



Research and Development

Commissioned Research

Short Report

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This report should not exceed 20 pages

Commissioned Research: Short Report

Project Title

2014 Tobacco Call: A randomised controlled trial evaluation of the Dead Cool (Cancer Focus NI) Smoking Cessation/Prevention Programme in Schools

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One page brief

Why did we start?

Smoking is still a persistent problem amongst young people in Northern Ireland. In recent year Cancer Focus Northern Ireland have been developing a smoking prevention programme, 'Dead Cool'. Staff from the School of Education at Queen's University Belfast responded to a commissioned-call to evaluate the Dead Cool programme as a smoking prevention programme. What follows is the report of the ensuing research.

What did we do?

The project

The evaluation of Cancer Focus Northern Ireland's (Cancer Focus NI) Dead Cool smoking prevention programme began on 1st September 2014 and comprised two strands:

- An efficacy randomised controlled trial (RCT) aimed at evaluating the impact of the programme on smoking outcomes and establishing potential for a full scale-up trial.
- Qualitative interviews with teachers and focus groups with young people aimed at understanding the process of programme delivery and exploring outcomes in more depth.

The aim of the current study

The aim of this study was to use a pragmatic randomised controlled trial design to assess the efficacy of the Dead Cool programme on smoking related outcomes in Year 9 young people and assess whether it may be suitable to proceed to full trial.

What answer did we receive?

The trial findings indicate that young people in the intervention group who received the Dead Cool intervention were less likely to begin to smoke and showed less intention of smoking than their control group counterparts. Evidence that the intervention group was less likely to begin to smoke was obtained from analysis of exhaled breath Carbon Monoxide levels. Carbon Monoxide levels were significantly lower in the intervention group when multi-level modelling was used to account for clustering effects. Results indicated that students from the intervention group reported minimally significant lower intentions to smoke than the control group. Findings are important given the low prevalence of smoking in this age group and the sample size used in this feasibility study. Given that all three of the main measures showed that the intervention group reported less smoking behaviour and less likelihood to smoke then it could be concluded that the Dead Cool programme shows promise as a smoking prevention programme for Year 9 students and is suitable for testing in a fully scaled randomized controlled trial.

What should be done now?

The research made the following conclusions and recommendations.

1. Dead Cool is effective in reducing the likelihood of beginning smoking in Year 9.
2. Young people who received the programme were less likely to say that they will try a cigarette than their control group counterparts.
3. Dead Cool is an inexpensive intervention. Teachers can be trained and given resource packs in twilight group sessions (i.e. those taking place between 4-6pm).
4. Dead Cool works as intended, encouraging young people to challenge those who influence smoking behaviour impact on future behaviour and intention to smoke.
5. Dead Cool was perceived by teachers to fill a gap in the curriculum. They reported that materials in the resource pack, and the DVD in particular, were enjoyed by students.
6. These findings are consistent with the existing of evidence around onset of smoking behaviour and contribute to the extant theoretical literature on planned behaviour.
7. Further research should include:
 - a. Follow up of the current cohort to measure the potential long term impact of Dead Cool
 - b. Ongoing evaluation and development of the programme based on study recommendations including a scaled randomised controlled trial

Background (Please duplicate page(s) if additional space is required)

The intervention

Dead Cool is a smoking prevention programme for Year 9 students designed by Cancer Focus NI. Year 9 students in Northern Ireland are normally in the range 13-14 years old. They are attending post-primary school by this stage. Post-primary school is used in Northern Ireland to refer to the disparate ‘secondary/high’ school system and includes secondary, grammar, ‘comprehensive’, religious affiliated, state run and independent schools that may be single sex or co-educational. Dead Cool is delivered by teachers and comprises four lesson plans (that can be delivered over five sessions if required) and accompanying resource pack and videos on a DVD. The programme aims to reduce the number of young people who start smoking and encourage them to challenge those who influence smoking behaviour such as friends, parents, other family members, and explore the influence of direct and indirect cigarette placement in the media. Teachers from the school deliver the programme in their own classes over a four-week period. The lessons last for approximately 40 minutes. There is an accompanying DVD of short video clips that supplement each lesson. Prior to the programme the students have an introductory session delivered by a Cancer Focus NI employee. The total time that the students are engaged by the programme varies between three to four hours during a period of up to six weeks. In addition to the ‘pack’ teachers receive 90 minutes of professional development where the focus and epistemology behind the product design is outlined.

Background

Research suggests that 7% of children aged 11-16 Northern Ireland were smoking in 2010 (Department of Health, Social Services and Public Safety Northern Ireland, 2012). In 2013, 19% of adults in Great Britain were smokers in 2013 (HSC, 2015). It is estimated that around 40% of regular smokers in Great Britain began smoking before age 16 (Office for National Statistics, 2013). Half of all smokers will die prematurely as a result of their smoking (World Health Organisation, 2006). Evidence shows that teenagers become quickly addicted to tobacco (DiFranza, Savageau, Fletcher, O’Loughlin, Pbert, Ockene & Wellman, 2007) and that those who begin to smoke earlier are more likely to be regular smokers in adulthood (Chassin, Presson, Sherman & Edwards, 2000; Taioli & Wynder, 1991).

In 2014, 26% of children in the UK aged between 11-15 years reported that it was “OK to try smoking” (Fuller, 2014). A number of factors have been found to be significant in influencing young people’s decision making and intentions regarding tobacco use. Children whose parents, siblings and/or peers smoke are more likely to become smokers themselves (National Health Service, 2013). The influence of parents and peers can be direct and indirect, with peers having a greater impact on behaviour than parents. (Vitória, Salgueiro, Silva, and de Vries, 2011). Recent research suggests that young people who notice tobacco point of sale displays and recognize a greater range of tobacco brands are more susceptible to smoking (Spanopoulos, Britton, McNeill, Ratschen and Szatkowski, 2014; Bogdanovica, Szatkowski, McNeill, Spanopoulos and Britton, 2015). *In an attempt to assess how tobacco features in popular media*, Cranwell, Murray, Lewis, Leonardi-Bee, Dockrell and Britton, (2015) *quantified* adolescents’ exposure to tobacco and alcohol content in the top 40 YouTube music videos over a 12 week period in 2013/14. *They found that tobacco related imagery was found in 22% of videos while e-cigarettes featured in 2% of samples. The use of electronic cigarettes and their impact on intention to smoke is currently a topic of significant debate. A largescale study in the USA found that e-cigarette use among adolescents who had never smoked was associated with intention to smoke* (Bunnell, Agaku, Arrazola, Apelberg,

Caraballo, Corey & King, 2014). Given the examples cited above, it is important that tobacco control policies target those most susceptible to becoming lifelong smokers and schools provide an ideal setting for such interventions (Marmot, Allen, Goldblatt, Boyce, McNeish, Grady, & Geddes 2010). While much focus has been given to smoking cessation programmes in the later teens, there is growing evidence that applying interventions underpinned by Planned Behaviour Theory may be helpful in delaying or avoiding smoking initiation (Hassandra, Vlachopoulos, Kosmidou, Hatzigeorgiadis, Goudas & Theodorakis, 2011).

Between 1998 and 2009 smoking rates in the UK reduced by 23%. This reduction can be attributed to tobacco control policies, such as tax increases, smoke-free air laws, the restriction of tobacco advertising and the increased availability of tobacco cessation services (Levy, Currie and Clancy, 2013). It is crucial that policy is informed by evidence. There is still some debate around the optimal time to intervene to prevent smoking initiation in young people. However, as initiation begins to increase around the ages of 11-12 years, this is potentially a good time to intervene (Fuller, 2014).

The aim of the current study

The aim of this study was to use a pragmatic randomised controlled trial design to assess the efficacy of the Dead Cool programme on smoking related outcomes in Year 9 young people and assess whether it may be suitable to proceed to full trial. In addition there was intent to examine the programme and make judgements regarding any adaptations and developments that might be required if attempts were to be made to scale Dead Cool into a full rigorous randomised controlled trial. A qualitative process evaluation was therefore conducted alongside the trial to explore the pathways through which the programme might work. Overall, this work aims to contribute to knowledge around the prevention of smoking initiation in Year 9 young people.

Aims & Objectives (Please duplicate page(s) if additional space is required)

The aim of the current study

The aim of this study was to use a pragmatic randomised controlled trial design to assess the efficacy of the Dead Cool programme on smoking related outcomes in Year 9 young people and assess whether it may be suitable to proceed to full trial.

Research questions

This project aimed to answer the following research questions:

- a) How effective is the Dead Cool programme at preventing the initialisation of smoking behaviours in Year 9 students?
- b) How effective is the Dead Cool programme at changing self-reported attitudes to smoking behaviours in Year 9 students?

Methods (Please duplicate page(s) if additional space is required)**Introduction**

A randomised controlled trial was undertaken to explore the impact of the programme on smoking related outcomes. Alongside this a qualitative process evaluation was conducted which aimed to explore the validity of the logic model and the pathways through which the programme might work.

This project, which will represent a significant test of the feasibility of the scaling of this project, will comprise a randomised controlled trial (RCT) design which will run alongside a process evaluation. As stated above the project will aim to evaluate:

- c) How effective is the Dead Cool programme at preventing the initialisation of smoking behaviours in Year 9 students?
- d) How effective is the Dead Cool programme at changing self-reported attitudes to smoking behaviours in Year 9 students?

In this respect then the primary outcomes from the study were exhaled breath CO measures and self-reported attitudes to smoking in Year 9 students in Northern Ireland. Alongside the RCT a process evaluation examined aspects of the Dead Cool programme that could be developed to enhance any observed effects and/or adapted if the programme proceeded to a full-scaled trial in the future. Smoking behaviours is used in terms of actual smoker/non-smoker status and planned intentions to smoke,

Randomised Controlled Trial*Design*

1. **Logic model development:** The team worked with the developers (Cancer Focus NI) to design a logic model for the intervention and explore the implications for the outcome and mediator instruments (see Appendix 1). The final choice of primary outcome measures was informed by the outcomes identified in the logic model. The logic model also helped situate the work within the most plausible Behaviour Change theoretic framework.
2. **RCT evaluation:** The main outcomes were evaluated using a pragmatic RCT with 'intention to treat' analysis. The RCT tested changes in self-reported attitudes and smoking behaviours, and actual smoking behaviours measures by exhaled breath CO levels, in the group that receives Dead Cool against a 'treatment as usual' (control) group. No placebo was used in this pragmatic RCT.
3. **Process evaluation:** A process evaluation complemented the RCT to measure the fidelity, delivery and acceptability of programme. This included: focus groups (n= 6) with young people taking part and interviews with teachers of classes taking part (n=6). In addition similar activities were undertaken in the control group to explore the counterfactual, for example what other smoking prevention interventions are currently being used in schools. Qualitative data was subjected to a thematic content analysis.

Sample

Staff at Queen's University Belfast recruited schools for this study independent from Cancer Focus NI. Prior to recruitment schools that had piloted Dead Cool were excluded from being involved in the main trial. This resulted in the exclusion of two schools from the recruitment process. 62 schools were then invited to take part in the study. Schools were identified as

being within a 30-mile radius of Belfast City Hall or were located in the South Eastern Library Board areas. Each of these areas would give close geographical access from the base of operations of the research team. Schools were provided with an information sheet that set out the aims, methods, intervention and commitments associated with being involved in the research. Schools were sent this information in the post and via email. Schools were asked to respond and express further interest in the programme. A total of 21 schools expressed an interest in receiving further information. Of these 18 schools committed to taking part after further discussion with the research team.

Randomisation

Northern Ireland has a diverse post-primary sector. The sample that was recruited for this study matched the funding available for the work. With a total sample of 20 classes being randomised, it was deemed necessary to randomise the sample using both ‘blocking’ and ‘minimisation’, in order to avoid risk of Type 1 error. In particular, adaptive randomisation was used on the basis of school type and free school meal percentage with additional checks being made on final intervention and treatment-as-usual groups to ensure parity in school size and free school meal percentage. There would be potential for skewness in the sample if simple randomization had been used. Post-primary schools were recruited including secondary /grammar/integrated/single sex/coeducational, rural and urban schools from both the maintained and controlled state sector and independent/voluntary sector schools. Northern Ireland has a complex post-primary school composition. This includes grammar and secondary sectors which are split between those associated with Catholic and Protestant Churches. In addition there are integrated schools with presence from both Catholic and Protestant Churches and independent schools (which may or may not have a religious affiliation). Schools may have co-educational or single sex intake. Obviously this disparate mix of school types needed to be balanced between intervention and treatment-as-usual groups to ensure parity between grammar/secondary school status (a proxy for student attainment at the end of Year 7), gender, ethnic background and socio-economic status. During recruitment to this sample, the evaluation team paired schools of a similar nature together. So, for example, two girls only, maintained, grammar schools were paired, two coeducational, controlled secondary schools were paired and so on. Then randomisation took place using adaptive minimisation at the pair level to ensure that there was balance in the type of school in the intervention and treatment-as-usual samples. Schools were rank ordered on the basis of free –school meal percentage (a proxy for socio-economic deprivation) and schools were block randomised to condition. When the first school was randomised in a block then schools were sequentially assigned to condition to ensure that even numbers of samples were present in each condition. Note that in a small sample of 20 classes it was perfectly possible to have ended up with uneven intervention and control group numbers if randomisation had taken place without blocking.

