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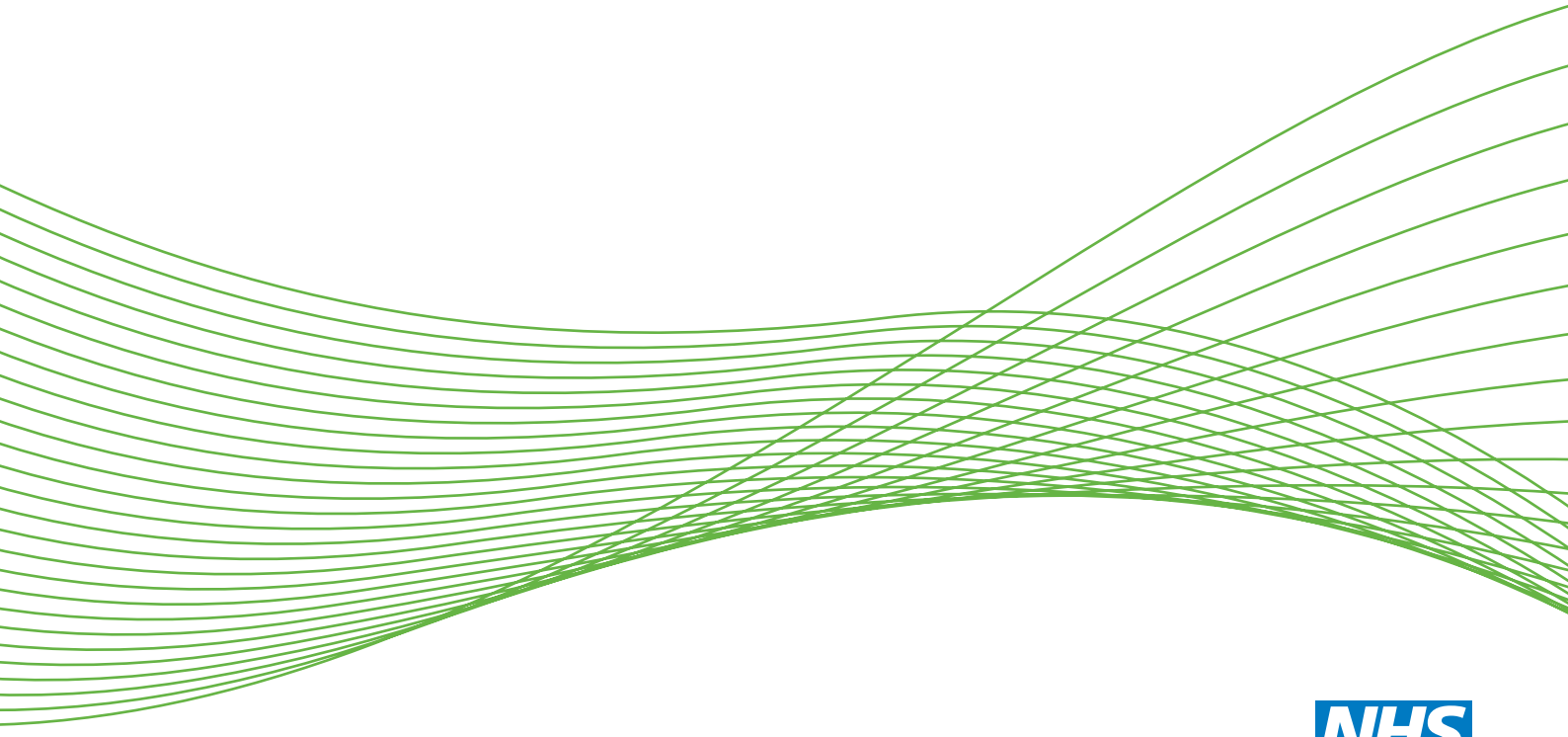

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Abstract

The clinical effectiveness and cost-effectiveness of brief intervention for excessive alcohol consumption among people attending sexual health clinics: a randomised controlled trial (SHEAR)

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Background: Excessive use of alcohol is associated with poor sexual health, but the clinical effectiveness and cost-effectiveness of brief alcohol intervention in this setting has not been investigated.

Objective: To examine the effects and cost-effectiveness of brief intervention for excessive alcohol consumption among people who attend sexual health clinics.

Design: A two-arm, parallel-group, single-blind, pragmatic, randomised controlled trial. Participants were randomised via an independent and remote telephone randomisation service using permuted blocks, stratified by clinic.

Setting: Study participants were recruited from three sexual health clinics in central and west London.

Participants: For inclusion, potential participants had to be aged ≥19 years, drink excessive alcohol according to the Modified-Single Alcohol Screening Question, and be willing to provide written informed consent. We excluded those who were unable to communicate in English sufficiently well to complete the baseline assessment and those who could not provide contact details for the follow-up assessment.

Interventions: Brief advice was delivered by the treating clinician and comprised feedback on the possible health consequences of excessive drinking, a discussion of whether the participant's clinic attendance was linked to current alcohol use, written information on alcohol and health and an offer of an appointment with an alcohol health worker (AHW). Appointments with AHWs took place either in person or by telephone, lasted up to 30 minutes, and used the 'FRAMES' (**F**eedback about the adverse effects of alcohol, an emphasis on personal **R**esponsibility for changing drinking behaviour, **A**dvice about alcohol consumption, a **M**enu of options for further help and advice, an **E**mpathic stance towards the

patient and an emphasis on **S**elf-efficacy) approach. Those in the control arm of the trial were offered a copy of a leaflet providing general information on health and lifestyle.

Main outcome measures: Outcomes were assessed 6 months after randomisation. The primary outcome was mean weekly alcohol consumption during the previous 90 days. The main secondary outcome was unprotected sex during this period.

Results: Eight hundred and two people were recruited to the study of whom 592 (74%) were followed up 6 months later. Among 402 participants who were randomised to brief intervention, 397 (99%) received brief advice from the treating clinician and 81 (20%) also received input from an AHW. The adjusted mean difference in alcohol consumption after 6 months was –2.33 units per week [95% confidence interval (CI) –4.69 to 0.03 units per week, $p = 0.053$] for those in the active arm compared with the control arm. Unprotected sex was reported by 154 (53%) of those who received brief intervention and by 178 (59%) of controls (adjusted odds ratio 0.89, 95% CI 0.63 to 1.25, $p = 0.496$). Participants randomised to brief intervention reported drinking a mean of 10.4 units of alcohol per drinking day compared with 9.3 units among control participants (difference 1.10, 95% CI 0.29 to 1.96, $p = 0.009$). We found no statistically significant differences in other outcomes. Brief intervention (brief advice and input from an AHW) cost on average £12.60 per person to deliver and did not appear to provide a cost-effective use of resources.

Conclusions: Introduction of universal screening and brief intervention for excessive alcohol use among people who attend sexual health clinics does not result in clinically important reductions in alcohol consumption or provide a cost-effective use of resources. While people attending sexual health clinics may want to achieve better sexual health, attempts to reduce alcohol consumption may not be seen by them as a necessary means of trying to achieve this aim.

Trial registration: This trial is registered as ISRCTN 99963322.

Funding: This project was funded by the NIHR Health Technology Assessment programme and will be published in full in *Health Technology Assessment*; Vol. 18, No. 30. See the NIHR Journals Library website for further project information.

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List of abbreviations

AD-SUS	Adult Service Use Schedule
AHW	alcohol health worker
CEAC	cost-effectiveness acceptability curve
CI	confidence interval
EQ-5D	European Quality of Life-5 Dimensions
FRAMES	**F**eedback about the adverse effects of alcohol, an emphasis on personal **R**esponsibility for changing drinking behaviour, **A**dvice about alcohol consumption, a **M**enu of options for further help and advice, an **E**mpathic stance towards the patient and an emphasis on **S**elf-efficacy
HIV	human immunodeficiency virus
ICER	incremental cost-effectiveness ratio
IMOR	informative missingness odds ratio
IQR	interquartile range
M-SASQ	Modified-Single Alcohol Screening Question
OR	odds ratio
QALY	quality-adjusted life-year
SD	standard deviation
SHEAR	Sexual Health and Excessive Alcohol: Randomised trial
STI	sexually transmitted infection

Plain English summary

Many people who attend sexual health clinics drink more than the recommended amount of alcohol. We therefore set out to examine whether or not giving advice about alcohol and health to people who attend these clinics and drink excessively helped them drink less and achieve better sexual health, and whether or not the provision of such advice provided good value for money.

We conducted the study in three sexual health clinics in London. We gave half of the people attending these clinics who were drinking above recommended levels of alcohol a leaflet on health and lifestyle. The other half was offered brief intervention. This consisted of brief advice, a leaflet on alcohol and health, and the offer of an appointment with an alcohol health worker (AHW) who could provide further information and support. We collected follow-up information from people 6 months after they entered the study.

At follow-up, we found little difference in the amount that people who had been offered brief intervention were drinking. People offered the intervention drank just over 2 units of alcohol – about one pint of lager – less per week. We did not find differences in sexual health between those who were offered brief intervention and those who were not.

Many people who attend sexual health clinics are drinking at above recommended levels but the type of intervention we examined did not lead to big differences in the amount they drank. Offering this type of intervention to people who attend sexual health clinics and drink excessively does not provide a good use of resources.

Scientific summary

Background

Concerns have been expressed about high levels of alcohol consumption among people attending sexual health clinics. Cross-sectional surveys have repeatedly demonstrated that a high proportion of people attending these clinics are drinking above recommended levels. It has been reported that those who drink excessively are more likely to be diagnosed with a sexually transmitted infection (STI). Brief intervention for excessive alcohol consumption has been shown to be effective across a range of medical settings, but there is very little evidence about its impact when offered to people attending sexual health clinics. The effects of brief intervention for excessive alcohol consumption on sexual health outcomes have not been examined and cost-effectiveness of this approach is unknown.

Objectives

We aimed to examine the clinical effectiveness and cost-effectiveness of opportunistic brief intervention for excessive alcohol use among people who attend sexual health clinics. To achieve this aim we:

- examined whether or not brief intervention reduced subsequent alcohol consumption measured 6 months later compared with control treatment
- examined whether or not brief intervention compared with control treatment was associated with changes in sexual behaviour
- examined the cost-effectiveness of brief intervention compared with control treatment.

Methods

Study design

The study was a single-blind, parallel-group, randomised controlled trial.

Participants

Study participants were recruited from three sexual health clinics in central and west London. To take part in the study, potential participants had to be aged 19 years or above, be drinking excessively according to the Modified-Single Alcohol Screening Question and be willing to provide written informed consent. We excluded any person who was unable to communicate in English sufficiently well to complete baseline questionnaires, anyone who did not have an address or contact telephone number and anyone who believed they may not have been contactable again 6 months later.

Main outcome measures

All outcomes were measured 6 months after randomisation and assessed behaviour in the 3 months prior to the date of the assessment. The primary outcome was mean weekly alcohol consumption (measured using the Form 90) and the main secondary outcome was the proportion of participants who reported any unprotected sex during the previous 3 months. Secondary outcomes were mean units of alcohol consumed per drinking day and percentage days abstinent (both measured using the Form 90); whether or not the participant was drinking excessively; total number of sexual partners; number of unprotected sexual partners; any incidence of regretted sex; any incidence of unprotected sex after drinking alcohol or while drunk; how long they knew their last sexual partner before they had sex with them; unplanned pregnancy; and any new diagnosis of a STI. Finally we collected data on health-related quality of life

(measured using the European Quality of Life-5 Dimensions scale), and resource use during the past 6 months measured using a modified version of the Adult Service Use Schedule.

Study procedures

On days when recruitment took place, clinic staff gave all those attending the service a postcard with information about the study and asked people whether or not they would be willing to meet a researcher. If they agreed, the researcher met with them and provided information about the study. If the participant provided written informed consent, the researcher assessed eligibility and collected baseline data. Baseline assessments were completed using a computer-assisted self-completion questionnaire. Following completion of baseline assessments, participants were randomised via an independent and remote telephone randomisation service by an independent Clinical Trials Unit using permuted blocks, stratified by site. Block size was randomly assigned between four and six. Equal numbers of participants were randomised to each arm of the trial. The researcher then notified the treating clinician which arm of the trial the participant was in.

