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Screening and brief interventions for adolescent alcohol use disorders presenting through emergency departments: a research programme including two RCTs

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Abstract

Screening and brief interventions for adolescent alcohol use disorders presenting through emergency departments: a research programme including two RCTs

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Background: Alcohol consumption and related harm increase steeply from the ages of 12–20 years. Adolescents in the UK are among the heaviest drinkers in Europe. Excessive drinking in adolescents is associated with increased risk of accidents, injuries, self-harm, unprotected or regretted sex, violence and disorder, poisoning and accidental death. However, there is lack of clear evidence for the most clinically effective and cost-effective screening and brief interventions for reducing or preventing alcohol consumption in adolescents attending emergency departments (EDs).

Objectives: To estimate the distribution of alcohol consumption, alcohol-related problems and alcohol use disorders in adolescents attending EDs; to develop age-appropriate alcohol screening and brief intervention tools; and to evaluate the clinical effectiveness and cost-effectiveness of these interventions.

Design: The research has been conducted in three linked stages: (1) a prevalence study, (2) intervention development and (3) two linked randomised controlled trials (RCTs).

Setting: Twelve EDs in England (London, North East, and Yorkshire and The Humber).

Participants: A total of 5376 participants in the prevalence study [mean age 13.0 years, standard deviation (SD) 2.0 years; 46.2% female] and 1640 participants in the two linked RCTs (mean age 15.6 years, SD 1.0 years; 50.7% female).

Interventions: Personalised feedback and brief advice (PFBA) and personalised feedback plus electronic brief intervention (eBI), compared with alcohol screening alone. These age-appropriate alcohol interventions were developed in collaboration with the target audience through a series of focus groups and evaluations during stage 2 of the research programme and following two literature reviews.

Main outcome measures: Total alcohol consumed in standard UK units (1 unit = 8 g of ethanol) over the previous 3 months at 12-month follow-up, assessed using the Alcohol Use Disorders Identification Test, Consumption (3 items) (AUDIT-C).

Results: In the prevalence study, 2112 participants (39.5%) reported having had a drink of alcohol that was more than a sip in their lifetime, with prevalence increasing steadily with age and reaching 89.5% at the age of 17 years. The prevalence of at-risk alcohol consumption was 15% [95% confidence interval (CI) 14% to 16%] and the optimum cut-off point of the AUDIT-C in identifying at-risk drinking was ≥ 3 . Associations of alcohol consumption and early onset of drinking with poorer health and social functioning were also found. In the RCT, the analysis of the primary outcome (average weekly alcohol consumption at month 12) identified no significant differences in effect between the three groups in both trials. In the high-risk drinking trial, the mean difference compared with control was 0.57 (95% CI -0.36 to 1.70) for PFBA and 0.19 (95% CI -0.71 to 1.30) for eBI. In the low-risk drinking trial, the mean difference compared with control was 0.03 (95% CI -0.07 to 0.13) for PFBA and 0.01 (95% CI -0.10 to 0.11) for eBI. The health economic analysis showed that eBI and PFBA were not more cost-effective than screening alone.

Conclusions: The ED can offer an opportunity for the identification of at-risk alcohol use in adolescents. A simple, short, self-completed screening instrument, the AUDIT-C, is an effective tool for identifying adolescents who are at risk of alcohol-related problems. Associations of alcohol consumption and earlier onset of drinking with poorer health and social functioning were observed in the prevalence study. The trials were feasible to implement and exceeded the recruitment target and minimum follow-up rates. However, PFBA and eBI were not found to be more effective than screening alone in reducing or preventing alcohol consumption in 14- to 17-year-olds attending EDs.

Limitations and future work: Only one-third of participants engaged with the application program; this is likely to have limited the effect of the intervention. We recommend that future research should focus on methods to maximise engagement with digital interventions and evaluate the effect of such engagement on clinical outcomes.

Trial registration: Current Controlled Trials ISRCTN45300218.

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List of abbreviations

A&E	accident and emergency	MI	motivational interviewing
app	application program	MINI-KID	Mini International Neuropsychiatric Interview for Children and Adolescents
AUD	alcohol use disorder	NICE	National Institute for Health and Care Excellence
AUDIT	Alcohol Use Disorders Identification Test	OR	odds ratio
AUDIT-C	Alcohol Use Disorders Identification Test, Consumption (3 items)	PFBA	personalised feedback and brief advice
CI	confidence interval	PMG	Programme Management Group
CRAFTT	Car, Relax, Alone, Forget, Friends, Trouble	PSA	probabilistic sensitivity analysis
CSRI	Client Service Receipt Inventory	PSS	Personal and Social Services
eBI	electronic brief intervention	QALY	quality-adjusted life-year
ED	emergency department	RCT	randomised controlled trial
EQ-5D-5L	EuroQol-5 Dimensions, five-level version	SBI	screening and brief intervention
eSBI	electronic screening and brief intervention	SD	standard deviation
ESPAD	European School Survey Project on Alcohol and Other Drugs	SE	standard error
GP	general practitioner	SIPS	Screening and Intervention to Promote Sensible drinking
ICD-10	<i>International Classification of Diseases</i> , Tenth Edition	SMS	short message service
ICER	incremental cost-effectiveness ratio	WTP	willingness to pay

Plain English summary

Adolescents in the UK are among the heaviest-drinking adolescents in Europe. Drinking in adolescence is associated with alcohol-related harms, and early drinking is linked to intellectual impairment and more serious alcohol problems later on in life.

This research was conducted in three stages and targeted adolescents presenting to emergency departments to identify the size of the problem and develop and evaluate age-appropriate interventions.

First, we surveyed 5000 adolescents attending emergency departments, 40% of whom had drunk more than a sip of alcohol in their lifetime. Drinking earlier was linked to poorer health, and to alcohol and social problems. We found that a short questionnaire can identify adolescents who are drinking at risky levels.

Second, we reviewed published research and developed interventions. We met adolescents and parents to design the third stage of our research.

We then did two studies: (1) a study among adolescents drinking little who were aiming to delay starting drinking and (2) a study among adolescents drinking more who were aiming to reduce their consumption. Participants were allocated to one of three groups by chance: (1) screening only and care as usual, (2) feedback and brief alcohol advice, and (3) feedback and an application program with alcohol advice.

We successfully ran both studies and exceeded targets for recruitment and follow-up. However, we found that neither of our interventions was effective in reducing alcohol consumption in adolescents drinking high quantities of alcohol, or in delaying drinking in those drinking less or not drinking, compared with screening alone. Moreover, these interventions did not represent value for money compared with screening alone.

We later interviewed adolescents in the studies to explore their understanding and experience of taking part. Adolescents felt that they should know more about the risks of alcohol, that the advice was helpful and that emergency departments were a useful setting.

Scientific summary

Background

Alcohol consumption is a major public health concern. Although the main burden of chronic alcohol-related disease is in adults, its foundations often lie in adolescence. Alcohol consumption and related harm increase steeply from the age of 12 years, and although the proportion of young people in England aged between 11 and 15 years who reported that they had drunk alcohol had decreased in the last 30 years, the mean amount consumed by those who drank doubled. About 10% of 11- to 15-year-olds and 33% of 15- to 16-year-olds in England had reported alcohol intoxication in the past month.

Alcohol use and alcohol use disorders (AUDs) are relatively uncommon in early adolescence. Nevertheless, alcohol has a disproportionate effect on younger adolescents, for example by predisposing them to alcohol dependence in later life and damage to the developing brain. In middle adolescence (ages 15–17 years), binge drinking emerges. Although binge drinking does not necessarily meet the criteria for an AUD, it is associated with an increased risk of unprotected or regretted sexual activity, criminal and disorderly behaviour, suicidality and self-harm, injury, drink driving, alcohol poisoning and accidental death.

In 2009, the Chief Medical Officer for England provided recommendations on alcohol consumption in young people based on an evidence review (Donaldson L. *Guidance on the Consumption of Alcohol by Children and Young People*. London: Department of Health and Social Care; 2009). These recommendations stated that children should abstain from alcohol before the age of 15 years and that 15- to 17-year-olds should not drink, but, if they do drink, then they should consume no more than the recommended limits for adults (currently 14 units per week).

Alcohol screening and brief interventions in health settings

Opportunistic alcohol screening and brief interventions (SBIs) in emergency departments (EDs) capitalise on the 'teachable moment' when a connection can be made between alcohol consumption and ED attendance. SBIs in EDs have shown efficacy in adults and adolescents, and evidence of cost-effectiveness in adults. However, although there has been an increase in SBIs for adults, adolescents remain a comparatively neglected group.

Several alcohol screening methods have been developed in the USA but not evaluated in the UK. Questionnaires were found to perform better than blood markers or breath alcohol concentration in all age groups. However, most of these had low sensitivity and specificity and are therefore suboptimal for effective screening.

The validity of alcohol screening methods in younger adolescents is also unclear. Existing approaches do not sufficiently take account of the age and developmental stage of adolescents.

Moreover, a systematic review of brief alcohol interventions in young people attending health settings identified nine randomised controlled trials (RCTs) between 1999 and 2008. Eight were based in the USA and one was based in Australia. Six trials tested brief interventions based on one or two sessions of motivational interviewing (MI) that lasted between 20 and 45 minutes. One trial tested a more intensive programme of four MI sessions over 1 month. Two studies used information technology to deliver brief interventions, one using an audio programme in primary care and the other using an interactive computer program in a minor injury unit.

Five trials reported significant positive effects of brief interventions on a range of alcohol consumption measures, whereas three trials reported null effects after brief interventions. One trial reported an increase in alcohol use and binge drinking among brief intervention subjects, which is a possible adverse effect.

Therefore, there is a need to develop more effective alcohol screening tools and interventions for adolescents in the ED that are age appropriate and cover a wider range of alcohol consumption and alcohol-related problems than do existing methods. Although evidence suggests that brief interventions may be beneficial for adolescents, particularly in EDs, there is a clear need for a UK trial to examine this further.

This research programme was designed to address these key gaps in the evidence base for the most clinically effective and cost-effective SBIs for at-risk adolescent heavy drinkers, and prevent alcohol uptake or increased alcohol consumption in low-risk adolescents attending EDs.

Work package 1: prevalence study of alcohol consumption and alcohol use disorders in adolescents aged 10–17 years attending emergency departments

This work package investigated the prevalence of alcohol consumption in adolescents presenting to EDs and the association between that consumption, age at onset, and health and social behaviours. In addition, we assessed the diagnostic performance of brief screening tools.

Methods

We included 5376 consecutive attenders, aged 10–17 years, at 10 EDs. We collected information on alcohol use, alcohol-related health and social consequences, general health and social functioning, and quality of life.

Results

Nearly 40% of adolescents reported that their consumption of alcohol was more than a sip in their lifetime. First alcohol consumption before the age of 15 years was associated with tobacco use [odds ratio (OR) 2.8, 95% confidence interval (CI) 1.8 to 4.2; $p < 0.001$], lower quality of life (OR 1.5, 95% CI 0.5 to 2.6; $p = 0.003$) and diagnosis of AUD (OR 2.4, 95% CI 1.3 to 4.4; $p = 0.002$). It was also associated with impaired general social functioning [presence of conduct disorder (OR 4.5, 95% CI 1.8 to 11.4; $p < 0.001$) and hyperactivity (OR 2.6, 95% CI 1.4 to 4.8; $p < 0.001$)], alcohol-related health and social consequences [accidents (OR 1.8, 95% CI 1.0 to 3.2; $p = 0.046$), and problems with parents (OR 4.4, 95% CI 1.3 to 15.4; $p = 0.017$), school (OR 3.7, 95% CI 1.2 to 11.3; $p = 0.0117$) or police (OR 13.5, 95% CI 1.7 to 102.4; $p = 0.012$)].

We tested the screening properties of the questionnaire against the standard (Timeline Followback) criteria for at-risk drinking, heavy episodic alcohol consumption and the *International Classification of Diseases*, Tenth Edition (ICD-10), for hazardous alcohol use and dependence. We identified appropriate cut-off points for each instrument. An Alcohol Use Disorders Identification Test, Consumption (3 items) (AUDIT-C) score of ≥ 3 was the optimal cut-off point for at-risk drinking (sensitivity 0.89, 95% CI 0.89 to 0.91; specificity 0.97, 95% CI 0.96 to 0.97), monthly episodic alcohol use (sensitivity 0.76, 95% CI 0.73 to 0.80; specificity 0.98, 95% CI 0.97 to 0.98) and alcohol abuse (sensitivity 0.91, 95% CI 0.85 to 0.95; specificity 0.90, 95% CI 0.88 to 0.91). A score of 7 for the full Alcohol Use Disorders Identification Test was considered the optimal cut-off point for identifying alcohol dependence (sensitivity 0.96, 95% CI 0.89 to 0.99; specificity 0.90, 95% CI 0.88 to 0.91).

Conclusions

We found associations of alcohol consumption and earlier onset of drinking with poorer health and social functioning. EDs offer opportunities to identify at-risk alcohol use in adolescents. A simple, short, self-completed screening instrument, the AUDIT-C, is an effective tool for identifying adolescents who are at risk of alcohol-related problems, or engage in monthly heavy episodic alcohol use or in harmful alcohol use, according to the ICD-10 criteria. A score of 7 on the AUDIT-C is effective in identifying adolescents who are alcohol dependent.

Work package 2: exploratory modelling of the interventions

This work package developed age-appropriate alcohol interventions in collaboration with the target audience through a series of focus groups and evaluations.

Personalised feedback and brief advice

The personalised feedback and brief advice (PFBA) intervention is structured brief advice that takes approximately 5 minutes to deliver. It is based on an advice leaflet from Screening and Intervention to Promote Sensible drinking (SIPS), Brief Advice About Alcohol Risk, and was adapted for the target age group in this study. The advice covers recommended levels of alcohol consumption for young people; summarises the screening test results and their meaning; provides normative comparative information on prevalence rates of high- and low-risk drinking in young people; summarises the risks of drinking and highlights the benefits of stopping or reducing alcohol consumption; outlines strategies that the young person might employ to help stop or reduce alcohol consumption; and indicates where to obtain further help if they are unsuccessful or need more support.

Electronic brief intervention based on smartphone or web

The electronic brief intervention (eBI) smartphone intervention is an offline-capable mobile web application that works on a variety of platforms, but it was optimised for recent iPhone (Apple Inc., Cupertino, CA, USA) and Android (Google Inc., Mountain View, CA, USA) phones. It has been developed using the concept of gamification so that users can navigate, explore, learn facts and figures about alcohol, receive personalised feedback and set goals in an engaging format. The content adapts to provide the most pertinent information and advice for high- or low-risk drinkers. Game components of the web application supported high-risk drinkers to reduce or stop their alcohol consumption and low-risk users to maintain abstinence or low-risk drinking.

Work package 3: linked randomised controlled trials of face-to-face and electronic brief intervention methods to prevent alcohol-related harm in young people aged 14–17 years presenting to emergency departments

In work package 3, we conducted two linked RCTs to evaluate the clinical effectiveness and cost-effectiveness of PFBA and eBI (the two alcohol interventions described above), compared with screening alone, in 14- to 17-year-olds attending 10 EDs in England. One trial focused on at-risk adolescent drinkers (AUDIT-C score of ≥ 3) and the other focused on abstinent or low-risk drinkers (AUDIT-C score of < 3). Our primary (null) hypothesis was similar for both trials: PFBA and personalised feedback plus eBI are as effective as screening alone in reducing or preventing alcohol consumption, in standard UK units (1 unit = 8 g of ethanol), over the past 3 months, at 12 months after randomisation, as measured with the AUDIT-C. Our secondary (null) hypothesis for related health economics states that PFBA and eBI are as cost-effective as screening alone.

Methods

We undertook participant recruitment, baseline data collection, randomisation, intervention delivery and follow-up electronically via an ad hoc, secure computer tablet application developed as part of this programme. We recruited 1639 participants into the trials from 10 EDs: 756 high-risk drinkers and 883 low-risk drinkers or abstainers. Follow-up at 6 and 12 months was 82.9% and 73.0%, respectively.

Results

The mean age of participants was 16.1 [standard deviation (SD) 0.9] years in the high-risk study and 15.2 (SD 1.0) years in the low-risk study. There was a similar proportion of male and female participants, with 50.7% female overall. Primary analysis employed an intention-to-treat approach, in which participants were allocated as members of their allocated group irrespective of the treatment received. Analysis of the primary outcome, namely average weekly alcohol consumption in standard UK units (1 unit = 8 g of ethanol) at month 12, was conducted using analysis of covariance, adjusting for baseline values, age and gender. There were no significant differences between the three groups in either trial: in the high-risk trial, the mean difference compared with control was 0.57 (95% CI –0.36 to 1.70) for PFBA and 0.19 (95% CI –0.71 to 1.30) for eBI; in the low risk trial, the mean difference compared with control was 0.03 (95% CI –0.07 to 0.13) for PFBA and 0.01 (95% CI –0.10 to 0.11) for eBI. No significant interactions were observed between baseline alcohol consumption and allocated intervention. Alcohol consumption at 12 months was predicted at baseline by higher alcohol consumption, younger age at first drink, older age, being female, greater positive alcohol expectancy and greater alcohol-related problems. Health economic analysis supported the null hypothesis that neither PFBA nor eBI is more cost-effective than screening alone in both trials.

Conclusions

Findings from this research indicate that both face-to-face and electronic interventions were neither more effective nor more cost-effective than screening alone in reducing or preventing alcohol consumption in 14- to 17-year-olds attending EDs.

Qualitative study

Once follow-up was completed for all trials, we interviewed a sample of participating adolescents to explore their understanding of the study, as well as their views about the information and advice they received.

Methods

We interviewed 27 adolescents aged 14–17 years. Audio-recorded interviews were transcribed verbatim and thematically analysed, guided by four ethical principles (autonomy, beneficence, non-maleficence and justice).

Results

Participants were broadly positive about their experience of being approached and involved in the research process, and the emergency care context was felt to be acceptable. Participants reported a 'need to know' about risks from alcohol consumption, as this behaviour was seen to be common among young people. However, the presence of a primary caregiver during screening procedures could influence a young person's disclosure about alcohol use. The majority of participants demonstrated a high degree of moral agency, that is, an awareness and capacity to be responsible for actions related to their own health and well-being, and this extended to providing consent, on their own behalf, to participate in the relevant clinical trial.

Conclusions

There is limited evidence regarding effective behaviour change interventions for young people attending health services owing to concerns about involving vulnerable adolescents in research. However, even relatively young adolescents reported the capacity to provide informed consent and showed a clear interest in research that was relevant to them and had potential to benefit young people like them.

Discussion

The results of both the low- and the high-risk trials showed that we were able to recruit a sufficient number of participants to each trial to meet our target. We were also able to exceed the minimum follow-up targets in both trials. However, in both trials no significant differences in outcome were found between groups on either primary or secondary outcome measures. This supported the null hypothesis that PFBA and eBI are no more effective in preventing or reducing alcohol consumption in either low- or high-risk drinkers than screening alone.

In both trials, we found that engagement with the eBI was low among participants randomised to eBI. Only one-third of participants engaged with the eBI platform after leaving the ED. This may have limited the impact of the eBI compared with the control intervention. However, as these were pragmatic trials, this is likely to be the level of engagement expected in the typical patient recruited from an ED.

Low application program (app) usage or engagement is a common issue. The vast majority of apps, and other online interventions, are not used 1 month after they are downloaded. We also know that patients are less likely to engage in extended interventions when the onus to engage is on them.

A large proportion of the literature based on eBI has focused on the provision of websites, as opposed to smartphone apps. Arguably, the most important problem with developing an effective eBI app is engaging participants enough for them to find it useful.

Further research should explore strategies to improve engagement with the intervention.

Patient and public involvement

We worked closely with the British Youth Council and the Family and Parenting Institute, which facilitated focus group workshops in London and Newcastle. About 150 members of our target age group contributed to both methodology and materials. This activity changed our screening and intervention, notably the use of tablet computers for consent and data collection, and the design of specific materials, notably our PFBA brief advice leaflet and SIPS City app (version 2.1, King's College London, London, UK). We now maintain a database of young people interested in taking this work forward, whom we intend to engage in disseminating study findings.

Overall conclusions

This research programme was designed to address key gaps in the evidence base for the most clinically effective and cost-effective SBIs for adolescents attending EDs. The research has advanced our understanding of the nature and prevalence of AUDs in adolescents, and provided a firm foundation for future research to improve care for this population. We established the prevalence of AUDs and consequences of drinking in young people attending EDs using validated research tools. We developed age-appropriate and acceptable interventions for this population, in partnerships with national and local organisations, and tested them in two linked randomised trials.

Trial registration

This trial is registered as ISRCTN45300218.

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SYNOPSIS

Setting the scene

The excessive consumption of alcohol is a major global public health issue,¹ and, in Europe, alcohol accounted for 6.5% of deaths and 11.6% of disability-adjusted life-years in 2004.² Although the main burden of chronic alcohol-related disease is in adults, its foundations often lie in adolescence.³ The proportion of young people in England aged between 11 and 15 years who reported that they had drunk alcohol decreased from 62% to 54% between 1988 and 2007, but the mean amount consumed by those who drank doubled (from 6.4 to 12.7 units of alcohol per week) between 1994 and 2007.⁴ About 10% of 11- to 15-year-olds and 33% of 15- to 16-year-olds in England report alcohol intoxication in the past month.^{5,6} Adolescents in the UK are now among the heaviest drinkers in Europe.⁶ The Chief Medical Officer for England provided recommendations on alcohol consumption in young people in 2009,⁷ based on an evidence review.⁸ These advise that children abstain from alcohol before the age of 15 years and that 15- to 17-year-olds should not drink, but, if they do drink, then they should consume no more than the recommended limits for adults (currently 14 units per week).⁷

Alcohol consumption and related harm increase steeply from the age of 12 to 20 years.⁹ In early adolescence, alcohol use and alcohol use disorders (AUDs) (alcohol abuse, harmful alcohol use and alcohol dependence) are relatively uncommon. However, alcohol has a disproportionate effect on younger adolescents, for example by predisposing them to alcohol dependence in later life^{10,11} and damage to the developing brain.¹² In middle adolescence (ages 15–17 years), binge drinking emerges. Although binge drinking does not necessarily meet the criteria for AUDs, it is associated with increased risk of unprotected or regretted sexual activity, criminal and disorderly behaviour, suicidality and self-harm, injury, drink driving, alcohol poisoning and accidental death.^{6,13–16}

Alcohol screening

Opportunistic alcohol screening and brief interventions (SBIs) in emergency departments (EDs) capitalise on the 'teachable moment' when a connection can be made between alcohol consumption and ED attendance.^{17–20} Alcohol SBI in EDs has shown efficacy in adults²⁰ and adolescents,^{17,18,21} with evidence of cost-effectiveness in adults.²² Over the past 15 years, the World Health Organization, the US Surgeon General, the American Medical Association and the American Academy of Pediatrics have called for practitioners to carry out SBIs for adolescent drinkers.^{23–26} The alcohol strategies for both England and Scotland identify adolescents as a key target group in which to reduce alcohol consumption and related harm.^{27,28} However, although there has been an increase in alcohol SBIs for adults, adolescents remain a neglected group. A recent audit of EDs in Scotland found that only 5% of alcohol-related attenders aged < 18 years receive an alcohol intervention before discharge, and that ED staff focus more on those young people presenting with acute intoxication or self-harm.²⁹ Of the 12 EDs in the north-east of England and London approached during our research programme, none used routine alcohol screening in 10- to 17-year-olds and only three did so in adults.

Several alcohol screening methods have been developed in the USA but have not been evaluated in the UK. A recent systematic review of alcohol SBIs in young people (aged 10–17 years) and adults (aged ≥ 18 years), conducted for the National Institute for Health and Care Excellence (NICE),³⁰ examined 51 studies of alcohol screening. Questionnaires were found to perform better than blood markers or breath alcohol concentration in all age groups. In adolescents, the Alcohol Use Disorders Identification Test (AUDIT) questionnaire was found to have greater sensitivity and specificity than other questionnaires, including CAGE (Cut Down, Annoyed, Guilty, Eye Opener), TWEAK (Tolerance, Worried, Eye-opener, Amnesia, K/Cut Down),

CRAFT (Car, Relax, Alone, Forget, Friends, Trouble), RAPS4-QF (Rapid Alcohol Problems Screen – Quantity Frequency), FAST (Fast Alcohol Screening Test), RUFT (Cut-Riding, Unable, Family/Friends, Trouble, Cut down) and POSIT (Problem Oriented Screening Instrument for Teenagers). AUDIT sensitivities for adolescents range from 54% to 87% and specificities range from 65% to 97%.³¹ However, the majority were at the lower end of these ranges and are therefore suboptimal for effective screening.

Additional shortcomings of existing alcohol screening methods for adolescents have been identified.³¹ Existing approaches do not sufficiently take into account the age and developmental stage of adolescents. Any alcohol consumption under 15 years of age is of concern, whereas the identification of AUDs is more relevant in older adolescents. There is therefore a need for screening methods that are sensitive to the developmental stage of the adolescent to maximise opportunities for intervention. Alcohol screening has been mostly studied in older adolescents and young adults of college age (18–24 years). Therefore, the validity of alcohol screening methods in younger adolescents is unclear. Questionnaires such as the AUDIT may be too lengthy (10 items) to implement in busy EDs, pointing to the need for briefer tools for routine clinical practice. Methods to increase compliance, particularly by younger adolescents, are also needed. The use of computer screening and interviewing adolescents confidentially and separately from parents has shown some promise in the USA.^{32,33}

Alcohol brief interventions in health settings

Several systematic reviews have noted the effectiveness of SBIs in adults in health settings.^{34–38} Less research in this area has been conducted in adolescents. A systematic review of brief alcohol interventions for young people attending health settings identified nine randomised controlled trials (RCTs) between 1999 and 2008.³⁰ Eight were based in the USA^{17–19,21,39–41} and one was based in Australia.⁴² Most trials were considered to be methodologically sound, although two were considered to be weak in randomisation and allocation concealment.^{40,42} Sample sizes ranged from 34 to 655 and ages ranged from 12 to 24 years. Three trials^{40–42} targeted socioeconomically disadvantaged groups among whom drug and alcohol misuse were more prevalent. Four trials^{17–19,21} were based in EDs to maximise the potential for ‘teachable moments’ when the connection between alcohol consumption and its adverse consequences can be more readily highlighted. Two studies^{39,40} recruited adolescents during routine general check-ups in primary care and one⁴³ recruited in a university health centre. The remaining trials targeted homeless adolescents⁴¹ and those attending a youth centre that delivered health services.⁴²

Six trials^{17,18,21,40,41,43} tested brief interventions based on one or two sessions of motivational interviewing (MI) that lasted between 20 and 45 minutes. Delivery was carried out by a range of trained professionals, including physicians, nurse practitioners, psychologists, addiction clinicians and youth workers. One trial tested a more intensive programme of four MI sessions over 1 month.⁴² Two studies used information technology to deliver brief interventions, one using an audio programme in primary care³⁹ and the other using an interactive computer program in a minor injury unit.¹⁹ The length of follow-up ranged from 2 to 12 months. Loss to follow-up was generally low (0–20%), although the authors of one study⁴⁰ reported that 34% of their study population were lost to follow-up.

Five trials^{17,18,21,42,43} reported significant positive effects of brief interventions on a range of alcohol consumption measures. Bailey *et al.*⁴² reported that brief intervention participants showed increased readiness to reduce alcohol consumption, an initial reduction in alcohol consumption and an improvement in knowledge of alcohol and related problems, compared with control subjects. Schaus *et al.*⁴³ also reported reductions in blood alcohol concentration, number of drinks per week and risk-taking behaviour. Monti *et al.*¹⁸ reported that brief intervention subjects were less likely than control subjects to drink and drive or to experience alcohol-related injury, although both treatment groups significantly reduced their alcohol consumption. A subsequent trial, conducted by the same research group,¹⁷ reported that alcohol consumption also significantly decreased in both the brief intervention group and the control group. Last, Spirito *et al.*²¹ reported a significant reduction in alcohol consumption at follow-up in both the brief intervention group

and the control group. However, adolescents who screened positive for alcohol problems at baseline reported more change after MI than the control subjects.

Three trials reported null effects after brief intervention.^{19,40,41} One trial that used an audio-taped programme with 12- to 17-year-old adolescents³⁹ reported an increase in alcohol use and binge drinking among brief intervention subjects, representing a possible adverse effect of this type of intervention.

Summary

In summary, there is a need to develop more effective alcohol screening tools for adolescents in the ED, which are age appropriate and cover a wider range of alcohol consumption and alcohol-related problems than do existing methods. Furthermore, as most of the existing research has been conducted in the USA, screening methods appropriate to EDs are needed in the UK context of the NHS.

Moreover, the majority of alcohol SBI studies among adolescents in health-care settings were conducted in EDs and reported positive outcomes. However, three trials reported alcohol consumption reductions in both the intervention group and the control group, and three more trials reported no effect of brief intervention. None of these trials was in the UK and few studies were conducted in young adolescents. Thus, although there is evidence to suggest that brief intervention may be beneficial for adolescents, particularly in EDs, there is a clear need for a UK trial of this.

This monograph describes the results of our findings linked to the original programme objectives (a full list of publications arising from our programme of work can be found in *Overall conclusions, Dissemination*).

Work package 1: screening prevalence study of alcohol consumption and alcohol use disorders in adolescents aged 10–17 years attending emergency departments

Introduction

Adolescence is a critical period of development, during which the initiation and continuing use of alcohol may have detrimental consequences for the young person.⁴⁴ Several adverse health and social consequences of alcohol use in young people are widely reported in research and health policy, including an increase in depressive feelings, an increase in sexual risk taking, a reduction in educational performance, difficulties in maintaining relationships with peers and friends, and an increase in vulnerability to becoming a victim of crime.⁸ Although it is difficult to establish a direct causal relationship between alcohol use in adolescents and social and behavioural problems, several studies have shown that earlier consumption is associated with alcohol-related problems in later life.^{45–51} A recent review⁵² recommended further research to establish the advantages of delaying the onset in drinking when establishing guidelines for drinking in adolescence.

The identification of adolescents who consume alcohol at problematic levels is a key element of any screening and intervention strategy. To offer such interventions, practitioners need access to screening tools that are high in both sensitivity and specificity and are quick and easy to apply at minimal cost. Biochemical markers of alcohol use, such as gamma-glutamyl transferase, aspartate aminotransferase, erythrocyte mean cell volume and carbohydrate-deficient transferrin, are impractical and of little use in this population, and have been found to be inferior to short screening questionnaires in adult populations.⁵³

The AUDIT⁵⁴ is a 10-item self-completion questionnaire with established diagnostic properties for hazardous and harmful alcohol use in adults. It addresses three domains: alcohol consumption, harmful consequences and symptoms of dependence. AUDIT is one of the few screening instruments that specifically incorporates consumption into the scoring algorithm and may be particularly suitable for adolescents who are more likely to experience a range of alcohol-related harms as a result of consumption rather than experiencing symptoms of alcohol dependence. Furthermore, it may be the case that the three specific alcohol consumption questions constituting the Alcohol Use Disorders Identification Test, Consumption (3 items) (AUDIT-C) may be as efficient and brief a screening instrument as the full AUDIT. Previous studies suggest that the AUDIT may be more useful than other brief screening instruments in adolescent populations, but there is limited evidence regarding appropriate cut-off points for different severities of alcohol misuse,^{55–60} and no previous research has compared the relative effectiveness of AUDIT with that of AUDIT-C in adolescent populations.

Aims

This work package had three principal aims:

1. to estimate and compare the sensitivity, specificity and diagnostic odds ratios (ORs) of the AUDIT and AUDIT-C in identifying at-risk alcohol use, monthly heavy episodic alcohol use, alcohol abuse and alcohol dependence in the context of an opportunistic screening programme for adolescents attending EDs in England
2. to examine the prevalence of alcohol consumption among adolescents (aged 10–17 years) presenting to hospital EDs in England
3. to determine the association between alcohol consumption and age at onset of alcohol consumption with health and social consequences among adolescents presenting to EDs in England.

Findings from aim 1 have been published in Coulton *et al.*⁶¹ and findings covering aims 2 and 3 have been published in Donoghue *et al.*⁶² These are summarised here and reproduced in full in the appendices.

Methods

Patient and public involvement in work package 1

For work package 1, we collaborated with three organisations to ensure that both parents and young people were engaged in the development of our methodology and materials (the British Youth Council, Parenting UK and the Family and Parenting Institute). We organised focus groups in the north and south of England, at which we presented our planned protocols and then engaged the public to critique our plans and to make suggestions for change. Our work with the parent groups helped to shape the study protocol in terms of the optimal way to introduce the study and obtain informed consent. Consultation with the young people indicated that electronic data capture methods would be better received than interview or paper-and-pencil approaches and, as a consequence, we developed an iPad-based screening and data collection tool (Apple Inc., Cupertino, CA, USA) that we utilised throughout the entire programme of research.

The initial intention of the prevalence study was to examine the prevalence of alcohol consumption and AUDs among adolescents presenting to EDs. The questionnaire included demographic and lifestyle questions, attitude scales and a range of alcohol measures to determine which to use in the main trial, and it was expected to be around 30 pages in length. The patient and public involvement showed that adolescents were unlikely to consent to such a survey and, if consent was given, completion was not likely. A tablet interface and shorter questionnaire were more acceptable and would encourage participation in the study.

iPad data collection tool

Following a consultation stage with the target groups, we decided to develop an iPad application to better engage adolescents in the prevalence study and to facilitate data collection and improve data quality. The iPad application for the prevalence study has been developed for this research by the software developer Codeface Ltd (Hove, UK) in collaboration with the research team. Codeface Ltd, study investigators and target groups have all been actively involved in its development, testing and piloting. The application provided a flexible approach to conduct the prevalence study and was an innovative method to administer a relatively long battery of measures to this target group (*Figure 1*). It also had the advantage of automating the routing through the questionnaire, showing the respondent only applicable questions in an engaging and clear layout. Moreover, encrypted data were uploaded securely onto a secure server and could be monitored by the co-ordinating centre in real time. This allowed the research team to check daily when quotas for each year group had been reached. It also reduced the time needed for data entry and cleaning, negating the need for manual data entry for most of the data collected. This data collection application program (app) was further developed and adapted for the data collection and randomisation of participants in the RCTs as part of work package 3.

Participants

Data collection took place between December 2012 and May 2013. Participants were aged between their 10th and 18th birthdays and were attending 1 of 10 participating EDs across England: in the North East, Yorkshire and The Humber, and London. To be eligible for inclusion in the research, the participant had to be alert and orientated and able to speak sufficient English to complete the research assessments. Participants were not eligible for inclusion if they had a severe injury, were suffering from a serious mental health problem or were grossly intoxicated (as determined by ED staff). Participants were also not eligible to take part if they or their parent or guardian (as applicable) were unable or unwilling to provide informed consent.

We excluded grossly intoxicated patients on the basis that they would not be able to provide informed consent. Clinical protocols for young people presenting to accident and emergency (A&E) departments in a grossly intoxicated state would involve escalation to consider safeguarding concerns and potentially referral

Show dev panel



Participant details for 4 test12

Inclusion & Exclusion criteria

Does the patient fulfill all of these criteria?

The patient...

Is aged between 14 – 17 years*	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Is alert & orientated*	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Is able to speak & understand English *	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Is capable of providing informed consent to participate*	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Has a Smartphone or access to the internet at home*	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Lives within 20 miles of this A&E*	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Is NOT suffering from a serious mental health issue*	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Is NOT grossly intoxicated*	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Is NOT receiving specialist service input due to social or psychological need*	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Either NOT currently or in the last 6 months has received treatment for an alcohol or drug use disorder*	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Is NOT currently involved in this or any other alcohol research*	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No

Save and continue later

Next

FIGURE 1 Screenshot of the data collection app developed for the programme and available from the authors.

to specialist services in most of the hospitals involved in this programme of research. Therefore, the brief interventions being studied in this programme would have been less than the minimal intervention considered necessary for this group.

However, if those patients sobered up during their stay in A&E, then they were approached at a later stage about participating in the research, provided that there were no other clinical concerns or reasons for exclusion.

Procedure

Following clearance by ED staff, a researcher approached consecutive ED attenders meeting the study criteria every day of the week between 8 a.m. and midnight. For those participants aged < 16 years and unaccompanied by a parent or guardian, Gillick competence was assessed by a member of ED staff. Those assessed as Gillick competent were approached by the researcher and invited to provide informed consent for participation.⁶³

We extended Gillick competency to consent for participation in research on the grounds of minimal/no risk in taking part in this prevalence study.⁶⁴

Those aged 16 or 17 years provided informed consent without recourse to a parent or guardian.

Participants completed the study questionnaires independently in a private area of the ED. The researcher was available in case clarification of questions or help with the software program was required. The study data were anonymised and collected using an iPad electronic tablet device, with the exception of the Timeline Followback questionnaire, which was manually administered by the researcher. A £5 gift voucher was given to all participants at the end of the interview to thank them for their time. All young people participating in the study were also given age-appropriate material containing information on alcohol and local services and helplines providing further support.

Measures

Figure 2 illustrates the flow of research questions. Demographic data, including age, gender and ethnicity, were collected for all participants, as was information on general health behaviours and lifestyle, including tobacco smoking. Health-related quality of life was assessed using the health-related quality-of-life questionnaire for children and young people and their parents (Kidscreen);⁶⁵ this is a 10-item generic health-related quality-of-life measure, with established validity and reliability in this population. Behavioural and emotional functioning was measured using the Strengths and Difficulties Questionnaire.^{66,67} In addition, several questions relating to age-relevant service use, including questions on previous use of health and social services, school attendance and contact with the criminal justice system, were asked.

Results

Among participants who reported any alcohol consumption, the age of first consumption in years was recorded using a single question ['how old were you when you had your first drink of alcohol (beer, cider, alcopops wine, etc.)?'], and further questions about whether or not they had consumed alcohol in the past 3 months and past 24 hours were asked. In addition, all participants who had ever drunk alcohol were asked question 19 ('experienced alcohol intoxication in your lifetime?') and question 21 ('personal experience of alcohol?') from the European School Survey Project on Alcohol and other Drugs (ESPAD).⁶⁸ Further questions were included to assess the feasibility of conducting a future alcohol intervention study, including whether or not the participant wanted further information or advice about alcohol, and whether or not they were willing to participate in an intervention and follow-up study, if this was offered. They were also asked how easy they had found it to complete the questionnaire electronically.

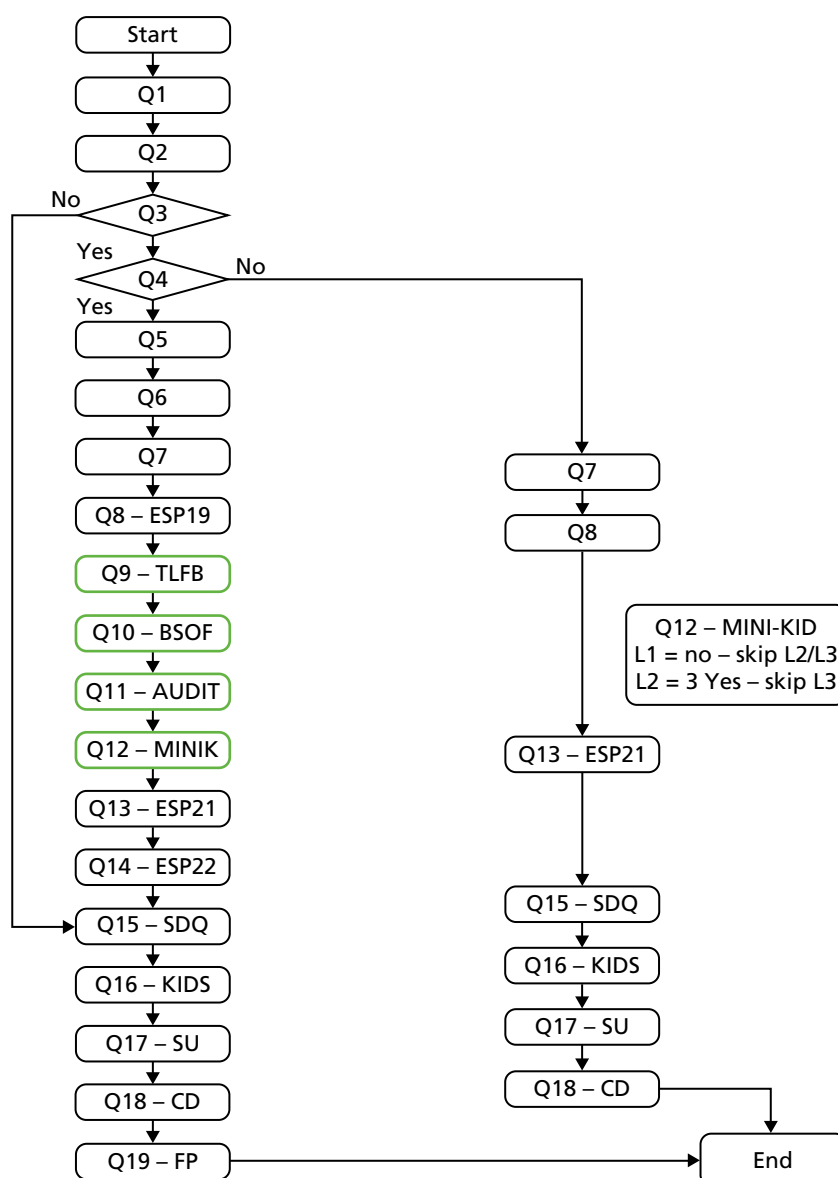


FIGURE 2 Flow of research questions. Q1, Demographics. Q2, Health and Lifestyle questionnaire. Q3, Filter question 1: have you ever drunk alcohol? Do not include just a sip of somebody else's drink. Q4, Filter question 2: have you ever drunk alcohol in the past 3 months? Do not include just a sip of somebody else's drink. Q5, Have you had a drink of alcohol in the past 24 hours? Q6, Have you consumed any alcohol prior to attendance at ED? Q7, How old were you when you had your first sip of alcohol (beer, cider, alcopops, wine, etc.)? Q8, European School Survey Project on Alcohol and Other Drugs Q19 (alcohol intoxication). Q9, Timeline Followback 90.^{a,c} Q10, Beverage Specific Quantity Frequency Questionnaire.^{a,c} Q11, AUDIT.^{b,c} Q12, Mini International Neuropsychiatry Interview for Children and Adolescents (MINI-KID) Alcohol.^{b,c} Q13, European School Survey Project on Alcohol and Other Drugs Q21. Q14, European School Survey Project on Alcohol and Other Drugs Q22. Q15, Strengths and Difficulties Questionnaire (SDQ). Q16, health-related quality of life questionnaire for children and young people and their parents (Kidscreen). Q17, service utilisation. Q18, cognitive debrief. Q19, future participation details. BSQF, Beverage Specific Quantity Frequency; ESP19, European School Survey Project on Alcohol and Other Drugs Q19; L, Level; Q, Question; SDQ, Strengths and Difficulties Questionnaire; TLFB, Timeline Followback. a, The order of presentation of quantity–frequency measures (Timeline Followback and Beverage Specific Quantity Frequency Questionnaire) were allocated at random, stratified by age group. b, The order of presentation of diagnostic measures (AUDIT and MINI-KID) were allocated at random, stratified by age group. c, The order of presentation of quantity–frequency measures and diagnostic measures were allocated at random, stratified by age group.

Those participants who indicated that they had consumed alcohol that was 'more than a sip' in the past 3 months were asked additional questions about alcohol use. Hazardous alcohol use, harmful alcohol use and harmful alcohol dependence were assessed using the three-item AUDIT-C,⁵⁴ the full 10-item AUDIT and the alcohol section of the Mini International Neuropsychiatric Interview for Children and Adolescents (MINI-KID), respectively.⁶⁹ Quantity of alcohol consumed in the past 90 days was derived from the Timeline Followback Form 90⁷⁰ and converted to standard units, for which one unit was the equivalent of 8 g of pure ethanol. In addition, beverage-specific quantity and frequency questions were asked for consumption of beer, cider, alcopops, spirits and wine. This is an ad hoc tool developed for this study. The Beverage Specific Quantity Frequency Questionnaire's measure of alcohol consumption is derived from methods used to measure consumption in adolescent populations⁶ and conforms with European guidance on the standardisation of measurement of consumption. This questionnaire measures total quantity and frequency of consumption of specific beverages and episodes of excessive consumption over a 90-day period.

