Physical Activity Patterns after Knee Arthroplasty (PAPrKA)
or
How active are people after a knee replacement

Participant Information Sheet (PIS)

You are being invited to take part in a research study looking at physical activity before and after knee replacement in people with knee osteoarthritis. The study will be undertaken as part of a Medical Research Council funded program and for a doctoral degree. Before you decide whether to take part, it is important for you to understand why the research is being conducted and what it will involve. Please take time to read the following information carefully before deciding whether to take part and discuss it with others if you wish. Please ask if there is anything that is not clear or if you would like more information. Thank you for taking the time to read this.

About the research

➢ Who will conduct the research?

The study is being undertaken by researchers at the University of Manchester and King's College London and will involve members of the National Joint Registry from the University of Bristol, and the University of Sheffield. The study is being led by Professor Will Dixon, University of Manchester.

➢ What is the purpose of the research?

We are doing this study because we want to understand changes to physical activity after knee replacement. Knee replacement is used to treat knee osteoarthritis. It aims to reduce pain and improve physical activity. While we know a lot about reducing pain, we know less about how physical activity changes after knee replacement. People who are considering knee replacement often have many questions about their physical activity. For example, (a) how much their physical activity will improve after surgery (b) if, and when, they can do the things they did before their knee problems started; and (c) what a 'normal' recovery of physical activity looks like for people like them.

This study aims to help us answer these questions using data that already exists. This requires us to bring together two forms of data. First, past physical activity data from your fitness tracker around the time of your knee replacement to help us understand activity changes over time. Second, we need permission to join this to your knee replacement data from the NHS National Joint Registry (NJR) to understand what surgery was conducted when, and how successful it was based on patient-reported information. The NHS NJR collects and manages joint replacement information in United Kingdom. The combination of both types of data, from and about you, will help us in tracking activity recovery and improvements through time.

Thank you for showing interest in joining the PAPrKA study. We hope to recruit around 1,000 participants to the study to generate a better understanding of people's recovery patterns and physical activity following a knee replacement. This information could help future patients and clinicians to make more informed decisions about knee replacement. This would be a decision based on knowledge of anticipated future physical activity levels, and recovery patterns.

➢ Am I suitable to take part?

You can take part in our study if you:

- Have (or had) knee osteoarthritis and had your knee replaced, either total or partial:
    - between January 2016 and December 2022.
    - in England, Wales, Northern Ireland, the Isle of Man or Guernsey.
- And were 18 years of age or over at the time of your knee replacement.
- And monitored your physical activity in the months before your knee replacement and the year following surgery, using:
    - a smart phone application (which can be any of the following: Google Fit, Strava or Apple health*).
    - a wearable (which can be any of the following: Fitbit, Apple watch*, Polar, Garmin, or Withings).
- Can read and understand English or have support from someone who can.
- Are willing to give us permission to access your physical activity data and join it to your knee replacement information in the National Joint Registry.
- Are able and willing to provide informed electronic consent**.

*If you use Apple devices (iPhone and Apple Watch), you have automatic tracking of physical activity even if you have not actively installed a physical activity tracker on your smartphone. This is because iPhone come pre-installed with a health app and Apple watches have an activity app that automatically measures physical activity.

** Informed consent means that you voluntarily agree to take part in the study after being provided with enough information which you have read and have fully understood.

If you use more than one fitness tracking device or you have switched between different fitness tracking manufacturers between your surgery period and December 2022, you can take part in the study. You can take part with one fitness device that you know best captures your physical activity before and after your knee replacement surgery. If you use multiple fitness devices from the same

manufacturer, you need not worry about choosing a device because we can capture your activity across all of them.

What would my involvement be?

➢ What would I be asked to do if I took part?

To take part, you will sign an electronic informed consent and complete a single questionnaire. You can do this on any electronic devices (for example, smartphone, tablet, and computer). It will take approximately 30 minutes to sign the consent form and complete the questionnaire. The two steps are:

Step 1: Sign an electronic consent form:

You will sign an electronic consent form on the University of Manchester approved survey tool to provide your consent for taking part. We call this the informed electronic consent (e-consent) form.

After completing the e-consent form, you will receive an email with a copy of your signed consent form attached. In addition, the email will contain two other important bits of information:

i) Your unique study identification (ID) participant-ID
ii) A link to a questionnaire for the study data collection.

The participant-ID is unique to you and will be used to identify your data instead of your name, meaning your name will not be used to identify you. You can state this ID whenever you want to reach out to us to ask questions, or if you want to report a concern.

