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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Scientific summary

Sexual Health and Excessive Alcohol: Randomised trial

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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.

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