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Screening and Intervention Programme for Sensible drinking - Primary Health Care

Submission date	Recruitment status
30/04/2007	No longer recruiting
Registration date	**Overall study status**
08/06/2007	Completed
Last Edited	**Condition category**
22/02/2013	Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.sips.iop.kcl.ac.uk/

Contact information

Type(s)
Scientific

Contact name
Prof Colin Drummond

Contact details
Section of Alcohol Research
National Addiction Centre, PO48
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4 Windsor Walk
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
SIPS-PHC

Study information

Scientific Title
Pragmatic cluster randomised controlled trial evaluating the effectiveness and cost-effectiveness of primary health care screening and brief alcohol intervention

Acronym
SIPS (PHC)

Study objectives
The more intensive brief interventions for hazardous and harmful drinkers will be more effective, as follows: lifestyle counselling is more effective than simple structured advice, which is in turn more effective than a patient information leaflet.

As of 11/03/2009 this record was updated to include an extended anticipated end date; the initial end date at the time of registration was 31/12/2008. At this time, the sponsor field was also updated to include the current sponsor of Institute of Psychiatry, King's College London (UK). The initial sponsor at the time of registration was St George's University of London (UK).

Ethics approval required
Old ethics approval format

Ethics approval(s)
London Local Research Ethics Committees (LREC) approved on the 30th March 2007 (ref: 06 /MRE02/90)

Study design
Pragmatic cluster randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Quality of life

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

Health condition(s) or problem(s) studied
Hazardous alcohol consumption in primary care

Interventions
1. Control condition: Practices in the control condition will record the screening outcome, feedback the result of screening to patients and offer them a Patient Information Leaflet (PIL).

The PIL to be used in this trial Alcohol and Sensible Drinking is readily available to Primary Health Care (PHC) clinicians via the EMIS computer system and contains details of a Drinkline telephone number. We will ensure that practice not using EMIS have a comparable written PIL available.

2. Simple structured advice: Clinicians who may be GPs or primary care nurses will feed back the results of screening to patients and deliver up to 5 minutes of simple structured advice, using the Drink-Less brief intervention materials (level 1), and offer them a PIL identical to that in the control condition.

3. Brief lifestyle counselling: Clinicians who may be GPs or primary care nurses will feedback the results of screening to patients and deliver 15-20 minutes of lifestyle counselling using the Drink-Less brief intervention materials (level 2).

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Alcohol Use Disorders Identification Test (AUDIT) at baseline and 6 months.

Secondary outcome measures
The following will be assessed at baseline and 6 months:
1. EQ-5D questionnaire (quality of life assessment)
2. Service utilisation
3. Alcohol Problems Questionnaire
4. Staff attitudinal and organisational measure

Overall study start date
01/04/2007

Completion date
30/06/2010

Eligibility

Key inclusion criteria
1. Positive screening result on Fast Alcohol Screen Test (FAST) or the Single Alcohol Screening Questionnaire (SASQ)
2. Patient who is alert and orientated
3. Aged 18 or over, either sex
4. Able to speak English sufficiently well to complete study questionnaires
5. Resident within England

Participant type(s)

Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
744

Key exclusion criteria
1. Patients already in contact with alcohol services
2. Those already included in the study
3. Those requesting tertiary level help with alcohol problems
4. Significant psychiatric disorder

Date of first enrolment
01/04/2007

Date of final enrolment
30/06/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Section of Alcohol Research
London
United Kingdom
SE5 8BB

Sponsor information

Organisation
Institute of Psychiatry, Kings College London (UK)

Sponsor details

4 Windsor Walk
London
England
United Kingdom
SE5 8BB
paolo.deluca@iop.kcl.ac.uk

Sponsor type
University/education

Website
http://www.iop.kcl.ac.uk

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
Department of Health (UK) - part of an action under the governments Alcohol Harm Reduction Strategy for England (2004)

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	10/08/2009		Yes	No
Results article	results	09/01/2013		Yes	No