the control arm (control: 8.0, intervention: 10.0). No formal comparisons were carried out, so any differences must be interpreted with caution.

There was a high level of clustering in weekly smoking status (ICC = 0.08, 95% CI = 0.00 to 0.21) and the use of cannabis in the last 30 days (ICC = 0.11, 95% CI = 0.01 to 0.60) at the one year follow-up. In contrast, there was very little clustering in lifetime smoking status (ICC = 0.01, 95% CI = 0.00 to 0.19), lifetime cannabis use (ICC <0.00001), and use of cannabis more than four times in the last 30 days (ICC <0.00001). The internal consistency across items in the HSI ($\alpha = 0.17$) was poor and AUDIT ($\alpha = 0.58$) moderate.

Twenty percent of students (n=233) were weekly smokers at baseline. A number of smokers were lost to follow-up, such that baseline prevalence of weekly smoking among those who remained in the study at follow-up was (n=69) 16.8%. Of these weekly smokers, 18 (5.3%) were no longer weekly smokers at follow-up. There was no discernible difference by arm, with 7.4% (n = 10) in the control and 4.0% (n = 8) in the intervention arm not classified as a weekly smoker at follow-up. Of the 336 students who were not a weekly smoker at baseline and had data at follow-up, 21 (6.3%) were classified as a weekly smoker at follow-up. The difference in weekly smoking uptake was slightly higher in the control (8.9%, n = 12) than intervention arms (4.5%, n = 9).

Exploratory multilevel logistic regression models adjusting for baseline weekly smoking status, age, gender, residence with an employed adult, ethnicity and educational attainment (\geq five GSEs A*-C) indicated there was very little difference in the risk of weekly smoking at follow-up between intervention and control students (odds ratio = 0.93, 95% confidence interval = 0.23 to 3.76).

To examine the reliability of reporting on having ever smoked, we calculated the percentage of participants who recanted. This is where participants provide an illogical permutation of responses. We used responses to the question, “Have you EVER tried smoking a cigarette, even if it was only a puff or two?”. Participants who recanted were those at baseline who said they had ever smoked then at the one-year follow-up said they had never smoked. Of the 412 participants, 206 (50.0%) at baseline and 238 (57.7%) at the one-year follow-up had ever tried smoking. Out of the baseline ever smokers, 17 (8.3%) recanted by responding that they had never smoked at the one-year follow-up.

Table 9: Pilot primary outcome and categorical secondary outcomes at follow-up

	One-year follow-up data: distribution over categories by trial arm (%)		
Variable	Control, n = 174	Intervention, n = 238	Overall, N = 412
<i>Ever tried smoking, even if a puff?</i>			
Missing	0.6	0.8	0.7
Yes	60.3	55.9	57.7
<i>Do you smoke at all nowadays?</i>			
Missing	1.2	0.8	0.9
Yes, every day	16.7	13.0	17.3
Yes, at least once a week	4.6	1.3	3.4
Yes, occasionally but not once a week	6.9	7.6	8.0
No, never	70.7	77.3	70.2
<i>Weekly smoking status</i>			
Missing	1.2	0.8	0.9
Weekly smoker	21.3	14.3	17.2
<i>Ever smoked cannabis?</i>			
Missing	1.2	0.8	1.0
Yes	21.8	26.1	24.3
<i>Smoked cannabis in past 30 days?</i> ^a			
Missing	0	0	0

Yes	44.7	32.3	37.0
<i>Smoked cannabis ≥ 4 days in last 30 days?</i> ^b			
Missing	0	0	0
Yes	88.2	85.0	86.5
<i>AUDIT-C</i>			
Missing	0	0	0
Hazardous drinker (scoring ≥ 2) ^c	71.3	77.3	74.8
Hazardous drinker (scoring ≥ 5) ^c	36.2	37.4	36.9

^a Percentages calculated only in those who reported ever smoking cannabis; ^b Percentages calculated only in those who reported smoking cannabis in last 30 days; ^c AUDIT-C: cut-point validated in adolescents is ≥ 2 ; in adults ≥ 5

Table 10: Numerical secondary outcomes at follow-up

	One-year follow-up data by trial arm (%)									
Variable (potential scale range)	Trial arm	N	Missing	Minimum	25th	Median	75th centile	Maximum	Mean	SD
<i>AUDIT-C (0-12)</i>	Control	174	0.0	0.0	1.0	3.5	6.0	11.0	3.6	2.6
	Intervention	238	0.0	0.0	2.0	4.0	6.0	10.0	3.7	2.5
	Overall	412	0.0	0.0	1.0	4.0	6.0	11.0	3.6	2.6
<i>Number of cigarettes a day^a (0-100)</i>	Control	37	0.0	0.0	5.0	8.0	13.0	30.0	10.1	7.3
	Intervention	34	0.0	0.0	6.2	10.0	15.0	25.0	10.9	6.2
	Overall	71	0.0	0.0	5.0	10.0	15.0	30.0	10.5	6.8
<i>Heaviness of smoking index^a (0-6)</i>	Control	37	0.0	0.0	0.0	2.0	3.0	4.0	1.6	1.3
	Intervention	34	0.0	0.0	0.0	2.0	3.0	4.0	1.6	1.6
	Overall	71	0.0	0.0	0.0	2.0	3.0	5.0	1.6	1.6

^a Information only recorded on weekly smokers.