The Sexual Health and Excessive Alcohol: Randomised trial (SHEAR) had two treatment conditions. Brief intervention comprised brief advice delivered by the treating clinician followed by input from an alcohol health worker (AHW) for those willing to receive it. Those randomised to control treatment received a general health information leaflet with advice about smoking, alcohol, diet and exercise. Brief advice from the treating clinician consisted of feedback on the possible health consequences of excessive alcohol consumption, written information about alcohol and health, and an offer of an appointment with an AHW. The appointment with the AHW lasted up to 30 minutes. In the case of any participant who was drinking at a harmful or dependent level, the AHW had the option of arranging a follow-up appointment or referring the participant to local alcohol services for individual alcohol counselling, detoxification or other treatments. Any participant who was unable to attend an appointment on the day was offered an appointment at a later date or the option of telephone-based information and advice.

After 6 months the participants were contacted by a researcher masked to the participant allocation status and asked to complete a telephone interview. Participants who completed the follow-up interview were offered a £15 honorarium in recognition of their time and any inconvenience related to their involvement in the study.

Statistical methods

The initial sample size calculation was based on identifying differences in mean weekly alcohol consumption found in our previous trial of brief intervention in an emergency department. In the first few months of the trial the rate of recruitment was higher than expected and the sample size was therefore increased to provide additional power to test both the primary and main secondary outcome: the proportion reporting unprotected sexual intercourse during the previous 3 months.

The final sample size was based on a practical size of 380 per arm (760 in total). If 65% of participants had unprotected sex in the control group compared with 50% in the intervention arm, the power to detect such an effect would be above 90%, assuming 25% drop-out, and a clustering design effect of 1.15.

Results

Eight hundred and two participants were recruited to the trial between August 2010 and May 2012, of whom 402 were randomised to brief intervention and 400 to control treatment. Participants had a median age of 27 years (interquartile range 24–30 years) and 432 (54%) were female. All but five participants in the active arm of the trial received brief advice from the treating clinician ($n = 397$, 99%). Of these, 81 participants (20%) also received input from an AHW.

Two hundred and ninety-one participants (72%) in the intervention arm and 301 participants (75%) in the control arm completed the follow-up interview. The participants allocated to the intervention arm were drinking 18.1 units per week and those allocated to the control arm were drinking 20.3 units per week. The adjusted mean difference in alcohol consumption between those in the active arm of the trial and those in the control group was therefore –2.33 units per week [95% confidence interval (CI) –4.69 to 0.03 units per week, $p = 0.053$]. Unprotected sex was reported by 154 (53%) of those randomised to brief intervention and by 178 (59%) of those randomised to the control treatment (adjusted odds ratio 0.89, 95% CI 0.63 to 1.25, $p = 0.496$). Participants randomised to brief intervention reported drinking a mean of 10.4 units of alcohol per drinking day compared with 9.3 units among the control group (a difference of 1.1 units, 95% CI 0.29 to 1.96 units, $p = 0.009$). We did not find significant differences in any other secondary outcomes between each arm of the trial.

Mean costs per participant over 6 months were £319 among those randomised to brief intervention and £311 among those randomised to the control treatment. Although the additional cost of brief intervention was small compared with the total cost of care provided (£12.57, standard deviation £6.59), we did not find evidence to support the cost-effective use of this intervention.

Conclusions

We did not find evidence that brief intervention for excessive alcohol use among people attending sexual health clinics is associated with clinically important reductions in alcohol consumption or provides a cost-effective use of resources.

Recommendations for future research

1. Interventions for young people who present to sexual health services and drink at a level that may be harmful to their health should be developed and tested.
2. The impact that population-based strategies for reducing levels of alcohol misuse have on sexual health outcomes should be examined as part of wider efforts to assess their impact on health-related outcomes.

Trial registration

This trial is registered as ISRCTN 99963322.

Funding

Funding for this study was provided by the Health Technology Assessment programme of the National Institute for Health Research.

Chapter 1 Aims

The Sexual Health and Excessive Alcohol: Randomised trial (SHEAR) aimed to examine the effects and cost-effectiveness of opportunistic brief intervention for alcohol misuse among people who attend sexual health clinics and are found to consume excessive alcohol. To achieve this aim we:

1. tested whether or not brief intervention reduced subsequent alcohol consumption measured 6 months later compared with control treatment
2. examined whether or not brief intervention compared with control treatment was associated with changes in sexual behaviour
3. examined the cost-effectiveness of brief intervention compared with control treatment.

Hypotheses

i. Brief intervention for those attending sexual health clinics and drinking excessively reduces mean weekly alcohol consumption over a 12-week period prior to the 6-month follow-up interview (i.e. weeks 13–24 after intervention).
ii. Brief intervention for those attending sexual health clinics and drinking excessively reduces the likelihood of unprotected sexual intercourse over a 12-week period prior to the 6-month follow-up interview.
iii. Brief intervention for those attending sexual health clinics and drinking excessively is more cost-effective than control treatment.

Chapter 2 Background

Concerns have been raised regarding increases in levels of alcohol consumption in many countries.[1] It is estimated that as many as one in five adults in the UK drinks too much alcohol.[2] This may take the form of sustained excessive consumption or episodic bouts of 'binge' drinking. Excessive alcohol consumption can lead to a range of physical and mental health problems which are estimated to result in direct costs to the NHS of £3B a year.[3]

Increasing levels of alcohol misuse in the UK have been accompanied by large increases in rates of sexually transmitted infections (STIs).[4] Data from observational studies show that alcohol consumption and sexual ill health may be linked. Bellis and colleagues found among a large sample of young people in nine European cities that alcohol consumption was associated with number of sexual partners and age at first sexual contact.[5] In the USA, changes in the price of alcohol in the 1980s and 1990s were highly correlated with changes in rates of gonorrhoea,[6] and policies which succeeded in reducing drunk driving rates in young men in the USA were noted to be associated with reductions in gonorrhoea rates among young males.[7] A meta-analysis of data from a range of observational studies concluded that excessive alcohol use is associated with increased likelihood of STIs.[8]

A number of cross-sectional studies among people attending sexual health clinics have demonstrated high levels of alcohol consumption. We found that one-third of people attending a sexual health clinic in London were drinking excessively,[9] and others have reported even higher levels.[10] Among teenagers, levels are higher still, with up to 70% drinking excessively.[11] In a pilot study which involved collecting cross-sectional data from 253 patients attending a sexual health clinic in central London, we found that 40% of people who drank excessively believed their attendance was related to alcohol.

Within the NHS, interventions for individuals who drink excessively include those delivered to people who request help with their drinking and those who are found to be drinking excessively when they present to health-care services for other reasons. These 'opportunistic' interventions involve assessment of alcohol use followed by information, advice and techniques aimed at promoting behavioural change. Research conducted in other contexts has demonstrated the value of brief interventions for excessive drinking.[12,13] Systematic reviews of brief interventions for excessive alcohol use have shown that interventions delivered in one session appear to be as effective as more lengthy ones.[14,15] More recently, 'stepped interventions,' in which people receive interventions of greater intensity depending on the extent of their needs, have also demonstrated positive effects.[16] Those with excessive use of alcohol are offered brief feedback and information and the offer of additional treatment, and those with harmful or dependent alcohol misuse are offered referral on to other services, if required.

The content of brief interventions for alcohol misuse varies but generally includes features incorporated in the acronym FRAMES (**F**eedback about the adverse effects of alcohol, an emphasis on personal **R**esponsibility for changing drinking behaviour, **A**dvice about alcohol consumption, a **M**enu of options for further help and advice, an **E**mpathic stance towards the patient and an emphasis on **S**elf-efficacy).[17,18] In addition to reducing levels of alcohol consumption, brief interventions have also been shown to lead to reductions in accidents and injuries and reattendance to hospital.[16,19,20]

Although many studies have drawn attention to associations between alcohol misuse and poor sexual health, very few studies have examined the acceptability or impact of opportunistic intervention for alcohol use among people attending sexual health clinics. We have previously reported that most people who attend sexual health clinics and are found to be drinking excessively are willing to receive brief advice.[9] In their study of young people aged 14–17 years who attended a sexual health clinic in Glasgow, UK, and were found to be drinking excessively, Keogh and colleagues reported that 68% accepted the offer of brief intervention and two-thirds of these received it.[11] The only randomised trial of brief intervention for alcohol in a sexual health setting to have been published to date was conducted by Lane and colleagues in

a single clinic in Sydney, Australia.[21] Among 133 people who took part in the study and completed a 3-month follow-up interview, there was a non-statistically significant trend towards lower levels of excessive drinking among those in the active arm of the trial.

Recognition of the link between alcohol misuse and poor sexual health led to the Royal College of Physicians to call for research examining the impact of interventions to reduce alcohol misuse on sexual behaviour.[22] However, to date, no study has been large enough to demonstrate clinically important reductions in alcohol use among people attending sexual health clinics or examined the impact of this intervention on sexual behaviour.

Chapter 3 Methods

The study was a parallel-arm, single-blind, individually randomised controlled trial exploring the clinical effectiveness and cost-effectiveness of brief intervention for excessive alcohol consumption among adults aged ≥19 years who attend sexual health clinics. The trial was an integrated clinical and economic evaluation and compared the effects of brief intervention with the effects of control treatment on excessive alcohol consumption, sexual behaviour, health-related quality of life and costs in the 6 months after randomisation.

Ethical approval was obtained from West London Research Ethics Committee 3 (10/H0706/29) and the study protocol was registered with Controlled Clinical Trials (ISRCTN 99963322) prior to the start of data collection.

Changes to original protocol

Prior to the start of the study, but following trial registration, one of the clinics where we were due to recruit participants withdrew from the study as it was unable to provide input from an alcohol health worker (AHW). Recruitment was therefore restricted to three sites. Another clinic started to provide additional support for young people aged ≤18 years aimed at promoting sexual health. This intervention included discussion of alcohol use. We therefore changed our eligibility criteria to include only those aged ≥19 years.

We made one additional change to the study after commencement. The original sample size for the study was set at 320, which was judged to be large enough to detect clinically important differences in levels of alcohol consumption among those offered active and control treatment. In the first few months of the trial it became clear that the rate of recruitment was higher than we had originally anticipated. With the support of the funder and the independent Trial Steering Committee and following approval of the Research Ethics Committee we increased the sample size to 760 in order to have sufficient power to examine clinically important differences in our main secondary outcome: the proportion of participants who reported any unprotected sex at follow-up.

The public and patients were involved at several stages of the study (see *Appendix 1* for further details).

Study setting and sample

Study participants were recruited from three sexual health clinics in central and west London. These clinics serve a diverse population of over 500,000 people with high levels of alcohol misuse and poor sexual health.[22,23]

To participate in the study people had to be aged ≥19 years, be drinking excessively according to the Modified-Single Alcohol Screening Question (M-SASQ)[24] and be willing to provide written informed consent to take part in the study. We excluded any person who was unable to communicate in English sufficiently well to complete baseline questionnaires, anyone who did not have an address or contact telephone number and anyone who believed they may not have been contactable in 6 months' time.

Study interventions

The SHEAR had two treatment conditions: brief intervention for excessive use of alcohol and control treatment.

Brief intervention

Brief intervention was based on that used in a previous trial conducted in an emergency department[16] and was found previously to be acceptable to clinicians in a sexual health clinic.[9] The intervention is designed to be used by busy front-line clinicians such that it can be delivered within 2 or 3 minutes. The intervention is designed to deliver the treating clinician after they have dealt with the person's presenting complaint. The intervention consists of four components:

i. confirming the current level of alcohol use and brief feedback that alcohol use at that level has the potential to harm health
ii. making a link between alcohol and clinic attendance
iii. written information on alcohol and health in the form of a leaflet recommended by the Department of Health: 'How much is too much?'[25]
iv. the offer of an appointment with an AHW.

This form of brief advice is shorter than some other forms of intervention, which can take 5–10 minutes to deliver. It is focused on these four simple tasks. Verbatim text that can be used to deliver each of these is available at: www.alcohollearningcentre.org.uk/_library/PAT_2011_Paddington_Alcohol_Test.pdf.

On days when participants were recruited from the clinics, an AHW was available to see those who were willing to receive further help. The appointment with the AHW lasted up to 30 minutes and used the FRAMES approach.[17,18] In the case of any participant who was drinking at a harmful or dependent level, the AHW had the option of arranging a follow-up appointment or referring the participant to local alcohol services for individual alcohol counselling and other services. In the event that the participant was unable to attend an appointment that day, he or she was offered an appointment at a later date or telephone-based support and advice.

