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Alcohol misuse and sexual health: a randomised trial of brief intervention among people attending sexual health clinics.

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1. BACKGROUND AND RATIONALE

It is estimated that as many as one in five adults drink too much alcohol [1]. Alcohol misuse leads to a range of physical and mental health problems that are estimated to cost the NHS £3 billion a year and a further £15 billion of indirect costs to the UK economy [2]. The number of people who drink excessively is increasing, particularly among the young [3]. Rising levels of alcohol misuse in the UK have been accompanied by large increases in rates of sexually transmitted infections [4]. As with changes in alcohol consumption, the greatest increase in rates of sexually transmitted infections have been among young people. Excessive use of alcohol decreases the likelihood of condom use and increases the likelihood of sexually transmitted infections [5;6]. The impact of brief interventions for alcohol misuse on sexual behaviour has not been examined.

In the last decade there has been a 63% increase in the number of new sexually transmitted infections diagnosed in the UK each year [7]. It is estimated that over 75,000 people in the UK have HIV, of whom over a quarter are unaware of their infection [7]. In addition to the impact of HIV/AIDS on morbidity and mortality, other sexually transmitted infections impair quality of life and give rise to other medical problems such as cancer and infertility. Brief intervention for alcohol misuse among people who attend sexual health clinics would target a group of young adults for whom the consequences of alcohol misuse may be especially significant.

2. AIMS AND OBJECTIVES

The study aims to examine the process and outcomes of brief advice for alcohol misuse for people who attend sexual health clinics and are drinking excessively. We will use these findings to develop a feasible plan for a definitive multi-centre randomised trial of this intervention.

2.1 Study objectives

The main objectives are:

1. To examine whether brief advice for alcohol misuse reduces subsequent alcohol consumption over a six month period.
2. To examine whether brief advice is associated with changes in sexual behaviour.
3. To estimate the cost of this intervention and any impact on service utilisation.
4. To estimate the rate of recruitment, uptake of treatment, and follow-up that can be achieved in a randomised trial of brief advice in this setting.
5. To explore the experiences of service providers and users who deliver and receive this intervention in order to develop a better understanding of its impact and identify factors which facilitate or hinder successful delivery of this intervention.

3. TRIAL DESIGN

The design is a two-arm, parallel group, individually randomised trial of brief advice for alcohol misuse among people attending sexual health clinics who drink excessively. The trial will be integrated with a parallel qualitative study in which a sub-sample of service users and providers will be interviewed to obtain a detailed understanding of the experience of receiving and delivering this intervention.

3.1 Primary outcome

Alcohol consumption during the previous three months using the 90I drink diary [8].

3.2 Secondary outcome measures

- Sexual behaviour - measured using six key variables that have been validated in other studies [9]
- Health related quality of life - measured using the EuroQol (EQ-5D) [10].
- Resource use - using a modified version of the Adult Service Utilization questionnaire [11].

3.3 Study sample and population

The study population is people who present to a sexual health service and drink excessively. The study sample will be recruited from sexual health centres at Charing Cross Hospital and Chelsea & Westminster Hospital. People attending at one of two clinics at each of these centres will be provided and asked to consider taking part in the study. Those drinking excessively will be asked to complete baseline measures. Those who provide written informed consent will be randomised using pre-prepared envelopes. We will use permuted stacked blocks, with block size randomly assigned between two and four. Randomisation status will then be communicated to the treating clinician by the researcher prior to the start of the clinical consultation.

3.4 Sample size

The sample size calculation for the study is based on the primary hypotheses: that, compared to control treatment, brief intervention for excessive use of alcohol among people attending sexual health clinics and drinking excessively reduces mean weekly alcohol consumption measured six months later. If clustering by therapist is ignored, a sample of 194 (97 receiving experimental treatment and 97 receiving control treatment) participants need to be randomised to have 80% power and 5% level of significance to demonstrate a reduction in mean weekly units of alcohol consumed of 23.4 (SD = 58) at six months. These figures are based on those reported by Crawford and colleague. However, previous research into the effects of brief intervention opportunistic for alcohol misuse indicates that clustering can occur, and that an intra-class correlation coefficient of 0.04 is appropriate. Assuming a cluster size of the order seven patients per clinician in the intervention group (4 people delivering BI at each of the four centres) and no clustering effect in the control arm, we require 112 patients to complete the trial in each arm (7 x 16) to achieve 80% power. This inflates the sample size by a factor of 1.15. Further, we anticipate that up to 30% of the sample will be lost to follow-up and we therefore intend to recruit a total of 320 patients (160 control, 160 treatment).

