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

Submission date
27/04/2017

Recruitment status
No longer recruiting

Registration date
25/05/2017

Overall study status
Completed

Last Edited
19/02/2020

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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Protocol serial number
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

Primary study design
Interventional

Study design
Cluster randomised controlled trial

Study type(s)
Prevention

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(s)
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

Key secondary outcome(s)
Short and medium term intention to smoke, measured by self-report questionnaire administered by Research Health Visitor at baseline, 3 months and 6 months

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

Healthy volunteers allowed
No

Age group
Child

Lower age limit
13 Years

Upper age limit
14 Years

Sex
All

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
United Kingdom

Northern Ireland

Study participating centre

Queen's University Belfast
Belfast
United Kingdom
BT71LN

Sponsor information

Organisation
Public Health Agency

ROR
https://ror.org/03ek62e72

Funder(s)

Funder type
Government

Funder Name
Public Health Agency

Alternative Name(s)
Public Health Agency (PHA), Public Health Agency (Northern Ireland), HSC Public Health Agency, publichealthni, PHA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Cancer Focus NI

Results and Publications

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

Study outputs

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