Control treatment

Those randomised to control treatment were offered a copy of the leaflet 'Five Choices to Help You Stay Healthy'.[26] This provides general information on health and prevention of ill health including information on alcohol use, diet, exercise and cigarette smoking and details of how to obtain further information about health and lifestyle.

Training and support for the delivery of brief intervention

A short training session was delivered at each of the hospital sites before participants were recruited. This session was incorporated into existing staff meetings. In the session, we provided background to the study, an overview of study logistics and details of each of the four components of the brief advice that clinicians were asked to provide those in the active arm of the trial. Clinicians were asked to use recommended text for delivering each of the four components of the intervention and encouraged to use web-based information at www.alcohollearningcentre.org.uk.[27]

In addition to this, the lead researcher (RS) spoke to front-line clinicians on the days when recruitment was taking place. She provided support and advice to clinicians, gave feedback on their performance and checked that brief advice was being delivered in accordance with the trial protocol.

All AHWs who took part in the study were experienced practitioners who had undertaken specific training in counselling people who misuse alcohol. Three were employed by the NHS and one was employed by a statutory organisation (Turning Point). All AHWs received regular clinical supervision. AHWs were encouraged to discuss work with trial participants along with other patients they saw during these sessions.

Treatment fidelity

In order to assess treatment fidelity, clinicians delivering brief advice and AHWs were asked to complete a treatment proforma for each person they saw. These proforma can be found in *Appendices 2* and *3* of this report. The proforma completed by clinicians was based on one we used in a previous trial.[16] Front-line clinicians were asked to indicate whether or not they had delivered each of the four components of brief advice and AHWs were asked to complete a longer proforma which recorded the number and length of session(s), interventions delivered during the session(s) and further information of referrals that were subsequently made. A member of the research team was on hand to check completion of these proforma and to support and advise clinicians on delivering brief advice if required. Proforma were examined at the end of the study to identify the proportion of those in the active arm of the trial who received brief advice and brief intervention.

Outcome measures

Primary and secondary outcomes

The primary outcome was mean weekly units of alcohol consumed during the previous 90 days. The main sexual health outcome of interest was having had any unprotected vaginal or anal sex in the past 3 months; this was referred to as our 'main secondary outcome'. Both of these variables were measured at follow-up. The other secondary outcomes are detailed below in the report.

Baseline

Basic demographic and clinical data on age (years), gender, ethnicity and reason for presentation were extracted from clinic records at baseline and checked with the participants.

Alcohol consumption was assessed using the M-SASQ. The M-SASQ is a brief validated measure of excessive alcohol use that is acceptable to patients in general medical settings.[24] It consists of a single question – for men: 'How often do you drink more than 8 units of alcohol on one occasion?' and for women: 'How often do you drink more than 6 units of alcohol on one occasion?' To help people answer this question they are shown a card which describes what 1 unit of alcohol is. Those drinking this amount once a month or more were considered eligible to participate in the trial. The question on alcohol was embedded in a series of four other questions asking about diet, exercise and smoking. In addition, eligible participants were asked about:

i. Sexual behaviour during the last 3 months using key variables that have been validated in other studies.[28] The variables comprised: number of sexual partners; number of people with whom they had unprotected sex with (vaginal or anal sex without a condom); any incidence of regretted sex; and how long they had known their last sexual partner before they had sex with them.
ii. Health-related quality of life using the European Quality of Life-5 Dimensions (EQ-5D).[29] This is a generic preference-based measure for describing and valuing health-related quality of life assessed in five domains (mobility, self-care, usual activities, pain/discomfort, anxiety/depression). Utility scores are then derived from the EQ-5D, with higher scores indicating a better quality of life.

Six-month follow-up

Follow-up data were obtained by a telephone interview carried out by a researcher who was masked to the participant's allocation status. The following outcomes were examined:

i. Alcohol consumption in the last 90 days using the Form 90. The Form 90 is a validated alcohol consumption assessment tool which provides a detailed day-by-day account of alcohol use in the 90 days prior to the interview.[30] Data from this questionnaire were used to calculate the primary outcome – mean weekly units of alcohol consumed during the previous 90 days.

Secondary alcohol-related outcomes were mean units consumed per drinking day, percentage of days abstinent and whether the participant was drinking excessively according to the M-SASQ criteria.

ii. Sexual behaviour in the last 90 days was assessed by a set of questions including total number of sexual partners; number of partners with whom the participant had had unprotected sex; any incidence of regretted sex; any incidence of unprotected sex after drinking alcohol and while feeling drunk; how long participants knew their last sexual partner before they first had sex with them; unplanned pregnancy; and any new diagnosis of a STI.

iii. Service use data for the economic evaluation were collected using the Adult Service Use Schedule (AD-SUS), an interviewer-assessed instrument designed by one of the authors and based on previous economic evaluations in similar adult mental health and addiction populations.[31] The AD-SUS records the number and duration of contacts with a range of health and social service professionals, all hospital contacts and medications taken. Data on uptake of the brief intervention were collected from records to avoid participants revealing their treatment group to the research assessors. Data on indirect time, including preparation and supervision, were collected directly from the treating clinician.

Study procedures

Recruitment

At each clinic where recruitment took place we displayed posters in the waiting room providing information about the study. On days when recruitment took place, clinic staff gave all those attending the service a postcard with information about the study and asked people whether or not they would be willing to meet a researcher. If they agreed, the researcher explained the rationale for the study and gave the person a copy of the patient information leaflet. The researcher encouraged potential participants to spend as much time as they wanted asking questions about the study and considering whether or not they wish to take part. Average waiting times in these clinics between presenting to reception and seeing a clinic doctor are over 2 hours. This ensured that potential participants had sufficient time to hear about the study, consider whether or not they wanted to participate and complete the baseline assessment. Prior to completing the baseline assessment, participants signed and dated the informed consent form. For those willing to provide consent, eligibility to participate in the study was assessed and baseline clinical and demographic data were collected. Baseline assessments were completed using a computer-assisted self-completion interview.[32,33]

Contact details were then sought to enable the researchers to contact the participant at follow-up. Researchers were assisted in recruitment by clinical studies officers of the UK Mental Health Research Network.

The researcher provided all those who were ineligible with written information about health and lifestyle if they wanted this.

Randomisation

Participants were randomised via an independent remote automated telephone-based service operated by the Clinical Trials Unit at the University of Aberdeen, UK. Permuted blocks stratified by the clinic were used, with allocation ratio between arms of 1 : 1 and block sizes randomly assigned to four or six.

The researcher notified the treating clinician as to which arm of the trial the participant was in. All other members of the trial team, including researchers involved in the collection of follow-up data, were masked to treatment allocation.

Follow-up

Three months after randomisation, study participants received a telephone call, text or e-mail, thanking them for taking part in the study and reminding them that they would be contacted in 3 months' time to complete the follow-up interview. They were also asked whether or not their contact details were likely to change during this period. If, at 6 months, our attempts to contact a participant were unsuccessful, and consent had been given, the researchers checked the participant's contact details against those given during any subsequent visits to the clinic and contacted a nominated family member or friend. Follow-up interviews were carried out by telephone.

Masking of raters

Data were held securely and were password protected. Details of allocation status were held separately and were not accessible to the researchers involved in collecting follow-up data. Researchers involved in recruiting study participants played no part in follow-up interviews. Information on receipt of brief advice and brief interventions was gathered separately from proforma completed by clinicians and AHWs.

Participant honoraria

Participants who completed the follow-up interview were offered a gift voucher for £15 in recognition of their help with the study and to compensate them for any inconvenience they experienced.

Sample size

In the absence of information on weekly alcohol consumption among people attending sexual health clinics we based our sample size calculation on data from a previous trial set in an emergency department.[16] We calculated that 97 evaluable participants would be needed per treatment arm to have 80% power to detect a difference in mean weekly alcohol consumption of 23.4 units with a standard deviation (SD) of 58.0 units (or 0.40 standardised difference), using a 5% level of statistical significance. However, a clustering effect may occur in the intervention arm due to different clinicians delivering the intervention. Power calculation formulae for a partially clustered design have been reported by Roberts and Roberts.[34] Based on an average cluster size of 7 and an intraclass correlation coefficient of 0.04 in the intervention arm, a total of 112 evaluable patients in each arm (16 clusters of 7 in the control group) would provide above 80% power to detect such a difference. This corresponds to an inflation factor for clustering (design effect) of 1.15. Expecting a 30% drop-out rate at 6 months, we therefore aimed to recruit 320 participants.

During the first few months of the trial it became clear that the rate of recruitment was higher than we anticipated; the sample size was therefore modified to provide additional power to test both the primary and main secondary hypotheses (a reduction in unprotected sexual intercourse).

The final sample size was based on a practical size of 380 per arm (760 in total). If 65% of participants had unprotected sex in the control group, compared with 50% in the intervention arm, the power to detect such an effect would be above 90%, assuming 25% drop out, and a clustering design effect of 1.15. The power would remain above 80% if the absolute difference was above 13%.

Statistical analysis

A detailed statistical analysis plan was developed and published online before analysis.[35] We used the statistical package Stata (StataCorp LP, College Station, TX, USA; version 12) for all of the descriptive analysis, graphs and regression models. All analyses were carried out according to randomisation arm

(intention to treat), and two-sided *p*-values were considered significant when < 0.05. Descriptive analyses, including tables and graphs of baseline demographic and clinical variables, were conducted.

The primary outcome was compared between arms using random-effects linear regression adjusted for age (years), sex, clinic and M-SASQ measured at baseline. A random effect was included in the intervention arm to take into account any possible clustering by the clinician delivering the intervention, and residuals were allowed to differ by arm. This corresponds to the analysis suggested for partially nested trial design by Walwyn and Roberts.[36] Sensitivity analyses were then performed to confirm the validity of the result. Different hierarchical models were fitted and standard errors were calculated using approaches more robust to non-normally distributed residuals, such as robust standard errors or non-parametric bootstrapping. Ten thousand bootstrap resamples were obtained to achieve stable estimates. Results of direct mean comparison (*t*-test) and of adjustment for imbalanced baseline characteristics were also explored.

The main secondary outcome was analysed using random-effects logistic regression and adjusting for unprotected sex at baseline. As for the primary outcome, various sensitivity analyses were also performed. Other secondary outcomes were compared using appropriate regressions or tests and adjusted for age (years), sex, clinic and the corresponding outcome variable at baseline. As the addition of a clinician random effect was found to have little effect on results, it was ignored for the comparison of secondary outcomes.

Baseline data were missing for one participant, and mean imputation was used in this case for adjusted analyses.[37] Baseline characteristics of participants who dropped out from the trial were compared with the completers. Multiple imputation by chained equations was performed to impute the primary and main secondary outcomes at the follow-up visit. The imputation model included the important predictors of missingness and outcomes. Predictive mean matching was used to impute the alcohol consumption. Imputation was performed stratified by randomisation arm, and clustering by clinician was ignored in the imputation and analysis model. In order to reach negligible Monte Carlo error, 500 imputations were performed. Further sensitivity models allowing for missing not-at-random mechanism were also considered.[38] They were based on a pattern mixture approach, considering a large range of possible differences in outcomes between participants who completed the follow-up and those who did not. Mean difference and confidence intervals (CIs) were estimated using the 'rctmiss'[39] user-written command in Stata.

To assess for possible heterogeneity of the intervention effect, primary and main secondary outcomes are also reported by the following subgroups: gender, age (< 25 years, 25–35 years, > 35 years), number of sexual partners in the 6 months preceding baseline (1 vs. > 1), and sexual orientation (heterosexual vs. non-heterosexual). We then tested for the presence of an interaction term between the subgroups and treatment arm. Age (years) was additionally tested as a continuous variable and considered to have a linear effect in the regression. For participants in the intervention arm, the alcohol consumption was also described by categories of intervention received.

Economic analysis

Estimation of costs

The economic evaluation took a NHS/Personal Social Service perspective, as recommended by the National Institute for Health and Care Excellence (NICE),[40] and included all hospital contacts (inpatient, outpatient, accident and emergency), community health and social services (primary health care, community health services and social services) and medication.