The AUDIT has been validated in adolescent populations in EDs in the USA.^{56,58} As part of the current programme of research, the shorter, three-question AUDIT-C was validated with a cut-off point of 3 [see *Characteristics analysis of screening tools (aim 1)*]. The Timeline Followback Form 90 has been validated for use among this population.⁷¹⁻⁷³ Perceived consequences of alcohol consumption were assessed by question 22 of ESPAD: 'because of your own alcohol use, how often during the last 12 months have you experienced the following?'.⁶⁸

Overall, 5781 participants were asked to participate in the survey, of whom 5377 (93%) consented to participate across the 10 EDs. The mean age of participants was 13.3 [standard deviation (SD 2.1)] years, with similar proportions of male (53.7%) and female (46.3%) participants and a majority of white participants (72.6%). Overall, 2112 (39.3%) participants had consumed alcohol at some time in the past and 1378 (25.6%) participants had consumed alcohol in the past 3 months. Those who had consumed alcohol tended to be older (14.8 years vs. 12.3 years) and were more likely to be white (83.4% vs. 65.6%).

Characteristics analysis of screening tools (aim 1)

A significant positive correlation was identified for AUDIT score for the total number of standard drinks consumed in the past 3 months [Spearman's $r = 0.72$, 95% confidence interval (CI) 0.71 to 0.73; $p < 0.001$] and a similar correlation was identified for AUDIT-C score (Spearman's $r = 0.69$, 95% CI 0.68 to 0.70; $p < 0.001$).

Screening properties of the AUDIT-C and the 10-item AUDIT questionnaire were tested against the gold-standard criteria for at-risk drinking, heavy episodic alcohol consumption, alcohol abuse and alcohol dependence, and appropriate cut-off points were identified for each instrument.

The optimum cut-off point for AUDIT in identifying either at-risk drinking, monthly heavy episodic drinking or alcohol abuse was a score of ≥ 4 ; this provided acceptable sensitivity, specificity and diagnostic odds. An AUDIT-C score of ≥ 3 demonstrated almost identical diagnostic properties but with a significantly better sensitivity for at-risk drinking.

An AUDIT score of ≥ 7 provided a significantly more effective cut-off point for alcohol dependence than any other cut-off point, and demonstrated significantly better diagnostic properties than an AUDIT-C score of ≥ 5 .

Sensitivity analysis that incorporated age, gender and ED into the analysis as covariates indicated no influence of these covariates on the observed outcomes.

Prevalence of alcohol consumption (aim 2)

A total of 2112 (39.3%) of the 5377 participants who consented to take part in the research reported having had a drink of alcohol that was more than a sip in their lifetime, with prevalence increasing steadily with age (*Figure 3*).

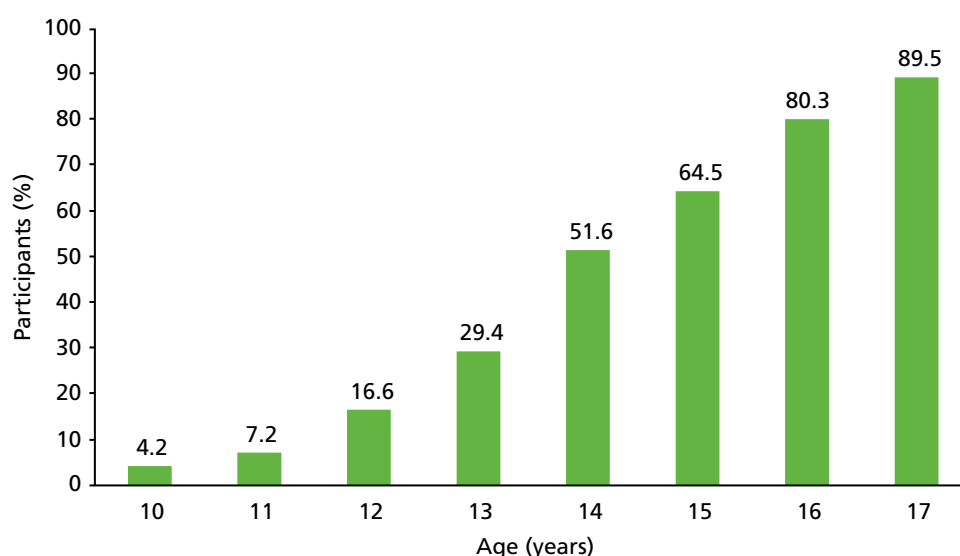


FIGURE 3 Percentage of participants who had a drink of alcohol that was more than a sip in their lifetime by current age. Reproduced from Donoghue *et al.*⁶² Reprinted from *Journal of Adolescent Health*, vol. 60, Donoghue K, Rose H, Boniface S, Deluca P, Coulton S, Alam MF, *et al.* Alcohol consumption, early-onset drinking, and health-related consequences in adolescents presenting at emergency departments in England pp. 438–446, 2017, with permission from Society for Adolescent Health and Medicine.

A total of 1374 participants (25.6% of the whole sample) reported drinking more than a sip of alcohol in the previous 3 months. The average age of first alcoholic drink was 12.9 years, ranging from 5 to 17 years of age (17 years was the upper limit for inclusion in this study). The prevalence of at-risk drinking was 14.8% (95% CI 13.9% to 15.8%), of monthly heavy episodic alcohol use was 10.6% (95% CI 9.8% to 11.4%), of alcohol abuse was 2.4% (95% CI 2.0% to 2.8%) and of alcohol dependence was 1.2% (95% CI 0.9% to 1.5%). Among the sample of those who had consumed alcohol in the past 3 months, the prevalence of these behaviours was significantly higher.

Relationship between alcohol consumption and harm (aim 3)

Alcohol consumption in the previous 3 months was associated with older age, being female, being white and having smoked tobacco. In addition, those who had consumed alcohol within the previous 3 months were more likely to report a lower quality of life and to have peer and social problems.

We also found that total alcohol consumed in the previous 90-day period was associated with tobacco use, lower quality of life, poorer general social functioning (conduct and hyperactivity), and the ESPAD questions on health and social problems.

Further analysis investigated the association between age of first alcohol consumption and psychological and social problems. Only participants aged 16 or 17 years who had consumed alcohol in the past 3 months ($N = 609$, $n = 316$ female) were included in this analysis. This analysis showed that consumption of alcohol before the age of 15 years was associated with an increased risk of a number of health and social problems. These included a greater risk of smoking tobacco ($p < 0.001$), lower quality of life ($p = 0.003$) and a diagnosis of an AUD, as indicated by the MINI-KID ($p = 0.002$). Consumption of alcohol before the age of 15 years was also associated with a greater risk of experiencing conduct ($p = 0.001$) and hyperactivity problems ($p = 0.001$), and more alcohol-related social problems, including having an accident ($p = 0.046$), problems with a parent ($p = 0.017$), school problems ($p = 0.0117$) and experiencing problems with the police ($p = 0.012$).

Discussion

In this work package, we investigated for the first time the screening properties of a short tool, the prevalence of alcohol consumption, the relationship with emotional and behavioural problems, and alcohol-related harms in adolescents presenting to the ED. The strengths of this study include the large sample size, the wide age range of those studied who were not seeking alcohol treatment and the broad spread of study across 10 EDs in England.

We found that a simple, short three-item self-completed screening instrument, the AUDIT-C, is overall more effective than the longer 10-item AUDIT in identifying adolescents who engage in at-risk alcohol consumption, monthly heavy episodic alcohol use and fulfil the ICD-10 criteria for alcohol abuse. Furthermore, the AUDIT with a cut-off score of 7 is more efficient than the AUDIT-C in identifying adolescents with alcohol dependence. In addition, the AUDIT-C and the AUDIT are widely employed as screening tools for adults in clinical and non-clinical settings and these can be applied equally to adolescent populations with these lower cut-off scores. We conclude that the AUDIT-C should be employed with this population with a cut-off score of 3 as a positive screen for at-risk drinking, monthly heavy episodic alcohol use and alcohol abuse. For those who score ≥ 5 on the AUDIT-C, we recommend that the additional seven questions constituting the full AUDIT be administered. Those scoring ≥ 7 should be clinically assessed for alcohol dependence.

We also found that nearly 40% of the adolescents presenting to the study EDs in England reported that they had consumed a drink of alcohol that was more than a sip in their lifetime. Rates of consumption increased considerably with age, ranging from just 4% for those aged 10 years to 90% for those aged 17 years. Among adolescents who had consumed alcohol in the past 3 months, 14.8% of drinkers screened positive for hazardous alcohol use (≥ 3 on the AUDIT-C).

This work package shows an association between earlier alcohol consumption and harm in adolescents. The prevalence of a diagnosis of harmful alcohol use or dependence was considerably higher among participants who started drinking before the age of 15 years, but it remains to be established whether or not these persist into adulthood. Although the results of this work package do not establish causality, effective interventions to reduce alcohol consumption in this population could potentially mitigate the harmful consequences related to alcohol that are experienced from a young age in this group.

This study identified a high prevalence of AUDs in adolescents attending EDs; we suggest that this setting is relevant for research on alcohol screening in young people. The ED also has a high level of staff expertise, which is well placed to initiate safeguarding procedures when required and provide a good point of onward referral to specialist services. The possibility of conducting alcohol screening among adolescents presenting to the ED and the potential for providing interventions to help reduce alcohol consumption in this population was investigated further in the following work packages of this programme.

The use of technology to collect data was successful in this study, and it is known that technology shows promise as a tool to deliver interventions.

Work package 2: exploratory modelling of the interventions

This work package focuses on the development of age-appropriate alcohol interventions for adolescents. These interventions have been developed with extensive patient and public involvement through a series of focus groups and evaluation work; a review of reviews to explore the evidence base on alcohol SBI for adolescents to determine age-appropriate screening tools; and a systematic review of electronic alcohol interventions.

Systematic review of electronic alcohol interventions

We conducted a systematic review and meta-analysis of the available literature to determine the effectiveness of electronic screening and brief interventions (eSBIs) over time in non-treatment-seeking hazardous/harmful drinkers.

This systematic review has been published in Donoghue *et al.*⁷⁴

The widespread use of computers, the internet and smartphones has led to the development of electronic systems to deliver alcohol SBIs that can potentially address some of the barriers to implementation of traditional face-to-face SBIs. eSBIs have the potential to offer greater flexibility and anonymity for the individual and to reach a larger proportion of the in-need population. For both adults and adolescents, eSBIs (computer, web and phone based) can offer effective delivery of interventions in both educational and health-care settings, which may prove to be more acceptable than more traditional (face-to-face) approaches.^{75–77} In addition, eSBIs could offer a more cost-effective alternative to face-to-face interventions.

A systematic search of the literature was conducted in May 2013 (with no restriction on publication date) to identify RCTs investigating the effectiveness of eSBIs to reduce alcohol consumption through searching the electronic databases PsycINFO, MEDLINE and EMBASE. Two members of the study team independently screened studies for inclusion criteria and extracted data. Studies reporting data that could be transformed into grams of ethanol per week were included in the meta-analysis. The mean difference in grams of ethanol per week between eSBI and control groups was weighted using the random-effects method based on the inverse-variance approach to control for differences in sample size between studies.

We defined an eSBI as an electronic intervention aimed at providing information and advice designed to achieve a reduction in hazardous/harmful alcohol consumption, with no substantial face-to-face therapeutic component. A SBI was defined as screening followed by a brief intervention composed of a single session, ranging from 5 to 45 minutes in duration, and up to a maximum of four sessions aimed at providing information and advice designed to achieve a reduction in hazardous/harmful alcohol consumption. Studies were not deemed eligible for inclusion if participants were alcohol dependent, mandated to complete eSBIs or part of a preselected specific group (e.g. pregnant women). There were no restrictions on age.

A total of 23 studies^{78–101} were deemed eligible for inclusion in this systematic review. All study interventions were either computer or web based. The content of the interventions included an assessment followed by personalised and/or normative feedback. Control conditions generally consisted of an assessment with no further feedback, but four studies^{82,85,90,91} included general information on alcohol consumption for those in the control conditions. There was some variation in the dose of the intervention, with the reported time taken to complete the intervention ranging from < 5 minutes⁹¹ to 45 minutes.⁹⁴ The dose of exposure to the intervention could also be increased through repeated access during the study period⁸¹ and/or a printed copy of the personalised feedback provided.^{83,88,93,95,97,100} The attrition rate was highly variable between studies, ranging from 1% or 2%⁸⁷ to > 50%.⁹⁹

We found that there was a statistically significant mean difference in grams of ethanol consumed per week between those receiving an eSBI and those in the control group at up to 3 months (mean difference –32.74, 95% CI –56.80 to –8.68), from 3 months' to < 6 months' (mean difference –17.33, 95% CI –31.82 to –2.84), and from 6 months' to < 12 months' follow-up (mean difference –14.91, 95% CI –25.56 to –4.26). No statistically significant difference was found at a follow-up period of ≥ 12 months (mean difference –7.46, 95% CI –25.34 to 10.43).

The results of this systematic review and meta-analysis suggest that eSBIs are effective in reducing alcohol consumption in the follow-up post-intervention period between 3 months and < 12 months, but not in the longer-term follow-up period of ≥ 12 months.

A review of alcohol screening and brief interventions for adolescents

In addition to the systematic review, we conducted a review of reviews to explore the evidence base on alcohol SBIs for adolescents, and to determine age-appropriate screening tools, effective brief interventions and appropriate locations to undertake these activities, in order to address the lack of consensus about the most effective components of effective interventions. This review of reviews has been published¹⁰² and is reproduced in full in *Appendix 4*.

We conducted a review of reviews based on publications from 2003 to 2013 identified through a search of electronic databases (e.g. PubMed, Web of Science). These were judged to capture all trials of alcohol SBIs in an adolescent population. Thirteen review papers^{76,77,103–113} were identified and summarised. We also found five additional studies^{114–118} of alcohol SBIs for adolescents (all published between 2010 and 2012) that were not included in any of the published systematic reviews, and these were also included in this review. Studies that focused on primary prevention of alcohol use were excluded from this review.

Various alcohol screening methods for adolescents have been developed in the USA but have not been evaluated in the UK. Questionnaires were found to perform better than blood markers or breath alcohol concentration in all age groups. The CRAFFT and AUDIT tools are recommended for identification of 'at-risk' adolescents. In particular, the AUDIT questionnaire⁵⁴ was found to have greater sensitivity and specificity than other tools. AUDIT sensitivities for adolescents ranged from 54% to 87% and specificities ranged from 65% to 97%.³¹

A number of reviews on effective interventions for adolescents identified as being in need of help or advice about their drinking have now been published; the most recent of these have focused on the use of internet, computer and mobile phone technologies, collectively referred to as electronic brief interventions (eBIs). These reviews present limited evidence that eBIs significantly reduce alcohol consumption compared with minimal or no intervention controls,^{76,77,104} and our review presented in the previous section extends this work, indicating effectiveness of eBIs in a meta-analysis.⁷⁴ However, some caution should be exercised when interpreting these findings, as an earlier meta-analysis by Carey *et al.*,¹¹⁹ which compared eBIs with a more traditional face-to-face delivery of interventions, concluded that face-to-face delivery was superior. Indeed, motivational interventions delivered over one or more sessions and based in health-care or educational settings are effective in reducing levels of consumption and alcohol-related harm.¹⁰⁷

Further research to develop age-appropriate screening tools needs to be undertaken. The effect of SBI activity should be investigated in settings in which young people are likely to present; further assessment at venues such as paediatric EDs, sexual health clinics and youth offending teams should be evaluated. The use of electronic (web-/smartphone-based) screening and intervention shows promise and should be another focus of future research.

Overall, this review of reviews and recent RCTs suggests that, despite an increasing interest in applying SBIs to an adolescent population, there are no clear indications of which target population, setting,

screening tool or intervention approach can be recommended. The relationship between age, alcohol consumption and harm is complex, and further research is required to establish guidelines for consumption and thresholds of harm for different age groups.

Patient and public involvement in work package 2

In addition to the reviews described above, we engaged with a number of youth organisations (British Youth Council, The Well Centre and Redthread) to help refine our methodology and interventions. There was a clear indication that the stepped care motivational enhancement therapy approach that we had proposed during the application stage was not well received by our target group. As a result, we adopted their suggestions to undertake brief ED-based interaction and to use technology, and we developed a smartphone-based intervention app and a personalised feedback and brief advice (PFBA) (leaflet-based) condition for use in the intervention trials. We have involved young people in the design and content of the app and the leaflet, and have found this to be a particularly useful exercise that has helped us to achieve credibility with young people and to engage young people with our proposed interventions.

The second phase of the patient and public involvement was conducted to develop the interventions. Initially, we had planned to screen adolescents (using the optimal screening method from work package 1) and invite them to participate in a prospective RCT, using therapist-guided brief interventions and, where indicated, intensive motivational enhancement therapy (stepped care intervention). These interventions were to be compared with treatment as usual. The patient and public involvement work showed that young people felt electronic screening and consent was acceptable. A face-to-face brief intervention was acceptable in the ED, but any form of extensive intervention was not. An educational app was recommended by our focus group participants. Furthermore, the prevalence study showed that the questionnaire was too long to be acceptable to participants.

As a result, the iPad screening tool was shortened and refined to include the consent procedure to improve participant management. Participants and parents were e-mailed the information leaflets instead of being given paper copies, with laminated versions kept in the ED for reference. The iPad app was also developed to randomise participants to the different arms of the trial and to record a random sample of brief interventions for fidelity purposes.

The study design was revised so that the intervention comprised a brief intervention (PFBA) with a web-enabled smartphone app (eBI). The smartphone app was not in the initial plan for the trial but was included on the basis of the patient and public involvement, as young people had said that an educative app would be better received than our planned interventions. Adolescents had a preference for images over text, and it was suggested to make the app look and feel like a game.

The eBI takes the form of an app called 'SIPS City' [Screening and Intervention to Promote Sensible drinking (SIPS)]. The app home screen is a cartoon street with different places for young people to visit (and learn facts about alcohol), and includes gamification features that encourage participants to find and collect coins. It is designed to be engaging and educational, and to provide ongoing feedback and advice about alcohol consumption. It is loosely based on the FRAMES (Feedback of personalized risks: Responsibility, Advice, Menu of options, Empathy, Self-efficacy) motivational brief intervention approach.¹²⁰ A demonstration version of the SIPS City app was installed on iPads in the EDs to show to participants randomised to the eSBI arm of the trial, who were not able to access the app on their own smartphone while in the ED. Participants without a smartphone were asked to use an online web browser version of the app; participants who did have a smartphone but were not able to use it while in the ED were sent a link to download the app later.

The final phase of the patient and public involvement was conducted to develop an online self-completion form of the retrospective Timeline Followback-28 (alcohol consumption in the past 28 days), which was later modified in favour of a shorter outcome measure (AUDIT-C).

Work package 3: linked randomised controlled trials of face-to-face and electronic brief intervention methods to prevent alcohol-related harm in young people aged 14–17 years presenting to emergency departments

Background

A number of trials^{17,18,42,43,117,118} focusing on young people (aged 12–21 years) have reported significant positive effects of brief interventions on a range of alcohol consumption measures. Our systematic review (reported in *Work package 2: exploratory modelling of the interventions*) suggested that eBIs can significantly reduce alcohol consumption compared with minimal or no intervention controls, and have the added advantage of being more acceptable and easier to implement than more traditional face-to-face interventions. Our study of the prevalence of risky drinking among an adolescent population (aged 10–17 years) reported in *Work package 1: screening prevalence study of alcohol consumption and alcohol use disorders in adolescents aged 10–17 years attending emergency departments* found that about one in four young people presenting to EDs was consuming three or more drinks on one or more occasion over the preceding month, and that this level of consumption was associated with increased physical, social and educational adverse consequences. We also observed a steep transition in drinking prevalence between 13 and 17 years of age.

Several school-based interventions¹²¹ that target non-drinking adolescents have been found to delay the onset of drinking behaviours, and a recent study of adolescents¹²² found lower rates of substance misuse initiation among those exposed to a web-based intervention. Web-based alcohol interventions for adolescents also demonstrated significantly greater reductions in consumption and harm among ‘high-risk’ drinkers.¹²³ However, changes in risk status at follow-up for non-drinkers or low-risk drinkers have not been assessed in controlled trials of brief intervention.

Recruitment of both ‘high-risk’ and ‘low-risk’ drinkers has the additional benefit of addressing a major concern among both young people and parents, namely that participation in a trial of this nature may identify the young person as drinking at a level that warrants concern and intervention. Young people interviewed as part of our patient and public involvement work in work package 2 indicated that they would prefer to take part in a trial if there was no implication that they had an ‘alcohol problem’ and were assured that information about their drinking would not be disclosed to parents or health-care staff. Recruitment of both high- and low-risk-drinking young people was more acceptable to both young people and their parents, as was emphasising participant confidentiality.

Thus, we conducted two linked RCTs that included both high- and low-risk drinkers and abstainers, informing them that the study sought to prevent alcohol-related harm in young people. In addition, embedded within the proposed study was an internal feasibility study conducted prior to proceeding to the main trial.

The trials protocol has been published in Deluca *et al.*¹²⁴ and parts of this section have been reproduced from Deluca *et al.*¹²⁴ This article is published under license to BioMed Central Ltd. This is an Open Access article distributed under the terms of the Creative Commons Attribution License (<http://creativecommons.org/licenses/by/4.0>), which permits unrestricted use, distribution, and reproduction in any medium, provided

the original work is properly credited. The Creative Commons Public Domain Dedication waiver (<http://creativecommons.org/publicdomain/zero/1.0/>) applies to the data made available in this article, unless otherwise stated.

Objectives

Primary objective

The primary objective was to conduct two linked RCTs to evaluate the clinical effectiveness and cost-effectiveness of brief intervention strategies compared with screening alone. One trial focused on high-risk adolescent drinkers attending EDs and the other focused on those identified as low risk or abstinent from alcohol. In both trials our primary outcome measure was quantity of alcohol consumed at 12 months after randomisation.

Secondary objectives

The secondary objectives of each study were:

- to identify key predictors of recruitment to the trials
- to explore the process of intervention through key psychological constructs that may lead to further refinement of the proposed interventions
- to identify prognostic factors related to better outcomes
- to explore interactions between participant factors, setting factors, treatment allocation and outcomes.

Our primary (null) hypothesis was similar for both trials: PFBA and personalised feedback plus eBIs is no more effective than screening alone in reducing alcohol consumed at 12 months after randomisation as measured with the AUDIT-C. Our secondary (null) hypothesis relating to health economics states that PFBA and eBIs are no more cost-effective than screening alone.

Methods

The linked trials were granted ethics approval by the National Research Ethics Service London – Fulham (reference 14/LO/0721). The trials comply with the Declaration of Helsinki¹²⁵ and Good Clinical Practice¹²⁶ and have been registered as ISRCTN45300218.

Study setting and participants

The trials were carried out in 10 EDs across three regions of England: North East, Yorkshire and The Humber, and London. Data collection was carried out from 10 a.m. to 10 p.m., 7 days per week, over an 8-month period (October 2014–May 2015). During these screening hours, consecutive ED attenders who were between their 14th and 18th birthdays and who met the inclusion criteria but none of the exclusion criteria were approached by a researcher and invited to participate in the study once cleared by ED staff to do so.

Eligibility criteria

Inclusion and exclusion criteria were chosen to maintain a balance between ensuring the sample was representative of the ED population while also able to engage with both the relevant interventions and follow-up.

Inclusion criteria

The inclusion criteria were being aged between 14 and 17 years inclusive; being alert and orientated; being able to speak English sufficiently well to complete the research assessment; living within 20 miles of the ED; being able and willing to provide informed consent to screening, intervention and follow-up; if under aged < 16 years, being 'Gillick competent' or having a parent or guardian who was able and willing to provide informed consent; and owning a smartphone or having access to the internet at home.

Exclusion criteria

The exclusion criteria were having a severe injury; suffering from a serious mental health problem; being grossly intoxicated; specialist services being involved because of social or psychological needs; receiving treatment for an AUD or substance use disorder within the past 6 months; or currently participating in other alcohol-related research.

The inclusion and exclusion criteria were discussed with hospital nurses/doctors before a potential participant was approached and after clinical staff assessed the participant. We relied on their knowledge and professional judgement.

Those who were grossly intoxicated on attendance were not the population of interest. The study addressed those who consumed alcohol at levels at risk to their health, rather than alcohol-related attendances. Although it is possible that these two groups overlapped, we were mindful of the issue of informed consent for those who presented as grossly intoxicated; however, if their intoxicated state reduced to an acceptable level while they were in the ED, they were approached.

Those who met the inclusion criteria and none of the exclusion criteria and scored ≥ 3 on the screening questionnaire, AUDIT-C, were eligible for the high-risk study; those who scored < 3 on AUDIT-C were eligible for the low-risk study.

Consent procedure

The study was introduced to patients, and to their parent or guardian if they were aged < 16 years, as a study about alcohol, lifestyle and health, with the focus on preventing alcohol-related harm in all young people attending ED irrespective of their alcohol consumption. Patients aged < 16 years attending the ED without their parent or guardian were also approached to take part if ED staff confirmed that they were 'Gillick competent'. We extended Gillick competency to consenting for participation in research on the grounds of minimal/no risk in taking part in this study, the potential direct benefit that they would gain from the advice received and the potential benefit to the wider society in the roll-out of the findings.⁶⁴

The study was first introduced by ED staff and then explained in more detail by research staff, both verbally and using the patient information sheet. If the patient was under the age of 16 years and accompanied by a parent or guardian, the parent or guardian would also receive the patient information sheet. Patients, and parents or guardians if applicable, had up to 4 hours to ask any questions about the study and to decide whether or not to take part. To obtain the most valid self-report data, patients were told as part of the informed consent procedure that their answers, including those on alcohol consumption, would not be disclosed to their parent or guardian or the ED staff without their consent (*Figure 4*).

If patients agreed to participate, their informed consent was recorded using an electronic device (iPad), overseen by a research assistant who also introduced and delivered the allocated intervention to each patient in a private area of the ED. Consent to participate included permission to give the patient's data and contact details to the research staff, to provide the research team with access to the patient's ED records, and to participate in follow-up at 6 and 12 months after recruitment.

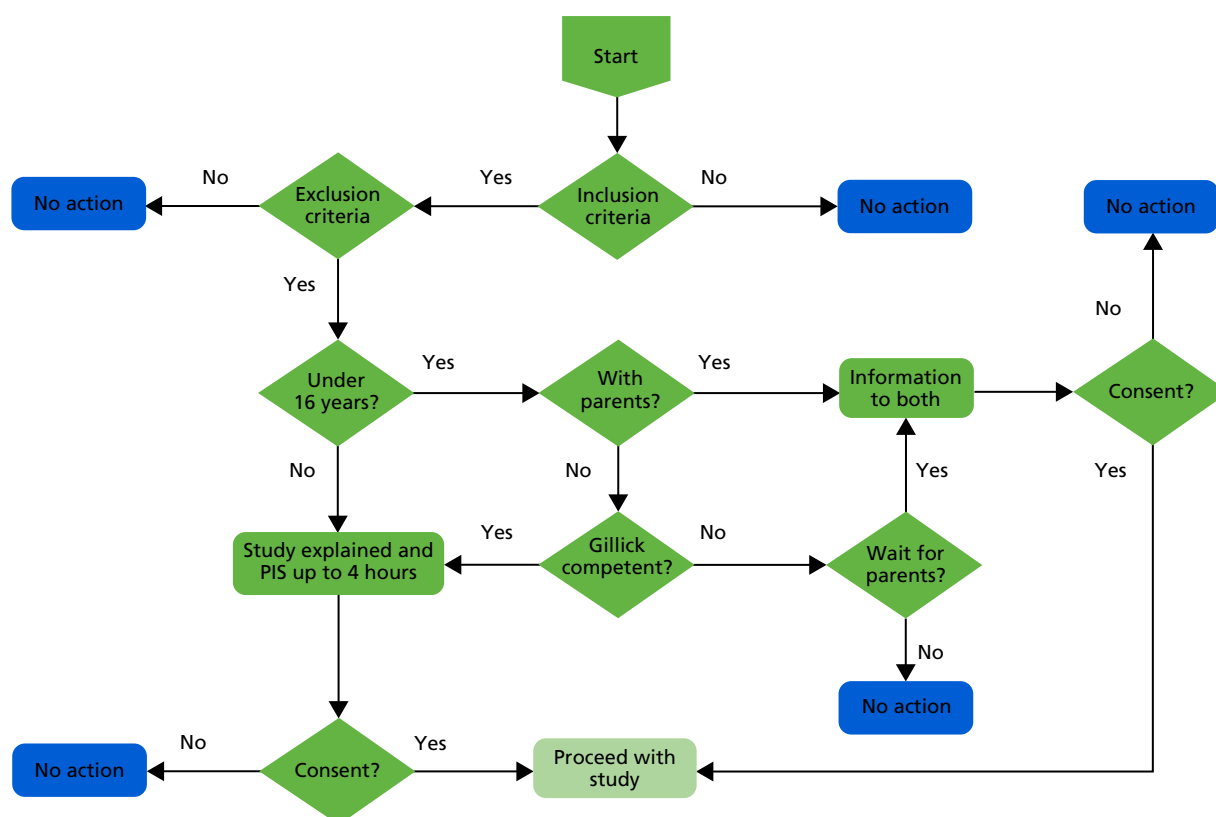


FIGURE 4 Decision tree for consent. PIS, patient information sheet.

Screening and baseline assessment

After consent was given by the patient or their parent or guardian, as appropriate, the participant completed a screening and baseline assessment (*Figure 5* shows the sequence of tools administration). All participants scoring ≥ 3 on the AUDIT-C (high-risk drinkers) were randomised between three groups [two intervention groups (PFBA and eBIs) and the control group receiving screening alone]. Of those scoring < 3 on the AUDIT-C (low-risk drinkers or abstainers), one in three was randomly selected to continue with the study and then randomised between three analogous groups. Participants who scored < 3 but were not selected for the trial were thanked for their participation, given a £5 voucher and returned to the care of the ED staff.

The screening and baseline assessment includes demographic information and contact details; health and lifestyle questions; the AUDIT-C;⁵⁴ questions 19, 21 and 22 from ESPAD;⁶⁸ the Strengths and Difficulties Questionnaire,¹²⁷ the EuroQol-5 Dimensions, five-level version (EQ-5D-5L);¹²⁸ and a short service use questionnaire.¹²⁹ This took approximately 10 minutes to complete.

To simplify and enhance data collection, we used a bespoke electronic interface (developed in work package 1), which automated question routing, showing participants only relevant questions. To maximise completion rates, we used an attractive graphical interface. Participants were able to skip questions or withdraw consent at any stage. All of the instruments have been designed and validated for those aged 14–17 years. The screening and baseline assessment was conducted by trained researchers with experience of working with adolescents, and all researchers had completed enhanced Disclosure and Barring Service checks prior to working in the ED. All information that participants gave was treated in confidence.

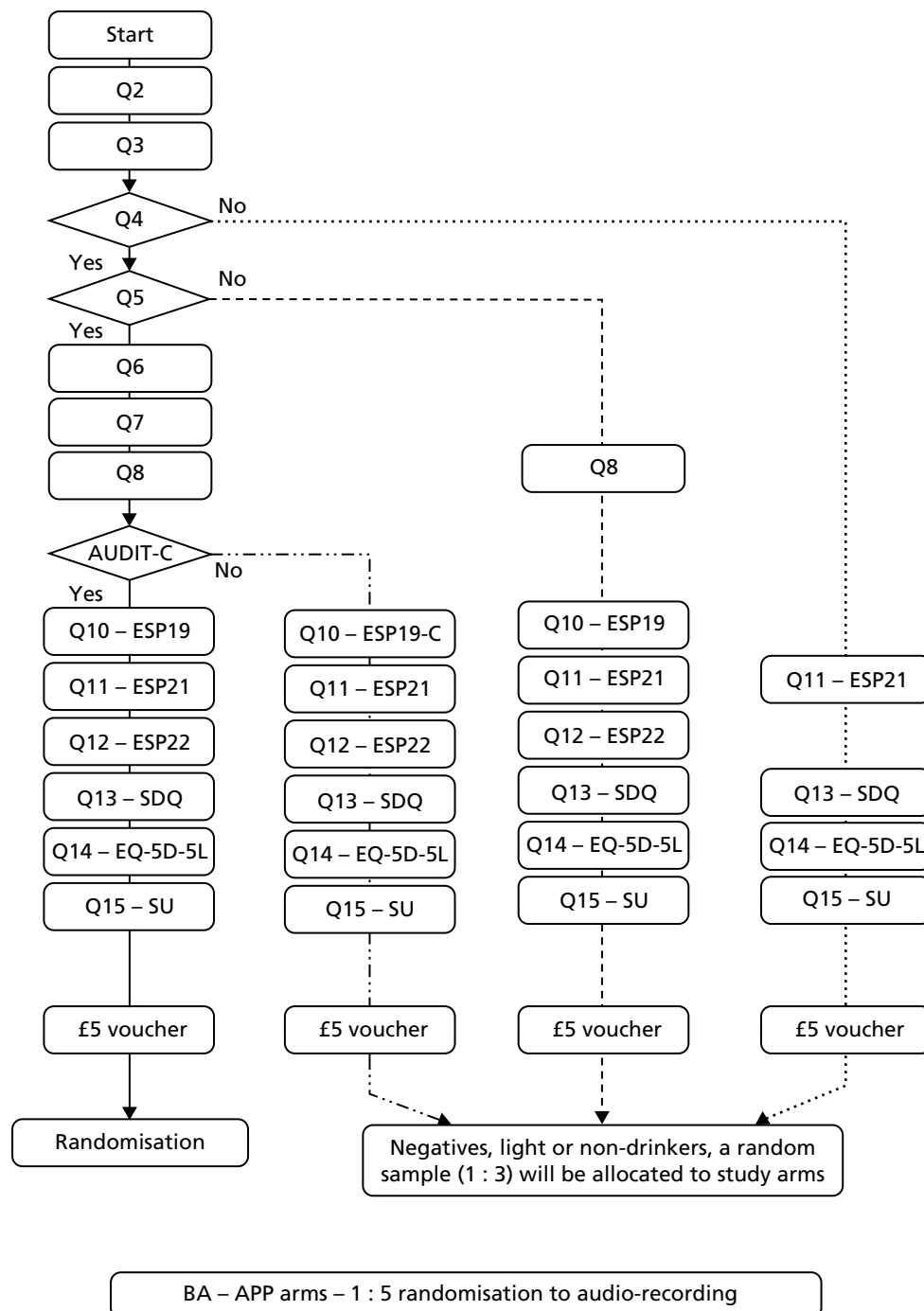


FIGURE 5 Baseline sequence. APP, SIPS Jr City app; BA, brief advice; EQ-5D-5L, EuroQol-5 Dimensions, five-level version; ESP19, European School Survey Project on Alcohol and Other Drugs Q19; ESP19-C, European School Survey Project on Alcohol and Other Drugs Q19c; ESP21, European School Survey Project on Alcohol and Other Drugs Q21; ESP22, European School Survey Project on Alcohol and Other Drugs Q22; Q, question; SDQ, Strengths and Difficulties Questionnaire; SU, Service Use Questionnaire.

Participants were remotely randomised with equal probability, stratified by centre, between a screening only control group and one of the two interventions: a single session of face-to-face PFBA or personalised feedback plus a smartphone- or web-based brief intervention (eBI). All participants were eligible to receive treatment as usual in addition to any trial intervention.

Randomisation

Randomisation to trial participant or non-participant was conducted using a simple block randomisation, with a one in three probability of selection. For those selected as participants, randomisation to study group was conducted using strings of randomly selected block sizes, three or six, stratified by ED and gender. Each iPad within a centre had a separate pre-programmed allocation sequence derived by an independent party and made secure using encryption. Researchers engaged in the baseline assessment were not aware of allocated group until after outcomes had been completed. Participants were not blind to allocated group.

Interventions

Screening only group: treatment as usual

After completing the baseline assessment, participants in the screening arm were thanked for their participation, reminded that a member of the research team would contact them in 6 and 12 months to conduct a follow-up interview and returned to the care of the ED staff for usual care.

Personalised feedback and brief advice

The PFBA intervention is structured brief advice that takes approximately 5 minutes to deliver (*Figure 6*) in one session. It is based on an advice leaflet adapted for the target age group in this study from the SIPS brief advice about alcohol risk intervention.^{130,131} It is based on the FRAMES model:¹³²

Feedback: Give feedback on the risks and negative consequences of alcohol use. Seek the patient's reaction and listen.

Responsibility: Emphasise that the individual is responsible for making his or her own decision about his/her alcohol use.

Advice: Give straightforward advice on modifying alcohol use.

Menu of options: Give menus of options to choose from, fostering the patient's involvement in decision-making.

Empathy: Be empathic, respectful and non-judgemental.

Self-efficacy: Express optimism that the individual can modify his or her alcohol use if they choose.

Self-efficacy is one's ability to produce a desired result or effect.

It is conveyed verbally to the participant by trained research assistants or nurses and tailored to their risk status (high or low). It was delivered in a quiet room in the ED.

The advice covers recommended levels of alcohol consumption for young people; gives feedback on the screening results and their meaning; provides normative comparison information on prevalence rates of high- and low-risk drinking in young people; summarises the risks of drinking and highlights the benefits of stopping or reducing alcohol consumption; outlines strategies that they might employ to help stop or reduce alcohol consumption; highlights goals they might wish to consider; and indicates where to obtain further help if they are unsuccessful or need more support.

Each participant received a copy of the leaflet, which included additional information about alcohol intoxication, alcohol poisoning, and alcohol and the law.

Personalised feedback plus a smartphone- or web-based brief intervention

The eBI smartphone intervention SIPS City is an offline-capable mobile web application that works on a variety of platforms but is optimised for recent iPhone (Apple Inc., Cupertino, CA, USA) and Android (Google Inc., Mountain View, CA, USA) phones (*Figure 7*). It was developed for this research by the software developer Codeface Ltd (Hove, UK) in collaboration with the research team. It followed the recommendations from patient and public involvement, and it was developed using the concept of gamification so that users can navigate, explore, learn facts and figures about alcohol, receive personalised feedback and set goals in an engaging format. The content was adapted to provide the most pertinent information and advice for high- or

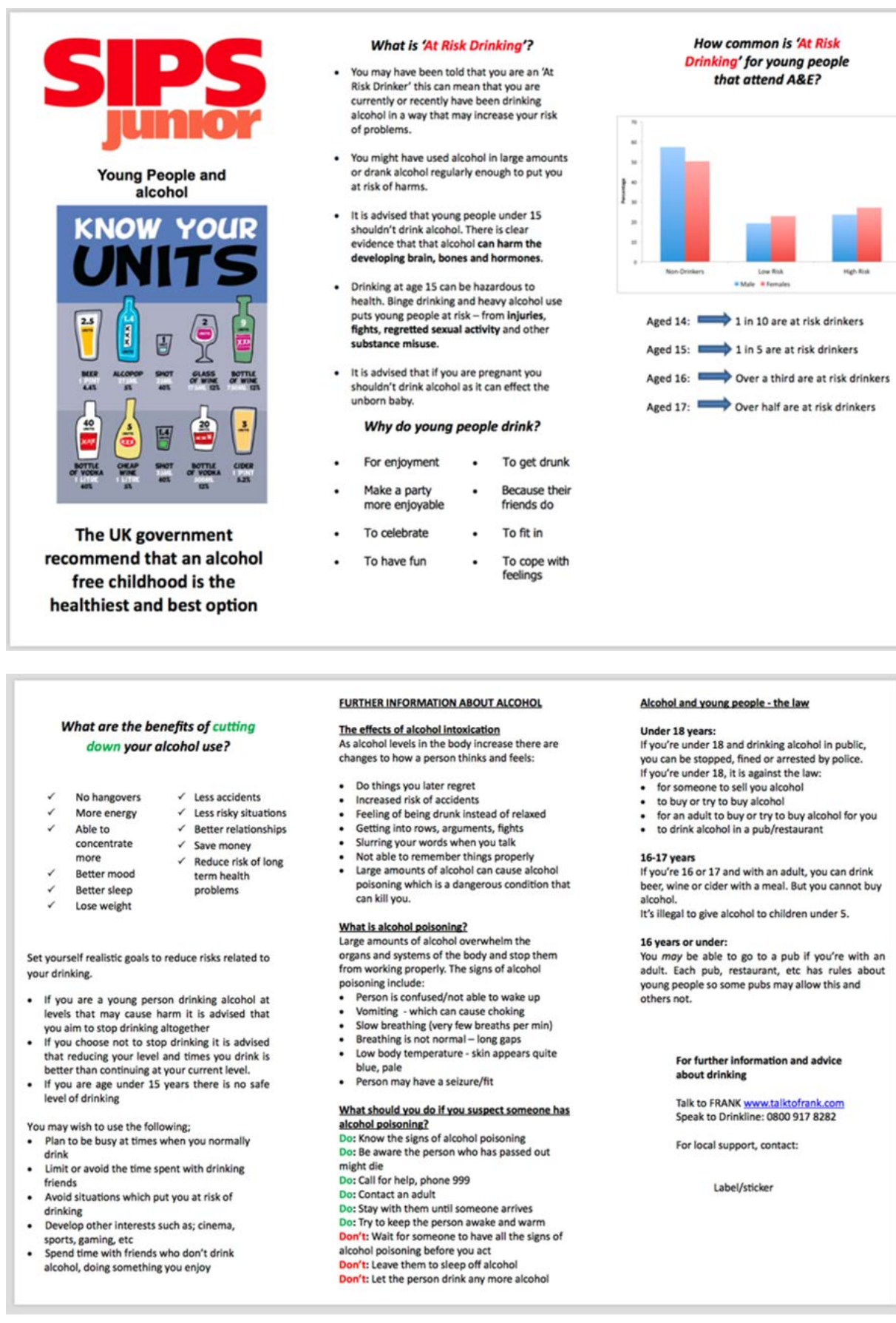


FIGURE 6 Brief advice leaflet.



FIGURE 7 SIPS Jr Street app with full view of East and West Streets.

low-risk drinkers and was similar in content to what was provided in the PFBA intervention arm described above in *Personalised feedback and brief advice*. Games components of the web application supported high-risk drinkers to reduce or stop their alcohol consumption and low-risk users to maintain abstinence or low-risk drinking.

The SIPS City app was formatted into a virtual reality of two streets, west and east, in which there were multiple buildings such as a general practice, a pub and a youth centre. To gain access to some buildings, participants had to collect a certain number of coins, which could be obtained from talking to characters on the street or by answering questions correctly. When interacting with people on the street, participants were directed to certain buildings depending on the problem that person was encountering, for example the doctor for alcohol poisoning. It was also possible to drive in the car of 'Rod McDuff's School of Motoring', and facts regarding the risks of alcohol and drinking were portrayed while inside the car.

The first building was the participants' home, where they could fill out a drinking diary and receive feedback from this. It was also possible to view information on units and a letter from the local A&E about the participant's drinking. Interaction with a health worker at the general practice allowed a user to follow-up the A&E letter and set personal alcohol goals. There was a sexual health clinic building that provided information on the increase of sexual health risks with increased alcohol intake. After two coins had been obtained, access to East Street was granted. The pharmacy was here, which provided information on how to reduce the effects of a hangover. The school provided information on the harmful effects of alcohol in relation to education, which provided relatable information to those in the age group in this study.

Whenever possible, the app was installed, with the help of a research assistant/nurse, on the participant's smartphone while they were attending A&E and the participant was encouraged to use it. In the instances when they did not have access to their phone (e.g. flat battery, left at home, no data plan), patients were introduced to a demonstration version of the app on a study device (iPad) and allowed to play with it while in A&E. An e-mail and short message service (SMS) were also sent to the patient within 24 hours with instructions on how to download and install the app on their smartphone once they were at home.

Two further reminders (e-mail and SMS) were sent in the following 2 weeks to those who had failed to install the app on their smartphone.

For participants without access to a smartphone but with access to the internet through other computerised devices, access to a web-based version of the application was provided along with appropriate instructions for its use.

After receiving their allocated intervention (including the screening only group), all participants were thanked for their participation, reminded that a member of the research team would contact them in 6 and 12 months to conduct a follow-up interview, given a £5 voucher to thank them for their time and returned to the care of the ED staff.

Intervention fidelity

Research assistants were responsible for recruiting participants and delivering the interventions. The research assistants were trained during a 2-hour training session, which covered the rationale and procedures of the trial, the importance of reducing alcohol consumption and the correct delivery of the interventions. Filmed examples of delivery were presented and discussed, and role-play sessions were undertaken.

During the trial, we assessed fidelity of the delivery of the PFBA interventions by audio-recording a random sample of 20% of intervention sessions for each researcher. Each recording was assessed by a senior clinician member of the team on whether or not key aspects of the intervention were delivered as intended against a predefined checklist. When necessary, feedback was provided to researchers to improve fidelity. These recordings were prespecified in the protocol analysis plan.