A total of 18 schools agreed to take part. It was noted that only a single school from each of three categories of school had opted to take part in the study. These schools were a maintained all boys secondary school, a maintained all girls secondary school and a large rural location integrated controlled school. Within these schools it was decided to select one intervention and one treatment-as -usual class. This was decided due to the risk of the sample being skewed by one of these types of school being randomly assigned to either condition. The issue of contamination and counter measures to mitigate this was discussed

with the head teachers and teachers undertaking the intervention in these schools. Therefore, 21 classes were randomised to either condition. After randomisation, but before treatment, it was announced that one of the schools was to be closed as a result of budget cuts and it dropped out of the study, leaving 20 schools in the sample. Table 1 shows free school meal and school size data for the samples. There were no significant differences between the intervention and control on the basis of free school meals ($F(1, 19)=0.54, P=0.47$) or school size ($F(1, 19)=0.06, P=0.80$).

Table 1: Mean free school meal and school size data for the samples

	Free school meal (SD)	School size (SD)
Intervention N=10	26.36 (10.54)	881.55 (402.10)
Control N=10	30.56 (15.40)	922.7 (338.59)

Intervention – The Dead Cool Programme

Fidelity: Teachers were asked to complete a record form for each Dead Cool session they delivered. The information they were asked to record included how much of the programme session content was covered, attendance in class and satisfaction with resources. Completed booklets were returned directly to the research team who collated this information to provide a measure of the quality and consistency of programme implementation.

Control Group: Children in classes allocated to the control group did not receive the programme but instead continued as normal.

Outcomes and Measures

The RCT aimed to test outcomes identified in the logic model. This was by measuring changes in outcomes between the intervention and control groups over the period of programme delivery. Outcomes and measures are described below.

All pupils taking part underwent testing on the following measures before, immediately after, and up to three and a half months after the intervention:

- a. Smoking behaviour (measured using Carbon Monoxide monitor and by self-report questionnaire administered by Research Health Visitor).
- b. Short and medium term intention to smoke (by self-report questionnaire administered by Research Health Visitor).
- c. Level of ‘treatment’ involved collecting data from teachers on pupil attendance at sessions where the programme was delivered. This will measure the fidelity and delivery of the programme.

Instruments

Questionnaire: The research team developed a survey comprising 27 items for use with the Year 9 sample. The items were a combination of previously used questions and new items (contact the authors for a copy of this document which was included in the interim report). Unless otherwise specified, items were selected from the Smoking, Drinking and Drug Use among Young People Survey (Fuller, 2012). This survey series began in 1982 and has been widely used and adapted by other researchers (e.g. Spanopoulos, Britton, McNeill, Ratschen

& Szatkowski, 2014; Campbell Starkey, Holliday, Audrey, Bloor, Parry-Langdon, & Moore, 2008). The 2012 survey achieved a sample of 7,589 pupils aged between 11 and 15 in 254 schools. It has clear protocols for question design and clearly defined marking and scoring scales (NatGen, 2012). It should be noted that data was collected that went beyond the primary outcome of smoking behaviour. This was to allow more fine-grained analysis of influence on smoking behaviours. Analysis and interpretation of this large data set is ongoing and goes beyond the original application protocol and findings reported in the present report. Only data related to the original protocol is presented in this report and additional data from other items will be reported elsewhere. There were some issues with scaling of these instruments. However, the deficiencies in terms sensitivity of scaling and nominal scaling were felt acceptable to be able to employ well used and independently generated measures to assess planned smoking behaviours.

Exhaled CO level: The PICOSimple Smokelyser was chosen as a reliable instrument for measuring exhaled air CO. This quick and cost effective measure has been used for some time to assess smoking status. Exhaled CO is a proxy for measurement of CO Haemoglobin levels. Those who have smoked in the hours leading up to the test are reported to have exhaled CO levels of >10ppm. Smokers of more than 20 cigarettes per day will record CO levels of 20-30ppm and heavy smokers of greater than 30 cigarettes per day will record CO levels in excess of 30ppm (Kendrick, 2015). In terms of cut off points, there has been some debate. One study found that when smokers and non-smokers were looked at as a whole, a cut off of 6.5 ppm had a sensitivity of 90% and specificity of 83% (Deveci, Deveci, Açık, & Ozan, 2004). Others have argued for more stringent cut off points such as 5ppm (Perkins, Karelitz, & Jao, 2013). However, most studies have reported a non-smoking/smoking border of 9ppm exhaled Carbon Monoxide. This would be within one standard deviation of levels reported by Deveci *et al.*, (2004) and in line with the level reported in a 'light smoker' by Kendrick (2015). Two PICOSimple Smokelyser were used to speed up sampling in large classes and as a contingency measure should a machine malfunction during attesting period. The PICOSimple Smokelyser is self-diagnosing and requires recalibration every six-months. If calibration is required sooner then the machine senses this and gives a warning (Bedfont, 2015). During the sampling period (which was shorter than six-months) there was no indication that either of the PICOSimple Smokelyser machines required recalibration. A student was only considered to have started smoking if their pre-test exhaled CO was <9ppm and their post-test exhaled CO was >9ppm.

Data collection

Data collection was carried out between November 2014 and June 2015. Both experimental and control groups were tested at three points during the evaluation as described in Table 2:
 Time 1 (baseline): children were tested before the programme was implemented.
 Time 2 (post-test 1): children were tested directly after the programme ended.
 Time 3 (post-test 3): children were tested up to 3.5 moths after the programme had ended.

Table 2. *Description of the outcomes and measures at pre- and post-test*

Outcome	Measures
Demographics (items 1-5)	Age, gender, postcode, ethnicity and detail on who the child lives with
Smoking behaviour(items 6-17)	Smoking behaviour past and present
Intention to smoke (Items 18-20)	Assesses susceptibility and intention to smoke and ask respondents to report on a five-point Likert scale from definitely yes to definitely not (Pierce, Choi, Gilpin, Farkas, & Berry, 1998).
Carbon Monoxide Measurement	A hand-held PICOSimple Smokelyser was used to measure expelled air Carbon Monoxide in the students at the three testing time points.

