Screening and brief alcohol intervention to prevent risky drinking in young people aged 14-15 in a high school setting

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
21/08/2015		[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
15/09/2015	Completed	[X] Results		
Last Edited 10/10/2023	Condition category Mental and Behavioural Disorders	Individual participant data		

Plain English summary of protocol

Background and study aims

In England between 2007 and 2013, alcohol consumption in 11-15 year olds decreased from 54% to 39%. Although this reduction in underage drinking is encouraging, teenagers in the UK are still amongst the heaviest drinkers in Europe. There is a great deal of evidence to show that underage drinking can lead to health and social problems in later life. It can also lead to risky behaviour in teenagers, such as smoking and promiscuity (sleeping around). "Alcohol screening and brief intervention" is a preventive strategy targeting people whose drinking habits are likely to be harmful to their health or well-being. The scheme works by identifying young people engaging in risky drinking behaviour, and then providing structured advice or counselling to help them drink less and more responsibly. A key feature of this programme is that it is designed by GP's rather than addiction specialists, as the participants themselves may not be aware that they have a problem with alcohol. The aim of this study is to find out whether an alcohol screening and brief intervention programme in schools is a successful and cost-effective way of reducing drinking in young people.

Who can participate? Healthy adolescents between 14 and 15 years old who have a risky level of alcohol consumption.

What does the study involve?

Participants are randomly allocated into one of two groups. Those in the first group (control) continue their usual school lessons to help them understand alcohol issues. They are also given minimal feedback from their alcohol consumption screening, as well as an alcohol information leaflet which includes information about how to get help with alcohol-related issues. Those in the second group (intervention) receive the same leaflet and normal school lessons as the control group, however they also take part in a 30 minute personalized, interactive worksheetbased session designed to explore the young persons' drinking habits and their motivation for change. These participants also receive structured feedback from the alcohol use screening, as well as advice about the long-term problems linked with drinking too much alcohol.

What are the possible benefits and risks of participating?

There are no direct benefits of participating, although information gained from the study will be used for an intervention manual to be used in schools in the future. All young people involved will be given an information leaflet with information about alcohol and contact details of local help services however. There are no specific risks involved.

Where is the study run from? Seven schools in the County Durham area.

When is the study starting and how long is it expected to run for? September 2015 to December 2017

Who is funding the study? National Institute for Health Research (UK)

Who is the main contact? Dr Emma Giles

Contact information

Type(s) Scientific

Contact name Dr Emma Giles

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Additional identifiers

EudraCT/CTIS number Nil known

IRAS number

ClinicalTrials.gov number Nil known

Secondary identifying numbers 002

Study information

Scientific Title

A multi-centre randomised controlled trial of screening and brief alcohol intervention to prevent risky drinking in young people aged 14-15 in a high school setting (SIPS JR-HIGH)

Acronym

SIPS JR-HIGH

Study objectives

The aim of the study is to evaluate the effectiveness and cost-effectiveness of alcohol screening and brief intervention to reduce risky drinking in young people aged 14-15 in the English high school setting.

Ethics approval required Old ethics approval format

Ethics approval(s) Teesside University Ethics Committee, 03/09/2015, ref: 164/15

Study design Multi-centre two-arm randomized controlled trial

Primary study design Interventional

Secondary study design Randomised controlled trial

Study setting(s)

Study type(s) Treatment

Participant information sheet

Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Risky alcohol consumption

Interventions

Participants are randomised in a 1:1 ratio into the intervention and control arms, with individual randomisation stratified by school.

Control arm: Involves usual practice on alcohol issues as delivered normally to all students in personal, social and health education (PSHE) lessons and curriculum delivered by class teachers as well as minimal feedback on their alcohol screen and an alcohol information leaflet with information on local sources of help for problems relating to alcohol, given by the learning mentor to those that consent to the trial.

Intervention arm: In addition to input equivalent to the control arm; the young people who are eligible and consent to participate in a 30-minute personalised interactive worksheet-based session. This will be delivered by the learning mentor (at school) and will contain structured feedback about the individual student's drinking behaviour and advice about the health and social consequences of continued risky alcohol consumption. The intervention encompasses the elements of the FRAMES approach for eliciting behaviour change.

Intervention Type

Behavioural

Primary outcome measure

Total alcohol consumed in the last 28 days, using the 28 day Alcohol Timeline Followback (TFLB) questionnaire at 12-month follow-up.