Follow-up assessments

All participants were followed up with a brief set of questions at 6 months after randomisation (*Figure 8*), and then at 12 months for a full assessment (*Figure 9*). Follow-up interviews were conducted over the telephone, face to face or electronically via self-completion web survey, as preferred by the participant. The telephone and face-to-face follow-ups were conducted by research assistants trained in the administration of the assessment tools and blinded to the group allocation of the participants. Letters of thanks were sent to participants after each follow-up stage. On completion of each follow-up interview, participants were sent a gift token for £5 by post in recognition of their participation. On completion of the 12-month follow-up, participants were additionally entered in to a prize draw to win an iPad Air (Apple Inc., Cupertino, CA, USA), iPad mini (Apple Inc., Cupertino, CA, USA) or iPod (Apple Inc., Cupertino, CA, USA).

Outcome measures

Primary outcome measure

The primary outcome was the total amount of alcohol consumed in standard UK units (1 unit = 8 g of ethanol) over the previous 3 months, measured at the 12-month follow-up using the AUDIT-C, which was either self-completed by web survey or administered by researchers blinded to treatment allocation.

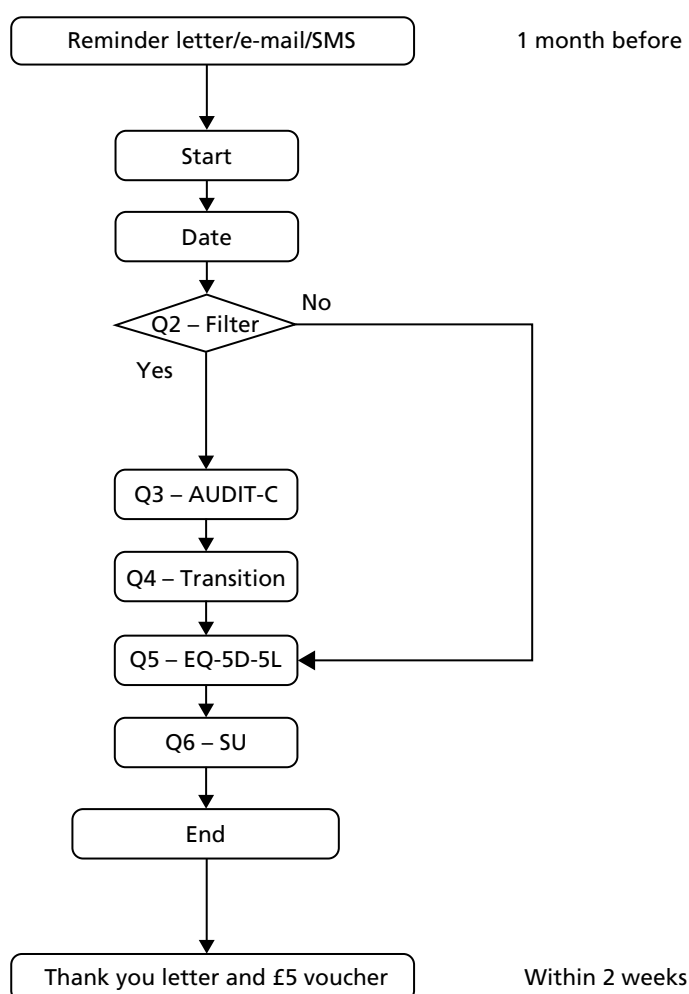


FIGURE 8 List of tools and order of presentation at 6-month follow-up. Q, question; SU, service utilisation.

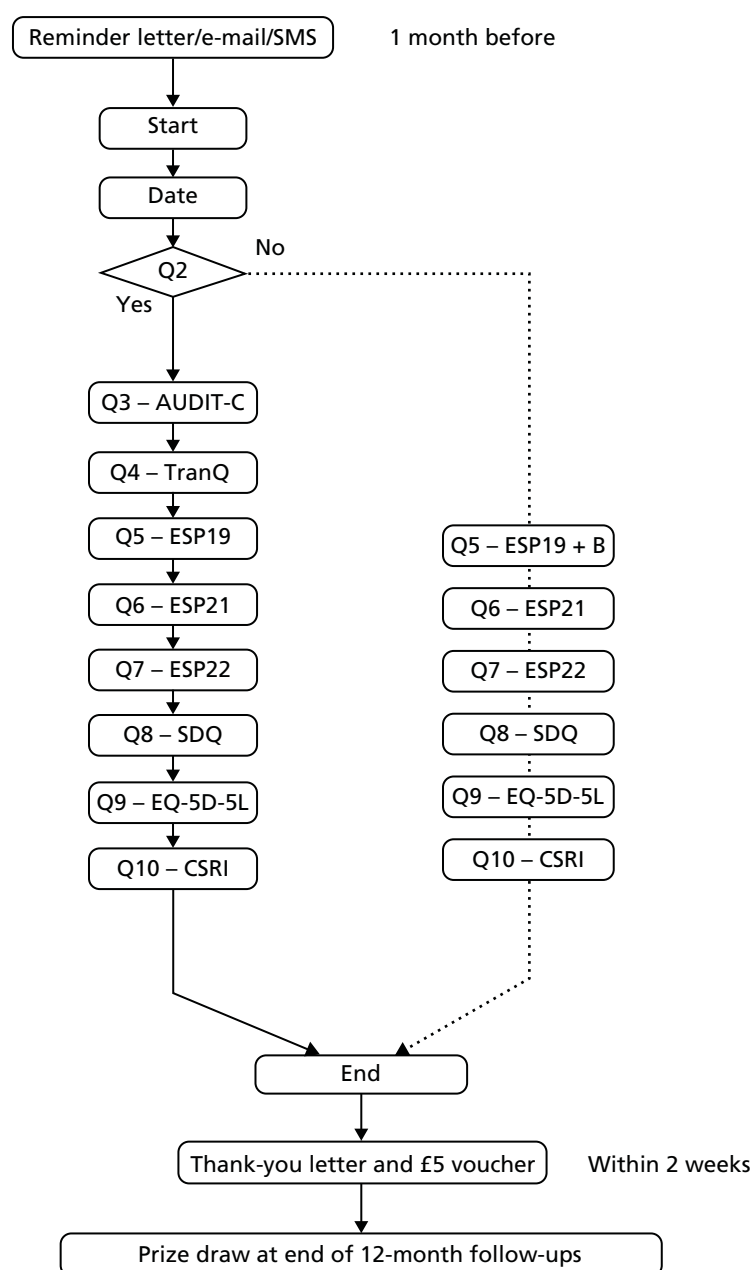


FIGURE 9 List of tools and order of presentation at 12-month follow-up. B, items A (lifetime) and B (last 12 months) in question 19; CSRI, Client Service Receipt Inventory; EQ-5D-5L, EuroQol-5 Dimensions, five-level version; ESP19, European School Survey Project on Alcohol and Other Drugs Q19; ESP21, European School Survey Project on Alcohol and Other Drugs Q21; ESP22, European School Survey Project on Alcohol and Other Drugs Q22; Q, question; SDQ, Strengths and Difficulties Questionnaire; TranQ, transition question.

In the published protocol¹²⁴ we intended to use the Timeline Followback interview (28-day version). However, this was subsequently changed to the AUDIT-C to facilitate completion rate at follow-up. The AUDIT-C is a much shorter tool (three items) and can be self-administered.

Calculation of weekly units from the AUDIT-C was conducted as follows. The extended AUDIT-C asked two questions regarding frequency and quantity of alcohol consumed. Question 1 asks about frequency, and these values are converted to weekly frequency using the following algorithm: never (0), monthly (0.25), two to four times per month (0.75), two or three times per week (2.5), four or five times per week (4.5) and six or more times per week (6.6). Question 2 asks about quantity on each drinking occasion and is converted to standard units using the following algorithm: none (0), one or two (1.5), three or four (3.5),

five or six (5.5), seven to nine (8), ten to twelve (11), 13 to 15 (14) and 15 or more (15). Weekly units are calculated by multiplying converted values for frequency and quantity.

This value allocates participants to 1 of 35 categories of consumption. An ordinal is one in which values are ranked, A is greater than B, but the relative magnitude of A relative to B is unknown. The weekly consumption calculation not only ranks participants but also allows a derivation of the relative difference between participant drinking levels. The large number of data points and the ability to assess relative magnitude means that the weekly consumption can be taken as a continuous measurement variable. This implicit assumption was tested as part of the overall analysis.

Moreover, any ordinal scale with > 11 data points can be treated as continuous.¹³³

Secondary outcome measures

Participants were also asked questions about the consequences of alcohol consumption using questions 19, 21 and 22 from ESPAD.⁶⁸ Hazardous alcohol use was assessed using the extended AUDIT-C questionnaire⁵⁴ at baseline and after 6 and 12 months. General health and functioning was measured using the Strengths and Difficulties Questionnaire¹²⁷ at baseline and 12 months.

Economic outcome measures

The primary outcome measure for the economic evaluation in the trial was a preference-based measure calculated from the EQ-5D-5L. The EQ-5D-5L quality-of-life instrument is preferred by NICE for the economic evaluation of NHS interventions. The tool focuses on five dimensions of health: mobility, self-care, usual activities, pain/discomfort and anxiety/depression.¹²⁸ The original EuroQol-5 Dimensions had three response categories (EuroQol-5 Dimensions, three-level version) for each dimension. A newly released validated version with five response categories (EQ-5D-5L) for each dimension, providing enhanced discriminatory power, was used in the study.¹³⁴ EQ-5D-5L requires no more than a few minutes to complete and thus imposes minimal burden on participants.

The EQ-5D-5L scores were converted to health utilities (1 = perfect health, 0 = equivalent to dead) using a tariff provided by the EuroQol group derived from UK social preference surveys. Resulting utilities were combined with survival data (unlikely to be affected by the service) and expressed in quality-adjusted life-years (QALYs). The estimated incremental cost per QALY from the service can be compared with the willingness-to-pay (WTP) threshold of £20,000–30,000 per extra QALY currently used by NICE to determine whether or not an intervention is 'cost-effective' and hence recommended for use in the NHS.¹³⁵

Process outcome measures

Expectancy was measured using the ESPAD question 21⁶⁸ at baseline and 12 months after randomisation. Adherence to the eBI was assessed by monitoring remotely either when the smartphone device was connected to the internet or when the web application was accessed.

Analysis

Sample size calculation

For both studies, the sample size addresses the effect of interventions on the primary outcome measure (alcohol consumption at 12 months after randomisation). We aimed to detect a meaningful effect size difference of ≥ 0.3 , based on literature relating to adults and similar to differences observed for adolescents; this would equate with a difference in weekly consumption between intervention and control of 0.1 units in the low-risk trial and 2 units in the high-risk trial.¹³⁶ To detect this with a significance level of 5% and statistical power of 80% when using a two-sided continuity-corrected test requires 175 in each of the three groups, yielding a target of 525 analysable participants in each of the two trials.

As there was little prior research in this specific area, our sample size calculation was based on similar UK RCTs^{137,145} addressing alcohol use in primary care populations. These RCTs reported effect size differences between brief interventions and minimal intervention of 0.36 and 0.27.^{138,145} Similar effects have been reported from studies in the USA, and an effect size of 0.3 is considered clinically important for alcohol brief intervention studies.¹³⁹ As there is no literature on what might be a clinically important difference for the low-risk trial, we hypothesised that a small effect size difference, of a similar magnitude to or greater than that for the high-risk trial, could be interpreted as an important effect.

Predicting that follow-up at 12 months would be 70%, we needed to randomise 750 high-risk drinkers and 750 low-risk drinkers. Based on the estimated prevalence of 24.2% for high-risk drinking (namely AUDIT-C ≥ 3) from our earlier survey, and a consent rate of 60% (see *Work package 1: screening prevalence study of alcohol consumption and alcohol use disorders in adolescents aged 10–17 years attending emergency departments*), we estimated a number needed to approach of 5165 potential participants over the recruitment period. Of these participants, our survey predicts that 2350 will be low-risk drinkers consenting to the study.

Statistical analysis

The outcomes for both trials were analysed in a similar manner. Analysis was conducted using an intention-to-treat principle, whereby participants were analysed as members of their allocated group irrespective of treatment received. All analysis was conducted using SAS® software 9.4 (SAS Institute Inc., Cary, NC, USA) and conducted blind to allocated group.

The analytical approach employed a mixed-effects model, with a fixed effect for allocated group and a random effect for ED. The covariates age, gender and baseline alcohol consumption were included as baseline covariates, as these are known to influence outcome. The distribution of the primary outcome was assessed prior to analysis and, if necessary, appropriate transformations were undertaken. A sensitivity analysis was undertaken using a non-parametric approach and assessed change in consumption. Wilcoxon rank-sum indices were generated and analysed using a similar mixed-effects approach. The influence of missing data was assessed using a series of multiple imputation models, and these were synthesised to assess the sensitivity of the observed results to missing data. Secondary outcomes were assessed using a similar mixed-model approach and adjusting for respective baseline values. To explore the value of the findings, we performed a post hoc analysis and calculated the Bayes' factor of the primary outcome, comparing eBI and PFBA with control.

Two exploratory analyses were undertaken. The first was to investigate the relationship between potential prognostic pre-randomisation factors and alcohol consumption at 12 months. The factors included were alcohol expectancy, alcohol-related problems and demographics, and any interaction between these factors and intervention group. An initial analysis explored the relationship between alcohol consumption and each factor individually, with factors or interaction terms with a p -value of < 0.2 combined to create a full model. Backward elimination was used, retaining factors with a p -value of < 0.2 in the final model. If an interaction term had a p -value of < 0.2 but the p -value for the main effect was > 0.2 , both terms were retained in the model. A second exploratory analysis explored the relationship between eBI usage and alcohol consumption at month 12 for those allocated to eBI using a linear regression approach, controlling for baseline alcohol consumption and gender.

We estimated in a sample size calculation that we would assess 70% of those allocated at baseline and we achieved this end. In our analysis, we explored the nature of missing data at 12 months post randomisation using multiple imputation and assessed the impact of these imputation models on the observed outcome using sensitivity analyses. The derived models, which assume potential bias in loss to follow-up, had no effect on the outcomes observed, so these data without imputation were employed for the primary analysis.

Cost-effectiveness analysis

Individual-level data were used to estimate mean differential costs between interventions. As data were not normally distributed, 95% CIs were calculated using a non-parametric bootstrapped method.¹⁴⁰ This was also done for effects, the EQ-5D-5L score and QALYs at 6- and 12-month follow-up. Difference in QALYs was estimated using the area under the curve method.

Sensitivity analysis

Cost-effectiveness results [mean total costs and effects, hence the incremental cost-effectiveness ratio (ICER)] are subject to uncertainty or sampling error. A joint uncertainty in costs and effects was investigated via a stochastic sensitivity analysis. Using a large number of non-parametric bootstrapped replications ($n = 10,000$) of costs and effects (jointly), this uncertainty was quantified through a 95% CI of the ICER.^{141,142} Based on the above bootstrapped replications, a two-dimensional cost-effectiveness plane was created, plotting the joint uncertainty in costs and effects between two groups. Furthermore, a cost-effectiveness acceptability curve was undertaken to show the probability that an intervention was cost-effective at a range of WTP values (£20,000 and £30,000 per QALY gain in the UK).

Valuation of resource use

All NHS resource use was reported in appropriate physical units and valued using relevant unit costs.¹⁴³ All figures were based on 2014 costs. As costs were incurred only over 12 months, discounting was not necessary. The cost of screening and delivering the two interventions were ascertained by prospectively monitoring resource inputs to each arm of the trial at 6- and 12-month follow-up, including training, and valued using standard methods.¹⁴¹

Training costs

All resources involved in training were costed, including:

- (a) trainer time in preparing for training sessions, in travelling to training sessions and in delivering the training sessions (and anything else); this was costed by using the number of trainers and their salary or university/NHS grade/band
- (b) trainee time in travelling to training session and in attending training session; costed accordingly as in (a)
- (c) expenses incurred by trainers or trainees (e.g. train/bus fares, taxis, parking); for car travel, the travel time reported above was converted into motoring costs
- (d) cost of any materials used (either described or in pounds sterling spent).

NHS and non-NHS costs

Effects on NHS and non-NHS costs was based on information gathered on patient contact with primary care, secondary care, specialist health services, social service and criminal justice, and other resources. These were collected prospectively using the appropriately modified version of the Client Service Receipt Inventory (CSRI). The CSRI captures any resource implication for the last 6 months. Service utilisation in CSRI was valued using local costs and, when possible, supplemented by national resources and information from previous alcohol studies.^{130,144,145} Appropriate unit costs were used to derive a cost of any NHS resource [e.g. hospitalisation, general practitioner (GP) visit] or non-NHS resource (e.g. cost of criminal offence) use.¹⁴³

Missing data

Multiple imputation was used to handle missing values related to individual EQ-5D-5L input variables, with EQ-5D-5L utility values calculated from the imputed variables. Ten imputations were calculated. For missing costs, it was first determined whether costs were truly missing or truly zero, and for the truly missing costs the average costs for each intervention were imputed.

Results

Low-risk drinkers trial

Participant flow

Participant progress throughout the trial is presented in the CONSORT (Consolidated Standards of Reporting Trials) flow diagram (*Figure 10*). Of the 7854 attendees, 5016 were approached (63.9%). All reasons for exclusion are reported in *Figure 10*. Approximately 1% ($n = 83$) were intoxicated at the time of presentation and not approached for participation in the study. Twenty-five patients were excluded, because they did not own a smartphone or have internet access to receive the intervention. Of the patients approached, a total of 3326 met all of the inclusion criteria and consented to be screened (66%). Of these patients, 2571 (77.3%) scored < 3 on the AUDIT-C and were eligible for the low-risk study. One-third of these potential participants ($n = 884$) were selected at random and randomly allocated into one of the three groups.

Sample characteristics

Demographic and outcome variables were similar across all three groups at baseline (*Table 1*). Overall, the mean age of those participating in the study was 15.1 years, 51% were female and 62.5% of the sample classified their ethnicity as white. Participants' mean age at the time of first drink was 13.8 years and mean weekly alcohol consumption was low at 0.14 units of alcohol.

Main outcomes in the low-risk trial

The primary outcome, weekly alcohol units consumed at month 12, was derived from the AUDIT-C. As consumption was positively skewed, we explored transformations using the Box–Cox transformation approach and identified a cube-root transformation as appropriate to fit the data.

Outcomes at 6 and 12 months were back-transformed and are presented in *Table 2*. Mean differences and associated 95% CIs are presented in *Table 3*. No differences were observed between the groups for the primary outcome at 6 or 12 months. A sensitivity analysis employing the Wilcoxon rank-sum of the change score demonstrated similar results, as did an assessment of multiple imputation of missing values. A similar pattern was observed for secondary outcomes.

A post hoc analysis was also performed for the Bayes' factor comparing eBI and PFBA with control: 0.05 [standard error (SE) 0.13] and 0.05 (SE 0.18), respectively. These results indicate that the null result is a true null finding of no effect of either intervention.

An analysis exploring potential interactions between quantity of alcohol consumption at baseline and allocated group found no significant interactions for the low-risk study ($F = 1.78$; $p = 0.17$).

Our exploratory analysis of prognostic factors that may impact on alcohol consumption at month 12 identified a number of significant positive predictors: higher baseline consumption, lower age of first drink, older age, being female, greater positive alcohol expectancy and greater alcohol-related problems (see *Table 15*, *Appendix 1*).

For those allocated to eBI, 103 (35.0%) participants actually engaged with the intervention after leaving the ED. No relationship was identified between engagement with the intervention and alcohol consumption at month 12.

Cost-effectiveness analysis in the low-risk trial

Cost-effectiveness analysis compared both the eBI and PFBA intervention groups with the control group for all societal costs (*Table 4*) and for NHS/Personal and Social Services (PSS) costs only (*Table 5*). The analyses show that, for both the societal cost perspective and the narrower NHS/PSS perspective, the eBI is dominated by the control, whereas the PFBA intervention generates ICERs of £130,822 (societal) and £120,693 (NHS/PSS) per QALY gained, respectively.

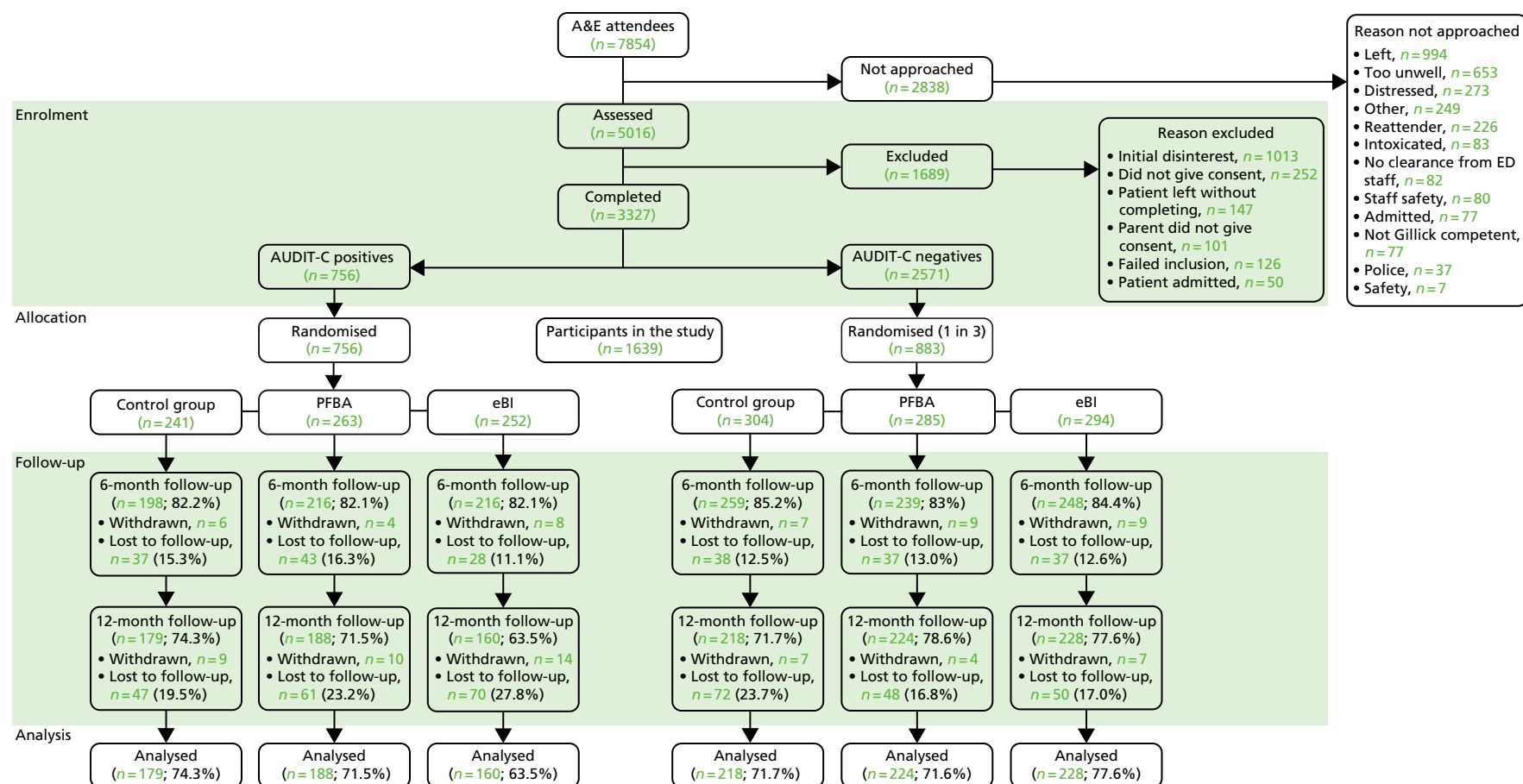


FIGURE 10 The CONSORT flow diagram of the linked trials.

TABLE 1 Demographic and baseline outcomes by allocated group in the low-risk trial

Demographic	Control (<i>n</i> = 304)	PFBA (<i>n</i> = 285)	eBI (<i>n</i> = 294)
Mean age in years (SD)	15.2 (1.1)	15.1 (1.0)	15.2 (1.0)
Mean age (years) of first drink (SD)	13.8 (1.7)	13.6 (1.9)	13.9 (1.8)
Male (%)	47.4	50.9	48.6
White (%)	61.5	64.9	61.2
Smoker (%)	10.3	7.1	8.7
Alcohol use			
Mean weekly alcohol consumption (SD) ^a	0.14 (0.28)	0.14 (0.28)	0.15 (0.29)
Mean AUDIT-C score (SD)	0.38 (0.66)	0.40 (0.71)	0.43 (0.72)
Monthly episodic alcohol use (%) ^b	2.6	7.4	6.4
Ever intoxicated (%) ^c	34.7	35.4	34.7
Intoxicated in past 12 months (%) ^c	25.0	26.6	26.0
Intoxicated in past 30 days (%) ^c	6.0	7.5	8.0
Alcohol-related problem (%)			
Ever fighting	10.9	9.2	5.4
Ever accident or injury	16.7	14.1	10.9
Ever parent problem	10.9	7.0	6.1
Ever peer problem	10.3	11.3	6.8
Ever school problem	9.0	9.2	6.8
Ever victim of theft	5.8	2.1	4.1
Ever police problem	3.8	4.9	5.4
Ever hospitalised	10.8	7.9	6.8
Ever unprotected sex	4.5	2.8	6.1
Ever regretted sex	2.5	2.1	3.4
Strengths and difficulties, mean (SD)			
Total score	10.9 (5.7)	10.7 (5.5)	11.0 (5.7)
Emotional symptom score	3.0 (2.2)	3.1 (2.3)	3.2 (2.4)
Conduct problem score	2.0 (1.7)	1.9 (1.6)	2.0 (1.6)
Hyperactivity score	3.7 (2.3)	3.8 (2.3)	3.7 (2.2)
Peer problem score	2.1 (1.6)	1.9 (1.6)	2.1 (1.6)
Prosocial behaviour score	7.8 (1.8)	7.9 (1.8)	7.8 (1.7)

SD, standard deviation.

^a Measured in standard drinks, in which one standard drink equates to 8 g of ethanol.^b Assessed as six or more standard drinks on a single drinking episode.^c Intoxication is self-defined.

From the societal cost perspective, probabilistic sensitivity analysis (PSA) indicated that approximately 9% of the simulations for eBI compared with control were cost-effective at both the £20,000 and the £30,000 WTP thresholds, whereas approximately 26% and 30% of the simulations for PFBA compared with control were cost-effective at the £20,000 and £30,000 WTP thresholds, respectively (*Table 6*).

TABLE 2 Adjusted least mean squares and 95% CI for outcomes at 6 and 12 months by allocated group in the low-risk trial

Measure	Control (n = 304)	PFBA (n = 285)	eBI (n = 294)
Alcohol use			
<i>Weekly alcohol consumption^a</i>			
Month 6	0.06 (0.03 to 0.10)	0.04 (0.02 to 0.07)	0.05 (0.03 to 0.09)
Month 12	0.10 (0.05 to 0.18)	0.12 (0.06 to 0.21)	0.10 (0.05 to 0.19)
AUDIT-C score			
Month 6	0.14 (0.08 to 0.22)	0.08 (0.04 to 0.14)	0.06 (0.19 to 0.21)
Month 12	0.22 (0.12 to 0.36)	0.21 (0.11 to 0.35)	0.21 (0.11 to 0.35)
Strengths and difficulties (12 months)			
Total score	10.8 (10.2 to 11.4)	10.2 (9.58 to 10.8)	10.4 (9.76 to 11.0)
Emotional symptom score	3.32 (3.07 to 3.57)	3.06 (2.81 to 3.30)	3.14 (2.90 to 3.39)
Conduct problem score	1.58 (1.40 to 1.77)	1.59 (1.41 to 1.77)	1.75 (1.57 to 1.93)
Hyperactivity score	3.48 (3.21 to 3.75)	3.35 (3.08 to 3.61)	3.23 (2.97 to 3.50)
Peer problem score	2.41 (2.20 to 2.61)	2.17 (1.96 to 2.37)	2.29 (2.08 to 2.49)
Prosocial behaviour score	7.95 (7.71 to 8.19)	7.98 (7.74 to 8.22)	7.75 (7.51 to 7.99)
a Measured in standard drinks, in which one standard drink equates to 8 g of ethanol.			

TABLE 3 Adjusted least mean squares difference vs. control and 95% CI for outcomes at 6 and 12 months by allocated group in the low-risk trial

Measure	PFBA	eBI
Alcohol use		
<i>Weekly alcohol consumption^a</i>		
Month 6	-0.06 (-0.14 to 0.03)	-0.02 (-0.10 to 0.06)
Month 12	0.03 (-0.07 to 0.13)	0.01 (-0.10 to 0.11)
AUDIT-C score		
Month 6	-0.08 (-0.18 to 0.02)	-0.03 (-0.13 to 0.07)
Month 12, Bayes' factor (SE)	-0.01 (-0.12 to 0.11), 0.05 (0.13)	-0.01 (-0.12 to 0.11), 0.05 (0.18)
Strengths and difficulties (12 months)		
Total score	-0.58 (-1.45 to 0.28)	-0.40 (-1.26 to 0.46)
Emotional symptom score	-0.27 (-0.62 to 0.09)	-0.18 (-0.53 to 0.17)
Conduct problem score	0 (-0.25 to 0.26)	0.16 (-0.09 to 0.42)
Hyperactivity score	-0.14 (-0.52 to 0.24)	-0.25 (-0.63 to 0.13)
Peer problem score	-0.24 (-0.50 to 0.03)	-0.12 (-0.38 to 0.15)
Prosocial behaviour score	0.03 (-0.27 to 0.33)	-0.20 (-0.51 to 0.10)
SE, standard error.		
a Measured in standard drinks, in which one standard drink equates to 8 g of ethanol.		

TABLE 4 Results of the cost-effectiveness analysis, societal perspective, in the low-risk trial

	Control	eBI	Difference
Total costs (£)	1132	1884	751
Total QALYs	0.90	0.89	-0.01
ICER (£/QALY gained)	eBI dominated		
	Control	PFBA	Difference
Total costs (£)	1132	1735	603
Total QALYs	0.90	0.91	0.005
ICER (£/QALY gained)	130,822		

TABLE 5 Results of the cost-effectiveness analysis, NHS/PSS perspective, in the low-risk trial

	Control	eBI	Difference
Total costs (£)	912	1683	771
Total QALYs	0.90	0.89	-0.01
ICER (£/QALY gained)	eBI dominated		
	Control	PFBA	Difference
Total costs (£)	912	1468	556
Total QALYs	0.90	0.91	0.005
ICER (£/QALY gained)	120,693		

TABLE 6 Results of the PSA, societal perspective, in the low-risk trial

	WTP	
	£20,000	£30,000
eBI vs. control (%)	8.7	8.8
PFBA vs. control (%)	26.4	30.2

From the NHS/PSS cost perspective, PSA again indicated that approximately 9% of the simulations for eBI compared with control were cost-effective at both the £20,000 and the £30,000 WTP thresholds, whereas approximately 31% and 33% of the simulations for PFBA compared with control were cost-effective at the £20,000 and £30,000 WTP thresholds, respectively (*Table 7*).

The deterministic analyses and PSA show that it is highly unlikely that either intervention is cost-effective at either the £20,000 or the £30,000 WTP threshold when compared with the control intervention in low-risk patients.

TABLE 7 Results of the PSA, NHS/PSS perspective, in the low-risk trial

	WTP	
	£20,000	£30,000
eBI vs. control (%)	9.1	8.8
PFBA vs. control (%)	30.6	33.2

High-risk drinkers trial

Participant flow: high-risk trial

Participant progress throughout the trial is presented in the flow diagram (see *Figure 10*). Of the 7854 attendees, 5016 (63.9%) were approached. A total of 3326 participants consented to be screened (66.0%) and, of these, 756 (22.7%) participants scored ≥ 3 on the AUDIT-C and were eligible for the high-risk study.

Sample characteristics: high-risk trial

Demographic and outcome variables were similar across all three groups at baseline (*Table 8*). Overall, the mean age of those participating into the high-risk study was 16.1 years, 50.2% were female and 84.9% of the sample classified their ethnicity as white. Mean age at first drink was 13.5 years and mean weekly alcohol consumption was higher than in the low-risk trial, at 4.7 units of alcohol.

Main outcomes in the high-risk trial

The primary outcome, weekly alcohol units consumed at month 12, was derived from the AUDIT-C. As consumption was positively skewed, we explored transformations using the Box–Cox transformation approach and identified a cube-root transformation as appropriate to fit the data.

TABLE 8 Demographic and baseline outcomes by allocated group in the high-risk trial

Demographic	Control (<i>n</i> = 241)	PFBA (<i>n</i> = 263)	eBI (<i>n</i> = 252)
Mean age in years (SD)	16.1 (0.9)	16.0 (0.9)	16.1 (0.9)
Mean age (years) at first drink (SD)	13.4 (2.1)	13.7 (1.7)	13.3 (2.2)
Male (%)	51.9	48.3	49.2
White (%)	85.9	84.8	84.1
Smoker (%)	40.3	36.1	38.2
Alcohol use			
Mean weekly alcohol consumption (SD) ^a	5.01 (7.82)	4.33 (8.96)	4.55 (7.43)
Mean AUDIT-C score (SD)	4.86 (1.80)	4.77 (1.93)	4.87 (1.88)
Monthly episodic alcohol use (%) ^b	37.8	34.6	42.1
Ever intoxicated (%) ^c	80.7	80.8	82.5
Intoxicated in past 12 months (%) ^c	70.6	70.9	72.4
Intoxicated in past 30 days (%) ^c	31.4	30.7	27.2
Alcohol-related problem (%)			
Ever fighting	17.1	17.6	22.6
Ever accident or injury	32.8	32.4	33.3
Ever parent problem	17.0	15.0	19.7
Ever peer problem	22.8	23.4	28.3
Ever school problem	10.0	17.9	15.1
Ever victim of theft	15.9	17.6	17.5
Ever police problem	7.5	11.8	15.5
Ever hospitalised	14.9	13.3	12.4
Ever unprotected sex	19.1	14.9	24.3
Ever regretted sex	13.4	14.8	18.8

TABLE 8 Demographic and baseline outcomes by allocated group in the high-risk trial (*continued*)

Demographic	Control (<i>n</i> = 241)	PFBA (<i>n</i> = 263)	eBI (<i>n</i> = 252)
Strengths and difficulties, mean (SD)			
Total score	12.0 (5.6)	11.9 (6.1)	12.6 (5.9)
Emotional symptom score	3.4 (2.4)	3.3 (2.4)	3.4 (2.5)
Conduct problem score	2.3 (1.7)	2.3 (1.7)	2.6 (1.8)
Hyperactivity score	4.2 (2.2)	4.3 (2.3)	4.4 (2.3)
Peer problem score	2.2 (1.7)	2.0 (1.7)	2.3 (1.6)
Prosocial behaviour score	7.3 (1.9)	7.3 (2.0)	7.5 (2.0)
a Measured in standard drinks, in which one standard drink equates to 8 g of ethanol.			
b Assessed as six or more standard drinks on a single drinking episode.			
c Intoxication is self-defined.			

Outcomes at 6 and 12 months were back-transformed and are presented in *Table 9*. Mean differences and associated 95% CIs are presented in *Table 10*. No differences were observed between the groups for the primary outcome at 6 or 12 months. A sensitivity analysis employing the Wilcoxon rank-sum of the change score demonstrated similar results, as did an assessment of multiple imputation of missing values. A similar pattern was observed for secondary outcomes.

We computed the Bayes' factor comparing eBI and PFBA with control: 0.08 (SE 0.16) and 0.08 (SE 0.36), respectively. These results indicate that the null result is a true null finding of no effect of either intervention.

An analysis exploring potential interactions between quantity of alcohol consumption at baseline and allocated group found no significant interactions for the high-risk study ($F = 0.27$; $p = 0.76$).

TABLE 9 Adjusted least mean squares and 95% CI for outcomes at 6 and 12 months by allocated group in the high-risk trial

Measure	Control	PFBA	eBI
Alcohol use			
<i>Weekly alcohol consumption^a</i>			
Month 6	2.42 (1.84 to 3.11)	2.13 (1.62 to 2.74)	2.33 (1.77 to 3.00)
Month 12	2.99 (2.38 to 3.70)	3.56 (2.90 to 4.32)	3.18 (2.50 to 3.97)
AUDIT-C score			
Month 6	4.64 (4.17 to 5.11)	4.30 (3.85 to 4.75)	4.64 (4.18 to 5.11)
Month 12	5.04 (4.65 to 5.44)	5.25 (4.87 to 5.63)	5.12 (4.70 to 5.54)
Strengths and difficulties (12 months)			
Total score	11.0 (10.2 to 11.7)	10.9 (10.2 to 11.6)	10.9 (10.1 to 11.6)
Emotional symptom score	3.14 (2.82 to 3.46)	3.23 (2.91 to 3.54)	3.09 (2.75 to 3.43)
Conduct problem score	1.90 (1.70 to 2.10)	1.74 (1.55 to 1.94)	1.86 (1.65 to 2.07)
Hyperactivity score	3.54 (3.23 to 3.84)	3.73 (3.43 to 4.02)	3.87 (3.55 to 4.19)
Peer problem score	2.30 (2.06 to 2.54)	2.21 (1.97 to 2.44)	2.05 (1.80 to 2.30)
Prosocial behaviour score	7.91 (7.66 to 8.16)	8.21 (7.97 to 8.45)	7.75 (7.49 to 8.01)
a Measured in standard drinks, in which one standard drink equates to 8 g of ethanol.			

TABLE 10 Adjusted differences from control and 95% CIs for outcomes by allocated group

Measure	PFBA	eBI
Alcohol use		
<i>Weekly alcohol consumption^a</i>		
Month 6	−0.286 (−0.903 to 0.478)	−0.0886 (−0.756 to 0.737)
Month 12	0.570 (−0.362 to 1.70)	0.186 (−0.714 to 1.30)
AUDIT-C score		
Month 6	−0.334 (−0.858 to 0.189)	0.00685 (−0.528 to 0.542)
Month 12	0.206 (−0.334 to 0.747)	0.0818 (−0.488 to 0.652)
Strengths and difficulties (12 months)		
Total score	−0.0170 (−1.02 to 0.981)	−0.0998 (−1.14 to 0.945)
Emotional symptom score	0.0891 (−0.340 to 0.518)	−0.0523 (−0.501 to 0.396)
Conduct problem score	−0.161 (−0.436 to 0.113)	−0.0426 (−0.330 to 0.245)
Hyperactivity score	0.193 (−0.232 to 0.618)	0.334 (−0.111 to 0.779)
Peer problem score	−0.0901 (−0.386 to 0.206)	−0.249 (−0.559 to 0.0608)
Prosocial behaviour score	0.293 (−0.0406 to 0.626)	−0.165 (−0.514 to 0.183)
a Measured in standard drinks, where one standard drink equates to 8 g of ethanol.		

Our exploratory analysis of prognostic factors that may impact on alcohol consumption at month 12 identified a number of significant positive predictors: higher baseline consumption, lower age of first drink, older age, being female, greater positive alcohol expectancy and greater alcohol-related problems (see *Table 15, Appendix 1*).

For those allocated to eBI, 84 (33.3%) actually engaged with the intervention after leaving the ED. No relationship was identified between engagement with the intervention and alcohol consumption at month 12.

Cost-effectiveness analysis

Cost-effectiveness analysis compared both the eBI and PFBA intervention groups with the control group for all societal costs (*Table 11*) and for NHS/PSS costs only (*Table 12*). The analyses show that, for both the societal cost perspective and the narrower NHS/PSS perspective, the eBI is dominated by the control, whereas the PFBA intervention generates ICERs of £7580 (societal) and £6213 (NHS/PSS) per QALY gained, respectively.

TABLE 11 Results of bootstrapped cost-effectiveness analysis from societal perspective

	Screening only	eBI	Difference ^a
Total costs	£1703 (SD £6049)	£2110 (SD £7040)	£406 (95% CI –£1334 to £2331)
Total QALYs	0.900 (SD 0.096)	0.892 (SD 0.105)	–0.008 (95% CI –0.038 to 0.021)
ICER (£/QALY gained)	Screening dominates eBI		
	Control	PFBA	Difference ^a
Total costs	£1703.65 (SD £6049)	£1726.39 (SD £6152)	£22.74 (95% CI –£1860 to £1663)
Total QALYs	0.900 (SD 0.096)	0.903 (SD 0.089)	0.003 (95% CI –0.023 to 0.028)
ICER (£/QALY gained)	£7580 (95% CI from –£1,088,865 to £794,373) (not at all significant)		
a Difference = intervention – control.			

TABLE 12 Results of bootstrapped cost-effectiveness analysis from NHS/PSS perspective

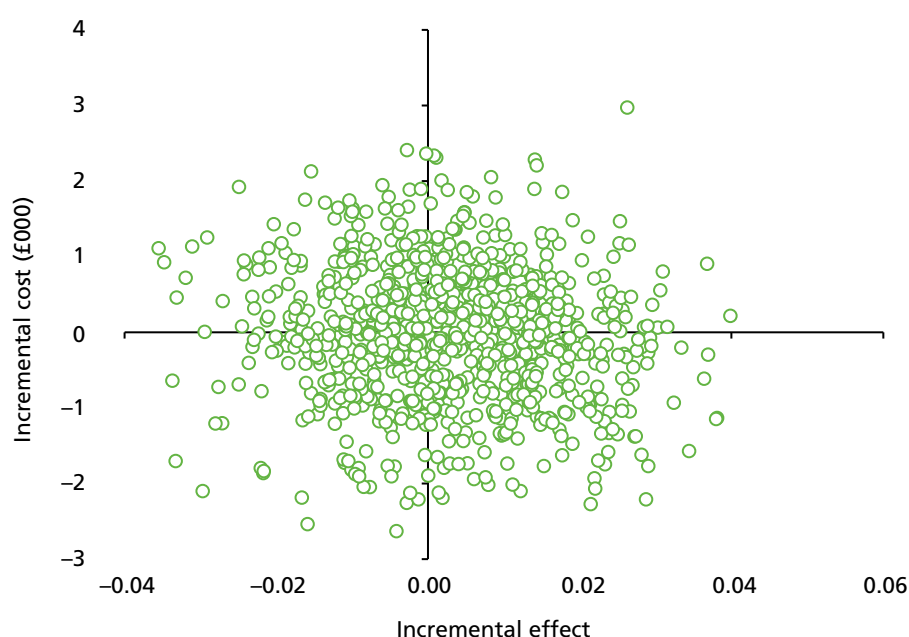
	Screening only	eBI	Difference
	Bootstrapped mean (bootstrapped SD)		Intervention – control (bootstrapped 95% CI)
Total costs	£1552 (SD £6019)	£1953 (SD £6960)	£401 (95% CI –£1424 to +£2346)
Total QALYs	0.900 (SD 0.096)	0.892 (SD 0.105)	–0.008 (95% CI –0.037 to +0.019)
ICER (£/QALY gained)	Screening dominates eBI		
	Control	PFBA	Difference ^a
Total costs	£1552.69 (SD £6019)	£1571.33 (SD £6114)	£18.64 (95% CI –£1752 to +£1586)
Total QALYs	0.900 (SD 0.096)	0.903 (SD 0.089)	0.003 (95% CI –0.023 to +0.026)
ICER (£/QALY gained)	£6213 (95% CI from –£736,843 to £812,884) (not at all significant)		

a Difference = intervention – control.

From the societal cost perspective, PSA indicated that approximately 28% of the simulations for eBI compared with control were cost-effective at the £20,000 WTP threshold and 27% at the £30,000 WTP threshold; whereas approximately 54% and 55% of the simulations for PFBA compared with control were cost-effective at the £20,000 and £30,000 WTP thresholds, respectively (*Table 13*). Although PFBA has a chance of being cost-effective when compared with control, the distribution of the bootstrapped ICERs show that there is a wide distribution (*Figure 11*).

TABLE 13 Results of the PSA, societal perspective, in the high-risk trial

	WTP	
	£20,000	£30,000
eBI vs. control (%)	28.3	26.9
PFBA vs. control (%)	54.2	55.2

**FIGURE 11** Cost-effectiveness plane: PFBA vs. control, societal perspective, in the high-risk trial.

From the NHS/PSS cost perspective, PSA again indicated that approximately 30% of the simulations for eBI compared with control were cost-effective at the £20,000 WTP threshold and 29% at the £30,000 threshold; whereas approximately 54% and 56% of the simulations for PFBA compared with control were cost-effective at the £20,000 and £30,000 WTP thresholds, respectively (*Table 14*). Again, although PFBA has a chance of being cost-effective when compared with control, the distribution of the bootstrapped ICERs show that there is a wide distribution (*Figure 12*).

