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Screening and brief interventions for alcohol misuse delivered in the community pharmacy setting

Submission date	Recruitment status	[ ] Prospectively registered
05/02/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
16/03/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
11/07/2016	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title

Screening and brief interventions for alcohol misuse delivered in the community pharmacy setting: a pilot study using a pragmatic cluster randomised controlled trial design

Study objectives
Excessive alcohol consumption causes substantial morbidity and mortality. Screening, followed by brief interventions, is effective in reducing alcohol consumption and can be delivered in primary care. Evidence from small, proof-of-concept studies, shows that screening for excessive alcohol consumption can be delivered in community pharmacies, and can be followed by the delivery of brief interventions to clients identified as harmful or hazardous drinkers. A large-scale randomised controlled trial (RCT) of screening and brief interventions in the community pharmacy setting is needed to derive evidence of the effectiveness and cost-effectiveness of this approach. Firstly, a pilot study is needed to assess recruitment, participation and follow-up rates, to derive accurate data (including loss to follow up rates and effect size estimates) to inform sample size calculations for the RCT. In addition, the acceptability of this novel service to service providers and users needs to be explored.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Grampian Local Ethics Committee and NHS R&D, 14/01/2010, ref: 09/S0802/119

Study design
Pragmatic cluster randomised controlled pilot study

Primary study design
Interventional

Study type(s)
Screening

Health condition(s) or problem(s) studied
Alcohol misuse

Interventions
Each pharmacy will be required to screen 100 clients within a two-month period. Based on the proof-of-concept studies, 40% are expected to be identified as harmful or hazardous drinkers.

All adult clients entering the community pharmacy will be eligible for screening (in control and intervention pharmacies). A tally sheet will be used in each participating pharmacy to record clients who refuse to undertake screening or brief interventions. Any trained member of the pharmacy team will invite the client to complete the Fast Alcohol Screening Test (FAST). Clients who score above the threshold score (greater than 3) will be invited to have a consultation with the pharmacist to discuss participation in the study. Clients who do not consent will be given the standard information leaflet about healthy lifestyle mentioned above and thanked for participating in the screening activity. Clients who score below the threshold score will also be given this leaflet.

All clients who are eligible (i.e. FAST score greater than 3) and who consent to participate, will be asked to provide written consent and then asked to complete the baseline questionnaire. The purpose of this questionnaire will be to collect additional information on alcohol consumption

and demographic information (including their full postal address for the dissemination of follow-up surveys). They will also be informed that a short questionnaire will be sent to them at three and six months to explore their alcohol consumption.

Clients in the control group pharmacies will then be given a generic information leaflet about healthy lifestyle and thanked for their involvement. Clients in the intervention group pharmacies will receive a brief intervention to raise their awareness of their alcohol consumption in relation to recommended limits. The Reference Group (see later) will devise referral criteria that the pharmacists in both groups can use if they suspect a client requires referral to specialist services.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Average screening rate per pharmacy per week
2. Average recruitment rate per pharmacy per week
3. Number or proportion of clients who score greater than 3 using FAST
4. Self-reported measures of alcohol consumption (which may include number of episodes of 'binge' drinking, alcohol free days)
5. Follow-up rate at three and six months
6. Number of referrals to other agencies
7. Identification of barriers and facilitators to delivering screening and brief interventions in the community pharmacy setting (pharmacy staff and client perspective)
8. Exploration of the public's opinion of screening and brief interventions in the community pharmacy setting

Data to derive outcome measures (e.g. FAST score, other measures of alcohol consumption) will be collected at baseline, three and six months. Baseline data will be collected by pharmacy staff during the screening process and pharmacist consultation. Data at three and six months will be collected from clients using mailed questionnaires. The pharmacists and staff will be required to document additional information including the duration of screening and brief intervention consultations.

Key secondary outcome(s))
No secondary outcome measures

Completion date
05/02/2011

Eligibility

Key inclusion criteria
1. Community pharmacists and staff from 20 community pharmacies (i.e. 10 pharmacies in each group)
2. Adult clients presenting in participating community pharmacies
3. Clients aged 18 or over, either sex

Participant type(s)

Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Clients who have already been screened
2. Received an alcohol brief intervention elsewhere
3. Clients identified as dependent drinkers

Date of first enrolment
05/02/2010

Date of final enrolment
05/02/2011

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
University of Aberdeen
Aberdeen
United Kingdom
AB25 2AY

Sponsor information

Organisation
University of Aberdeen (UK)

ROR
https://ror.org/016476m91

Funder(s)

Funder type
Government

Funder Name
Chief Scientist Office

Alternative Name(s)
CSO

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration