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A feasibility trial of screening and brief alcohol intervention to prevent hazardous drinking in young people aged 14-15 in a high school setting (SIPS JR-HIGH)

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1. Aims/Objectives:

The work outlined in this proposal will answer the following research questions: 'is it feasible to deliver screening and brief alcohol intervention in schools in England' and 'what are the likely eligibility, consent, participation and retention rates of young people in a UK-relevant trial of brief intervention compared to standard practice?' Answers to these research questions will inform the development of a definitive randomised controlled trial (RCT) to evaluate the effectiveness and cost-effectiveness of screening and brief alcohol intervention to reduce hazardous drinking in adolescents. Our hypothesis for the definitive RCT will be that brief intervention is more effective and cost-effective at reducing hazardous drinking in adolescents than a control condition of usual advice in high/comprehensive schools.

Project Objectives:

1. To conduct a 3 arm pilot trial (with randomisation at the level of school) to assess the feasibility of a future full trial of brief alcohol intervention in a school setting.
2. To explore the feasibility and acceptability of brief alcohol intervention and study measures to staff, young people and parents.
3. To explore the fidelity of the interventions as delivered by school based Learning Mentors (LMs).
4. To estimate the parameters for the design of a full trial of brief alcohol intervention, including rates of eligibility, consent, participation and retention at 6 and 12 months.
5. To develop the protocol for a definitive trial and economic evaluation of the impact of brief alcohol intervention compared to standard advice to reduce alcohol consumption.

2. Background:

Although the proportion of young people in England aged between 11-15 years who report that they have drunk alcohol decreased from 62% to 51% between 1988 and 2009, the mean amount consumed rose from 6.4 to 11.6 units of alcohol per week between 1994 and 2009 [1]. Approximately 33% of 15-16 year olds in England report alcohol intoxication in the past month [2] and adolescents in the UK are amongst the heaviest drinkers in Europe [3]. In particular, the North East of England has been shown to have the highest rates of alcohol misuse by young people in England [4]. In North Tyneside 48% of young people aged 11-17 reported they had ever had an alcoholic drink compared to 42% nationally [4]. Moreover, in the UK drinking increases steadily throughout adolescence [1]. The Chief Medical Officer for England recently provided recommendations on alcohol consumption in young people [5] based on an evidence review of the risks and harms of alcohol to young people [6]. The recommendations state that children should abstain from alcohol before the age

of 15 and those aged 15-17 are advised not to drink, but if they do drink it should be no more 3-4 units and 2-3 units per week in males and females, respectively, on an occasional basis [5].

The impact of alcohol on the development and behaviour of young people has been well characterised in early [7] middle [8] and late adolescence [9]. It is now well known that young people are much more vulnerable than adults to the adverse effects of alcohol due to a range of physical and psycho-social factors which often interact [6]. These adverse affects include: physiological factors resulting from a typically lower body mass and less efficient metabolism of alcohol [7, 8]; neurological factors due to changes that occur in the developing adolescent brain after alcohol exposure [8, 10, 11]; cognitive factors due to psychoactive effects of alcohol which impair judgement and increase the likelihood of accidents and trauma [12]; and social factors which arise from a typically high-intensity drinking pattern which leads to intoxication and risk-taking behaviour. The latter are compounded by the fact that young people have less experience at dealing with the effects of alcohol than adults [13] and they have fewer financial resources to help buffer the social and environmental risks that result from drinking alcohol [9].

As a result of the above risk factors, the list of negative consequences that result from heavy drinking in young people is extensive and includes physical and psychological and social problems in both the shorter and longer term. Immediate problems result from accidents and trauma, physical and sexual assault including rape in young people, criminal behaviour including driving whilst intoxicated and riding as a passenger with an intoxicated driver and early onset of sexual intercourse and sexual risk taking [6, 14]. Longer-term problems include the development or exacerbation of mental health problems [15], self-harm and/or suicidal behaviour [16]. Moreover, individuals that begin drinking in early life have a significantly increased risk of developing alcohol use disorders including dependence later in life [17, 18]. As a result of this extensive array of damage, the prevention of excessive drinking in young people is a global public health priority [19].