Step 2: Data collection process:

The questionnaire has five parts, four needs to be completed and one part is optional. You will be asked to do the following:

i) **Need to do:** Enter your personal information, e.g., your name, postcode, and NHS number. If you do not know your NHS number, we will let you know on the form where to find it.
ii) **Need to do:** Enter details about your education and work.
iii) **Need to do:** Give us permission to access the data from your fitness tracker. The data collection page will direct you to your fitness tracker website, where you will log in and click "allow" to grant access. We have included more details about the kind of physical activity information we will collect and for how long in the 'Data protection and confidentiality' section.
iv) **Need to do:** Answer a question about whether you are satisfied with your knee replacement.

v) **Optional:** Tell us whether you would like to be entered into a prize draw and answer three optional feedback questions.

The questionnaire will take approximately ten to fifteen minutes to complete and can be completed in more than one sitting. If you need support to complete the questionnaire, you can contact the PAPrKA team using our contact information at the end of this document. We will provide you with detailed instructions to help you.

Below is a diagram of step 1 and step 2.

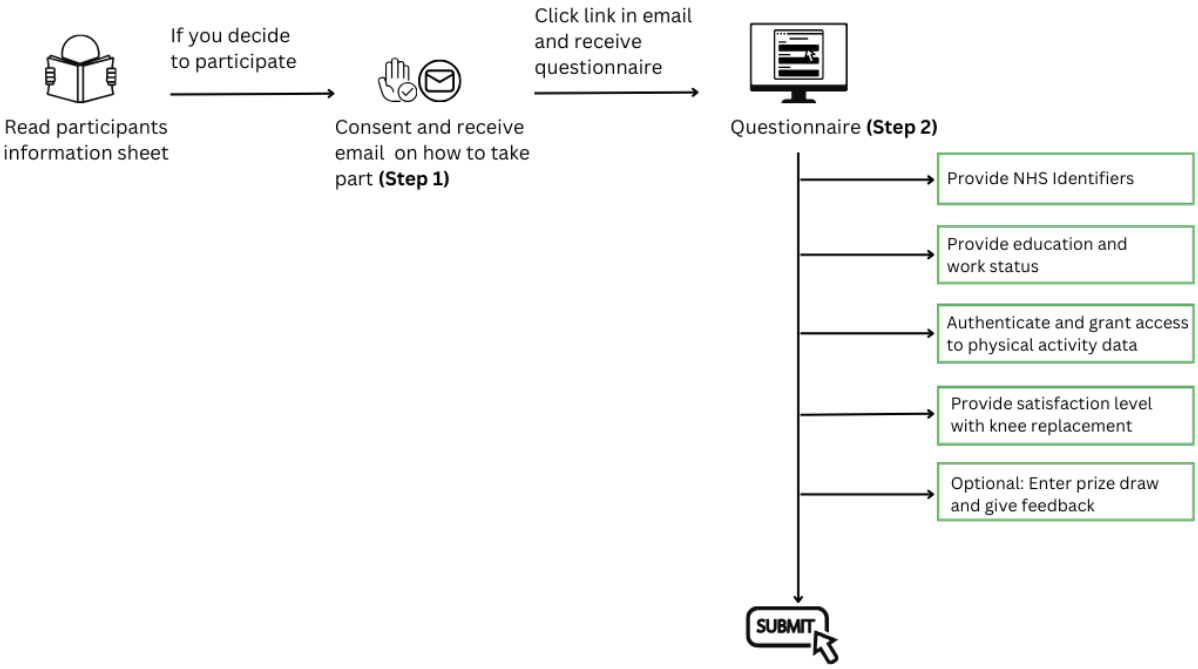

Diagram 1: Participants' journey in the PAPrKA study.

Once you have submitted the questionnaire, you do not need to do anything further. You may be contacted by the research team if there is a need to check with you any information you have provided on the questionnaire. The team will send you up to four follow up reminders if we get no response. If we see you completed your e-consent form but have not completed the questionnaire, we will email you up to four reminders within the recruitment period.

Access to other data

The PAPrKA team will securely send your NHS identifiers (NHS number, surname, date of birth, gender, and postcode) with your unique study identifier (study ID, this is different from your participant-ID) to the National Joint Registry (NJR). This information will be used by NJR to filter out your relevant surgical information. Once your data is filtered out, the NJR will remove your name and any other identifying information and replace it with your unique study identifier. This will create what we call

a pseudonymised research dataset, which means your name and other identifying information is replaced with something else. The research dataset (surgical information + study ID) will be in the NJR's secure data environment called a project specific area. NJR will provide the PAPrKA team with access to the project-specific area in their secure data environment. This means the team can work on the research dataset in this safe environment and your data does not leave this area.

