



Protocol: A randomised controlled trial evaluation of Cancer Focus NI's 'Dead Cool' smoking prevention programme in post-primary schools



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ABSTRACT

This paper presents a research protocol for a randomised controlled efficacy trial of the 'Dead Cool' smoking prevention programme. Dead Cool is a three to four-hour programme designed to be used by teachers with Year 9 students in Northern Ireland. The main outcome of the programme is to prevent students from starting to smoke. The protocol reports a research design intended to test the efficacy of the programme in 20 post-primary school settings. Selected schools included those from secondary /grammar/integrated/single sex/coeducational, rural and urban schools from both the maintained and controlled state sector and independent sector schools. Outcome measures include self-reported behaviours, monitoring of carbon monoxide (CO) in exhaled breath and focus groups designed to assess implementation fidelity and opinions on efficacy in intervention schools and explore the 'counterfactual' potential treatments in control schools.

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1. 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). Children whose parents, siblings and/or peers smoke are more likely to become smokers themselves (Leonardi-Bee, Jere, & Britton, 2011). 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 Organization, 2006). Evidence shows that teenagers become quickly addicted to tobacco (DiFranza et al., 2007) and that those who begin to smoke earlier are more likely to be regular smokers in adulthood (Chassin, Presson, Sherman & Edwards, 1990; Taioli & Wynder, 1991).

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, 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 et al., 2011).

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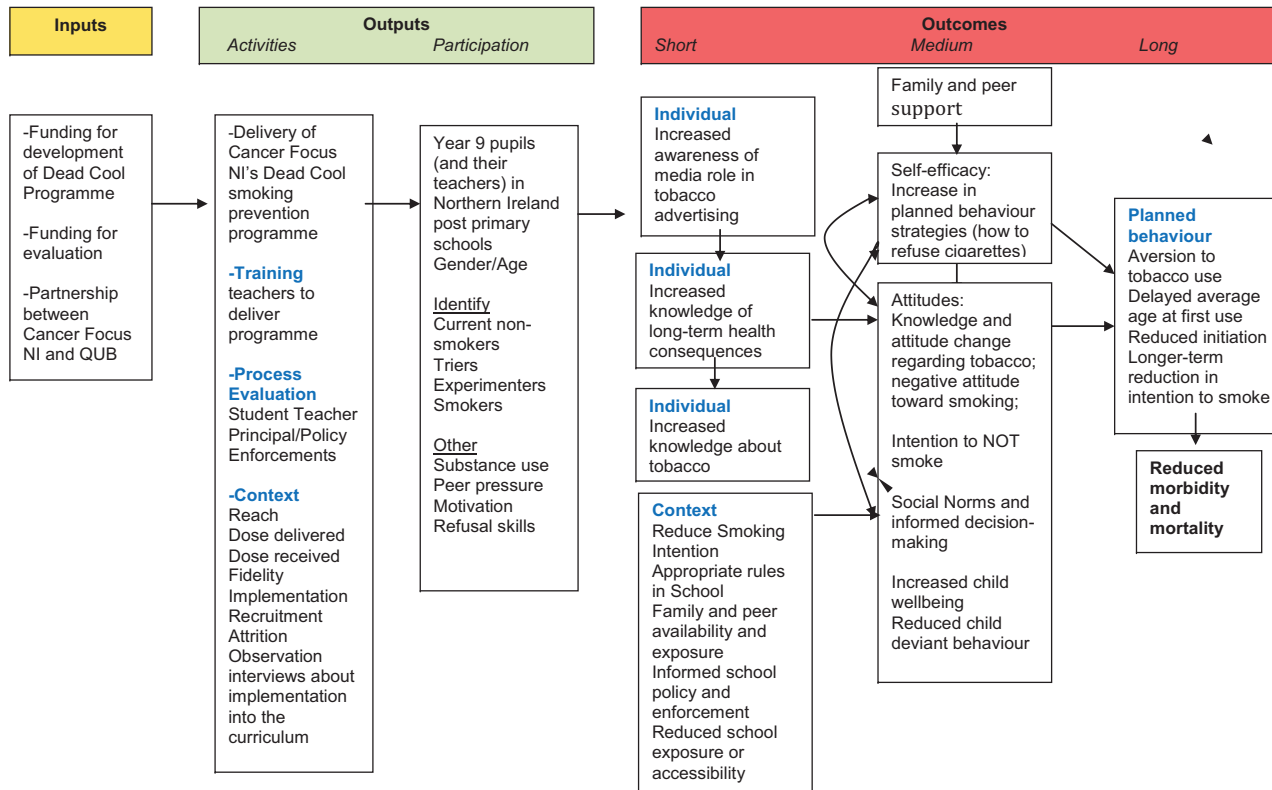


