Level 10N, King George V Building
Royal Prince Alfred Hospital (C39)
PO Box M179, Missenden Road NSW 2050
AUSTRALIA

T: +61 2 8627 6447
F: +61 2 8052 4301

Stakeholders' perceptions of the Early Intervention after Knee Replacement (EPIK) model of care: a qualitative study

Participant Information Statement

Dr Giovanni Ferreira (Chief Investigator)
Research Fellow
Sydney Musculoskeletal Health, Faculty of Medicine and Health Sydney School of Public Health
Phone +61 2 8627 6691 | Email: giovanni.ferreira@sydney.edu.au

1. What is this study about?

We are conducting a research study about a new proposed model of care is 'Early Pain Intervention after Knee replacement' (EPIK). EPIK will leverage routinely collected national data on total knee replacement (TKR) outcomes as a 'safety net' to efficiently identify patients with persistent pain following TKR and embed early assessment and care coordination. EPIK will be nested within the Australian Orthopaedic Association National Joint Replacement Registry, allowing the early identification and assessment of people with pain that compromises their quality life at 3 months after TKR.

You are invited to take part in a research study to help researchers better understand what factors lead to some patients continuing to have persistent pain following TKR and to investigate perceptions of the EPIK model of care to inform its adaptation.

Taking part in this study is voluntary.

Please read this sheet carefully and ask questions about anything you don't understand or want to know more about.

2. Who is running this study?

The study is being carried out by the following researchers:

- Dr Giovanni Ferreira, Research Fellow, The University of Sydney
- A/Prof Sam Adie, Conjoint Associate Professor, University of New South Wales
- Dr Joshua Zadro, Research Fellow, The University of Sydney
- Mrs Navneet Chadha, Physiotherapist, Western Sydney University

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This study is being funded by a research grant from the National Health Medical Research Council by the Australian federal government. The study is sponsored by The University of Sydney. There are no potential or actual conflicts of interest or financial benefits to the researchers, sponsor or institutions from this research.

3. Who can take part in the study?

This study is recruiting people with total knee replacement, caregivers of people with total knee replacement, health professionals involved in the management of total knee replacement, and other healthcare stakeholders involved with the management of total knee replacement.

This Participant Information Statement tells you about the research study. Knowing what is involved will help you decide if you want to take part in the research. Please read this sheet carefully and ask questions about anything that you don't understand or want to know more about. Participation in this research study is voluntary.

By giving your consent to take part in this study you are telling us that you:

- ✓ Understand what you have read.
- ✓ Agree to take part in the research study as outlined below.
- ✓ Agree to the use of your personal information as described.

You will be given a copy of this Participant Information Statement to keep.

4. What will the study involve for me?

If you agree to participate in this study, you will be asked to complete a short survey about you (10-15 minutes). You may then be asked to attend a one-on-one interview, but this is not guaranteed. We aim to interview people with diverse characteristics and opinions, so whether you are selected for an interview will depend on whom we have already interviewed. Interviews will be conducted remotely via Zoom and will between 30-60 minutes. Interviews will be facilitated by one of the research investigators listed above. The facilitator will guide the discussion based on your responses and a series of questions to prompt your responses.

All aspects of the study, including results, will be strictly confidential and only the study investigators will have access to the data. The data from this study may be used again in the future, for further research purposes within the research team. All your identifying data will remain confidential. Study materials will be stored on The University of Sydney's Research Data Store (RDS) system. Data will be kept in perpetuity, but future projects that aim to use the data will seek ethics approval before using such data. A report of the study may be presented at a conference or in a scientific journal, but individual participants will not be identifiable in such a report.

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5. Can I withdraw once I have started?

Participation in this study is entirely voluntary. You are not obliged to participate. If you do participate, you can withdraw at any time without having to give any reason and without suffering any penalty. If you choose to withdraw after data have been collected (questionnaire, interview, or both), you are free to do so. However, any information that we have already collected will be kept and will be included in the study results. Whatever your decision, it will not affect your relationship with The University of Sydney.

Interviews will be audio-recorded and transcribed verbatim. If you take part in the interview, you are free to stop participating at any stage or to refuse to answer any of the questions. At the end of the interview, you will have the opportunity to review the recording and edit any of your responses.

6. Are there any risks or costs?

Aside from giving up your time, we do not expect that there will be any risks or costs associated with taking part in this study.

7. Are there any benefits?

By participating you will be contributing to important research that helps us understand stakeholders' perceptions of the EPIK model of care for people with persistent pain after knee replacement surgery. You will also be compensated for your time with a $100 voucher if you complete both the questionnaire and the interview.

8. What will happen to information that is collected?

By providing your consent, you are agreeing to us collecting personal information about you for the purposes of this research study. Your information will only be used for the purposes outlined in this Participant Information Statement, unless you consent otherwise. Your information will be stored on University of Sydney servers.

Your identity/information will be kept strictly confidential, except as required by law. Study findings may be published, but you will not be individually identifiable in these publications.

We will keep the information we collect for this study, and we may use it in future projects. By providing your consent you are allowing us to use your information in future projects and share it locally and internationally with other research collaborators as needed. We don't know at this stage what these other projects will involve. We will seek ethical approval before using the information in these future projects.

We will use Microsoft Word's transcription feature to transcribe interviews. This will involve sharing your information with Microsoft. We will not share this information with anyone else

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without your consent unless we are required to do so by law. Microsoft word is owned by Microsoft and located in Redmond, Washington, US.

We will store this information and dispose of it securely following the University's Recordkeeping Policy. For more details about how your information will be handled please see the University's privacy webpage.

Sharing research data is important for advancing knowledge and innovation. A de-identified set of the data collected in this study may be made available for use in future research.

9. Will I be told the results of the study?

You have a right to receive feedback about the overall results of this study. You can tell us that you wish to receive feedback by selecting 'yes' to feedback at the start of the questionnaire and entering your email address. This feedback will be in the form of a one-page lay summary of the results. You will receive this feedback after the study is finished. Feedback regarding personal results will not be available.

10. What if I would like more information?

When you have read this information, please store it in a safe place. The study researchers will telephone you in the next two weeks to further discuss the study and answer any questions you may have. We will then arrange a time when it is convenient for you to be interviewed. If you would like to know more at any stage, please feel free to contact the EPIK research study team on (02) 8627 6691 or email epik.study@sydney.edu.au.

11. What if I have a complaint or any concerns?

The ethical aspects of this study have been approved by the Human Research Ethics Committee (HREC) of The University of Sydney [ethics reference: 2024/HE000870] according to the National Statement on Ethical Conduct in Human Research. This statement has been developed to protect people who agree to take part in research studies.

If you are concerned about the way this study is being conducted or wish to make a complaint to someone independent from the study, please contact the university using the details outlined below. Please quote the study title and protocol number.

The Manager, Ethics Administration, University of Sydney:

- Telephone: +61 2 8627 8176
- Email: human.ethics@sydney.edu.au
- Fax: +61 2 8627 8177 (Facsimile)

This information sheet is for you to keep