A recent review of preventive interventions to reduce the harm associated with adolescent substance use outlined the positive potential of brief alcohol intervention [20]. Brief intervention is secondary preventive activity, aimed at individuals whose consumption level or pattern that is likely to be harmful to their health or well-being [21]. Brief interventions generally consist of structured advice or counselling of short duration which is aimed at reducing alcohol consumption or decreasing the number or severity of problems associated with drinking [22]. Although there is a large volume of evidence on primary prevention, which aims to delay the age that drinking begins and which uses general health education to prevent underage drinking, this body of work has been reported to be methodologically weak [23] and only a relatively small number of programmes have reported positive outcomes [24]. Thus targeting interventions at young people who are already drinking alcohol is likely to be a more effective strategy, since the intervention will have more salience for the individuals receiving them.

Brief interventions are based on social cognitive theory (from health psychology) which is drawn from the concept of social learning [25]. Here behaviour is regarded to be the result of an interaction between individual, behavioural and environmental factors. It is assumed that each individual has cognitive (thinking) and affective (feeling) attributes that affect not only how they behave but also how their behaviour is influenced and/or reinforced by aspects of the external world. Thus brief interventions generally focus on individuals' beliefs and attitudes about a behaviour, their sense of personal confidence (self-efficacy) about changing it, and a focus on how an individual's behaviour sits in relation to other people's actions (normative comparison).

A key feature of brief intervention is that it is designed to be delivered by generalist practitioners (not addiction specialists) and targeted at individuals who are generally not experiencing severe problems (such as alcohol dependence) and who may not be aware that they are experiencing alcohol-related problems. Thus the goal is usually reduced alcohol consumption or a decrease in alcohol-related problems [26].

There is variation in the duration and frequency of brief alcohol intervention [27] but there are two broad types: 1. simple structured advice - based on the FRAMES structure; and 2. behaviour change counselling - based on motivational interviewing.

Motivational interviewing (MI) is a person-centred approach which aims to resolve conflicts regarding the pros and cons of behaviour change and thus enhance motivation. MI is characterised by empathy and an avoidance of direct confrontation. Elicited statements associated with positive behaviour change are encouraged so as to support self-efficacy and a commitment to take action. Since the time available for delivering brief intervention may not allow for MI in its full form [27], its ethos and techniques have been distilled into a more directive format called Behaviour Change Counselling (BCC)[28].

Numerous systematic reviews have been published on brief alcohol interventions in young people. Recent work has focused on BI delivered using electronic media (often the internet).However, this work has focused on older adolescents (generally 18+college students) and the results have been mixed (some positive and often null findings). Thus there is insufficient evidence to consider using IT-based BI in younger adolescents. Just one systematic review has focused on brief intervention in health settings and this identified eight controlled trials [29]. Whilst the health literature has included adolescents as young as 14, the results have been equivocal in terms of decreased alcohol consumption.

The evidence-base for brief interventions is most substantial in educational settings. Two recent systematic reviews have focused on individual-level alcohol interventions delivered to students attending colleges [30, 31]. Across these reviews, 62 unique studies were identified, of which a sub-set of 16 trials included brief interventions directly delivered by a range of practitioners (including physicians, nurses, counsellors and psychologists). Most studies evaluated a single brief intervention session, although a couple of trials included two or more sessions. The duration of

the interventions ranged from 30 minutes to around 2 hours (modal duration was one hour). The number of participants in the trials ranged from around 60 [32] to over 500 students [33]. The methodological quality of the studies appears to have improved over time with larger samples and clearer random assignment to study conditions [31]. Nevertheless, subjects in these trials have tended to be a selective group of older adolescents aged between 18-21 [34] who were mostly white American college students and highly motivated to participate in an alcohol intervention programme. There have been no UK studies of brief alcohol intervention with younger adolescents.