Fig. 1. Dead Cool Logic Model Dead Cool Logic Model.

2. Intervention

Dead Cool is a smoking prevention programme for Year 9 students designed by Cancer Focus NI. Students in Year 9 in Northern Ireland normally range from 13 to 14 years old. Dead Cool is designed to be delivered by teachers and comprises four lesson plans and an accompanying DVD available as a pack. 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 presence 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 20–30 min. 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 exact total time that the students are engaged by the programme varies between three to four hours. In addition to the 'pack' teachers receive 90 min of professional development where the focus and epistemology behind the product design is outlined.

3. Research plan

3.1. Research questions

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. The project will aim to evaluate:

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

In this respect then the primary outcomes from the study will be self-reported attitudes to smoking in Year 9 students in Northern Ireland. In addition there will be monitoring of exhaled breath CO. Alongside the RCT a process evaluation will examine what aspects of the Dead Cool programme could be developed to enhance any observed effects.

The survey will also examine secondary outcomes based on risk-taking behaviour and will also look at exhaled CO levels in Year 9 students.

3.2. Design summary

1. Logic model development: The team has 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 Fig. 1). This will be useful for evaluation and for situating it within the post plausible Behaviour Change theoretic framework.
2. RCT Evaluation: The main outcomes will be evaluated using an RCT with 'intention to treat' analysis. The RCT will test changes in self-reported attitudes and smoking behaviours in the group that receives Dead Cool against a 'treatment as usual' (control) group. No placebo will be used in this pragmatic RCT.
3. Process evaluation: A process evaluation will complement the RCT to measure the fidelity, delivery and acceptability of programme. This will include: focus groups ($n=6$) with young people taking part and interviews with teachers of classes taking part ($n=6$). In addition similar activities will be undertaken in the control group to explore the counterfactual, for example what other smoking prevention interventions are currently being used in schools. Qualitative data will be subject to a thematic content analysis using NVIVO

4. Outcome measures

All pupils taking part will undergo testing before and after the intervention:

- a. Pre-test—smoking behaviour in last week (measured using carbon monoxide monitor, administered by Research Health Visitor). Occasional, experimental and ex-smoking behaviour will be measured by questionnaire prior to the introduction of the programme. Questions designed to capture the influence of friends, parents and family and media will be included.
- b. Post-test—the measures carried out in (a) will be repeated one week and 3.5 months after the intervention has been delivered.
- c. Level of 'treatment' will involve collecting data from teachers on pupil attendance and content covered at sessions where the programme was delivered. This will measure the fidelity and delivery of the programme.

5. Instruments

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. Unless otherwise specified, items were selected from the smoking, drinking and

drug use among young people survey (Fuller & Hawkins, 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 et al., 2008). The 2012 survey achieved a sample of 7589 pupils aged between 11 and 15 in 254 schools. It has clear protocols for question design and clearly defined marking and scoring scales (NatCen, 2012).

The first section of the survey (Items 1–5) asks about demographics such as age, gender, postcode, ethnicity and detail on who the child lives with.

The next group of questions (6–17) explore smoking behaviour, past and present. This includes peer and family smoking behaviour and attitude to smoking; exposure to smokers e.g. at home and in cars. Each question had a unique scaled response appropriate to the question being asked. One of this set (Item 13) asks the student to name their five best friends in the class, putting a mark alongside the name of their best friend. This item seeks to explore whether social networks can affect peer behaviour (Hunter et al., 2015).

