GETTING IT RIGHT FIRST TIME

Participant Information Sheet

Study title: Understanding patient experiences' of same-day total joint replacement: A qualitative interview study.

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You are being invited to take part in this research study. In this sheet we explain why the research is being done and this should help you decide whether you would like to take part. Please read the information about the study below. You can ask questions if anything is not clear, or you would like more information. If you are happy to participate we will take your contact details and be in touch to arrange an interview date and time.

The problem and why it is important.

Same day or day-case surgery involves no overnight hospital stay. Performing more day-case surgery might help to ease pressures on hospitals and reduce waiting times for surgery. It is becoming more common to offer day-case surgery for total knee and total hip replacement surgery. We know that this can be done safely, but we do not know what the experience is like for patients.

We are interested to know what it is like for patients who go home on the day of surgery after they have had hip or knee joint replacement surgery. We hope that the findings will tell us about how to improve the experience for patients in future.

What we aim to achieve

We aim to perform a one-off interview with patients at a convenient time in the days or weeks after their recent surgery. We are interested to find out about the patient experience of hip or knee replacement surgery in the National Health Service.

We will interview patients who been discharged on the same day as their hip or knee replacement operation. We hope to understand about positive and negative aspects of the process. This will help us to design surgery pathways that provide a better experience for patients in future.

Our findings will influence national guidance from the Getting It Right First Time (GIRFT) programme. GIRFT are a part of NHS England and they make recommendations to hospitals across the country.

Why have I been asked to take part?

You have been asked to take part because you will have undergone one of the operations of interest and have been discharged on the same day. We aim to involve approximately 16-20 participants in this study. Participants will differ in age, gender, where they live in the country, where they had their treatment, and what operation they had. This variety should provide us with a wide range of different perspectives and experiences. Participation is entirely voluntary and you are under no obligation to take part.

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

The study involves a one-off interview on a one-to-one basis with an interviewer. This will last from between 15 and 45 minutes. If you express an interest in being involved, we will ask you to complete a short form. We will then contact you within several weeks of your operation to see whether you would like to take part, and to arrange a time for an interview that suits you shortly after.

The interview can take place in one of two ways and depends on your preference. The options are:

1. Over the telephone
2. Online using video conferencing software

The interview will be arranged for a time that suits you. During the interview, we will start off by making sure that you are happy to take part. This involves checking your understanding about the study. We would gain your consent, either verbally with a recording or asking you to sign an electronic consent form and store either method securely.

You will then answer a few basic questions about yourself, and then questions about your surgery and your recovery. The interviews will be recorded so they can be analysed later. Your answers will be anonymised so you cannot be identified, and none of the video or audio footage will be shared publicly or to your surgical team. There are no right or wrong answers – we are just interested to find out about your thoughts and experiences.
Once the interview transcripts have been written, there may be a limited opportunity for you to review the information we have gathered from the interview prior to any formal publication.

We do not carry out any medical tests or treatments as part of this study, and involvement in the study will not affect any of your medical care.

What should I consider?

This study is finding out about your thoughts and experiences as a patient who recently had surgery and was discharged the same day. You do not have to prepare for the interview in any particular way. Being involved in this study will not prevent you from being involved in any other research studies.

Are there any possible disadvantages or risks from taking part?

As an interview, this study poses no risks to your physical health. The interview questions include asking about you and about your experience of your recent operation and discharge. It is possible that the questions could unintentionally cause emotional distress. If you do experience distress at any time the interview can be stopped.

What are the possible benefits from taking part?

We hope that the information we discover will allow us to understand how to develop safe and effective same day hip and knee replacement surgery treatment pathways across the country. There is unlikely to be any direct personal benefit to you by taking part in the study.

Will my General Practitioner (GP) be informed about my participation?

This study does not involve any changes to your medical care and therefore we do intend to routinely inform your general practitioners. If during the interview you inform us about any symptoms or conditions of concern that your GP does not know about, then we might recommend that you contact your GP or ask your permission to do so on your behalf.

Will my taking part in the study be kept confidential?

