PRE-OP BIRDS

To be printed onto local headed note paper

Preoperative Behavioural Intervention to Reduce Drinking before elective orthopaedic Surgery (PRE-OP BIRDS): A Pilot Randomised Controlled Trial

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 trial. 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 trial, 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 undergone hip or knee replacement surgery and agreed to take part in the pre-op BIRDS trial. As such, we are interested in hearing your thoughts on this experience.

What is the purpose of the trial?
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.

This trial 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 the trial itself, we are also asking if they would be willing to take part in an interview once they have been completed the trial visits. This is to gather the thoughts and feelings of those involved to see how they felt about it.

Do I have to take part?
It is up to you to decide whether you want to take part or not. You can withdraw from the trial 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 trial visit 6 (which is after you have received your operation and have been discharged from hospital). It will last up to one hour and will take place at a time and place convenient for you. The interview will explore your experience of being in the trial 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
The interview can be conducted at either your home or over the telephone, at a time convenient to you. This ensures that you won't incur any additional costs as a result of taking part in this trial.

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 trial. We cannot promise the trial will help you directly but the information we get from this trial may help other patients in the future.

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

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.

What if there is a problem?
If you have a concern about any aspect of this trial 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 trial 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 trial?
To protect your interests, all research in the NHS is looked at by an independent group of people called a Research Ethics Committee. This trial has been reviewed and given favourable opinion by [insert name of REC].

How have patients and the public been involved in this trial?
Members of Voice North have been involved in the design of this trial. 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

Patients have also been involved in a feasibility study as part of this project to help inform the design of the screening and intervention materials as well as the development of this pilot trial.

What will happen to the results of this trial?
Data from this trial will be used to inform future research. Data from your interview may be used (anonymously) in the trial report and in other publications from the research.

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

[insert local details here]