Statistical analysis

Main analysis

Data were analysed using SPSS (version 21) and STATA (version 12). Data preparation involved checking the proportion of missing data and that minimum and maximum values were within the appropriate range. Descriptive statistics were generated for each variable and the distribution checked. Internal reliability was evaluated using Cronbach’s alpha. The core demographic characteristics of the intervention and control groups were compared and differences between groups across pre-test scores were evaluated. Due to slight, but non-significant, differences in post-test scores on the main outcome measures, it was decided that ANCOVA and regression would present the best analysis approach. In particular, items 18-20 from the survey focussed on the main outcome measures of smoking and intention to smoke would be deemed suitable for analysis by ANCOVA. Due to the scaled nature of the exhaled CO measure this variable would be analysed using multi-level modelling to establish patterns of changes within clusters (in this instance the classroom that the intervention was delivered in). The exhaled breath Carbon Monoxide levels also presented data on a scale that met criteria for analysis by multi-level modelling. Analysis was undertaken on an ‘intention to treat’ basis.

The selected sample size should be large enough to detect an Effect Size of +0.25 at 80% power and alpha=0.05 if analysed by ANCOVA. This analysis is judged to be valid due to the strong influence that the family unit is reported to have on smoking behaviours in socio-economically deprived families. A study of 508 families with children aged 11-13 years old found that parental smoking behaviour was the largest influence on adolescent smoking behaviour (William & William, 1994). The trial is an efficacy trial and has limited funding to explore clustering effects of the classroom/school setting. However, the sample was large enough to detect Effect Sizes of 0.4 with an ICC of 0.05 and 20 classes of at least 20 students in each, to analyse CO in exhaled breath. HLM analysis explored clustering effects of classroom/school on outcomes in the trial as peer influence has also been reported to be important in predicting adolescent smoking behaviours (Wang, Fitzhugh, Westerfield & Eddy, 1995) and the intervention was delivered at the class level.

Process evaluation

The purpose of the qualitative element of the evaluation was threefold:

1. To provide a commentary on the process of the evaluation
2. To qualitatively test the theory hypothesised in the Dead Cool logic model
3. To explore participant (teacher and student) satisfaction and engagement with the Dead Cool programme

These aims were explored from the perspectives of teachers delivering the programme and young people participating in Dead Cool. Four of the 10 intervention schools were selected for interview in order to represent diversity in term of geographic location (rural/urban setting) and school type (selective/single sex/coeducational/religion). In each school, the Principal was contacted in writing and asked to facilitate the research and allow the use of the school premises for conducting the focus groups. Four teachers in participating schools were invited and agreed to take part and three focus groups were conducted with 6-10 students in each.

The data from the interviews were analysed using a broad interpretive qualitative approach based on the principles of thematic analysis (Braun and Clarke 2006). Thematic analysis is a flexible and descriptive method that allows the emergence of a narrative to formulate the important features relevant to the research questions. With prior consent qualitative interviews and were tape-recorded and transcribed verbatim.

Ethics

The study was approved by the School of Education, Queen's University Belfast Ethics Board. Information sheets were provided to all participants and opt out consent from students, teachers and senior management teams in schools was required to participate in the study.

Analysis (Please duplicate page(s) if additional space is required)

Sample Characteristics

Data was collected from 480 students. Mean age of the control group was 12.51 (SD 0.51) years and of the intervention group it was 12.50 (SD 0.51) years. Ages between groups did not differ significantly ($F(1, 478)=0.06, p=0.81$). The sample was composed of 229 female students, 250 male students and 1 student who did not identify their gender. The ethnicity of the sample was 305 white Irish, 135 white British, 21 Asian, 5 African, 4 Chinese and 5 other ethnicity not defined in the questionnaire. 129 students were from Grammar School and 351 were from Secondary School. In terms of school type, 123 were from the Controlled Sector, 282 from the Maintained Sector and 75 were from the Integrated Sector. 410 students were based in urban locations and 70 were based in a rural location. Pre and post-test data was collected for 399 students. 7 students were excluded from the study because they were giving exhaled CO breath readings that indicated they were already smoking. Other students (76 in total) were sampled at pre or post test, but were absent either for the companion pre or post testing session due to school absence on the day of testing and have also been excluded from analysis due to missing baseline or outcome data.

Pre test prevalence of cigarette smoking/intention to smoke and comparability between groups

At pre-test, 7 out of 399 students presented Carbon Monoxide (CO) exhaled breath tests that indicated they were smokers. These 7 students had exhaled CO levels of greater than 9ppm (mean=11.14 with *SD* 2.91, range 9-17). This would indicate that these students had started smoking, but would not yet be heavy smokers. 39 students refused to take a CO test at pre-test and 48 students refused to take a CO breath test at post test. One student had to leave the lesson before a breath test was completed and so completed the survey, but did not give a CO level breath test. These students may have been smokers. Self-report of smoking indicated that 19 of these students self-reported that they were smokers, with 3 students choosing not to answer that question on the survey. Of those self-reporting as being a smoker, 12 students who self-reported that they were smokers did not present a CO breath test level greater than 9ppm. It is assumed either that smoking frequency levels in the 12 of the cases who self-reported smoking were not yet of the magnitude to raise exhaled CO breath levels to greater than 9ppm, or their smoking reports were false positives. Therefore smoking levels for the group could be reported as between 1.75% as a lower limit (those who had levels of CO in exhaled breath that confirmed they were smokers), to 5.01% (those who either self-reported they were smokers or who chose not to provide an answer as to whether they were smokers in the survey) or as an upper limit 12.78% (the number of positive breath tests added to those who refused a breath test, assuming those that refused did so because they were smokers).

Pre test characteristics of the intervention and control samples on pre test measures indicated that mean exhaled CO of the intervention group, 2.48 (SD 1.82) ppm was significantly higher than exhaled CO breath of the control group, 2.09 (1.35) ppm when analysed using ANOVA ($F(1, 397)=6.01, P<0.05$). ANOVA indicated that mean pre test responses to survey items ‘Do you think you will try a cigarette soon?’ (scored 0=no, 1=yes) were not significantly different being 0.27 (SD 0.71) for the control and 0.30 (SD 0.80) for the intervention group ($F(1, 390)=0.21, p=0.648$). Neither were pre test differences for the survey item ‘Do you think you will smoke a cigarette at any time in the next year?’ (scored 1=yes to 5=no on a five-point

Likert scale) 4.7 (SD 0.66) control and 4.56 (0.95) for intervention ($F_{1,390}=3.00, p=0.084$).

Carbon Monoxide in exhaled breath

Mean pre and post test t1 and post test t2 Carbon Monoxide reading in parts per million (ppm) for control and intervention samples are presented in Table 3.

