

# Evaluation of Cancer Focus Northern Ireland's 'Dead Cool' smoking prevention programme in Northern Ireland post-primary schools

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| <b>Submission date</b><br>27/04/2017   | <b>Recruitment status</b><br>No longer recruiting             | <input type="checkbox"/> Prospectively registered<br><input checked="" type="checkbox"/> Protocol |
| <b>Registration date</b><br>25/05/2017 | <b>Overall study status</b><br>Completed                      | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>19/02/2020       | <b>Condition category</b><br>Mental and Behavioural Disorders | <input type="checkbox"/> Individual participant data  |

## Plain English summary of protocol

### Background and study aims

Dead Cool is a smoking prevention programme for Year 9 students designed by Cancer Focus NI. It is delivered by teachers and comprises an introductory session followed by four lesson plans and accompanying videos on DVD. It is available as a pack to schools. 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 impact of direct and indirect cigarette promotion in the media. The aim of this study is to assess the impact of the Dead Cool programme on smoking in Year 9 students and assess whether it may be suitable to test in a larger study.

### Who can participate?

Students in Year 9 (normally aged 13-14) at state-funded secondary schools

### What does the study involve?

Participating schools are randomly allocated to either deliver the Dead Cool smoking prevention programme or to not deliver the programme. Teachers deliver the programme in their own classes over a four-week period. The lessons last for about 40 minutes. There is an accompanying DVD of short video clips that supplement each lesson. Before the programme the students have an introductory session delivered by a Cancer Focus NI employee. The total time that the students are involved in the programme varies between three to four hours during a period of up to six weeks. Teachers also receive 90 minutes of professional development. The participants' smoking behaviour is measured using a Carbon Monoxide monitor and a questionnaire at the start of the study and after 3 and 6 months.

### What are the possible benefits and risks of participating?

The study may help prevent Year 9 students from starting to smoke and may raise awareness of product placements by tobacco companies. For those already smoking the Carbon Monoxide result would reveal their smoking to the researchers (note this is not revealed to classmates or teachers).

Where is the study run from?  
Queen's University Belfast (UK)

When is the study starting and how long is it expected to run for?  
September 2014 to July 2015

Who is funding the study?  
1. Public Health Agency (UK)  
2. Cancer Focus NI (UK)

Who is the main contact?  
Prof. Allen Thurston

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Allen Thurston

**ORCID ID**  
<http://orcid.org/0000-0001-9518-3257>

**Contact details**  
School of Social Sciences  
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BT71LN

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
CFNI001

## Study information

**Scientific Title**  
A randomised controlled trial evaluation of Cancer Focus Northern Ireland's 'Dead Cool' smoking prevention programme in Northern Ireland post-primary schools

**Study objectives**

The principal research question is: How effective is the Dead Cool programme at preventing the initialisation of smoking behaviours in Grade 8 students?

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

School of Social Sciences, Education & Social Work Ethics Committee, Queen's University Belfast, 29/05/2014

### **Study design**

Cluster randomised controlled trial

### **Primary study design**

Interventional

### **Secondary study design**

Cluster randomised trial

### **Study setting(s)**

School

### **Study type(s)**

Prevention

### **Participant information sheet**

See additional files

### **Health condition(s) or problem(s) studied**

Smoking prevention

### **Interventions**

Participating schools are randomised to deliver the Dead Cool smoking prevention programme or 'treatment as usual'.

### **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.

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. The lessons engage the students in cooperative learning. The lessons create learning contexts where social interdependence is required for success (Johnson, Johnson & Roseth, 2010; Johnson & Johnson 2012):

1. Goal structure (the groups work together with the aim of completing a group booklet about social and media issues surrounding smoking)
2. Positive interdependence (in the cooperative learning processes clear tasks are assigned within each group whereby group members take responsibility)
3. Individual accountability (all group members must contribute and express opinions to allow

the booklet to be completed)

4. Interaction patterns (the cooperative learning processes were structured to stimulate promotive interaction, group processing and enhance social skills)

### **Intervention Type**

Other

### **Primary outcome measure**

Smoking behaviour, measured using a Carbon Monoxide monitor and by a self-report questionnaire administered by Research Health Visitor at baseline, 3 months and 6 months

### **Secondary outcome measures**

Short and medium term intention to smoke, measured by self-report questionnaire administered by Research Health Visitor at baseline, 3 months and 6 months

### **Overall study start date**

01/09/2014

### **Completion date**

01/07/2016

## **Eligibility**

### **Key inclusion criteria**

1. State funded post-primary (secondary) schools willing to be randomised and deliver the intervention if selected for the intervention group
2. Students in Year 9 (normally in the range 13-14 years old)

### **Participant type(s)**

Other

### **Age group**

Child

### **Lower age limit**

13 Years

### **Upper age limit**

14 Years

### **Sex**

Both

### **Target number of participants**

20 classes

### **Total final enrolment**

17

### **Key exclusion criteria**

At the individual level those who were already smoking were excluded from analysis

**Date of first enrolment**

01/06/2015

**Date of final enrolment**

01/12/2015

## **Locations**

**Countries of recruitment**

Northern Ireland

United Kingdom

**Study participating centre**

**Queen's University Belfast**

Belfast

United Kingdom

BT71LN

## **Sponsor information**

**Organisation**

Public Health Agency

**Sponsor details**

12-22 Linehall Street

Belfast

United Kingdom

BT2 8BS

**Sponsor type**

Government

**ROR**

<https://ror.org/03ek62e72>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

Public Health Agency

**Alternative Name(s)**

PHA

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Other non-profit organizations

**Location**

United Kingdom

**Funder Name**

Cancer Focus NI

## Results and Publications

**Publication and dissemination plan**

Planned publication in a high-impact peer reviewed journal with submission in June 2017

**Intention to publish date**

01/06/2017

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study will be stored in a publically available repository: <http://pure.qub.ac.uk/portal/en/datasets/search.html>

**IPD sharing plan summary**

Stored in repository

**Study outputs**

| Output type                                   | Details   | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|--------------|------------|----------------|-----------------|
| <a href="#">Participant information sheet</a> |   | 24/05/2017   | 25/05/2017 | No             | Yes             |
| <a href="#">Protocol article</a>              | protocol  | 01/01/2016   | 19/02/2020 | Yes            | No              |
| <a href="#">Results article</a>               | results   | 01/01/2019   | 19/02/2020 | Yes            | No              |
| <a href="#">Results article</a>               | results of secondary analysis on social environment | 28/08/2019   | 19/02/2020 | Yes            | No              |