

A study on health and alcohol

Participant Information Sheet

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 leaflet, one of our team will go through it with you and answer any questions you may have. This will take about 10 minutes. 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 leaflet.

Purpose of the study

This is a study about health and alcohol consumption among young to middle-aged men (25 – 44 years). Some men in this age group drink too much and we want to find ways to encourage them to reduce the frequency of drinking at harmful levels. We therefore want to look at alcohol consumption among a group of men, and find out whether keeping in touch by mobile phone influences patterns of drinking.

Men will be invited to take part if they have had at least two days in the past month where they have consumed more than eight units of alcohol in one session (one unit of alcohol is half a pint of normal strength beer, one measure of spirits or one small glass of wine).

What we would like you to do

After you have read this leaflet and have had a few days to think about it, a researcher will call you back 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 see if you are eligible for the study. If you are eligible, we will send you a series of text messages over the next twelve weeks. The men taking part in the study will be put into one of two groups which will receive different text messages.

The messages present information about health as well as providing interesting facts. Please note that some of the messages you will receive will come from characters named Dave, Stevie and others. These are fictional characters, but their comments are based on our recent research with men in Scotland.

When the twelve weeks of text messages is over, we will get in touch by telephone two more times: at three months and twelve months after you have received the text messages, to ask you some

more questions. These will be short interviews and you will have the opportunity to ask any questions.

Why have I been chosen?

Men living in different regions of Scotland, selected by postcode area, 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 fifteen 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 and without this affecting your future medical care.

Expenses and payment

You will be given gift vouchers as a thank you for taking part in the study and to reimburse you for the cost of any text messages you send to us. You will be sent a £10 gift voucher after you have completed the first telephone interview. You will then receive a £5 gift voucher every three weeks for the three months you receive the text messages. You will also receive another £10 voucher when you complete the second and third telephone interviews. The gift vouchers will be posted to your home.

What are the possible benefits of taking part?

Throughout the study we will give you information on health issues. 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 telephone 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, St Andrews, Glasgow Caledonian University and NHS Tayside. Funding has been

provided by the National Institute for Health Research. The *East of Scotland Research Ethics Service* has examined the proposal and has raised no objections from the point of view of medical ethics. It is a requirement that your records in 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:

Landline telephone:

Mobile:

email:

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:

email:

Concerns or complaints about the research

If you have a concern about any aspect of this study, you should ask to speak to <name> on <phone number> 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 by telephone or by email

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