Table 3: Student pre and post test t1 and post test t2 Carbon Monoxide reading in parts per million (ppm)

Group	Pre test CO ppm (SD)	Post test t1 CO ppm (SD)	Change at t1	Post test t2 CO ppm (SD)	Change at t2
Control	2.09 (1.35) n=197	1.81 (1.02) n=154	-0.28	1.56 (2.19) n=141	-0.53
Intervention	2.48 (1.82) n=202	1.90 (1.47) n=175	-0.58	1.27 (1.24) n=150	-1.21
Total	2.29 (1.61) n=399	1.85 (1.28) n=329		1.41 (1.77) n=291	

The decision was taken to use 9ppm as the entry level exhaled breath CO to indicate smoking behaviours. This was based on previous reports that indicated that exhaled breath greater than 9ppm was indicative of smoking and that levels were not significantly different in children and adults. Exhaled CO levels have a half life of about 5 hours. In addition level of CO at 9ppm would not be presented due to 'passive smoking', which would remain lower than 8ppm (Deveci *et al.*, 2004; Kendrick, 2015). Students with a Carbon Monoxide reading greater than 9ppm at pre-test are excluded from data analysis. These would already be classified as smokers and therefore, would not be targeted by this smoking prevention intervention. Analyses were undertaken on students who had a pre-test Carbon Monoxide level of less than or equal to 9 ppm. This was because the programme was a smoking prevention, rather than cessation programme and these students were already being classified as smokers. This excluded 7 students from the study. Effect Size indicated that exhaled CO measurements were lower at post-test (correcting for pre tests differences) in the intervention group and of a magnitude of -0.38 or mean exhaled CO measurements were 0.38 of a standard deviation lower in the intervention than the control group.

Multi-level modelling and clustering effects

Analysis was performed on the sample that scored less than 9ppm on the CO reading at pre-test. This excluded data from students who were already identified as smokers. The aim was to model potential differences due to the programme at Post-test t1 (immediately at the end of the intervention) and at post-test t2 (about 3 months after the end of the intervention). The following models were used in the analysis and models are presented in Table 4:

$$\text{Model A: } \text{Post-test } t2_{ij} = \beta_{0ij} + \beta_1 (\text{pre-testscore}_{ij}) + \beta_2 (\text{interventiongroup}_{ij})$$

$$\text{Model B: } \text{Post-test } t1_{ij} = \beta_{0ij} + \beta_1 (\text{pre-testscore}_{ij}) + \beta_2 (\text{interventiongroup}_{ij})$$

Table 4: Multi-level model analysis of exhaled breath Carbon Monoxide

Description	Outcomes	
	Model A post test t2	Model B post test t1
	coef. (s.e.)	coef.(s.e.)
Pretest	.08(.07)	.20(.05)
Group (Intervention)	-.65 ^a (.29)	.17 ^b (.19)
Constant	1.45(.27)	1.25(.21)
-2 Log Likelihood	-552.49824	.494.24163
School level variance (s.e.)	.48(.22)	.47(.18)
Pupil level variance (s.e.)	2.47(.21)	1.07(.09)
Intraclass correlation	.22	.26
Effect size	-.37	.13
95% confidence intervals	-.05, -.70	.40, -.15
N(groups)	289(17)	328(17)

^a p=.03 (significant finding), ^b p=.37 (not significant)

There was no significant effect of the intervention on the CO levels of the students at post-test t1 when controlling for pre-test scores (p=.37, ES=.13). However, the intervention showed longer term benefits. There was a significant difference between the students' levels of carbon monoxide in the intervention group and control group at the second post-test when controlling for the pre-test scores. The intervention group had a significantly lower reading of carbon monoxide at the second post-test in comparison with the control group (p=.03, ES=-.37). This finding indicated that even when taking into account the clustered nature of the data, the Dead Cool programme students showed significantly lower levels of Carbon Monoxide in exhaled breath than the control students. This was indicative of significantly lower levels of smoking in the intervention group. It was not possible to explore data further with a more fine grained model that looked at issues such as school type, sex or socio-economic factors as potential moderators of the effect because of limitations of sample size.

Data indicated that three students who were not smokers at the start of the intervention started to smoke and gave positive CO exhaled breath tests in the control group, but no students were in this position in the intervention group. This represented a reduction in smoking in 1.8 students per hundred. This gives a number needed to treat figure of 55.55 (i.e. treat 55.55 children to stop one smoking case).

Self-reported intention to smoke

The self-reported intention to smoke of intervention and control groups at pre and post test t1 and post test t2 are reported in Table 5. Responses to survey item 18 'Do you think you will try a cigarette soon?' were coded No=0, Don't know=2, Yes=4. A lower score on this question indicates a lower intention to smoke.

Table 5: Self-reported intention to smoke of intervention and control groups at pre and post test t1 and post test t2 in response to the question ‘Do you think you will try a cigarette soon?’

Group	Mean response at pre test	Mean response at post test t1	Change at t1	Mean response at post test t2	Change at t2
Control	0.27 (0.71) n=194	0.32 (0.77) n=170	+0.05	0.46 (1.05) n=167	+0.19
Intervention	0.30 (0.80) n=198	0.42 (1.00) n=190	+0.12	0.40 (0.93) n=171	+0.1
Total	0.29 (0.76) n=392	0.37 (0.90) n=360		0.42 (0.97) n=338	

Students with a Carbon Monoxide reading greater than 9ppm at pre-test are excluded from data. These would already be classified as smokers and therefore, would not be targeted by this intervention.

Students reported increasing intention to try a cigarette during Year 9. The increases were greater for the control group compared to the intervention group. ANCOVA indicated that differences at post test t2-were not significant when corrected for pre-test differences ($F(1, 329)=0.74, p=0.39$). The test was underpowered (14%) due to the interaction of the sample size and the Effect Size. Effect Size indicated that self-reported intentions to smoke were lower at post-test (correcting for pre tests differences) in the intervention group and of a magnitude of -0.51, (i.e. 0.51 of a standard deviation on the intentions scale lower in the intervention than the control group.

Missing data in this survey item was very low with only one student refusing to answer the question. Therefore, imputation was not required nor undertaken in this section of the data set.

In the control group at pre-test, one student reported that they would try a cigarette soon, This number remained at one at t1, but had risen to 8 students at t2. In the intervention group 3 reported they would try a cigarette soon at pre-test, rising to 5 at t1 and 8 at t2.

The self-reported responses to the question ‘Do you think you will try a cigarette in the next year?’ are reported in Table 6. This item was scaled 1-5 with poles marked ‘Definitely yes’ (1) and ‘Definitely no’ (5). Data from this response is presented in Table 6.

Table 6: Self-reported intention to smoke of intervention and control groups at pre and post in

response to the question ‘Do you think you will try a cigarette in the next year?’

