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Pharmacy Alcohol Study: The effectiveness of alcohol brief intervention delivered in community pharmacies

Submission date
16/03/2012

Recruitment status
No longer recruiting

Registration date
16/03/2012

Overall study status
Completed

Last Edited
30/08/2018

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims:
Many people drink more alcohol than is healthy. This study aims to find out if advice given by pharmacists can change drinking behaviour. This service is commonly provided by general practitioners (GP) or nurses. Our research team would like to find out if this service can also be offered in community pharmacies.

Who can participate?
To take part you need to be, 18 years old or over, drink alcohol and not currently be in treatment for alcohol problems. You need to have a home address in the UK, and must be able to speak, read and write English sufficiently to take part in the study. You would need to be able to access a community pharmacy that is participating in this study.

To take part you will need to use the pharmacy for one of the following activities:
1. Making a general health queries or seeking advice which could be linked to alcohol use
2. Receiving pharmacy services for smoking cessation, review of medication use, general health check, emergency hormonal contraception.
3. Receiving treatments with prescriptions for cardiovascular disease, depression, anxiety, diabetes and gastric problems
4. Buying smoking cessation aids, gastrointestinal remedies, sleep aids and central nervous system depressants.

What does the study involve?
If you agree to take part, the pharmacist will ask you questions in the private pharmacy consultation room, in confidence, about your alcohol use. From your responses, the pharmacist will be able to decide whether you could participate in the study. You may have your drinking assessed and be informed about other alcohol services. If you are eligible to participate in the study the pharmacist will find out which type of intervention you will receive. This will not be known to you or the pharmacist until just before you are about to receive an intervention.

This study is being done in this way as we dont know the effects of pharmacists providing advice on alcohol to the public. To find out, we need to compare the two treatments to see which is better. Both will consist of a short conversation with the pharmacist about your drinking which is expected to take between 5 to 10 minutes. Which one you get will be decided by chance.

Whichever treatment you receive, the pharmacist will ask you for your contact details and other information about yourself. You will then be telephoned twice by the researcher.
The first telephone call will be within 2 weeks of you participating in the pharmacy study and you will be asked to confirm your contact details. The first telephone call is expected to take about 2 to 3 minutes.
The second telephone call will be approximately 3 months later to ask about your drinking, general health and your experiences of participating in this study. It is expected the telephone interview will take approximately 10 to 15 minutes. During this telephone call you will be invited to take part in another telephone interview about your experience of taking part in this study. Some people, who are interested will be contacted to arrange a convenient time for this third telephone call. This telephone conversation, about your study experience, will be tape recorded so we can get an accurate picture of your experience of participating in the Pharmacy Alcohol Study.

What are the possible benefits and risks of participating?
We cannot promise the study will help you, but the information from this study will tell us if alcohol interventions delivered by pharmacists to their customers can change drinking behaviour. There are no known risks of participating in the trial.

Where is the study run from?
This study is being organised from Kings College London. There are 17 community pharmacies participating in this study and all are located within Hammersmith and Fulham Primary Care Trust, London, United Kingdom.

When is study starting and how long is it expected to run for?
The study is will be open to participants, from approximately May 2012 and until 17th February 2013.

Who is funding the study?
Pharmacy Practice Research Trust

Who is the main contact?
Ms Ranjita Dhital
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Contact information

Type(s)
Scientific

Contact name
Ms Ranjita Dhital

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
11920

Study information

Scientific Title
The effectiveness of alcohol brief intervention delivered in community pharmacies: A randomised controlled trial

Acronym
PAS

Study objectives
In the UK alcohol misuse leads to an estimated cost to society of £25.1 billion per annum (NHS costs £2.7billion) and is the third leading cause of ill health. Alcohol Brief Intervention (BI) includes all practices aimed at identifying a real or potential alcohol problem by asking questions about alcohol use and motivating the person to take positive action about their drinking. There is strong evidence to support the effectiveness of BI to reduce and prevent alcohol misuse in primary healthcare but little is known about how effective this is delivered through community pharmacy. Therefore, the research team purpose to conduct the first randomised controlled trial in community pharmacies to assess if BI delivered by community pharmacists is effective at reducing customers risky alcohol use.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Research Ethics Service Committee London Queen Square First MREC approval date 12 /12/2011, ref: 11839/241643/1/425

Study design
Randomised; Interventional; Design type: Prevention, Screening

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

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
Topic: Primary Care Research Network for England; Subtopic: Not Assigned; Disease: All Diseases

Interventions
Treatment arm of the trial will receive:
1. Approximately 10 minutes of Brief Intervention by the pharmacist.
2. Written information about alcohol use together with services and organisations to contact for further support.

Control arm of the trial will receive:
Alcohol: The Basics leaflet.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Mean difference in alcohol risk measured using the 10-item Alcohol Use Disorder Identification Test (AUDIT) between intervention and control group at three-month follow-up

Secondary outcome measures
1. Changes in alcohol use risk categories (low risk, hazardous/harmful or possible dependence), using the AUDIT, between intervention and control group at three-month follow-up
2. Proportion of possible dependent drinkers identified by pharmacists, using the AUDIT, and advised to access further support on their drinking
3. Difference in general health status, measured using EQ-5D, between intervention and control groups
4. Pharmacy customers experience of participating in the trial

Overall study start date
15/05/2012

Completion date
15/05/2013

Eligibility

Key inclusion criteria
1. Male and female pharmacy customers aged 18 years or over, who are accessing pharmacy services within the 17 participating pharmacies within NHS Hammersmith and Fulham and are able to consent for themselves are eligible to be recruited.
2. Currently drink alcohol
3. Be contactable by phone during the three months, after receiving a procedure for follow-up telephone calls
4. Have a home address in the UK
5. Be able to speak, read and write English sufficiently to take part in the study
6. Target Gender: Male & Female ; Lower Age Limit 18 no age limit or unit specified

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 408; UK Sample Size: 408; Description: 204 intervention and 204 control subjects

Key exclusion criteria
1. Currently in treatment for alcohol problems
2. Currently involved in any other alcohol research
3. Not accessing pharmacy services
4. Under 18 years old
5. Employees of the trial pharmacies

Date of first enrolment
15/05/2012

Date of final enrolment
15/05/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Florence Nightingale School of Nursing and Midwifery
London
United Kingdom
SE1 8WA

Sponsor information

Organisation
King's College London (UK)

Sponsor details
Room 1.1 Hodgkin Building
Guy's Campus
London
England
United Kingdom
SE1 1UL

Sponsor type
University/education

Website
http://www.kcl.ac.uk/index.aspx

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Charity

Funder Name
Pharmacy Practice Research Trust (UK)

Alternative Name(s)
PPRT

Funding Body Type
Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location
United Kingdom

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	18/02/2013		Yes	No
Results article	results	01/10/2015		Yes	No