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PARTICIPANT INFORMATION SHEET
(PATIENTS)

A qualitative research study to explore patient and surgeon considerations for revision knee replacement for unexplained, chronic pain

We would like to invite you to take part in our research study. Before you decide whether or not to participate, it is important that you understand why the research is being done and what it would involve for you. Please take time to read this information and discuss it with others if you wish. If there is anything that is not clear, or if you would like more information, please ask us.

What is the purpose of the study?

The purpose of this study is to find out what is important to patients and surgeons when considering further surgery to the knee to treat unexplained, chronic pain after knee replacement.

Why have I been invited?

You have been invited to participate because you have unexplained pain in your knee after knee replacement, or you have previously had revision surgery to treat this condition. We intend to recruit 10-15 patients and 10-15 surgeons to this study.

What does the study involve?

The study will involve completing a short data collection form to capture information on your background (age, gender, ethnicity, marital status, employment status, dependents, living arrangements, other health conditions, hobbies). This will be followed by an interview where we will ask you about the problems that you have had with your knee replacement, how these have affected you and your thoughts on the role of revision surgery for this problem.

What will happen to me if I decide to take part?

If you decide that you would like to take part, Mr Shiraz Sabah (who is a trainee surgeon undertaking this research as part of a PhD) will contact you to complete a

consent form and schedule an interview. The interview will last around an hour. He will discuss with you how you would prefer to be interviewed, with options to do this face-to-face, as a video call or over the telephone. The interview will be audio recorded with consent so that it can be analysed later and sent to an approved transcription service so that it can be typed up word-for-word. The transcription service will be required to delete the recording once the transcript has been returned to us and checked. The researcher will remove information such as names and places that can be used to identify you and add your transcript to our research software under a under an anonymous identifier (e.g. Participant 1). After we have analysed the interview, we will ask you if you would like to receive a summary to check that we have correctly understood what you told us. We will invite you to provide any feedback or clarifications, but this is optional. We will then write up our findings as a research paper for publication. With your permission, we may use some direct quotations that you have provided us in our reports and publications. These will be anonymised so that they cannot be used to identify you (e.g. Participant 1). We will send you a summary of our main findings at the end of the study.

Do I have to take part?
No. Taking part in this study is entirely voluntary and you are free to withdraw at any time without giving a reason. If you choose to take part and then change your mind it will not affect your usual clinical care.

What should I consider?
We understand that talking about chronic pain may be difficult or upsetting. You do not have to answer any questions that you do not wish to, and the interview can be stopped at any time. We can also direct you to sources of support. The interview transcript will be kept separate from your medical notes. We will remove information, such as your name and places, that can be used to identify you. However, with this type of research it is not possible to guarantee that no one will recognise your account. You are free to take part in other research studies at the same time.

What are the possible benefits of taking part?
This study may not benefit you directly. However, it may benefit patients and surgeons in the future by providing a better understanding of the considerations that are important to you and other patients with chronic pain after knee replacement.

Will my General Practitioner/family doctor (GP) be informed of my participation?
We will not routinely inform your GP of study participation.

Will my taking part in the study be kept confidential?
Yes. Any personal data collected will be stored on a secure database at the University of Oxford. All interview transcripts will be anonymised prior to analysis. Responsible members of the University of Oxford may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

Will I be reimbursed for taking part?
Reasonable travel expenses for any visits additional to normal care will be reimbursed on production of receipts, or a mileage allowance provided as appropriate. A contribution of £30 will be made, to thank you for your time, in the form of a gift voucher.

What will happen to my data?
Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.' The University of Oxford is the data controller and is responsible for looking after your information and using it properly. We will be using information from you and your medical records in order to undertake this study and will use the minimum personally-identifiable information possible. We will keep your contact details (name and address) for 12 months after the study has finished. This is so that we can inform you about the study findings and send a gift voucher to thank you for your participation. Research documents will be held securely at the University of Oxford for 3 years after the end of the study. This includes documents with personal information, such as consent forms, and those which have been anonymised (such as interview transcripts).

Our interview with you will be audio recorded. If you are joining remotely, joining instructions will be sent from a secure email address.

The interview recording will be encrypted and transferred to a transcription company approved by the University of Oxford. They are subject to the same requirements of confidentiality. They will destroy all data they hold on return of transcripts to the researcher.

The local study team and Oxford University Hospitals NHS Foundation Trust will use your name, NHS number, home address, and contact details to contact you about the research study and to oversee the quality of the study. They will keep identifiable

information about you from this study in keeping with their policy for retention of medical notes.

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at https://compliance.web.ox.ac.uk/individual-rights

You can find out more about how we use your information by contacting Mr Shiraz Sabah (shiraz.sabah@ndorms.ox.ac.uk).

What will happen if I don't want to carry on with the study?

- Participation is voluntary and you can change your mind at any stage.
- This will not affect the care you receive from the hospital and you will receive normal follow-up.
- If you withdraw from the study, we will ask you whether you would like data collected up to your withdrawal to be used in the study or destroyed.
- It is important to note that after we have anonymised your interview transcript it will not be possible for us to trace data back to you and so you will not be able to withdraw after this point.

What will happen to the results of this study?

The results of this study will be published as a peer-reviewed paper, presented at orthopaedic conferences and contribute to the fulfilment of a doctoral thesis. We will also write a summary of the study for our research page at the University of Oxford. We will share this summary with you. Your name will not be used when reporting findings and information that may identify you, such as names and locations, will be removed. However, with this type of research it is not possible to guarantee that no one will recognise your account. You can contact us if you would like further information on the results of this study.

What if there is a problem?

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 study.

If you wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of this study, you can contact: Mr Shiraz Sabah (shiraz.sabah@ndorms.ox.ac.uk), the Knee

Team (hipandknee.noc@nhs.net) or you may contact the University of Oxford Research Governance, Ethics and Assurance Team on 01865 616480, or the director of RGEA (ctrg@admin.ox.ac.uk).

The Patient Advisory Liaison Service (PALS) is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. PALS is unable to provide information about this research study. If you wish to contact the PALS team please contact 01865 738126 or email PALS@ouh.nhs.uk.

Who is organising and funding the study?
This study has been organised by Professor Price and the Knee Team at the Nuffield Orthopaedic Centre. The study is sponsored by the University of Oxford. The study is funded by the National Institute for Health Research (NIHR).

Who has reviewed the study?
All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given favourable opinion by the Wales Research Ethics Committee 4, Wrexham.

Further information and contact details:
Please contact Mr Shiraz Sabah (shiraz.sabah@ndorms.ox.ac.uk).

Thank you for considering taking part.