Group	Mean response at pre test	Mean response at post test t1	Change at t1	Mean response at post test t2	Change at t2
Control	4.70 (0.66) n=196	4.67 (0.71) N=173	-0.03	4.74 (0.62) n=159	+0.04
Intervention	4.56 (0.82) n=198	4.52 (0.91) N=186	-0.04	4.54 (0.98) n=166	-0.02
Total	4.63 (0.82) n=392	4.59 (0.82) n=359		4.55 (0.85) n=332	

Students with a Carbon Monoxide reading greater than 9ppm at pre-test are excluded from data. These would already be classified as smokers and therefore, would not be targeted by this smoking prevention intervention. ANCOVA indicated that differences between groups were minimally significant ($F(1, 332)=3.56, p=0.06$) with an Effect Size of -0.09 indicating that those in the control group reported slightly lower intentionality towards smoking a cigarette than those in the control group by 0.09 standard deviations. It should be noted that this analysis is underpowered at 46%. It would not have been appropriate to use multi-level models on the reported behaviour outcomes because of the binary nature of responses.

The frequency of responses to this question are reported in Table 7. The frequencies show that self-reported intentions to smoke in the next year remain largely static, but with slight decreases in the intervention group, and slight increases in the control group.

Table 7: Frequency of self-reported intention to smoke of intervention and control groups at pre and post in response to the question ‘Do you think you will try a cigarette in the next year?’

Responses	Number of responses at pre-test		Number of responses at post test t1		Number of responses at t2	
	Control	Intervention	Control	Intervention	Control	Intervention
Definitely yes	1	4	2	3	1	2

Probably yes	1	5	0	5	2	5
Not sure	13	14	12	16	16	19
Probably not	26	23	25	32	21	24
Definitely not	155	149	134	134	120	122

4. Findings from the Process Evaluation

Introduction

This section presents the findings from the qualitative process evaluation that was undertaken to examine the implementation and fidelity of the Dead Cool Smoking prevention programme in post primary schools in Northern Ireland and more specifically:

- How the programme was delivered across different sites, identifying any variations in implementation and any other relevant factors where differences may be evident (e.g. whether all lessons were covered, timetable, resources).
- To provide insights into elements of the programme that tended to work or not, and the reasons why.
- To explore the experiences and perspectives of key stakeholders on the programme, the extent to which the programme was delivered and issues raised and some of reasons or the findings to subsequently emerge from the main trial.

Process Evaluation

It is important to know *how*, *why* and *if* interventions such as Dead Cool works and to understand which programme components are critical, how they work and interact within the constraints of real-world settings. This includes exploring whether the target audience can be reached, how users respond to the intervention, examination of barriers to and facilitators of implementation and how these are related to the outcomes data (Greenberg et al., 2005). Therefore we need to know how the programme is delivered, how it is received, how people respond to it and how the context influences all of these. Implementation data are vital for interpreting outcomes and conclusions cannot be drawn about the effectiveness of a programme unless the extent to which the programme has been implemented has also been considered (Durlak, 1998). This section provides evidence from an overview of the key stakeholders’ views and perceptions of the implementation and fidelity of the Dead Cool programme relating to programme content, training and support, programme limitations and challenges. This is followed by a description of the stakeholders’ perceptions of the benefits of the Dead Cool programme and a final section on suggestions from the key stakeholders for how the programme may be improved further.

Methodology

A process evaluation was conducted alongside the randomized controlled trial in order to provide data on programme implementation and to capture the perceptions and experiences of key stakeholders’ engagement with the programme. Key areas explored were the quality of implementation of the intervention, fidelity and perceived programme outcomes. Four

teachers in participating schools agreed to be interviewed and three focus groups were conducted with 6-10 students in each. The data from the interviews were

Findings

Implementation and Fidelity

Overall the programme was delivered with high fidelity. Of the 10 schools delivering the intervention, seven completed and returned the *Programme Fidelity Proforma* supplied by the research team (see Appendix 2). All responding schools completed all four programme lessons. However, due to time constraints only 3 schools managed to complete only one of four possible extension activities. The mean time spent on class preparation was 17 minutes and the mean class length was 41 minutes.

The passionate commitment of staff involved with implementing the Dead Cool programme emerged from the interviews with the key stakeholders. This importance is reflected in the quotes below:

'I really enjoyed doing the Dead Cool lessons with my form class. I have them for an hour every week so I was able to fit in the preparation and delivering it no problem'.

'I am their year head and the initial contact came to me and I'd spoken to my line manager who said definitely go ahead and I choose the class I wanted to do it with cause I knew there were for a start a lot of smokers in the family and I thought these are the children that might benefit or being most easily influenced'.

Although all of the teachers reported being able to deliver the four core lessons from the Dead Cool programme, the majority of the teachers interviewed referred to time constraints being a challenge to implementing the optional extension activities as well as the core activities.

'I think it takes longer than 4 weeks. I think that's quite ambitious, there's a lot of material in it and then you get into doing group work, discussion work, with the best intention in the world, group work especially by the time you set it up, give them time to do it and then the plenary at the end, if there's a 10 minute slot allowed for it you can easily double it if not triple that time'.

On a similar note, some tensions around the time constraints due to 30-minute teaching periods within the school timetable were highlighted. In one case, classes were divided into half hour periods so the teacher had to plan a double period on the timetable to deliver the Dead Cool Lesson. This was considered challenging at times but it was reflected that having more time to plan facilitating the Dead Cool programme in advance of next year's timetable would facilitate a more seamless delivery of the programme. A description of this is below:

'We have half hour periods so we were trying to have to do part of it and think where's a good place to stop and pick it up next lesson. So sometimes we were running one lesson over 2 days. That was difficult at times but next year our timetable is changing completely and we are having 45min periods. It will be easier to fit the Dead Cool in because we are planning that timetable now'.

Programme content

The majority of references to the Dead Cool curriculum and teaching materials outlined by the teachers were very positive. Areas that were considered as very strong were the four lesson themes and it was suggested by most of the teachers that these aligned with various parts of the Year 9 curriculum. This is reflected in the comment below:

'I think it is really cross curricular, all that stuff about smoking really you could incorporate into the sciences, or lifelong learning and certainly the Personal Development Curriculum'.

Teachers and students were very positive about the materials used to support the Dead Cool programme, in particular references to the films being fun to watch, good for prompting discussion and high level of engagement from the students.

'The DVD worked well as a discussion starter... now perhaps the students that were on it were a bit more... streetwise..... because they were city based I thought perhaps our students found them maybe a little bit unrealistic for them but it definitely got a discussion going'. (Teacher)

In a similar narrative a teacher highlighted that a benefit of the group work from the Dead Cool programme involved a constructive interaction among the students, by encouraging a connectedness and sense of responsibility between the students to not ever take up smoking. This important point is reflected in the comment below:

'I suppose it has given the class a sense of togetherness. I believe the group now are saying 'we are not going to do this', so I think if they found out someone in the group was smoking, I think the rest of them would nearly be on top of them saying 'do you not remember the Dead Cool programme'.