All unit costs were for the financial year 2010–11. A summary of unit costs applied is listed in *Table 1*. Costs for NHS hospital contacts were sourced from NHS reference costs 2011[41] and community health and

TABLE 1 Unit costs and sources used in economic evaluation

Variable	Unit cost or range (£)	Source
Inpatient (per night)	415.00–550.00	NHS reference costs[41]
Outpatient (per appointment)	29.00–1178.00	NHS reference costs[41]
Accident and emergency (per attendance)	130.00	NHS reference costs[41]
GP (per minute)	1.10–2.10	Curtis 2011[42]
Practice nurse (per minute)	0.72	Curtis 2011[42]
Health visitor/district nurse (per visit)	46.00	NHS reference costs[41]
Physiotherapist (per contact)	47.00	NHS reference costs[41]
Counsellor (per minute)	1.10	Curtis 2011[42]
Chiropody/podiatry (per contact)	47.00	NHS reference costs[41]
Advice centre (per minute)	0.45	Curtis 2011[42]
Complementary medicine (per contact)	60.00	Web search February 2013
NHS Direct (per call)	15.64	www.nhsdirect.nhs.uk[43]
Community sexual health clinic (per contact)	65.00	NHS reference costs[41]

GP, general practitioner.

social service costs were taken from the annual unit costs of health and social care publication from the University of Kent[42] or from relevant websites (as outlined in *Table 1*). The cost of medications were calculated based on averages for *British National Formulary* chapters and were taken from Prescription Cost Analysis.[44]

The cost of the intervention was estimated using the micro-costing (bottom-up) approach set out by the Personal Social Services Research Unit at the University of Kent, UK.[42] We assumed that the brief advice was delivered by registrars, so used the median salary for registrars as the starting point. To this, employer national insurance and pension contributions were added as well as direct and indirect overhead costs to reflect hospital costs, administrative and managerial support costs, and capital costs. Total salary and overhead costs were then divided by the number of working hours per year, taken from Curtis,[42] to calculate the cost per hour. Adjustments to this cost were made to reflect time taken by physicians in direct contact with patients and time spent on other activities. If the study participant saw an AHW in addition to the treating clinician then the cost of the AHW was added separately and reported as part of the cost of the intervention. The costs of the training were not included in the cost of the intervention.

Calculation of quality-adjusted life-years

Quality-adjusted life-years (QALYs) were calculated on the basis of the EQ-5D health state classification instrument, where health states are assigned a utility score using responses from a representative sample of adults in the UK.[45] QALYs were calculated as the area under the curve defined by the utility values at baseline and 6-month follow-up and it was assumed that changes in utility score over time followed a linear path.[46] An individual with perfect health would have an EQ-5D score of 1, which would translate to a QALY estimate of 0.5 QALYs over the 6-month follow-up.

Cost-effectiveness analysis

Differences in use of services between randomised groups at the 6-month follow-up are reported descriptively.

Differences in mean cost per participant were tested between groups using the Student's *t*-test with ordinary least squares regression, and bootstrapping to confirm the validity of the results.[47] Standard statistical tests were used because of the importance of the arithmetic mean in the analysis of cost data.[48] The main analysis used cases for which complete data were available at follow-up and missing data imputation were not used. We used multiple imputation to test for the influence of missing cases in a sensitivity analysis.

Cost-effectiveness planes were produced to show the probability that: brief intervention is more effective and more costly than the control treatment; brief intervention is more effective and less costly than the control treatment; brief intervention is less effective and less costly than the control treatment; and brief intervention is less effective and more costly than the control treatment. The planes were constructed using regression models of total cost and outcome by treatment group, from which 10,000 bootstrapped resamples were run.

Knowledge of uncertainty around incremental cost-effectiveness is not sufficient for decision-making, which will depend on the how much society is willing to pay for improvements in outcomes. Cost-effectiveness acceptability curves (CEACs) were constructed, which show the likelihood that brief intervention is more cost-effective than the control treatment for different values a decision-maker is willing to pay for improvements in outcome.[49]

Chapter 4 Results

Recruitment and randomisation

Study recruitment commenced in August 2010. Between August 2010 and May 2012, 1640 people were assessed for participation in the study. Recruitment stopped at this point as the revised target sample size had been exceeded and a decision was made to stop recruitment in a trial management meeting. Of the 1640 people assessed, 802 (49%) were eligible and willing to provide consent and were randomised. The reasons for non-participation were not willing to provide consent ($n = 447$, 53%), not drinking alcohol excessively ($n = 369$, 44%) and insufficient spoken English to complete the baseline assessment ($n = 22$, 3%) (*Figure 1*). Of the 802 people who took part in the study, 400 were allocated to the control group and 402 were allocated to brief intervention.

Characteristics of the study sample

Sociodemographic and clinical characteristics of study participants at baseline are presented in *Table 2*. Participants were recruited from three hospital sites. Just under two-thirds of the participants were recruited from the West London Centre for Sexual Health based at Charing Cross Hospital, London, UK (hospital site 1; $n = 495$, 61.7%); one-quarter were recruited from the John Hunter Clinic for Sexual Health based at Chelsea and Westminster Hospital, London, UK (hospital site 2; $n = 206$, 25.7%); and the others were recruited from the Jefferiss wing based at St Mary's Hospital, London, UK (hospital site 3; $n = 101$, 12.6%). Participants ranged in age from 19 to 55 years (median age 27 years) and just over half (54%) were female. Most participants presented to the service either because they were experiencing genitourinary symptoms or for a health check.

The results of the baseline assessment are presented in *Tables 2* and *3* and show that, while the groups were generally well balanced, in the intervention group there was a lower proportion of heterosexual participants and a lower proportion who reported having had unprotected sex in the previous 6 months.

Flow of participants through the trial

The Consolidated Standards of Reporting Trials (CONSORT) diagram (see *Figure 1*) summarises the flow of participants through the trial. A total of 592 participants (73.8%) were followed up at 6 months. Of the 210 (26.2%) participants who were not followed up at 6 months, 61 (29%) formally withdrew from the study and the other 149 (71%) either could not be traced or did not take up repeated offers to be assessed.

Participants who did not complete the follow-up ($n = 210$, 26.2%) were on average younger (26.8 years old vs. 28.1 years old, $p = 0.009$) and with higher-risk sexual behaviour (e.g. 45.2% did not use a condom the first time they had sex with their last partner vs. 34.9%, $p = 0.008$) than those who completed the study. The attrition rate was not significantly different between arms (24.7% in the control group vs. 27.6% in the intervention group, $p = 0.36$). There were no significant differences in predictors of drop out between arms.

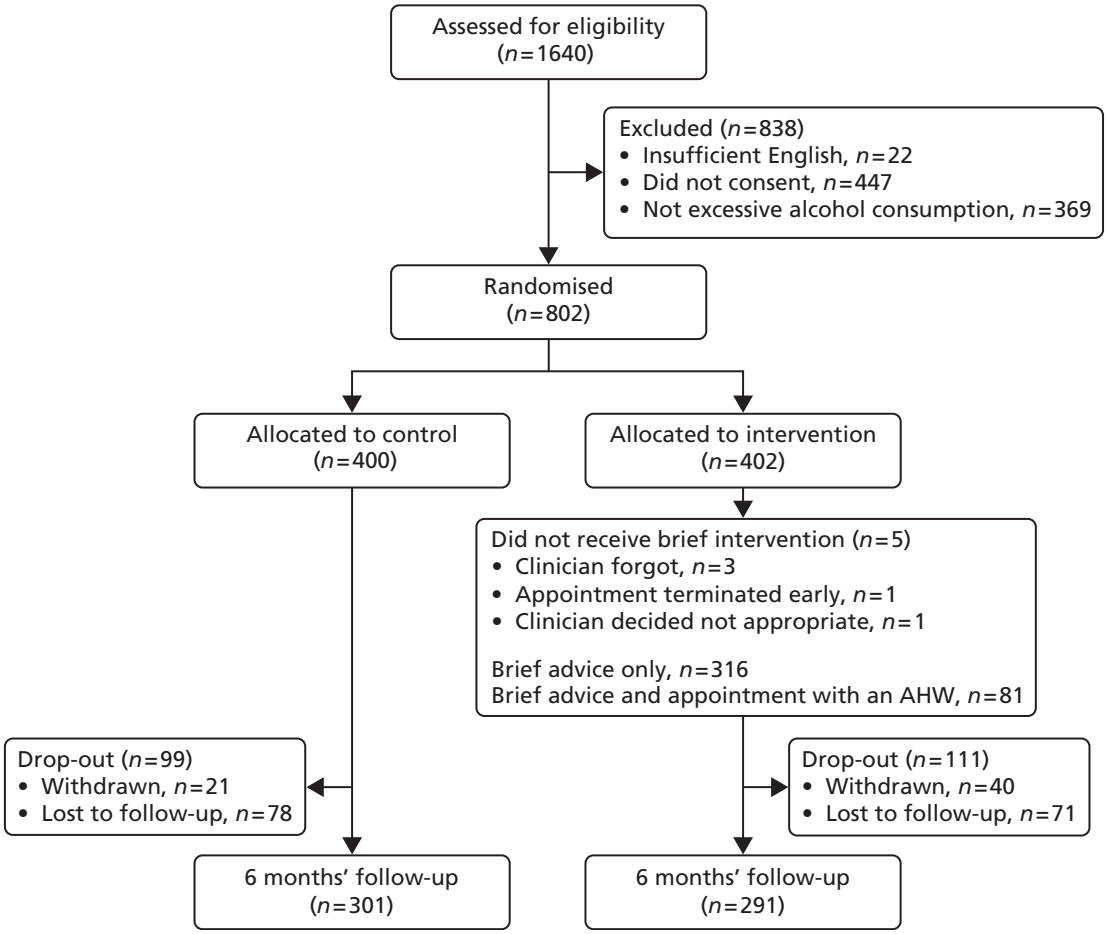

FIGURE 1 Study flow chart.

Masking of researchers conducting follow-up interviews

Researchers reported nine occasions when they became aware of a participants' allocation status. All the participants were from the brief intervention arm of the trial. This occurred on each occasion because the participant told the researcher which arm of the trial they had been allocated to.

Uptake of allocated treatments

Four hundred and two participants were allocated to the brief intervention treatment, of whom 397 (99%) received the treatment. The brief advice was delivered by a total of 79 clinicians, each seeing a median of three trial participants [interquartile range (IQR) 1–6]. Three hundred and sixteen (79.9%) participants received brief advice only from the clinician and 81 participants (20.1%) received brief advice and an appointment with an AHW. Of those who had contact with the AHW, 33 (40.7%) met with the AHW for their appointment and the remaining 48 (59.3%) received advice and support over the telephone. *Table 4* details the alcohol consumption at follow-up by intervention for participants in the intervention arm.

Treatment fidelity

Data from treatment proforma showed that, of the 402 randomised to brief intervention, 397 (99%) received brief feedback that alcohol use at that level has the potential to harm health; 370 (92%) were asked whether or not there was a link between alcohol use and attendance at the clinic; 397 (99%) were given a leaflet on alcohol and health, of whom 372 (92.5%) took the leaflet; and 397 (99%) were offered an appointment with an AHW.

TABLE 2 Sociodemographic and clinical characteristics of study participants at baseline

Variable	Control ($n = 399$)[a]	Intervention ($n = 402$)	Total ($n = 801$)[a]
Clinic			
Hospital site 1	247 (61.8%)	248 (61.7%)	495 (61.7%)
Hospital site 2	103 (25.8%)	103 (25.6%)	206 (25.7%)
Hospital site 3	50 (12.5%)	51 (12.7%)	101 (12.6%)
Gender			
Male	183 (45.8%)	187 (46.5%)	370 (46.1%)
Female	217 (54.3%)	215 (53.5%)	432 (53.9%)
Age, years (median, IQR)	26.8 (23.4–30.4)	26.3 (23.7–30.4)	26.7 (23.6–30.4)
Ethnicity			
White	309 (77.6%)	309 (77.1%)	618 (77.3%)
Black/mixed	52 (13.1%)	52 (13.0%)	104 (13.0%)
Asian/mixed	13 (3.3%)	16 (4.0%)	29 (3.6%)
Other	24 (6.0%)	24 (6.0%)	48 (6.0%)
Sexual orientation			
Heterosexual	361 (90.5%)	325 (80.8%)	686 (85.6%)
Homosexual	34 (8.5%)	59 (14.7%)	93 (11.6%)
Bisexual	4 (1.0%)	18 (4.5%)	22 (2.7%)
Smoking status			
No	228 (57.1%)	228 (56.7%)	456 (56.9%)
Yes	171 (42.9%)	174 (43.3%)	345 (43.1%)
Reason for presentation			
Sexual health check only	166 (42.3%)	175 (44.2%)	341 (43.3%)
Symptoms	188 (48.0%)	185 (46.7%)	373 (47.3%)
Emergency contraception	6 (1.5%)	8 (2.0%)	14 (1.8%)
Further treatment/vaccination	20 (5.1%)	17 (4.3%)	37 (4.7%)
Other	12 (3.1%)	11 (2.8%)	23 (2.9%)

IQR, interquartile range.
a Baseline characteristics (except clinic, age and gender) were not recorded for one participant.