The next three questions (18–20) were used to assess 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). Question 21 includes seven items about perceptions of friends and peer smoking behaviours with respondents asked to answer “true” or “false” to each item (Spanopoulos et al., 2014). The next questions (Item 22) ask respondents to rank their self-perceived wellbeing using a scale developed by the Children’s Society, based on Huebner’s life satisfaction scale (Rees, Bradshaw, Goswami, & Keung, 2010). A further set of four questions (Item 23) were included to measure rebelliousness and sensation seeking using four items on a four point Likert scale ranked “exactly like me” to “not at all like me”. Cronbach’s alpha values for these items were 0.76 when reported in a sample of 660 elementary- and middle-school children and 168 clinic-referred male children during a study undertaken in the United States (Russo et al., 1993).

The research team added another question (Item 24), asking if the student had ever stayed off school without permission. They were also asked how their school did and should educate students about smoking (questions 25 and 26). Finally, the team added two questions (questions 27 and 28) to reflect access to and disposal of pocket money (Cremers, Mercken, Oenema, & de Vries, 2012)

A hand-held PICOSimple Smokelyser (Bedfont) will be used to measure expelled air carbon monoxide in the students at the three testing time points. This is a calibration free electrochemical sensor which measures CO in parts per million (ppm). It measures a range of 0–100 ppm with an accuracy of $\pm 2\%$. This will be administered by a trained/registered nurse who was part of the research team.

6. 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 2 schools from the recruitment process. Over 60 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 in the South Eastern Library Board area. 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 if they were interested 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. This number will yield a total study sample of approximately 560 students.

6.1. 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.

The characteristics of the sample of schools indicated that there would be great potential for skewness in the sample if simple randomisation had been used. Post-primary schools were recruited; secondary /grammar/integrated/single sex/coeducational, rural and urban schools from both the maintained and controlled state sector and independent 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

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

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

Table 2

Workplan and timeline for the protocol.

Task	Date/deadline	Responsibility
Develop survey measure; methods of data collection are established and tested and proven to be robust	August 2014	Allen Thurston, Laura Dunne, Aideen Gildea, Anne Lazenbatt, Frank Kee
Develop logic model for Dead Cool	August 2014	Allen Thurston, Laura Dunne, Aideen Gildea, Anne Lazenbatt, Frank Kee
Recruit schools to trial and randomise to condition	October 2014	Allen Thurston, Laura Dunne, Aideen Gildea
Train teachers	November 2014	Cancer Focus, Laura Dunne, Aideen Gildea
Collect pre-test data in schools	November/ December 2014	Laura Dunne, Aideen Gildea
Collect post-test data in schools (Time 1)	February 2015	Laura Dunne, Aideen Gildea
Collect post-test data in schools (Time 2)	June 2015	Laura Dunne, Aideen Gildea
Conduct qualitative interviews with teachers and focus groups with students	February/March 2015	Laura Dunne, Aideen Gildea
Analyse data on outcomes:	September 2015	Allen Thurston, Laura Dunne, Aideen Gildea, Anne Lazenbatt
a Interview and focus groups		
b Critical analysis of effective components of Dead Cool (obtained through exit/change interviews with teachers and focus group students)		
Data analysis on outcomes including:	September 2015	Allen Thurston, Laura Dunne, Frank Kee
a Probability analysis on planned smoking behaviour		
Impact activities undertaken as highlighted in 'Pathways to Impact' document including:	December 2015	Allen Thurston, Laura Dunne, Aideen Gildea, Anne Lazenbatt
a Participating schools will be provided with project findings.		
b Launch event at Queen's University Belfast: This will be held at a time and date whereby teachers and students could attend and will be publicised and accompanied by a press release. The CEE is a collaborator in the Science Media Centre who will advise on the strategy for capturing press interest.		
c Peer reviewed publications: Staff in CEE have a strong track record in publishing work on refereed academic journals. Work will be published in targeted international academic journals.		
d Conference presentations: Prior to publication in journals project staff will present data at international conferences. This will publicise results of the research.		
e Presentations to Trusts		
f Presentations to regional School Principal meetings in Northern Ireland		
g Presentations to Northern Ireland Assembly		
h Newsletters to schools: Centre for Effective Education Newsletter drop to Northern Ireland schools (CEE uses Campaign Manager to disseminate materials in this way)		
i Social Media: Centre for Effective Education Twitter and Facebook newsfeeds would be used to publicise results (currently these have approximately 700 followers). In addition, the final report will be made available via the CEE website.		
Draft report written and made available to Cancer Focus NI for comment	November 2015	Allen Thurston, Laura Dunne, Aideen Gildea, Anne Lazenbatt, Frank Kee
Final report written and submitted to PHA	December 2015	Allen Thurston, Laura Dunne, Aideen Gildea, Anne Lazenbatt, Frank Kee