Teachers reported that the pupils really enjoyed the Northern Ireland and local context of the Dead Cool programme. One teacher stated:

'In terms of improving the programme I felt that because the videos were local as well as the young people in them were from Northern Ireland, the students loved that, and they loved the debating nature. I can't think of any problems other than it led into other discussions that we didn't have time to go into'.

The general consensus from the majority of teachers was that the Dead Cool programme content complemented the Personal Development learning and was considered a key building block in enriching this experience for the student in the school. The importance of this is reflected in the comments below:

'I felt it fitted in well with the PD Programme, I think it's a topical issue that they're (the students) interested in cause it did combine the media and smoking'.

'Yes, cause drugs education is a key component of the Personal Development Programme at all Key Stages'.

When asked about the technical aspects of implementing the programme, teachers suggested the links to the media features were effective as most schools are linked up to Wi-

Fi. Teachers made comments as below:

'I think the links to the media and films on YouTube are good, because we have surround Wi-Fi and it just saves sorting out equipment and stuff to play DVD's'.

'Having the all the resources provided with the Dead Cool pack, you know the DVD, the film clips and all the works books linked in, I did like that aspect of it'.

The pupils when asked about the contents of the Dead Cool programme were very enthusiastic and most of them were able to recall some of the details of their favourite parts:

'I liked doing the presentation on how the media influenced us'.

In one of the focus groups a student referred to the name of the programme 'Dead Cool' not being suitable. This then led other student's to reiterate some similar responses. This is reflected in the comments below:

"Dead Cool" its really a bit cheesy, they should change the name'.

'I don't like the name at all, I think it's a bit of a weird name'.

Training and Support

Dead Cool programme fidelity is supported by mentoring from Cancer Focus NI. Teachers undergo a half day of training from Cancer Focus NI prior to commencing the programme. The trainer provides ongoing mentoring support by being available via telephone or email if required. All of the teachers that were interviewed were positive about the training and support they received and in particular they were positive about ongoing support and communication with the service.

'Oh it was good to have a discussion with other teachers to see how they were going to implement it or just even have our own discussions in the group about problems different Schools have. It was delivered well, I mean I didn't feel at any stage that I didn't know what I was doing and if I did have any questions I did email the trainer, maybe once or and that was easily solved'.

Benefits

The overwhelming majority of pupils from all of the groups when asked what they had learned from the programme, enthusiastically made reference to an increased knowledge on the awareness of the influences of the media and tobacco industry. The pupils spontaneously linked learning outcomes from the programme with concepts relating to gaining more knowledge about what influences their thoughts on smoking and the power of this, as well as the concept of addiction and the cost of smoking.

'So just for example say your idol is Taylor Swift said she smoked and she started smoking in one of her videos, people would think oh she's young enough, she's cool, let's try this, it's cool, she's doing it, she's like my idol'. (Female student)

'Dart players are getting sponsored by Tobacco Company's like Michael Van Georling is

sponsored by ZigZag and Golden Virginia. He's got that all over his t-shirt cause he's been given money to sponsor like cigarettes. Like there's a load of people that watch darts and they're obviously going to see like if he likes smoking and is sponsored then they're obviously going to want to do it cause they look up to him and do everything he does'. (Male student).

Teachers felt that the majority of pupils were more aware of the social influences on smoking such as media, peers and family.

'The main learning I think for our students is they are now more aware of smoking and the myths around it and they are analysing the influence of media in a bit more depth.....and realising that they are being manipulated a wee bit'.

One teacher further noted that the Dead Cool programme appeared to help young people think about what influences their decisions on smoking without using scare tactics:

'It has helped them be more aware of the influences on them so that they won't start smoking or if they are smoking they might consider, do I really want to be doing this without the shock factor. It was more to inform them and give them facts but without scaring them'.

Several teachers commented that the programme made the students think about the financial cost of smoking.

'I think what really came through the programme for them was seeing that idea that people are making big money out of them smoking, they were horrified'. (Teacher)

'They don't care if they're like their (the tobacco industry) buyers are dying, they don't care they just want more money, it's disgusting that they don't even care about other people and they're selling stuff that could kill them, just think they want the money'.

A few students mentioned that the programme overall helped them reflect and think about smoking, which is not something that was previously on their mind. They suggested that the Dead Cool programme helped to reaffirm their opposition and future intentions to smoking in this regard. Student's comments reflect this below:

'I have never actually thought about smoking before, but after the Dead Cool I am never going to smoke'.

Main Challenges

As previously mentioned teachers reported time constraints as a challenge and these fell broadly into two categories: time constraints related to fitting the programme within class periods and secondly finding extra time to implement the extension and group activities.

'We have half hour periods so I was trying to do part of it and think where's a good place to stop and pick it up next lesson. So fortunately the class I did it with I had them last thing, well nearly last thing on a Monday and first thing on a Tuesday so they hadn't forgotten

everything’.

Again time constraints were mentioned as a challenge, particularly with optional extension activities within the Dead Cool programme.

‘I think it takes longer than 4 weeks. I think that’s quite ambitious, there’s a lot of material in it and then you get into doing group work, discussion work, with the best intention in the world, group work especially by the time you set it up, give them time to do it and then the plenary at the end, if there’s a 10 min slot allowed for it you can easily double it if not triple that time’.

Summary of process evaluation

Key stakeholders were very positive regarding the benefits of the Dead Cool programme and highlighted the students’ increased awareness of the pervasive influences of the media and tobacco industry. The pupils linked learning outcomes from the programme with concepts about what influences their thoughts on smoking and the power of this, as well as the concept of addiction and the cost of smoking. Teachers reported few difficulties in engaging the students with the programme. Overall, the interviews with the teachers and students disclosed a strong sense of engagement and supportiveness for the Dead Cool programme. However one issue that the majority of teachers appeared to agree upon was time constraints related to the delivery of some of the activities within the programme over and above the four core lessons.

Discussion (Please duplicate page(s) if additional space is required)

Significantly lower levels of exhaled breath Carbon Monoxide readings were found in the Dead Cool group compared to the control group at post-test t2 when multi-level modelling analysis of the data was undertaken (adjusting for pre-test differences). This analysis took account of clustering. Clustering could have influenced outcomes due to two factors. The intervention was delivered at the class level in schools. Given the selective nature (on the basis of academic attainment or sex) of the majority of schools in the sample, it is probable that the intervention would have differing impacts on different groups of students, but that these impacts would be similar within classes. Given that peers are reported to have the greatest impact on smoking behaviours (compared to parents), this could amplify clustering effects in the data (Vitória et al., 2011). Imputation was not used in this analysis. Imputation is very common in smoking prevention studies. All studies (49 in total) reviewed by Thomas, McLellan and Perera (2013) used some form of imputation. However, the nature of imputation varied from sample norms, to predicting norms for the specific sub-population that had missing data. The latter appeared to be the most standard use of imputation. It was judged that not enough was known about patterns of data and patterns of missing data to use imputation in this instance.