3.4.3 Feasibility of assessing cost effectiveness

EQ-5D-5L items and Health service use at baseline

Participants were requested to tick one box that best describes their health today across five domains: mobility, self-care, usual activities (e.g. work, study, housework, family or leisure activities), pain/ discomfort, and anxiety/ depression. Table 11 shows the distribution of responses to each item at baseline. They were then asked to put a cross on a line to indicate how good or bad their health is on a scale ranging from 0 (worst health you can image) to 100 (best health you can image). Table 12 shows the distribution of responses for each numerical item.

Health service use over the last 30 days was defined as going to see a doctor or nurse about a health problem, excluding visits for contraceptive advice. For those who had visited a doctor or nurse, they were asked on how many occasions. Hospital admittance was also assessed over the last 30 days. For those that reported being admitted to hospital, they were asked whether it was for day care, or the number of nights. Table 11 shows that around a fifth of participants had visited a doctor and five percent had been admitted to hospital.

Table 11: Categorical EQ-5D-5L items and health service use at baseline

Variable	Baseline data: distribution over categories by trial arm (%)		
	Control, n = 470	Intervention, n = 660	Overall, N= 1,130
EQ-5D-5L			
<i>Mobility</i>			
Missing	3.6	3.2	3.4
I have no problems in walking about	88.7	91.1	90.1
I have slight problems in walking about	5.1	4.5	4.8
I have moderate problems in walking about	1.5	0.6	1.0
I have severe problems in walking about	0.4	0.2	0.3
I am unable to walk about	0.6	0.5	0.5
<i>Self-care</i>			
Missing	3.6	3.5	3.5
I have no problems washing or dressing myself	92.8	94.4	93.7
I have slight problems washing or dressing myself	1.7	1.1	1.3
I have moderate problems washing or dressing myself	0.6	0.7	0.7
I have severe problems washing or dressing myself	0.9	0	0.4
I am unable to wash or dress myself	0.4	0.3	0.4
<i>Usual activities</i>			
Missing	3.8	3.8	3.8

I have no problems doing my usual activities	85.3	88.5	87.2
I have slight problems doing my usual activities	7.7	5.2	6.2
I have moderate problems doing my usual activities	2.3	1.8	2.0
I have severe problems doing my usual activities	0.4	0.5	0.4
I am unable to do my usual activities	0.4	0.3	0.4
<i>Pain/ discomfort</i>			
Missing	4.3	3.5	3.8
I have no pain or discomfort	75.3	72.6	73.7
I have slight pain or discomfort	13.4	18.9	16.6
I have moderate pain or discomfort	4.0	3.9	4.0
I have severe pain or discomfort	2.8	0.8	1.6
I have extreme pain or discomfort	0.2	0.3	0.3
<i>Anxiety/ depression</i>			
Missing	4.0	3.6	3.8
I am not anxious or depressed	69.8	60.6	64.4
I am slightly anxious or depressed	14.0	18.9	16.9
I am moderately anxious or depressed	6.4	11.7	9.5
I am severely anxious or depressed	3.6	4.1	3.9
I am extremely anxious or depressed	2.1	1.1	1.5
<i>During the last 30 days, have you visited a doctor or nurse?</i>			

Missing	1.7	2.6	2.2
Yes	17.0	22.6	20.3
<i>During the last 30 days, have you been admitted to hospital</i>			
Missing	2.3	2.6	2.5
Yes	4.3	5.8	5.1
<i>How many nights admitted to hospital in last 30 days? ^a</i>			
Missing	0	0	0
Day case	65.0	65.8	65.5
1 night	25.0	18.4	20.7
2 nights	0	2.6	1.7
3+ nights	10.0	13.2	12.1

^a Information only recorded on those who had been admitted to hospital in last 30 days.

Table 12: Numerical EQ-5D-5L items and health service use at baseline

Variable (potential scale range)	Baseline data: characteristics by trial arm (%)									
	Trial arm	N	Missing	Minimum	25 th	Median	75 th centile	Maximum	Mean	SD
<i>How good or bad is your health TODAY</i> 0 (worst you can imagine) to	Control	449	4.5	0.0	72.0	85.0	96.0	100.0	80.0	21.5
	Intervention	639	3.2	6.0	75.0	87.0	95.0	100.0	81.8	17.5
	Overall	1081	4.4	0.0	74.0	87.0	95.0	100.0	81.1	19.3
	Control	78	2.5	1.0	1.0	2.0	3.0	5.0	1.9	1.1

<i>How many visits to a doctor or nurse in last 30 days? (0-6) ^a</i>	Intervention	148	0.7	1.0	1.0	1.0	2.0	6.0	1.6	1.0
	Overall	226	1.3	1.0	1.0	1.0	2.0	6.0	1.7	1.0
<i>EQ-5D-5L index score (-1.0-1.0)</i>	Control	470	0.0	-0.3	0.9	1.0	1.0	1.0	0.9	0.1
	Intervention	660	0.0	0.1	0.9	1.0	1.0	1.0	0.9	0.1
	Overall	1130	0.0	-0.3	0.9	1.0	1.0	1.0	0.9	0.1

^a Information only recorded on those who had been visited a doctor or nurse in last 30 days.

EQ-5D-5L items and health service use at follow-up

Participants were asked to repeat the EQ-5D-5L and health service use questions at follow-up. As at baseline they were asked to tick one box that best describes their health on the day of survey over five domains: mobility, self-care, usual activities (e.g. work, study, /housework, family or leisure activities), pain/discomfort, and anxiety/depression. Table 13 shows distribution of responses to each item at follow-up. As with the baseline survey, participants were also asked to put a cross on a line to indicate how good or bad their health is on a rating scale from 0 (worst health you can imagine) to 100 (best health you can imagine). Table 14 shows distribution of numerical responses and reported use of health services at follow-up for those respondents who indicated that they had visited a doctor or nurse over the last 30 days. Control group mean at follow up: 1.8 visits (SD 1.3), Intervention group mean at follow up 1.7 (SD 1.1). The means for the EQ-5D-5L index score in the control and intervention group were both 0.9 (SD 0.1).

