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A brief alcohol intervention to prevent hazardous drinking in young people aged 14-15 in a high school setting

Submission date
11/08/2011

Recruitment status
No longer recruiting

Registration date
26/09/2011

Overall study status
Completed

Last Edited
21/07/2015

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Early and heavy drinking by younger adolescents is a significant public health problem which is linked to intellectual impairment, increased risk of accidents, injuries, self harm, unprotected sex, violence and sometimes accidental death. To date, there has been very little work in the UK on early identification (screening) and brief intervention to reduce risky drinking in this age group. This research aims to test if it is possible to conduct a research project with younger adolescents attending high school, and their parents, which tries to reduce risky youth drinking.

Who can participate?
All year 10 students (aged 14-15) will be invited to take part in the study in seven high schools in the North East of England (North Tyneside, Tyne and Wear).

What does the study involve?
Students will be randomly allocated to one of three groups:
Control group: Standard alcohol advice as delivered as part of the school curriculum in Personal, Social and Health Education (PSHE).
Level One Intervention group: In addition to PSHE the young people who screen positively for alcohol misuse using the alcohol screening questionnaire will take part in a 30 minute personalised session delivered by the Learning Mentor (LM) (at school) of structured feedback about their drinking behaviour and advice about the health and social consequences of continued hazardous alcohol consumption. The young people will also receive a healthy living booklet and information on local sources of help for drinking problems. The intervention encompasses the elements of the FRAMES approach for eliciting behaviour change (Feedback, Responsibility, Advice, Menu, Empathy and Self-efficacy).
Level Two Intervention group: In addition to PSHE and the level one intervention, the young people will be invited to attend a subsequent one hour session of behaviour change counselling delivered by the Learning Mentor which will occur after school hours and will have parental involvement. This session will only take place if both the parent and the young person consent. This intervention utilises the technique of motivational interviewing and aims to address the individual's motivation to change their drinking behaviour. The counselling is manual guided.

Level Two Interventions will take place at the young person and parents convenience in a community centre either within the school or nearby.

What are the possible benefits and risks of participating?
What participants will gain from enrolling is a leaflet on healthy lifestyles/alcohol use. There are no known risks to participating in the study.

Where is the study run from?
The study is run from the Institute of Health and Society, Newcastle University.

When is the study starting and how long is it expected to run for?
The study start date is 1st October 2011 for 22 months. The trial will be recruiting participants between December 2011 and May 2012 and then carrying out follow ups 6 and 12 months after.

Who is funding the study?
The National Institute for Health Research, Public Health Research Programme (NIHR PHRP).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
01

Study information

Scientific Title
A feasibility trial of screening and brief alcohol intervention to prevent hazardous drinking in young people aged 14-15 in a high school setting

Study objectives

Alcohol screening and brief interventions carried out in the school setting can prevent hazardous drinking in young people

Ethics approval required
Old ethics approval format

Ethics approval(s)
Newcastle University Ethics Comittee, August 2011

Primary study design
Interventional

Study design
Cluster randomised controlled trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Alcohol use disorders

Interventions
Level One Intervention: In addition to Personal Social and Health Education (PSHE) the young people in year 10 (aged 14 to 15) who screen positively for alcohol misuse using the alcohol screening questionnaire and consent to take part in the study will take part in a 30 minute personalised session delivered by the Learning Mentor (LM) (at school) of structured feedback about their drinking behaviour and advice about the health and social consequences of continued hazardous alcohol consumption. The young person (YP) will also receive a healthy living booklet and information on local sources of help for drinking problems. The intervention encompasses the elements of the FRAMES approach for eliciting behaviour change (Feedback, Responsibility, Advice, Menu, Empathy and Self-efficacy) (Miller and Sanchez 1993).

Level Two Intervention: In addition to PSHE and the level one intervention, the YP will be invited to attend a subsequent one hour session of behaviour change counselling delivered by the LM which will occur after school hours and will have parental involvement. This session will only take place if both the parent and the young person agrees. This intervention utilises the technique of motivational interviewing (Rollnick, Mason et al. 1999) and aims to address the individual's motivation to change their drinking behaviour. The counselling is manual guided. Level Two Interventions will take place after school hours in a community centre either within the school or nearby.

Adolescents in the control and intervention will all receive Personal Social Health and Economic education (PSHE) as usually delivered in the high school setting.

Intervention Type
Behavioural

Primary outcome(s)
1. To assess the acceptability of the proposed methods used in this study to be used in a definitive trial to assess total alcohol consumed in a 28 day period of the study population. This is ascertained using the 28 day timeline follow back questionnaire. Three other variables can be

derived from the data:
1.1. Percent days abstinent
1.2. Drinks per drinking day
1.3. Total alcohol consumed

The time line follow back interview will be conducted by a trained individual and takes approximates 20 minutes to complete. The primary outcome will only be measured at 12 months post intervention so as not to bias the control group's responses.

Key secondary outcome(s)
1. Alcohol use frequency, quantity (on a typical occasion) and binge drinking will be assessed using the Alcohol Use Disorders Identification Test (AUDIT). Each item scores between zero and four and the maximum score is forty. A score of 2+ will be used to categorise someone as hazardous / harmful drinking (2+) and 3+ for possible dependence (3+)
2. Alcohol related problems will be assessed using the validated Rutgers Alcohol Problems Inventory (RAPI) which includes measures on aggression
3. The 12 item General Health Questionnaire (GHQ) will be used to assess general psychological health
4. Cost data will be collected using the client receipt approach
5. The EQ-5D-Y which is a recently developed child-friendly version of the EQ-5D will be used to investigate if this instrument achieves acceptable completion rates and to see if it detects any differences in health utility scores between the intervention groups and the control group

Measured at baseline, 6 months post intervention and 12 months post intervention

Completion date
31/07/2013

Eligibility

Key inclusion criteria
1. Pupils aged 14-15 years inclusive, scoring positive on the Single Alcohol Questionnaire (SAQ)
2. Willing and able to provide informed consent for intervention and follow up

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
14 Years

Upper age limit
15 Years

Sex

All

Key exclusion criteria
1. Parental refusal
2. Those already seeking help for an alcohol use disorder (AUD)

Date of first enrolment
01/12/2011

Date of final enrolment
01/05/2012

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Newcastle University
Newcastle upon Tyne
United Kingdom
NE2 4AX

Sponsor information

Organisation
Newcastle University (UK)

ROR
https://ror.org/01kj2bm70

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Public Health Research Programme ref: 10/3002/07

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2014		Yes	No
Protocol article	protocol	13/09/2012		Yes	No