*To be printed onto local headed note paper*

PRE-OP BIRDS

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

## Participant Information Sheet

We would like to invite you to take part in a 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 PRE-OP BIRDS?**
You have been invited to take part because you have recently been placed on the waiting list for elective hip or knee replacement surgery. Also the AUDIT C screening that you recently completed indicates that you are eligible to take part in this trial. The AUDIT C is a commonly used questionnaire to find out how much alcohol patients consume on a regular basis.

**What is the purpose of the trial?**
Alcohol consumption is known to be associated with increased complications after surgery, which can prevent early recovery.

This trial aims to test a method which aims to reduce alcohol intake in patients known as a 'behavioural intervention'. This will be used with patients being referred for surgery. The behavioural intervention will be used by healthcare professionals to provide simple advice and guidance to patients on how they can reduce their alcohol consumption should they want to and what benefits this could bring.

**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?**
Taking part in the trial will not influence if or when you receive your surgery. After you have signed the trial consent form you will be asked to complete the AUDIT questionnaire, which is a slightly longer version of the AUDIT C questionnaire that you previously completed. You will then be randomly allocated to one of two groups:

- Behavioural intervention plus treatment as usual

Or

- Treatment as usual only

You will have a 50-50 chance of being allocated to one of the groups. Your group will be randomly picked by a computer. Neither you nor the trial team will have a say on which group you are put in, but you will be told straight away which group you have been allocated to. You will then attend your pre-assessment appointment, receiving your usual care.

**What will I have to do?**
As part of this trial there are some visits that you will be required to attend/take part in. In this trial all visits to the hospital have been scheduled to take place either when you are already at hospital (for example during routine appointments or whilst you are an in-patient around the time of your surgery) or at your home/by telephone. This is to ensure you do not have to make additional trips to hospital.

Once you have been randomised you will be informed straight away which group you have been allocated to either (a) behavioural intervention or (b) usual care.

(a) Behavioural intervention

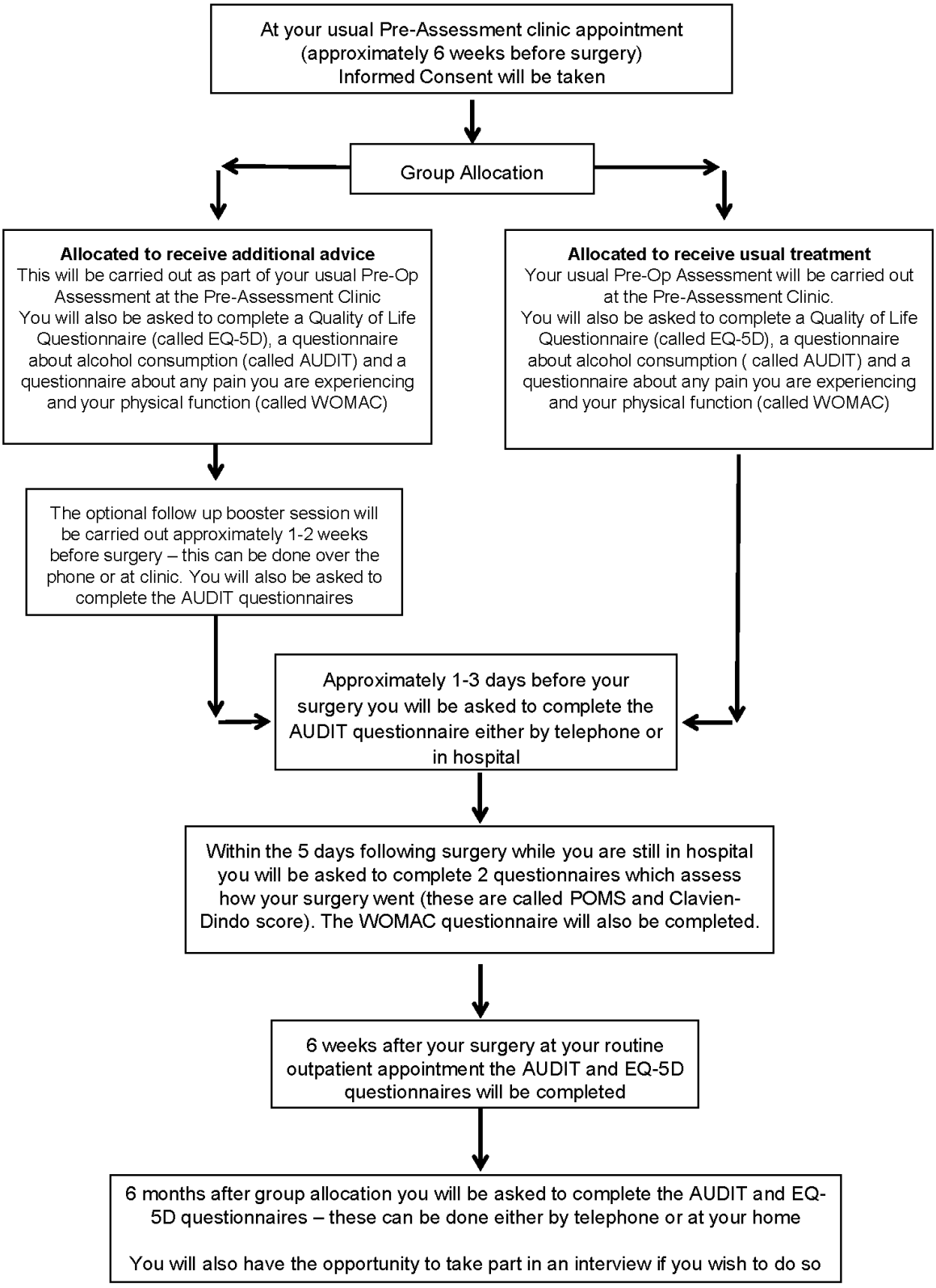
If you are allocated to receive the behavioural intervention, the trial team will go through the intervention with you as part of your pre-assessment appointment. As part of the behavioural intervention you will be provided with brief advice on alcohol intake and support to reduce your alcohol consumption before surgery should you want to. The team will also ask you some questions about your alcohol use and feelings of wellbeing. The behavioural intervention session will last approximately 30 minutes which means your pre-assessment appointment will last approximately 30 minutes longer than usual. Approximately one to two weeks before your surgery the research team will contact you (by telephone) to ask you a few more questions and to offer you a second intervention session. This session will last approximately 10 to 20 minutes and can be delivered by telephone if it is easier for you. During this second session you will be asked to complete the AUDIT tool and receive the behavioural intervention which will involve some feedback and support. The aim of this session is to provide a refresher of the advice and guidance you received during the first session and to provide you with an opportunity to receive feedback and ask any questions. This second session is optional and you will be asked when signing the consent form to indicate if you are willing to take part in a second session and this will be confirmed with you again when you are contacted by the team one to two weeks before surgery.