The deterministic analyses and PSA show that it is highly unlikely that the eBI is cost-effective at either the £20,000 or the £30,000 WTP threshold when compared with the control intervention in high-risk patients, although there is an approximately 55% chance that the PFBA intervention is cost-effective compared with the control.

TABLE 14 Results of the PSA, NHS/PSS perspective, in the high-risk trial

	WTP	
	£20,000	£30,000
eBI vs. control (%)	29.9	29.4
PFBA vs. control (%)	54.0	55.6

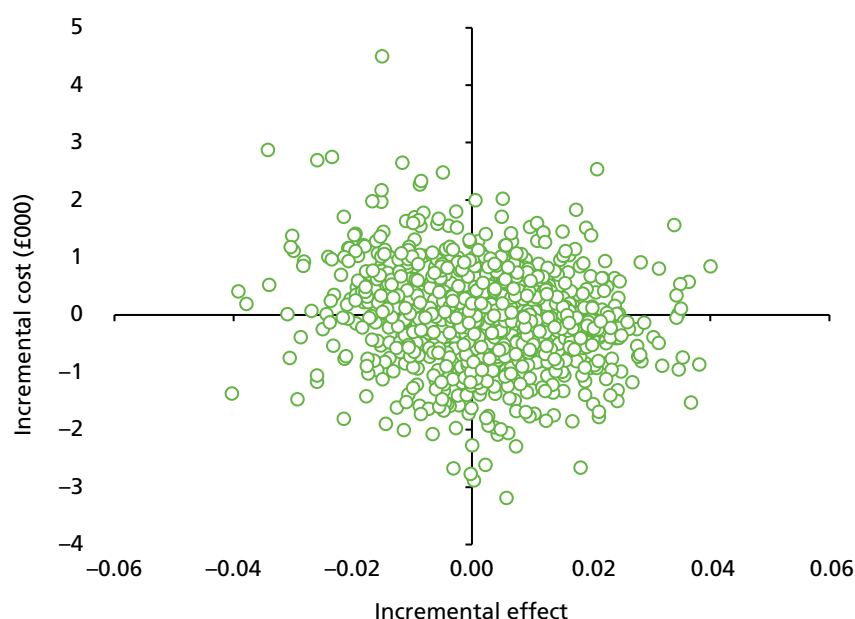


FIGURE 12 Cost-effectiveness plane: PFBA vs. control, NHS/PSS perspective, in the high-risk trial.

Discussion

The results of both the low- and the high-risk trials showed that we were able to recruit a sufficient number of participants to each trial to meet our target recruitment informed by the power calculation. We were also able to exceed the minimum follow-up targets in both trials. Both trials were therefore adequately powered to detect significant differences between intervention groups on our primary outcome measure.

Analyses of baseline characteristics comparing different intervention groups showed that the groups were well matched based on our randomisation methods reducing the risk of bias in detecting effects in both trials. To further mitigate potential bias, we also controlled for key baseline characteristics in outcome analyses.

In the low-risk trial, no significant differences in outcome were found between groups on either primary or secondary outcome measures. The additional post hoc calculation of the Bayes' factor supported the null hypothesis that PFBA and eBI are no more effective in reducing alcohol consumption in low-risk drinkers than screening alone. However, we did find that higher baseline consumption, lower age of first drink, older age, being female, greater positive alcohol expectancy and greater alcohol-related problems at baseline predicted higher levels of drinking at 12 months follow-up, which is similar to previous research findings.

The economic analysis undertaken for the low-risk cohort showed that, from both the societal and the NHS/PSS perspectives, the eBI generated more costs and slightly fewer QALYs and was thus dominated by the control, whereas the PFBA intervention generated higher costs and slightly more QALYs than the control, resulting in unacceptably large ICERs.

Probabilistic sensitivity analysis showed that the eBI was cost-effective in between 8% and 9% of simulations at the £20,000 and £30,000 WTP thresholds, respectively, for both the social and the NHS/PSS perspectives, and between 26% and 33% of simulations at the £20,000 and £30,000 WTP thresholds, respectively, for the PFBA intervention.

As there was very little difference observed in utility between the interventions and the control, the differences observed in the cost-effectiveness analyses were driven by costs. There was also very little difference observed in resource use between the intervention groups and the control group, therefore the difference observed in costs was due to the cost of the intervention. The health economic analysis supported the null hypothesis that neither PFBA nor eBI is more cost-effective than screening alone in low-risk drinkers.

In the high-risk trial, no significant differences in outcome were found between the intervention groups on either primary or secondary outcome measures. The additional post hoc calculation of the Bayes' factor supported the null hypothesis that PFBA and eBI are not more effective in reducing alcohol consumption in high-risk drinkers than screening alone. The health economic analysis also supported the null hypothesis that PFBA and eBI are not more cost-effective than screening alone in high-risk drinkers. Predictors of increased alcohol consumption at 12 months were similar to those in the low-risk study: higher baseline consumption, being female, older age, younger age at first drink, greater alcohol-related positive expectancy and greater alcohol-related problems.

The economic analysis undertaken for the high-risk cohort showed that, from both the societal and NHS/PSS perspectives, the eBI generated more costs and slightly less QALYs and was thus dominated by the control; whereas the PFBA intervention generated higher costs and QALYs of negligible difference than the control, resulting in ICERs of £7580 and £6213 per QALY, respectively.

Probabilistic sensitivity analysis showed that the eBI was cost-effective in between 26% and 30% of simulations at the £20,000 and £30,000 WTP thresholds, respectively, for both the social and the NHS/PSS perspectives, and between 54% and 56% of simulations at the £20,000 and £30,000 WTP thresholds, respectively, for the PFBA intervention.

Although the analyses showed that the PFBA intervention has a chance of being cost-effective when compared with control, the distribution of the bootstrapped ICERs showed that there is a wide distribution due to a large level of variability and uncertainty in the model parameters.

As there was very little difference observed in utility between the interventions and the control, the differences observed in the cost-effectiveness analyses were, again, driven by costs. In general, very little difference was observed in the resource use between the intervention groups and the control group, though social care resulted in some large observed costs.

In both trials, we found that engagement with the eBI was low in participants randomised to eBI. One-third of participants engaged with the eBI platform after leaving EDs. This may have limited the impact of the eBI compared with the control intervention. However, as these were pragmatic trials, this is likely to be the level of engagement expected in the typical patient recruited from an ED.

Low app usage or engagement is a common issue. The vast majority of apps, and other online interventions, are not used 1 month after they are downloaded.¹⁴⁶ We also know that patients are less likely to engage in extended interventions when the onus to engage is on them.^{131,147,148}

A large proportion of the literature based on eBI has focused on the provision of websites as opposed to smartphone apps.⁷⁴ Arguably, the most important problem with developing an effective eBI app is engaging participants enough for them to find it useful.

Engagement can be defined as how a user interacts with and experiences the technology in question.¹⁴⁹ The method of measuring engagement varies depending on what subjects are being engaged with. For example, engagement and usage patterns of smartphone apps can be measured using the pattern of downloads, number of page visits and average session lengths. Usage patterns can be used to determine the most and least useful features of an app and identify user's preferences to improve engagement and outcomes. Bewick *et al.*¹⁵⁰ demonstrated the value of participant engagement with a web based electronic intervention in achieving a reduction in the consumption of alcohol. Further evidence has emerged on user preferences for content, features and style, and strategies to improve engagement.^{149,151,152} However, recent findings from two personalised alcohol interventions apps [Drinks Metre (version 2.5.0, Global Drug Survey Ltd, London, UK) and OneTooMany] for young adults have found no impact on their risky drinking.¹⁵³

Exploring adolescent perspectives on participation in alcohol intervention research based in emergency care (the SIPS Junior trials): a qualitative study

The aim of this part of the work programme was to explore the acceptability of trial tools and processes to young people presenting to EDs. Although assessments of acceptability have received increasing focus in recent years,¹⁵⁴ there is no clear consensus as to how acceptability should be defined and measured.¹⁵⁴ In this work the authors consider that, to be acceptable, research and intervention processes should be not only appropriate, comprehensible, effective and well received by participants but also ethical. The latter is particularly key in work with young adolescents, as there is debate about the extent to which they can and should participate in treatment and also in research about treatment and care.^{155–157} In addition, the issue of whether or not adolescents should rely on parental consent to participate in research (or indeed treatment *per se*) is increasingly contested, with a growing view that adolescents should have the opportunity to contribute to these decisions themselves, albeit with due consideration of their developmental capacity to understand the implication that participation might have for them.^{157,158}

Although there is a distinction between clinical and research ethics,¹⁵⁹ recent work that has argued that the distinction between what is research and what is care can be overemphasised,¹⁶⁰ especially when it comes to pragmatic effectiveness research,^{161,162} which is embedded in clinical practice and ultimately aims to achieve practical, timely care improvement.¹⁶¹ As this study was based in routine practice, the contemporary view that clinical and research ethics are relatively indistinct was taken and the widely accepted four principles of biomedical ethics outlined by Beauchamp and Childress¹⁶³ were deemed to provide a suitable and crucially simple framework to guide our analysis and data interpretation.

As such, this section draws on the four key principles of research ethics – autonomy, beneficence, non-maleficence and justice¹⁶³ – to explore adolescents' perspectives about their participation in two linked alcohol intervention trials described above. We considered these principles in relation to two key aspects of the research process:

1. consent and enrolment procedures, which governed how young people were approached, how they experienced explanation of the study and how consent was understood and given for individuals to become research participants
2. SBI activities, which related to the actual study procedures that were delivered to and experienced by young participants and which varied according to the trial arm to which they had been randomly allocated.

Four principles of research ethics outlined by Beauchamp and Childress:¹⁶³

- autonomy – the right of an individual to make their own choice
- beneficence – the principle of acting with the best interest of the other in mind
- non-maleficence – do no harm, as stated in the Hippocratic Oath
- justice – a concept that emphasises fairness and equality among individuals.

A purposive sample of participants was selected from the pool of participants in the two linked trials, across the three intervention arms, for interviews about their experience of being involved in the research and the acceptability of receiving the interventions.

We used semistructured interviews to structure the conversations, covering issues relating to consent by young people aged 14–17 years; alcohol screening; the baseline questionnaire and the burden on emergency care; and young people's experiences of intervention delivery.

Individual interviews were preferred to focus groups for practical reasons, as it would have been too difficult to organise a focus group meeting with participants from 10 different geographical areas.

An initial framework for coding based on participants' experience and understanding of the different stages of the research process (approach, screening, intervention and follow-up) was developed and employed to analyse interview transcripts. The four guiding principles of biomedical ethics were then employed to structure coding, data analysis and interpretation and to provide a framework for discussing the findings.

A paper incorporating an extended analysis has been submitted for publication¹⁶⁴ and is reproduced in full in *Appendix 2*.

Our analysis shows that the majority of participants understood the context of the study, including the fact that participation was voluntary, and they seemed to grasp most aspects of the complex SBI procedures. Participant reports focused on the ease of process as well as the benefits of employing technology. Furthermore, the study interventions were generally seen as acceptable, relevant and helpful to participants, who welcomed having something to do while waiting for treatment in the ED.

Although findings do not differ greatly from those we would expect in adult populations, interviews were often fairly brief, with more curtailed responses than one might expect when working with adult participants. Harden *et al.*¹⁶⁵ query the assumption that a young person who talks less during an interview has provided fewer data, suggesting instead that this young person has provided an account in their own words. In this case, the shorter responses are interpreted as offering an authentic account of adolescents' participation in the research and also a demonstration of the lack of demand characteristics influencing interview responses. Indeed, comparison across interviews reveal that older participants, who were approaching adulthood, tended to provide longer, more in-depth responses than younger participants. For example, when asked how clearly the researcher had explained the study and if they knew that taking part was voluntary, a 17-year-old participant responded:

Yes, everything was made clear to me. All the ethical considerations were made clear to me, that I could pull out at any point.

Male, 17, south, high-risk, control

By contrast, a 14-year-old simply stated, 'Yeah' (female, 14, north, high-risk, control), and repeated this response when probes such as 'did you know that you didn't have to take part if you didn't want to?' were used to explore understanding in more depth.

The findings have implications for future trials. Although the majority of participants showed good understanding of the study, there were some instances of a lack of recall about the study and understanding of the randomisation procedure was particularly limited. Thus, it is imperative that information be provided in a clear succinct manner, that opportunities for participants to seek clarification are provided and that researchers check participants' understanding before proceeding. When complex research designs are employed, this may be just as important when working with adults as it is with young people.

All participants seemed to be in favour of young people participating in research, even on a potentially sensitive topic such as alcohol use. It is possible that participants who agreed to be interviewed were those who were more engaged with the research and may have held better informed or more positive views about our trial or research participation in general. Nevertheless, it was striking across our range of narrative accounts that the young people in our study displayed good understanding about research participation and the ability to assess the scope for benefit and harm, not only for themselves but also potentially for other people. This should offer reassurance for those seeking to conduct research with adolescents.

There are also implications for future intervention research. Previous research in the field of brief interventions, and especially those related to alcohol use, has tended to focus on adult populations.¹⁶⁶ The need for more research in this area is illustrated by the fact that over half ($n = 15$) of our participants were identified as drinking at risky levels and enrolled in the high-risk trial, and young people who had not started to consume alcohol accepted the intervention as useful for 'when' (not 'if') they eventually started drinking alcohol. That alcohol consumption was already framed as inevitable at the time of screening in our trial makes it seem crucial that young people have access to high-quality information and advice that can enable them to take steps to reduce potential health risk in the future.

We found no indication that brief intervention methods cannot or should not be employed with young people. The participants interviewed were able to understand what was being proposed and were able to provide informed consent, and welcomed being treated with respect for their autonomy. There was no evidence to support fears that talking about alcohol with young people will necessarily lead to early initiation of alcohol consumption or have a negative effect on existing drinking behaviours. On the contrary, a number of participants identified that education in this area is important because alcohol is a part of adolescents' lives. Most of our participants already appeared to possess a clear sense that alcohol use could pose a health risk to them. Davison *et al.*¹⁶⁷ coined the term 'lay epidemiology' to describe the way in which beliefs and values about health and causes of disease are gained from one's own experiences, as well as what is witnessed through popular media, family and social networks.¹⁶⁸ Although such knowledge may have some utility, it is important that young people are provided with accurate information from reputable sources to combine with the knowledge gained from other areas, to allow them to make informed decisions about their own health behaviour.

However, parental presence during screening and intervention may limit disclosure or lead to socially desirable responding. The involvement of parents or carers in the process was accepted by many, especially if the young person was not currently drinking or if their alcohol use was already known. Yet some young people were less comfortable about parental involvement or gate-keeping within the study and felt this might inhibit both their own and others' ability to speak or participate freely. Although parental involvement could create a home environment with increased parental supervision and a clear awareness of alcohol risk, which has been shown to influence adolescent alcohol consumption^{169,170} where the presence of parents restricts disclosure, it may also restrict intervention delivery for those who could benefit most. The fact that young people were able to provide consent under Gillick competence means that intervention procedures need not always involve parents, which should encourage more confidence when working with young people.

Even in the absence of parents, there was indication that some participants may have felt the need to provide socially desirable responses or to hide the reason they were attending the ED. Therefore, researchers need to find ways of explaining (or reassuring adolescents) that being open in the research process will not lead to them being judged and, wherever possible, provide a private environment in which confidentiality can be assured.

Young people aged 14–17 years seemed to be enthusiastic about receiving information about alcohol use that they felt to be relevant to their current and future lifestyles. The participants in this study also reported that the ED was a suitable context both for the delivery of interventions and for the conduction of research. Young people welcomed the invitation to participate in research, especially when it specifically related to their age group. They demonstrated the ability to understand the implications of participation, making informed decisions by weighing the costs and benefits both to themselves and to wider society. Further research exploring the effectiveness of brief interventions for alcohol use in adolescent populations is recommended.

Overall conclusions

This research programme was designed to address key gaps in the evidence base for the most effective and cost-effective screening, and brief interventions for at-risk adolescent heavy drinkers in EDs. As a consequence of extensive engagement with young people and parents, we changed the direction of the research considerably from that originally planned. In particular, this patient and public involvement identified the greater acceptability and potential of electronic data collection and intervention delivery with adolescents, which had not been considered at the application stage. Although eSBIs have been previously studied, they have received limited attention to date in younger adolescents. A systematic review and meta-analysis conducted as part of this programme revealed promising findings about the efficacy of eSBIs.

Consequently, in collaboration with application developers, we developed two electronic applications for use in this programme: (1) a bespoke data collection and trial management tool and (2) an eBI, SIPS City app. The data collection and trial management tool much reduced the cost of conducting several aspects of the research, which in turn allowed us to carry out two linked RCTs that were larger than planned in the original budget.

Our first work package carried out a large-scale prevalence study of 5376 10- to 17-year-olds attending 10 EDs across England. Again, the patient and public involvement work facilitated successful implementation. It influenced our informed consent procedures for adolescents aged < 16 years and was helpful in obtaining NHS research ethics approval. We followed up this issue in work package 3, a qualitative study with a sample of participants in the RCTs, to explore participants' experience of taking part in research and investigate whether or not we achieved the ethics requirements for clinical research. We found that young people welcomed invitations to participate in research, especially when it related to their own age group. They clearly understood the implications of participation, making informed decisions by weighing the costs and benefits both to themselves and to wider society. This will be helpful in informing future research in this age group.

In work package 1, we established the prevalence of hazardous drinking and AUDs in young people attending EDs, using validated research tools delivered mostly by an electronic application. We were further able to validate short alcohol screening tools, AUDIT and AUDIT-C, against standard research interview methods (Timeline Followback), and establish age-appropriate cut-off points. These tools will have wide application in the NHS, as the validity of these short screening approaches in this population was previously unknown. Indeed, Public Health England has already issued clinical guidance to EDs on alcohol screening in adolescents based on this research.¹⁷¹

Beyond validation of short screening tools against research standard methods, we were also able to explore the clinical significance of hazardous and harmful drinking levels in this population. We found that the clinical cut off for hazardous drinking derived from this research was strongly associated with a wide range of adverse health and social consequences. This research also provided support for the Chief Medical Officer's guidance on alcohol consumption before the age of 15 years, showing that any consumption before this age was strongly associated with increased risk of a wide range of health and social adverse consequences.⁷

In work package 2, we again made extensive use of our partnerships with national and local organisations to develop age-appropriate and acceptable interventions for this population. This radically changed the approaches proposed in the original application through feedback from young people and parents. In particular, we were able to develop an age-appropriate electronic alcohol brief intervention application in collaboration with young people and specialist application developers. We produced an age-appropriate brief intervention that could be disseminated for use in the NHS. We also developed a bespoke SIPS Trial Management app (version 3.14, King's College London, London, UK) for use on iPads and other electronic platforms; this was acceptable to patients and much reduced the cost of conducting the clinical trials. It also allowed us to conduct two linked randomised trials in work package 3, which were considerably

larger than planned in the original application. The application also allowed us to manage trial recruitment and data collection much more efficiently in real time by uploading trial data to a central server.

In work package 3, we had the benefit of our previous prevalence study in refining our recruitment methods to include 14- to 17-year-olds. The trial management application we developed for work package 3, built on our screening application from work package 1. Questionnaire content was adapted for the trials, and we developed additional consent and randomisation features and the capability to record a random sample of interventions to examine the fidelity of delivering the interventions. We extensively piloted this with patient and public involvement representatives before the trial went live, thus achieving effective implementation of the trial protocol across the 10 EDs. In total, we recruited 1640 participants to the two trials: 756 high-risk drinkers and 884 low-risk drinkers or abstainers. Together with higher follow-up than predicted at 6 and 12 months, this provided two adequately powered RCTs, both of which compared two forms of brief intervention with screening alone. To our knowledge, these were the first large effectiveness trials in this population, and the study design addressed many of the shortcomings of previous trials. However, face-to-face PFBA and eBI were no more clinically effective or cost-effective than screening alone. We are conducting further analysis of both the application usage data and qualitative interviews with participants to gain greater understanding of how the interventions were perceived and used by participants. This will inform further development of the interventions for study in future research.

Hence, the research programme has advanced our understanding of the nature and prevalence of AUDs in adolescents and provided a firm foundation for future research to improve care for this population. Based on this work, we have conducted a new programme of research on eSBI and young adults and developed a new alcohol screening and intervention app (BRANCH). This was conducted as part of the National Institute for Health Research Collaborations for Leadership in Applied Health Research South London. This research was informed by our earlier work on eSBI in this programme and explored strategies to enhance engagement with digital interventions in young adults.

Recommendations for future research

- We found that the risks of drinking are not restricted to those with an early onset. Future studies should explore how the risks associated with drinking alcohol vary by age at onset in more detail.
- A limitation of the eBI was that only one-third of participants engaged with the application after leaving the ED; this is likely to have limited the effect of the eBI. We recommend that future research focus on methods to maximise engagement with digital interventions and evaluate the effect of such engagement on clinical outcomes.
- Our study identified only a small proportion of young people who attended EDs in an intoxicated state, about 1%, and in workstream 1 a proportion of those surveyed exhibited symptoms associated with alcohol dependence. Although this proportion is smaller than similarly intoxicated adults presenting to ED, they have substantial alcohol-related health, psychological and social problems and consume more health and social care resources than young people in general. Research is needed to identify clear treatment pathways and liaison with external agencies to address the needs of this population.
- There is a paucity of research addressing the longitudinal epidemiology of alcohol using young people, and research that employs large-scale longitudinal data sets has the potential to provide additional information on the relationship between drinking in adolescence and future health, social and economic costs.
- Our qualitative research showed that young people welcome invitations to participate in research. This should encourage greater clinical research in this population rather than speculatively extrapolating research findings from adult populations to adolescents.
- A greater consensus in the reporting of outcome measures and more uniform reporting of the content and theoretical basis of eSBIs would generate more robust conclusions on the effectiveness of eSBIs in reducing alcohol consumption and alcohol-related harms in the longer term.

Implication for practice

A simple three-item self-completed screening instrument, the AUDIT-C, is generally more effective than the full 10-item AUDIT in identifying adolescents who engage in at-risk alcohol consumption or heavy episodic alcohol use and fulfil the ICD-10 criteria for harmful alcohol use. Furthermore, the 10-item AUDIT with a cut-off score of 7 is more efficient than the AUDIT-C in identifying adolescents with alcohol dependence. In addition, the AUDIT-C and AUDIT are widely employed as screening tools for adults in clinical and non-clinical settings and these can be applied to adolescent populations with lower cut-off scores. We conclude that the AUDIT-C could be used with this population with a cut-off score of 3 as a positive screen for at-risk drinking, monthly heavy episodic alcohol use and harmful alcohol use. For those who score ≥ 5 on the AUDIT-C, we recommend the use of the additional seven questions constituting the full AUDIT. Those scoring ≥ 7 should be clinically assessed for alcohol dependence.

We also found that face-to-face PFBA and eBIs were no more clinically effective or cost-effective than screening alone in reducing alcohol consumption in the high-risk group and preventing it in the low-risk group. Hence, the roll-out of these interventions is not supported by evidence.

Dissemination

A range of dissemination activities occurred throughout the programme to facilitate the progress of the programme. These included presentations to national and international conferences and the setting up of a dedicated website at URL: www.sipsjunior.net (accessed 17 May 2019).

The main public/policy and academic dissemination activities are listed in *Acknowledgements, Publications*.

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Patient and public involvement organisations

Parenting UK, Family and Parenting Institute, British Youth Council and The Well Centre/Redthread.

Participating emergency departments

Prevalence study in work package 1

St Thomas' Hospital, London; King's College Hospital, London; University Hospital Lewisham, London; Ealing Hospital, London; Hull Royal Infirmary, Hull; Darlington Memorial Hospital, Darlington; Queen Elizabeth Hospital, Gateshead; University Hospital of North Tees, Hartlepool; South Tyneside District Hospital, South Shields; and James Cook University Hospital, Middlesbrough.

Randomised controlled trials in work package 3

St Thomas' Hospital, London; King's College Hospital, London; Ealing Hospital, London; Croydon University Hospital, Croydon; Hull Royal Infirmary, Hull; Darlington Memorial Hospital, Darlington; Queen Elizabeth Hospital, Gateshead; University Hospital of North Tees, Hartlepool; South Tyneside District Hospital, South Shields; and Sunderland Royal Hospital, Sunderland.

List of researchers who participated in the data collection of work package 1

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List of researchers who have participated in the data collection and follow-up stages of work package 3

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Members of the Independent Steering Committee

Chairperson, Professor Paul Wallace; members, Professor Ian White, Dr Lynn Owens, Professor Jim McCambridge, Professor Mat Hickman and Professor Jonathan Chick.

Software developer

We also thank Richard McGregor and Danny Berzon at Codeface Ltd (Hove, UK) for developing the trial management app and the eBI app (SIPS City).

Contributions of authors

Paolo Deluca (Senior Research Fellow/Senior Lecturer) was a co-applicant and the programme manager. He contributed to study design and protocol writing. He was responsible for study management, oversight of study conduct, and the writing and final editing of the report. He co-led the development of the SIPS Jr City app, as well as the trial management app, and is the corresponding author.

Simon Coulton (Professor of Health Services Studies) was a co-applicant. He contributed to study design and writing the protocol. He contributed to study management as a member of the Programme Management Group (PMG) and contributed to the writing and final editing of the report. He led the methodological and statistical aspects, wrote the statistical analysis plan, provided statistical support and performed the statistical analysis of the study.

Mohammed Fasihul Alam (Research Fellow, Health Economist) contributed to study design, particularly the health economics, and writing the protocol. He contributed to study management as a member of the PMG, and to the writing and final editing of the report.

Sadie Boniface (Research Fellow) was the local trial co-ordinator. She contributed to data collection and study management as a member of the PMG, and to the writing and final editing of the report.

Kim Donoghue (Research Fellow) contributed to study design and writing the protocol, contributed to study management as a member of the PMG, and to the writing and final editing of the report.

Eilish Gilvarry (Consultant Psychiatrist in Addictions) was a co-applicant. She contributed to study design and writing the protocol, provided clinical advice, contributed to study management as a member of the PMG, and to the writing and final editing of the report.

Eileen Kaner (Professor of Public Health and Primary Care Research) was a co-applicant. She contributed to study design and writing the protocol, contributed to study management as a member of the PMG, contributed to the writing and final editing of the report, and led on the qualitative components.

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Ruth McGovern (Senior Research Associate) was the local trial co-ordinator. She contributed to data collection and study management as a member of the PMG, contributed to the writing and final editing of the report, and led on patient and public involvement and engagement activities in Newcastle.

Dorothy Newbury-Birch (Professor of Alcohol and Public Research) was a co-applicant. She contributed to study design and writing the protocol, contributed to study management as a member of the PMG, and to the writing and final editing of the report.

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Tracy Pellatt-Higgins (Senior Research Fellow and Statistician) was responsible for the statistical analysis and reporting of the data. This included presenting summaries of the data and primary and secondary analysis results and the interpretation of results. She contributed to the writing and final editing of the report.

Ceri Phillips (Professor of Health Economics) contributed to study design and writing the protocol, contributed to study management as a member of the PMG, and to the writing and final editing of the report. She led the health economics components of the programme and provided health economic supervision and advice.

Thomas Phillips (National Institute for Health Research Research Fellow and Deputy Director for Nursing and Quality) was a co-applicant. He contributed to study design and writing the protocol, to study management as a member of the PMG, and to the writing and final editing of the report. He co-led the development of the SIPS Jr City app, as well as the Trial Management app, and provided clinical advice.

Rhys Pockett (Epidemiologist) contributed to the health economic components and the health economic analysis plan, and conducted the health economic analysis. He contributed to study management as a member of the PMG, and to the writing and final editing of the report.

Ian T Russell (Professor of Clinical Trials) was a co-applicant. He contributed to study design and writing the protocol, to study management as a member of the PMG, and to the writing and final editing of the report.

John Strang (Professor of Psychiatry of Addictions) was a co-applicant. He contributed to study design and writing the protocol, contributed to study management as a member of the PMG, and to the writing and final editing of the report.

Colin Drummond (Professor of Addiction Psychiatry) was the chief investigator for this programme. He contributed to study design and protocol writing, study management, oversight of study conduct, and to the initial writing and final editing of the report.

All authors also provided a critical review and final approval of the report. They all agreed to be accountable for all aspects of the work.

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Data-sharing statement

All data requests should be submitted to the corresponding author for consideration. Access to anonymised data may be granted following review. Exclusive use will be retained until the publication of major outputs.

Patient data

This work uses data provided by patients and collected by the NHS as part of their care and support. Using patient data is vital to improve health and care for everyone. There is huge potential to make better use of information from people's patient records, to understand more about disease, develop new treatments, monitor safety, and plan NHS services. Patient data should be kept safe and secure, to protect everyone's privacy, and it's important that there are safeguards to make sure that it is stored and used responsibly. Everyone should be able to find out about how patient data are used. #datasaveslives You can find out more about the background to this citation here: <https://understandingpatientdata.org.uk/data-citation>.

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Appendix 1 Unpublished tables

TABLE 15 Exploratory prognostic linear regression of pre-randomisation factors on mean weekly alcohol consumption at month 12

Effect	Residual	p-value
Baseline alcohol consumption	20.42	<.001
Age in years	64.37	<.001
Sex	3.97	0.05
Ethnicity	2.06	0.06
Smoking status	1.77	0.13
Consume fruit	1.15	0.33
Age (years) at first drink	2.14	0.01
Alcohol-related problems		
Fighting	1.93	0.10
Parents	1.40	0.22
Friends	2.53	0.04
Police	2.14	0.10
Alcohol expectancy		
Feel more relaxed	5.60	0.01
More trouble with police	2.51	0.04
Forget problems	0.80	0.53
Unable to stop drinking	3.37	0.01
More friendly	3.09	0.02
Regretful activity	2.39	0.05

Appendix 2 Published research content

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RESEARCH ARTICLE

Adolescent perspectives about their participation in alcohol intervention research in emergency care: A qualitative exploration using ethical principles as an analytical framework

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Data Availability Statement: Due to ethical restrictions it is not possible to provide the full transcripts from the interviews. However, excerpts of data have been made available as a Supporting Information file. The authors confirm that the anonymised excerpts provided will give enough detail to replicate the findings of the study.

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Abstract

Aims

To explore adolescents' experiences of consenting to, and participating in, alcohol intervention trials when attending for emergency care.

Methods

In-depth semi-structured interviews with 27 adolescents (16 males; aged 14–17 years ($M_{age} = 15.7$)) who had taken part in one of two linked brief alcohol intervention trials based in 10 accident and emergency departments in England. Interviews were transcribed verbatim and subject to thematic analysis.

Results

Research and intervention methods were generally found to be acceptable though confidentiality was important and parental presence could hinder truthful disclosures regarding alcohol use. Participants discussed the importance of being involved in research that was relevant to them and recognised alcohol consumption as a normative part of adolescence, highlighting the importance of having access to appropriate health information. Beyond this, they recognised the benefits and risks of trial participation for themselves and others with the majority showing a degree of altruism in considering longer term implications for others as well as themselves.

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Competing interests: The authors have declared that no competing interests exist.

Abbreviations: AUDIT, Alcohol Use Disorders Identification Tool; AUDIT-C, Alcohol Use Disorders Identification Tool Consumption; e-BI, Electronic Brief Intervention.

Conclusions

Alcohol screening and intervention in emergency care is both acceptable and relevant to adolescents but acceptability is reliant on confidentiality being assured and may be inhibited by parental presence.

Trial registration

ISRCTN Number: 45300218

Introduction

Although the proportion of young people who have never tried alcohol has increased in recent years, alcohol remains the most widely used psychoactive drug in this population [1]. Adolescence is the key period for alcohol initiation with over 70% of young people having their first alcoholic drink by the age of 15 [2] and normative increases in both frequency and quantity of alcohol consumption occur from early adolescence through to early adulthood [3]. Adolescents may be especially vulnerable to the adverse effects of alcohol use [4]. Adolescent alcohol use can influence brain development and resultant cognitive, emotional and social development [5]. Research has identified associations between adolescent alcohol use and: heightened family conflict and lower educational outcomes [6, 7]; poorer physical [8] and mental health [9]; the development of alcohol use disorders [9, 10]; and disease in adulthood [11].

Forty per cent of adolescents aged 10–17 attending emergency departments in England reported drinking significant amounts of alcohol [12] yet a large proportion of hospitals in the UK do not offer alcohol support for young people [13]. Thus, emergency care is a key setting for prevention-focused alcohol intervention work with adolescents.

Screening and brief alcohol intervention is effective in reducing risky drinking in adults when delivered in healthcare settings [14, 15]. Although brief interventions have been shown to benefit younger people, most trials have been conducted in educational settings [16] with participants aged 18 or more [17] or have been conducted outside the United Kingdom (UK) [18–20]. A previous trial of BI delivered to underage drinkers in the ED setting in the United States of America demonstrated benefits of both therapist and tablet delivered BI in bringing about reductions in alcohol consumption at 3 month follow up and reduced alcohol consequences at 3 and 12 months post intervention [21]. Additional analysis of this data [22, 23] have shown that those who are younger, lived with their parents, reported lower alcohol consumption and higher levels of readiness to change at baseline are more likely to show positive responses to BI. These findings show promise for the effectiveness of BI in UK adolescents who, given the lower drinking age of 18 years are more likely to be younger and still living with their parents.

Despite long-standing calls for more work on preventing or reducing underage drinking [24], there remains little specific evidence to guide the prevention of alcohol-related harms in adolescents in the UK [25]. Historically, this absence of evidence was due, at least in part to concern about the vulnerability of children and debate about the reliability of data collected from them [26]. However, developments in children's rights [27] have led to greater focus on children contributing to decisions about their lives, care and treatment [28] and participation in research [29]. The challenges become most evident when research focuses on risk behaviours, as parental attitudes about the issues may hinder youth participation and thus

undermine research validity and applicability [30]. There is a growing focus on the importance of gaining consent from children, including how best to do so [31–33]. However, there has been less attention on hearing young people's direct views about participation in research [34] and little is known about the acceptability of alcohol screening and interventions methods to younger adolescents in healthcare settings in the UK.

The current study aimed to build on existing research by exploring the experiences of adolescents aged 14 to 17 who participated in two linked alcohol intervention trials (SIPS Junior) based in emergency care [35]. Although assessments of acceptability have received increasing focus in recent years [36] there is no clear consensus as to how acceptability should be defined and measured [36]. In this work the authors consider that to be acceptable research and intervention processes should not only be appropriate, comprehensible, effective and well received by participants but also ethical. The latter is particularly key in work with adolescents as there is debate as to the extent to which they can and should participate in treatment and also in research about treatment and care [28, 29].

We drew on the four principles of biomedical ethics—autonomy, beneficence, non-maleficence and justice [37]—as a framework within which to consider participants experiences of: consent and enrolment procedures; research design; and study interventions.

Respect for autonomy: respecting the decision-making capacities of autonomous persons; enabling individuals to make reasoned informed choices.

Beneficence: this balances the benefits of treatment against the risks and costs; the healthcare professional should act to benefit the patient.

Non maleficence: avoiding causing harm; the healthcare professional should not harm the patient. Though all treatment risks harm, that should be proportionate to the benefits of treatment.

Justice: distributing benefits, risks and costs fairly; patients in similar circumstances should be treated in a similar manner.

While a number of ethical guidelines have been developed to guide the ethical conduct of research and others for the provision care in an ethical manner this work was pragmatic in nature, based in routine practice and ultimately aimed to inform care improvement. As such, the contemporary view that the distinction between care and research can be overstated [38] especially in pragmatic healthcare research [39, 40] was adopted. Thus, the four widely accepted principles of biomedical ethics [37] were considered to provide an appropriate framework to guide the analysis and interpretation of data.

Materials and methods

Trial procedure

The randomised controlled trials aimed to evaluate the effectiveness and cost effectiveness of brief alcohol interventions for adolescents aged 14–17 who had attended 10 emergency departments in England; full protocol details have been published elsewhere [35].

Enrolled participants who scored less than 3 out of 12 on the Alcohol Use Disorders Identification Test: Consumption items (AUDIT-C) [41] were eligible for the low-risk trial whilst those scoring 3 or more were eligible for the high-risk trial. Within each trial, participants were randomised to one of: personalised feedback and brief face-to-face advice; or personalised feedback plus a smartphone or web-based electronic brief intervention (e-BI); or screening only (control group).

Those allocated to the screening only group were thanked for completing the baseline assessment and reminded that they would be contacted by the research team to complete follow-up in six and 12 months' time.

Both interventions aimed to motivate and support young people to either reduce their drinking or delay the onset of drinking (as applicable based on low or high risk status).

Participants allocated to the personalised feedback and brief face-to-face advice group were provided with: feedback on screening results; information on recommended levels of alcohol consumption for young people; normative comparison; information about the risks associated with drinking; the potential benefits of reducing, ceasing or delaying the onset of alcohol use (and strategies to achieve this. This advice took approximately five minutes to deliver. Participants also received a copy of a leaflet summarising this information and providing details of sources of further support.

Participants in the personalised feedback and e-BI group were provided with access to the 'SIPS City' web application which was co-produced with young people. This application allows the user to navigate around a 'city' learning facts about alcohol, recording and gaining feedback on their own alcohol consumption and setting goals. Participants were provided with a demonstration of the application either on their own phone or on the tablet used for baseline data collection.

Participants in both the intervention conditions were thanked for taking part and reminded that a researcher would contact them to conduct the trial follow up in 6 and 12 months' time.

All participants were followed up at 6 and 12 months after randomisation. Participants received a £5 gift voucher for completing the screening and baseline assessment and each follow up questionnaire. On completing 12 month follow up, participants were also entered into a prize draw to win an iPad.

Qualitative study procedure

Between March and November 2015 data were gathered through embedded qualitative interviews which explored young peoples' perceptions of participating in the trials after completion of the 12 months of follow-up. While interviews were scheduled to take place approximately 2 weeks after follow up this varied based on the number of contact attempts required and resultant period of time taken to contact each participant for follow up and interview. Each interview was conducted by one of two post-doctoral Research Associates, one male (MB) and one female (CE) both of whom had previous experience conducting qualitative interviews. At the beginning of each interview the researchers briefly introduced themselves giving their name and role on the project as well as the name of the institution where they were based. Both research associates were also involved in recruiting participants to the overall trials, to minimise any bias participants were never interviewed by the same researcher who recruited them.

Participants

The pool of potential participants included all those who had consented to take part in linked trials and who agreed to be contacted about participation in an interview. Purposive sampling was based on data regarding participants' characteristics that were collected in the parent trials. Sampling aimed to achieve a maximum variation sample based on the following criteria: age, gender, ethnicity, hospital from which they were recruited, high or low risk status, allocated intervention group, and whether a parent was present at screening. Young people in the e-BI intervention group were further sampled according to whether or not they had downloaded the intervention app. Sampled participants were posted a study information sheet along with a letter inviting them to take part in an interview. For those under 16, a parent or guardian was

also sent a letter telling them about the invitation. Follow-up phone calls, conducted on at most four separate occasions, were utilised to confirm willingness to participate. Consenting participants were offered the choice between an interview face to face or by telephone; all chose telephone interviews which have been shown to generate data similar to that collected in face-to-face interviews [42]. Interviews were arranged to take place at a time convenient for the young person and when they would be comfortable talking however it was left up to the young person to decide whether they wanted to be somewhere private at the time of the telephone interview. Attempts were made to contact 139 participants in total. Of the 139 contacted, 27 agreed to be interviewed. Among the remaining 112: 11 declined to take part; 2 parents declined on participants behalf; 6 agreed to telephone interview but then failed to answer, 12 were contactable but provided no definitive agreement to participate, 5 hung up following introduction, 5 contact details were no longer active, 71 contact details appeared active but voicemail, text and/or SMS contacts were not responded to. All interviewees received a £5 gift voucher.

The final sample comprised 11 females and 16 males aged 14–17 years ($M_{\text{age}} = 15.7$, standard deviation [SD] = 1.30). Fifteen were higher risk drinkers ($M_{\text{AUDIT C score}} = 5.6$, SD = 0.70) and 12 low risk drinkers ($M_{\text{AUDIT C score}} = 0.67$, SD = 0.26) at baseline assessment. Participants were predominantly white (22 White, 2 Asian, 1 black, 1 mixed, 1 other). Twelve received the brief intervention face to face, 8 received the electronic intervention (e-BI) and 7 were controls. Seven had a parent or guardian present during the screening and intervention conducted within the trial. As with the parent trials, interviewees from the low risk trial tended to be younger than those from the high risk trial. Among female interviewees, those from the high risk trial tended to have been allocated to the face to face intervention and those from the low risk trial had been allocated to the control or e-BI conditions.

Materials

To guide the interviews a semi-structured topic guide (see [S1 File](#)) was developed which explored young peoples' views about the research, screening and intervention processes. This guide predominantly focused on the acceptability of methods but was flexible, permitting the addition of issues emerging from earlier interviews and allowing participants to raise any issues they felt were important. The topic guide was not piloted but was revised following the completion of the first seven interviews. Some closed questions were amended to more open phrasing but no further changes were made.

Transcription and analysis

Length of interview varied from just 5 minutes to 45 minutes with the majority lasting between 10 and 25 minutes. All interviews were audio-recorded and transcribed verbatim before being anonymised. To minimise burden on participants' transcripts were not returned to them for comment. Framework analysis [43], an approach recommended for qualitative health research [44], was employed. An initial framework for coding based on participants' experience and understanding of the different stages of the research process (approach, screening, intervention and follow up) was developed and left flexible enough to accommodate additional issues emerging from the data. Initial application of this framework identified a number of emergent themes relating autonomy and beneficence with further ethical considerations emerging in codes relating to each stage of the research process. This led the research team to employ the four guiding principles of biomedical ethics to structure coding, data analysis and interpretation, and provide an overarching framework for discussing the findings. Three researchers (EL, CE, MB) independently read transcripts and coded data within this framework using

NVivo 10. Researchers and two senior staff (RMcG, EK) discussed codes on an on-going basis with emergent themes added to the framework and any disagreement in interpretations resolved. The initial descriptive account of the data was refined through further group discussions, leading to the final interpretation. Findings are supported by exemplar quotes (interviewees identified by gender, age, trial and intervention). Data saturation was considered to have been met when the first twenty interviews had been complete with no new themes or contradictory responses emerging, however recruitment continued to 27 participants to ensure diversity across the purposive sampling criteria.

Ethics and Governance

The studies were granted ethical approval by the National Research Ethics Service London—Fulham (ref:14/LO/0721). The trial registration reference was: ISRCTN45300218 dated 5th July 2014.

Results

Autonomy

The involvement of young people in research is in itself an acknowledgement of their autonomy. Many of the young people in this study voiced support for youth participation in research that was relevant to them. Some also explained the added benefit of engaging young people in the co-production of materials to ensure that they were appropriate and appealing to the target group:

I think it's a good idea to ask like the younger ones of what they would think would be best to pass on, more information to younger ones rather than asking like adults.

(Female/17/High-Risk/face-to-face)

Yeah I think so, I think they need to sort of be more involved and make it easier to understand for them because it sort of applies more to people their age.

(Male/17/Low-Risk/E-BI)

However, autonomy encompasses much more than just supporting the idea that an individual has something to offer in terms of research data. In order to be autonomous and provide informed consent young people must feel at ease about being approached, have a clear understanding of what participation will involve, what their rights are as a participant and what they are being asked to do. Young people in this study were happy to be approached whilst in emergency care and some thought it was a good place to capture a diverse sample:

I think it's a good way of like getting a good sample of people I guess.

(Male/16/High-Risk/E-BI)

I felt it was fine, I wasn't fazed by it at all

(Male/14/Low-Risk/Control)

Nevertheless, for some, the issue of being approached may not have been fully considered until the interview.

I: OK, and what did you think about being asked to be involved in a study about alcohol whilst you were in A&E?

P: Erm, I didn't really think about that.

I: Yeah.

P: It didn't really cross my mind

(Female/16/High-risk/face-to-face)

Adolescents reported understanding their rights as participants with specific references to confidentiality, right to refuse and right to withdraw. Much of this understanding appeared to be gained from the verbal explanations of the trials provided by research staff rather than the written information sheets that were given to participants:

Well she showed me what her like research like what it was the project was about [mmhmm] and she explained that if I don't want to do it then it's totally up to me like and everything's confidential and I was totally agreed with her and I just said I would do it for her no bother and I just did it for her

(Female/14/Low-Risk/Control)

It was evident that participants were clear that the decision to participate was their own and that they could have time to consider their participation. There was no evidence in the interview transcripts that participants felt they should seek approval or guidance from parents or guardians when deciding whether to participate and no suggestion that they felt ill-equipped to make the decision alone:

she came to me holding my name, and was very pleasant and made it very clear from the start. She gave me a few minutes to sort of have a think about it. . . and I came back to her and agreed to take part. And then filled out all the information, and yeah she was nice and friendly, and very approachable so yeah

(Male/17/High Risk/Control)

Participants also identified that the research itself had been clearly described, or 'explained rather well'. In support of this they were also able to offer descriptions of the research study which broadly fitted its purpose and hence showed some understanding of the aims of the project and what participation would involve:

If I took part it would like help you get a better understanding of how it could pass information to younger people about the causes of drink and that.

