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

Submission date	Recruitment status	[X] Prospectively registered		
16/03/2012	No longer recruiting	[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
16/03/2012	Completed	[X] Results		
<b>Last Edited</b> 30/08/2018	Condition category  Mental and Behavioural Disorders	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 gueries 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 ranjita.dhital@kcl.ac.uk

## Contact information

**Type(s)**Scientific

Contact name

Ms Ranjita Dhital

#### Contact details

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### Additional identifiers

Protocol serial number 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

#### Study type(s)

Treatment

#### 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(s)

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

#### Key secondary outcome(s))

- 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

#### 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

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

18 years

#### Sex

All

#### 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

**United Kingdom** 

England

# Study participating centre Florence Nightingale School of Nursing and Midwifery

London United Kingdom SE1 8WA

# Sponsor information

#### Organisation

King's College London (UK)

#### **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**

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?
Results article	results	01/10/2015	Yes	No
<u>Protocol article</u>	protocol	18/02/2013	Yes	No
Participant information sheet	Participant information sheet	11/11/2025 11/11/2025	No	Yes