Table 13: Categorical EQ-5D-5L items and health service use at follow-up

Variable	One-year follow-up data: distribution over categories by trial arm (%)		
	Control, n = 174	Intervention, n = 238	Overall, N = 412
EQ-5D-5L			
<i>Mobility</i>			
Missing	2.9	0.8	1.7
I have no problems in walking about	90.8	93.3	92.2
I have slight problems in walking about	4.0	3.4	3.6
I have moderate problems in walking about	2.3	1.3	1.7
I have severe problems in walking about	0	0.8	0.5
I am unable to walk about	0	0.4	0.2
<i>Self-care</i>			
Missing	2.9	0.8	1.7
I have no problems washing or dressing myself	93.7	96.6	95.4
I have slight problems washing or dressing myself	1.7	0.4	1.0
I have moderate problems washing or dressing myself	1.2	1.7	1.5
I have severe problems washing or dressing myself	0.6	0.4	0.5
I am unable to wash or dress myself	0	0	0
<i>Usual activities</i>			
Missing	2.9	0.8	1.7

I have no problems doing my usual activities	90.8	90.8	90.8
I have slight problems doing my usual activities	3.5	6.3	5.1
I have moderate problems doing my usual activities	2.9	0.8	1.7
I have severe problems doing my usual activities	0	0.8	0.5
I am unable to do my usual activities	0	0.4	0.2
<i>Pain/ discomfort</i>			
Missing	3.5	0.8	1.9
I have no pain or discomfort	79.9	80.3	80.1
I have slight pain or discomfort	11.5	13.9	12.9
I have moderate pain or discomfort	4.0	3.8	3.9
I have severe pain or discomfort	1.2	0.8	1.0
I have extreme pain or discomfort	0	0.4	0.2
<i>Anxiety/ depression</i>			
Missing	2.9	1.3	1.9
I am not anxious or depressed	74.7	64.3	68.7
I am slightly anxious or depressed	8.6	17.2	13.6
I am moderately anxious or depressed	6.3	13.5	10.4
I am severely anxious or depressed	5.8	3.4	4.4
I am extremely anxious or depressed	1.7	0.4	0.9
<i>During the last 30 days, have you visited a doctor or nurse?</i>			

Missing	3.5	0.8	1.9
Yes	23.6	23.1	23.3
<i>During the last 30 days, have you been admitted to hospital</i>			
Missing	2.9	0.8	1.7
Yes	6.9	5.0	5.8
<i>How many nights admitted to hospital in last 30 days? ^a</i>			
Missing	0	0	0
Day case	83.3	83.3	83.3
1 night	8.3	8.3	8.3
2 nights	8.3	8.3	8.3
3+ nights	0	0	0

^a Information only recorded on those who had been admitted to hospital in last 30 days.

Table 14: Numerical EQ-5D-5L items and health service use at follow-up

		One-year follow-up data: characteristics by trial arm (%)								
Variable (potential scale range)	Trial arm	N	Missing	Minimum	25th	Median	75th centile	Maximum	Mean	SD
<i>How good or bad is your health TODAY</i> 0 (worst you can imagine) to 100 (best you can image)	Control	168	3.0	10.0	70.1	84.0	90.1	100.0	80.5	16.5
	Intervention	236	0.8	8.0	75.0	85.0	93.1	100.0	83.0	14.3
	Overall	404	1.9	8.0	75.0	85.0	92.0	100.0	82.0	15.3
	Control	41	0	1.0	1.0	1.0	2.0	6.0	1.8	1.3

<i>How many visits to a doctor or nurse in last 30 days? (0-6) ^a</i>	Intervention	55	0	1.0	1.0	1.0	2.0	5.0	1.7	1.1
	Overall	96	0	1.0	1.0	1.0	2.0	6.0	1.8	1.2
<i>EQ-5D-5L index score (-1.0-1.0)</i>	Control	174	0.0	0.3	0.9	1.0	1.0	1.0	0.9	0.1
	Intervention	238	0.0	0.1	0.9	1.0	1.0	1.0	0.9	0.1
	Overall	412	0.0	0.1	0.9	1.0	1.0	1.0	0.9	0.1

^a Information only recorded on those who had been visited a doctor or nurse in last 30 days.

3.5. Pilot intermediate (outcome) measures

Participants were asked to complete items addressing attitudinal and knowledge-based precursors to smoking, including perceived prevalence of smoking (perceived norms), at baseline. The aim was to explore potential changes in these individual level characteristics that were targeted via the intervention and explicit in the logic model. NatCen attitudinal scales⁴¹ and European Smoking Prevention Framework Approach (ESFA) items assessing social and situational self-efficacy and skills^{42,43} were used in this study. Table 15 shows the distribution of responses by arm at baseline.

Participants completed a follow-up survey on attitudinal and knowledge-based precursors to smoking, including perceived prevalence of smoking (perceived norms). The survey tool was adapted from NatCen Items⁴¹ social and situational self-efficacy and skills, using the European Smoking Prevention Framework Approach (ESFA) items.^{42,43} At follow-up the survey incorporated questions on institutional-level influences, including awareness of college practices on smoking and *The Filter* project. It also considered community-level data to understand participant experience of tobacco purchasing and local retailer behaviour. Table 16 shows distribution of responses by arm at follow-up. Table 16 illustrates that a majority of students who attempted to purchase tobacco were able to do so. Only 5.1% students were aware of *The Filter* project at follow-up, although this was higher in the intervention group (7.1%) than in the control group (2.9%).