(Female/17/High-Risk/Face-to-face)

However, none of the descriptions demonstrated a full understanding of the randomisation process or the differences between trial arms. Instead participants often spoke about participating in a 'survey' and seemed more focused on topic than study design:

I just thought it was a survey to ask about like young peoples' lifestyles and what they do.

(Female/17/High Risk/Face-to-face)

Similarly, participant descriptions of the research tended to focus on completion of the baseline measures and the initial trial visit with limited detail pertaining to follow up visits being offered even when specifically asked about this aspect of the trial:

I can't remember I think she might have put my details down. . .she said you'll probably get a letter through the post and I got that last week and then obviously I had the phone call yesterday

(Female/14/Low-Risk/Control)

Because participants were interviewed up to a year after being enrolled in the trials, recall inaccuracy may have contributed to misunderstanding. Some of the participants voiced this issue in interviews.

Oh god I can't remember, erm ah it's a long time ago.

(Male/14/Low-Risk/Control)

When asked during the qualitative interviews, participants could not think of any aspect of the approach or explanation of the research which could be improved. Nevertheless, it is clear that care needs to be taken when communicating the complex aspects of research design.

Participants identified that they had understood the screening questions; however, a small number of participants suggested that some questions could have been clearer. These participants reported seeking clarification from trial staff who were then able to provide the required assistance and enable continued participation.

Some of the questions were a bit erm confusing let's say, I mean I wasn't completely thrown by it but some of them you did have to think about.

(Male/17/High-Risk/Control)

Regarding the interventions specifically, the majority of participants were happy to receive information and advice about alcohol; with no suggestion of difficulties in understanding the advice provided.

I was given a leaflet and she explained the leaflet as well. . . I understood her, I understood what she was saying

(female/17/High-Risk/Face-to-Face)

Information was predominantly considered to be relevant, appropriate for the age group and some participants recognised the non-judgemental approach to delivery:

P: *I was aware of the risks but it did highlight other key things that I wasn't aware of*

INT: *do you think that the information or how it's delivered could be improved at all?*

P: *no, no I think that was pretty good as well like she was just really nice about it like she didn't make me feel like I'd done anything wrong or anything*

(Female/17/High-Risk/Face-to-Face)

Beneficence

Most participants expressed clear views about the importance of research being conducted with young people, particularly when the research subject was relevant to them; they often mentioned the benefits for others:

I think it helps not just themselves but everybody else out there. Just because we need to learn don't we

(Female/14/Low-Risk/Control)

Aside from a sense of altruism, some felt that participation in research was itself a positive experience:

It was quite nice to be involved in the study. I thought it was quite interesting, yeah.

(Male/16/High-Risk/E-BI)

With regards to the intervention, participants identified the availability and wide spread use of alcohol as a key reason for needing access to reliable and accurate information about alcohol. Further, participants recognised that being under the legal drinking age (18 years of age in the UK) does not protect one from this exposure to alcohol and thus younger adolescents should be included in interventions:

Because they're underage and they're like exposed to alcohol you know. . . Most people at that age actually drink alcohol a fair bit . . . Yeah, it's a good idea to involve under-ages.

(Male/17/High-Risk/Control)

One participant also identified the issue of screening and intervening before potentially problematic behaviours develop, highlighting the benefits of universal and targeted approaches:

We need to learn young before we get older and just think it's acceptable.

(Female/14/Low-Risk/Control)

Participants who received an intervention described the process as 'informative', 'relevant', 'good', 'helpful', or 'useful'. Many felt they had gained additional knowledge about alcohol, such as learning how many units were in a particular drink:

yeah it had some different things on like unit levels and things like that, stuff like that, that aren't really taught. . . I was aware of the risks but it did highlight other key things that I wasn't aware of

(Female/17/High-Risk/Face-to-face)

However, some participants described the content of interventions as already familiar to them from their parents and school lessons, with no additional knowledge or benefit having been gained with one stating:

alcohol erm like I know everything about it I think even though I don't drink it

(Male/14/Low-Risk/E-BI)

Despite this, the advice was typically seen as helpful to participants and could have wider reaching harm reduction effects with friends and peers also potentially benefiting:

if you are like having a drink and that and something does go wrong, what, what you should do. . . 'cos I know loads of people who don't actually have a clue and say someone like is absolutely mortal on the floor they actually just leave them because they don't know what to do.

(Male/17/High-Risk/Face-to-face)

Non-maleficence

When conducting research in healthcare settings one of the primary concerns of research staff is often ensuring that the research does not detract from or delay the care participants receive. No participants reported feeling they had experienced harm from participating in this research nor did they feel that it had influence their care:

it seemed totally harmless and you know I was happy to do it. . . I'm totally open to it.

(Male/16/High-Risk/E-BI)

It didn't prolong me or delay me in any way and so I thought that was alright.

(Male/17/High-Risk/Control)

Conversely, participation was seen to have the benefit of providing young people with something to do while waiting to be treated, something which did not necessarily extend to completion of the follow up sessions when some participants explained that they had other priorities:

when you sort of see someone in hospital, you know approach them, you haven't really got, what I mean I don't want to offend but you know that's all they've got to do really, sitting in the waiting room. But when you follow them up, I think a lot of people don't really want to give you their time

(Male/16/High-Risk/E-BI)

There was some evidence that those attending with alcohol-related injuries may have felt less comfortable taking part and that this may have resulted in socially desirable responses:

I actually fell down the stairs the night before because I had alcohol. . . I didn't tell the researcher at the time because it was very bad.

(Female/17/High-Risk/Face-to-face)

With regard to potential harm from participation the manner and approach adopted by research staff including interventionists appeared to be important. Participants' responses to staff approach and intervention delivery were positive with exchanges described as 'nice', 'lovely' 'positive' and 'very welcoming':

she was just really nice, she just asked us nicely if I wanted to take part and I didn't mind

(Female/17/High-Risk/Face-to-face)

Beyond this young people were primarily concerned with confidentiality. Alcohol use can be a sensitive subject with scope for embarrassment. Most participants, whether from high or low risk categories, reported that screening did not present a problem for them as long as confidentiality and privacy were assured:

I guess because all of the information is like private and everything you could erm, it is sort of erm, what's the word? Acceptable. Obviously if it wasn't kept secret and some information was leaked it could affect that person's, say, chances of getting a job or something. But I guess as it's a confidential study then it's alright, it's acceptable.

(Male/17/High-Risk/Control)

The importance of ensuring confidentiality is evidenced by the fact that some participants sought assurance from the researchers that their responses would be protected:

"I did ask her at the time and she said no one would know"

(Female/17/High-Risk/Face-to-Face)

Within this, a sub-theme of 'parental presence' also emerged from the data. When a parent is present during research, screening or intervention procedures the circle of confidentiality may be expanded to include not only the participant and the researcher but also the parent. In this work, there was no requirement for parents to be present during completion of the baseline measures or intervention delivery. Instead, participants attending the ED with a parent or guardian were offered the option of moving away from their parent or guardian during participation. Some accepted this offer while others declined. This potentially reflects the finding that opinion was split with regards to the acceptability of having a parent present during screening or intervention. Some described being '*absolutely fine*' with having a parent present, while others explained they would '*prefer to do it without her [mother] there*'. Although the majority of our participants reported feeling comfortable discussing alcohol use in front of a parent or guardian, some still expressed concern for others:

Some people [who] might not want their parents to know about that sort of thing but I'm not particularly fussed.

(Male/16/High-Risk/E-BI)

There was also evidence that the presence of a parent or guardian could inhibit participants' ability to talk freely or accurately about their alcohol use:

say if somebody like my parents were there, I would say that I don't drink at all. But when they're not there, I can be more honest so I think, what was it, a private interview or something

(Female/17/High-Risk/Face-to-face)

Completing the screening questions on an electronic device was seen to offer a greater sense of confidentiality and allow participants to protect their answers even in the presence of a parent:

no one can see what you're doing, which is pretty good... it was a bit personal if someone didn't want to, you know, especially with your mum there

(Male/17/High-Risk/Control)

Finally, participants considered, not only their own experiences but also those of others who might be more vulnerable than they perceived themselves to be, highlighting the importance of having appropriate and carefully considered inclusion criteria:

Because my injury was not like fatal, and I was alright, I was OK, it would be OK for me, but I think somebody was in a lot of pain and they're waiting for emergency, like serious, serious, then for somebody to approach them about something completely unrelated could be annoying to them and they might get angry.

(Female/17/High Risk/Face-to-face)

Justice

Participants did not report feeling 'singled out' and were aware that researchers were approaching all individuals within the age category for inclusion with one participant going so far as to identify the questions as 'standard practice':

Yeah, I mean it didn't really worry me at all, I wasn't thinking they were going to attribute something to me because I've got a broken leg, so. But no, it didn't feel like they came to me for a particular reason, I think it was just like a random sample, wasn't it? people between certain ages like, yeah

(Male/17/High-Risk/Control)

the questions didn't. you know. they didn't like offend or upset me [mmm] they just seemed like standard practice so that was fine.

(Male/16/High-Risk/E-BI)

The issue of facilitating widespread participation seemed to be of importance to many interviewees. In this case the intervention was seen to be useful and accessible to the target population though potentially of more use in the future:

I'll probably use it more in the future when I'm older and I drink more often. . . it was really good for the age category that it's aimed at 'cos there's not too much information that you get bored of reading it but there's enough so that you know exactly the importance of alcohol.

(Female/17/High Risk/E-BI)

Again, the importance of involving adolescents, in the co-production of materials was identified as potentially enabling effective communication with this age group:

Yeah I think so, I think they need to sort of be more involved and make it easier to understand for them

(Male/17/Low-Risk/E-BI)

Further to this, the use of technology was predominantly seen as helpful for those who had difficulties with reading or writing but participants identified that this would possibly have the opposite effect for research with older populations who were considered to be less familiar with technology:

people like me who've got dyslexia, it's probably a bit messy writing it down by hand so by doing it on the iPad it's a lot quicker and neater, so yeah.

(Male/17/High Risk/Control)

it depends on who your target audience is, because obviously I'm young, and young people wouldn't mind but if you were targeting a more older audience like people with diabetes and stuff and older people, they might sort of like, not know how to use the technology and stuff

(Female/14/Low-Risk/Control)

While young people generally saw the benefits of technology in widening participation there did appear to be some difficulties relating to accessing the e-BI intervention. Specifically, one participant had not downloaded the app and another had deleted it due to not having sufficient memory space on their phones, while one more explained that the app was not available in the app store so they had never downloaded it.

Discussion

In this study, many of the interviewees recognised the importance of young people having the opportunity to take part in research on topics of significance to them. The findings generally support the acceptability of alcohol screening, interventions and alcohol intervention research with adolescent populations in emergency care. We found no indication that alcohol intervention per se or the emergency care setting was viewed as unacceptable to participants.

However, acceptability was dependent on certain criteria being met. Firstly, the friendly, non-judgemental approach adopted by research staff appeared to be important and is something that should be maintained in future research and intervention work. Secondly, confidentiality must be assured. Some participants pointed to the benefit of completing questions on an iPad or tablet in affording them a greater sense of privacy and reducing concerns about the potential for their responses to be misplaced. In some cases maintaining confidentiality also meant having the option to complete screening and receive intervention without a parent present. Although the presence of parents or carers during consent and/or intervention activity seemed to be accepted by many participants, some were less comfortable about parental presence and felt this might inhibit their own and others' ability to speak freely. This could, in turn, limit identification of those who would benefit most from intervention delivery or identification of the most appropriate intervention to deliver. This finding supports previous research which reported that parental involvement could restrict adolescent uptake of health-care [45] especially among those engaged in risky behaviours [46]. Future research should carefully weigh the benefits of having parents present during adolescent research participation against the potential for gaining more honest and open responses if participation is completed one to one. Although there was no evidence in this work that participants felt the need to defer to or consult their parents when making decisions about research participation consideration should also be given to how best offer participants a legitimate choice to complete research activities in private if they are attending treatment with a parent. Finally, it was important that young people were aware that they were not the only ones being approached and thus that they did not feel 'singled out'. This has direct implications for future intervention work: although targeted interventions allow the delivery of the most relevant information a universal approach to screening and identification is likely to be more acceptable to young people.

Most of the adolescents we interviewed appeared to have a good understanding of their rights as participants, including the fact that participation was voluntary, and of many aspects

of the trials procedures, particularly the subject matter, this is in line with previous research [47–49]. However, specifics relating to the technical design of the trials including randomisation procedures and follow up were less well reported. This may simply be a result of the time which elapsed between initial participation and interview, alternatively it may be an indication of limited understanding of these details. Although shortfalls in understanding are not uncommon in research with adult participants [50] this finding demonstrates the importance of providing information in a clear, succinct manner, and offering opportunities for participants to seek clarification to inform their decision making. In this work, much of the understanding of the research and research involvement appeared to be gained from the verbal explanations offered by staff rather than the written information sheets that participants were given. As such allocating additional time for researchers to verbally introduce research and discuss participation may enhance understanding more than provision of additional or alternative written guidance.

Similarly, where participants had difficulty understanding questions in the baseline questionnaire, this was overcome by seeking clarification from the researcher highlighting the importance of having researchers available to provide assistance and guidance if needed. Many young people in this work pointed to the benefits of involving young people in the co-production of research and intervention materials to ensure their acceptability to the target audience. Indeed, the co-produced intervention materials employed in this work were generally found to be appropriate for adolescent participants. As such, involving young people in the co-production of baseline questionnaires may help to overcome difficulties in understanding and interpretation but this can be problematic when existing validated tools, especially those that do not have child or adolescent specific variants available, are utilised. Finally, with poor recollection relating to follow up, using initial contact by text message, email or postal mail to prompt recall of study participation may facilitate completion of follow up visits.

In line with previous research, many of the young people also appeared able to assess possible implications of research participation and weigh up decisions about participating [51], based not only on relevance and helpfulness to themselves but also to other people [52], typically younger adolescents. The benefits identified included research participation itself as well as knowledge gained from the study interventions—generally seen as interesting, relevant and helpful to participants, who welcomed having something to do while waiting for treatment in the emergency department.

There was no evidence to suggest that participants experienced any harm as a result of involvement or that talking about alcohol with adolescents would lead to adverse consequence such as encouraging initiation of drinking or increased consumption. Over half of our participants were reportedly drinking at risky levels whilst the remainder had not really started to consume alcohol. Nevertheless, they all described alcohol as a normative behaviour—a view supported by other work (e.g. [12 53]). Many individuals in the low-risk trial described the intervention content as useful for ‘when’ (not ‘if’) they started drinking alcohol. That alcohol consumption was already framed as inevitable highlights the need for effective interventions to reduce future health risks.

Although some participant responses were more succinct than others this was considered to be typical of the way young adolescents speak and the assumption that a young person who talks less during an interview has provided less useful data has been queried [54]. These accounts not only appeared authentic but they also provide some reassurance about the possibility of social desirability during interviews. The primary limitation of this work is that participants who agreed to be interviewed had already participated in the trials and may be more positive about the issues being explored or better informed about the topic than those who elected not to take part. This may in part account for why participants offered few criticisms of

the trial or areas for improvement. Where those who decline initial participation are comfortable giving reasons for non-participation, collection and analysis of this data could provide additional insight and areas for improvement, though it is important for ethical research conduct that individuals not be required to provide such information. In this work, although purposive sampling was adopted, participants also self-selected in that they had to be contactable at the time of the interviews and had to agree to take part. Diversity was achieved across age, gender, high or low risk status and allocated intervention however, the final sample had limited diversity with relation to participant ethnicity (80% of participants identified as 'white'). Even taking into account the majority white participant pool in the parent trials non-white participants are still under represented in this sample. Further to this, a high number ($n = 71$) of those contacted did not respond to contact. This may be symptomatic of the minimal number of attempts made to contact each participant about the study ($n = 3$). While this helped reduce any pressure participants may have felt to participate it also means that only those who were easy to reach participated. The fact that interviews took place around a year after initial participation in the trial, something which likely contributed to limited recall of certain aspects of the research and potentially contributed to shorter, less detailed responses. A final limitation to consider related to the framework analysis employed. While the principles of biomedical ethics were adopted as an overarching structure based on the themes emerging from the data and all major codes were able to be captured within this framework an alternative approach to coding may have led to the identification of different themes.

Conclusions

The research and intervention methods were generally found to be acceptable. The perceived relevance of the study seemed to be a key influence on willingness to become involved. The universal approach to screening, assurances of confidentiality and the non-judgemental approach of researchers contributed to acceptability which may in turn be inhibited by parental presence. Typical adolescents in this study appeared to understand the implications of participating in research; they described a process of considering potential benefits and harms both for themselves and for other people during the consent processes. Nevertheless, it is clear that many of the adolescents in this study did not have a full understanding of the specific research design. Future work would benefit from engaging young people in identifying how to explain the technical aspects of research designs as well as in the co-production of study materials and processes.

Supporting information

S1 File. Appendix interview topic guide.

(DOCX)

S2 File. Appendix excerpts from interview transcripts.

(DOCX)

S3 File. COREQ checklist.

(DOCX)

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Appendix 3 Incremental cost-effectiveness ratios tables

Table 16 outlines each of the resources costed for use within the cost-effectiveness analysis. It shows the cost identified for each resource, any assumption of calculation used and the reference for the costs. All costs were recorded in 2014 UK sterling prices. Resource use, their subsequent costs and any benefits observed were modelled over a 12-month time horizon. A discount rate of 3.5% was used.

TABLE 16 Details of costs

Contact with health professional	Unit cost (£)	Details of cost component(s)	Reference
Consultation with GP	46.00	11.7 minutes of consultation, including direct care staff costs, with qualification costs (p. 195)	Curtis ¹⁴³
Seen the practice nurse	13.69	£53 per hour for face-to-face consultation, including qualification costs. Average consultations last 15.5 minutes. Cost calculated as follows: £53/60 × 15.5 (p. 192)	Curtis ¹⁴³
Seen the health visitor	19.69	£76 per hour of patient-related work, including qualification costs. Average consultation time for a practice nurse (15.5 minutes). So, £1.27 per minute × 15.5 = £19.69 (pp. 187, 189, 192)	Curtis ¹⁴³
Hospital inpatient elective stay	3375.42	National average unit cost	Department of Health and Social Care ¹⁷²
Hospital inpatient elective stay: excess bed days	326.90	National average unit cost	Department of Health and Social Care ¹⁷²
Hospital inpatient non-elective short stay (1–3 days)	602.52	National average unit cost	Department of Health and Social Care ¹⁷²
Hospital inpatient non-elective long stay (4–6 days)	2837.31	National average unit cost	Department of Health and Social Care ¹⁷²
Hospital inpatient non-elective excess bed-days (incurred for stays > 6 days)	275.05	National average unit cost	Department of Health and Social Care ¹⁷²
Hospital day case	697.55	National average unit cost	Department of Health and Social Care ¹⁷²
Regular day/night admission	400.23	National average unit cost	Department of Health and Social Care ¹⁷²
A&E visit	123.67	National average unit cost	Department of Health and Social Care ¹⁷²
Outpatient department visit	109.00	Weighted average of all outpatient attendances (p. 111)	Curtis ¹⁴³

continued

TABLE 16 Details of costs (*continued*)

Contact with health professional	Unit cost (£)	Details of cost component(s)	Reference
Consulted or visited other health-care professional	34.67	Calculated average of hospital-based health-care staff, including qualification costs: physiotherapist (£37), occupational therapist (£36), SALT (£37), dietitian (£37), radiographer (£38), allied health professional support worker (£23) = £34.67 (pp. 235–241). Assumed 1-hour consultation, given that there is no average consultation time	Curtis ¹⁴³
Community services			
Visited optician	21.00	Average Specsavers cost	Curtis ¹⁴³
Visited family therapist	45.83	£50 per hour. Average consultations last 55 minutes. Cost calculated as follows: $(£50/60) \times 55 = £45.83$ (p. 51)	Curtis ¹⁴³
Visited individual therapist	45.83	£50 per hour. Average consultations last 55 minutes. Cost calculated as follows: $(£50/60) \times 55 = £45.83$ (p. 51)	Curtis ¹⁴³
Visited psychiatrist/psychologist	69.00	£138 per hour for client-related work, including qualification costs. Average consultations last 30 minutes (assumption). Cost calculated as follows: $(£138/60) \times 30 = £69.00$ (p. 183)	Curtis ¹⁴³
Visited social worker	39.50	£79 per hour for client-related work, including qualification costs. Average consultations last 30 minutes (assumption). Cost calculated as follows: $(£79/60) \times 30 = £39.50$ (p. 207)	Curtis ¹⁴³
Home visit optician	31.00	Estimated cost of optician visit at £21.00 + £10.00 travel costs	
Home visit family therapist	70.83	£50 per hour. Average consultations last 55 minutes + 15 minutes each way travel costs (assumption). Cost calculated as follows: $(£50/60) \times 85 = £70.83$ (p. 51)	Curtis ¹⁴³
Home visit individual therapist	70.83	£50 per hour. Average consultations last 55 minutes + 15 minutes each way travel costs (assumption). Cost calculated as follows: $(£50/60) \times 85 = £70.83$ (p. 51)	Curtis ¹⁴³
Home visit psychiatrist/psychologist	138.00	£138 per hour for client-related work, including qualification costs. Average consultations last 30 minutes + 15 minutes each way travel (assumption). Cost calculated as follows: $(£138/60) \times 60 = £138.00$ (p. 183)	Curtis ¹⁴³
Home visit social worker	39.50	£79 per hour for client-related work, including qualification costs. Average consultations last 30 minutes (assumption). Cost calculated as follows: $(£79/60) \times 30 = £39.50$ (p. 207)	Curtis ¹⁴³

TABLE 16 Details of costs (continued)

Contact with health professional	Unit cost (£)	Details of cost component(s)	Reference
Home visits			
GP	91.26	11.4-minutes home visit, plus 12-minutes travel time per visit on average. 1 minute of GP time is costed at £3.90 (including direct care staff costs with qualification costs) (p. 195), this is multiplied by 23.4 to estimate cost of home visit (pp. 194–5)	Curtis ¹⁴³
Community nurse	30.25	£66 per hour of patient-related work, including qualification costs. Average consultation time for a practice nurse (15.5 minutes) and average travel time for a GP (12 minutes) used to calculate cost per visit. So, (£1.10 per minute × 15.5 = £17.05) + (£1.10 × 12 = £13.20) = £30.25 (pp. 187, 192, 194–5)	Curtis ¹⁴³
Practice nurse	24.29	£53 per hour for face-to-face consultation at GP surgery, including qualification costs. Average consultations last 15.5 minutes (assumed to be the same for home visits). Average travel time for a GP (12 minutes) used to calculate travel costs. So, (53/60 × 15.5 = £13.69) + (53/60 × 12 = £10.60) = £24.29 (pp. 192, 194–5)	Curtis ¹⁴³
Health visitor	34.93	£76 per hour of patient-related work, including qualification costs. Average consultation time for a practice nurse (15.5 minutes) and average travel time for a GP (12 minutes) used to calculate cost per visit. So, (£1.27 per minute × 15.5 = £19.69) + (£1.27 × 12 = £15.24) = £34.93 (pp. 187, 189, 192, 194–5)	Curtis ¹⁴³
Other health-care professional	48.48	Calculated average of community-based health-care staff, including qualification costs: physiotherapist (£36), occupational therapist (£36), SALT (£36), palliative care nurse specialist (£74), clinical support worker (£20) = £40.40. Then added travel costs, estimated by using GP travel time of 12 minutes. So, additional travel cost = (40.40/60 × 12 = £8.08) (pp. 235–241). Assumed 1-hour consultation, given that there is no average consultation time	Curtis ¹⁴³
Drug and alcohol services			
CAMHS face to face	84.00	CAMHS cost per hour ranges between £84 and £115 per hour of face-to-face contact, depending on case mix. Average face-to-face meeting lasts 60 minutes (assumption) (pp. 222–5)	Curtis ¹⁴³
CAMHS telephone	16.38	11.7-minute consultation (average GP telephone consultation time) as a proportion of CAMHS cost	Curtis ¹⁴³
Other face to face	84.00	Assumed same as CAMHS	Curtis ¹⁴³
Other telephone	16.38	Assumed same as CAMHS	Curtis ¹⁴³

continued

TABLE 16 Details of costs (*continued*)

Contact with health professional	Unit cost (£)	Details of cost component(s)	Reference
Sick/truancy days			
School exclusion (permanent)	4000.00		Department for Education ¹⁷³
Educational help			
Individual tuition at home	35.00	Fees average between £29 and £41 per hour	Journalism.co.uk ¹⁷⁴
Individual tuition in some classes	14.26	£14.26 per hour, based on an average teaching salary of £27,813.5 and 37.5 hours per week of working time	Department for Education ¹⁷⁵
Lessons in a special unit in school	14.26	Assumed same as individual tuition in some classes	Department for Education ¹⁷⁵
School professionals			
School nurse (per contact)	53.00	£53 per contact, school-based children's health-care (other) services (p. 85)	Curtis ¹⁴³
Educational psychologist (per contact)	41.00	£41 per contact, educational psychologist (p. 156)	Curtis ¹⁴³
Educational welfare officer (per contact)	22.50	£22.50 per contact, EWO. Checklist completed by EWO £18 + TAC meeting attended by EWO £27. Average calculated (p. 155)	Curtis ¹⁴³
School counsellor/health advisor (per contact)	41.00	Assumed same as educational psychologist	Curtis ¹⁴³
Additional meetings with tutors (per minute)	0.24	£0.24 per minute, based on an average teaching salary of £27,813.5 and 37.5 hours per week of working time	Department for Education ¹⁷⁵
Other care			
Foster care (days)	427.86	£2995 establishment costs per week/ 7days = £427.86 per day (p. 86)	Curtis ¹⁴³
Residential care (days)	90.43	£633 establishment costs per week/ 7days = £90.43 per day (p. 64)	Curtis ¹⁴³
Supported accommodation (days)	90.43	Assumed same as residential care. £633 establishment costs per week/ 7days = £90.43 per day (p. 64)	Curtis ¹⁴³
Other (days)	90.43	Assumed same as residential care. £633 establishment costs per week/ 7days = £90.43 per day (p. 64)	Curtis ¹⁴³
Policing and crime			
Police contact (spoken to by)	21.85	Cost of police constable, per hour (p. 16)	NPCC ¹⁷⁶
Court appearance	100.00	Costs vary massively depending on type of court and whether the defendant pleads guilty or goes to trial. We have calculated the cost based on the lowest costed court attendance at a magistrates court. Costs exclude lawyers	Crown Prosecution Service ¹⁷⁷
Custody (day)	418.00		Alexander ¹⁷⁸
CAMHS, Child and Adolescent Mental Health Services; EWO, Educational Welfare Officer; NPCC, National Police Chiefs' Council; SALT, Speech and Language Therapist; TAC, Team Around the Child.			

Incremental cost-effectiveness ratios for interventions compared with control for the low- and high-risk populations are given in *Tables 17* and *18*.

TABLE 17 Incremental cost-effectiveness ratios for interventions vs. control: low-risk population

Perspective	Trial group	Total		Difference		ICER (£/QALY)
		QALY	Cost (£)	QALY	Cost (£)	
Societal	Control	0.904	1132	–	–	–
	PFBA	0.909	1735	0.005	603	130,822
	eBI	0.894	1884	–0.013	751	eBI dominated
NHS/PSS	Control	0.904	912	–	–	–
	PFBA	0.909	1468	0.005	556	120,693
	eBI	0.894	1683	–0.013	771	eBI dominated

TABLE 18 Incremental cost-effectiveness ratios for interventions vs. control: high-risk population

Population	Trial group	Total		Difference		ICER (£/QALY)
		QALY	Cost (£)	QALY	Cost (£)	
Societal	Control	0.900	1704	–	–	–
	PFBA	0.903	1726	0.003	23	8683
	eBI	0.892	2110	–0.008	407	eBI dominated
NHS/PSS	Control	0.900	1553	–	–	–
	PFBA	0.903	1571	0.003	19	7115
	eBI	0.892	1953	–0.008	401	eBI dominated

Appendix 4 Copies of previously published papers

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Opportunistic screening for alcohol use problems in adolescents attending emergency departments: an evaluation of screening tools

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ABSTRACT

Objective To estimate and compare the optimal cut-off score of Alcohol Use Disorders Identification Test (AUDIT) and AUDIT-C in identifying at-risk alcohol consumption, heavy episodic alcohol use, ICD-10 alcohol abuse and alcohol dependence in adolescents attending ED in England.

Design Opportunistic cross-sectional survey.

Setting 10 emergency departments across England.

Participants Adolescents ($n = 5377$) aged between their 10th and 18th birthday who attended emergency departments between December 2012 and May 2013.

Measures Scores on the AUDIT and AUDIT-C. At-risk alcohol consumption and monthly episodic alcohol consumption in the past 3 months were derived using the time-line follow back method. Alcohol abuse and alcohol dependence was assessed in accordance with ICD-10 criteria using the MINI-KID.

Findings AUDIT-C with a score of 3 was more effective for at-risk alcohol use (AUC 0.81; sensitivity 87%, specificity 97%), heavy episodic use (0.84; 76%, 98%) and alcohol abuse (0.98; 91%, 90%). AUDIT with a score of 7 was more effective in identifying alcohol dependence (0.92; 96%, 94%).

Conclusions The 3-item AUDIT-C is more effective than AUDIT in screening adolescents for at-risk alcohol use, heavy episodic alcohol use and alcohol abuse. AUDIT is more effective than AUDIT-C for the identification of alcohol dependence.

Keywords adolescent, alcohol, diagnosis, screening

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Introduction

The excessive consumption of alcohol is a major global public health issue^{1,2} and places a significant burden on international health systems. While the majority of this burden lies with adult populations, for many the roots of problematic alcohol use lies in adolescence.³ Adolescence is a critical developmental stage when young people make behavioural and lifestyle choices that have the potential to impact on their health and wellbeing into adulthood. Inappropriate risk-taking is significantly associated with health and social harm during adolescence.⁴ Young people are much more vulnerable than adults to the adverse effects of alcohol use due to a range of physical and psychological factors that often interact. Adolescence is also a unique period whereby neural proliferation and subsequent 'pruning' processes may leave brain structures particularly vulnerable to the effects of alcohol.^{5,6}

A recent survey of alcohol consumed by 14–15 years old across 36 European countries reported that in the United Kingdom (UK) 87% had consumed alcohol at least once in their lifetime and 57% had consumed alcohol at least once in the past month.⁷ The prevalence of consuming alcohol increases with age, with data from 2016 indicating that 9% of boys aged 11–15 years, and 11% of girls had consumed alcohol in the past 7 days. Of these, 1% of 11 years old consumed alcohol in the past 7 days, increasing to 24% at age 15. In terms of quantity of alcohol consumed in the past 7 days mean consumption was 10.3 units for boys and 8.9 units for girls aged 11–15 years.⁸

An evidence based review of the risks and harms of alcohol consumption in young people⁹ provided a basis for the Chief Medical Officer for England recommendations for alcohol consumption in young people—that young people up to the age of 15 abstain completely from drinking and those aged 15–17 are advised not to drink, but if they do drink, they should not exceed 2–3 standard drinks in any day and no more than once per week.¹⁰

While there is a body of evidence addressing the effects of school based interventions for delaying the onset of drinking in adolescents,¹¹ and some evidence for interventions to delay the age of onset or reduce alcohol consumption for adolescents in other settings,^{12,13} there exists a paucity of evidence of the effectiveness of interventions to reduce adolescent alcohol use in primary care settings. Recommendations from the World Health Organization, US Surgeon General and American Academy of Paediatrics advocate that more evidence is needed on the effectiveness of opportunistic screening and interventions for adolescents who consume alcohol^{14,15} and this population has been identified as a key target group for the reduction of alcohol

use and related harm^{16,17} in both English and Scottish alcohol strategies.

The identification of adolescents who consume alcohol at problematic levels is a key element in any screening and intervention strategy. To offer such interventions practitioners need access to screening tools that are high in both sensitivity and specificity and are quick and easy to apply at minimal cost. Biochemical markers of alcohol use such as γ -glutamyl-transferase, aspartate aminotransferase, erythrocyte mean cell volume and percent carbohydrate deficit transferrin are impractical and of little use in this population and have been found to be inferior to short paper instruments in adult populations.¹⁸ The Alcohol Use Disorders Identification Test (AUDIT)¹⁹ is a 10-item self-completion instrument with established diagnostic properties for problematic alcohol use in adults that addresses three domains of alcohol-related problems; consumption, negative consequences and symptoms of dependence. AUDIT is one of the few screening instruments that specifically incorporates consumption into the scoring algorithm and may be particularly suitable for adolescents who are more likely to experience a range of alcohol-related problems as a result of consumption rather than psychological consequences of alcohol use. Further, it may be the case that the three specific alcohol consumption questions, AUDIT-C, may be equally efficient as a brief screening instrument as the full AUDIT. Previous studies suggest that the AUDIT may be more useful than other brief screening instruments in adolescent populations, but there is less consensus regarding appropriate cut-off points for different severities of alcohol use^{20–25} and no previous research has compared the relative effectiveness of AUDIT versus AUDIT-C as opportunistic screening approaches for adolescent populations. Much of the prior research has aimed to compare the performance of a variety of different screening instruments^{21,26–28} against more severe clinical alcohol use disorder criteria whereas adolescents are more likely to experience alcohol-related difficulties at lower levels of consumption and this is in part due to the pattern of consumption in the form of heavy episodic alcohol use.²⁹ In addition, the majority of studies have been conducted in older adolescent populations^{20,22} and often involve college students, primary care or hospitalized participants, rather than an opportunistic sample and are limited in their generalizability to the wider adolescent population and particularly limited in their generalizability to the UK.

Our aim was to estimate and compare the sensitivity, specificity, and diagnostic odd ratio of the AUDIT and AUDIT-C in identifying at-risk alcohol use, monthly heavy episodic alcohol use, alcohol abuse and alcohol dependence in the context of an opportunistic screening programme for adolescents, aged between 10 and 17 years, attending emergency

departments (ED) in England. To be acceptable as a screening test in clinical practice we expected the sensitivity and specificity at a selected cut-point would exceed 0.70.

Methods

The study was conducted in accordance with ethical approval from the National Health Service Multi-Centre Research Ethics Committee (ref: 12/L0/0799) and was registered in an appropriate trial registry (ref: ISRCTN 45300218).

Design

An opportunistic cross-sectional survey conducted between December 2012 and May 2013 across 10 ED's in England, encompassing a mix of metropolitan urban and rural centres across the North East, Yorkshire and Humber, London and the South. Consecutive attendees, between the hours of 8 am and midnight were approached by trained researchers after the initial triage assessment.

Researcher assessment was conducted blind to the results of the screening measure and the order of presentation of all measures was randomized using random permuted blocks of random length and embodied within the electronic data collection tool, stratified by age and centre. All assessment instruments used a 3-month assessment time-frame.

Measures

Gold standard measures

To elicit the gold-standard measures of at-risk drinking and monthly heavy episodic alcohol use we used the Time-Line Follow Back –90 days (TLFB90). This is a reliable and valid method to ascertain the frequency and quantity of alcohol consumed in clinical and non-clinical populations for periods ranging from 1 to 365 days.³⁰ The method has established psychometric properties for adolescent populations³¹ and is conducted by a trained researcher and the 90-day version takes ~30 min to complete. The responses to the interview are converted to UK standard drinks and can be used as either continuous or categorical outcomes. At-risk drinking was defined as consuming three or more standard drinks, where a standard drink equates to 8 g of pure ethanol, in a single day in the past 90 days. Monthly heavy episodic alcohol consumption was defined as consuming six or more standard drinks in a single drinking episode in each month over the past 3 months.

MINI-KID has established validity and reliability in the identification of psychiatric diagnoses for children and adolescents.³² The alcohol use module consists of seven detailed

questions that diagnose both alcohol abuse and alcohol dependence in accordance with ICD-10 criteria.

Screening tools

The AUDIT¹⁹ is a 10-item self-completion questionnaire that measures the quantity and frequency of alcohol consumption, drinking behaviour, alcohol-related problems and the symptoms of alcohol dependence. Each item is scored 0–4 and summed to create an overall score with a maximum of 40. The instrument is widely used in adult populations and a cut-off score of 8 or more has high levels of sensitivity (92%) and specificity (94%) for at-risk drinking in adult populations.¹⁹ The AUDIT-C³³ consists of the three consumption items of AUDIT and has been validated as a short-screen in adults, AUDIT-C scores range from 0 to 12, with five or more being indicative of at-risk alcohol use.

Participant recruitment

To be included in the survey, participants had to be aged between their 10th and 18th birthday, alert and orientated and able to communicate in English sufficiently to complete the survey. Participants were excluded if they had a severe injury requiring immediate intervention, were grossly intoxicated, had a serious mental health presentation or if they, or their parent or guardian, refused to provide consent.

Participants were provided with the study information sheet and allowed to ask any questions prior to providing consent. Where a child was aged 16 years or less Gillick competency was assessed³⁴ by a member of the clinical staff in the ED, and where a participant was not found competent consent was sought from the parent or carer. If a parent or carer was present with the child, parent consent was sought in addition to child consent. The survey was conducted in a private area of the ED with a trained researcher who was available to answer any questions and provide appropriate assistance. The survey was anonymous and self-completed using an electronic tablet device with the exception of the time-line follow back interview (TLFB)³⁰ that was conducted by the researcher. At the end of the survey participants were thanked for their time and returned to the care of the ED, were provided with an age-appropriate alcohol awareness leaflet and given a £5 gift voucher for participating.

Statistical methods

We compiled and analysed the results using STATA14. The influence of potential covariates of age and gender, and clustering by ED, were incorporated into the analysis using the ROCREG function. We constructed receiver operator characteristic curves on the basis of all continuous values of the

test results for AUDIT and AUDIT-C compared with each of the gold-standards; at-risk drinking, monthly heavy episodic alcohol use, alcohol abuse and alcohol dependence. We estimated the sensitivity and specificity of each cut-off point and generated the diagnostic odds ratio and associated 95% confidence interval. The diagnostic odds ratio was used to estimate optimal cut-points and is a measure of effectiveness of a dichotomous classification that is the ratio of the odds of being positive if truly positive relative to the odds of being positive if truly negative. It has advantages over other methods of diagnostic test effectiveness in that it is less susceptible to statistical artefacts, a criticism of the Youden Index, and does not rely on the sample prevalence, making it more useful for comparison across different study samples.³⁵

Results

Overall 5781 participants were asked to participate in the survey of whom 5377 (93%) consented to participate across the 10 ED's. The mean age was 13.3 (SD 2.1) years with

similar proportions of male (53.7%) and female (46.3%) participants and the majority White (72.6%). Overall 2112 (39.3%) had consumed alcohol at some time in the past and 1378 (25.6%) had consumed alcohol in the past 3 months. Those who had consumed alcohol tended to be older (14.8 versus 12.3 years) and were more likely to be white (83.4 versus 65.6%) (Table 1).

Using the sample to estimate the prevalence of drinking behaviours in adolescents attending ED, the prevalence of at-risk drinking was 14.8% (95% CI: 13.9–15.8%). The prevalence of monthly heavy episodic alcohol use was 10.6% (9.8–11.4%), alcohol abuse 2.4% (2.0–2.8%) and alcohol dependence 1.2% (0.9–1.5%). In the sample of those who had consumed alcohol in the past 3 months the prevalence of these behaviours was significantly higher (Table 2).

A significant positive correlation was identified for AUDIT score with the total number of standard drinks consumed in the past 3 months (Spearman rho, $r = 0.72$, 95% CI: 0.71–0.73; $P < 0.001$) and a similar correlation identified for AUDIT-C score ($r = 0.69$, 95% CI: 0.68–0.70; $P < 0.001$). Screening properties of the questionnaire were tested

Table 1 Demographic variables in 5377 adolescent attendees overall and by drinking status

Variable	All attendees (n = 5377)	Drinkers (n = 2112)	Non-drinkers (n = 3265)
Mean age (SD)	13.28 (2.07)	14.77 (1.64)	12.33 (1.74)
Age 10, n (%)	570 (10.6)	24 (1.1)	543 (16.8)
Age 11, n (%)	701 (13.0)	50 (2.4)	647 (20.0)
Age 12, n (%)	809 (15.0)	133 (6.3)	668 (20.6)
Age 13, n (%)	845 (15.7)	248 (11.7)	595 (18.4)
Age 14, n (%)	751 (14.0)	387 (18.3)	363 (11.2)
Age 15, n (%)	784 (14.6)	502 (23.8)	276 (8.5)
Age 16, n (%)	534 (9.9)	428 (20.3)	105 (3.2)
Age 17, n (%)	382 (7.1)	340 (16.1)	40 (1.2)
Male, n (%)	2886 (53.7)	1093 (51.8)	1793 (54.9)
Ethnicity, n (%)			
White	3726 (72.6)	1687 (83.4)	2039 (65.6)
Black	698 (13.6)	150 (7.4)	548 (17.6)
Chinese	4 (0.1)	1	3 (0.1)
Mixed	289 (5.6)	97 (4.8)	192 (6.2)
Asian	255 (5.0)	35 (1.7)	220 (7.1)
Other	144 (2.8)	45 (2.2)	99 (3.2)
Mode of arrival, n (%)			
Own means	3953 (74.0)	1667 (79.1)	2286 (70.6)
Ambulance	331 (6.2)	143 (6.8)	188 (5.8)
Police	2 (0.05)	2 (0.1)	0
Other	1059 (19.8)	295 (14.0)	764 (23.6)
Smoker, n (%)	481 (9.0)	455 (21.6)	26 (0.8)
Consumed alcohol in the past 3 months, n (%)	1378 (25.6)	1378 (64.9)	0

Table 2 Alcohol-related variables for all participants and those who consumed alcohol in the past 3 months

Variable	All participants (n = 5377)	Those who consumed alcohol in past 3 months (n = 1378)
Consumed alcohol in past 24 h, n (%)	115 (2.1)	115 (8.5)
Mean age in years (SD)	13.28 (2.07)	15.12 (1.51)
Mean age of first drink in years (SD)	12.74 (2.24)	12.90 (2.17)
Total alcohol consumed in past 3 months in standard units ^a (SD)	7.19 (39.47)	33.09 (79.28)
Hazardous alcohol consumption in past 3 months ^b , n (%)	796 (14.8)	796 (67.9)
Heavy episodic alcohol consumption in past 3 months ^c , n (%)	572 (10.6)	572 (48.8)
Alcohol abuse ^d , n (%)	127 (2.4)	127 (9.2)
Alcohol dependent ^d , n (%)	67 (1.2)	67 (5.0)
Mean AUDIT score (SD) (values can range from 0 to 40 with higher scores indicative of greater problems)	1.18 (1.78)	4.83 (5.03)
Mean AUDIT-C score (SD) (values can range from 0 to 12 with higher scores indicative of greater problems)	0.75 (3.23)	2.98 (2.46)

^aStandard unit equivalent to 8 g of ethanol.

^bHazardous consumption defined as drinking three or more standard units in a single day.

^cHeavy episodic consumption defined as drinking six or more standard units in a single drinking episode.

^dUsing ICD-10 criteria using MIN-KID.

against the gold standard criteria for at-risk drinking, heavy episodic alcohol consumption, alcohol abuse and alcohol dependence. Screening results for all cut-points were assessed and the results of those around the optimal cut-point are reported in Table 3.

The optimum cut-off point for AUDIT in identifying either at-risk drinking, monthly heavy episodic drinking or alcohol abuse was 4 or more, which provided the optimal cut-point to provide acceptable sensitivity, specificity and diagnostic odds. An AUDIT-C score of 3 or more demonstrated almost identical diagnostic properties but with a significantly better sensitivity for at-risk drinking.

An AUDIT score of 7 or more provided a significantly more effective cut-point for alcohol dependence than any other cut-point and demonstrated significantly better diagnostic properties than an AUDIT-C score of 5 or more.

We assessed the potential influence of age, gender and ED on our findings and found these effects to minimal and not statistically significant from our main findings. The results without incorporation of these variables is therefore reported.

Discussion

Main findings of this study

A simple short three item self-completed screening instrument, the AUDIT-C, is overall more effective than the longer 10-item AUDIT in identifying adolescents who engage in

at-risk of alcohol consumption, monthly heavy episodic alcohol use and fulfil ICD-10 criteria for alcohol abuse. Further the AUDIT with a cut-off score of 7 is more efficient than AUDIT-C in identifying adolescents with alcohol dependence. In addition, AUDIT-C and AUDIT are widely employed as screening tools for adults in clinical and non-clinical settings and these can be applied equally to adolescent populations with these lower cut-off scores. We conclude that AUDIT-C should be employed with this population with a cut-off score of 3 as a positive screen for at-risk drinking, monthly heavy episodic alcohol use and alcohol abuse. For those who score 5 or more on AUDIT-C we recommend the use of the additional 7 questions constituting the full AUDIT be administered. With those scoring 7 or more being clinically assessed for alcohol dependence.

What is already known on this topic

There is a body of evidence suggesting that interventions for alcohol using adolescents are effective and that they are more effective when targeted as secondary prevention strategies, i.e. at those already engaged in consuming alcohol.^{12,13} A critical first step in the delivery of interventions is employing opportunistic screening tools and the combination of effective screening tools and intervention strategies offers significant potential to reduce the burden of alcohol use on adolescents, health systems and wider society and further consideration should be given to the routine opportunistic

Table 3 Area under the receiver operator curve (AUC), sensitivity, specificity and diagnostic odd ratio of AUDIT and AUDIT-C cut-points for hazardous drinking, monthly episodic alcohol use, alcohol abuse and alcohol dependence for 5377 adolescent attendees at ED

<i>Outcome</i>	<i>Prevalence % (95% CI)</i>	<i>AUC (95% CI)</i>	<i>Sensitivity % (95% CI)</i>	<i>Specificity % (95% CI)</i>	<i>Diagnostic odd ratio (95% CI)</i>
At-risk/hazardous drinking	15 (14; 16)				
AUDIT					
≥3		0.81 (0.79; 0.94)	78 (75; 82)	94 (94; 95)	55 (47; 87)
≥4		0.81 (0.79; 0.94)	75 (72; 78)	98 (98; 99)	147 (126; 351)
≥5		0.84 (0.82; 0.87)	65 (61; 69)	98 (98; 99)	91 (77; 220)
AUDIT-C					
≥2		0.84 (0.82; 0.87)	91 (88; 93)	89 (87; 91)	81 (49; 134)
≥3		0.98 (0.97; 0.99)	89 (86; 91)	97 (96; 97)	261 (147; 242)
≥4		0.98 (0.97; 0.98)	72 (68; 77)	97 (96; 97)	83 (51; 108)
Monthly episodic use	10 (10; 11)				
AUDIT					
≥3		0.92 (0.90; 0.95)	80 (77; 82)	92 (89; 95)	46 (27; 86)
≥4		0.87 (0.84; 0.91)	78 (74; 81)	97 (97; 98)	114 (92; 109)
≥5			58 (54; 63)	98 (94; 99)	67 (18; 168)
AUDIT-C					
≥2			82 (79; 85)	89 (87; 90)	37 (25; 51)
≥3			76 (73; 80)	98 (97; 98)	155 (87; 196)
≥4			61 (57; 66)	99 (96; 99)	77 (32; 192)
Alcohol abuse	2 (2; 3)				
AUDIT					
≥3			94 (88; 97)	85 (82; 88)	88 (33; 237)
≥4			93 (87; 96)	88 (87; 89)	97 (44; 194)
≥5			83 (75; 88)	92 (91; 93)	56 (30; 97)
AUDIT-C					
≥2			91 (85; 95)	85 (84; 86)	57 (30; 116)
≥3			91 (85; 95)	90 (88; 91)	91 (42; 192)
≥4			65 (56; 73)	93 (92; 93)	25 (15; 36)
Alcohol dependent	1 (1; 2)				
AUDIT					
≥6			96 (89; 99)	92 (90; 94)	276 (73; 1551)
≥7			96 (89; 99)	94 (95; 95)	376 (154; 1881)
≥8			91 (81; 96)	95 (95; 96)	192 (81; 576)
AUDIT-C					
≥4			85 (79; 88)	92 (91; 93)	65 (43; 97)
≥5			80 (67; 89)	95 (95; 95)	76 (39; 154)
≥6			67 (55; 77)	97 (96; 97)	65 (39; 108)

implementation of screening strategies for adolescent populations.

What this study adds

Routine alcohol screening of adolescents should be considered across the UK National Health Service. This study

demonstrates that the process can be simplified by using short screening tools already in use for adult populations. This requires appropriate training, resources and incentives for staff. Identifying those adolescents that may benefit from interventions to address alcohol use and associated multiple risk behaviours will help to reduce the burden of alcohol use

across the health service and society. This has the potential to enhance the future health of the adolescent population well into adulthood.

Limitations of this study

Our study was conducted in ED and this could be seen as compromising the generalizability of the findings to other health settings. Yet adolescents are far less frequent attenders at primary care and the ED provides an opportunity to access this population and in turn provides the 'teachable moment', that is hypothesized to play a crucial role in effective behaviour change.³⁶ Further, we aimed to ensure generalizability of our sample to other EDs in the UK by including centres covering rural and urban areas and areas with the lowest and highest population prevalence of adolescent alcohol use and areas of high and low socio-economic status. In addition, our estimates of alcohol use problems compare well with national epidemiological surveys, that suggest 27% of adolescents consume alcohol versus 26% in our study, 9% have been drunk three or more times in the past 4 weeks compared with 11% of episodic drinkers in the past 3 months in our study.³⁷ We also recognize that those who scored negative on the screening tool and outcome assessments may have misreported their alcohol consumption and we took a variety of steps to ameliorate this by ensuring anonymity and confidentiality. Previous evidence would suggest this form of social desirability bias is limited.³⁸ This study was the first study of the screening instruments in a real-life health setting in the UK, one where the burden of alcohol use is a real concern.

Conflicts of interest

The authors have no conflict of interest to declare.

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Authors contributions

SC, PD, KD, e.g. EK, IM, PM, RM, DNB, RP, TP, IR, JS and CD contributed to the design of the programme of research. FA, SB, EL, CP, HR contribute to the ongoing data collection analysis and interpretation of the research. SC conducted the analysis reported in the article and wrote the initial draft. All authors have read and commented on subsequent drafts of the article.

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JOURNAL OF MEDICAL INTERNET RESEARCH

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Review

The Effectiveness of Electronic Screening and Brief Intervention for Reducing Levels of Alcohol Consumption: A Systematic Review and Meta-Analysis

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Abstract

Background: Electronic screening and brief intervention (eSBI) has been shown to reduce alcohol consumption, but its effectiveness over time has not been subject to meta-analysis.

Objective: The current study aims to conduct a systematic review and meta-analysis of the available literature to determine the effectiveness of eSBI over time in nontreatment-seeking hazardous/harmful drinkers.

Methods: A systematic review and meta-analysis of relevant studies identified through searching the electronic databases PsychINFO, Medline, and EMBASE in May 2013. Two members of the study team independently screened studies for inclusion criteria and extracted data. Studies reporting data that could be transformed into grams of ethanol per week were included in the meta-analysis. The mean difference in grams of ethanol per week between eSBI and control groups was weighted using the random-effects method based on the inverse-variance approach to control for differences in sample size between studies.

Results: There was a statistically significant mean difference in grams of ethanol consumed per week between those receiving an eSBI versus controls at up to 3 months (mean difference -32.74 , 95% CI -56.80 to -8.68 , $z=2.67$, $P=.01$), 3 to less than 6 months (mean difference -17.33 , 95% CI -31.82 to -2.84 , $z=2.34$, $P=.02$), and from 6 months to less than 12 months follow-up (mean difference -14.91 , 95% CI -25.56 to -4.26 , $z=2.74$, $P=.01$). No statistically significant difference was found at a follow-up period of 12 months or greater (mean difference -7.46 , 95% CI -25.34 to 10.43 , $z=0.82$, $P=.41$).

Conclusions: A significant reduction in weekly alcohol consumption between intervention and control conditions was demonstrated between 3 months and less than 12 months follow-up indicating eSBI is an effective intervention.

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KEYWORDS

alcohol drinking; intervention studies; Internet; computers; meta-analysis

Introduction

The hazardous and harmful use of alcohol is a global problem, contributing 4.6% of the total global burden of disease, with the highest rates reported in the European and American regions (17.3% and 14.2%, respectively) [1]. It is well documented that

those with problem alcohol use seldom seek help [2]; this may be due to problems accessing treatment, or an unwillingness to do so, or failure of clinicians to identify their problem [3]. There is a large body of research to support the effectiveness of opportunistic screening and brief intervention (SBI) in reducing alcohol consumption and other alcohol-related outcomes in a

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number of health care settings, including primary care [4,5] and the emergency department [6,7]. A brief intervention typically comprises a single face-to-face session, ranging from 5-30 minutes in duration, and up to a maximum of 4 sessions aimed at providing information and advice that is designed to achieve a reduction in hazardous/harmful alcohol consumption [4]. Despite the effectiveness of SBI, there are a number of barriers to its widespread implementation in health care settings. Health care staff report that they lack the time and resources to carry out training and delivery of SBI in routine practice and that they lack the skills and knowledge necessary to do so [8,9].

The widespread use of computers, the Internet, and smartphones has led to the development of electronic systems to deliver SBI that can potentially address some of the barriers to implementation of traditional face-to-face SBI. Electronic SBI (eSBI) has the potential to offer greater flexibility and anonymity for the individual and reach a larger proportion of the in-need population. For both adults and adolescents, eSBI (computer-, Web-, and phone-based) can offer effective delivery of interventions in both educational and health care settings that may prove to be more acceptable than more traditional (face-to-face) approaches [10-12]. Also, eSBI can offer a more cost-effective alternative to face-to-face interventions. Previous studies have shown that 1 in 8 individuals respond to SBI; therefore, large numbers of people need to be screened to obtain a time-limited effect in reduction in alcohol consumption [4,5]. With the advent of mobile and e-technologies potentially increasing the population coverage of SBI, the potential cost of delivery can be reduced because the main cost is incurred during development of the intervention with limited additional costs associated with its delivery [13]. Evidence from recent systematic reviews has found eSBIs to be effective in reducing alcohol consumption [14,15]. However, these reviews did not address the effect of length of follow-up on alcohol outcomes.

Cunningham and colleagues [16,17] conducted a randomized controlled trial of the effectiveness of an Internet-based intervention for alcohol misuse. They found that at 3- and 6-month follow-ups, those who had received the intervention had a greater reduction in alcohol consumption compared to controls. However, at 12-month follow-up the beneficial effects of the intervention were no longer apparent.

The current study aims to conduct a systematic review and meta-analysis of the available literature to determine the effectiveness of eSBI over time in nontreatment-seeking hazardous/harmful drinkers.

Methods

Search Strategy

A systematic search of the literature was conducted to identify randomized controlled trials investigating the effectiveness of eSBI to reduce alcohol consumption. Relevant studies were identified through searching the electronic databases PsychINFO, Medline, and EMBASE in May 2013. The search strategy was adapted from the search terms used for the National Institute for Health and Care Excellence (NICE) guideline systematic review for the effectiveness of acamprosate/naltrexone [18], and the search terms used for the Cochrane systematic review for the effectiveness of SBI for alcohol misuse [4], combined with additional search terms specific to electronic interventions to ensure a comprehensive search of the available published literature. The search terms used for this review are listed in Table 1. No date or language restrictions were applied. In addition, the reference lists of relevant review articles and key papers were hand searched. Unpublished literature was considered to be beyond the scope of this review.

Table 1. Electronic database search terms.

Search term topic	Search terms
Terms for alcohol use	<ol style="list-style-type: none"> 1. alcohol-related disorder.mp. 2. alcohol drinking.mp. 3. (alcohol and (use\$ or abuse or misuse or dependen\$ or drink\$ or intoxication\$ or disorder\$ or consumption)).mp. 4. exp Alcoholism/ or (alcoholi\$).mp. 5. ((hazard\$ or binge or heavy or harmful or risk\$) and drink\$).mp. 6. 1 or 2 or 3 or 4 or 5 7. limit 6 to abstracts 8. (drinker\$1 or (drink\$ adj2 use\$1) or ((alcohol\$ or drink\$) adj5 (binge\$ or disorder\$ or harm\$ or hazard\$ or heavy or high risk or intoxicat\$ or misus\$ or problem\$))). ti.ab. 9. 7 or 8
Terms for e-formats	<ol style="list-style-type: none"> 10. exp Text Messaging/ or ((text-messag\$) or (SMS) or (short message service) or (text adj messag\$)).mp. 11. ((phone adj application\$) or (phone adj app)).ti.ab,kw. 12. ((social-network) or (social network) or (social-media) or (social-media)).ti.ab,kw. 13. skype.ti.ab,kw. 14. exp telemedicine/ 15. facebook.ti.ab,kw. 16. ((personal adj digital adj assistant) or pda).ti.ab,kw. 17. (surf\$ near4 internet\$).ti.ab,kw. 18. (surf\$ near4 web\$).ti.ab,kw. 19. (virtual adj reality).ti.ab,kw. 20. Second life.ti.ab,kw. 21. User-computer interface/ 22. (consumer adj health adj informatics\$).ti.ab,kw. 23. ((e adj health) or e-health or (electronic adj health)).ti.ab,kw. 24. (interactive adj ((health adj communicat\$) or televise\$ or video\$ or technolog\$ or multimedia)).ti.ab,kw. 25. ((bulletin adj board\$) or bulletinboard\$ or messageboard\$ or (message adj board\$)).ti.ab,kw. 26. (blog\$ or web-log\$ or weblog\$).ti.ab,kw. 27. ((chat adj room\$) or chatroom\$).ti.ab,kw. 28. (online or on-line).ti.ab,kw. 29. exp internet/ or ((internet adj based) or internet-based).ti.ab,kw. 30. ((web adj based) or web-based).ti.ab,kw. 31. ((world adj wide adj web) or (world-wide-web) or WWW or (world-wide adj web) or (worldwide adj web) or website\$).ti.ab,kw. 32. ((electronic adj mail) or email\$ or email\$).ti.ab,kw. 33. (((mobile or cellular or cell or smart) adj (phone\$ or telephone\$)) or smartphone).ti.ab,kw. 34. ((CD adj ROM) or cd-rom or cdrom or (compact adj dis\$)).ti.ab,kw. 35. (decision adj (tree\$ or aid\$)).ti.ab,kw. 36. (Internet or (local adj area adj network)).ti.ab,kw. 37. (computer\$ or microcomputer\$ or laptop).ti.ab,kw. 38. exp Software-/ 39. exp Computer-Graphics/

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Search term topic	Search terms
Brief interventions	40. exp Public-Health-Informatics/ 41. exp Audiovisual-Aids/ 42. exp Decision-Support-Techniques/ 43. exp Medical Informatics/ 44. exp Computer-Systems/ 45. (or/10-44)
	46. alcohol reduction.mp. 47. brief intervention.mp. 48. early intervention.mp. 49. minimal intervention.mp. 50. alcohol therapy.mp. 51. Harm Reduction/ 52. screening.mp. 53. (counseling or counselling).mp. 54. controlled drinking.mp. 55. (brief counseling or brief counselling).mp. 56. physician based intervention.mp. 57. general practitioner intervention.mp. 58. Secondary Prevention/ 59. general practitioner's advice.mp. 60. brief physician-delivered counseling.mp. 61. brief nurse-delivered counseling.mp. 62. identification.mp. 63. intervention.mp. 64. or/46-63
Terms for randomized controlled trial	65. exp clinical trial/ or (crossover procedure or double blind procedure or placebo\$ or randomization or random sample or single blind procedure).sh. 66. exp clinical trial/ or cross-over studies/ or double-blind method/ or random allocation/ or randomized controlled trials as topic/ or single-blind method/ 67. exp clinical trial/ or (placebo or random sampling).sh. 68. (clinical adj2 trial\$).tw. 69. (crossover or cross over).tw. 70. (((single\$ or doubl\$ or trebl\$ or tripl\$) adj5 blind\$) or mask\$ or dummy or singleblind\$ or doubleblind\$ or treble-blind\$ or tripleblind\$).tw. 71. (placebo\$ or random\$).mp. 72. (clinical trial\$ or controlled clinical trial\$ or random\$).pt. or treatment outcome\$.mp. 73. animals/ not human\$.mp. 74. animal\$/ not human\$/ 75. (or/65-72) not (or/73-74) 76. and/9,45,64,75

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Selection Criteria

The inclusion criteria for this review were as follows:

1. Randomized controlled, parallel group trial comparing eSBI with a control condition (ie, care as usual, assessment only, nonintervention);
2. Participants were identified, through screening, as consuming alcohol to a hazardous level;
3. Measured alcohol reduction by independent reports of drinking quantity (eg, average consumption of alcohol per specified time period), including self-reports or reports from others of drinking frequency (eg, number of drinking occasions per specified time period), drinking intensity (eg, number of drinks per drinking day), or drinking within recommended limits (eg, official recommendations per specified time period), or levels of laboratory markers of reduced alcohol consumption, such as serum gamma-glutamyltransferase (GGT) or mean corpuscular volume (MCV); and
4. Trial arms had at least 10 participants.

We defined eSBI as an electronic intervention aimed at providing information and advice designed to achieve a reduction in hazardous/harmful alcohol consumption with no substantial face-to-face therapeutic component. SBI was defined as a brief intervention comprised of a single session, ranging from 5–45 minutes in duration, and up to a maximum of 4 sessions aimed at providing information and advice designed to achieve a reduction in hazardous/harmful alcohol consumption. Studies were not deemed eligible for inclusion if participants were alcohol dependent, mandated to complete eSBI, or a preselected specific group such as pregnant women. There were no restrictions on age.

Identification of Included Studies

After each search, references were downloaded to the electronic bibliographic management software EndNote and duplicates were removed. Relevant titles were first identified and then abstracts were screened against inclusion criteria. If insufficient information was available in the abstract, the full text was retrieved. Eligibility was confirmed by at least one other member of the review group. The methodological quality of each study was assessed using the Scottish Intercollegiate Guidelines Network (SIGN) validated checklist [19]. Each question in the checklist covers an aspect of research methodology and was rated as present, absent or “can’t say” if inadequate information was available in the research article. An overall rating of quality was assigned to each article based on the checklist criteria:

1. High quality: Majority of criteria met with little risk of bias and conclusions unlikely to change by further research.
2. Adequate: Most of the criteria met with some risk of bias and conclusions may change in light of further research.
3. Low quality: Most criteria not met or significant flaws relating to key aspects of the study design and conclusions likely to change in light of future research.

Data Extraction

A Microsoft Word-based form was used to extract data from eligible research papers. Data extraction was conducted

independently by 2 members of the research team and consensus agreement reached by discussion between the 2 members if discrepancies arose. An intention-to-treat analysis was used wherever possible. If the study was a 3-arm trial, the control group sample size was divided by 2; if it was a 4-arm trial, it was divided by 3 to avoid double counting.

Data Analysis

For the continuous variable (grams ethanol consumed per week) the mean difference was weighted using the random-effects method based on the inverse-variance approach to control for differences in sample size between studies. Alcohol consumption data are often not normally distributed. Because of this, some studies reported the sample median and range/interquartile range (IQR) and not the mean and standard deviation (SD). If appropriate data were not available in the published research papers, to calculate an effect size (ie, the mean, SD, and sample size), authors were contacted to request the required data. If the authors were unable to provide this data, the mean and SD were imputed from the median and range using the method proposed by Hozo et al [20]. If only the median and the IQR were available, the median was taken as an estimate of the mean and the IQR was divided by 1.35 (the distance in SDs from the mean). If appropriate data to estimate an effect size could not be obtained or imputed, the trial was not included in the meta-analysis. Some of the studies included in the meta-analysis had more than one trial arm. The number of participants in the control arm was divided by 2 for a 3-arm trial and by 3 for a 4-arm trial to avoid double counting and undue weighting.

Alcohol consumption, reported as the number of standard drinks per week, was converted into grams of ethanol per week using the definition for a standard drink reported in the research article. If this was not reported, the established standard for the country in which the research took place was used [21]. If alcohol consumption was reported per month versus per week, it was adjusted by multiplying by 52/12, or multiplied by 7 if reported as grams per day [4].

To check for the consistency of effects across studies, Cochran Q was calculated to determine the presence of heterogeneity and the magnitude was measured using I^2 . The I^2 statistic was interpreted in the following way based on Higgins et al [22]: Research studies that produce statistically significant results may be more likely to be published than those with nonstatistically significant results, resulting in a “file-drawer” effect. Similarly, those studies that produce results in an opposite direction to that hypothesized and have a small sample size may be less likely to be published. This is referred to as publication bias and it was assessed using funnel plots and Egger’s weighted regression method. A significant Egger’s test indicates the possibility of the presence of publication bias.

The length of follow-up period can vary between individual studies and there may be more than one point of follow-up per study. Therefore, subgroup analysis was performed for up to 3 months, between 3 and less than 6 months, between 6 and less than 12 months, and 12 months or greater follow-up length postintervention.

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Results

Study Characteristics

A total of 23 studies were deemed eligible for inclusion in this systematic review [16,17,23-44] (Figure 1); Tables 2 and 3 present the study characteristics. Sufficient data was available to allow analysis of just one variable: grams per week of ethanol consumed. If sufficient data to calculate means and SDs for this outcome were not reported in the published article, authors were contacted. Data were provided by the authors for 3 studies [17,39,41]. Data on alcohol consumption that could be transformed into grams per week of ethanol were not collected in 2 studies [25,27] and insufficient data to calculate the weighted mean difference (WMD) in grams of ethanol per week were reported in 4 studies [23,28,29,42]. Therefore, a total of 17 studies were included in the meta-analysis (1 study was

published in 2 papers [16,17]. Most of these studies were conducted with student populations (13/17, 76%) and in the United States (10/17, 59%). All study interventions were either computer- or Web-based. The content of the interventions included an assessment followed by personalized and/or normative feedback. Control conditions generally consisted of an assessment with no further feedback, but 4 studies included general information on alcohol consumption for those in the control conditions [25,28,33,35]. There was some variation in the dose of the intervention with the reported time taken to complete the intervention ranging from less than 5 minutes [34] to 45 minutes [37]. The dose of exposure to the intervention could also be increased through repeated access during the study period [24] and/or a printed copy of the personalized feedback provided [26,31,36,38,40,43]. The attrition rate was highly variable between studies, ranging from 1% or 2% (eg, Hester et al [30]) up to more than 50% [42]

Table 2. Size and nature of study population and method of recruitment.

Study ID ^a	Male, n (%)	Mean age (SD)	Population	Recruitment
Araki et al, 2006 [23]	24 (100)		Japan, employees of a manufacturing plant with available annual health check-up data	Not reported
eSBI (n=12)		44.3 (7.2)		
Control (n=12)		43.8 (7.3)		
Blankers et al, 2011 [24]			Netherlands, adult general population	Visitors to the Collaborating Substance Abuse Treatment (SATC) website
eSBI (n=68)	40 (58.8)	41.1 (9.6)		
Control (n=69)	35 (50.7)	43.7 (9.3)		
Boon et al, 2011 [25]	450 (100)		Netherlands, adults in the general population	Nationally representative online household survey
eSBI (n=230)		40.6 (15.2)		
Control (n=220)		40.3 (15.1)		
Butler et al, 2009 [26]			United States, undergraduate university students	Not reported
eSBI (n=30)	11 (36.7)	20.6 (1.48)		
Control (n=26)	9 (34.6)	20.4 (1.49)		
Cunningham et al, 2009 [16]; Cunningham et al, 2010 [17]			Canada, adults in the general population	Randomly selected from an on-going general population telephone survey
eSBI (n=92)	53 (57.6)	39.5 (13.5)		
Control (n=93)	45 (48.4)	40.8 (13.4)		
Cunningham et al, 2012 [27]	118 (52.5)	22.6 (12.2)	Canada, university students	Randomly selected using student email addresses
eSBI (n=211)				
Control (n=214)				
Ekman et al, 2011 [28]			Sweden, third-year university students	Email invitation to all third-year students
eSBI (n=330)	152 (46.1)	N (%): 18-20=43 (13), 21-25=264 (80), ≥26=23 (7)		
Control (n=324)	120 (37.0)	N (%): 18-20=49 (15), 21-25=233 (72), ≥26=29 (9)		
Hansen et al, 2012 [29]			Denmark, adults in the general population	Identified through the Danish Health Examination Survey, those identified as heavy drinkers were sent an email invitation to take part
eSBI PFI (n=476)	271 (56.9)	median=61		
eSBI PBA (n=450)	246 (54.7)	median=59		
Control (n=454)	244 (53.7)	median=60		
Hester et al, 2012 [30]			United States, university students	Identified through advertisements in the college newspaper and around the campus
Exp 1: eSBI (n=65)	41 (63.1)	20.5 (1.80)		
Exp 1: Control (n=79)	49 (62.0)	20.3 (1.63)		
Exp 2: eSBI (n=42)	23 (54.8)	20.0 (1.52)		
Exp 2: Control (n=40)	23 (57.5)	20.3 (2.09)		

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Study ID ^a	Male, n (%)	Mean age (SD)	Population	Recruitment
Hester et al, 2005 [31]	32 (52.5)	Males=46.1 (13.8); females=45.2 (9.4)	United States, adult general population	Identified through advertisements in the media
eSBI (n=35)				
Control (n=26)				
Kypri et al, 2009 [32]			Australia, random sample of undergraduate university students	Students were sent a letter by mail followed by an email containing a Web link to the study questionnaire; up to 4 email reminders were sent
eSBI=1251	687 (54.9)	19.7 (1.8)		
Control=1184	645 (54.5)	19.7 (1.8)		
Kypri et al, 2008 [33]			New Zealand, users of a university student health service	Those leaving the student health service reception desk were consecutively approached and invited to participate
eSBI (n=138)	67 (48.6)	20.1		
Control (n=146)	70 (47.9)	20.1		
Kypri et al, 2013 [34]			New Zealand, Maori university students	Invited by email with up to 3 reminder emails
eSBI (n=939)	35.7	20.2 (1.9)		
Control (n=850)	33.2	20.1 (2.2)		
Kypri et al, 2004 [35]	52 (50.0)		New Zealand, users of a university student health service	Those checking into the reception of the student health service were invited to take part
eSBI (n=51)		19.9 (1.4)		
Control (n=53)		20.5 (1.8)		
Lewis et al, 2007 [36]		18.5 (2.04)	United States, university students enrolled in first-year orientation	All students enrolled for first-year orientation were invited to take part
eSBI specific (n=75)				
eSBI neutral (n=82)				
Control (n=88)				
Murphy et al, 2010 [37]		18.6 (1.2)	United States, university students	Students enrolled in introductory classes were invited to take part
eSBI (n=45)				
Control (n=42)				
Neighbors et al, 2004 [38]	104 (41.3)	18.5 (1.24)	United States, university students from psychology classes	Students attending psychology classes were invited to take part
eSBI (n=126)				
Control (n=126)				
Neighbors et al, 2010 [39]	208 (42.4)		United States, incoming university freshmen students	Incoming university freshmen were invited to complete a Web-based survey sent via email and post
eSBI GSF (n=163)				
eSBI GNSF(n=164)				
Control (n=163)				
Neumann et al, 2006 [40]			Germany, trauma center	Patients attending a trauma center were invited to take part after provision of initial care and resolution of significant pain
eSBI (n=561)	449 (80.0)	median=30		
Control (n=575)	449 (78.1)	median=31		

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Study ID ^a	Male, n (%)	Mean age (SD)	Population	Recruitment
Palfai et al, 2011 [41]		18.6 (1.45)	United States, university students attending an introductory psychology class	Students attending an introductory psychology class were invited to take part
eSBI (n=56)				
Control (n=63)				
Spijkerman et al, 2010 [42]			Netherlands, volunteer members of an open access panel aged 15-20	Registered members of an open access panel were invited to take part via email
eSBI NNF (n=192)	74 (38.5)	18.2 (1.55)		
eSBI NF (n=193)	82 (42.5)	18.1 (1.54)		
Control=190	69 (36.3)	18.1 (1.59)		
Wagener et al, 2012 [43]			United States, university students	Invited to participate via email using an online participant pool management system
eSBI (n=39)	18 (46.2)	20.3 (1.67)		
Control (n=37)	19 (51.4)	20.3 (1.49)		
Walters et al, 2009 [44]		19.8 (SD not reported)	United States, university students	University students invited via email, presentations, and posters at the university
eSBI (n=67)				
Control (n=69)				

^a eSBI: electronic screening and brief intervention; GNSF: gender-nonspecific; GSF: gender-specific; NF: intervention with normative feedback; NNF: intervention without normative feedback; PBA=personalized brief advice intervention; PFI=brief personalized feedback intervention.

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Table 3. Characteristics of screening, experimental, and control interventions, and nature and timing of assessments.

Study ID	Screening cutoff ^a	eSBI details ^a	Control group	Dropouts at follow-up, n (%) ^a
Araki et al, 2006 [23]	Abnormal levels of gamma-glutamyl transpeptidase	Personalized feedback and advice sent via 2 emails 1 month apart; encouraged to ask questions via email	Assessment only	2 mo: (1 participant was not included in the analysis but the group that they were randomized to was not reported)
Blankers et al, 2011 [24]	AUDIT score ≥ 8 and reported drinking average 14 standard drinks per week	Access to an online self-help program based on motivational interviewing and cognitive behavioral therapy principles, suggested daily use for 4 weeks	Assessment only	3 mo: eSBI: 20 (29.4), control: 18 (26.1)
Boon et al, 2011 [25]	Exceeding Dutch guideline for low risk drinkers (>20 alcohol units per week or > 5 alcohol units on a single occasion on at least 1 day/week)	Single, 20-min brief personalized feedback session through website with the opportunity to print the feedback	Assessment and educational leaflet, instructed to read the leaflet for 20 min and could print the material	1 mo: eSBI: 18 (7.8), control: 19 (8.6) 6 mo: eSBI: 22 (9.6), control: 25 (11.4)
Butler et al, 2009 [26]	≥ 2 binge drinking occasions (≥ 5 drinks in 1 sitting for men and 4 or more for women) and 2 alcohol-related problems in the past 28 days Standard drink=14 g ethanol	Single, average 11-min session of computer-delivered personalized feedback and a paper copy to take home	Assessment only	4 w: eSBI: 9 (30.0), control: 4 (15.4)
Cunningham et al, 2009 [16] and Cunningham et al, 2010 [17]	Score ≥ 4 on the AUDIT-C (standard drink=13.6 g ethanol)	Single, 10-min session completing Check Your Drinking online intervention of normative and personalized feedback	Assessment and a list of possible components to include in an intervention	3 mo: eSBI=7 (7.6), control: 3 (3.2) 6 mo: eSBI: 7 (7.6), control: 8 (8.6) 12 mo: eSBI: 11 (12.0), control: 11 (11.8)
Cunningham et al, 2012 [27]	Score ≥ 4 on the AUDIT-C	Access to the Check Your Drinking University version online intervention of normative and personalized feedback; intervention could be accessed repeatedly	Assessment only	6 w: eSBI: 59 (28.0), control: 75 (35.0)
Ekman et al, 2011 [28]	(1) Weekly alcohol consumption >120 g ethanol (women) or 180 g ethanol (men) in a typical week in the past 3 months and/or (2) engaged with heavy episodic drinking defined as consuming ≥ 48 g of ethanol (women) or ≥ 60 g of ethanol (men) on ≥ 2 occasions in the past month	Single session intervention of personalized normative feedback delivered via email	Assessment and brief feedback consisting of 3 statements	3 mo: eSBI: 125 (37.9), control: 113 (34.9) 6 mo: eSBI: 78 (24), control: 80 (24)
Hansen et al, 2012 [29]	Above recommended max drinking limit set by the Danish National Board of Health of 14 drinks/168 g ethanol for women or 21 drinks/252 g for men (standard drink=12 g ethanol)	PFI: fully automated, Internet-based single session of brief personalized and normative feedback; PBA: fully automated, Internet-based single session of brief personalized feedback and advice	Assessment only	6 mo: eSBI PFI: 186 (39.0), eSBI PBA: 171 (38.0), control: 150 (33.0) 12 mo: eSBI PFI: 109 (22.9), eSBI PBA: 108 (24.0), control: 95 (20.9)
Hester et al, 2012 [30]	Met the National Institute for Alcohol and Alcohol Abuse (2004) criteria for heavy episodic drinking of ≥ 4 drinks per occasion (women) or ≥ 5 drinks per occasion (men) at least once in past 2 weeks and an estimated peak blood alcohol concentration of 80 mg% or more (standard drink=14 g ethanol)	Self-guided College Drinkers Check-up, delivered online, single session taking up to 35 min to complete; assessment, normative feedback, and advice	Assessment only	Exp 1 (1 mo): eSBI: 2 (3.1), control: 2.5) Exp 1 (12 mo): eSBI: 6 (9.2), control: 8 (10.1) Exp 2 (1 mo): eSBI: 0 (0.0), control: 1 (2.5)

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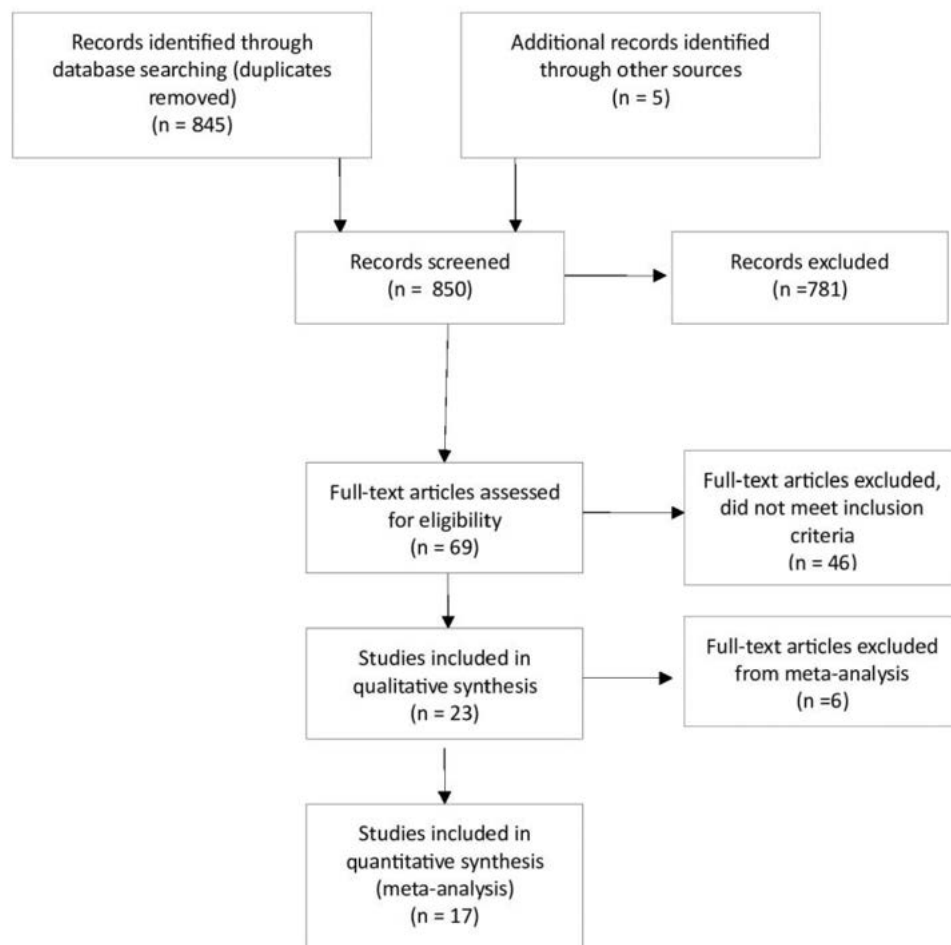
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Study ID	Screening cutoff ^a	eSBI details ^a	Control group	Dropouts at follow-up, n (%) ^a
Hester et al, 2005 [31]	Score ≥ 8 AUDIT (standard drink=14 g ethanol)	Computer-based DCU, assessment, feedback, and decision-making modules; single session can take up to 90 min to complete with the option of printing the feedback	Assessment only	4 w: not reported
Kypri et al, 2009 [32]	Score ≥ 8 on AUDIT and exceeding the Australian National Health and Medical Research Councils guideline for acute risk (defined as 4 standard drinks for women or 6 for men in a single occasion in the last 4 weeks); standard drink=10 g ethanol	Single online session of personalized feedback	Assessment only	1 mo: eSBI: 288 (23.0), control: 237 (20.0) 6 mo: eSBI: 442 (35.3), control: 420 (35.5)
Kypri et al, 2008 [33]	AUDIT score ≥ 8 ; standard drink=10 g ethanol	Single computer-delivered session of personalized and normative feedback taking a median 9.3 min to complete	Assessment and alcohol facts leaflet	6 mo: eSBI: 22 (15.9), control: 22 (15.1) 12 mo: eSBI: 25 (18.1), control: 20 (13.7)
Kypri et al, 2013 [34]	Score ≥ 4 on AUDIT; standard drink=10 g ethanol	Single online session of personalized and normative feedback taking a median 4.3 min to complete	Assessment only	5 mo: eSBI: 207 (22.0), control: 170 (20.0)
Kypri et al, 2004 [35]	Score ≥ 8 on AUDIT and consuming >4 standard drinks for men or >6 for women on ≥ 1 occasion in past 4 weeks (standard drink=10 g ethanol)	Computer-delivered single session of personalized feedback	Assessment and alcohol facts leaflet	6 w: eSBI: 9 (17.6), control: 12 (22.6) 6 mo: eSBI: 4 (7.8), control: 6 (11.3)
Lewis et al, 2007 [36]	≥ 1 heavy episode (≥ 4 standard drinks in 1 sitting for women and ≥ 5 standard drinks in 1 sitting for men) in the previous month; standard drink=14 g ethanol	eSBI specific: gender-specific Web-based personalized normative feedback; eSBI neutral: gender-neutral Web-based personalized normative feedback; feedback was read on screen and participants were given printout to take home	Assessment only	5 mo: eSBI specific: 11 (14.7), eSBI neutral: 15 (18.3), control: 10 (11.4)
Murphy et al, 2010 [37]	≥ 2 heavy drinking episodes in the past month (described as ≥ 4 standard drinks on 1 occasion for women and ≥ 5 standard drinks for men) or ≥ 1 heavy drinking episodes for minority students; standard drink=14 g ethanol	Interactive, Web-based intervention, E-CHUG (Electronic Check-up and Go), assessment and personalized feedback in a single session lasting up to 45 min with a brief comprehension test on completion	Assessment only	1 mo: eSBI: 7 (15.6), control: 3 (7.1)
Neighbors et al, 2004 [38]	≥ 1 heavy drinking episode in the previous month (defined as 4 standard drinks in 1 sitting for women and 5 standard drinks for men); standard drink=14 g ethanol	Single computer-delivered session of personalized normative feedback presented on screen for 1 min plus a printout	Assessment only	3 mo: whole sample: 53 (21.0) 6 mo: whole sample: 45 (17.9)
Neighbors et al, 2010 [39]	≥ 5 drinks for men and ≥ 4 drinks for women on ≥ 1 occasions in the past month; standard drink=14 g ethanol	eSBI GSF: single session delivered online giving personalized gender-specific feedback; eSBI GNSF: single session delivered online giving personalized gender-nonspecific feedback	Assessment and an attention test (facts about the university students were presented in the same format as the intervention)	6 mo: eSBI GSF: 10 (6.1), eSBI GNSF: 16 (9.8), control: 13 (8.0) 24 mo: eSBI GSF: 33 (20.2), eSBI GNSF: 25 (15.2), control: 31 (19.0)
Neumann et al, 2006 [40]	AUDIT score ≥ 5	Single session of computer-generated feedback and a printout to take home	Assessment only	6 mo: eSBI: 213 (37.9), control: 207 (36.0) 12 mo: eSBI: 252 (44.9), control: 224 (39.0)

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Study ID	Screening cutoff ^a	eSBI details ^a	Control group	Dropouts at follow-up, n (%) ^a
Palfai et al, 2011 [41]	Hazardous drinkers who either (1) consumed alcohol in the past month and scored ≥ 8 on AUDIT or (2) reported ≥ 2 heavy drinking episodes (defined as ≥ 5 drinks for men or ≥ 4 drinks for women in the past month; standard drink=14 g ethanol)	Single computer-delivered session of personalized, normative, and gender-specific feedback	Assessment and health guidelines for sleep and consumption of fruit and vegetables	1 mo: whole sample: 0 (0.0)
Spijkerman et al, 2010 [42]	Age 15-16 y: engage in binge drinking at least once a month; age 17-20 y: engaged in binge drinking ≥ 1 /week; binge drinking defined as drinking ≥ 4 alcoholic drinks for women or ≥ 6 for men on 1 occasion; standard drink=10 g ethanol	eSBI NNF: single online session of personalized feedback tailored to age and gender, took ~ 15 min to complete; eSBI NF: single online session of personalized normative gender- and age-specific feedback, took ~ 15 min to complete	Assessment only	1 mo: eSBI NNF: 92 (47.9), eSBI NF: 93 (48.2), control: 68 (35.8) 3 mo: eSBI NNF: 106 (55.2), eSBI NF: 104 (53.9), control: 87 (45.8)
Wagener et al, 2012 [43]	≥ 1 heavy drinking session (≥ 5 drinks on 1 occasion for men or ≥ 4 for women), drinking ≥ 20 drinks/month on average and experiencing negative consequences of that use in the last month (standard drink=14 g ethanol)	Single session using of computer-delivered assessment personalized feedback using an interactive program (DRAFT-CS), took ~ 45 min to complete; participants were given printout of their feedback	Assessment only	10 w: eSBI: 2 (5.1), control: 3 (8.1)
Walters et al, 2009 [44]	Reported ≥ 1 heavy drinking session in the past 2 weeks defined as ≥ 5 standard drinks for men and ≥ 4 standard drinks for women (standard drink=14 g ethanol)	eSBI: single session of personalized feedback delivered through the online Check-Up to Go	Assessment only	3 mo: eSBI: 9 (13.4), control: 6 (8.7) 6 mo: eSBI: 13 (19.4), control: 8 (11.6)

^a eSBI: electronic screening and brief intervention, AUDIT: Alcohol Use Disorders Identification Test, PFI: brief personalized feedback intervention, PBA: personalized brief advice intervention, DCU: Drinkers Check Up, GSF: gender-specific, GNSF: gender-nonspecific, NNF: intervention without normative feedback, NF: intervention with normative feedback, FBO: feedback only, DRAFT-CS: Drinking Assessment and Feedback Tool for College Students.

Figure 1. Flow diagram of study selection and inclusion.

Grams of Ethanol per Week

Nine studies included data for a follow-up period of up to 3 months (mean 1.06 months, SD 0.18), 6 studies with a follow-up period between 3 and less than 6 months (mean 3.86 months, SD 1.07), 8 studies with a follow-up period between 6 and less than 12 months (all included studies had a follow-up period of 6 months), and 5 studies included data for a follow-up period greater than 12 months (mean 16 months, SD 6.20) (Figure 2). There was a statistically significant difference in pooled mean difference in grams of ethanol per week consumed between those who received the eSBI and controls for follow-up period subgroups up to 3 months, between 3 and less than 6 months, and between 6 and less than 12 months (Table 4). This difference

represents a significantly lower mean number of grams of ethanol consumed per week at follow-up by those in the eSBI group compared to controls. There was no statistically significant difference between groups in pooled mean difference in grams of ethanol per week for long-term follow-up. The greatest difference was found at less than 3 months follow-up, which decreased with length of follow-up (Figure 3).

There was statistically significant and moderate heterogeneity between studies included at less than 3 months follow-up. Heterogeneity was not statistically significant for any of the other follow-up groups. Egger's test was not statistically significant for all follow-up periods, indicating an absence of publication bias.

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Table 4. Results of meta-analysis including significance test and heterogeneity statistics.

