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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 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 led by Professor Will Dixon, University of Manchester. If you would like to know more about the team, please see the PAPrKA website <<insert link>>.

➢ 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 three forms of data. First, past physical activity data from your fitness tracker around the time of your knee replacement to help us understand how your activity changes over time. Second, survey data. Third, we need permission to join both these forms of data to your knee replacement data from the NHS National Joint Registry (NJR) to understand what surgery you had

and when you had the surgery. The NJR collects and manages joint replacement information in United Kingdom. The combination of these three types of data, from and about you, will help us in tracking activity recovery and improvements through time.

We will also look at how user-friendly the study's website is. For example, we will consider how those looking to take part in the study as well as those people that decide to join the study use the website, and how easy they have found it. To do this we will use Google analytics and a feedback survey (which you can chose to complete or not). This information will help researchers improve the experience of people joining this type of research in the future. We will in addition, look at the quality of information from smartphone and wearable devices which will help researchers have a better understanding of this type of data. Finally, to make sure our findings are as useful as possible we will look at whether and how those that join our study represent other people who have had a knee replacement.

Thank you for showing interest in joining the PAPrKA study. We hope that 1000 or more people will take part so we can have a better understanding of how people recover from knee replacement surgery. Information from our study could help people and Doctors in the future when making decisions about knee replacement surgery.

➢ 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 2017 and December 2023.
    - 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 (which can be Apple health*).
    - a wearable (which can be any of the following: Fitbit, Apple watch*, Garmin, or Oura rings).
- 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. The 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.

Please note, if you use more than one fitness tracking device, or you have switched between different eligible fitness tracking manufacturers (Apple, Fitbit, Garmin and Oura ring) between your surgery period and December 2023, you can take part in the study. You can either take part with one fitness device that you know best captures your physical activity before and after your knee replacement surgery or take part with the multiple devices.

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, register for a PAPrKA account and complete four tasks on the PAPrKA website. You can do this on any electronic devices (for example, smartphone, tablet, and computer). It will take approximately 50 minutes or less to sign the consent form, register an account and complete the tasks. We explain below the 3 steps further:

Step 1: S*ign an electronic consent form*:

You will sign an electronic consent form on the PAPrKA website to give consent. We call this form, 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 participant-ID
ii) A link to register for a PAPrKA account. The PAPrKA account allows you to login to provide data for the study.

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 tell us this ID whenever you want to reach out to us to ask questions, or if you want to report a concern.

Step 2: *Register an account*

You will click on the PAPrKA account registration link in your email, which you will get after filling out the e-consent. The link will take you to the PAPrKA website where you will fill in your details and choose a password. Once you finish this registration (sign up), you will receive a new email asking you to confirm the information. Click on this link to confirm your identity. You are now ready to complete all the information needed on the PAPrKA website.

Step 3: Filling in the information for the PAPrKA website

We need you do 4 things in total, 3 of those things need to be completed. For the 4th task you have a choice. We will ask you to:

i) **Need to do:** Enter your personal information, e.g., your full name, email address, postcode, sex, DOB and NHS number. If you do not know your NHS number, we will give you help to find it.
ii) **Need to do:** answer four question on (a) your surgery date, (b) what qualifications you have, (c) your current work status, and (d) whether you are satisfied with your most recent knee replacement surgery.
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. If you use a Fitbit, Garmin or Oura rings you can log in and click "allow" or “authorize" to grant access. If you use an Apple device (phone or watch), you can download <<insert name of app>> app from the Apple store. Next, you login to the app using the instructions provided on the PAPrKA website task page to provide access to your physical activity data held on your Apple device. You can get to the Apple store either by using a QR code (if you are on a laptop or computer,) or directly on your iPhone. 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) **Optional:** Answer three optional feedback questions.

Each task will take approximately five to ten minutes to complete, and *you don’t need to do them all at once*. We think that granting permission to your activity tracker may take longer than five minutes due to the login and possible app download involved, which is why we estimated 15 minutes for this process. **While we provide a step-by-step guide for each task on the website, if you need more support to complete the tasks, you can contact the PAPrKA team using our contact information at the end of this documen**t. We will provide you with detailed instructions to help you.