Table 15: Pilot intermediate outcome measures at baseline

Variable	Baseline data: distribution over categories by trial arm (%)		
	Control, n = 470	Intervention, n = 660	Overall, N = 1,130
<i>People of my age smoke because it helps them to relax</i>			
Missing	2.3	2.9	2.7
True	60.0	61.8	61.1
False	37.7	35.3	36.3
<i>People of my age smoke because they are addicted to tobacco</i>			
Missing	2.6	2.7	2.7
True	77.8	77.3	77.5
False	19.6	20.0	19.8
<i>People of my age smoke because they believe it helps them to stay slim</i>			
Missing	3.2	3.0	3.1
True	27.0	27.3	27.2
False	69.8	69.7	69.7
<i>People of my age smoke because it helps them with stress in their life</i>			
Missing	3.0	3.0	3.0
True	77.7	77.3	77.4
False	19.4	19.7	19.6
<i>People of my age smoke to look cool in front of their friends</i>			
Missing	2.6	2.7	2.7
True	77.2	77.7	77.5
False	20.2	19.6	19.8
<i>People of my age smoke because they find it exciting to break the rules</i>			
Missing	3.0	3.0	3.0
True	52.6	52.6	52.6
False	44.5	44.4	44.4
<i>People of my age smoke because their friends pressure them into it</i>			
Missing	2.6	3.0	2.8
True	74.0	72.1	72.9

False	23.4	24.9	24.3
<i>People of my age smoke because it gives them a good feeling</i>			
Missing	3.0	3.3	3.2
True	66.2	63.2	64.4
False	30.9	33.5	32.4
<i>Have you ever felt pressure to smoke from your best friend?</i>			
Missing	2.6	3.0	2.8
Often	3.6	1.5	2.4
Sometimes	13.0	10.2	11.3
Never	77.5	81.1	79.6
I don't have one/ any	3.4	4.2	3.9
<i>Have you ever felt pressure to smoke from other friends?</i>			
Missing	3.0	3.2	3.1
Often	4.3	2.1	3.0
Sometimes	20.4	18.0	19.0
Never	69.8	73.5	72.0
I don't have one/ any	2.6	3.2	2.9

Table 16: Pilot intermediate outcome measures at follow-up

Variable	One-year follow-up data: distribution over categories by trial arm (%)		
	Control, n = 174	Intervention, n = 238	Overall, N = 412
Individual level			
<i>People of my age smoke because it helps them to relax</i>			
Missing	2.9	0.8	1.7
True	63.8	73.1	69.2
False	33.3	26.1	29.1
<i>People of my age smoke because they are addicted to tobacco</i>			
Missing	3.5	0.8	1.9
True	77.0	83.6	80.8

False	19.5	15.6	17.2
<i>People of my age smoke because they believe it helps them to stay slim</i>			
Missing	2.9	1.3	1.9
True	28.7	28.2	28.4
False	68.4	70.6	70.0
<i>People of my age smoke because it helps them with stress in their life</i>			
Missing	2.9	0.8	1.7
True	80.5	86.6	84.0
False	16.7	12.6	14.3
<i>People of my age smoke to look cool in front of their friends</i>			
Missing	2.9	0.8	1.7
True	81.0	80.7	80.8
False	16.1	18.5	17.5
<i>People of my age smoke because they find it exciting to break the rules</i>			
Missing	2.9	0.8	1.7
True	60.9	60.0	59.2
False	36.2	41.2	39.1
<i>People of my age smoke because their friends pressure them into it</i>			
Missing	2.9	0.8	1.7
True	71.8	71.9	71.8
False	25.3	27.3	26.5
<i>People of my age smoke because it gives them a good feeling</i>			
Missing	2.9	0.8	1.7
True	60.3	71.0	66.5
False	36.8	28.2	31.8
<i>Have you ever felt pressure to smoke from your best friend?</i>			
Missing	2.9	1.3	1.9
Often	3.5	1.7	2.4
Sometimes	13.2	10.1	11.4
Never	78.2	84.8	82.0

I don't have one/ any	2.3	2.1	2.2
<i>Have you ever felt pressure to smoke from other friends?</i>			
Missing	2.9	1.3	1.9
Often	3.5	2.5	2.9
Sometimes	16.1	14.3	15.1
Never	76.4	80.7	78.9
I don't have one/ any	1.2	1.3	1.2
Institutional-level			
<i>Do you ever see students smoking at your college?</i>			
Missing	1.7	0.8	1.2
Never	6.3	1.3	3.4
Once or twice a year	2.3	0.8	1.5
Yes, every month	1.7	0.0	0.7
Yes, every week	9.2	6.3	7.5
Yes, daily	78.7	90.8	85.7
<i>Do you think your college could do more to prevent or restrict smoking to certain areas on site?</i>			
Missing	2.3	0.8	1.5
Yes	54.6	47.5	50.5
No	27.0	33.6	30.8
Not sure	16.1	18.1	17.2
<i>Does your college have a designated smoking area for students to smoke?</i>			
Missing	2.3	0.8	1.5
Yes	68.9	76.5	73.3
No	23.6	15.6	18.9
Not sure	5.2	7.1	6.3
<i>Do you ever see staff smoking at your college?</i>			
Missing	2.9	0.8	1.7
Never	47.7	62.2	56.1
Once or twice a year	8.6	8.4	8.5
Yes, every month	4.0	2.9	3.4

