





My Knee Plan Delphi Questionnaire study

A project to develop a care plan with a named Healthcare Professional



Clinician information booklet

Helping you decide whether or not to join our study

We would like to invite you to take part in our research study. Before you decide to take part it's important for you to understand why the research is being done and what it will involve. Please read the following information to help you decide if you wish to take part.

If you have questions or if you would like further information, please contact:

0117 414 7847

or

MyKneePlan@bristol.ac.uk

Clinician Delphi Information Booklet, v1, 08-03-2024, IRAS 318565

Part 1 tells you the purpose of the study and what will happen if you take part.

Part 2 gives you more detailed information about how the study will happen.

Part 1

1. What is the purpose of the study?

We'd like to make care better for patients having knee replacements. We hope that this study will improve the care and support around knee replacement surgery.

We want to build a care plan with a named healthcare professional working to help patients to get the treatments, support and education they need before and after surgery. They would be the person to contact with any problems or questions.

We hope that this proactive approach before surgery, addressing expectations and known risk factors for poor outcomes, may improve outcomes and satisfaction, reduce the risk of short notice cancellations, and decrease the need for post-surgical treatments.

2. Why have I have been asked to take part?

We are approaching you because you are a clinician involved in the care of knee replacement patients.

We would like understand your views on the care patients receive.

3. Do I have to take part?

No, it is up to you to decide if you want to take part. If you decide not to take part you do not need to give a reason and your decision will not affect your employment in any way. Taking part in the study is voluntary.

4. What will happen to me if I take part?

We will ask you to complete two questionnaires, one now and another in the Autumn 2024).

The first questionnaire (round one) is a long list of components that could be offered in a care plan for people waiting for and having knee replacement surgery.

We would like you to tell us what you think is most important. You can write in comments about components on the list. You can also write in things you think are important that are not on the list.

The questionnaire will take about 20 minutes to complete.

The second questionnaire will include components from round one that were rated important by at least 7 out of 10 participants. It will also include new things that were written in during round one.

If you would like to take part, please click the link in your email invitation to complete the first questionnaire. We will contact you in the Autum with the second questionnaire.

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Your answers to the questionnaire are confidential and no-one outside the research team will know your answers or what you have written.

5. What happens after this study is finished?

After both questionnaires are completed, we will use the answers to build a new care plan for people who are waiting for and having knee replacement surgery.

6. What are the possible benefits and disadvantages of taking part?

Although this study will not benefit you directly, we hope that the results will help build a care plan to help people having knee replacement surgery in future.

A disadvantage is the time it takes you to take part.

This completes Part 1 of the information booklet.

If the information in Part 1 has interested you and you are considering taking part please continue to read the additional information in Part 2 before making any decisions.

7. Is the study confidential?

Yes, all the information you give us will be kept strictly confidential. We keep a record of your name and email address for one year after the study ends, so that we can send you details of the study results, on the understanding that the information remains confidential.

When we write about the results of the study we will not include your name or anything that might mean people could identify you.

We will remove anything that may identify you from the information that you give to us. With your permission we would like to share this information with other researchers, for ethically approved research projects, on the understanding that the information remains confidential. We do this to ensure other researchers can benefit from understanding your experiences. They will not know who you are from the information we share with them.

8. What will happen to my data?

Your data will be stored securely by the study sponsor, North Bristol NHS Trust, based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means we are responsible for looking after your information and using it properly.

Personal information (your name, date of birth etc) will be kept for one year after the study has ended. Paper copies of the research data (questionnaires) will be archived for 10 years after the study has ended. Anonymised electronic data will be stored indefinitely on the University of Bristol data repository data.bris.

After the end of the study, we would like to keep the information you have given us to support other research in the future and share this with other researchers. We will ask your permission to do this. If we do share your information, we will not include any names or anything that might mean that people could identify you.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

9. Will the use of my data meet GDPR rules?

GDPR stands for the General Data Protection Regulation. In the UK we follow the GDPR rules and have a law called the Data Protection Act. All research using patient data must follow UK laws and rules.

Universities, NHS organisations and companies may use patient data to do research to make health and care better.

When companies do research to develop new treatments, they need to be able to prove that they need to use patient data for the research, and that they need to do the research to develop new treatments. In legal terms this means that they have a 'legitimate interest' in using patient data.

Universities and the NHS are funded from taxes and they are expected to do research as part of their job. They still need to be able to prove that they need to use patient data for the research. In legal terms this means that they use patient data as part of 'a task in the public interest'.

If they could do the research without using patient data they would not be allowed to have your data.

Researchers must show that their research takes account of the views of patients and ordinary members of the public. They must also show how they protect the privacy of the people who take part. An NHS research ethics committee checks this before the research starts.

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If you want to complain about how researchers have handled your information, you should contact the research team. If you are not happy after that, you can contact the Data Protection Officer, Helen Williamson, on 0117 414 2019.

If you are not happy with their response or believe they are processing your data in a way that is not right or lawful, you can complain to the Information Commissioner's Office (ICO) (www.ico.org.uk or 0303 123 1113).

11. What will happen to the results of the study?

The results will be used to build a care plan for people waiting for and having knee replacement surgery.

You will also be provided with a brief report once the study has finished, if you would like it. A summary will also be placed on the University of Bristol's website.

Nothing that could identify you will be included.

The results will be published in reports, scientific journals and presented at conferences to healthcare professionals, health policy makers, researchers and other patients.

12. Who is organising and funding this study?

The project is sponsored by North Bristol NHS Trust and funded by a grant from the National Institute for Health Research, which is funded by the Department of Health.

13. How to ask for advice or make a complaint

- For general advice about research please contact: Research & Innovation, North Bristol NHS Trust Level 3, Learning & Research building Southmead Hospital, Bristol, BS10 5NB 0117 414 9330 or research@nbt.nhs.uk
- If you wish to make a formal complaint please contact:
 Advice and Complaints Team, Beaufort House, Southmead Hospital, Bristol BS10 5NB 0117 323 3741 or complaints@nbt.nhs.uk

If you express that harm has been done, that suggests negligence we may ask your permission to contact a senior member of the research team.

14. Who has reviewed the study?

This study has been given a favourable opinion for conduct in the NHS by the Health and Social Care Research Ethics Committee A.

15. What happens next?

If you would like to take part in this study, please use the link in your invitation email to complete the questionnaire online. If you would prefer a paper copy of the questionnaire, please reply to your invitation email and the research team will be in touch to arrange this.

If you have questions or would like to speak to a member of the research team, please feel free to contact us:

0117 414 7847

or

MyKneePlan@bristol.ac.uk

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