Follow-up period	Sample size, n		Mean difference significance test		Heterogeneity statistic			
	Experimental	Control	z	P	Q	df	P	I ²
<3 months	1305	1307	2.67	.01	17.19	8	.03	53.5%
3-6 months	1211	811	2.34	.02	8.62	6	.20	30.4%
6-12 months	1921	1751	2.74	.01	10.91	8	.21	26.7%
≥12 months	899	816	0.82	.41	8.49	5	.13	41.1%

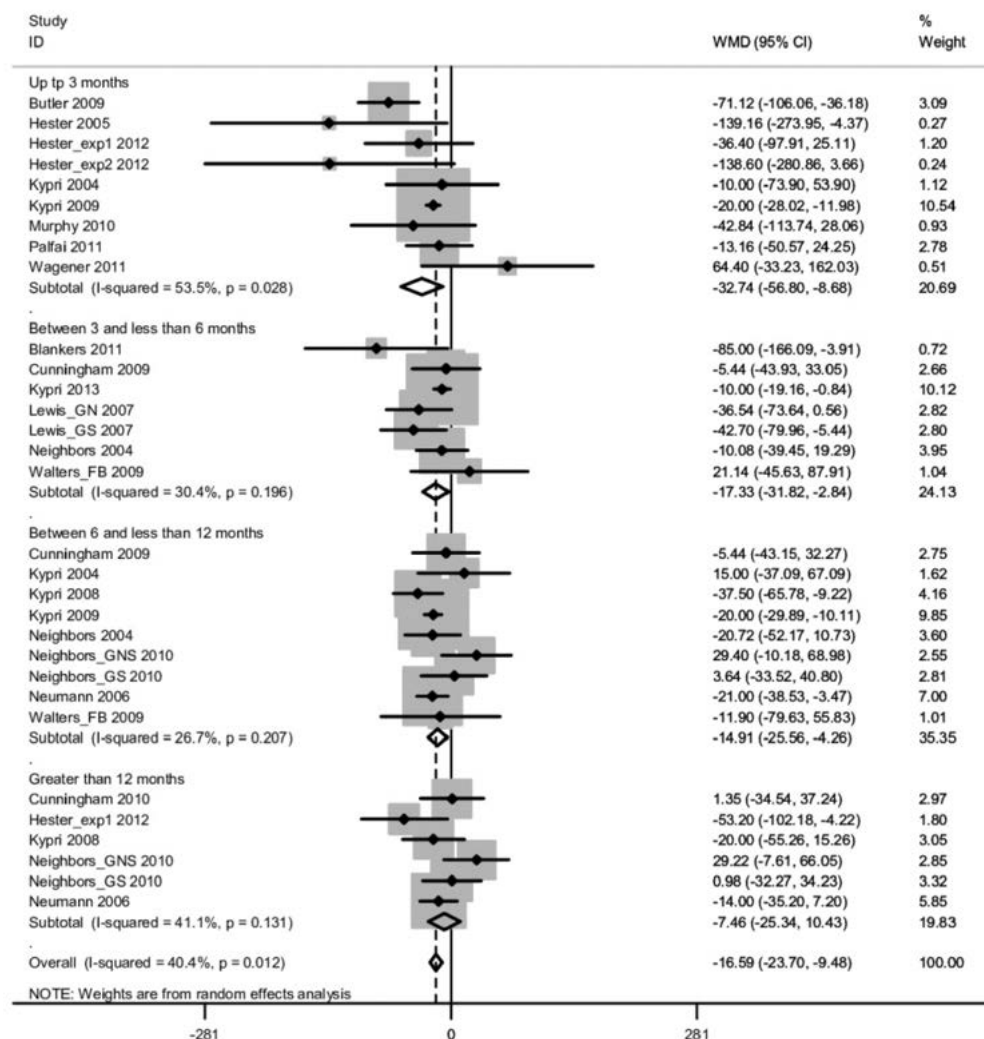
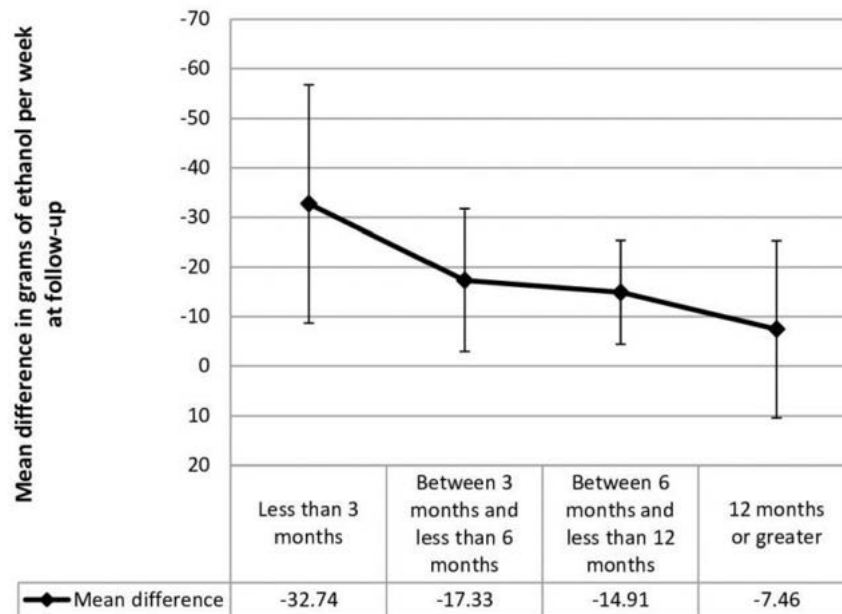
Figure 2. Forest plot for weighted mean difference (WMD) in grams of ethanol per week at follow-up between those in the eSBI group and controls.

Figure 3. Mean difference in grams of ethanol per week at follow-up postintervention with 95% confidence intervals.

Sensitivity Analysis

Participants in the intervention arm of the study conducted by Blankers et al [34] had access to the online self-help intervention at any time, but it was suggested that they access it daily during a 4-week period. This methodology is different from other studies included in this review in that the other studies allowed participants access to the electronic intervention for a single session. Therefore, sensitivity analysis was conducted to assess the impact of this study on the overall mean difference in consumption of alcohol between 3 and less than 6 months. Removal of the Blankers et al [34] study from the meta-analysis had little effect on the mean difference in grams of alcohol consumed per week for those in the intervention groups compared to controls (mean difference -13.40, 95% CI -23.94 to 2.85).

The length of the intervention in the study conducted by Hester et al [31] was on average 90 minutes; this is longer than the definition of brief intervention for eligibility of inclusion in this systematic review and meta-analysis. However, because the intervention was completed in 1 session it was decided that a sensitivity analysis would be conducted to explore the impact of this study on the pooled mean difference in alcohol consumption at up to 3 months. Removal of the study conducted by Hester et al [31] had minimal impact on the pooled mean difference in grams of alcohol consumed per week for those in the intervention group compared to controls (mean difference -29.53, 95% CI -52.50 to 6.56).

Risk of Bias

The quality of the evidence reviewed was considered to be acceptable with most studies included in this review assessed as being adequate in terms of their methodological quality.

Three studies were considered to be of high methodological quality [24,32,34]. The addition of future research may have an impact on the conclusions of the review and meta-analysis.

Discussion

The results of this systematic review and meta-analysis suggest that eSBI is effective in reducing alcohol consumption in the follow-up postintervention period of less than 3 months, between 3 months and less than 6 months, and between 6 months and less than 12 months, but not in the longer term follow-up period of 12 months or longer. The overall mean difference in grams of ethanol per week consumed between those in the intervention and controls groups was 16.59 (Figure 2), which is equivalent to 2 standard drinks in the United Kingdom (1 standard drink=8 g ethanol). This difference is somewhat smaller compared to a previous review, which found an overall mean difference of 25.88 g of ethanol per week [14]. The current review did not include studies of treatment seeking populations or those in which individuals were randomized regardless of their drinking status at baseline; this may account for some of the variation in mean difference in alcohol consumption. Furthermore, there may have been a variation in the length of follow-up for studies included in the current research and Khadjesari et al's [14] meta-analysis. The inclusion of more studies with a shorter follow-up length may have resulted in an inflated overall mean difference in alcohol consumption between controls and those who received the intervention.

The pattern of results found here are in-line with the results of Cunningham et al [16,17]. They reported significantly lower levels of weekly alcohol consumption in those who received a Web-based brief intervention compared to controls at 3 and 6 months, but not at 12-month follow-up. Cunningham et al

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[16,17] is the only eSBI study included in this systematic review and meta-analysis to follow up participants over the 3 time points: 3-, 6-, and 12-month follow-ups. Meta-analysis allowed for replication of their results with a much larger sample size. The magnitude of the effect in this study reduced with increasing length of the follow-up period, from nearly 4 standard drinks at a follow-up point of less than 3 months to less than 1 standard drink at a longer duration of follow-up of 12 months or greater, indicating a decline in the effectiveness of eSBI to significantly reduce alcohol consumption. All the data included in this review were from studies using a single eSBI session, although the option of returning to the eSBI was available for one study [23] and a printout of personalized feedback was generally offered (see Table 3). Neighbors et al [39] found no compelling evidence to suggest that multiple doses of electronic personalized brief advice, administered every 6 months for 2 years, was more effective than a single one-off intervention.

There was a variation in the extent of eSBI delivered between studies included in this review with some interventions taking substantially longer to complete and one study encouraged daily use of their online self-help program [24]. It is possible that more extensive interventions will have a greater impact on alcohol consumption. However, a recent large cluster randomized controlled study of face-to-face SBI in primary care found no difference in effectiveness between an information leaflet, 5 minutes of structured brief advice, or 20 minutes of brief lifestyle counseling on proportion of individuals with a negative AUDIT score (≤ 8) at 6- and 12-month follow-ups [5]. Furthermore, a meta-analysis of face-to-face SBI found that although the reduction in alcohol consumption (grams of ethanol per week) was greater for more substantial interventions (including those that were longer in duration and administered in more than one session) compared to less intensive interventions, the difference was not statistically significant [4]. To date there has been no comparable studies for eSBI.

A large attrition rate (up to 55%) has been noted in some of the eSBI studies included in this review. High attrition rates are common in electronic interventions for nontreatment-seeking individuals and reasons for this are likely to be complex and varied [45]. Attrition will have an obvious impact on the validity of results obtained and introduce bias, for example, those more committed to reducing their alcohol intake may remain in the trial and inflate positive alcohol outcomes. This has led to research into ways of reducing attrition using incentives. Khadjesari et al [46] investigated whether attrition could be improved in their study of a Web-based intervention (Down Your Drink) for reducing alcohol consumption by incentivizing study completion. Participants were randomized to receive no incentive, a £5 Amazon voucher, £5 donation to Cancer Research, or entry into a £250 prize draw. There was no significant difference in response rate between any of the study arms. A second study by Khadjesari et al [46] randomized participants to receive a higher value incentive of £10 Amazon voucher or no incentive. This resulted in a 9% difference in response rate between the 2 groups, suggesting that appropriate incentivization can reduce participant attrition. However, some caution is required when considering the use of incentives to reduce attrition in online interventions. In the previous study,

incentives were given on completion of the intervention and follow-up, rather than on sign-up to the intervention; this prevented individuals signing up who were only doing so for the incentive not the potential benefits of the research. Further exploration of the mechanism of action of incentives is required in eSBI, socioeconomic status, cultural factors, and reasons for attrition may all influence how effective incentives are at improving attrition in research [45].

Seventeen studies were included in the meta-analysis and most of these took place in the United States and with student populations. Binge drinking among young adult and student populations continues to be a concern. In the United Kingdom, 45% of males and 46% of females aged 16-24 years drink more than twice the recommended amount of alcohol (3-4 units for males and 2-3 units for females) in a single session in the previous week [47]. Binge drinking can increase the risk of behaviors that are illegal, violent, or risky (eg, unprotected sex) [48,30,48]. Binge drinking at university may also lead to long-term problems with physical and mental health [48]. This may help to explain why the majority of studies included in this systematic review and meta-analysis were conducted with student populations. Furthermore, the population of a university is generally large with up-to-date information technology facilities, which would be ideal for the implementation of an eSBI. A culture of binge drinking is evident among student populations; the pattern of drinking is likely to be somewhat different to the general population. Because of the limited number of relevant eSBI trials available, further analysis to investigate the impact of population on the effectiveness of eSBI is needed. Therefore, the generalizability of the current findings for the general population is not known.

The studies included in this meta-analysis also varied in the length, content, and theoretical basis of the intervention. Although almost all the included studies incorporated an element of personalized feedback as part of the intervention, there remains variation in both the mechanism and the context of how this was delivered. Further investigation into the effective components of these interventions was not possible and this should form an area for future research.

A comprehensive search strategy was used to identify relevant published randomized controlled trials for inclusion in this review and meta-analysis. However, it is possible that some trials may have been missed because unpublished research was not sought although an Egger's test suggested that no publication bias was present.

The results of this systematic review and meta-analysis demonstrate significant reductions in weekly alcohol consumption between intervention and control conditions at a follow-up point of less than 3 months, between 3 and 6 months, and between 6 and 12 months; as such, eSBI should be judged an effective intervention, a recent review of effective interventions targeting adolescent populations adds further support for the use of Web-/smartphone-based technology [49]. Advantages inherent to eSBI, such as reduced cost of implementation and wider accessibility compared to conventional face-to-face SBI, should also be considered. However, because of a lack of consistency in reporting of

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alcohol consumption outcome measures, this review could only report on grams of ethanol consumed per week. A greater consensus in the reporting of outcome measures and more uniform reporting of the content and theoretical basis of eSBI

would result in the ability to make more robust conclusions regarding the effectiveness of eSBI in reducing alcohol consumption and alcohol-related harms in the longer term.

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Conflicts of Interest

None declared.

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Abbreviations

AUDIT: Alcohol Use Disorders Identification Test
eSBI: electronic screening and brief intervention
MCV: mean corpuscular volume
NIHR: National Institute for Health Research
SBI: screening and brief intervention
SIGN: Scottish Intercollegiate Guidelines Network

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Alcohol Consumption, Early-Onset Drinking, and Health-Related Consequences in Adolescents Presenting at Emergency Departments in England



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ABSTRACT

Purpose: Globally, alcohol use is the leading cause of ill health and life years lost in adolescents, although its clinical impact is often overlooked, particularly in England where most research is based in schools. This study aims to examine the prevalence of alcohol consumption and the association between alcohol consumption and age of onset with health and social consequences among adolescents presenting to emergency departments (EDs).

IMPLICATIONS AND CONTRIBUTION

Alcohol consumption and earlier onset of drinking are associated with poorer health and social functioning. The emergency

Conflicts of Interest: J.S. is a researcher and clinician who has worked with a range of types of treatment and rehabilitation service-providers. J.S. is supported by the National Institute for Health Research (NIHR) Biomedical Research Centre for Mental Health at South London and Maudsley NHS Foundation Trust and King's College London. He has also worked with a range of governmental and nongovernmental organizations and with pharmaceutical companies to seek to identify new or improved treatments from whom he and his employer (King's College London) have received honoraria, travel costs, and/or consultancy payments. This includes work with, during past 3 years, Martindale, Reckitt-Benckiser/Indivior, Mundipharma, Braeburn/MedPace and trial medication supply from iGen. His employer (King's College London) has registered intellectual property on a novel buccal naloxone formulation, and he has also been named in a patent registration by a pharma company as inventor of a concentrated nasal naloxone spray. (For a fuller account, see J.S.'s Web page at <http://www.kcl.ac.uk/ioppn/depts/addictions/people/hod.aspx>.) C.D. is partly funded by the NIHR Biomedical Research Centre for Mental Health at South London and Maudsley NHS Foundation Trust and King's College London and partly funded by the NIHR Collaborations for Leadership in Applied Health Research and Care South London at King's College Hospital NHS Foundation Trust. T.P. is funded by an NIHR Clinical Doctoral Research Fellowship. H.R. is in receipt of the PhD studentships from the Society for the Study of Addiction and Alcohol Research UK. E.K. is a senior scientist in the NIHR School of Primary Care Research and NIHR School of Public Health Research as part of Fuse, a UKCRC Centre of Excellence in Translation Public Health Research. The other authors have no conflicts of interest to report.

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Methods: Consecutive attenders ($n = 5,576$) aged 10–17 years at 10 EDs were included. Information was collected on general health and functioning, quality of life, alcohol use, and alcohol-related health and social consequences.

Results: Nearly 40% of adolescents reported the consumption of alcohol that was more than a sip in their lifetime. Age of the first alcohol consumption before the age of 15 years was associated with tobacco use ($p < .001$), lower quality of life ($p = .003$), and evidence of an alcohol use disorder ($p = .002$). It was also associated with general social functioning (problems with conduct $p = .001$ and hyperactivity $p = .001$) and alcohol-related health and social consequences (accident $p = .046$, problems with a parent $p = .017$, school $p = .0117$, or police $p = .012$).

Conclusions: Rates of alcohol consumption in adolescents presenting to the ED were similar to those reported in schools in England and globally. Associations of alcohol consumption and earlier onset of drinking with poorer health and social functioning were observed. The ED can offer an opportunity for the identification of hazardous alcohol use in adolescents.

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department offers an opportunity for the identification of hazardous alcohol use in adolescents.

Adolescence is a critical period of development during which, the initiation and continuing use of alcohol may have detrimental consequences for the young person [1]. Several adverse health and social consequences of alcohol use in young people are widely reported in research and health policy including an increase in depressive feelings, increased sexual risk taking, lower educational performance, difficulties in maintaining relationships with peers and friends, and an increased vulnerability to becoming a victim of crime [2]. The European School Survey Project on Alcohol and Other Drugs (ESPAD) in 40 countries reported at least 70% of students aged 15–16 years having had alcohol in their lifetime [3]. A survey conducted in schools in England of adolescents aged 11–15 years found that 38% of those aged 11–15 years had consumed alcohol in their lifetime [4]. Worldwide, alcohol is the largest single risk factor for incident Disability-Adjusted Life-Years (7%) in adolescents aged 10–24 years [5]. Although it is difficult to establish causality of alcohol use in adolescents and social and behavioral problems, several studies have shown earlier consumption is associated with alcohol-related problems in later life [6–12]. A recent review recommended further research to establish the value of later onset in drinking when establishing drinking guidelines in adolescence [13].

Previous research examining the association between alcohol use and health and social consequences in adolescents has generally taken place in the context of the school in England, but the accuracy of this picture may be incomplete owing to the absence of those most vulnerable, who may be missed by school surveys through truancy or sickness at the time of the survey [14]. The current research aims to examine the prevalence of alcohol consumption and the association between alcohol consumption and age of onset of alcohol consumption with health and social consequences among adolescents presenting at hospital emergency departments (EDs) in England.

Methods

Participants

This research forms part of the SIPS (Screening and Intervention Programme for Sensible Drinking) Junior research program [15]. Data collection took place between December 18, 2012, and May 31, 2015. Participants were aged between their

10th and 18th birthdays attending 1 of 10 participating EDs across England: North East, Yorkshire and Humber, and London. The participating EDs were geographically spread across England covering both rural and urban populations. To be eligible for inclusion in the research, the participant had to be alert and orientated and able to speak sufficient English to complete the research assessments. Participants were not eligible for inclusion if they had a severe injury, were suffering from a serious mental health problem, and were grossly intoxicated; this was determined by ED staff. Participants were also not eligible to take part if they, their parent, or guardian were unable or unwilling to provide informed consent to take part. The present study included the data for those participants reporting that they had consumed any alcohol in their lifetime. The study received ethical approval from National Health Service Research Ethics Committee London–Camden and Islington 12/LO/0799, ISRCTN: 45300218.

Procedure

After clearance by ED staff, a researcher approached consecutive ED attenders meeting the study criteria between 8 A.M. and midnight. All potential participants, and their parents or guardians where applicable, were given written information about the study and informed that the information disclosed to researchers about the use of alcohol would be kept confidential and not passed to the parent or guardian or ED staff without prior consent of the participant. For those participants aged <16 years and unaccompanied by a parent or guardian, Gillick competencies were assessed by a member of ED staff when taking informed consent for participation [16]. Those participants aged 16 or 17 years provided informed consent for themselves.

Participants completed the study questionnaires independently in a private area of the ED; the researcher was available in case clarification of questions or help with the iPad was required. The study data were anonymized and collected using an electronic tablet device, with the exception of the timeline follow-back questionnaires, which were manually completed with the researcher. A £5 gift voucher was given to all participants to thank them for their time. All young people participating in the study were also given age-appropriate material containing information on alcohol and local services or help lines providing further support.

Measures

Supplementary Figure 1 illustrates the flow of research questions. Demographics including age, gender, and ethnicity were collected for all participants as was information on general health behaviors and lifestyle including tobacco smoking. Health-related quality of life was assessed using the Kidscreen [17], a 10-item generic health-related quality-of-life measure with established validity and reliability in this population. Behavioral and emotional functioning was measured using the Strengths and Difficulties Questionnaire [18,19] (SDQ). In addition, several questions related to age-appropriate service use including questions on previous use of health and social services, school attendance, and contact with criminal justice were asked.

Among participants who reported any alcohol consumption, the age of the first consumption in years was recorded using a single question [How old were you when you had your first drink of alcohol (beer, cider, alcopops wine etc?)], and further questions on whether they had used alcohol in the past 3 months and the past 24 hours were asked (see Supplementary Figure 1). In addition, all participants who had ever drunk alcohol were asked question 19 (“experienced alcohol intoxication in their lifetime?”) and question 21 (“personal experience of alcohol?”) of the ESPAD [3]. Further questions were included to assess the feasibility of conducting a future alcohol intervention study [15] including whether the participant would like further information or advice about alcohol and whether they would be willing to participate in an intervention and follow up study if offered.

Those participants who indicated that they had consumed alcohol that was “more than a sip” in the past 3 months were asked additional alcohol-specific questions. Hazardous alcohol use and alcohol abuse and dependence were assessed using the three-item Alcohol Use Disorders Identification Test [20] (AUDIT-C) and the alcohol section of the Mini International Neuropsychiatric Interview for Children and Adolescents [21] (MINIKID). Quantity of alcohol consumed in the past 90 days was derived from the Timeline Follow-Back Form 90 [22] (TLFB) and converted to standard units where 1 unit was the equivalent of 8 g of pure ethanol. The AUDIT has been validated in adolescent populations in the ED in the United States [23,24]. As part of the current program of research, the shorter, 3-question AUDIT-C was validated with a cutoff of 3. The TLFB has been validated for use in this population [25–27]. Perceived consequences (physical fight, accident/injury, severe problem with parents, severe problem with friends, performing poorly at school, victimized by robbery or theft, trouble with the police, hospitalized or admitted to the emergency department, engaged in sexual intercourse with no condom, engaged in sexual intercourse that was regretted the next day) of alcohol consumption were assessed by ESPAD question 22 “Because of your own alcohol use, how often during the last 12 months have you experienced the following?” (Supplementary Table 1).

Statistical analyses

Logistic regression was used to examine the relationship between demographics (age, gender, and ethnicity) and measures of health and social functioning as predicted variables and whether a participant had consumed alcohol in the previous 3 months as a predictor variable. Logistic, linear, or multinomial regression analysis was undertaken to explore the relationship between alcohol consumption in the previous 90 days and

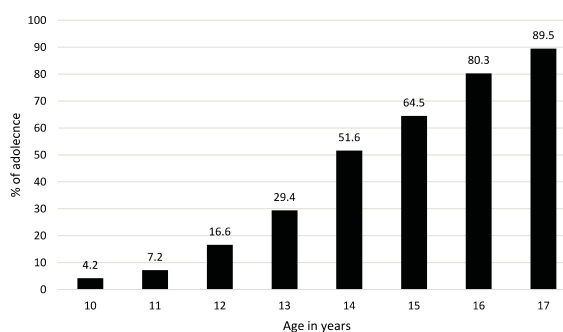


Figure 1. Percentage of participants who have had a drink of alcohol that was more than a sip in their life by current age.

psychological and social problems. Age, gender, and ethnicity were included in the analysis with total alcohol consumed (in standard UK units) in the previous 90 days as the predictor variable. Alcohol consumption was transformed taking the natural logarithms to ameliorate its non-normal distribution. The scores for the SDQ were transformed into a categorical scale (normal, borderline, and abnormal) using the original three-band categorization cutoffs. Alcohol-related consequences (measured using ESPAD), tobacco use, MINIKID diagnosis, SDQ domains, and quality of life (measured using the Kidscreen) were included as predicted variables. There is a reciprocal relationship between alcohol and behavioral and emotional functioning, whereby alcohol may result in problems with functioning or problems with functioning may lead to alcohol use. This relationship is difficult to disentangle. To demonstrate this, linear regression analyses were performed with alcohol consumption as the predicted variable and SDQ, Kidscreen, and tobacco use as individual predictors taking into consideration age, gender, and ethnicity. The results of these analyses are presented in Supplementary Table 2.

Regression analysis was also used to explore the relationship between age of the first drink of alcohol and psychological and social problems in participants aged 16 or 17 years. Current UK drinking guidelines recommend an alcohol-free childhood and that young people choosing to consume alcohol should not do so until age 15 years, not exceeding adult daily unit recommendations, not drink more than once a week [28]. To reflect these guidelines, only those aged 16 or 17 years were included in the analysis of time of onset of alcohol consumption. Consumption in the previous 90 days (transformed by taking the logarithms), gender, and ethnicity were covariates in the analysis with age of the first alcohol consumption (two categories, aged <15 and >15 years) as the predictor variable. Those variables that showed a relationship that was significant at the 20% level were included as predicted variables.

Results

A total of 5,376 participants consented to take part in the research. Of these, 2,112 (39.5%) reported having had a drink of alcohol that was more than a sip in their lifetime; Figure 1 presents a breakdown by age. The mean age of those who took part in the research was 13 years (SD 2.07); proportions of males and

Table 1

Overview of study sample and regression analysis to explore the relationship between demographics and measures of general health and social functioning and the consumption of alcohol in the previous 3 months

	Whole sample (N = 5,376)	No alcohol in the past 3 months (N = 3,960)	Consumed alcohol in the past 3 months (N = 1,374)	Odds of having consumed alcohol in the past 3 months
Age, mean (SD)	13.28 (2.074)	12.65 (1.850)	15.12 (1.511)	OR = 2.147, $p < .001$, 95% CI = 2.050–2.248
Gender, n (%) ^a				
Male	2,869 (53.8)	2,183 (55.1)	686 (49.9)	^k
Female	2,465 (46.2)	1,777 (44.9)	688 (50.1)	OR = 1.232, $p = .001$, 95% CI = 1.090–1.393
Ethnicity, n (%) ^b				
Other	1,396 (27.4)	1,215 (32.1)	181 (13.8)	^k
White	3,699 (72.6)	2,565 (67.9)	1,134 (86.2)	OR = 2.968, $p < .001$, 95% CI = 2.501–3.521
Tobacco, n (%) ^c				
No	4,846 (91.1)	3,843 (97.36)	1,003 (73.2)	^k
Yes	476 (8.9)	108 (2.7)	368 (26.8)	OR = 13.056, $p < .001$, 95% CI = 10.420–16.357
Emotion scale, n (%) ^{d,j}				
Normal	4,556 (86.9)	3,442 (87.4)	1,114 (85.6)	^k
Borderline	284 (5.4)	211 (5.4)	73 (5.6)	OR = 1.069, $p = .634$, 95% CI = .812–1.407
Abnormal	400 (7.6)	285 (7.2)	115 (8.8)	OR = 1.247, $p = .057$, 95% CI = .994–1.56
Conduct scale, n (%) ^{e,j}				
Normal	1,404 (78.6)	3,082 (78.7)	1,022 (78.3)	^k
Borderline	519 (9.9)	382 (9.8)	137 (10.5)	OR = 1.082, $p = .459$, 95% CI = .879–1.331
Abnormal	600 (11.5)	453 (11.6)	147 (11.3)	OR = .979, $p = .831$, 95% CI = .802–1.194
Hyperactivity scale, n (%) ^{f,j}				
Normal	3,919 (74.9)	2,941 (74.9)	978 (75.2)	^k
Borderline	495 (9.5)	380 (9.7)	115 (8.8)	OR = .910, $p = .403$, 95% CI = .730–1.135
Abnormal	815 (15.6)	608 (15.5)	207 (15.9)	OR = 1.024, $p = .790$, 95% CI = .861–1.218
Peer scale, n (%) ^{g,j}				
Normal	4,471 (85.5)	3,393 (86.4)	1,078 (82.7)	^k
Borderline	584 (11.2)	413 (10.5)	171 (13.1)	OR = .303, $p = .007$, 95% CI = 1.077–1.577
Abnormal	175 (3.3)	121 (3.1)	54 (4.1)	OR = 1.405, $p = .042$, 95% CI = 1.012–1.950
Prosocial scale, n (%) ^{h,j}				
Normal	4,704 (89.6)	3,639 (92.3)	1,065 (81.5)	^k
Borderline	328 (6.2)	204 (5.2)	124 (9.5)	OR = 2.077, $p < .001$, 95% CI = 1.6452.623
Abnormal	218 (4.2)	101 (2.6)	117 (9.0)	OR = 3.958, $p < .001$, 95% CI = 3.007–5.210
Quality of life, mean (SD) ⁱ	42.92 (5.32)	43.58 (5.03)	40.92 (5.66)	OR = .906, $p < .001$, 95% CI = .894–.918

Number of participants with missing data.

CI = confidence interval; OR = odds ratio.

^a 1.

^b 245.

^c 25.

^d 112.

^e 129.

^f 124.

^g 122.

^h 102.

ⁱ 25.

^j Derived from the Strengths and Difficulties Questionnaire.

^k Reference group.

females were roughly even, but a greater proportion of participants were white compared to other ethnicities (Table 1).

A total of 1,374 (25.6% of the whole sample) reported drinking more than a sip of alcohol in the previous 3 months. The average age of the first alcoholic drink was 12.9 (standard deviation = 2.19), ranging from 5 to 17 years of age (17 was the upper limit for inclusion in this study). Alcohol consumption in the previous 3 months was associated with older age, being female, white, and having smoked tobacco. In addition, those who had consumed alcohol within the previous 3 months were more likely to report a lower quality of life and to have peer and social problems. Supplementary Table 1 presents the descriptive data on demographics, general social functioning, and quality of life for those who had consumed alcohol in the previous 3 months.

The results of the regression analysis found that total alcohol consumed in the previous 90-day period was associated with tobacco use, lower quality of life, poorer general social

functioning (conduct and hyperactivity), and ESPAD questions on health and social problems (Table 2).

Further regression analysis investigated the association between age of the first alcohol consumption and psychological and social problems. Only participants aged 16 or 17 years who had consumed alcohol in the past 3 months were included in this analysis (10% of the total study sample, 44% of those who had consumed alcohol in the past 3 months). Variables that did not show an association with alcohol use were excluded from the analysis. Supplementary Table 3 gives an overview of the subsample.

Table 3 presents the results of the regression analysis. Consumption of alcohol before the age of 15 years was associated with an increased risk of a number of health and social problems. These included a greater risk of smoking tobacco and a diagnosis of an alcohol use disorder as indicated by the MINIKIDS. Consumption of alcohol before the age of 15 years was also

Table 2

Regression analysis for the association between alcohol consumption (timeline follow-back) and psychological and social problems

Variable	β	Odds ratio	<i>p</i>	95% Confidence interval
Tobacco ^a				
No	0	1.0		
Yes	.640	1.897	<.001	1.670, 2.155
Emotion ^{b,d}				
Normal	0	1.0		
Borderline	-.015	.893	.985	.787, 1.231
Abnormal	.057	1.059	.523	.889, 1.261
Conduct ^{b,d}				
Normal	0	1.0		
Borderline	.235	1.265	.005	1.074, 1.490
Abnormal	.270	1.309	.001	1.115, 1.538
Hyperactivity ^{b,d}				
Normal	0	1.0		
Borderline	.167	1.182	.065	.990, 1.412
Abnormal	.193	1.212	.006	1.057, 1.391
Peer ^{b,d}				
Normal	0	1.0		
Borderline	.003	1.003	.971	.866, 1.162
Abnormal	.158	1.171	.213	.913, 1.501
Prosocial ^{b,d}				
Normal	0	1.0		
Borderline	.087	1.091	.332	.915, 1.300
Abnormal	.076	1.079	.404	.902, 1.291
Quality of life ^{c,e}	-.537		<.001	-.802, -.271
Alcohol measures				
AUDIT-C ^a				
Score <3		1.0		
Score ≥ 3	0-.047	.954	.505	.830, 1.096
MINIKID ^a				
No diagnosis	0	1.0		
Diagnosis	1.049	2.855	<.001	2.388, 3.414
Physical fight ^{a,f}				
No	0	1.0		
Yes	.880	2.410	<.001	1.998, 2.907
Accident ^{a,f}				
No	0	1.0		
Yes	.709	2.032	<.001	1.737, 2.378
Serious problem with parents ^{a,f}				
No	0	1.0		
Yes	.924	2.519	<.001	2.039, 3.112
Serious problem with friends ^{a,f}				
No	0	1.0		
Yes	.633	1.883	<.001	1.601, 2.214
Performed poorly at school ^{a,f}				
No	0	1.0		
Yes	.625	1.869	<.001	1.520, 2.298
Victimized by robbery or theft ^{a,f}				
No	0	1.0		
Yes	.576	1.778	<.001	1.493, 2.118
Trouble with the police ^{a,f}				
No	0	1.0		
Yes	.850	2.340	<.001	1.877, 2.918
Emergency admission ^{a,f}				
No	0	1.0		
Yes	.765	2.150	<.001	1.765, 2.618
Engaged in sexual intercourse with no condom ^{a,f}				
No	0	1.0		
Yes	.787	2.197	<.001	1.833, 2.634
Engaged in sexual intercourse and regretted it the next day ^{a,f}				
No	0	1.0		
Yes	.781	2.183	<.001	1.803, 2.644

After adjusting for age, gender and ethnicity as covariates.

p Values given in bold were statistically significant at the 5% level.

OR = odds ratio.

^a Logistic regression.^b Multinomial regression.^c Linear regression.^d Derived from the Strengths and Difficulties Questionnaire.^e Kidscreen.^f European School Survey Project on Alcohol and Other Drugs.

Table 3

Regression analysis of whether age of alcohol onset was <15 years on psychological and social problems—in respondents aged 16 and 17 years

Variable	β	Odds ratio	<i>p</i>	95% Confidence interval
Tobacco ^a				
No	0	1.0		
Yes	1.039	2.827	<.001	1.861–4.295
Conduct ^{b,d}				
Normal	0	1.0		
Borderline	.944	2.569	.014	1.209–5.461
Abnormal	1.523	4.588	.001	1.841–11.433
Hyperactivity ^{b,d}				
Normal	0	1.0		
Borderline	.359	1.431	.322	.704–2.910
Abnormal	.977	2.657	.001	1.462–4.830
Quality of life ^{c,e}	1.591		.003	.562–2.620
MINIKID ^a				
No diagnosis	0	1.0		
Diagnosis	.903	2.467	.002	1.379–4.414
Physical fight ^{a,f}				
No	0	1.0		
Yes	.683	1.979	.073	.938–4.174
Accident ^{a,f}				
No	0	1.0		
Yes	.591	1.807	.046	1.010–3.232
Serious problem with parents ^{a,f}				
No	0	1.0		
Yes	1.500	4.483	.017	1.303–15.426
Serious problem with friends ^{a,f}				
No	0	1.0		
Yes	.089	1.093	.768	.606–1.972
Performed poorly at school ^{a,f}				
No	0	1.0		
Yes	1.332	3.789	.017	1.266–11.344
Victimized by robbery or theft ^{a,f}				
No	0	1.0		
Yes	.280	1.324	.434	.655–2.673
Trouble with the police ^{a,f}				
No	0	1.0		
Yes	2.605	13.526	.012	1.785–102.481
Hospitalized or admitted to an emergency room ^{a,f}				
No	0	1.0		
Yes	.389	1.475	.350	.653–3.335
Engaged in sexual intercourse with no condom ^{a,f}				
No	0	1.0		
Yes	.550	1.733	.074	.949–3.166
Engaged in sexual intercourse and regretted it the next day ^{a,f}				
No	0	1.0		
Yes	.434	1.543	.210	.783–3.043

After adjusting for gender, ethnicity and alcohol consumption (timeline follow-back) as covariates.

p Values given in bold were statistically significant at the 5% level.^a Logistic regression.^b Multinomial regression.^c Linear regression.^d Derived from the Strengths and Difficulties Questionnaire.^e Kidscreen.^f European School Survey Project on Alcohol and Other Drugs.

associated with a greater risk of experiencing conduct and hyperactivity problems and more alcohol-related social problems including having an accident, problems with a parent, school problems, and experiencing problems with the police.

Discussion

Nearly 40% of the adolescents presenting to the ED in England reported that they had had a drink of alcohol that was more than a sip in their lifetime. Rates of consumption increased considerably with age raging from just 4% for those aged 10 to 90% for those aged 17 years. Comparable rates of lifetime alcohol consumption have been found in school surveys. A recent survey conducted in schools in England reported that 38% of those aged

11–15 years had consumed alcohol in their lifetime; the present study found a lifetime consumption rate of 34% among those of the same age [4]. In older adolescents (aged 15–16 years), the ESPAD study reported an average lifetime consumption rate across 40 countries of 70%; in the same age group, this study found a lifetime alcohol consumption rate of 71%.

Among adolescents who had consumed alcohol in the past 3 months, 15.8% of drinkers screened positive for harmful alcohol use (three or more on the AUDIT-C) and 15% screening positive for alcohol abuse or dependence (using MINIKID). The prevalence of a diagnosis of alcohol abuse or dependence was considerably higher among participants who started drinking before the age of 15 years, with almost 1 in 3 meeting the criteria for alcohol abuse or dependence. Participants were less

likely to report parent and school problems compared to young drinkers in the ESPAD 2011 survey of school pupils in Europe [3]. However, they were more likely to have reported experiencing an accident or injury, been a victim of robbery or theft, or been hospitalized or admitted to an emergency room as a result of their own alcohol consumption. It is possible that at least in part these risk behaviors reflect the underlying “behavioral disinhibition” reported to characterize young people who use substances [29]. This may lead to young people being at a greater risk of alcohol use and a series of other risk behaviors.

Regression analysis (Table 3) showed that higher alcohol consumption in the past 90 days (from the TLFB) was associated with increased odds of all the negative consequences of alcohol consumption studied (from ESPAD). Heavier drinking was also associated with smoking, worse quality of life, and conduct and hyperactivity problems on the SDQ, as well as alcohol use disorders and alcohol abuse. Earlier onset of drinking (under 15 years) was associated with increased odds of 4 of the 10 ESPAD alcohol consequences studied, as well as smoking, worse quality of life, and conduct and hyperactivity problems on the SDQ, and also alcohol use disorders and alcohol abuse (Table 3). This study clearly shows an association between earlier alcohol consumption and harm in adolescents, but it remains to be established whether this persists into adulthood [9]. A large birth cohort study found that around half of the adolescents studied who were exposed to drugs or alcohol before the age of 15 years had no history of conduct disorder, but they were still at an increased risk of behavioral and social problems in adulthood [10]. Although the results of the present study do not establish causality, effective interventions to reduce alcohol consumption in this population could potentially mitigate the negative consequences related to alcohol that are experienced from a young age in this group.

It is difficult to establish the direction of causality relationship between alcohol consumption and emotional and behavioral functioning, with little consensus being reached in the literature [10,11]. We investigated this association with two sets of linear regressions: one with alcohol consumption as the predicted variable and one with consumption as the predictor. Similar results were found for both analyses (Supplementary Table 2). The relatively high rates of self-report “abnormal” hyperactivity and conduct problems, which are related to behavioral disinhibition and seen as developmental symptoms that generally appear early in life, and their continuing predictive power in regression analyses would tend to support the view that these young people had differed from their peers before drinking alcohol. The adolescent manifestation of behavioral disinhibition depends on environmental factors such as high or low availability of alcohol and other substances. However, the odds ratios (ORs) associated with hyperactivity and conduct problems were relatively weak compared to the predictive power of most of the ESPAD social and behavioral “consequences” of alcohol. This suggests that even among a group at generally high risk for social and behavioral problems, early alcohol use and greater alcohol consumption add considerably to risk.

This is the first study to investigate the prevalence of alcohol consumption and the relationship with emotional and behavioral problems and alcohol-related harms in adolescents presenting to the ED in England. The strengths of this study include the large sample size, the wide age range of non-alcohol treatment-seeking adolescents studied, and the broad spread of

study across 10 EDs across England. Fieldwork took place over several months every day of the week and from 8 A.M. to midnight, so our findings are a good indication of the prevalence of alcohol use disorders in this population. Most of the evidence on alcohol screening and brief intervention in young people comes from a school setting and older adolescents. However, as this study identified a high prevalence of alcohol use disorders in adolescents attending EDs, we suggest this setting is a relevant one for research on alcohol screening in young people. The questionnaire asked participants about a comprehensive range of alcohol measures (TLFB, Beverage Specific Quantities and Frequencies, AUDIT, MINIKIDS, and the ESPAD questions on intoxication), which will be explored fully in a separate article. Use of technology to collect data was successful in this study, and it is known that technology shows promise as a tool to deliver interventions [30].

This study does have some limitations. Those with a severe injury or mental health problem were excluded from participating due to ethical reasons. The association between alcohol and severe injury and mental health problems has been well established; therefore, excluding these participants may have introduced bias. Many of the measures used (such as TLFB) were initially developed for adults, although some have also been validated for use in this population (e.g., the TLFB) [21,25–27]. Some of the questions about alcohol consequences (e.g., ESPAD) are usually asked about the past 12 months; however, in the present study, these questions were only asked of participants who drank alcohol in the past 3 months. Some of the outcomes measured may have been experienced among less recent drinkers (or nondrinkers), and these may not have been captured, especially as at a young age, drinking patterns are often infrequent or irregular [31]. This suggests that questions routinely used to measure drinking in young people may not be sufficiently detailed. Data on those eligible participants who declined to take part were not collected; this is a potential source of bias that was not investigated. Finally, for some of the less common outcomes studied, there was a small sample size in some subgroups and resulting ORs should be interpreted with caution (e.g., the OR of 13.5 for early onset and involvement with the police).

It is possible that the self-completion nature of the survey and the study setting may have biased our estimates. There is evidence to suggest that self-reported measures of alcohol consumption are reliable with importance placed on factors such as privacy, confidentiality, and completion of questionnaires electronically [32–34]. Focus groups were held with members of a national youth organization to explore young people's views of answering questions about alcohol in the ED. Anonymous self-completion of the questionnaires on an electronic tablet device was perceived as highly confidential and secure by the members of the national youth organization. To minimize bias in the current research, study questionnaires were self-completed using an electronic tablet device in a private area of the ED, and confidentiality was assured. A further limitation of the current research may be the potential recall bias for the age of the first alcohol use, this variable only asked for adolescents to recall the first time they had a drink of alcohol. Forward telescoping may occur where participants recall the age of the first consumption closer to their current age, and this is more common in infrequent drinkers [35]. There is some debate in the literature regarding the importance of “sips” of alcohol [35]; however, a recent study called for greater importance to be placed on “sips”

when considering the association between alcohol consumption and health and social consequences [36].

Current UK drinking guidelines recommend an alcohol-free childhood and that young people choosing to consume alcohol should not do so until age ≥ 15 years, and if they drink, it should not exceed adult recommendations and should not drink more than one occasion per week [28]. Our study supports this but also shows a similar prevalence of hazardous drinking among participants who started drinking at age ≥ 15 years (Supplementary Table 3); therefore, the risks of drinking are not restricted to those with an early onset. Future studies should explore how the risks associated with drinking alcohol vary by age of onset in more detail.

A high prevalence of alcohol use disorders among adolescents presenting at EDs in England was identified in this study. Associations between alcohol consumption and earlier onset of drinking and negative consequences of drinking (as measured by the ESPAD questions) and poorer health and functioning were also observed. This study found ED waiting rooms a source of willing research participants, and this context may also represent a teachable moment to change young people's behavior using either face-to-face or electronic interventions [31,37,38]. The ED also has a high level of staff expertise who are well placed to initiate safeguarding procedures where required and who provide a good point of onward referral to specialist services. The possibility of conducting alcohol screening among adolescents presenting at the ED in England should be investigated, and the potential for providing interventions to help reduce alcohol consumption in this population and setting established [15,39].

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Supplementary Data

Supplementary data related to this article can be found at <http://dx.doi.org/10.1016/j.jadohealth.2016.11.017>.

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Alcohol Screening and Brief Intervention for Adolescents: The How, What and Where of Reducing Alcohol Consumption and Related Harm Among Young People

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Abstract — **Aim:** The aim of the study was to explore the evidence base on alcohol screening and brief intervention for adolescents to determine age appropriate screening tools, effective brief interventions and appropriate locations to undertake these activities. **Methods:** A review of existing reviews (2003–2013) and a systematic review of recent research not included in earlier reviews. **Results:** The CRAFFT and AUDIT tools are recommended for identification of 'at risk' adolescents. Motivational interventions delivered over one or more sessions and based in health care or educational settings are effective at reducing levels of consumption and alcohol-related harm. **Conclusion:** Further research to develop age appropriate screening tools needs to be undertaken. Screening and brief intervention activity should be undertaken in settings where young people are likely to present; further assessment at such venues as paediatric emergency departments, sexual health clinics and youth offending teams should be evaluated. The use of electronic (web/smart-phone based) screening and intervention shows promise and should also be the focus of future research.