Nevertheless, meta-analyses have consistently reported that students who received brief interventions subsequently reduced their drinking behaviour compared to control conditions who typically received assessment only [30, 31]. The key elements of the brief interventions were personalised feedback on alcohol consumption typically with a normative component [31] and/or motivational interviewing approaches. Such brief interventions typically achieved small to medium effect sizes [35] across multiple measures of alcohol consumption including quantity, frequency and intensity of drinking. The effects of brief interventions on drinking behaviour often peaked in the shorter term (generally 6 months) then diminished over time [30]. However, reductions in alcohol-related problems often took longer to emerge but were found in longer-term follow-up (12 to 18 months). Hence it is important to have brief intervention outcomes measuring both consumption and alcohol-related problems and to follow-up participants at shorter and longer-term time-points.

Thus brief alcohol intervention in young people have been successful for selected individuals, in certain settings. In particular, the current available evidence relates primarily to white, USA-based subjects most often in educational settings and at the older end of the youth spectrum. However, there is currently insufficient evidence to be confident about the use of brief intervention to reduce excessive drinking and/or alcohol-related harm in younger adolescents. Nevertheless, the current evidence-based suggests that the most effective forms of brief intervention are those containing personalized feedback about a young person's drinking behaviour and motivational interviewing approaches to help reduce levels of alcohol-related risk.

3. Need:

Our proposal builds on the evidence base by focusing on screening and brief intervention to reduce hazardous drinking in younger adolescents (aged 14-15). Evidence suggests that hazardous drinking among young people occurs commonly in the context of other forms of 'disinhibitory behaviour' such as aggression and risk-taking [36]. Whilst these behaviours are well known to be linked, it is not clear if drinking leads to these behavioural problems or if they all arise due to a common linked trait [37]. Nevertheless, it is highly likely that if a brief intervention was effective at reducing hazardous drinking, it might also result in a range of other positive behavioural outcomes. A significant positive association between alcohol dose and aggression for both genders has been found [38], and a study of US accident and emergency attendees, showed reductions in aggression as well as reductions in

alcohol misuse following a brief alcohol intervention [39]. For this reason, in addition to measuring alcohol use, we have included a range of behavioural measures as study outcomes.

Moreover, there is some evidence in the UK that parents' attitudes about alcohol may shape their children's views (particularly in younger children) about drinking [40]. It would therefore be advantageous to include parents in brief advice sessions with young people about alcohol, but equally may be difficult to get both children and parents to agree to such sessions. The feasibility trial will include two brief intervention conditions: one that only involves young people and one that includes young people and their parents.

The MRC has presented a framework for the evaluation of complex interventions [41]. This proposal represents the development and piloting phases of the framework. Conducting a full-scale RCT and economic evaluation of screening and brief intervention vs 'standard care' in this population is likely to need many schools and to be resource intensive. As there are uncertainties regarding rates of eligibility, consent, participation in the intervention and retention for follow-up and regarding the feasibility and acceptability of the intervention for a range of stake-holders (teachers, LMs, young people and parents) we deem that this feasibility study is essential to inform the design and conduct of a larger scale study.

4. Methods:

a. Setting

Participants

Participants will be pupils aged 14-15 in Year 10 at High Schools across North Tyneside.

Inclusion criteria

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

Exclusion criteria

Parental refusal; those already seeking help for an alcohol use disorder (AUD).

b. Design

Feasibility 3 arm pilot trial with cluster randomisation (at the level of school) of young people aged 14-15 in year 10 at 7 Secondary/High schools in North Tyneside, Tyne and Wear and integrated qualitative process evaluation.

