

REC Ref:
Short Title: **PIS v1.2**
Document Name: Patient information Sheet
Version: **1.2**
Date: **25/09/2007**

[Insert Header – University of York & Practice]

Randomised Evaluation of a Stepped Care Treatment Approach for Older Alcohol Users in Primary Care.

Patient Information Sheet

You are being invited to take part in a research study. Before you decide whether to take part it is important that you understand why the research is being done and what taking part in the research will involve. Please find the time to read the following information and discuss it with family, relatives, friends or your GP if you wish.

It is entirely up to you if you take part in the research study. If you do not wish to take part your usual care will not be affected in any way. If you do decide to take part you are free to stop taking part in the study at any time, you do not need to provide a reason.

The research is being conducted by the University of York, in conjunction with your local GP practice. The research is funded by the Department of Health and the study has been checked by [insert ethics committee].

Please read the following information carefully. If you have any questions about this study you can ask the practice nurse, [insert practice nurse name & telephone], or you can contact the study manager, [insert trial manager name and telephone]. The study is taking place in [No of practices] across England. We hope that 500 patients who are eligible will consent to take part in the study.

All patients attending [insert practice details] between [start date] and [end date] are being asked to complete a questionnaire about how much they drink alcohol. You completed this questionnaire and the results indicate that you may be drinking more alcohol than is good for your health. [Practice nurse name] telephoned you and made an appointment for you to discuss the study on [insert appt date time].

At the appointment [practice nurse name] will discuss the study with you. If you are happy to take part in the study you will be asked to sign a consent form, a copy of which is enclosed. [Practice Nurse Name] will ask you some questions about how much and when you drink alcohol, you will then be asked to fill in a short questionnaire about your general health and how often you use healthcare resources. Once this is completed the practice nurse will use a computer to decide what treatment you will receive. The practice nurse has no influence over the treatment you receive. All treatment provided will be tape recorded for quality assurance purposes. If you would prefer not to have your treatment session recorded you can indicate this on the consent form. The two treatment approaches are detailed below.

1. Treatment 1: You will receive a short 5 minute discussion about your drinking with the practice nurse and some written information about alcohol and your health.

2. Treatment 2: You will receive a 20 minute discussion with the practice nurse about your drinking and explore ways in which you could reduce the amount you drink. About 4 weeks later the practice nurse will call and discuss how much alcohol you have drunk in the 4 week period. If at this time the practice nurse feels you are still drinking too much alcohol for your health they will invite you to see a specialist at the general practice for three 40-minute appointments. The specialist is trained in a technique called Motivational Enhancement Therapy. This approach is known to be effective in helping many people reduce the amount of alcohol they drink. Four weeks after the last of these appointments the practice nurse will again contact you to discuss how much alcohol you are drinking. If at this time they feel you are still drinking alcohol at levels that are not good for your health they will ask the general practitioner to make a referral to the local specialist alcohol services.

Irrespective of what treatment you receive, we will send you two questionnaires by post. One will be sent 6 months and the other 12 months after the computer decided which treatment you would be receiving. These questionnaires will be similar to the one you completed just before your treatment was decided.

All information collected in this study is strictly confidential. We will inform your general practitioner that you are taking part in the study, but if you do not want your GP informed you can indicate this on the consent form. At the end of the study we will send you a copy of the brief report outlining the results of the study.

Thank you for taking the time to read this information sheet. If you need any advice or wish to discuss the study please feel free to contact the practice nurse, [practice nurse name & contact] or the trial manager at the address below. If you have any complaint about the study please contact the trial manager below who will deal with your complaint within 7 days.

[Trial Manager contact details]

If you are concerned about any issues related to the questions asked in this study or would like further information on where you can obtain help in relation to your drinking you can contact the National Alcohol Helpline:

Freephone DrinkLine 0800-917-8282 (11am-7pm Mon - Fri).

Drinkline offers the following services:

- Information and self-help materials.
- Help to callers worried about their own drinking.
- Support to the family and friends of people who are drinking.
- Advice to callers on where to go for help.

Drinkline is confidential and no names need be given. Callers to the above number have the option of listening to recorded information about alcohol or talking to an adviser.