from both Catholic and Protestant Churches and independent schools (which may or may not have a religious affiliation). Obviously this disparate mix of school types would need 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. Consequently, two girls only, Catholic maintained, grammar schools were paired; two coeducational, Protestant controlled secondary schools were paired and so on. Then randomisation took place 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 has taken place without blocking. Overall, stratifying on the basis of socioeconomic background led to better balance across the intervention and control groups, so that factors such as gender, school type are more evenly distributed between the two conditions and skew is less likely in the sample.

A total of 18 schools agreed to take part. It was noted that only a single school from three categories of school had opted to take part in the study. These schools were a Roman Catholic maintained all boys secondary school, a Roman Catholic maintained all girls secondary school and a large rural integrated controlled school. Within these schools it was decided to allocate 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 this, was discussed with the head teachers and teachers undertaking the intervention in these schools. Therefore, 21 classes were randomised to 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. [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 ($F(1,19)=0.06, P=0.80$).

7. Analysis plan

A two-way ANOVA pre vs posttest vs condition will be undertaken. If it is established that there are pre-test differences between the control and intervention samples then pre-test data will be used as a covariate and ANCOVA will be undertaken. Analysis will be undertaken on an 'intention to treat' basis.

8. Sample size calculations and analysis

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 two-way ANOVA or 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](#)). This trial is an efficacy trial and has limited funding to explore clustering effects of the classroom/school setting. However, if Effect Sizes >0.5 then analysis will explore 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](#)).

This trial might be best described as a feasibility RCT which may establish what the likely Effect Sizes of the intervention are and would inform a future trial of materials if effects are positive. We will interpret the findings in the context of the RE-AIM framework to ensure that we have a clearer understanding of the reach, effectiveness, adoption, implementation and maintenance of the programme.

9. Personnel

Professor Allen Thurston, Professor of Education, Director of Centre for Effective Education, Queen's University Belfast.
 Dr Laura Dunne, Senior Research Fellow, Centre for Effective Education, Queen's University Belfast.
 Ms Aideen Gildea, Research Assistant, Centre for Effective Education, Queen's University Belfast.
 Professor Frank Kee, Director, UKCRC Centre of Excellence for Public Health Research (NI), Queen's University Belfast.
 Dr Anne Lazenbatt, NSPCC Reader, School of Sociology, Social Policy and Social Work, Queen's University Belfast.
 Professor Sir John Britton, Director of the UK Centre for Tobacco Control Studies, Nottingham.

10. Timeline

The workplan and timeline for the protocol is presented in [Table 2](#).

11. Ethics

Ethical approval has been granted by the School of Education Ethics Committee, Queen's University Belfast.

The project will also adhere to the American Educational Research Association (AERA) guidelines on ethics, the professional body of the Principal Investigator and a body within which he is an office-bearer. Data handling, storage and security, will be ensured to meet acceptable ethical standards. In addition the study protocol has been approved by Queen's University Belfast School of Education Ethics Committee. Both the young person and their parents will be assured that what is communicated in the course of research will remain confidential to the research team, unless abuse/significant harm is disclosed, in which case the research team will follow our NSPCC protocol for informing the relevant professionals. All young people, parents and therapists will be provided with written information about the study prior to the RCT. Participation in the study is by voluntary informed consent, obtained by the researcher prior to all stages of data collection, allowing an

opportunity for the young person, parents and therapists to ask questions. A copy of the consent form will be given to the young person, parent, and therapist to keep, and copies retained by the researcher. It must be stressed that all participation is voluntary and all young people, parents and professionals may withdraw from the study at any time and for any reason. All withdrawals will be documented and the reasons, if given, recorded. Study documentation will be completed up to the point of withdrawal.

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