Yes, every week	14.9	9.7	11.9
Yes, daily	21.8	16.0	18.5
<i>Do you think that the staff at your college are concerned about student smoking?</i>			
Missing	2.3	0.8	1.5
Yes	40.2	38.7	39.3
No	33.3	37.4	35.7
Not sure	24.1	23.1	23.5
<i>Do you think that the staff at your college are working to prevent students from taking up smoking?</i>			
Missing	2.3	0.8	1.5
Yes	44.3	31.9	37.1
No	28.2	44.9	37.8
Not sure	25.3	22.3	23.5
<i>Do staff ever warn students about the health risks of smoking?</i>			
Missing	2.3	0.8	1.5
Yes	62.1	60.1	60.9
No	24.1	26.5	25.5
Not sure	11.5	12.6	12.1
<i>Do most staff appear confident when discussing a smoking-related issue with students?</i>			
Missing	2.3	0.8	1.5
Yes	60.3	60.9	60.7
No	8.1	10.8	9.2
Not sure	29.3	28.2	28.6
<i>Do staff encourage students to use e-cigarettes to help them smoke less at college?</i>			
Missing	2.3	0.8	1.5
Yes	12.1	5.9	8.5
No	58.1	65.6	62.4
Not sure	27.6	27.7	27.7
<i>Have you heard of The Filter youth project?</i>			
Missing	4.0	0.8	2.2
Yes	2.9	7.1	5.3

No	86.8	87.4	87.1
Not sure	6.3	4.6	5.3
Community-level			
<i>In the past year have you ever gone into a shop near your college to buy cigarettes or tobacco? (This includes buying for somebody else)</i>			
Missing	1.7	0.8	
Yes	14.4	12.2	
No	83.9	87.0	
<i>The last time you went into a shop near your college to buy tobacco or cigarettes, what happened? ^a</i>			
Missing	0.0	0.0	
I bought some cigarettes	96.0	93.1	
They refused to sell me cigarettes	4.0	6.9	

^a Information only recorded on those who had bought cigarettes or tobacco in a shop near their college.

4. Discussion

This section starts by considering the limitations of this study (4.1). First, the limitations of the recruitment methods and measures used to survey students about smoking and other health outcomes are discussed, including sampling and retention problems. Second, other practical and methodological limitations are discussed, including problems identified with the focus group data collection methods and the deviations from the study protocol. The discussion then focuses on key results from the process evaluation (4.2), before consideration of generalisability and the implications of findings for intervention development in FE settings and future research are discussed (4.3). The final section reports conclusions and recommendations (4.4).

4.1 Limitations

Student survey limitations

Although data indicate acceptability of survey methods to participants, with very low levels of missing data at both baseline and follow up, the utility of this survey approach was compromised by issues of access and recruitment highlighted in section 3.3.4. A key limitation with the survey methods was that establishing accurate data on total eligible sample size at each college at baseline was problematic due to lack of accurate, up-to-date enrolment data. These issues were especially prevalent in large FE settings, due to: students enrolling in principle prior to September but not registering at the start of term; students deferring or dropping out in early September; inclusion of students who study across multiple campuses but whose primary campus is not the study site; and the inclusion of some students aged over 18 due to incomplete information at enrolment. This meant that the number of potentially eligible students provided by colleges included some students who were either under the age of 16 or over 18 and therefore ineligible.

As accurate information on the number of students aged between 16 and 18 years who were attending colleges was not available, the denominator included ineligible participants and response rates would have been higher if they were not included. Ineligible participants were older, worked part-time and were more likely to be classified as a weekly smoker than those

who were eligible. Initial data provided by colleges did not – and could not – account for changes due to early exit by students or course changes. Although the intervention was specifically aimed at new students, commencement of the study at the start of the academic year emerged as problematic for student engagement, as staff did not yet know students or tutor group composition. Beginning the study further into the academic year would not likely have aided recruitment, with many students out on work placements and attending sporadically once courses are fully underway.

Although response rates reported at baseline are underestimates, overall the response and retention rates in this study would be too low to power a cluster RCT design aiming to assess effectiveness and it is uncertain whether those students undertaking the survey are representative of the student body as a whole. Attendance patterns further impacted data collection as students are not in set places and at set times, meaning no fixed data collection points, with researchers instead relying on passing traffic. Although access to tutor groups would appear to present a partial solution to these issues, lack of access to these groups was common.

Respondents in the intervention and control groups were not equivalent at baseline in terms of age or gender, which may have impacted outcomes if baseline smoking attitudes and behaviour differed. The trial arms were not well balanced for the indicative primary and secondary outcome measures at baseline or follow up. This imbalance is not unusual given there were few clusters and heterogeneity between clusters and would not be considered a risk in a larger cluster RCT assessing effectiveness.

Although baseline survey participation rates were reasonable, the research experienced high levels of attrition between baseline and follow up. Thirty-six percent of baseline respondents completed the one-year follow-up survey, constituting seventeen percent of potentially eligible participants. This low response at follow-up should be considered in interpreting results and, for future research, analysis of characteristics of non-responders at follow-up is recommended to understand how this may be better addressed.

Response rates at follow-up were impacted by lack of effective channels to contact students, including limited access to personal email, and student reluctance to respond to unsolicited

phone calls. Although it may have seemed reasonable to surmise that FE students would constitute a seemingly captive audience similar to that in schools, in practice this was not the case. The identification of multiple problems in recruitment and retention was evident in follow-up response rates, which indicate lack of feasibility for retention in this setting. Although it was assumed that existing social media channels would be a useful tool for promotion of – and retention in – the trial, in practice levels of engagement with these channels were low. It cannot be established whether this is typical of FE settings or specific to these sample sites, suggesting that this should be considered for future research through pre-intervention discussion with staff and students.

In relation to selection of survey tools, both the EQ-5D-5L scale and the health service use measures had limitations that should be considered for future research. As the age group under investigation generally have low engagement with health services and, due to the limited timescale of the study, it may have been unrealistic to expect change where rates of smoking-related health problems are likely to be low compared to older smokers. This further suggests that EQ-5D-5L would not be sensitive enough to pick up changes to health or quality of life over a timescale this short and it is recommended for future work in this area that other, purpose built, scales are developed which are more sensitive to likely health impacts among this age group.

Limitations with other data collection methods

There are some limitations in our assessment of student and staff views on acceptability associated with sampling and recruitment to focus groups. The process of gathering students and staff members together for focus groups proved time-consuming and challenging. It is uncertain how representative focus group participants were of the wider staff and student populations, and there was limited time to explore this in detail. No socio-economic information about the student participants in focus groups was obtained. Difficulties in securing staff time away from routine practice impacted both focus group participation and attendance at staff training, which was delivered under target levels due to limited demand by sites. This was attributed by staff to pressures on time and may have been further impacted by the lack of clarity on intervention content indicated in qualitative data obtained from the process evaluation.

Stratification to student focus groups by smoking characteristics was particularly challenging, not least because a key finding of this study (see section 3.3.1) indicates that many FE students who smoke were reluctant to define themselves as ‘smokers’. Although some people who were regular smokers clearly defined themselves as such, the grouping of ‘non-smokers’ was in practice divided into those who did not countenance smoking at all and those who were occasional, or ‘social’ smokers.

Mystery shopper activities were inconsistently delivered and recorded, with variation in how the same shops were classified at baseline and follow-up; for example, some shops which had been classified as convenience stores at baseline were classified as CTN (confectionary, tobacconist, newsagents) at follow-up, and vice versa. This suggests that the definition of some shop types was not clear and further guidance was required. The data for shops classified as convenience stores or CTN are therefore presented together in the results section of this report. Variance also occurred in how the mystery shopper survey was completed between baseline and follow-up, even when the accompanying fieldworker had remained the same. In particular, the dates and times of visits were not precisely recorded at follow-up (only afternoon/evening stated, rather than the exact time).

The retailer elements of the study were also impacted by the locations of participating sites and, particularly, the lack of retailers in close proximity to colleges, which may have effected consistency of staff interaction with shops. The combined limitations of implementation and access mean that the impact of the intervention on local sales practices, particularly underage sales to students aged 16-17, cannot be fully assessed at this time. Future interventions which aim to incorporate a retailer behaviour element should consider this prior to implementation.

Intervention staff checklists were poorly completed throughout the project, which partly reflects high staff turnover within some small, voluntary sector teams such as this. This turnover further impacted FE staff engagement, with frustrations expressed at the number of intervention staff involved and the lack of a consistent point of contact. For future intervention delivery in this setting, the utilisation of permanently contracted staff, if available, should be considered. Implementation may be supported by earlier engagement with FE settings to tailor and deliver the intervention with college managers and other staff.

No major problems were encountered in securing access to conduct observations in the intervention sites, however fieldworkers at the larger sites reported difficulties in ensuring that all locations had been checked thoroughly to identify whether messages were consistent and all possible data were collected. The same researcher did not always complete the baseline and follow-up observations at each site, so differences between baseline and follow-up data may be due to observer bias. More detailed observations could be obtained if fieldworkers were familiar with the site and can visit more than once and at different times of the day to observe smoking behaviours. A more structured survey to monitor sites at baseline and follow-up might provide more accurate detail about changes over time. The use of a tablet to input the online survey on site worked well in most cases, although data from one site did not upload properly, so the fieldworker completed the survey from memory.

Deviations from protocol

The only major deviation from the protocol was that post-follow-up saliva testing (cotinine and anabasine tests) did not go ahead as planned because the research team was unable to recruit students to provide these samples. This means that the validity of self-reported smoker status could not be verified in this study. For future research in this setting, prior exploration of the acceptability of saliva sample collection and testing should be undertaken with students to identify new methods of recruitment and better incentives that may improve participation.

The study protocol also included plans for economic analyses to include an assessment of the costs of the intervention based on reports of the resources used by ASH Wales' staff and FE colleges. Within this, key interventional resources were considered to include intervention staff time (intervention manager, training and education officers, web and social media officers, youth workers), as well as training event and youth workshop travel and resources, and other consumables relating to the delivery of the project. However, it was not possible to do these planned economic analyses based on the costs of staff time and other intervention expenses because we did not receive these data from the intervention team.

4.2 Key results and generalisability

Acceptability

This section considers key findings from the process evaluation, including the influence of non-interventionist institutional cultures identified at participating sites and the perceptions of acceptability of intervention components.

Although the study was not powered to detect adverse intervention effects, these were considered in analysis of qualitative data, with no unintended harms to student participants or staff identified. The acceptability of the intervention to FE colleges suggests little risk of disruption to practice. However, lack of delivery of the policy review component, and staff disappointment with this, may have affected the relationships between colleges and research teams, with implications for future participation in similar trials.

