



A study on health and alcohol

CI: Professor Iain Crombie

Participant Information Sheet

(Phase 2, recruited from GP practices)

We invite you to take part in a research study. Before you decide, we would like you to understand why the research is being done and what it would involve for you. We are therefore providing you with the following information. Please take time to read it carefully and discuss it with others if you wish. When you have read this information sheet, one of our team will go through it with you and answer any questions you may have. Be sure to ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for taking the time to read this information sheet.

Purpose of the study

This is a study about health and alcohol consumption among men aged 35-64 years, focusing on men who are overweight. Some men in this age group drink too much and we want to find ways to encourage them to avoid harmful drinking. We therefore want to look at alcohol consumption among a group of men, and find out whether discussing alcohol consumption with them influences patterns of drinking.

Men will be eligible to take part if they regularly consume more than 21 units of alcohol in a week (one unit of alcohol is about half a pint of normal strength beer, one measure of spirits or one small glass of wine). Only men who are overweight will be recruited.

What we would like you to do

After you have read this information sheet and have had a few days to think about it, a researcher will call you to see if you wish to take part. If you are willing to take part, you will be asked some questions about yourself and how much you drink to confirm that you are eligible for the study. If you are eligible, we will invite you for an interview at a place that is convenient for you, e.g. a community centre, GP surgery or at your home. At that appointment we will ask you to complete a questionnaire and will measure your height and weight. We will also discuss your health and explore your views about whether you might benefit from reducing your alcohol consumption. The appointment, which will be recorded, will take approximately half an hour. Men taking part in the study will be put into one of two groups which will discuss these issues in different ways, with one group receiving some text messages.

Five months after we meet with you for the first time, we will get in touch by telephone to arrange another appointment to see you. You will be asked to complete another questionnaire and you will be weighed again. We will also ask what you thought about taking part in the study. Once more, the discussion will be recorded. This appointment will be short, lasting about 15 minutes.

Why have I been chosen?

Men living in Tayside, who are overweight, are being invited to take part. Your GP has randomly selected men in this age group to be contacted to ask if they would be willing to take part. To take part you must be available to be contacted by mobile phone over the next five months.

Do I have to take part?

It is up to you to decide whether or not to take part. We will explain the study and go through the information leaflet. If you do decide to take part you will be asked to give consent. To do this you will be asked to reply to a text message from us to confirm that you are willing to take part. Participation in this study is entirely voluntary and you are free to refuse to take part or to withdraw from the study at any time without having to give a reason.

Expenses and payment

You will be given gift vouchers as a thank you for taking part in the study when you have completed the initial and the final interviews. You will also be given £10 to cover travel costs for attending each of the two interviews.

What are the possible benefits of taking part?

You will be given information on health issues and alcohol. You may find these useful in helping you to make healthier choices.

Confidentiality

Any information collected during the course of the study is confidential and access will be restricted to people conducting the study. Your name will not be disclosed, nor will details of your answers be given to anyone. With your permission, the interviews with the researcher will be recorded and typed up as a written document or transcript. The transcripts will then be examined to ensure that all of the important information has been captured. The transcripts will not contain your name or any information about you that would allow you to be identified. The only people who will have access to the transcripts are the researchers. Some of your comments may be included in a report on the study, but these will be completely anonymous.

What will happen to the results of the research study?

The overall findings of the study may be published in a scientific journal, but these will not mention you in any way. If you would like to receive information about the results of the study, please let us know, and we will forward a summary of the findings to you at the end of the study.

Who has designed and reviewed the study?

The study has been designed by a group of researchers from the Universities of Dundee, Aberdeen, Stirling, Newcastle, Glasgow and NHS Tayside. Funding has been provided by the National Institute for Health Research. The *East of Scotland Research Ethics Committee REC 2* has responsibility for

all proposals for medical research on humans in Tayside. It has examined the proposal and has raised no objections from the point of view of medical ethics. It is a requirement that your data from this research be made available to monitors from the University of Dundee and NHS Tayside, whose role it is to check that research is properly conducted and the interests of those taking part are adequately protected. The study is sponsored by the University of Dundee and NHS Tayside.

To obtain further information

If you have any questions about this research, please contact <name> who will be happy to discuss the study or answer any questions you may have.

<address>

Landline telephone: <telephone number> email: <email address>

Mobile: <mobile telephone number>

If you would like to talk to an independent researcher not involved in this study, please contact <name> who will be happy to answer any questions you may have about taking part in research.

Landline telephone: <telephone number> email: <email address>

Concerns or complaints about the research

If you have a complaint about your participation in the study you should first talk to the researchers involved in this study. If you have a concern about any aspect of this study, you should contact <name> on <telephone number> or by email at <email address> who will answer your questions.

If you remain unhappy and wish to complain formally, you can do this by contacting <name> who is the project leader. You can contact <him/her> by telephone on <telephone number> or by email at <email address>

You can also ask to speak to the Complaints Officer for NHS <Board Area>:

<address>

Freephone: <telephone number> email: <email address>

Thank you for taking the time to read this information sheet and considering taking part.