For your interview, you will be assigned a unique study code number. Afterwards, whenever we use the information you provide, it will only be identified by using your unique study code number and not your name. The link between your name and study code number will be recorded and stored separately and confidentially and will not be published. When we publish the study results, we will take care to avoid presenting the findings in a way that could identify you based on your answers and information provided. We will store all of the study data on an encrypted and password protected server controlled by NHS England.

Responsible members of the NHS England team or the local research team may be given access to data for monitoring and/or audit of the study to ensure that the research complies with applicable regulations.

The video/audio footage from your interview will be transcribed into text and held anonymously as described above. Once transcription has taken place, we will delete the video/audio files.

Will I be reimbursed for taking part?

Study participation is voluntary and you will not be reimbursed for your time. There should not be any personal financial cost to participating. Interviews over the internet or telephone will involve no travel expenses.

What will happen to my data?

We will be using information that you provide us with at interview to undertake this study. We will need to use information from you and from your medical records for this research project.

This information will include your initials/ NHS number/ name/ contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure.

Research is a task that we perform in the public interest. NHS England as sponsor, is the data controller. This means that we, as researchers, are responsible for looking after your information and using it properly. We will use the minimum personally identifiable information possible. We will keep identifiable information about you for 6 months after the study has finished.

This information will not be used for any other purposes outside of the research project. We will store the anonymised research data and any research documents with personal information, such as consent files, securely at the NHS England for 1 year after the end of the study, as part of the research record.

Your rights to access, change, or move your personal information may be limited, as we need to manage your information in specific ways for the research to be reliable and accurate.

To find out more about how your data will be used you can do one of the following:

- Ask a member of the research team. Oliver Adebayo is leading the research and can be contacted on:oliver.adebayo4@nhs.net
- Read about it at this website: https://www.hra.nhs.uk/information-about-patients/

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 time during the interview. Withdrawal will not affect your future healthcare or legal rights. If you withdraw before your interview is transcribed, all data that you provided will be deleted or destroyed. If transcription has already been performed, the information will be used but in the anonymised manner that we have described.

What will happen to the results of the study?

We will transcribe the audio footage from interviews into text and analyse the text to find themes. An external company will be involved in transcription of the interviews however all data will be treated confidentially and securely throughout. We will present our findings at conferences and through publication in a journal. We will also share the study findings with participants and everybody who helped to design the study. The findings might be used to inform future healthcare guidance and policy by
GIRFT and other healthcare organisations. We will present the results of the study in a way that means that you cannot be personally identified.

What if we find something unexpected?

There is a chance that we could discuss something that concerns you during the interview. For example, this could relate to the safety of you or other patients. If we discuss any information of concern during your interview, we will also discuss the matter within our study team. We will devise a strategy to address concerns that protects your confidentiality. This might involve discussing the concerns with the hospital where you had treatment.

If you report any symptoms that could represent and ongoing problem following your surgery, we might recommend that you see your doctor or attend your nearest emergency department. In such an event we would stop your interview short so that you can gain medical attention.

What if there is a problem or I have a complaint?

If you wish to complain or have any concerns about any aspect of the way you have been approached or treated during the course of this study, you can contact one of the following:

- Chief investigator – Oliver Adebayo [NHS England] – contact details below
- Patient Advice and Liaison Service (PALS) at your local hospital

How have patients and the public been involved in this study?

Patient and public representatives have provided feedback about the study design from the beginning. They have helped to design the study including the questions asked and how the interview will run.

Who is organising and funding the study?

The study sponsor is NHS England as part of the work being done by the Getting It Right First Time (GIRFT) Programme and is supporting the work, including providing funding for patient and public involvement and engagement (PPIE) and for professional transcription of the interviews. The rest of the work carried out in the study is funded by the salaries of employees working for NHS England, GIRFT, and the local trust. NHS England holds the appropriate insurance policies which apply this study in conjunction with your local hospital trust. NHS England holds appropriate insurance policies which apply to this study.

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 Leeds West Research Ethics Committee.

Further information and contact details:

Please scan the QR to register your interest for the study. You can also ask the clinical team to help you register your interest.

Please contact Oliver Adebayo for further queries by:

Email: oliver.adebayo4@nhs.net
Telephone: 07931461053

Thank you for reading this information.