A significant barrier to acceptability of intervention content, and the willingness of staff to fully engage, relates to culture within the FE sector, particularly large colleges, where personal choice and freedom are highly valued and the voluntary nature of attendance is recognised. Both staff and students strongly valued the transitional nature of FE as an environment where development from youth to adulthood occurs, with corresponding emphasis on personal responsibility, including for one's own smoking behaviour. This was evident in the contrast between support for formal smoke free norms as embodied in policy in FE settings, including approval for smokers to be regulated and restricted to approved territories, and the informal tolerance exhibited in staff attitudes to challenging smoking behaviour and intervening with young adult choices.

Although this finding reflects perceptions commonly found in Higher Education (HE) settings of students as adults free to pursue own choices, in contrast with HE, students in FE settings may not have the same legal status. As it is illegal to sell tobacco to those under 18, this suggests scope to query the non-interventionist stance commonly expressed. Further research would aid understanding of how to balance the necessary emphasis on students' transitional and developmental needs and the legal framework FE settings operate in. Cross-cultural comparisons with educational systems where attendance to age 18 is compulsory

may also aid understanding of the role of voluntary participation in further education as a contributor to the development of more permissive environments.

This cultural difference between school and FE was also evident in the view that FE may be 'too late' for prevention activities, suggesting a need to further explore smoking cessation in this context. Students and staff suggested they had 'heard it all before' and were well enough informed on smoking harms, especially non-smokers who did not want to engage with seemingly irrelevant information. The lack of acceptability of content was evident in low engagement with youth work sessions focussed on development of smoke free message campaigns, which were felt to be more relevant to younger age-groups, suggesting a more nuanced approach could be needed in this setting. This was recognised by the intervention team, and contrasted with previous experience of delivery in school settings. However, challenging the limited acceptability for prevention in the setting may be important in light of evidence that 60% of adult smokers commence regular smoking after age 16, suggesting an unmet need for prevention after compulsory education. Further exploration of prevention delivery in post-16 settings should consider what may constitute acceptable intervention content to target audiences.

Data suggests high acceptability among FE staff for intervention activities focussed on smoking policy review and development but, due to intervention management issues, policies were not reviewed as intended. Randomisation was acceptable to FE managers, who also perceived added value in participation through engagement with external organisations and student exposure to higher education research. Staff also indicated acceptability of the training component of the intervention, particularly where they perceived existing knowledge gaps, such as with e-cigarettes. However, this was not matched by perceived likelihood of utilising content in discussing smoking with students, reflecting the lack of support for interventionist approaches which contrast with the emphasis on personal responsibility.

The intervention team found FE settings challenging and not conducive to smoking prevention activities compared to other educational settings (e.g. they reported significant differences between the prevailing culture of FE colleges in this study and schools where they had worked), which was observed as impacting student engagement. They also noted

limitations in terms of access to target populations in FE settings due to existing organisational behaviours and activities.

Reach

Data indicate low levels of engagement with social media channels used for message dissemination, reflecting a possible misperception in intervention development, as well as institutional barriers, including college variations in the level of staff engagement in social media channels. Although students' reported routinely accessing social media, this did not seem to include use of formal college websites and social media channels, suggesting over-estimation of the likely impact of this approach. This finding is significant for future intervention delivery in this setting, including informing recruitment and retention strategies which may aim to utilise social media.

A further limitation of the intervention – and the logic model – emerged from process data, where students frequently reported obtaining tobacco from peers and family rather than local retailers, suggesting targeting local retailer practice was likely to have limited effect. The majority of students who tried to purchase cigarettes were able to do so successfully at follow up, suggesting limited penetration of community-level activities. The majority of students were unaware of *The Filter* project at follow up, suggesting limited impact of awareness-raising activities supporting roll-out, such as social media promotion, as discussed above.

The identification of 'informal' supply chains in this study has implications for targeting of any future interventions and further research would help to identify whether this supply was primarily taking tobacco products from inside the home or proxy purchasing (someone over age 18 purchasing tobacco products for someone under 18). Despite the legal age for tobacco purchasing increasing from 16 to 18 in the UK in 2007, the law on illegality of proxy purchasing was only implemented in October 2015 after follow-up analysis. It is important to note that retailer behaviour in any future interventions may be differentially impacted by any enforcement activity associated with this legal change.

4.3 Implications

Overall, the lack of support for the intervention, combined with institutional factors that impacted delivery, such as short run-in, FE timetabling and systems, and poor intervention management, meant that the Filter FE was not acceptable or feasible at any of the pilot sites at this time. However, it cannot be concluded from this research that individual components of the intervention could not transfer to FE settings effectively if some of the key implementation issues identified were addressed in future studies.

This research has identified multiple factors which suggest that these FE settings were not conducive contexts for the delivery of prevention interventions. The prevailing non-interventionist ethos evident in FE colleges – more so than school-based ‘sixth forms’ – suggests a different approach is required in such large, transitional environments to increase acceptability. However, although findings from the process evaluation appear to strongly support resistance to prevention messages, interpretation of the validity of other intervention components should be assessed in light of implementation issues, such as those impacting the assessment of retailer practices. Although not successful in this study, staff willingness to engage on policy-related matters may also suggest that this component would benefit from further investigation and re-assessment of impact. It is also noted that FE managers were keen to work with universities and outside agencies, particularly where knowledge gaps are perceived, as with e-cigarettes, suggesting co-production in future intervention development to identify issues and approaches deemed pertinent. Although smoking prevention was not a receptive message for this population, interest was further expressed in access to smoking cessation (i.e. not accessed via GP or health services, services that don’t need transport to get to), as well as policy support for colleges, suggesting scope for future work.

