REC Reference 15/SC/0019

Participant Information Sheet – Qualitative study

Community Based Rehabilitation after Knee Arthroplasty (CORKA), Qualitative Study

What is the purpose of this study?

The CORKA team would like to find out more about why people decided to take part in the CORKA trial and what they thought about taking part and the treatment they received. We would like to invite you to tell us your views about taking part in CORKA, and about living with a knee replacement to help the study team to explain the results of the study more fully.

Why have I been asked to take part in this study?

You are being invited to take part in this project because you are a participant in the CORKA study, which is comparing a community based rehabilitation programme against standard care, after knee replacement. We would like to invite you to tell us your views on this subject to help the study team to explain the results of the study more fully. The things you tell us will help other people make decisions about their treatment after knee replacement. There are no right or wrong answers to this and we are keen to hear a wide variety of opinions. The trial team will be contacting 15 participants to ask their views.

What will I have to do if I take part in this study?

If you decide to take part in the study you will be asked to discuss your views and experiences. This will be in an interview that will take place between your last treatment session and the 12 month follow up appointment.

A researcher would ask you for a one-off discussion about your views of the research study, the treatment you have received and about your experience of having a knee replacement. This discussion would last for 45-60 minutes and could either take place in your home or a local venue convenient to you as you prefer. If you choose to travel to a local venue then your travel expenses would be reimbursed.

The researcher would ask for your permission to audio record this discussion and to take some notes during this discussion to help them remember the discussion accurately. You can choose not to have the discussion recorded if you prefer.

If you wanted to the researcher can send you your transcript or a summary of the discussion. If you would like to discuss this with the researcher on the telephone then you can let them know and they will telephone you at a convenient time for you.

What are the benefits of taking part in the study?

There is no direct benefit to you in taking part in this study; although we have found in similar studies that people enjoy talking about their experience.

Is there any risk of taking part in this study?

We do not anticipate any risks from your participation in this study and from you telling us about your experiences.

What if there is a problem?

If you have a concern about any aspect of this study, please speak to the researchers who will do their best to answer your questions [01865 737526]. If you would prefer to speak to someone not involved in the study then you could contact the Patient Advice and Liaison Service (01865 221473 / 740868).

If you wish to complain about any aspect of the way in which you have been approached or treated during the course of this study, you should contact <*name of investigator*><*contact details (phone number & email)*> or you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 572224, or the head of CTRG, email ctrg@admin.ox.ac.uk.

The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this substudy.

Would anyone else know if I was taking part?

We will follow NHS guidelines with regard to ethical and legal practice and all information about you will be handled in confidence. We remove any personal

information from the audio recording and we give each discussion file a pseudonym (rather than using your name). We will keep this information, along with digitally stored audio recording on a password protected computer until five years after we have published the results (so we can help anyone contacting us with any questions) and then we will destroy your file. We keep your personal contact details in a separate place (in a locked filing cabinet in a locked office), so that we can send you a letter telling you about the results of this study. We will then destroy these paper files after we have posted you this letter. Your continued involvement in the CORKA study and your future NHS care will not influenced in any way by your taking part in this part of the project.

Do I have to take part in this study?

It is up to you to decide to join the study. If you agree to take part, we will ask you to sign a consent form. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive.

What will happen to the results of the study?

We plan to publish the results of the study. This will help clinicians and patients to make decision about treatment after knee replacement in the future. Although there is a possibility that you may recognize your own quotes if you read the final paper, we take the greatest care to ensure that no one else reading the results would ever know your identity. We would also present the results of the study to a scientific conference for health professionals to help them to know what it is like for someone with a knee replacement, in addition to helping them make the best decisions about treatment after knee replacement.

Who approves this study and who is funding the research?

All research in the NHS is reviewed by independent groups of people, called a Research Ethics Committee, this study has been reviewed and approved by South Central Oxford B Ethics committee, REC number 15/SC/0019. This research has been funded by the National Institute of Health Research's Health Technology Assessment Programme.

Who do I contact for further information?

If you would like any further details about this study or would like to ask us any questions then please do not hesitate to contact us. You may speak to

Fran Toye 01865 737526, email Francine.Toye@ouh.nhs.uk or Jonathan Room 01865 737526 email jonathan.room@ouh.nhs.uk

What do I do now?

If you are interested in taking part in this study then please fill in the reply slip and post it to us in the pre-paid envelope provided. You will then be contacted by a member of the research team who will discuss the study with you and arrange to meet you.

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