Diagram 1 below (see 3 to 5) shows you the process.

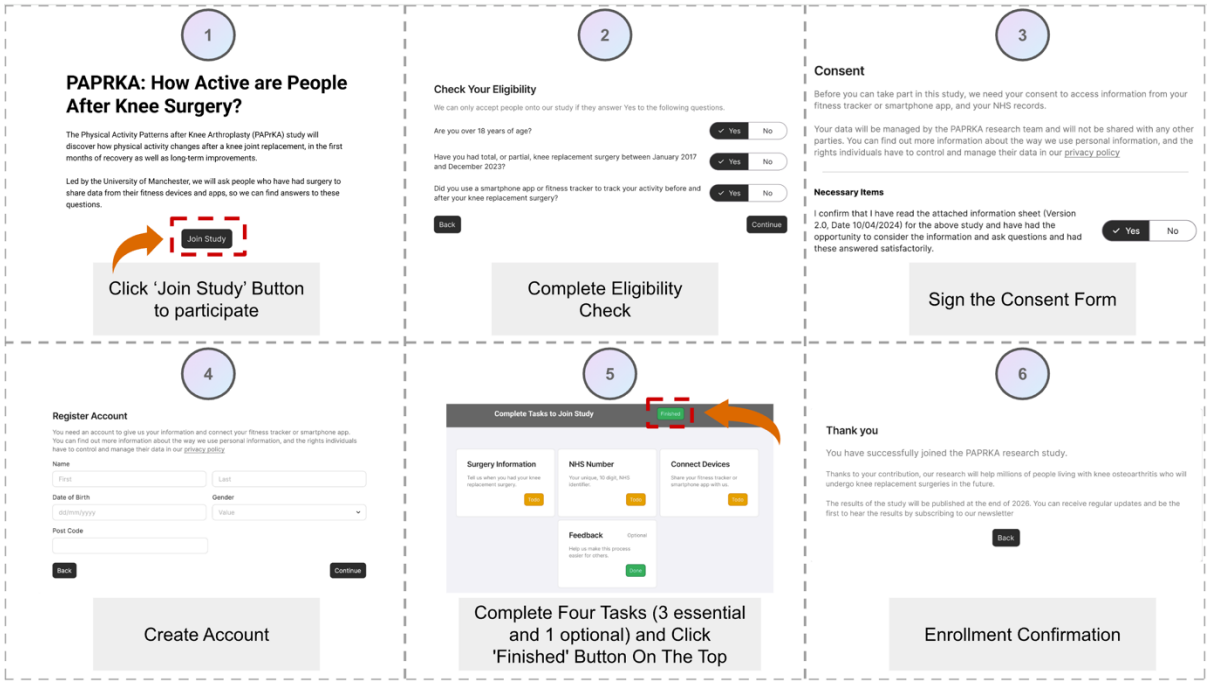

Diagram 1: Participants' journey in the PAPrKA study.

Once you complete all the three things you need to do, the 'Finished' button on the website will turn from the colour **grey** to **green**. This means you can now submit your data for the study. Once you have finished the tasks by clicking the 'Finished' button, you do not need to do anything further.

You will see an enrolment confirmation and a thank you message like label 6 on Diagram 1. The team will send you up to **four reminders** if we see you completed your e-consent form but have not completed the website tasks. In the fourth reminder, we will include a link to a survey to help us better understand why people may not wish to complete the data collection tasks. This information will help us improve the experience of people taking part in this type of study in the future.

We will contact you by email if:

(i) Your information cannot be found in the National Joint Registry or
(ii) We cannot access physical activity data for you from your fitness tracker provider.

In the email we will explain that we are *not able to include your (research) data in the research database* for analysis and therefore we will delete it. We will not ask you to do anything else.

Data captured and shared

The PAPrKA team will securely send your NHS identifiers (NHS number, full name, date of birth, sex, 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 find the relevant

information about your joint surgery. Once they have your surgery information 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 are removed and replaced by a study ID. The research dataset (surgical information + study ID) will be placed in the NJR's secure data environment. The NJR will provide the PAPrKA team with access to a 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 will not leave this area.