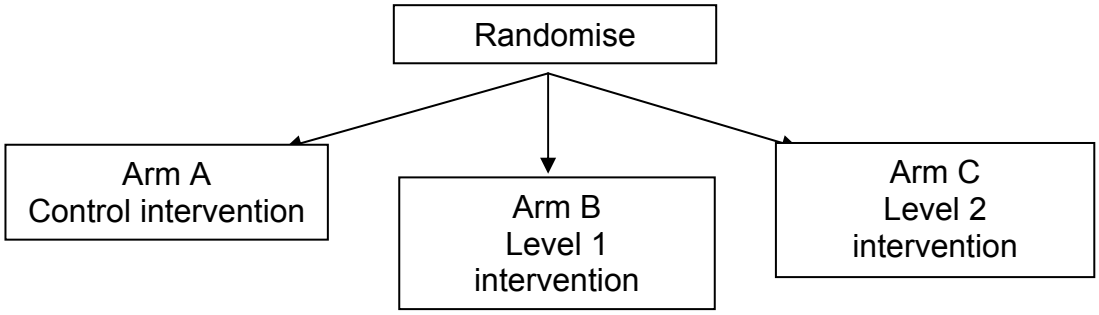


Figure 1.0 showing randomisation within study

c. Data collection

Screening

A screening questionnaire will be administered during PSHE lessons to all Year 10 pupils in each of the 7 schools taking part in North Tyneside.

In advance of screening all parents/caregivers will be informed by letter that screening and the study will be taking place in their child's school. This letter will be posted directly by Royal Mail to parents/caregivers by the research team and will include a pre-paid return envelope (addressed to the research team at the university) and a study information leaflet. Parents will have the option to indicate that they do not wish for their child to be screened or considered for participation in the study at this stage by contacting the research team or the school.

At the beginning of the session, student consent to the initial screening phase will be made clear both verbally (by the member of school staff overseeing completion of questionnaires) and in written form (clear instructions on the front cover of the questionnaire).

Procedurally, young people will be told that they have the option to:

- Not complete the questionnaire at all
- To partially complete the questionnaire
- To fully complete the questionnaire but not include their personal details
- To fully complete the questionnaire and give personal details

The envelope will contain a series of questionnaires including the screening questionnaire: The Single Alcohol Questionnaire (SAQ) '*In the last 12 months how often have you drunk more than 3 units of alcohol?'* With the response options of *'Never, less than 4 times, 4 or more times but not every month, at least once a month but not every week, every week but not every day, every day'.* Scoring '4 or more times', or more frequently indicates a positive screen. Alcohol use frequency, quantity (on a typical occasion) and binge drinking will be assessed using the modified Alcohol Use Disorders Identification Test (AUDIT) [42].A General Lifestyle

Questionnaire containing questions addressing a number of areas; diet, smoking, exercise and alcohol consumption will also be completed; and the 14 item Warwick Edinburgh Mental Well-being Scale (WEMWBS) will be used to assess general psychological health [43]. Alcohol related problems will be assessed using the validated Rutgers Alcohol Problems Inventory (RAPI) which includes measures on aggression [44]. The EQ-5D-Y which is a recently developed child-friendly version of the EQ-5D will be used to assess health utility scores in the intervention groups and the control group [45]. Demographic information will be collected including gender and ethnicity, as well as the following contact information: participant name; school; class; and PSHE teacher name.

Students will then be asked to put their questionnaire into an unmarked envelope which they themselves will seal and place in an open box at the front of the class.

It will be made clear to the young person after completing the questionnaire that the research team will be the only ones that have access to this information. However, for those that have completed their personal details, the students will be told that their information may be given to the Learning Mentor (LM).

The PSHE teacher will give all young people in the class a £5.00 retail gift voucher at baseline. Provision of a one-off gift voucher to all young people who complete the screening questionnaire is designed to be appreciative (to thank them for their efforts) and to act as compensation for the time and inconvenience of research participation.

Questionnaires will be completed at baseline, 6 and 12 months by all pupils who have not opted out of the study. The questionnaires completed at months 6 and 12 will be sealed in envelopes and scored by the Research Associate using the same method as outlined at baseline.

Trial

Returned questionnaires will be scored by the Research Associate (RA) and those that score as positive on the Single Alcohol Questionnaire (SAQ) and have consented to being contacted will be invited by the RA to meet with the LM within a week. Young people, in all three conditions who meet with the LM will have the project explained to them and informed consent will be sought to take part in the study. Potential participants will be informed that participation is not compulsory

The three armed cluster randomised controlled trial incorporates a control condition and two intervention conditions:

Control condition (Arm A): Standard alcohol advice as delivered as part of the school curriculum in Personal, Social and Health Education (PSHE). This will include a leaflet about healthy living.