Once the research team has access to the project specific area in NJR's secure environment, we will also upload the data collected from you through the questionnaire and physical activity data obtained from your fitness tracker. The PAPrKA team will link this data to the other information in the research dataset from NJR.

This means with your consent the research dataset will contain:

- Knee replacement surgical data (obtained from NJR)
- Data on co-morbidities (other diseases and conditions you live with) (obtained from NJR)
- Demographics data, for example, gender, age (obtained from NJR)
- Patient reported outcomes (obtained from NJR)
- Education, work status, satisfaction with knee replacement (collected by the research team)
- Physical activity data (e.g., step count, heart rate) (collected by the research team)

In addition to collecting information directly from you and obtaining data from the NJR, we will monitor the study webpage. We hope to understand how people interact with the study by looking at how long people spent on the webpage and what people do.

➢ Will I be compensated for taking part?

You will not receive any payment for taking part in this study. However, at the end of the questionnaire, you can indicate if you want to participate in a raffle. This will give you a chance to win one of ten £25 Amazon gift cards as a thank you for taking part.

We greatly value your involvement, which will help us improve knee osteoarthritis care in the future.

➢ What happens if I do not want to take part or if I change my mind?

It is up to you to decide whether or not to take part. If you decide not to take part you do not need to do anything further.

If you want to take part in the study, please join using the PAPrKA study link <<add PAPrKA Study link>>. This is also provided at the end of this information sheet. If you do decide to take part, you will be given this information sheet to keep and will be asked to sign an electronic informed consent form. If you decide to take part, you are still free to withdraw at any time without giving a reason and without detriment to yourself. However, it will not be possible to remove your data from the

project once it has been anonymised as we will not be able to identify your specific data. This does not affect your data protection rights.

Data Protection and Confidentiality

➢ What information will you collect about me?

In order to participate in this research project, we will need to collect information that could identify you, called "personal identifiable information". Specifically, we will need to collect:

- National Health Service (NHS) number
- Surname and First name
- E-consent forms (including name and signature)
- Date of birth
- Postcode
- Email address

We will also collect the following research data:

- Gender
- Education level
- Work Status
- Physical activity data from your physical activity tracker (for example, step count, duration of physical activity, heart rate, walking speed, distance, and other physical activity related metrics) where available for a period of fifteen months: three months before the knee replacement and one-year after. Please note, this data will not include GPS data, or location-related data (latitude, longitude).
- Your current satisfaction of having a knee replacement.
- Knee replacement details, for example, the date and type of your knee replacement, your patient-reported outcome measures, demographics information, and comorbidity. (This will be accessed within the National Joint Registry safe portal with your consent by the PAPrKA team, identified only by your unique study identifier).

Other data we will collect:

- The feedback responses if you provided it in the questionnaire.
- Web analytics from the study website.

➢ Under what legal basis are you collecting this information?

We are collecting and storing this personal identifiable information in accordance with UK data protection law which protect your rights. These state that we must have a legal basis (specific reason) for collecting your data. For this study, the specific reason is that it is "a public interest task" and "a process necessary for research purposes".

➢ What are my rights in relation to the information you will collect about me?

You have a number of rights under data protection law regarding your personal information. For example, you can request a copy of the information we hold about you. Sometimes your rights may be limited if it would prevent or delay the research. If this happens you will be informed by the research team.

If you would like to know more about your different rights or the way we use your personal information to ensure we follow the law, please consult our Privacy Notice for Research. Link: (https://documents.manchester.ac.uk/display.aspx?DocID=37095).

If you would like more general information on how researchers use data about patients, please visit: www.hra.nhs.uk/information-about-patients/.

➢ Will my participation in the study be confidential and my personal identifiable information be protected?

In accordance with data protection law, The University of Manchester is the Data Controller for this project. This means that we are responsible for making sure your personal information is kept secure, confidential, and used only in the way you have been told it will be used. All researchers are trained with this in mind, and your data will be looked after in the following way:

•All information will be kept confidential and will conform to General Data Protection Regulation (GDPR), with respect to data collection, storage, and destruction, with information being kept for ten years.

•The study team at the University of Manchester will have access to your directly identifying information such as name and contact information and store them separately to your research data. We will assign a uniquely identifying number to both your directly identifying information and your research data. We will destroy the link between your identifying information and research data at the end of the study, expected to occur on or before the 31st of December 2026. Destroying the link will make your research data anonymous. We may still hold your name and contact details if you have agreed to future contact, but those details will not be associated with your participant ID or your unique study identifier and research data. It will also not be used to make decisions about future services available to you.

•With your permission your past activity data will be obtained securely from your fitness tracker provider and stored securely in the University of Manchester research data storage.