INTRODUCTION

Alcohol is a major global threat to public health (Ofori-Adjei *et al.*, 2007). The World Health Organization (WHO) reports that alcohol consumption is related to 3.2% of mortality worldwide (Rehm *et al.*, 2003), while in Europe alcohol accounted for 6.5% of deaths and 11.6% of disability adjusted life years in 2004 (Rehm *et al.*, 2009). Although the main burden of chronic alcohol-related disease is in adults, its foundations often lie in adolescence (Bellis *et al.*, 2009). The latest ESPAD survey of alcohol use among 14–15-year olds in 36 European countries found that 87% reported lifetime alcohol use, with 57% consuming alcohol on one or more occasion in the previous month (Hibell *et al.*, 2011). ESPAD found considerable variation in the levels of youth alcohol consumption between countries, with adolescents in the UK and Nordic countries drinking three times more than in Southern and Eastern Europe. Rates of youth alcohol use are lower in the USA than in Europe, with 70% of 18-year olds reporting lifetime alcohol use, and 33% in the preceding month (Johnston *et al.*, 2011). While the proportion of young people in England aged 11–15 years who reported that they have drunk alcohol decreased from 62 to 45% between 1988 and 2011, the mean amount consumed approximately doubled (from 6.4 to 10.4 units of alcohol per week) between 1994 and 2011 (Fuller, 2012). In England there has been a rapid increase in regular alcohol consumption during school-aged years, with 1% of 11 years reporting weekly alcohol consumption compared with 28% of those aged 15 years of age (Fuller, 2012). Adolescents in the UK are now among the heaviest drinkers in Europe (Hibell *et al.*, 2009).

Alcohol consumption and related harm increase steeply from the ages of 12–20 years (NHS Information Centre, 2008). In early adolescence alcohol use and alcohol use disorders (AUDs)—alcohol abuse/harmful alcohol use and alcohol dependence) are relatively uncommon. But, alcohol has a disproportionately adverse effect on younger adolescents, for example, possibly predisposing them to damage the developing brain (Zeigler *et al.*, 2005), to develop alcohol dependence

in later life (Dawson *et al.*, 2008; Hingson and Zha, 2009) and increasing risk of disability (Sidorchuk *et al.*, 2012). In middle adolescence (ages 15–17 years) binge drinking (single occasion consumption leading to intoxication) emerges. Binge drinking is associated with increased risk of unprotected/regretted sexual activity (Windle and Windle, 2004; Hibell *et al.*, 2009, 2011), criminal and disorderly behaviour (Department of Health, 2007; Hibell *et al.*, 2009), suicide and deliberate self-harm (McCloud *et al.*, 2004), injury (Hibell *et al.*, 2009), drink driving or allowing oneself to be carried by a drink driver (Bukstein and Kaminer, 1994), alcohol poisoning (Rehm *et al.*, 2003) and accidental death (Thunstrom, 1988).

A review of national guidelines on consumption to limit alcohol-related harms (Furtwaengler and de Visser, 2013) found a lack of consensus between countries. Several nations had no official guidance on levels of consumption; others had a wide variety of definitions of a 'standard drink' (ranging from 8 g ethanol to 14 g). Actual guidance provided ranged from 20 to 56 g/day for males and 10 to 42 g/day for females. There are no specific guidelines for alcohol consumption among young people. In 2009 the Chief Medical Officer (CMO) for England provided recommendations (Donaldson, 2009) on alcohol consumption for young people based on an evidence review (Newbury-Birch *et al.*, 2009). The CMO advises that children should abstain before age 15 years and also suggests 15 to 17-year olds should not consume alcohol, but if they do drink, it should be no more than 3–4 units (24–32 g) and 2–3 units (16–24 g) per week in males and females, respectively, on an occasional basis.

Over the past 15 years the WHO, the US Surgeon General, the American Medical Association, and the American Academy of Paediatrics have called for practitioners to carry out screening and brief interventions (SBI) for adolescent drinkers (Elster and Kuznets, 1994; Committee on Substance Abuse, 2001; World Health Organisation, 2006; NIAAA, 2007). The alcohol strategies in both England and Scotland identify adolescents as a key target group in which to reduce alcohol consumption and related harm (Department of Health,

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findings as an earlier meta-analysis by Carey *et al.* (2012) that compared e-BI with more traditional face-to-face (F2F) delivery of interventions concluded that F2F is superior (Carey *et al.*, 2012).

BIs based on one or two sessions of motivational interviewing (MI) that lasted between 20 and 45 min have been studies in an adolescent population (Monti *et al.*, 1999, 2007; Peterson *et al.*, 2006; D'Amico *et al.*, 2008; Schaus *et al.*, 2009). Delivery of these interventions was carried out by a range of trained professionals including physicians, nurse practitioners, psychologists, addiction clinicians and youth workers. One trial tested a more intensive programme of four MI sessions during a 1-month period (Bailey *et al.*, 2004). Two studies used information technology to deliver BI, one involving the use of an audio programme in primary care clinics (Boekeloo *et al.*, 2004) and the other an interactive computer programme in a minor injury unit (Maio *et al.*, 2005). The length of follow-up ranged from 2 to 12 months. Overall, the loss to final follow-up evaluations was low (0–20%), although D'Amico *et al.* (2008) reported that 34% of their study population were lost to follow-up. MI is more effective when delivered across a series of sessions, rather than as a one-off intervention; the 2012 review by Carney and Myers (2012) included nine studies of MI in adolescent populations, concluding that individual interventions across multiple sessions had the strongest effect.

There have been several reviews of more intensive psychosocial interventions for adolescent AUDs (Williams and Chang, 2000; Deas and Thomas, 2001; Hser *et al.*, 2001; Perepletchikova *et al.*, 2008; Deas and Clark, 2009). Interventions have included behavioural and cognitive-behavioural therapies, motivational enhancement therapy (MET), contingency management and 12-step approaches (based on the principles of Alcoholics Anonymous). Family based interventions such as Multi Systemic Therapy and Multi Dimensional Family Therapy have been recommended by NICE for alcohol misusing adolescents with more complex needs (NICE, 2011); however, these are beyond the scope of this review. Interpretation of this literature is complicated because most studies examine comorbid drug and AUDs rather than AUD alone, and a wide age range from 12 to 18 years, and sometimes up to 25 years. Of these psychosocial approaches, MET shows promise as a treatment intervention for AUD in adolescents (Marlatt *et al.*, 1998; Kaminer and Burleson, 1999; Dennis *et al.*, 2004; McCambridge and Strang, 2004). MET has yet to be studied as a more intensive intervention in the context of a stepped care approach.

WHERE IS THE BEST PLACE TO DELIVER THESE INTERVENTIONS?

A systematic review of brief alcohol interventions in young people attending health settings identified eight randomized controlled trials between 1999 and 2008 (Jackson *et al.*, 2009). Seven were based in the USA (Monti *et al.*, 1999; Boekeloo *et al.*, 2004; Spirito *et al.*, 2004; Maio *et al.*, 2005; Peterson *et al.*, 2006; D'Amico *et al.*, 2008), and one in Australia (Bailey *et al.*, 2004). Subsequently, a further trial based in a US student health centre was published in 2009 (Schaus *et al.*, 2009). Study population sizes range from 34 to 655, and ages ranged from 12 to 24 years. Three trials targeted socioeconomically disadvantaged groups where drug and alcohol misuse were more prevalent (Bailey *et al.*, 2004; Peterson *et al.*, 2006; D'Amico *et al.*, 2008). Four trials were based in ED in order to maximize the 'teachable moment' (Williams *et al.*, 2005) in which the connection between alcohol consumption and its adverse consequences can be more readily highlighted (Monti *et al.*, 1999, 2007; Spirito *et al.*, 2004; Maio *et al.*, 2005). Two studies recruited adolescents in a primary care setting during routine general check-ups (Boekeloo *et al.*, 2004; D'Amico *et al.*, 2008) and one in a university health centre (Schaus *et al.*, 2009). The remaining trials targeted homeless youth (Peterson *et al.*, 2006) and those attending a youth centre that delivered health services (Bailey *et al.*, 2004). An earlier review of BIs in health settings (Jackson *et al.*, 2009) was based on eight Randomised Controlled Trials (RCTs) (mostly MI focused) conducted between 1999 and 2008, of which five reported positive effects upon consumption and related harms.

Opportunistic alcohol screening and brief intervention in emergency departments (ED) have shown efficacy in adolescents (Monti *et al.*, 1999, 2007; Spirito *et al.*, 2004), with evidence of cost effectiveness in adults (Barrett *et al.*, 2006). One systematic review has explored BI delivered in ED settings (Yuma-Guerrero *et al.*, 2012). Of the seven RCTs identified, six of these employed a MI based intervention, and of these, half demonstrated significant reductions in alcohol consumption and consequences for the MI groups. Six of the seven studies reported positive treatment effects in all arms of the trials. To date no trials have been undertaken in paediatric ED settings; however, one programme of research is currently underway (SIPS Junior). The effectiveness of MI for this population had been previously reported by Wachtel and Staniford (2010) in a general review of effective interventions for adolescents (Wachtel and Staniford, 2010).

Table 1. Additional RCTs included in the review

Study	Focus	Population	Intervention	Conclusion
Gmel <i>et al.</i> (2012)	Schools based	5633 pupils 13–16 years	MI based	Intervention was ineffective
Winters <i>et al.</i> (2012)	Schools based	315 pupils 12–18 years	MI based	Intervention groups had significant reduction in alcohol use
Segatto <i>et al.</i> (2011)	ED based	175 patients 16–25 years	MI based	No significant differences in outcomes between groups. All groups reduced consumption
Walton <i>et al.</i> (2010)	ED based	726 patients 14–18 years	e-BI vs. therapist delivered BI (both MI based)	Both active interventions reduced alcohol consequences
Bernstein <i>et al.</i> (2010)	ED based	853 patients 14–21 years	MI based vs. information only	Significant increase in attempts to stop drinking in MI group. Consumption reduced in both groups.

Most studies of schools based interventions have focused upon primary prevention aimed at children prior to the onset of alcohol use, and are therefore beyond the scope of this review. Two published RCTs describe the effect of MI on children identified as current alcohol users; both report significant impact on alcohol use (Winters and Leitten, 2007; Winters *et al.*, 2012). Gmel *et al.* (2012) reported borderline significant effects for MI on reduced levels of consumption, concluding that the intervention was ineffective. These findings should be interpreted with caution, however, as a recent critical review (Pape, 2009) reminds us to question the reliability of published reports of effectiveness in this setting. Calabria *et al.* (2011) reviewed interventions delivered outside of educational settings but were unable to identify any one approach that demonstrated superior impact.

DISCUSSION

With 12% of 11–15 year olds drinking weekly (Fuller, 2012) and at least in the UK a fall in the age of onset of many alcohol-related harms such as alcohol liver disease (NCEPOD, 2013) there is a need to develop public health measures to tackle adolescent drinking. Recent systematic reviews (NICE, 2007, 2010) have not identified validated screening instruments that could be easily introduced across settings to accurately detect alcohol misuse use in younger adolescents (10–14 years old), who are more vulnerable to alcohol-related harms. In the absence of sensitive instruments to detect alcohol misuse in this age group, there is a risk of defining alcohol misuse in young people through the incidence of gross intoxication or hospital admissions due to alcohol poisoning, which might miss a proportion who could potentially benefit from alcohol intervention.

Greater accuracy in determining the level of need for alcohol misuse in adolescence will support the broader implementation of public health measures at a national and local level, as well as identify those individuals who may benefit from specific interventions. Screening methods that are sensitive to the developmental stage of the adolescent should be tested to maximize opportunities for intervention. Alcohol screening has been mostly studied in older adolescents and young adults of college age (18–24 years). Therefore the validity of alcohol screening methods in younger adolescents is unclear. Questionnaires such as the AUDIT may be too lengthy (10 items) to incorporate into busy settings pointing to the need for briefer tools for use in routine clinical practice.

Increasing engagement in screening particularly with younger adolescents might result from using computer screening and interviewing adolescents confidentially, separately from parents (Ford *et al.*, 1997; Gregor *et al.*, 2003). Screening is perhaps the most important element of SBI—reactivity to assessment has an impact upon outcome and screening itself may be the briefest of BIs—and yet no single screening instrument has been identified that reliably determines a young person's risk status. It is likely that no single cut-off on any screening instrument will suit the broad age range encompassed by adolescence, and that lower thresholds for AUDs for younger age groups will be required. Research to develop to refine existing tools by establishing concordance with Time Line Follow Back data should be a priority.

Most of the published research on brief alcohol interventions for adolescents has been set in mainly acute medical and ED or educational settings. Other care interfaces (such as sexual health clinics, adolescent mental health services or Youth Offending Teams) should be considered as potential settings for both identification of AUDs and the delivery of BIs.

Based upon the reviews to date and the RCTs undertaken from 2010 onwards, MI/MET approaches appear to be associated with reductions in alcohol consumption and related harms, with health settings proving to be a promising location for such programmes. e-BIs (computer, web and phone based) offer both effective and cost effective delivery of interventions across settings that may prove to be more acceptable to the target population than more traditional (F2F) approaches, yet the most effective mechanism for e-BI is less apparent—the utilization of 'smart-phone' technology may add both function and credibility to interventions; however, their usefulness in this context remains untested, with several clinical trials currently underway.

This brief review of reviews and recent RCTs suggests that despite an increasing interest in applying screening and brief interventions to an adolescent population, there are no clear indications of which target population, setting, screening tool or intervention approach can be recommended. The relationship between age, alcohol consumption and harm is complex and further research is required in order to establish guidelines for consumption and thresholds of harm for different age groups.

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2007; Scottish Government, 2013). However, while there has been an increase in SBI activity in relation to adults presenting to health care providers, adolescents remain a neglected group.

BRIEF INTERVENTION FOR ADOLESCENTS

The term brief intervention (BI) encompasses a range of therapeutic processes from advice to extended counselling, and typically is delivered in short sessions on one or more occasions. A number of trials focusing upon young people (aged 12–21) have reported significant positive effects of BI on a range of alcohol consumption measures (Monti *et al.*, 1999, 2007; Bailey *et al.*, 2004; Schaus *et al.*, 2009; Bernstein *et al.*, 2010; Walton *et al.*, 2010). Walton *et al.* (2010) noted that BI reduced alcohol-related harms, and Bernstein *et al.* (2010) found significant reductions in alcohol consumption compared with ‘information only’ controls. Bailey *et al.* (2004) found that BI participants showed increased readiness to reduce alcohol consumption, an initial reduction in alcohol consumption, and an improvement in knowledge regarding alcohol and related problems compared with the control condition. Researchers from the USA have also reported reductions in blood alcohol concentration, number of drinks per week and risk-taking behaviour (Schaus *et al.*, 2009). Monti *et al.* (1999) concluded that BI subjects were less likely to drink and drive or experience alcohol-related injury than controls, although both treatment groups significantly reduced their alcohol consumption. A subsequent trial conducted by the same research group (Monti *et al.*, 2007) reported that alcohol consumption was also significantly decreased in both BI and control groups. Spirito *et al.* (2004) found a significant reduction in alcohol consumption at follow-up in both BI and control groups. However, adolescents who screened positive for alcohol problems at baseline reported more changes after BI than controls. Three trials reported null effects after BI (Maio *et al.*, 2005; Peterson *et al.*, 2006; D’Amico *et al.*, 2008). One trial that used an audio-taped programme with 12 to 17-year-old adolescents (Boekeloo *et al.*, 2004) reported an increase in alcohol use and binge drinking among BI subjects, although it should be noted that in this age group one would expect increase in uptake of drinking, so this does not necessarily represent an adverse effect, but rather potentially a lack of effect. There has been a lack of consensus regarding the most effective components of effective interventions. Therefore we conducted a brief review of reviews (and recent trials) to identify screening methods, types and settings for interventions applied to adolescent populations that are effective in reducing alcohol consumption and related harms.

METHOD

We conducted a review of reviews based upon publications from 2003 to 2013. A search of electronic databases (PubMed, Web of Science) was undertaken using the terms <alcohol>, <intervention> and <adolescent>. Search terms were expanded to include variations on these themes, and review papers were identified and summarized (Carey *et al.*, 2007; Deas, 2008; Lemstra *et al.*, 2010; Wachtel and Staniford, 2010; Calabria *et al.*, 2011; Jackson *et al.*, 2011; Carney and

Myers, 2012; Haug *et al.*, 2012; Mitchell *et al.*, 2013; Yuma-Guerrero *et al.*, 2012; Champion *et al.*, 2013; Newton *et al.*, 2013; Pilowsky and Wu, 2013). We defined adolescent as aged 10–21 years. Any studies of alcohol screening and brief intervention for adolescents that were not included in any of the published systematic reviews were identified and included in this review (Bernstein *et al.*, 2010; Walton *et al.*, 2010; Segatto *et al.*, 2011; Gmel *et al.*, 2012; Winters *et al.*, 2012) (Table 1). Studies that focused upon primary prevention of alcohol use were excluded from this review.

HOW TO IDENTIFY ADOLESCENTS WHO DRINK

Various alcohol screening methods have been developed in the USA but have not been evaluated in the UK. Pilowsky and Wu (2013) reviewed screening instruments used in primary care settings, concluding that the CRAFFT had the most consistent data to support its use for older adolescents (15–18 years) in this setting; however, research comparing brief screening methods with more in-depth measures (such as the Time Line Follow Back) was limited. An earlier systematic review of alcohol screening and brief interventions in young people across a wider range of settings for both adolescents (age 10–17 years) and adults (aged over 18 years), conducted for the English National Institute for Health and Clinical Excellence (NICE) (Jackson *et al.*, 2009), reviewed 51 studies of alcohol screening. Questionnaires were found to perform better than blood markers or breath alcohol concentration in all age groups. In adolescents, the AUDIT questionnaire (Saunders *et al.*, 1993) was found to have greater sensitivity and specificity than other questionnaires (including CAGE, TWEAK, CRAFFT, RAPS4-QF, FAST, RUFT-Cut and POSIT). AUDIT sensitivities for adolescents range from 54 to 87% and specificities from 65 to 97% (Clark and Moss, 2010); the majority of the findings were at the lower end of the range of sensitivity and specificity and are therefore suboptimal for effective screening. Electronic or computerized screening is becoming more widely used and has proved to be an effective and acceptable method of identifying ‘at risk’ adolescents (Pilowsky and Wu, 2013).

Several shortcomings of existing alcohol screening methods for adolescents have been identified (Clark and Moss, 2010). Existing approaches do not sufficiently take account of age and developmental stage of adolescents. Any alcohol consumption may be of concern in younger adolescents, whereas identification of AUDs is more relevant in the older adolescent.

WHAT INTERVENTIONS ARE EFFECTIVE?

A number of reviews on effective interventions for adolescents identified as being in need of help or advice about their drinking have now been published; the most recent of these have focused upon the use of internet, computer and mobile phone technologies, collectively referred to as electronic brief interventions (e-BIs). These reviews present limited evidence that e-BI significantly reduces alcohol consumption compared with minimal or no intervention controls (Champion *et al.*, 2013; Mitchell *et al.*, 2013; Newton *et al.*, 2013). However some caution should be exercised when interpreting these

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STUDY PROTOCOL

Open Access

Linked randomised controlled trials of face-to-face and electronic brief intervention methods to prevent alcohol related harm in young people aged 14–17 years presenting to Emergency Departments (SIPS junior)

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Abstract

Background: Alcohol is a major global threat to public health. Although the main burden of chronic alcohol-related disease is in adults, its foundations often lie in adolescence. Alcohol consumption and related harm increase steeply from the age of 12 until 20 years. Several trials focusing upon young people have reported significant positive effects of brief interventions on a range of alcohol consumption outcomes. A recent review of reviews also suggests that electronic brief interventions (eBIs) using internet and smartphone technologies may markedly reduce alcohol consumption compared with minimal or no intervention controls.

Interventions that target non-drinking youth are known to delay the onset of drinking behaviours. Web based alcohol interventions for adolescents also demonstrate significantly greater reductions in consumption and harm among 'high-risk' drinkers; however changes in risk status at follow-up for non-drinkers or low-risk drinkers have not been assessed in controlled trials of brief alcohol interventions.

Design and methods: The study design comprises two linked randomised controlled trials to evaluate the effectiveness and cost-effectiveness of two intervention strategies compared with screening alone. One trial will focus on high-risk adolescent drinkers attending Emergency Departments (Eds) and the other will focus on those identified as low-risk drinkers or abstinent from alcohol but attending the same ED. Our primary (null) hypothesis is similar for both trials: Personalised Feedback and Brief Advice (PFBA) and Personalised Feedback plus electronic Brief Intervention (eBI) are no more effective than screening alone in alcohol consumed at 12 months after randomisation as measured by the Time-Line Follow-Back 28-day version. Our secondary (null) hypothesis relating to economics states that PFBA and eBI are no more cost-effective than screening alone.

In total 1,500 participants will be recruited into the trials, 750 high-risk drinkers and 750 low-risk drinkers or abstainers. Participants will be randomised with equal probability, stratified by centre, to either a screening only control group or one of the two interventions: single session of PFBA or eBI. All participants will be eligible to receive treatment as usual in addition to any trial intervention. Individual participants will be followed up at 6 and 12 months after randomisation.

(Continued on next page)

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Discussion: The protocol represents an ambitious innovative programme of work addressing alcohol use in the adolescent population.

Trial registration: ISRCTN45300218. Registered 5th July 2014.

Keywords: Adolescents, SBI, eBI, Emergency Department

Background

Alcohol is a major global threat to public health [1]. Although the main burden of chronic alcohol-related disease is in adults, its foundations often lie in adolescence [2]. A recent survey of alcohol use among 14–15 year olds across 36 European countries found that 87% reported lifetime alcohol use, with 57% consuming alcohol on one or more occasion in the previous month [3]. While the proportion of young people in England aged 11–15 years who reported that they have drunk alcohol decreased from 62% to 45% between 1988 and 2011, the mean amount consumed approximately doubled (from 6.4 to 10.4 units of alcohol per week) between 1994 and 2011 [4]. In England there is a rapid increase in alcohol consumption during school years, with 1% of those aged 11 years reporting weekly alcohol consumption compared with 28% of those aged 15 years [4]. Adolescents in the UK are now amongst the heaviest drinkers in Europe [5].

Alcohol consumption and related harm increase steeply from the age of 12 until 20 years [6]. In middle adolescence (ages 15–17 years) binge drinking (single occasion consumption leading to intoxication) often emerges. Binge drinking is associated with increased risk of unprotected or regretted sexual activity [3,5,7], criminal and disorderly behaviour [5,8], suicide and deliberate self-harm [9], injury [5], drink-driving or allowing oneself to be carried by a drinking driver [10], alcohol poisoning [11] and accidental death [12].

Over the past 15 years the World Health Organisation (WHO), the US Surgeon General, the American Medical Association, and the American Academy of Paediatrics have called for practitioners to carry out screening and brief interventions (SBI) for adolescent drinkers [13–16]. The alcohol strategies in both England and Scotland identify adolescents as a key target group in whom to reduce alcohol consumption and related harm [8,17]. However, while there has been an increase in SBI activity in relation to adults presenting to health care providers, adolescents remain a neglected group.

The term Brief Intervention (BI) encompasses a range of therapeutic processes from advice to extended counselling, and typically is delivered in short sessions on one or more occasion. A number of trials focusing upon young people (aged 12 – 21) have reported significant

positive effects of brief interventions on a range of alcohol consumption measures [18–23]. Our recent review of reviews suggests that internet and smartphone delivered BIs (eBI) can significantly reduce alcohol consumption compared with minimal or no intervention controls, and have the added advantage of being more acceptable and easier to implement than more traditional face-to-face interventions [24,25]. Our recently completed study of the prevalence of risky drinking among an adolescent population (aged 10–17 years) found that about 1 in 4 young people presenting to Emergency Departments (EDs) were consuming three or more drinks on one or more occasion over the preceding month, and that this level of consumption was associated with increased physical, social and educational adverse consequences. We also observed a steep transition in drinking prevalence between 13 and 16 years of age.

Several school-based interventions that target non-drinking youths have been found to delay the onset of drinking behaviours [26] and a recent study of adolescents found lower rates of substance misuse initiation among those exposed to a web-based intervention [27]. Web-based alcohol interventions for adolescents also demonstrated significantly greater reductions in consumption and harm among 'high-risk' drinkers [28]; however changes in risk status at follow up for non-drinkers or low-risk drinkers have not been assessed in any well controlled trials of BI. Therefore our proposed work will assess both primary outcomes (delayed onset) and secondary outcomes (reduction of consumption and associated harms in those already drinking at a high level) among a population of adolescents.

Recruitment of both 'high-risk' and 'low-risk' drinkers will have the additional benefit of addressing a major concern among both young people and parents that participation in a trial of this nature may suggest that the participant is drinking at a level that warrants concern and intervention. Young people interviewed as part of this process indicated that they would prefer to take part in a trial if there was no implication that they had an "alcohol problem" and were assured that information about their drinking would not be disclosed to parents or healthcare staff.

Thus we shall conduct two linked trials that will include both high-risk and low-risk drinkers and abstainers, informing them that the study seeks to prevent alcohol-

related harm in young people. In addition embedded within the proposed study is an internal feasibility study conducted prior to proceeding to the main trial.

Objectives of the study

Two linked randomised controlled trials will be conducted. Both trials will evaluate the effectiveness and cost-effectiveness of BI intervention strategies compared with screening alone. One trial will focus on high-risk adolescent drinkers attending Emergency Departments and the other will focus on those identified as low-risk or abstinent from alcohol. In both trials our primary outcome measure will be quantity of alcohol consumed at 12 months after randomisation.

Secondary objectives for each study include:

- To identify key predictors of recruitment to the trials.
- To explore the process of treatment through key psychological constructs that may lead to further refinement of the proposed interventions.
- To identify prognostic factors that improve outcome.
- To explore interactions between participant factors, setting factors, treatment allocation and outcomes.

Our primary (null) hypothesis is similar for both trials: Personalised Feedback and Brief Advice (PFBA) and Personalised Feedback plus electronic Brief Intervention (eBI) are no more effective than screening alone in reducing alcohol consumed at 12 months after randomisation measured by the Time-Line Follow-Back 28-day version. Our secondary (null) hypothesis relating to economics states that PFBA and eBI are no more cost-effective than screening alone.

Methods

The linked trials have been granted ethical approval by the National Research Ethics Service London – Fulham (ref: 14/LO/0721). The linked trials comply with the

Declaration of Helsinki and Good Clinical Practice. Full flow diagrams for the studies are shown in Figure 1.

Both trials begin with a randomised internal pilot study to check that the process of recruitment, screening and intervention is effective and does not adversely affect the ED environment. If that pilot is successful, two linked prospective individually randomised controlled trials will be conducted using a similar design, measures and interventions with 6 and 12 months follow up.

Study settings and participants

The trial will be carried out in 10 EDs across three regions of England: North East, Yorkshire and Humberside, and London. Data collection will be carried out from 10 am to 10 pm seven days per week over a six-month period. During these hours of screening consecutive ED attenders between their 14th and 18th birthdays who meet the inclusion criteria but none of the exclusion criteria will be approached by a researcher and invited to participate in the study once cleared by ED staff to do so.

Eligibility criteria

Inclusion and exclusion criteria have been chosen to maintain a balance between ensuring the sample is representative of the ED population whilst able to engage with both the relevant interventions and follow up.

Inclusion criteria for participants: aged between 14 and 17 years; alert and orientated; able to speak English sufficiently well to complete the research assessment; resident within 20 miles of the ED; able and willing to provide informed consent to screening, intervention and follow-up; if under 16 years, are 'Gillick competent' or have a parent or guardian able and willing to provide informed consent; and own a smartphone or alternatively having access to the internet at home.

Exclusion criteria for participants: severe injury; suffering from serious mental health problem; gross intoxication; specialist services involved because of social or psychological

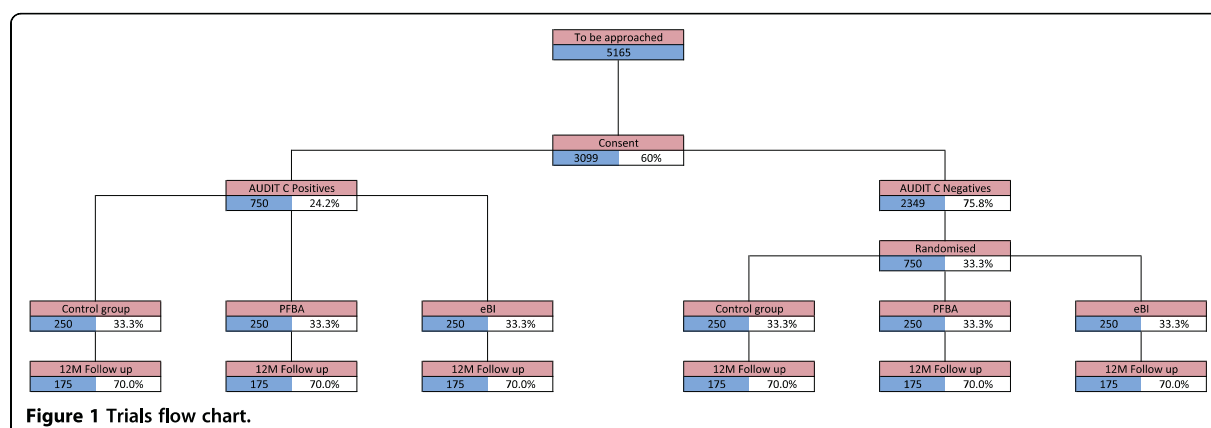


Figure 1 Trials flow chart.

needs; receiving treatment for an alcohol or substance use disorder within the past 6 months; or current participation in other alcohol-related research.

Those who meet the inclusion criteria, fail no exclusion criterion, and score 3 or more on the screening questionnaire – Alcohol Use Disorders Identification Test: Consumption (AUDIT-C) – are eligible for the high-risk study; those who score less are eligible for the low-risk study.

Consent procedure

The study will be introduced to patients, and their parents or guardians if they are aged less than 16 years, as a study about alcohol, lifestyle and health with the focus on preventing alcohol-related harm in all young people attending ED irrespective of their alcohol consumption. Patients attending ED without their parent or guardian will also be approached to take part if ED staff have confirmed that they are 'Gillick competent'.

The study will be first introduced by ED staff and then explained in more detail by research staff orally and in writing using the Patient Information Sheet (PIS). If the patient is under the age of 16 years and accompanied by a parent or guardian, the parent or guardian will also receive the PIS. Patients, and parents or guardians if applicable, will have up to 4 hours to ask any questions about the study and to decide whether or not to take part. To obtain the most valid self-report data patients will be told as part of the informed consent procedure that their answers, including alcohol consumption, will not be disclosed to their parent or guardian or the ED staff without their consent.

If patients agree to participate, informed consent will be collected using an electronic device (iPad) overseen by a research assistant who will also introduce and deliver the allocated intervention to each patient in a private area of the ED. Consent to participate will include permission to give the patient's data and contact details to the research staff, and provide the research team with access to the patient's ED records, and to participate in follow up 6 and 12 months after recruitment.

Screening and baseline assessment

After consent has been given, by parent or guardian if appropriate, the participant will complete a screening and baseline assessment. All participants scoring 3 or more on the AUDIT-C questionnaire (high-risk drinkers) will be randomised between three groups – two intervention groups and the control group receiving screening alone. Of those scoring less than 3 on the AUDIT-C (low-risk drinkers or abstainers) one in three will be randomly selected to continue with the study and then randomised between three analogous groups. Participants who score less than 3 but are not selected for the study will be

thanked for their participation, given a £5 voucher and returned to the care of ED staff.

The screening and baseline assessment includes demographic information and contact details, health and lifestyle questions, the AUDIT-C [29], questions 19, 21 and 22 from the European School survey Project on Alcohol and other Drugs (ESPAD) [5], the Strengths and Difficulties Questionnaire [30], the EQ-5D-5 L [31], and a short service use questionnaire [32]. This takes approximately 10 minutes to complete.

To simplify and enhance data collection we have developed an electronic interface which will only show relevant questions to participants. To maximise completion rates this interface uses an attractive graphic interface. Participants can skip questions or withdraw consent at any stage of the process. All of the instruments have been designed and validated for those aged 14 to 17. The screening and baseline assessment will be conducted by trained researchers with experience of working with adolescents; all researchers will have completed enhanced Disclosure and Barring Service checks in advance. All information given by participants will be treated in confidence.

In total 1,500 participants will be recruited into the trials, 750 high-risk alcohol users and 750 low-risk alcohol users. Participants will be randomized with equal probability, stratified by centre, between a screening only control group and one of the two interventions – a single session of faceto-face Personalised Feedback and Brief Advice (PFBA) or Personalised Feedback plus a smartphone or web-based brief intervention (eBI). All participants will be eligible to receive treatment as usual in addition to any trial intervention.

Planned interventions

Screening only group – Treatment as Usual

After completing the baseline assessment, participants in the screening arm will be thanked for their participation, reminded that a member of the research team will contact them in six and twelve months time to conduct a follow-up interview, and returned to the care of ED staff for usual care.

Personalised Feedback and Brief Advice (PFBA)

The PFBA intervention is structured brief advice that will take approximately 5 minutes to deliver. It is based upon an advice leaflet adapted for the target age group in this study from the SIPS Brief Advice About Alcohol Risk intervention [33,34]. It will be conveyed orally to the participant, and tailored to their risk status – high or low. The advice will cover recommended levels of alcohol consumption for young people; summarise the screening results and their meaning; provide normative comparison information on prevalence rates of high and low risk drinking in young people; summarise the risks of drinking

and highlight the benefits of stopping or reducing alcohol consumption; outline strategies that they might employ to help stop or reduce alcohol consumption; and highlight goals they might wish to consider; indicate where to obtain further help if they are unsuccessful or need more support. The participant will receive a copy of the leaflet, which includes additional information about alcohol intoxication, alcohol poisoning, and alcohol and the law.

Personalised Feedback plus a smartphone or web based brief intervention (eBI)

The eBI smartphone intervention is an offline capable mobile web application that work on a variety of platforms but has been optimised for recent iPhone and Android phones. It has been developed using the concept of gamification so users can navigate, explore, learn facts and figures about alcohol, receive personalised feedback and set goals in an engaging format. Its content will adapt to provide the most pertinent information and advice for high-risk or low-risk drinkers. Games components within the web application will support high-risk drinkers to reduce or stop their alcohol consumption, and low-risk users to maintain abstinence or low risk drinking.

For participants without access to a smartphone but with access to the internet through other computerised devices, access to a web based version of the application will be provided with appropriate instructions on its use.

All participants after receiving their allocated intervention (including the screening only group) will be thanked for their participation, reminded that a member of the research team will contact them in six and twelve months time to conduct a follow-up interview, receive a £5 voucher and returned to the care of ED staff.

Fidelity

To assess the fidelity of the delivery of the interventions to the norm we shall record a random sample of 20% of the interventions delivered by each researcher using the iPad application. The resulting audio files will not contain personal identifiable data and will be stored separately from the patient data.

Follow up assessments

All participants will be followed up at 6 months after randomisation with a brief set of questions and then at 12 months for a full assessment. Follow up interviews will be conducted over the telephone, face to face or electronically via web survey, as preferred by the participant – by research assistants trained in the administration of the assessment tools and blinded to the group allocation of the participants. Letters of thanks will be sent to participants after each follow up stage. On completion of each follow-up interview participants will receive a gift token for £5 in recognition of their participation.

Outcome measures

Primary outcome measure

Total alcohol consumed in standard UK units (1 unit = 8 g ethanol) over the 28 days before the 12-month follow-up, assessed using the Timeline Follow Back interview 28-day version (TLFB28) will be our primary outcome measure. TLFB28 is an established valid and reliable method of ascertaining alcohol consumption in adolescent populations over a reference period ranging from 7 to 365 days [35].

Secondary outcome measures

The TLFB28 will also provide secondary outcomes of percentage of days abstinent, drinks per drinking day, and number of days of heavy episodic alcohol use. Participants will also be asked questions about alcohol use over their lifetimes and the past year, and the consequences of alcohol consumption using questions 19, 21, and 22 from the ESPAD study [5] at baseline. Hazardous alcohol use will be assessed using the extended AUDIT-C questionnaire [29] at baseline and after 6 and 12 months. General health and functioning will be measured using the Strengths and Difficulties Questionnaire [30] at baseline and 12 months. We shall also ask about service use including previous use of health and social services, school attendance and contact with criminal justice; and health utility (EQ-5D-5 L; 31) at baseline, 6 and 12 months.

Process outcome measures

Expectancy will be measured using the ESPAD Question 21 [5] at baseline and 12 months after randomisation. Adherence to the eBI intervention will be assessed by monitoring remotely either when the smartphone device is connected to the internet, or else access to the web application. To assess treatment fidelity a random sample of treatment sessions will be audio-recorded, stratified by researcher, intervention, risk group and centre. These will be assessed for fidelity to behavioural change components using a behaviour rating scale employed in previous studies of alcohol brief intervention. Assessment will be conducted by two independent expert clinician assessors and analysed to take account of agreement between them.

Economic outcome measures

The primary outcome measure for the economic evaluation in the trial will be the quality adjusted life year (QALY) as assessed by the EQ-5D-5 L [31]. The secondary economic outcome measure will be alcohol consumption – derived from the TLFB28 for the high-risk group and from the maintenance of low-risk consumption for the low-risk group. The study will also collect data on the costs of the interventions and on the use of NHS, social care, criminal justice and other resources over 12 months follow-up.

period, using a bespoke version of the Client Service Receipt Inventory (CSRI).

Analysis

Sample size calculation

For both studies the sample size addresses the effect of interventions on the primary outcome measure – alcohol consumption at 12 months after randomisation. To detect the ‘clinically important’ effect size of 0.3 (that previously used for adults) with a significance level of 5% and statistical power of 80% when using a two-sided continuity-corrected test will require 175 in each of the 3 groups, yielding a target of 525 analysable participants in each of the two trials.

Predicting that follow-up at 12 months will be 70% we need to randomise 750 high-risk drinkers and 750 low-risk drinkers. Based on the estimated prevalence of 24.2% for high-risk drinking (namely AUDIT-C ≥ 3) from our earlier survey and a consent rate of 60%, we would need to approach 5165 potential participants over the recruitment period. Of these our survey predicts that 2,350 will be low-risk drinkers consenting to the study. Therefore we shall initially sample one third of these to participate in the study; and we shall adjust this ratio if necessary.

To assess fidelity we plan to record a random sample of 20% of allocations, stratified by researcher, intervention, risk group, and centre. This will provide a total sample of 300 – 50 in each of the six intervention groups across for high and low risks.

Statistical analysis

We shall review our basic design at the end of the internal pilot study, when we have recruited 100 participants, to assess recruitment, consenting and adherence. We shall study the impact of the research on observed screening and prevalence rates to confirm our design, especially the number of centres needed in the main trial.

The outcomes for both studies will be analysed in a similar manner. The primary analysis will be by treatment allocated using a two-sided 5% significance level. Analysis and results will be presented in accordance with the CONSORT guidelines. The primary outcome is total units of alcohol consumed in the 28-days before the 12-month follow-up. After checking the distributional assumption of normality, and transforming the data if necessary, we shall conduct multivariate analysis of covariance adjusting for baseline AUDIT-C score, age, gender and centre to estimate the magnitude of differences between groups. Analysis will be presented as mean differences between groups with 95% confidence intervals. Multiple imputation will be employed with sensitivity analysis to adjust for missing data. Secondary outcomes will be analysed in a similar manner.

Analysis will also model the relationship between pre-randomisation factors and observed outcomes, including whether positive or negative at 12 months according to AUDIT-C. This will take the form of a linear or logistic regression including interaction terms for allocated group. These models will also assess the effect of adherence and fidelity of interventions on observed outcomes.

Cost-effectiveness analysis

The clinical effectiveness analysis will be complemented by an economic evaluation that will estimate the cost-effectiveness of each intervention versus screening alone. Alcohol use disorders and associated problems generate high costs in health care and in society more widely, including costs to the criminal justice and social care systems. The incremental cost effectiveness of the two interventions versus screening will thus be assessed from a societal perspective that will account for resource savings beyond the NHS.

The costs of screening and of delivering the two interventions will be estimated by prospectively monitoring resource inputs to each arm of the trial, including training, valued using standard methods [36]. Effects on NHS and non-NHS costs will be estimated from information gathered on patient contact with primary care, secondary care, specialist health services, social services and criminal justice. These will be assessed retrospectively using the CSRI tool. Service use will be valued using local costs where possible supplemented by national sources and information from previous alcohol studies [34,37,38].

Cost effectiveness will be assessed in terms of the incremental net health benefit (NHB), which converts costs and Quality Adjusted Life Years (QALYs) gained, as estimated from EQ-5D-5 L scores and UK population utility values, into a single monetary value. Differences in QALYs will be estimated from the ‘area under the utility curve’. Both one-way and multi-way sensitivity analyses will be carried out to explore our basic assumptions. Non-parametric bootstrapping will be used to investigate joint uncertainty in costs and effects via cost effectiveness acceptability curves.

Three secondary analyses will be undertaken. The first will adopt a narrower NHS perspective including only costs and savings relating to the NHS and personal social services. This will us to compare the NHB with other interventions assessed using the narrower perspective recommended by the National Institute for Health and Care Excellence (NICE) for the economic evaluation of NHS interventions. The second will compare total societal costs with decreased alcohol consumption for the high-risk group. The third will compare total societal costs with the proportion of the low-risk group maintaining moderate alcohol use.

Qualitative analysis

To explore acceptability of trial tools and processes to young people presenting at emergency departments we shall use semi-structured interviews to study: issues relating to consent by young people aged 14–17 years; alcohol screening; the baseline questionnaire and the burden on emergency care; and young person experiences of intervention delivery. A purposive sample of participants will be selected from the pool of participants in the two linked trials for interviews about the experience and acceptability of receiving the interventions. The sampling will cover the key variables of interest including: gender; ethnicity; age; level of alcohol use; area of the country (North East, Yorkshire and Humber or London), allocated intervention and whether it was delivered. To achieve this, a sample of at least 20 young people is likely to be required. However, recruitment will continue until data saturation is deemed to have been achieved, that is no new issues or themes are arising in the interviews.

A participant information leaflet explaining the qualitative study will be sent to a sample of young people who provided consent to be contacted for interview and, when appropriate, their parents. The young people will be invited to attend a one-to-one semi-structured interview. The interviews will be conducted in a venue that is appropriate, taking consideration of confidentiality, risk assessment, participant convenience and comfort. The purpose of the interview will be explained orally to the participant before arranging interview time and date. Interviews will be audio-recorded and transcribed to support data analysis. Though the topic guide will be produced before the start of interviews, and state the aims and objectives of the study, emergent issues will be explored as they arise.

Data will be subjected to framework analysis, which is appropriate for qualitative health research with objectives linked to quantitative investigation. This analytic strategy is characterised by an approach more deductive than inductive, in which analysis is structured around given themes so findings have detailed relevance to applied research questions. Based on interview notes and review of the interview recordings, important or recurrent themes in interviewees' responses will be identified. These will be combined with a list of key themes of research interest derived from the aims and objectives of the study. All transcripts will be repeatedly read and coded within this framework of prior headings. Data coded under each heading will be reviewed to produce a detailed description, and revised through the course of analysis to take account of all material under that heading. Finally the descriptions of headings within the framework will be compared and the relationships between them elaborated to provide a consistent interpretation of the dataset as a whole. Analysis will continue throughout the process of

data collection, and will be discussed within the subgroup of the research team tasked with managing the qualitative study. This analytic process will assist in the identification of emerging themes and enhance credibility of the thematic framework and interpretation.

Discussion

This protocol represents an innovative and ambitious programme of work evaluating the use of novel interventions to address alcohol use in adolescent populations. The study addresses both effectiveness and cost-effectiveness and is designed to provide evidence of what works in reducing at-risk drinking in this population in addition to how to reduce the progression from low to high risk drinking.

Ethics and confidentiality

The study has been granted ethical approval by the National Research Ethics Service London – Fulham (Ref num 14/LO/0721). There are no anticipated risks in relation to either treatment. There is no documented evidence of adverse events arising from any of the proposed interventions.

All trial data will be identified using a unique trial identification number. No personally identifiable information will be held beyond the final 12-month follow up. Analytical datasets will not contain any patient identifiable information. Anonymised data will be retained for a period of 60 months.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

CD is chief investigator for the study. The study was conceived and designed in collaboration with a number of co-investigators with specific responsibilities for the ongoing conduct of the study; SC IR provide methodological design and quantitative analysis, PD DNB TP trial management and co-ordination, DC CP FA health economics, EG PM IM JS clinical experience, EK RM qualitative research. KD and RP are research workers involved in the ongoing conduct of the study. PD and SC wrote the first draft of the manuscript and all authors read and approved the final manuscript.

Authors' information

Paolo Deluca and Simon Coulton are joint authors.

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