Level One Intervention (Arm B): In addition to PSHE the young people in year 10 (aged 14 to 15) 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) [46].

Level Two Intervention (Arm C): 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 [28] and aims to address the individual's motivation to change their drinking behaviour. The counselling is manual guided. Level Two Interventions will take place either within the school or in a community centre nearby.

In addition to the questionnaire completed by all Year 10 pupils, all those that have consented to the trial, in all conditions, will have a one to one appointment arranged with a LM to complete the TLFB questionnaire at the 12 month follow up point when young people will have started the next school year (Year 11).

Qualitative embedded study

Following the intervention, students, parents and school staff will be given an additional information leaflet and asked if they consent to take part in a semi-structured interview. Potential participants will be informed that participation is not compulsory.

Interviews will be conducted with a purposive sample of i) teachers and mentors and ii) young people and parents to explore factors that potentially hinder or enhance the use of screening and brief intervention approaches in the school setting and with the target age-group. Teacher/mentor interviews will explore the feasibility of implementation of screening and interventions in a school setting including: prioritisation of educational and/or well-being work, the scope for team or individual professional input; staff skill mix and turnover, resources, role development and training needs, participant consent. The participant/parent interviews will explore acceptability of screening and brief alcohol intervention in the school setting including: consent procedures, parental involvement in consent and/or intervention, the comprehensibility and burden of study measures and follow-up procedures; and the appropriateness of school-led health promotion work across the school/home interface.

All staff employed on the project will be employed by academic organisations and subject to the Terms and Conditions of Service and contracts of employment of the employing organisations. The project will use standardised research protocols and

adherence to the protocols will be monitored by the Project Management Group and the Trial Steering Committee).

Data collected will be entered by the project staff on a secure validated clinical data management system (ACCESS) at the study coordinating centre. Completed paper CRFs will be transported to the coordinating centre by the Project Manager.

Data will be handled, computerised and stored in accordance with the Data Protection Act 1998The quality and retention of study data will be the responsibility of the Chief Investigator. All study data will be retained in accordance with the latest Directive on GCP (2005/28/EC) and local policy.

d. Data analysis

Statistical analysis

Sample size for pilot trials is typically determined pragmatically, with recommendations of a minimum of 30 responses per arm. We aim to obtain a minimum of 30 responses in each trial arm at 12 month follow-up, and our estimates of likely eligibility, recruitment and response rates from similar studies suggest that this should be more than achieved if all pupils in year 10 in 7 schools are invited to take part.

The statistical analyses will be primarily descriptive, providing a realistic estimate of eligibility, recruitment, intervention delivery and retention rates in the study population. These key trial parameters will inform the power calculations for a future definitive trial and confirm other aspects of trial design (in particular the acceptability of study processes and outcome measure to young people, their parents, teachers and learning mentors). Data pertaining to the flow of participants through the study will be ascertained and include numbers screened, prevalence of the target condition, numbers providing contact details, numbers eligible and willing to consent and numbers followed up successfully at 6 and 12 months. In addition we will ascertain data completeness of the instruments and any potential bias in the completion of follow-up data to inform the choice of instruments in a future definitive trial.
The primary outcome of the proposed definitive trial (total consumption at 12 months using the TLFB-28 within intervention groups) will be analysed in order to provide estimates of the variation within and between trial arms for exploration of sample size calculations for a definitive study.

The health economic analyses will describe the costs of introducing and running the brief intervention and will focus on examining what school resource data we should collect (and how) in terms of ongoing staff and capital costs. Following on from this analysis we will produce the protocol for a definitive trial, including a sample size calculation which will achieve objective 5.

