Evaluation of In:tuition - life-skills based interactive teaching resource for primary and secondary schools (study 1 10-and 11-year-old children)

Submission date 21/05/2013	Recruitment status No longer recruiting	 Prospectively registered Protocol
Registration date 29/07/2013	Overall study status Completed	 Statistical analysis plan [X] Results
Last Edited 06/02/2017	Condition category Other	[] Individual participant data

Plain English summary of protocol

Background and study aims

In:tuition is a life-skills education programme which aims to build young peoples confidence, personal and social skills, helping them to explore how they make decisions so they can understand what might influence them. One of its ultimate aims is to reduce alcohol misuse but its focus is wider, addressing a range of relevant personal needs in an age-sensitive way.

Who can participate? Students in year 5 of primary school.

What does the study involve?

In:tuition is being trialled in primary schools. We ask year 5 children a series of questions in the summer term 2013. They are then randomly allocated either to receive either In:tuition or their normal Personal, Social and Health Education provision during the autumn term 2013 and spring term 2014 i.e. when they are in year 6. In summer 2014, they are asked the same questions to determine whether In:tuition has worked.

What are the possible benefits and risks of participating? The programme may improve young peoples confidence, personal and social skills.

Where is the study run from?

The study is being run by National Foundation for Educational Research and takes place in 79 primary schools from across England (UK)

When is the study starting and how long is it expected to run for? October 2012 to March 2015

Who is funding the study? Alcohol Research UK Who is the main contact? Dr Ben Styles b.styles@nfer.ac.uk

Contact information

Type(s) Scientific

Contact name Dr Ben Styles

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers NFER1

Study information

Scientific Title

Cluster-randomised trial of a life-skills programme to manage peer pressure for 10- and 11-yearold children

Acronym INTU1

Study objectives

The aim of this study is to evaluate whether the use of the In:tuition teaching resource improves confidence to manage peer pressure in 10 and 11 year-olds.

Ethics approval required

Old ethics approval format

Ethics approval(s)

National Foundation for Educational Research's Code of Practice Committee, 09/05/2013

Study design Cluster randomised trial

Primary study design Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

Other

Study type(s)

Quality of life

Participant information sheet

See additional files

Health condition(s) or problem(s) studied

Peer pressure management in children

Interventions

Interventions as of 06/02/2017:

Schools are randomly allocated to intervention and control. Schools were randomised in five blocks. Block sizes are 46, 12, 10, 10 and 1. Schools are aware of their group allocation when they completed the baseline questionnaires, as they are simultaneously notified of their group and asked to complete questionnaires.

Intervention arm: The primary school programme consists of 12 lessons (a period of 40 minutes is recommended for each lesson). Alcohol is its theme but the focus is much wider and also includes:

- 1. Self-awareness
- 2. Attitudes and behaviour
- 3. Advertising, branding and the media
- 4. Personal choices
- 5. Emotions, communication skills and assertive behaviour
- 6. The influence of peers
- 7. Toal setting and confidence.

In:tuition uses a 'life skills approach' to help pupils learn and practice some important skills such as communication, working as a team and decision-making. The programme can be delivered through Personal, Social, and Health Education (PSHE) and Citizenship teaching but schools can also adopt a cross-curricular approach. Some digital tools are included, but each lesson has a paper-based alternative available to download. Home learning tasks are included to encourage discussion with parents/carers and promote consistent messages to young people at home and school.

Control arm: Control schools continued with their normal PSHE/alcohol education curriculum.

Original interventions:

In:tuition is a free life-skills based interactive teaching resource for primary and secondary schools developed by alcohol education charity Drinkaware.

Duration of intervention: 12 weeks of one lesson per week.

The participants are randomised to two groups:

The experimental group will consist of 875 pupils across 35 schools who shall receive the In: tuition programme over 12 weeks; one lesson per week.

The control group will consist of 875 pupils across 35 schools who shall receive their normal Personal, Social and Health education.

Intervention Type

Other

Phase Not Applicable

Primary outcome measure

1. Resistance skills (confidence to manage peer pressure)

All outcomes are measured using a bespoke questionnaire that consisted of new questions, questions from Fuller (2013) and questions from Lynch et al. (2013) at baseline and 12 months.

Secondary outcome measures

- 1. Knowledge of health effects of alcohol
- 2. Decision-making skills
- 3. Understanding of social norms relating to alcohol

All outcomes are measured using a bespoke questionnaire that consisted of new questions, questions from Fuller (2013) and questions from Lynch et al. (2013) at baseline and 12 months.

Overall study start date

25/10/2012

Completion date 09/03/2015

Eligibility

Key inclusion criteria Students in year 5 of primary school

Participant type(s) Patient

Age group Child

Sex Both **Target number of participants** 1750 students across 70 primary schools.

Key exclusion criteria Parental opt-out

Date of first enrolment 15/04/2013

Date of final enrolment 16/07/2013

Locations

Countries of recruitment England

United Kingdom

Study participating centre National Foundation for Educational Research The Mere Upton Park Slough United Kingdom SL1 2DQ

Sponsor information

Organisation Alcohol Research UK (UK)

Sponsor details 4th Floor 17-23 Willow House London United Kingdom SW1P 1JH +44 (0)20 7821 7880 jamesnicholls@alcoholresearchuk.org

Sponsor type

Charity

Website

http://alcoholresearchuk.org/

ROR https://ror.org/00dpq7q77

Funder(s)

Funder type Charity

Funder Name Alcohol Research UK (UK)

Alternative Name(s)

Funding Body Type Private sector organisation

Funding Body Subtype Other non-profit organizations

Location United Kingdom

Results and Publications

Publication and dissemination plan

Planned submission of another publication to the International Journal of Health Promotion and Education for publication.

Intention to publish date 06/02/2018

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available upon request from Dr Ben Styles (b.styles@nfer.ac.uk)

IPD sharing plan summary

Available on request

Study outputs					
Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Funder report results	results	01/03/2015		No	No
Participant information sheet		06/02/2017	06/02/2017	No	Yes