TABLE 3 Alcohol and sexual behaviour questionnaire at baseline

Variable	Control (*n* = 399)	Intervention (*n* = 402)	Total (*n* = 801)
Drinking 6+/8+ units in one session			
Monthly	141 (35.3%)	153 (38.1%)	294 (36.7%)
Weekly	253 (63.4%)	242 (60.2%)	495 (61.8%)
Daily	5 (1.3%)	7 (1.7%)	12 (1.5%)
In the past 6 months			
Number of sexual partners			
1	145 (36.3%)	164 (40.8%)	309 (38.6%)
> 1	254 (63.7%)	238 (59.2%)	492 (61.4%)
Had unprotected sex?			
No	45 (11.3%)	78 (19.4%)	123 (15.4%)
Yes	354 (88.7%)	324 (80.6%)	678 (84.6%)
Number of unprotected sexual partners (mean, SD)	1.7 (1.6)	1.4 (1.3)	1.6 (1.4)
Regretted sex?			
No	255 (63.9%)	269 (66.9%)	524 (65.4%)
Yes	144 (36.1%)	133 (33.1%)	277 (34.6%)
Last partner			
How long had known them before first had sex?			
Just met them	57 (14.3%)	38 (9.5%)	95 (11.9%)
A day	19 (4.8%)	13 (3.2%)	32 (4.0%)
A few days	27 (6.8%)	30 (7.5%)	57 (7.1%)
A week	46 (11.5%)	42 (10.4%)	88 (11.0%)
A month	131 (32.8%)	153 (38.1%)	284 (35.5%)
A year	119 (29.8%)	126 (31.3%)	245 (30.6%)
Used condom first time had sex?			
No	151 (37.8%)	150 (37.3%)	301 (37.6%)
Yes	248 (62.2%)	252 (62.7%)	500 (62.4%)
Used contraception with this person?			
No	150 (37.6%)	144 (35.8%)	294 (36.7%)
Yes	234 (58.6%)	243 (60.4%)	477 (59.6%)
Do not know	15 (3.8%)	15 (3.7%)	30 (3.7%)

TABLE 4 Alcohol consumption by intervention received

	Baseline		Follow-up (units of alcohol/week)				
Trial intervention received	*n* (*N* = 402)	M-SASQ baseline[a]	*n* (*N* = 291)	Mean	Median	First quartile	Third quartile
None	5 (1%)	3 (60%)	2	14.2	14.2	4.4	23.9
Brief advice only	316 (79%)	195 (62%)	221	18.2	15.1	6.8	24.3
Brief advice and input from AHW (face to face)	33 (8%)	22 (67%)	30	20.3	13.0	7.4	30.4
Brief advice and input from AHW (over the telephone)	48 (12%)	29 (60%)	38	16.0	11.8	4.1	25.4

a Number and proportion drinking more than 6 units for women or 8 units for men on one occasion weekly or daily at baseline.

Main and secondary outcomes

Primary and secondary outcomes at the 6-month follow-up are described in *Table 5*. In the intervention arm, weekly alcohol consumption was 2.33 units lower and fewer participants than in the control arm reported having unprotected sex.

Table 6 shows the effect of allocation to the intervention arm compared with the control treatment. At 6 months, participants allocated to brief intervention had a reduction in mean weekly alcohol consumption (adjusted mean difference –2.33 units/week; 95% CI –4.69 to 0.03 units/week; $p = 0.053$). This difference corresponds to a –0.14 standardised effect size (SD = 16.1). There was no evidence of a difference in the proportions who had had unprotected sex in the past 3 months [adjusted odds ratio (OR) 0.89, 95% CI 0.63 to 1.25; $p = 0.496$]. For other secondary outcomes, only the average number of units drunk per drinking day showed a statistically significant result (difference –1.13 units/drinking day; 95% CI –1.96 to –0.29 units/drinking day; $p = 0.009$), suggesting that during drinking days the intervention group drank fewer units on average than the control group.

Sensitivity analyses

The results of the different sensitivity analyses models are reported in *Appendix 5*. For the primary outcome, results were all consistent with there being a small difference in weekly alcohol consumption between the treatment arms, which was close to statistical significance. The bootstrap bias-corrected and accelerated CIs for the mean difference was –4.55 to 0.31. None of the calculated CIs included a difference between the treatment arms of ≥ 5 units. For the main secondary outcome, results were also consistent between sensitivity analyses, giving an OR of around 0.90, except when the difference in unprotected sex at baseline was not accounted for or ignored (OR = 0.78). None of the results were statistically significant at the 5% level.

Missing data

Baseline data were missing for only one participant and were imputed using mean imputation. Meanwhile, data for 210 patients were missing at the final follow-up owing to withdrawal and loss to follow-up: 99 in the control group and 111 in the intervention group (see *Figure 1*). After multiple imputation of these missing outcomes, the adjusted mean difference in the primary outcome was –2.43 (95% CI –4.73 to –0.13; $p = 0.038$) and the OR for the main secondary outcome was 0.89 (95% CI 0.63 to 1.25; $p = 0.494$) (see *Appendix 5*).

TABLE 5 Outcomes at follow-up by trial arm

Outcome	Control ($n = 301$)	Intervention ($n = 291$)
Primary		
Weekly alcohol consumption (units)		
Mean (SD)	20.3 (16.6)	18.1 (15.6)
Median (IQR)	15.7 (8.3–29.9)	14.1 (6.5–25.1)
Main secondary		
Had unprotected sex?		
No	123 (40.9%)	137 (47.1%)
Yes	178 (59.1%)	154 (52.9%)
Secondary: alcohol		
Average units on drinking days		
Mean (SD)	10.4 (5.8)	9.3 (5.3)
Median (IQR)	9.4 (6.5–13.4)	8.6 (5.6–11.4)
Proportion of days abstinent		
Mean (SD)	70.7 (22.6)	70.9 (22.1)
Median (IQR)	75.6 (62.2–87.8)	75.6 (58.9–87.8)
Drinking excessively according to M-SASQ?		
No	55 (18.3%)	70 (24.1%)
Yes	246 (81.7%)	221 (75.9%)
Secondary: sexual behaviour		
Number of sexual partners		
Mean (SD)	1.9 (2.9)	1.6 (2.2)
Median (IQR)	1 (1–2)	1 (1–2)
Number of unprotected partners		
Mean (SD)	0.8 (1.1)	0.6 (0.8)
Median (IQR)	1 (0–1)	1 (0–1)
Occurrence of regretted sex?		
No	273 (90.7%)	263 (90.4%)
Yes	28 (9.3%)	28 (9.6%)
Unprotected sex after drinking?		
No	165 (54.8%)	183 (2.9%)
Yes	136 (45.2%)	108 (37.1%)
Unprotected sex after feeling drunk?		
No	245 (81.4%)	234 (80.4%)
Yes	56 (18.6%)	57 (19.6%)
Had sex when just met (last partner)?		
No	280 (93.0%)	275 (94.5%)
Yes	21 (7.0%)	16 (5.5%)

TABLE 5 Outcomes at follow-up by trial arm (*continued*)

Outcome	Control ($n = 301$)	Intervention ($n = 291$)
Unplanned pregnancy ($n = 316$)?		
No	160 (98.8%)	152 (98.7%)
Yes	2 (1.2%)	2 (1.3%)
New STI diagnosis?		
No	287 (95.3%)	283 (97.3%)
Yes	14 (4.7%)	8 (2.7%)

TABLE 6 Impact of brief intervention on all the main study outcomes

	Comparison			
Outcome	Regression/test	Coefficient	95% CI	*p*-value
Primary outcome				
Weekly alcohol consumption	Linear	β = –2.33	–4.69 to 0.03	0.053
Main secondary				
Had unprotected sex	Logistic	OR = 0.89	0.63 to 1.25	0.496
Secondary outcomes				
Average units on drinking days	Linear	β = –1.13	–1.96 to –0.29	0.009
Proportion of days abstinent	Linear	β = 0.20	–3.03 to 3.44	0.902
Drinking excessively (M-SASQ)	Logistic	OR = 0.70	0.46 to 1.05	0.087
Number of sexual partners	Negative binomial	β = –0.13	–0.29 to 0.02	0.097
Number of unprotected partners	Poisson	β = –0.11	–0.31 to 0.08	0.252
Occurrence of regretted sex	Logistic	OR = 1.05	–1.84 to 0.60	0.871
Unprotected sex after drinking	Logistic	OR = 0.79	–1.11 to 0.56	0.174
Unprotected sex after feeling drunk	Logistic	OR = 1.15	–1.75 to 0.76	0.504
Had sex when just met	Logistic	OR = 0.80	–1.65 to 0.39	0.549
Unplanned pregnancy ($n = 316$)	Fisher's exact test	OR = 1.05	–	1.000
New STI diagnosis	Fisher's exact test	OR = 0.58	–	0.279

Regression adjusted for age, gender, clinic and corresponding variable at baseline (M-SASQ, more than one sexual partner, number of unprotected partners, regretted sex, unprotected sex or had sex when just met).

The results of a sensitivity analyses based on the assumption that outcome data were missing non at random are reported for the primary outcome and main secondary outcome in *Appendix 6*. The primary outcome result could differ if there is an important difference in the response pattern between the arms; however, in the more plausible scenarios the mean difference remained small (between –4 and 0 units per week). In the most extreme scenario missing control group participants were assumed to drink, on average, 15 units per week more than control group participants who completed follow-up, whereas intervention group non-completers were assumed to drink on average 5 units per week less than their completer equivalents. Under this scenario, the difference in mean alcohol consumption between the groups could be as high as –7.17 units per week. For the main secondary outcomes, all scenarios gave a non-significant difference between arms, with an OR likely to remain between 0.8 and 1.0.

Subgroup analysis

Differences in primary and main secondary outcomes by subgroups are reported in *Figure 2* and *Table 7*. There was a possible trend for the intervention to be more effective in reducing unprotected sex with increased age, although the result was not statistically significant and has to be interpreted in consideration of the multiple comparisons and low power of the interaction test.

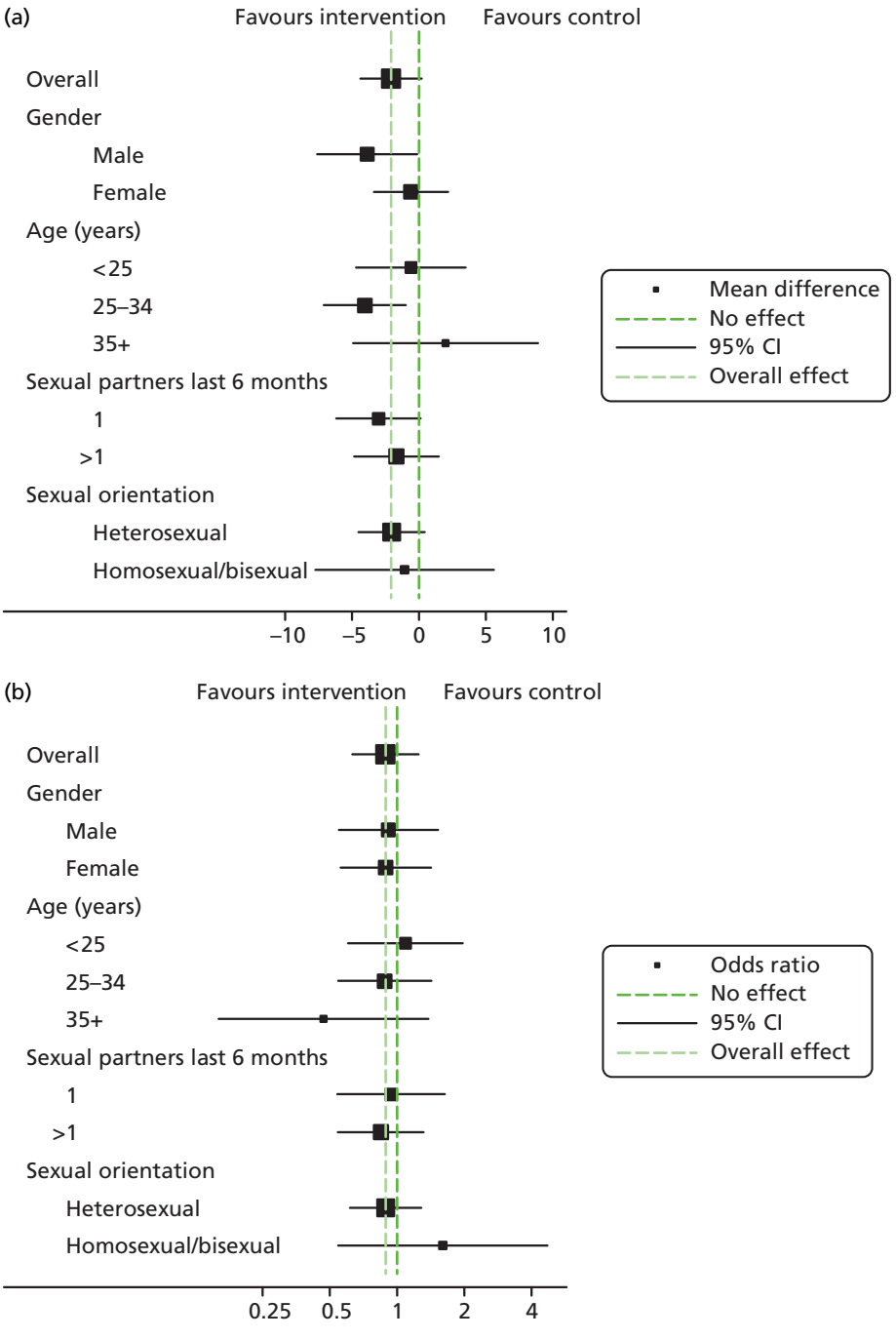

FIGURE 2 Forest plot of difference in primary and main secondary outcome by subgroups. (a) Difference in weekly alcohol consumption; and (b) OR of unprotected sexual relations.