No students in the Intervention Group presented CO exhaled breath readings that indicated they had started smoking during the intervention period. This was compared to three students in the Control Group presenting test data that indicated they had started to smoke. Placed at the correct moment in the school curriculum Dead Cool seems to prevent smoking behaviours. Extrapolation beyond the time period of the intervention and measurement period is speculative. However, *if* the short-term benefits persisted over time the potential health and financial benefits of Dead Cool could be modelled. If the potential health and financial benefits if the Dead Cool programmes were scaled to be implemented in all Northern Ireland schools, and the observed benefits were sustained over time, the effect of this can be estimated from the data. Extrapolated out, this would result in maybe 7.5 fewer deaths per 100 population due to smoking related disease (if smoking initiation could be stopped due to an intervention in Year 9). This may have a long terms effects of cutting smoking related deaths by (1326/year) or smoking related hospital admissions (9663/year) in Northern Ireland according to current estimates given by the BMA (2015). However, the longevity of the changes beyond this point was not established. Further study is needed to follow up the study group and ascertain whether the accrued benefits sustain over an extended time period.

Students in the intervention group were less likely to express intention to smoke at post-test. While these results were minimally significant when analysed by ANCOVA, careful interpretation is required. The prevalence of smoking behaviour in this age group is very low, meaning that a very large sample would be required to demonstrate statistically significant differences between control and intervention groups at this age. It is therefore encouraging to observe positive change in the intervention group. It has previously been reported that the significant predictor of intention to smoke is the attitudes of students and the student perception of what the student's significant others think about smoking. Dead Cool is delivered at the class level. That means that the 'significant others' from the students' own classes are also exposed to the intervention. The intervention also actively works on student attitudes towards smoking. Getting students to understand their own thinking, unpack what they think about smoking and why they think that should lead to development of student

metacognitive understanding on the topic. This should help students in understanding their cognition (or understanding of smoking issues), and also help students understand their affective approach towards smoking. This would involve both cognitive aspects of thinking i.e. why would I smoke/not smoke (taking into account issues of health, cost, media manipulation), affective aspects such as how do I feel about smoking, how do I feel about my health and how do I feel about media and advertisement manipulation of me and my generation and the metacognitive, i.e. how do I know what I know, am I secure in my knowledge and understanding? A critical component of this process will be the fact that students actively engage in effective groupwork during the Dead Cool programme. Each session involved cooperative group work. Use of cooperative groupwork has been reported to promote metacognition during learning (Campione *et al.*, 1995). In addition the cooperative learning activities that involved role-play would allow students to recognize their behaviours, shifting responsibility to them for the self-regulation of their own behaviour. These are reported to be essential components for the development of self-regulation and metacognition. In turn self-regulation and self-actualization are essential for transfer of planned behaviours to lived/actual behaviour (Simons, 1994). As evidence suggested that planned behaviour had resulted in reduced smoking in the Dead Cool group then the transfer of learning could be assumed to have taken place. This has been previously reported in academic contexts of learning in primary/post-primary schools (Thurston *et al.*, 2009), and this study indicates similar processes may be active in successful smoking prevention programmes.

In relation to programme delivery, it is notable that the Dead Cool programme was delivered with high fidelity, with all lessons being delivered in all of the intervention schools. This was seen as being the result of the clearly defined structure of the resources and the training and on going support provided to the teachers in the school. Several teachers remarked that time constraints meant that they were unable to deliver the extended activities offered by the programme (outside of the core activities) and it was suggested they would plan extra time to include these extra activities in the future. Teachers rated the resources highly and found that students engaged readily with the materials, particularly the DVD. The programme was well received in the schools overall and felt to include good resources and felt to be linked closely with the Northern Ireland Curriculum particular the element on Personal Development learning. Teachers noted that students developed an increased awareness of the pervasive influences of the media and the tobacco industry. The students demonstrated that they had learned more about what influences their thoughts on smoking, as well as the concept of addiction and the cost of smoking.

Limitations

A limitation to be considered is the representativeness of the sample and the generalizability of the results. It is not unusual for studies of this nature to attract participants who are self-selecting and motivated, who may seek out similar programmes to participate in. This can mean that the gap between control and intervention group is narrowed. Missing data may have played a part in findings. If cotinine levels had been measured instead of Carbon Monoxide (this would have been considerably more expensive and was outwith the budget of this study) then maybe there would have been fewer missing data. Alternatively testing could have taken place in a private area. However, this would have taken a lot longer and been

more disruptive to the school day resulting in attrition at the school, rather than the individual level. The differences in outcomes between the ANCOVA and the multi-level modelling indicated that there were some clustering effects. Further analysis of what caused these effects was not possible due to the small sample size. A future study in the Northern Ireland context may want to ensure a large enough sample to undertake sub-group analysis (again this was outwith the budget of this project).

5. Recommendations

A number of recommendations have emerged from both the trial and process evaluations.

1. There is significant evidence that the 'Dead Cool' programme showed impact on smoking behaviours of post-primary year 9 students. The programme could be delivered in the present format and with current content with reasonable security that it would have impact on smoking behaviour of Year 9 students.
2. Nearly 5% of students recorded exhaled breath CO measurements that indicated they were already smoking at the start of Year 9. Cancer Focus NI may consider delivering the programme during Year 8.
3. There was time pressure on teachers to fit lessons into the allotted timetabled period of about 40 minutes duration. Cancer Focus NI should consider expanding programme to a minimum of six lessons of slightly shorter duration. Splitting the content of the pack into separate lessons and developing an additional lesson to be delivered by teachers as an introductory session could achieve this.
4. Students reported some issues with the name of the programme 'Dead Cool'. The programme relies on quite subtle development of affective responses and self-actualisation of these. The reference to 'Dead' may be at odds with the aims and techniques of the programmes. Cancer Focus NI should consider a name change that captures the nuanced sophistication of the programme using focus groups of young people.
5. There is limitation in terms of applying generalizability to findings as there were some school effects. Additional funding should be explored to try and scale up to a full trial that allows an appropriate sample to explore differential effects on outcomes in the differing post-primary sectors in NI.
6. The logic model developed by the Cancer Focus NI team with research staff from QUB appears to represent a good fit to process of change associated with the intervention.

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