We do not have data on the impact of the intervention on sexual behaviour to calculate a sample size to explore these outcomes. However the study sample is sufficiently large to demonstrate medium/large sized effects on outcomes such as use of condoms and the proportion of people reporting regretted sex at six month follow-up.

3.5 Inclusion criteria and exclusion criteria
Patients must meet the following criteria to be eligible for enrolment:
1. Drinking excessively according to the Modified-Single Alcohol Screening Question (M-SASQ) [14].
2. Aged 19 years as above.
3. Inability to communicate in English sufficiently to complete baseline questionnaires.
4. Competent and willing to provide written, informed consent.

3.6 Governance
The trial will be registered with Clinicaltrials.gov, a publicly accessible database, before any participants are recruited. The study will be carried out in accordance with the International Conference on Harmonisation (ICH) Guidelines - Good Clinical Practice, (GCP-ICH: Good Clinical Practice - International Committee on Harmonisation 1997). All researchers working on the study will receive training in GCP-ICH guidelines.

4. CLINICAL ASSESSMENTS
4.1 At baseline
In addition to collecting basic demographic data on age, gender, ethnicity, marital status, and employment status we will collect data on:

- *Alcohol consumption* - Alcohol consumption will be assessed using the Modified-Single Alcohol Screening Question (M-SASQ). We selected the M-SAQ because we have previously used it is a brief validated measure of harmful alcohol use which has been used successfully in previous studies and found to be acceptable to patients in general medical settings [14]. It consists of a single question - for men: How often do you drink more than eight standard drinks on one occasion? And for women: How often do you drink more than six standard drinks on one occasion? To help people answer the question they are shown a card which describes what a 'standard drink' is.
- *Smoking, diet and exercise* - Using standard questions from the Preventive Nutrition Project. In addition to providing an overview of the general health of study participants these data will help to avoid focusing participants thoughts on their use of alcohol which the brief intervention will be focused on [15].
- *Sexual behaviour* - measured using six key variables that have been validated in other studies [9] to record the number and type of sexual partners in the previous three months and the numbers and type of those partners with whom there was any unprotected sex.

4.2 At six month follow up

- Alcohol consumption using the Alcohol Use Identification Test and the Form 90 [8].
- Sexual behaviour - using the same questions that were asked at baseline [9].
- Health related quality of life - using the five item EQ-5D [10]
- Resource use during the previous six months using the Adult Service Use Schedule [11].
- Contacts with the sexual health service in the six months following randomisation will be checked using the clinics electronic database.

5.0 TRIAL INTERVENTIONS
We will test the effects of a brief intervention delivered by the treating clinician. This will involve feedback, the offer of written information on alcohol and health and an appointment with an Alcohol Nurse Specialist (ANS) based in the same clinic. The appointment with the ANS will last up to 30 minutes and use the 'FRAMES' approach [16]. Control treatment will involve assessment of alcohol use, but the brief intervention will not be offered.

All clinicians who deliver the brief intervention will receive training in accordance with Department of Health guidelines (www.alcohollearningcentre.org.uk). Our Alcohol Nurse Specialists have received specific training on delivering this intervention. Treatment fidelity will be examined by inspecting a random sample of written records of nurses.

6.0 STUDY PROCEDURES
6.1 Recruitment

Recruitment will take place at sexual health clinics in Central and West London. At each clinic where recruitment takes place information about the study will be displayed on posters in waiting rooms. On days when recruitment is taking place clinic staff will hand all those attending the clinic a postcard with information about the study and ask people whether they would be willing to meet the study researcher. If they agree, the study will be explained to the patient by the researcher, and they will be provided with a copy of the Patient Information Leaflet. The researcher will encourage potential participants to spend as much time as they want asking questions about the study and considering whether they wish to take part or not. Before any trial specific procedures are performed, the patient must personally sign and date the Informed Consent Form, using the latest Research Ethics Committee (REC) approved version of the form. Written informed consent will be obtained from each subject prior to their inclusion in this study in line with the Information Sheets and Consent Forms.
For those willing to provide consent eligibility to participate in the study will be assessed and baseline clinical and demographic data will be collected. Collection of baseline data will take about 10 minutes to complete. Those who are eligible will be randomised to brief intervention or control treatment. Those who are ineligible will be thanked for their time and informed that they do not have the type of problems that the study is aimed at helping people with. The researcher will however be able to provide those who are ineligible with written information about health and lifestyle if they are interested in receiving this.