This research illustrates the variations within this sector that make generalising from results problematic. The diversity of the sector, in terms of mix of socio-economic groups, vocational and academic courses, and the settings students are exposed to, including workplaces, requires further enquiry to inform current knowledge on the impact of FE on health behaviours in young people. Exploratory analysis of organisational features, drawing on research into university culture and processes, could inform future intervention

development. The lack of homogeneity across FE illustrates the necessity of flexibility in intervention development and delivery.

Overall, the limitations to data collection methods, combined with the limited implementation of some components, means that the potential impacts of smoking prevention activities across multiple levels (student, college, community) remain hard to interpret. Findings are most robust at the level of individual influence, with this research increasing understanding of issues of reach and acceptability for individuals in these settings. Organisationally, the process evaluation has highlighted important procedural and attitudinal influences on on-site intervention components. Questions have been raised regarding the role of organisational processes and norms on implementation of prevention interventions, which can be considered for future development work and delivery. At the level of community effects, implementation issues relating to retailer engagement and monitoring mean that little can be asserted about the retailer component of the intervention. Although a socio-ecological approach presented challenges in terms of the range and complexity of intervention components involved, such a broad exploration was beneficial in highlighting the range of issues impacting smoking behaviour and intervention delivery in this setting.

4.4 Conclusions and recommendations for further research

The principle conclusion and recommendation of this report is for no further evaluation of this smoking prevention intervention in FE settings without consideration of how to address the issues identified in implementation of intervention components and acceptability of this type of intervention. However, even if some practical delivery constraints could be overcome in future interventions, issues of acceptability and reach may still occur in this setting due to relatively deep-rooted cultural and procedural constraints reported. The process evaluation data revealed how institutional cultures within FE settings limit the acceptability of prevention activities for smoking, although it is recommended that this be investigated across a broader range of FE schools and colleges, including those in denser urban areas and with other socio-demographics. It is also recommended that more information on SES is captured for future studies in FE settings to better understand potential contextual influences and barriers.

We would recommend that other pilot trials and process evaluations of pilot interventions adopt a mixed-methods, socio-ecological approach. Although there were various limitations with our data collection methods, these were partially counter-acted by the use of multiple data sources to aid triangulation and fieldworker immersion to enhance depth of understanding, as well as robust review methods among the staff team. This included development of a framework for assessing individual results against research questions and group discussion of identified contradiction in the data. The strength of multiple data collection was further enhanced by the adoption of a socio-ecological lens, which ensured consideration of influences across individual, institutional and community levels. This ensured that data saturation was probably reached, with some inductive themes emerging via the data which could be researched further (e.g. peer influence and the role of institutional culture).

Staff and student views suggest that smoking cessation activities may be appropriate and acceptable in this setting and it is suggested that these should be a focus for further intervention development research. Should further research and development take place in FE colleges, key considerations would include timing of engagement and intervention delivery of smoking cessation activities. Overall, this study suggests that there will be greater value in smoking cessation intervention activities than smoking prevention activities. This is due to the relatively low number of student who reported taking up smoking in the first year of their FE courses combined with the low levels of acceptability regarding prevention messages in this context.

It was feasible to recruit, randomise and retain FE settings within a cluster RCT design. FE managers valued the opportunity to be involved in health research, particularly the input of external agencies and the additional resources provided, and accepted randomisation. However, further methodological work is recommended to improve student recruitment and retention rates prior to any larger RCTs being conducted in this setting. Problems with identification of baseline population would suggest potential delivery later in the academic year when the student population has stabilised. However, differences between school and college-based FE settings are important, with more vocational colleges likely to have more sporadic campus attendance than more academic settings, suggesting a need for novel approaches to student engagement and recruitment.

Finally, this study benefitted from extensive PPI with young people through the ALPHA youth group. We would recommend further PPI with young people to help steer more successful evaluation design and develop trial methods in future research. For example, young people should be consulted prior to new research to develop new interventions targeting cessation as well as prevention, or new research to develop methods for recruiting and retaining more young people in FE settings.

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Contributions of authors

Adam Fletcher planned and managed the project, including management of baseline survey collection, and led on development of data collection tools, the synthesis of quantitative and qualitative data sources to assess progression criteria, and reporting.

Micky Willmott led on the analysis and write-up of qualitative data and contributed towards to the synthesis of quantitative and qualitative data sources to assess progression criteria and report drafting.

Rebecca Langford managed the process evaluation, led on the collection and analysis of the qualitative data, consultation with young people and write-up of process evaluation findings.

James White conducted the statistical analysis, led on the drafting of the statistical findings sections, and contributed to drafting other sections of the report.

Ria Poole managed the collection and analysis of follow-up survey data and contributed towards report drafting.

Rachel Brown provided support to the team on drafting and editing the report.

Honor Young contributed to the collection of baseline and follow-up survey data and commented on report drafts.

Graham Moore contributed to project planning, advised on pilot outcomes, and commented on report drafts.

Simon Murphy contributed to project planning and commented on report drafts.

Julia Townson contributed to project planning and commented on report drafts.

William Hollingworth advised on the economic evaluation and commented on report drafts.

Rona Campbell contributed to project planning and commented on report drafts.

Chris Bonell supported the design of the process evaluation and contributed to project planning and report drafting.

Data sharing statement

We shall make data available to the scientific community with as few restrictions as feasible. Please contact the corresponding author if you would like to access the data.

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