Secondary outcome measures

1. Percentage days abstinence over last 28 days, drinks per drinking day and days >2 units from TLFB

- 2. Risky drinking using the A-SAQ (last 6 months), AUDIT (last 6 months) and TFLB (last 28 days)
- 3. Smoking behavior (age of first use and amount used in last 30 days)
- 4. Alcohol related problems using the RAPI (last 6 months)
- 5. Drunkenness during the last 30 days, both dichotomised as 'never' and '1-2 times or more'
- 6. Emotional wellbeing using the WEMWBS in the last two weeks
- 7. Drinking motives using the DMQ (last 6 months)
- 8. Energy drink consumption (last week)
- 9. Use of NHS, educational, social, and criminal services data (S-SUQ) (last 6 months)
- 10. Quality of life and health utility measured using EQ-5D 5L (today)

11. Sexual risk taking: "After drinking alcohol, have you engaged in sexual intercourse that you regretted the next day?" and "After drinking alcohol, have you ever engaged in sexual intercourse without a condom?" (ever)

Overall study start date

01/09/2015

Completion date

31/12/2017

Eligibility

Key inclusion criteria

1. Aged between 14-15 years inclusive whose parents do not opt them out of the study 2. Scoring positively for risky alcohol consumption on the Self-Assessment Questionnaire A (A-SAQ)

Participant type(s) Learner/student

Age group Child

Lower age limit

14 Years

Upper age limit

15 Years

Sex

Both

Target number of participants

The proposed sample has been calculated to have a 90% power and will follow-up 257 young people in each arm at 12-month follow up.

Total final enrolment 443

Key exclusion criteria

1. Those already seeking or receiving help for an alcohol use disorder

2. Those with a recognised mental health or challenging behaviour issue

Date of first enrolment 01/01/2016

Date of final enrolment 31/03/2016

Locations

Countries of recruitment England

United Kingdom

Study participating centre Ferryhill Business & Enterprise College Merrington Road Ferryhill County Durham United Kingdom DL17 8RW

Study participating centre Greenfield Community College - A Specialist Arts & Science School Greenfield Way Newtom Aycliffe County Durham United Kingdom DL5 7LF

Study participating centre Woodham Academy

Washington Crescent Newton Aycliffe County Durham United Kingdom WC2R 2LS

Study participating centre Durham Johnston School Crossgate Moor Durham County Durham United Kingdom DH1 4SU

Study participating centre Consett Academy Dunelm Rd Consett County Durham United Kingdom DH8 8EG

Study participating centre Park View Community School Church Chare Chester le Street County Durham United Kingdom DH3 3QA

Study participating centre Teesdale School Prospect Pl Barnard Castle County Durham United Kingdom DL12 8HH

Sponsor information

Organisation

Newcastle University

Sponsor details

Faculty of Medical Sciences Newcastle University Framlington Place Newcastle upon Tyne England United Kingdom NE2 4HH

Sponsor type University/education

Website www.ncl.ac.uk

ROR https://ror.org/01kj2bm70

Funder(s)

Funder type Government

Funder Name National Institute for Health Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type Government organisation

Funding Body Subtype National government

Location United Kingdom

Results and Publications

Publication and dissemination plan

We will publish a full account of our research in the journal NIHR Public Health Research. In addition, we anticipate that this research will result in three open access peer-reviewed journal articles. Target journals include BMC Trials for the protocol and Addiction for the main results of the trial. We anticipate that a paper reporting further results will also be published in a specialist journal.

Furthermore we will ensure that our outputs are placed on Researchfish. We will also present our research at meetings of appropriate learned societies. Findings will also be disseminated with local and national education departments. We will work with press officers at Newcastle University to publicise the results of our work to local and national news media.

The Chief Investigator (Newbury-Birch) and other co-applicants are associate members of FUSE – The Centre for Translational Research in Public Health (www.fuse.ac.uk). FUSE is a UKCRC funded Centre of Public Health Research Excellence which includes members and partners from across public health research, policy and practice communities in the North East of England. We will use established Fuse initiatives including the Quarterly Research Meetings (with around 100 participants) to disseminate our findings to the wider public health community. A summary of these meeting, and podcasts of presentations, will be posted on the FUSE website. Key to the study is the role played by school staff and young people. We will consult with them at the start of the study, informing them about study activities and inviting them to comment on how the project can be improved. In so doing we will be encouraging those involved to engage with the project so that they will more readily contribute to meetings in the latter stages of the project where we will be asking for their input to help the research team generate ideas for dissemination. Finally, we have allocated funds for a member of the research team to attend one international and one national conference to disseminate findings to a wider practitioner /research community. We anticipate that the former will be to the Royal Society on Alcoholism and the latter will be the Alcohol Concern Conference.

Intention to publish date

30/06/2018

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?
Protocol article	protocol	23/12/2016	10/12/2020	Yes	No
Results article	results	01/05/2019	10/12/2020	Yes	No
Results article		12/03/2022	10/10/2023	Yes	No