We would like to make an audio recording of the behavioural intervention sessions in order to help with the training of staff delivering the intervention. For example, researchers will listen to the recording and make a note of whether the nurse delivering the session is covering everything they need to. The recordings will also ensure that the behavioural intervention is being delivered correctly and delivered in the same way each time. The recorded data will be anonymised and then analysed by a researcher to assist the research team in improving the intervention content for future use. The attached consent form will ask you to indicate whether or not you are willing to have your intervention sessions recorded. The recording will only be listened to by members of the research team.

(b) Usual Care

If you are allocated to receive treatment as usual you will not receive the intervention sessions and your consultations will not be audio recorded, but you will be asked some questions about your alcohol use and quality of life at the trial visits. These will only take a few minutes to complete.

Regardless of which group you are randomised to, you will be followed up for 6 months after randomisation. A schedule of the trial visits are listed in the diagram below along with what information will be collected:




When you come in for your surgery you will be asked if you would like to take part in the National Joint Registry. This is national registry which collects information on all hip, knee, ankle, elbow and shoulder

replacement operations and you will be provided with a separate information sheet which will contain much more detailed information about the National Joint Registry and what it does. The WOMAC questionnaire mentioned in the table above is collected as part of the National Joint Registry and therefore if you agree to take part in the registry we will be able to use the WOMAC questionnaires completed as part of that (with your permission) and you will not have to complete them again as part of this trial. If however you decide not to take part in the registry we will need to go through these questionnaires with you as part of the PRE-OP BIRDS trial.

You will also be offered the opportunity to take part in an interview after you have completed the trial. The interview will last around 60 minutes and will ask you how useful you found this trial. Again this is entirely optional and you do not have to take part in an interview if you don't want to. If you are interested in taking part we will provide you with an additional information sheet that provides more information on what the interview will involve.

**Expenses and payment**
As part of this trial you should not have to attend hospital for any additional visits outside of your routine appointments. However, in the unlikely event that you do have to attend an additional visit at hospital in order to complete a trial visit, reasonable travel expenses will be reimbursed.

**What are the possible benefits of taking part?**
By taking part in this trial and following advice provided it is possible that you may recover more quickly following your operation and you may not have to spend as much in time in hospital afterwards. We cannot promise that the trial will help you directly but the information we gain from this trial will inform future research and may help other patients in the future.

**What are the possible disadvantages of taking part?**
There are no direct risks involved in taking part in this study and the standard of care you receive will not be affected whether you decide to take part or not. If you do agree to take part in the study you will be required to give up a small amount of your time to complete the study visits, however we will ensure that you do not have to attend hospital for additional visits outside of routine appointments wherever possible.

You may be asked some potentially sensitive questions regarding your use of alcohol. These questions are asked routinely, as part of standard clinical practice, in the pre-assessment clinic prior to any surgery.

**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. With your permission, we will let your family doctor (GP) know that you are taking part. 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. It is possible that the trial team might share anonymous information collected with other researchers in the future. Sharing trial information with other researchers is very important as it helps us to make sure that we are running a trial in the best possible way and it means that we can make the most of the information collected during a trial. Any information that is shared will contain none of your personal details and will be fully anonymised. 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 always 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 study?**
You have the right to withdraw from the trial 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 on 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]

**Involvement of the General Practitioner/family doctor (GP)**
With your permission, we will let your family doctor (GP) know that you are taking part. Participation in the trial will also be noted in your hospital records so that anyone who treats you will know you are taking part in the trial.

**Who is organising and funding the research?**
This trial is being funded by the NIHR Health Technology Assessment (HTA) 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 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 study?**
Data from this trial will be used to inform future research. Data may be used, anonymously, in the trial report and publications from the research.

**Further information and contact details**
These are the key contacts on 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]