TABLE 7 Difference in outcomes, and significance of interaction terms for each subgroup analysis

Subgroup	*n*	Adjusted mean difference (95% CI)	*p*-value interaction	Adjusted OR (95% CI)	*p*-value interaction
Gender					
Male	276	–3.86 (–7.59 to –0.12)	0.15	0.92 (0.55 to 1.53)	0.99
Female	316	–0.59 (–3.35 to 2.17)		0.89 (0.56 to 1.42)	
Age (years): categories					
< 25	212	–0.61 (–4.69 to 3.48)	0.19	1.09 (0.60 to 1.97)	0.35
25–34	308	–4.04 (–7.11 to –0.98)		0.88 (0.55 to 1.42)	
≥ 35	72	1.99 (–4.92 to 8.89)		0.47 (0.16 to 1.38)	
Age: linear	592	–	0.92[a]	–	0.083[a]
Number of partners					
One	233	–3.02 (–6.16 to 0.13)	0.63	0.94 (0.54 to 1.64)	0.78
More than one	358	–1.68 (–4.83 to 1.48)		0.85 (0.54 to 1.32)	
Sexual orientation					
Heterosexual	500	–2.04 (–4.51 to 0.43)	0.74	0.89 (0.62 to 1.28)	0.55
Other	91	–1.08 (–7.74 to 5.59)		1.60 (0.55 to 4.71)	

a In the direction of greater intervention effect with increasing age.

Economic evaluation

Service use

Service use over the 6-month follow-up is detailed in *Table 8* and shows how use of health and community services was broadly similar in the control and brief intervention groups.

Cost

Mean cost of services per participant over 6-month follow-up is detailed in *Table 9*. There was no difference in service cost between those randomised to the control condition (£310.87) and those randomised to brief intervention (£319.28, $p = 0.879$). The cost of the brief intervention was on average £12.57 per participant, which represented around 4% of total service costs. The average cost per participant for outpatient STI appointments was £23.97 in the control group and £25.55 in the brief intervention group. Imputation of missing data did not alter the direction or difference in total costs [control ($n = 400$) £311.13; brief intervention ($n = 402$) £319.64, $p = 0.835$].

Economic outcomes

Quality-adjusted life-years are detailed in *Table 10*. Mean QALYs were similar between groups at 6-month follow-up and there were no statistically significant differences in EQ-5D scores or QALYs. Units of alcohol per week for those with complete economic data were 20 in the control group and 18 in the brief intervention group.

Cost-effectiveness

There were no significant between-group differences in costs or outcomes. QALYs over follow-up were 0.007 lower in the brief intervention group, and costs were £8.41 higher, which results in a negative incremental cost-effectiveness ratio (ICER) of –£1200.00 per QALY, suggesting that the control dominates

TABLE 8 Use of services over 6 months' follow-up, mean per participant

Service	Control ($n = 301$)			Brief intervention ($n = 290$)		
	% using service	Mean	SD	% using service	Mean	SD
Inpatient (nights)	5	0.11	0.69	4	0.11	0.68
Outpatient (appointments)	41	0.93	1.83	43	0.87	1.38
Accident and emergency (attendances)	19	0.21	0.46	11	0.12	0.40
GP surgery (contacts)	49	1.05	1.73	55	1.17	1.99
GP telephone (contacts)	5	0.02	0.13	0	0.00	0.00
Practice nurse (contacts)	18	0.20	0.45	16	0.21	0.59
Health visitor/district nurse (contacts)	0	0.00	0.00	1	0.00	0.06
Physiotherapist (contacts)	4	0.26	2.83	4	0.11	0.65
Counsellor (contacts)	4	0.15	0.95	2	0.18	1.38
Chiropody/podiatry (contacts)	0	0.00	0.00	1	0.01	0.13
Advice centre (contacts)	1	0.02	0.20	1	0.04	0.49
Complementary medicine (number)	2	0.16	1.56	1	0.09	0.87
NHS Direct (calls)	1	0.01	0.12	1	0.00	0.06
Community sexual health clinic (contacts)	1	0.01	0.10	1	0.01	0.14

GP, general practitioner.

TABLE 9 Mean cost per participant (£) over 6 months' follow-up

Service	Control ($n = 301$)		Brief intervention ($n = 290$)		Difference	95% CI	*p*-value
	Mean (£)	SD (£)	Mean (£)	SD (£)			
Brief alcohol intervention	0.00	0.00	12.57	6.59			
Hospital STI outpatient appointments	23.97	55.16	25.55	51.75			
All other hospital services	152.35	446.70	133.13	359.05			
Community health and social services	74.59	256.89	60.73	165.01			
Medication	59.96	235.87	87.30	404.71			
Total cost	310.87	681.12	319.28	662.69	8.41	–98 to 1154	0.879

TABLE 10 QALYs over 6 months' follow-up, mean per participant

Outcome measure	Control ($n = 301$)		Brief intervention ($n = 290$)		Difference	Bootstrapped, 95% CI
	Mean	SD	Mean	SD		
EQ-5D score baseline	0.903	0.153	0.889	0.165		
EQ-5D score follow-up	0.922	0.144	0.910	0.150		
QALYs over follow-up ($n = 589$)	0.457	0.063	0.450	0.066	–0.007	–0.0174 to 0.003
Units of alcohol per week ($n = 591$)	20.256	16.553	18.110	15.630	–2.280	–4.672 to 0.117

the brief intervention. For the alcohol consumption outcome, 2 fewer units per week were consumed on average in the brief intervention group and costs were £8.41 higher, resulting in an ICER of £4.20 per unit reduction in weekly alcohol consumption. Given the lack of statistical significance in these ICERs, attention needs to be given to uncertainty represented in the scatterplots and CEACs presented below.

The bootstrapped replications for costs and QALYs are shown on a cost-effectiveness plane in *Figure 3*. Most of the dots lie to the left of the *x*-axis (brief intervention associated with worse outcomes than control) and above the *y*-axis (brief intervention associated with higher costs than control) suggesting that the brief intervention is not cost-effective. The CEAC (*Figure 4*) confirms this finding, for willingness-to-pay values for a QALY up to £30,000 there is no more than a 42% probability that brief intervention is more cost-effective than the control treatment.

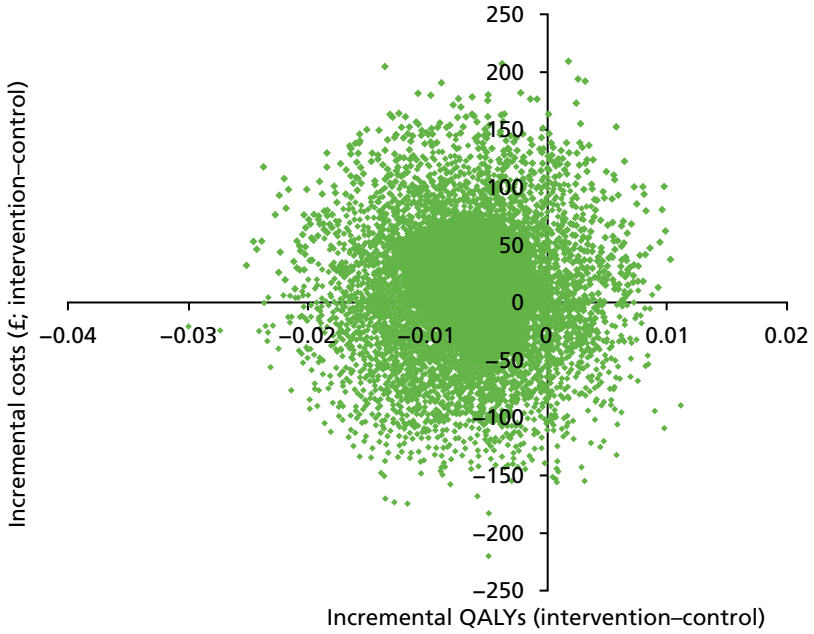

FIGURE 3 Cost-effectiveness plane for the comparison of the brief intervention and usual care, based on 10,000 bootstrapped cost–effect pairs, using QALYs.

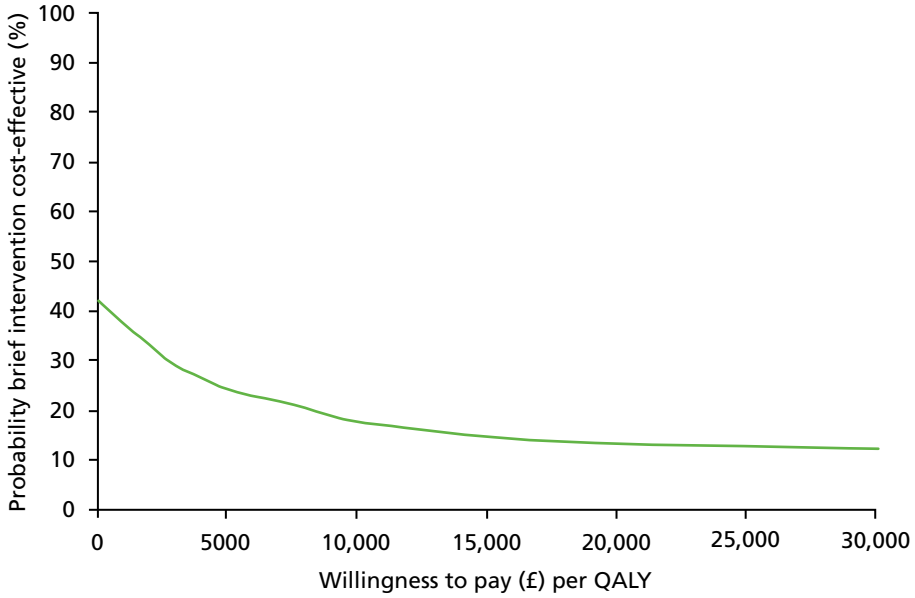

FIGURE 4 Cost-effectiveness acceptability curve showing probability that brief intervention is cost-effective compared with usual care for different values of willingness to pay per QALY.

The bootstrapped replications for costs and alcohol consumption are shown on a cost-effectiveness plane in *Figure 5*. Most of the dots lie to the left of the *x*-axis (brief intervention associated with better outcomes) and above the *y*-axis (brief intervention costs higher), suggesting that the brief intervention could be cost-effective, depending on society's willingness to pay for a unit reduction in weekly alcohol consumption. The CEAC (*Figure 6*) summarises information on willingness to pay and cost-effectiveness. If society places a value of zero on its willingness to pay for a unit reduction in alcohol consumption, then the probability of brief intervention being more cost-effective than the control treatment is 44%. However, if society is willing to pay up to £5 per unit reduction in alcohol consumption then the probability of cost-effectiveness increases to over 50%.

