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Sexual health and lifestyle advice: a clinical trial

Submission date	Recruitment status	[X] Prospectively registered
12/07/2010	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
29/07/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
18/06/2014	Urological and Genital Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
09/9104

Study information

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

Acronym
SHEAR (Sexual Health & Excessive Alcohol: Randomised trial)

Study objectives
Primary hypothesis:
Brief intervention among those attending sexual health clinics and drinking excessively reduces mean weekly alcohol consumption measured six months later.
Secondary hypotheses:
1. Brief intervention among those attending sexual health clinics and drinking excessively reduces the likelihood of regretted, unplanned and unprotected sexual intercourse
2. Brief intervention among those attending sexual health clinics and drinking excessively is more cost-effective than control treatment

Ethics approval required
Old ethics approval format

Ethics approval(s)
The West London Research Ethics Committee, 24/05/2010, ref: 10/H0706/29

Study design
Single-blind individually randomised parallel-arm controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use contact details to request a patient information sheet.

Health condition(s) or problem(s) studied
Alcohol misuse. Sexual health.

Interventions
We will test the effects of a brief intervention delivered by the treating clinician. The intervention consists of;
1. Brief assessment of current alcohol consumption
2. Feedback on level of alcohol use and its potential to effect health
3. Written information on alcohol and health in the form of a leaflet recommended by the

Department of Health: 'How much is too much'
4. An appointment with an Alcohol Nurse Specialist (ANS) based in the same clinic

The intervention delivered by the Alcohol Nurse Specialist will be based on recommendations by the Department of Health, will last up to 30 minutes and use the 'FRAMES' approach (Feedback, Responsibility, Advice, Menu of options, Empathy, Self-Efficacy). For any participant who is drinking at a harmful or dependent level the Alcohol Nurse Specialist will have the option of referring the patient for further help e.g. individual alcohol counselling, detoxification services etc. In the event that the participant is unable to attend an appointment that day they will be offered an appointment on a later date of their choosing.

Control treatment
Those randomised to control treatment will be offered a copy of leaflet 'Five Choices to Help You Stay Healthy' which provides general information on preventative health including alcohol use, diet, exercise, cigarette smoking and details of how to obtain further information about health and lifestyle.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Mean units of alcohol consumed per week measured at six months using the Form 90

Secondary outcome measures
1. Proportion of participants with harmful/ hazardous drinking measured using the Alcohol Use Disorders Identification Test (short form) (AUDIT-C)
2. Sexual behaviour measured using key variables that have been validated in other studies to record the number and type of sexual partners in the previous six months, and incidence of unprotected, regretted or forced sex
3. Health related quality of life, using the five item EQ-5D
4. Resource use during the previous six months using the Adult Service Use Schedule
5. Contacts with the sexual health service in the six months following randomisation will be checked using the clinics electronic database

Overall study start date
20/08/2010

Completion date
31/05/2012

Eligibility

Key inclusion criteria
1. Aged 18 years or above
2. Drinking excessively according to the Modified-Single Alcohol Screening Question (M-SASQ)
3. Willing to provide written informed consent to take part in the study

Participant type(s)

Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
320 patients (160 control, 160 treatment)

Key exclusion criteria
1. Unable to communicate in English sufficiently to complete baseline questionnaires (While a significant minority of people attending these clinics will speak English as a second language we anticipate that only a very small proportion will be excluded on the basis of the ability to complete baseline questionnaires [less than 5%])
2. No address or contact telephone number available
3. Participant believes they may not be contactable in six months time

Date of first enrolment
20/08/2010

Date of final enrolment
31/05/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Centre for Mental Health
London
United Kingdom
W6 8LN

Sponsor information

Organisation
Imperial College London (UK)

Sponsor details
Joint Research Office
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Sponsor type
University/education

Website
http://www3.imperial.ac.uk

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Government

Funder Name
Department of Health (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	25/08/2012		Yes	No

Results article	results	01/05/2014	Yes	No
Results article	results	01/02/2015	Yes	No