Qualitative analysis

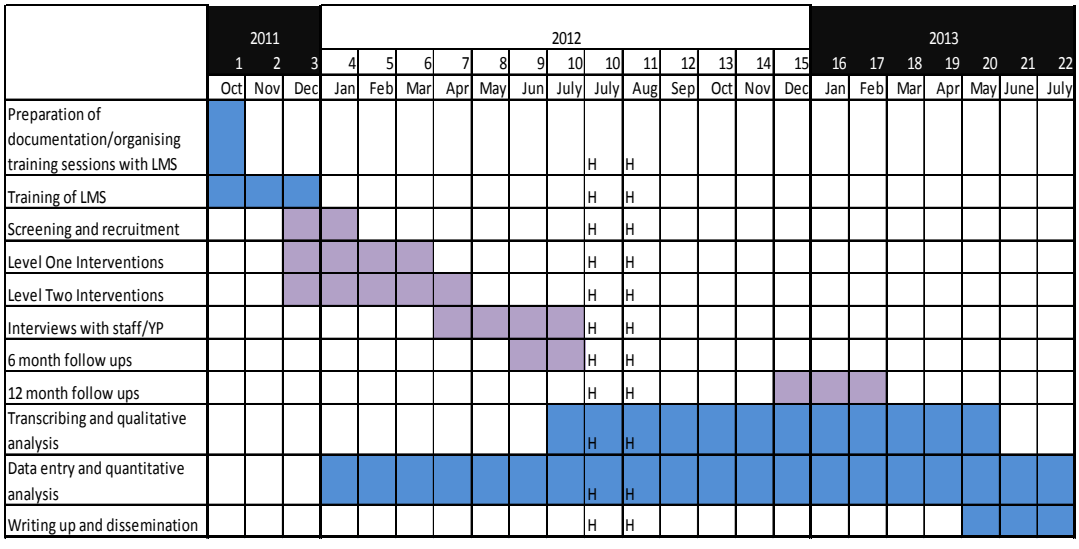
We will aim for a maximum variation sample to achieve a broad perspective on the

issues being explored and sampling criteria will be: school/area, intervention condition, participant type (teacher, mentor, pupil, parent) and gender. Emergent issues from earlier interviews will be explored in subsequent interviews and interview number will be determined by data saturation (no new issues or themes emerging from within/across participants). All interviews will be audio-tape recorded and transcribed verbatim. Analysis will be conducted using a structured thematic approach to systematically code, classify and organise interview content into key themes. Analysis will be conducted using QSR Nu*Dist software to assist systematic coding to identify emerging patterns between staff roles and centres.

5. Plan of Investigation:

PROJECT TIMETABLE AND MILESTONES (see Gantt chart below)

Months 1-3; Study set up, site recruitment, recruitment of staff, training of LMs
Months 3-7; Screening of young people and recruitment to the trial
Months 3-6; Carry out Level One Interventions
Months 3-7; Carry out Level Two Interventions
Months 7-10; Conduct interviews with staff/LMs and young people.
Months 9-10; Conduct 6 month follow ups.
Months 10-20; Transcribing interviews and conducting qualitative analysis.
Months 15-17; Conduct 12 month follow ups.
Months 4-22; Data entry, conduct statistical and economic analysis.
Months 20-22; Writing of report and dissemination of findings; preparation of definitive trial application.



7. Project Management:

This is a single-centre study and the Chief Investigator will have overall responsibility for the conduct of the study. The day-to-day management of the trial will be co-ordinated by the Project Manager.

A Programme Management Group (PMG) will be appointed and will be responsible for overseeing the progress of the trial. The PMG group has the primary aim of ensuring appropriate, effective and timely implementation of the SIPS JR-HIGH trial.

A Trial Steering Group (TSG) will also be appointed. The Trial Steering Committee (TSC) has the primary aims of monitoring implementation of the SIPS JR-HIGH feasibility trial, providing an independent assessment of the data analysis and determining if a future trial is merited.

8. Service users/public involvement:

For an intervention like SIPS JR-HIGH to be effective it needs to be acceptable to the target population. Representatives of young people and caregivers will take part in the Trial Steering Group (TSG) for the duration of this feasibility trial and will be involved in the development of the definitive trial.

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