•Your activity data and data obtained from your questionnaire will be sent securely to the study's specific area in NJR's secure environment to be linked with your knee replacement data (see '**Access to other data'** under 'What would I be asked to do if I took part?').

•Consent forms will be held securely for five years in an encrypted database, at the University of Manchester.

•If you win the raffle: so that we can provide you with the £25 Amazon voucher your full name and email address will be shared with our Finance department who will send the voucher to you. Your full name and email address will be securely retained for a period of up to 7 years for audit purposes only and then destroyed. It will not be used for any other purpose. The information collected for the prize draw will be destroyed at the end of study.

•With your consent, your data may be shared with other researchers to answer questions over and above those of the PAPrKA study, in accordance with the UK Policy Framework for Health and Social Care Research. https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/. The data shared will be pseudonymised meaning that information that directly identifies you such as your name will be removed. In addition, appropriate data protection measures will be used to ensure the confidentiality of the data is maintained.

•At the end of the project, we will archive the research data you provided to us (i.e., the questionnaire data and activity data but not data obtained from NJR) at the University of Manchester for ten years. Information about the study, the data obtained, and how one might make an access request, will be added to an open data repository, Figshare at the University of Manchester Library, for the same period.

•Individuals from the University, the National Joint Registry where the research is taking place, and the regulatory authorities may need to review the study information for auditing and monitoring purposes or in the event of an incident. This may involve looking at identifiable data. All individuals involved in auditing and monitoring the study will have a strict duty of confidentiality to you as a research participant.

➢ What if something goes wrong?

The University of Manchester will arrange insurance for research involving human subjects that provides cover for legal liabilities arising from its actions or those of its staff or supervised students, subject to policy terms and conditions.
In the unlikely event that something does go wrong, and you are harmed during the research you may have grounds for a legal action for compensation against the University of Manchester, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

➢ Will the outcomes of the research be published?

The research results will be published in peer reviewed scientific journals, internal reports, conference presentation, on the study website, and written-up in student's thesis/dissertations. The PAPrKA study webpage<<insert PAPrKA webpage link here>> will host a plain language summary of the results. In addition, the webpage will provide links to research publications of the results. Additionally, when you provide your informed consent, we will ask you if we may keep your contact information to allow us to provide you with a summary of our findings. If you show interest, we will provide the summary to you by email once it is available. The results are anticipated to be available at the end of 2026.

Who has reviewed the research project?

The research has been reviewed by an independent group of people from a Research Ethics Committee and from a panel at the National Joint Registry to protect your safety, rights, wellbeing, and dignity. This study has been reviewed and given a favourable opinion from <<insert NHS REC committee details (name and reference, xxx REC reference xx/xx/xx)>>. In addition, it received a favour opinion from the National Joint Registry <<insert details>>.

➢ Who is funding the research project?

The study is sponsored by the University of Manchester (Sponsor reference number: NHS002146). Funding for the study is provided by the Universities of Manchester and Melbourne training research group (https://www.manchester.ac.uk/study/postgraduate-research/golden/melbourne/) and from the UKRI's Medical Research Council as part of the 'Health Research from Home' partnership grant (Grant number: MR/Y003624/1).

What if I have a complaint?

➢ Contact details for complaints

If you have a complaint that you wish to direct to members of the research team, please contact the:

PAPrKA study team on <<(PAPrKA study email>> or Call << PAPrKA Teams number>>.

If you wish to make a formal complaint to someone independent of the research team or if you are not satisfied with the response you have gained from the researchers in the first instance, then please contact:

The Research Ethics Manager, Research Office, Christie Building, The University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing: research.complaints@manchester.ac.uk or by telephoning 0161 306 8089.

If you wish to contact us about your data protection rights, please email dataprotection@manchester.ac.uk or write to The Information Governance Office, Christie Building, The University of Manchester, Oxford Road, M13 9PL at the University and we will guide you through the process of exercising your rights.

You also have a right to complain to the Information Commissioner's Office about complaints relating to your personal identifiable information Tel 0303 123 1113

Contact Details

If you have any queries about the study or if you are interested in taking part, then please contact the researcher(s)

The PAPrKA study team:

<<PLEASE INSERT LOCAL RESEARCH NAME IN CAPS AND BOLD TYPE>>

<<PLEASE INSERT EMAIL IN CAPS AND BOLD TYPE>>

<<PLEASE INSERT A TELEPHONE NUMBER IN CAPS AND BOLD TYPE>>

If you are ready to take part, and do not have any questions or concerns, please click <<Join PAPrKA Study>> or copy this link <<insert the PAPrKA join study link>> into your browser, load the page and click on "Join PAPrKA Study".