6.2 Randomisation
Those who provide written informed consent will be randomised using pre-prepared envelopes. These envelopes will contain either a blank sheet of paper or a reminder to the clinician of the brief intervention for alcohol use that they should deliver.
We will use permuted stacked blocks, with block size randomly assigned between two and four. Randomisation status will then be communicated to the treating clinician by the researcher prior to the start of the clinical consultation.

6.3 Follow-up
All those who are randomised will receive a single follow-up interview at six months using the items listed above (section 4.2). Follow-up interviews will be conducted by a second researcher who is masked to the participants allocation status. Data will be held securely and all personal identifiers will be removed, with password protected randomisation details held separately. In most instances the follow-up interview will be by telephone. However, if participants decline this they will be offered the option of a face-to-face interview at a time of their choosing. Piloting of study instruments suggests that the six month follow-up interview takes between 20 and 30 minutes to complete. Participants completing the follow-up interview will be offered a £15 honorarium in recognition of any inconvenience related to their involvement in the study.
Finally researchers will extract data on the number of re-attendances in the sexual health clinic using electronic hospital-based records.

7.0 DATA ANALYSIS
Baseline data on alcohol consumption and other measures will be used to ascertain whether study groups differed. Our primary outcome measure will be alcohol consumption at 12 months measured by the 90I drink diary. Statistical analysis will be performed on the intention to treat basis. Differences in the level of alcohol consumption at 12 months will be compared among those receiving control treatment and experimental treatment using univariate tests (t test and/ or Mann-Whitney test). A two-level hierarchical model with the site/therapist as the first, and the patient as the second level will then be used for analysis in order to take account potential clustering effects and any differences in baseline alcohol consumption or other potential confounding factors such as gender or age. Differences in quality of life will then be examined using the same statistical techniques. A secondary analysis will be performed to compare outcomes among those who received the brief intervention and those who did not. We will estimate the intra- and interclass correlations for further use in calculation of the sample size for a definitive trial.

Total costs over follow-up will be calculated using the service use data measured in the AD-SUS and valued with routine unit cost data [17]. Mean total costs over follow-up will be compared using t-tests with confidence intervals.

8.0 PROCESS EVALUATION

In keeping with MRC guidelines on the development and evaluation of complex interventions [18], we will integrate a process evaluation with the exploratory randomised trial. We will measure the rate of recruitment and uptake of the intervention and explore service user beliefs about the impact of this intervention, mechanisms of action, and factors that facilitate or hinder its successful delivery.

8.1 Data collection

Throughout the course of the trial we will monitor the rate of recruitment and uptake of interventions. The researcher involved in recruitment will ask people, who meet inclusion criteria but decline to participate, about their reasons for refusal. These will be recorded and used to further inform process evaluation.

After we have recruited the sample we require for the randomised trial, we will recruit a further sample. This additional sample will be offered an appointment with an Alcohol Nurse Specialist and asked to consent to being contacted three to four weeks after their appointment for the purpose of participation in a semi-structured interview. We will explain that not all those who provide consent will be interviewed. Instead, we will purposively sample participants on the basis of demographic characteristics and whether they attended their session with the ANS. The interview will include open-ended questions on people's response to being screened for excessive alcohol consumption, what influenced their decision to attend/ not attend the appointment with the ANS, and what they found more or less helpful about the intervention. The interview schedule will be applied flexibly so that researchers are able to be responsive to each participant's account. The schedule will be refined as data collection progresses. All interviews will be recorded digitally and transcribed verbatim with consent from the participant. Where consent is withheld, contemporaneous notes made by the researcher will be written up and provided to the respondent for verification. We will interview at least 20 participants, and will continue to recruit new participants until a point of theoretical saturation has been reached.

8.2 Data analysis

Quantitative data from the process evaluation will be analysed in SPSS using simple descriptive statistics. Qualitative data collection and analysis will be mutually informing. We will use NVivo computer package (Scolari/Sage) to manage data and support analysis which will be undertaken using a thematic framework approach [19]. An initial framework will be based on the study aims. This will be further developed using analytic induction from early interviews and iteratively revised as data collection and analysis progress.

9.0 STUDY TIMETABLE

Start date	- 01.03.2010
Recruit study participants	- 01.06.2010 to 30.11.2010
Collect qualitative data	- 01.12.2010 to 31.01.2011
Complete collection of follow-up data	- 31.05.2011
Complete data analysis	- 31.08.2011

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