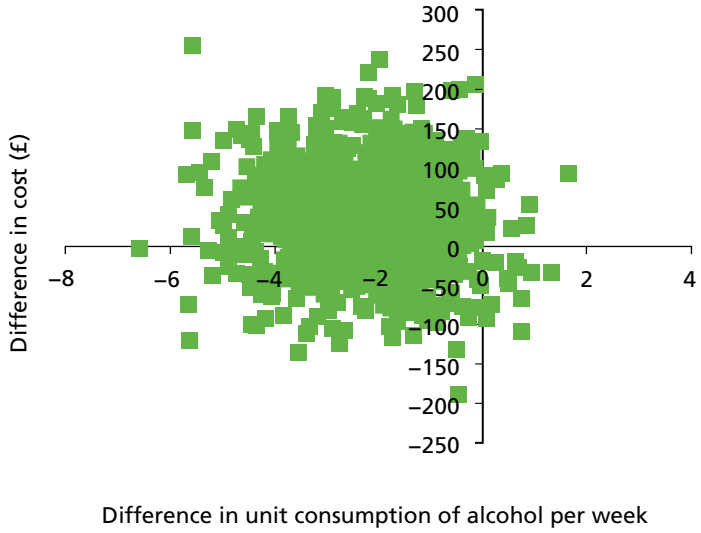

FIGURE 5 Cost-effectiveness plane for the comparison of the brief intervention and usual care, based on 10,000 bootstrapped cost–effect pairs using weekly alcohol consumption.

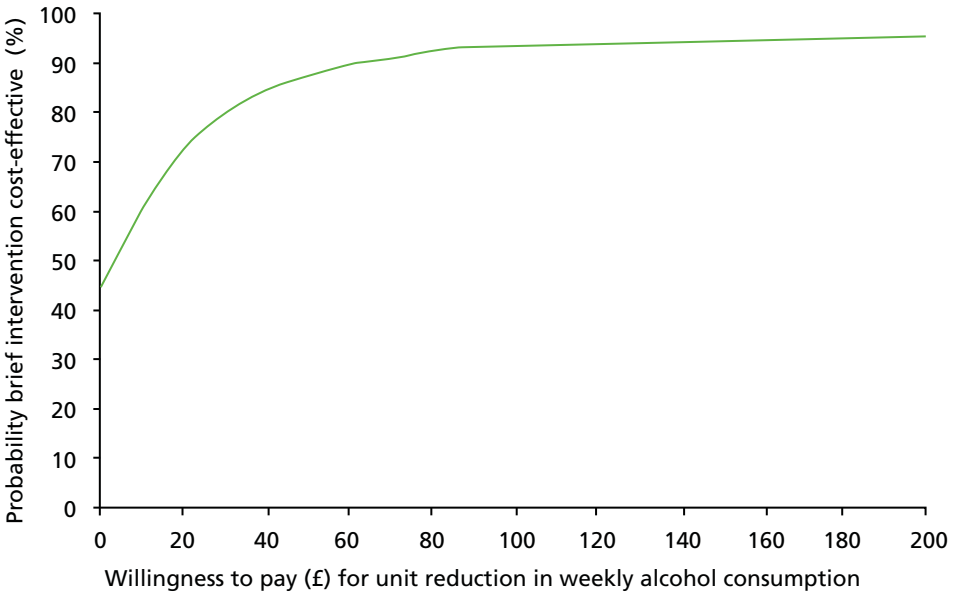

FIGURE 6 Cost-effectiveness acceptability curve showing probability that brief intervention is cost-effective compared with usual care for different values of willingness to pay per unit reduction in weekly alcohol consumption.

Chapter 5 Discussion

Study findings

Data from this randomised trial of brief intervention for excessive alcohol use among people attending sexual health clinics suggest that there is little, if any, difference in alcohol consumption between those who are and are not offered this intervention. Follow-up data collected from 592 (74%) of the 802 participants at 6 months showed that those who were randomised to brief intervention were drinking a mean of 2.3 units (18.4 g) of alcohol less per week than those randomised to the control group. Interpreting results of trials with borderline significance is not straightforward. In keeping with the recommendations of Hackshaw and Kirkwood,[50] we base this conclusion on the clinical significance of the changes we found rather than on the probability of the difference being the result of chance. Although a statistically significant difference in the number of units of alcohol per drinking day was observed, the scale of the difference (1.1 units/8.8 g) is unlikely to be clinically important. Significant differences in sexual health outcomes were not found between the groups, though we cannot rule out the possibility that brief intervention could be associated with small, but clinically important, changes in sexual health outcomes. At less than £13.00 per participant, brief intervention was inexpensive. When other costs and outcomes were taken into account we found little evidence that the intervention would provide a cost-effective use of resources. The results of the cost-effectiveness analysis suggest that if a service were to be willing to pay £5.00 for a weekly unit reduction in alcohol consumption, the brief intervention would have a > 50% chance of being cost-effective. However, the relevance of this interpretation is difficult since we know that a weekly reduction in alcohol consumption is not a clinically meaningful change.

Strengths and weaknesses of the study

The rate of recruitment to the study was higher than we initially anticipated. With the approval of the independent Trial Steering Group, Data Monitoring Committee and Research Ethics Committee and the support of the study funder we increased the planned sample size to increase the statistical power that we had to examine the impact of the intervention on our secondary outcomes. The sample of over 800 participants was large enough to detect clinically important changes in alcohol consumption and moderate to large changes in sexual behaviour. The rate of follow-up we achieved was also higher than we had planned, with 74% of all participants followed up at 6 months. Two other notable strengths of the study relate to the recruitment and assessment process we used and the type of intervention received by those in the active arm of the trial.

Recruitment to the study involved asking potential participants if they would be willing to take part in a study of 'sexual health and lifestyle'. Written and verbal information given to participants made no explicit reference to alcohol use. When assessing whether or not potential participants were eligible to take part, we used a single question on alcohol use which was embedded in a series of other questions about smoking, exercise and diet. By using this approach we were able to reduce exposure to prompts about alcohol use which could have encouraged those in the control arm of the trial to reflect on their use of alcohol and consider reducing this. In doing so, we believe that we have replicated normal clinical practice in sexual health clinics where information about alcohol is not normally collected. Previous trials of brief intervention for alcohol misuse have been criticised for underestimating the effects of screening and intervention by exposing control participants to more detailed questions about alcohol, which may in themselves lead to reductions in alcohol consumption.[51]

We based our intervention on a form of brief advice which is acceptable to staff working in busy clinical settings and can be delivered in under a minute.[52] Evidence for the acceptability of the approach was found by data from the active arm of the trial showing that almost 99% of people received brief advice. This approach does not require clinicians to deliver anything other than very simple advice to accompany a leaflet on alcohol and health and the offer of more intensive advice and support for those who want it. By testing an approach to intervention which was delivered by front-line clinicians rather than specially trained staff, we believe that we took a pragmatic approach to testing an approach to helping people who consume excessive alcohol which had the potential to be delivered widely as part of routine clinical practice.

The study has a number of limitations which should be considered when interpreting the findings. Although we recruited more participants than we planned, these were all from three sexual health clinics in inner and central London. Although this area covers over 500,000 residents from a range of different socioeconomic backgrounds, we do not know if our results would have been the same had participants been recruited from other parts of the country.

In our effort to maximise recruitment in this busy clinical setting and minimise exposure to prompts about alcohol use for control participants we used a very short baseline assessment which did not involve collecting detailed information about alcohol use or service utilisation. This meant that we had limited data to compare the characteristics of those in the two arms of the trial or information that could be used to impute follow-up data on those from whom this was not obtained.

Although we used validated outcome measures that have been widely used in previous trials, these were based on the self-reporting by study participants. We do not know the extent to which they provide an accurate measure of actual behaviour. In addition, the economic evaluation used the EQ-5D to measure quality of life, which has been shown to be insensitive to changes in levels of alcohol consumption amongst hazardous drinkers.

At 74%, the rate of follow-up we achieved is similar to that of other trials of brief intervention for alcohol misuse in secondary care settings.[16,21] This remains an important level of attrition, and the intervention effect observed in the completers could be a biased estimate of the effect in all participants, especially if the intervention had a different effect in the non-responders, or if the intervention affected the chance of response. However, the response rate was not highly different between the arms, and we perform different sensitivity analyses to see how missing data could have affected the results. Although the intervention effect estimate could be affected by the missing data, it appeared unlikely that the overall conclusions of the trial would change.

Only a minority of those in the active arm of the trial received brief intervention from an appointment with the AHW. This level of uptake of brief intervention is far higher than in a pilot study we conducted.[9] We believe that one of the reasons for this was that AHWs offered telephone-based intervention that did not require participants to come back to the clinic.

Comparison with results of other studies

Very little research has been conducted to examine the impact of intervention for excessive alcohol use among people attending sexual health services. Lane and colleagues compared the effects of brief intervention for risky drinking delivered by a trained nurse in a sexual health clinic in Sydney, Australia, among 184 people.[21] They found a small, non-statistically significant difference in the proportion of people drinking harmfully among those who did and did not receive a brief intervention. Three months after randomisation, 46% of those in the active arm of the trial and 39% in the control arm were drinking excessively according to AUDIT-C (a three-item quantity frequency measure of alcohol consumption derived from the 10-item Alcohol Use identification test). These small differences in levels of alcohol

consumption between treatment arms are of the same order of magnitude as the differences we found in this study. We are aware of two other trials of brief intervention for alcohol among people who attend sexual health clinics and are drinking above recommended limits, but neither has so far published their findings.

In contrast, a large number of studies have been conducted across a range of other health-care settings including primary care, emergency departments and specialist clinics. Findings from these trials have generally shown that brief intervention is associated with clinically important reductions in alcohol consumption over a 6- to 12-month period. In a systematic review of 22 clinical trials, Kaner and colleagues reported a standardised mean difference of 5 units of alcohol per week at 6 months among those who received active compared with control treatment.[53] Changes in alcohol consumption of this magnitude also seem to be associated with reductions in all-cause mortality.

There is no agreement about what constitutes a clinically significant reduction in alcohol consumption. However, other clinical trials have been powered to detect differences of between 3.5 and 10 units of alcohol per week.[16,54] Other trials have been powered to detect clinically important differences in the proportion of people drinking excessively; such trials have been powered to detect differences in proportions in the region of 13%[12,55,56] rather than the difference of 5.8% that we found in this study. It is unclear why larger differences in alcohol consumption were not found between the active and control arms of the SHEAR trial. Possible reasons for this include the level of alcohol misuse among people attending sexual health clinics, the intervention that people received and readiness to change.

Level of alcohol misuse among study participants

Previous research has established high levels of alcohol consumption among people attending sexual health clinics. As many as 70% of attendees are drinking above recommended levels.[10] In our study, 68% of the attendees who completed the baseline questionnaire were drinking excessively according to the M-SASQ criteria. We did not collect detailed information about the level of alcohol consumed at baseline. However, at follow-up, information on alcohol consumption over the previous 12 weeks revealed that participants were drinking a median of 15 units of alcohol a week – well below recommended maximum levels of weekly alcohol consumption. With a median of 10 units per drinking day, most study participants were regularly exceeding recommended limits for drinks per day and over three-quarters were therefore classified as 'drinking excessively' according to the M-SASQ criteria. However, overall levels of alcohol consumption were far lower than that seen in other intervention studies conducted in primary and secondary care, where study participants were reported to be drinking three or four times as much as SHEAR participants.[16,53] There is some evidence that brief intervention is less effective among people have lower levels of alcohol consumption.[53] By recruiting participants whose level of alcohol consumption may not have been as high as that in emergency departments and other hospital settings the likelihood of demonstrating clinically significant reductions in alcohol consumption may have been reduced.

Treatment fidelity

The intervention that we used in the SHEAR trial was designed to meet national recommendations for brief alcohol intervention and was modelled on that used in a previous trial which demonstrated positive effects. However, it could only have been effective if it was delivered in the intended manner. Data collected from treatment proforma indicate that nearly all those allocated to the intervention received each of the four components of brief advice that they should have been offered.

It has been argued that, in order to be effective, those delivering brief interventions need to have a positive attitude to the information they provide.[57] A survey of all clinicians who delivered the brief intervention that we conducted parallel to the trial demonstrated that the majority believed that there was

a link between alcohol use and sexual health, and that the intervention they were asked to deliver had the potential to help improve sexual health. Available data therefore suggest that the intervention was delivered in the manner intended and that the largely negative findings of the trial are not the result of the way the intervention was delivered.