Once the research team has access to the project specific area in NJR's secure environment, we will upload the data collected from you as well as the physical activity data from your fitness tracker. This data upload will be linked with the NJR data. This means that, with your consent, the research dataset will contain:

- Your study ID
- Knee replacement surgical data (from NJR)
- Data on other diseases and conditions you live with (from NJR)
- Demographics data, for example, sex, age (from NJR)
- Education, work status, satisfaction with knee replacement (collected from you)
- Physical activity data (e.g., step count, heart rate) (obtained from your fitness tracker provider).

In addition to collecting information directly from you and obtaining data from your fitness tracker provider and the NJR, we will look at data analytics from the study's website. By looking at this information from the website, we hope to understand how people interact with the study. For example, how long people spend on the webpage, what website they came from which told them about the study, and what pages or study tasks people looked at. Google analytics uses web cookies (this will not identify you) to help understand how people use websites. We will make sure that the Cookie statement on the website is clear so that you understand what you are agreeing to when you select *accept all cookies* or *accept essential cookies* only or *decline cookies*.

➢ Will I be compensated for taking part?

You will not receive any payment for taking part in this study. However, when completing the e-consent you can opt into the study's prize draw. 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, as it 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 the 'key' that links your name and contact information with your participant and study ID has been broken, 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
- Last name and First name
- E-consent forms (including full name and signature)
- Date of birth
- Postcode
- Email address

We will also collect the following research data:

- Sex
- Your education qualifications
- Current Work Status
- Date of surgery (This will be collected as **month and year**) in a situation where you have had both your knees done, we will collect the most recent surgery dates for both knees.
- Physical activity data (for example, step count, duration of physical activity, heart rate, walking speed, distance, and other physical activity related metrics) **as available between July 2016 and December 2024**. Please note, this data will not include GPS data, or location-related data (latitude, longitude).
- Your current satisfaction with your most recent knee replacement.
- Knee replacement details, that includes for example, the date and type of your knee replacement, your age and sex etc and details of other diseases and conditions you live

with. (This will be accessed within the National Joint Registry safe data access 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.
- The Google Web analytics from the study website (This will not identify you).

➢ 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 PAPrKA website is hosted by Kings College London (PAPrKA team collaborators) on a secure research platform called 'RADAR-base'. Your identifying information, survey data and physical activity data is captured on the website. The King's College London PAPrKA team securely sends a copy:

    - To the National Joint Registry of your study ID, full name, DOB, sex, postcode and NHS number.
    - To the University of Manchester of your study and participant ID, full name, DOB, sex, postcode, email address and consent form. As well as your survey data and physical activity data.

- At the end of the study, the University of Manchester will check they have a complete dataset and instruct Kings College London to delete all the data it holds related to the PAPrKA study. The University of Manchester will hold the information that directly identifies you and the research data (survey and physical activity data) separately. We attach a study ID to both your directly identifying information and research data, this is called a 'key'. We will destroy the 'key' i.e. 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. We (PAPrKA team at University of Manchester) may still hold your name and contact details if you have agreed to future contact in the e-consent, 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 physical activity data will be obtained securely from your fitness tracker provider and stored securely in the University of Manchester research data storage. If in the unlikely event we obtain more physical activity data than asked for from your fitness tracker provider, the extra data will be deleted.
- The UoM PAPrKA team will upload your physical activity data and survey data to a PAPrKA specific area in NJR's secure environment. This information will be linked with your knee replacement data (see 'Data captured and shared' under 'What would I be asked to do if I took part?').
- Consent forms will be held securely for five years in an encrypted folder, at the University of Manchester.
- If you win the prize draw: so that we can provide you with the £25 Amazon voucher your full name and email address will be shared with the Finance department at UoM 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 and thereafter destroyed. It will not be used for any other purpose.
- 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 and email 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. physical activity data + survey data) 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.

- Please also note that individuals from The University of Manchester or regulatory authorities may need to look at the data collected for this study to make sure the project is being carried out as planned. 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 humans taking part 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 North East - Newcastle & North Tyneside REC reference 24/NE/0090. In addition, it received a favour opinion from the National Joint Registry (reference: RSC2022/17, approval date: 20Sep2024).

➢ 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".