Pilot trial and process evaluation of a multilevel smoking prevention intervention in further education settings

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Disclaimer: This report contains transcripts of interviews conducted in the course of the research and contains language that may offend some readers.

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Scientific summary

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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- to 15-year-olds, smoking continues to grow rapidly among older youth. With > 1.5 million British 16- to 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 life 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 Action on Smoking and Health (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, multilevel intervention targeting 16- to 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 scalability 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 or not prespecified 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 (RQs):

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

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 RQs:

7. What are students', staff's and intervention team members' experiences of the intervention and views about its potential impacts on health?
8. What are the barriers to, and facilitators of, implementation, and how do these vary according to college context and/or other factors?
9. Were there any unexpected consequences?
10. How acceptable were the data collection methods to students and staff, and do participants think longer-term follow-up via e-mail or telephone interview would be feasible?
11. 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 RQs:

12. Does the primary outcome measure (smoking weekly or more) have an acceptable completion rate, adequate validity and minimise floor/ceiling effects?
13. Do cotinine concentrations of saliva samples indicate any evidence of response bias between arms in self-reported smoking status?
14. Was it feasible and acceptable to measure all the secondary and intermediate outcomes of interest at baseline and follow-up?
15. 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 > 500 students) ($n = 2$), small FE college campuses (new intake < 500 students) ($n = 2$) and 'sixth form' colleges attached to schools ($n = 2$).

In order to assess the feasibility and acceptability of delivering and trialling the intervention according to prespecified criteria (objective 1), we collected a range of quantitative and qualitative data via semistructured 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 semistructured 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 RQs 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 (1-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 per 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 EuroQol-5 Dimensions, 5-level version (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 because of 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 the management of intervention, which also impacted on limited community-level activities targeting local shops.

Six colleges were randomised into the two trial arms and all were retained at the 1-year follow-up. Recruitment and retention of students was challenging, despite the use of the multiple methods and incentives. In September 2014, 1320 students out of an estimated total sample of 2363 participated in the baseline survey. Of these 14.0% ($n = 185$) were ineligible as they were aged < 16 years or > 18 years, and five students provided no data, leaving a baseline sample of 1130 (47.8%) students. Although this equates to a response rate of < 50%, the number of potentially eligible students at baseline ($n = 2363$) was provided by each institution and overestimates the actual number of new students aged 16–18 years in that setting, thereby underestimating the true response rate, especially in large FE settings, as a result of 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 > 18 years because of 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's 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 members 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 numbers of missing data for all pilot primary and secondary outcomes from the student baseline surveys completed in September 2014 ($n = 1130$ eligible participants) and in the 1-year follow-up surveys completed in September 2015 ($n = 412$ eligible participants). The prevalence of weekly smoking at baseline was 20.6% and was 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 because of 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 the intervention group (7.1%) than in the control group (2.9%).

Conclusion and recommendations

This 1-year pilot study is the first reported evaluation of a universal smoking prevention intervention in an FE context to date, and the first cluster randomised controlled trial (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 at 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.

Trial registration

This trial is registered as ISRCTN19563136.

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