Readiness to change

The opportunity to help a person reduce his or her use of alcohol when presenting to services with health problems that may be related to excessive alcohol use has been called a 'teachable moment'.[58] Emergency departments may provide an effective point at which to intervene because the link between alcohol use and negative effects on health such as gastrointestinal problems, accidents, injuries and deliberate self-harm are closely related at the points at which the intervention is provided. In specialist settings, such as maxillofacial clinics, a patient may have a clear sense of a causal link between excessive alcohol consumption and physical trauma.[13] There is some evidence that people using sexual health clinics, while acknowledging a link between alcohol use and sexual behaviour, do not view this as one in which alcohol use leads to STIs or other negative health consequences. In semistructured interviews with 100 women attending sexual health and family planning clinics, Taylor and colleagues reported that participants rarely believed that alcohol consumption had led them to engage in sexual behaviour which they would not have engaged in had they not been drinking.[59] Instead participants said that sexual encounters tended to take place in environments where alcohol and/or drug use were likely to occur or they used alcohol instrumentally to engage in desired sexual behaviours.

We are in the process of analysing qualitative data from study participants which may help us develop a better understanding of why clinically important changes in alcohol consumption were not found in the study. Data analysis is ongoing and a report will be completed in 2014, but our impression thus far is that people attending sexual health clinics and drinking above recommended daily units of alcohol do not view the amount they consume as excessive. Instead it is seen as a normal part of their social life and a means of having fun. These observations are supported by a secondary analysis of data from brief advice proformas showing that 19% think that their attendance in the clinic could be related to their use of alcohol (compared with over 69% of those in our previous study in an emergency department). Although people attending sexual health clinics may want to achieve better sexual health, attempts to reduce alcohol consumption are generally not seen by them as a necessary means of trying to achieve this aim.

Implications for services and future research

The results of this study do not support the routine use of screening and intervention for excessive alcohol use among people attending sexual health clinics. Although assessment of alcohol use as part of wider efforts to help some people with poor sexual health take steps aimed at reducing risky sexual behaviour makes sense, universal use of screening and delivery of brief interventions does not appear to provide a clinically effective or cost-effective use of available resources.

It is, however, possible that there are subgroups of people for whom brief alcohol intervention would be helpful, for instance individuals with high levels of acquisition of new STIs in the context of high levels of alcohol misuse and those seeking human immunodeficiency virus (HIV) post-exposure prophylaxis or emergency contraception. Further research examining the impact of brief alcohol intervention among such groups is warranted. We recommend that such studies set a higher threshold of excessive alcohol consumption to determine entry into the study than the one we used (such as drinking above recommended limits on a weekly, rather than a monthly, basis).

We excluded people aged < 19 years from the trial. Levels of alcohol misuse may be higher among teenagers attending sexual health clinics than among adults and future research should develop and test the impact of age-appropriate methods to help young people reflect on, and reduce, their use of alcohol.

Data suggesting that population-based interventions that lead to lower levels of alcohol consumption also have an impact on levels of new STIs are also important. There is currently a debate about public health measures aimed at reducing alcohol consumption, such as setting a minimum price per unit alcohol. Such changes may have an impact on rates of STIs and, if introduced, future studies should examine the impact of these changes on sexual health outcomes.

Chapter 6 Conclusions

Introduction of universal screening and brief intervention for excessive alcohol use among people who attend sexual health clinics does not result in clinically important reductions in alcohol consumption or provide a cost-effective use of resources and should not be introduced in routine clinical practice.

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Contributions of authors

Mike J Crawford (Professor, Health Services Research) was the chief investigator of the SHEAR trial.

Mike J Crawford together with **Rahil Sanatinia** (Research Assistant, Mental Health Research) and **Robin Touquet** (Emeritus Professor, Interventions for Alcohol Misuse) designed the study with input from **Barbara Barrett** (Lecturer, Health Economics), **Baptiste Leurent** (Research Associate, Medical Statistics), **Sarah Byford** (Professor, Health Economics), **John Green** (Head of Psychology CNWL, Sexual Health), **Michael Sweeting** (Research Associate, Medical Statistics), **Anne Lingford-Hughes** (Professor, Addiction), **Peter Tyrer** (Professor, Health Services Research) and **Helen Ward** (Professor, Public Health).

Rachael Jones (Consultant Physician, Sexual Health) helped liaise with clinical services and oversee recruitment.

Baptiste Leurent, **Michael Sweeting** and **Mike J Crawford** designed the statistical analysis plan.

Outcome data were analysed by **Baptiste Leurent** with guidance from **Michael Sweeting**.

Sarah Byford designed the economic component of the trial and supervised the conduct of the economic evaluation.

Barbara Barrett carried out the cost-effectiveness analysis. **Rahil Sanatinia** recruited participants from all three sites with assistance from Shreena Ghelani and Lorraine O'Connell.

Madeleine Dean (Research Assistant, Psychology) completed follow-up interviews with assistance from **Bianca Hinds-Walters** and **Raphael Underwood**.

All study authors contributed to the preparation of this report.

Publication

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Appendix 1 Patient and public involvement

Members of the British Youth Council and advisers from Brook (the national young people's sexual health charity) were involved at several stages of the study. Prior to the start of data collection, they were asked for suggestions about the design and content of information sheets and study questionnaires which resulted in changes to these documents.

Towards the end of the study these advisers commented on emerging findings and their feedback helped us develop the discussion and conclusions of the study.

These advisers also helped us prepare a one-page summary of the results of the study which has been sent to all participants who requested feedback on the results of the study. Copies of this leaflet will also be distributed to patients at each of the clinics that took part in the study.

Finally, a member of the trial steering group was selected on the basis of their having experience of using health-care services.

Appendix 2 Proforma for clinicians delivering brief advice

SHEAR

Sexual health and lifestyle advice

_____ has been allocated to brief advice for alcohol misuse.

Please provide the patient with the four components of brief advice listed below and tick the box to indicate that each component was delivered.

BRIEF ADVICE ONLY TAKES A MINUTE!

	Please tick if delivered
1. Brief feedback on level of alcohol use and its potential to affect health ***'From the information that you gave our researcher it seems that your use of alcohol could be harmful to your health'*** (Eight units per drinking session for a man, six for a woman)	☐
2. Making a link ***'Do you feel your attendance here could be related to your use of alcohol?'***	***YES*** ☐ ***NO*** ☐
3. Given a copy of the information leaflet: *''Think about drink"* ***'I would like to give you a leaflet which has information about alcohol and health'***	☐
4. Offered an appointment with the Alcohol Nurse Specialist and provide appointment card ***'I would like to arrange for you to meet our Alcohol Nurse Specialist, they would be able to see you at*** <please see time and date on the card> ***in this clinic'***	☐

PLEASE PRINT YOUR NAME HERE ☐

THANK YOU FOR YOUR HELP WITH THE STUDY

Appendix 3 Proforma for alcohol health workers

SHEAR

Sexual health and lifestyle advice

Patient name _____ Date of birth _____

Telephone Intervention ☐

	Please tick if delivered
1. Assessment of current alcohol consumption and drinking history	☐
2. Exploration of negative consequences of excessive alcohol consumption	☐
3. Feedback and advice about alcohol consumption	☐
4. Discussion of options for further help and advice / **Referral to HA**	☐

Internet/ web site	☐	*Helpline*	☐
Follow-up in the clinic	☐	*Community alcohol service*	☐
AA	☐	*Detoxification service*	☐

How many times did you meet this person?	
What was the total amount of time you spent with them?	
How long did you spend organising appointments/ liaison?	
How long did you spend speaking to them on the phone?	

PLEASE PRINT YOUR NAME HERE

THANK YOU FOR YOUR HELP WITH THE STUDY

Appendix 4 Results of sensitivity analyses

TABLE 11 Results of sensitivity analyses

Primary outcome: weekly alcohol consumption						
Sensitivity analyses	**Adjusted (age, sex, clinic, M-SASQ)**	**Random effect for clinician**	**Residuals variance independent by arm**	**Mean difference**	**95% CI**	***p*-value**
Primary analysis model	Yes	Yes	Yes	–2.33	–4.69 to 0.03	0.053
Unadjusted (*t*-test)	No	No	No	–2.17	–4.76 to 0.43	0.102
Adjusted	Yes	No	No	–2.09	–4.37 to 0.19	0.073
Residuals heteroscedastic by arm	Yes	No	Yes	–2.08	–4.34 to 0.17	0.070
Robust variance estimates	Yes	No	No	–2.09	–4.36 to 0.19	0.072
Bootstrapping, normal-based CI	Yes	Yes	Yes	–2.33	–4.55 to –0.11	0.040
Bootstrapping, bias-corrected and accelerated CI	Yes	Yes	Yes	–2.33	–4.55 to 0.31	–
Adjusted for baseline imbalance in sexual orientation and unprotected sex	Yes	Yes	Yes	–2.03	–4.42 to 0.36	0.096
Multiple imputation	Yes	No	No	–2.43	–4.73 to –0.13	0.038
Main secondary outcome: unprotected sex in the last 3 months						
Sensitivity analyses	**Adjusted (age, sex, clinic, unprotected sex)**	**Random effect for clinician**	**OR**		**95% CI**	***p*-value**
Primary analysis model	Yes	Yes	0.89		0.63 to 1.25	0.496
Unadjusted (chi-squared test)	No	No	0.78		0.56 to 1.08	0.128
Adjusted	Yes	No	0.89		0.63 to 1.25	0.496
Adjusted for baseline imbalance in sexual orientation	Yes	Yes	0.93		0.66 to 1.32	0.688
Multiple imputation	Yes	No	0.89		0.63 to 1.25	0.494

Missing not-at-random results

TABLE 12 Mean difference (95% CI) in weekly alcohol consumption for different missing non-at-random scenarios

MNAR delta control group	MNAR delta intervention group (95% CI)			
	–5	0	8	15
–5	–2.24 (–4.53 to 0.06)	–0.85 (–3.14 to 1.44)	1.36 (–0.96 to 3.67)	3.29 (0.91 to 5.67)
0	–3.47 (–5.76 to –1.18)	–2.09 (–4.37 to 0.19)	0.12 (–2.18 to 2.43)	2.06 (–0.31 to 4.43)
8	–5.44 (–7.76 to –3.13)	–4.06 (–6.37 to –1.76)	–1.85 (–4.18 to 0.48)	0.08 (–2.31 to 2.48)
15	–7.17 (–9.55 to –4.80)	–5.79 (–8.16 to –3.42)	–3.58 (5.97 to –1.19)	–1.64 (–4.10 to 0.81)

MNAR, missing non at random.

Deltas represent the assumed mean difference in weekly alcohol consumption between the participants who did not complete follow-up compared with those who did (pattern-mixture approach). The likeliness of the scenarios is based on assuming that non-responders are more likely to drink slightly more than responders (probably between 0 and 8 units more per week), and that delta is more likely to be similar in both arms. Results are based on linear regression adjusted for age, sex, clinic and baseline M-SASQ.

Colour code, likeliness of scenario:

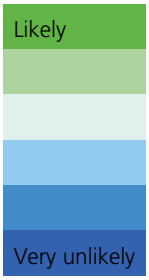


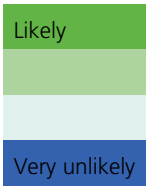
TABLE 13 Odds ratio (95% CI) for unprotected sex in the last three months for different missing non-at-random scenarios

Rate in non-responders: control[a]	Rate in non-responders: intervention[a] (95% CI)		
	52.9%	62.8%	73.7%
59.1%	0.89 (0.63 to 1.25)	0.99 (0.70 to 1.40)	1.12 (0.80 to 1.58)
68.4%	0.81 (0.57 to 1.14)	0.90 (0.64 to 1.27)	1.02 (0.72 to 1.43)
78.3%	0.73 (0.52 to 1.03)	0.81 (0.58 to 1.14)	0.92 (0.65 to 1.29)

a Rates of unprotected sex assumed in those who did not complete the follow-up. Corresponding to an informative missingness odds ratio (IMOR) of 1.0, 1.5 and 2.5.

Likeliness of scenarios is based on the assumptions that non-responders were more likely to have unprotected sex (IMOR around 1.5), and that the IMOR is more likely to be similar in both arms. Results based on logistic regression adjusted for age, sex, clinic and baseline unprotected sex.

Colour code, likeliness of scenario:



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