Feasibility Study: Preoperative Behavioural Intervention to promote Responsible Drinking before elective orthopaedic Surgery

(PRE-OP BIRDS)

Participant Information Sheet

Patient Interviews

We would like to invite you to take part in an interview as part of the PRE-OP BIRDS research study. Before you decide you need to understand why the research is being done and what taking part would mean for you.

Please take time to read the following information carefully, and feel free to talk to others about the study, if you wish. Take some time to consider it carefully before you decide.

Please ask us if there is anything that is not clear.

Why have I been invited to take part in an interview?
You have been invited to take part in an interview because you have recently attended an appointment with a pre-operative assessment nurse using the behavioural intervention. As such, we are interested in hearing your thoughts on this experience and how useful the newly developed intervention was for you.

What is the purpose of the study?
Alcohol consumption is known to be associated with increased complications after surgery, which prevent early recovery and prolong rehabilitation times. It is therefore important that we are able to detect increased alcohol intake by patients more accurately than we currently do.

This study aims to test a revised screening and behavioural intervention, which will be used with patients being referred for surgery. The behavioural intervention will help healthcare professionals provide simple advice and guidance to patients on how reducing alcohol consumption prior to surgery could improve recovery time and reduce the amount of time spent in hospital after an operation.

As well as asking patients to take part in two sessions using this behavioural intervention, we are also asking if they would be willing to take part in an interview once the sessions have been completed. This is to gather the thoughts and feelings of those that will actually be using the advice to see how they felt about it.

Do I have to take part?
You do not have to take part, and it is up to you to decide. You can withdraw from the study at any time, without giving a reason, and this will not affect the care that you receive.

What will happen if I take part?
After you have signed the consent form you will take part in an interview with a member of the research team. The interview will take place after you have received your operation and have been discharged from hospital. It will last approximately one hour and will take place at a time and place convenient for you. The interview will explore your thoughts regarding the intervention and how acceptable you found it.

The interview will be audio recorded. This is to make sure that the researchers have access to the information that you provide. This helps them make any changes needed to the intervention and improve how it works in the future. By recording the interview, they can concentrate on what you are saying, rather than being distracted by taking notes.

Expenses and payment
You will not receive payment or reimbursement of expenses for taking part in this study. However the interview can be conducted when you attend your 6 week post-operative follow up appointment or in your home, at a time convenient to you. This ensures that you won't incur any additional costs as a result of taking part in this study.

What are the possible benefits of taking part?
By taking part in an interview you are providing valuable information that will help us to further develop the screening and behavioural intervention used as part of this study. We cannot promise the study will help you directly but the information we get from this study may help other patients in the future.

Will my taking part in this study be kept confidential?
All study information, including personal details, will be kept confidential and will not be made public. The study data and your original medical records may be looked at by people who are monitoring or auditing the study, a Research Ethics Committee (REC) or other regulatory authorities, or the hospital Trusts involved in the study, to make sure that the study is being run correctly. By signing the consent form, you are giving your permission for this to happen. Everyone involved in this study has a duty of confidentiality to the participants and this will be maintained.

What will happen if I don't want to carry on with the interview?
You have the right to withdraw at any time for any reason, and without giving a reason. But we might ask you to allow us to record why you have decided to withdraw. We will also keep the data we have collected from you up to the point of withdrawal if you agree for us to do so.

What if there is a problem?
If you have a concern about any aspect of this study you should ask to speak to the researcher who will do their best to answer your questions: [insert staff details here]

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence, then you may have grounds for a legal action for compensation against The Newcastle upon Tyne Hospitals NHS Foundation Trust but you may have to pay your legal costs. NHS indemnity does not offer no-fault compensation (for harm that is not anyone's fault).

If you are still unhappy and wish to complain formally, you can do so through the hospital's procedure Patients Complaints Service (PALS) [insert details here]

Who is organising and funding the research?
This study is being funded by the NIHR Health Technology Assessment programme. This body is funded by the UK government to carry out research for the benefit of the NHS and its patients. It is being organised and carried out by a team of researchers based in Newcastle upon Tyne.

Who has reviewed the study?
To protect your interests, all research in the NHS is looked at by an independent group of people called a Research Ethics Committee. This study has been reviewed and given favourable opinion by Newcastle & North Tyneside 2 Research Ethics Committee.

How have patients and the public been involved in this study?
Members of Voice North have been involved in the design of this study. Voice North is a voluntary organisation that includes members of the public. Members actively volunteer to assist researchers with the design of research studies to improve the quality of the research and make sure it fits with what is important for both patients and the public. You can find out more about Voice North at: http://www.ncl.ac.uk/ageing/partners/voicenorth/#about

What will happen to the results of this study?
Data from this study will be used to improve the behavioural intervention and the next phase of the research. Data from your interview may be used (anonymously) in the study report and in other publications from the research.

Further information and contact details
These are the key contacts for this study. If you have any further questions or would like any further information about the study or the rights of participants, please feel free to contact them.

[insert local details here]