

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

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Study summary

You are being invited to take part in the **Physical Activity Patterns after Knee Arthroplasty (PAPrKA)** study. 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 us if there is anything that is not clear or if you would like more information. Thank you for taking the time to read this.

The study aims to:

- [1] Learn more about people's recovery and improvement after knee replacement so that in the future patients and doctors can make better informed decisions about knee replacement surgery.
- [2] Improve future research from studies like PAPrKA.

To do [1], *learn more about recovery and improvement after knee replacement*, we will bring together 3 pieces of information from people who have already had a knee replacement to create a joined research *dataset*: This will include:

1. Information you provide to us about your knee replacement (not your name or email).
2. A one-off collection of your past **physical activity information** e.g. activities such as walking, cycling, climbing stairs, doing housework etc. This information will be obtained from your fitness tracker provider(s) (iPhone, Apple Watch, Fitbit, and/or Oura ring), for the period of *01.07.2016 - 31.12.2024* if available. **Please note**, if you agree to share physical activity information from Apple Health (iPhone and Apple watch) Fitbit or Oura and have previously connected any other fitness tracking device or app (e.g. Strava, Polar, Garmin etc.) to them, you will be sharing physical activity data from those connected devices and apps as well.
3. Information about your **knee replacement surgery** (to be accessed through the UK National Joint Registry).

When we join this information together, we will only use the physical activity information for 6 months before your surgery date and 1 year after. The final analysis will be done using the data from people who have sufficient physical activity data either side of their surgery date.

To do [2], *improve future research from studies like PAPrKA*, we will look at:

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- i. How many people wished to join the study, if there were any barriers to people joining as well as how easy it was to join and complete the study tasks. We will use Google Analytics and feedback surveys for this.
- ii. The amount and quality of the information we obtain from peoples' fitness trackers (Apple Health, Fitbit, and/or Oura ring)

The information the study team obtains from you, and your fitness trackers, will be held securely by the universities working on the study. They are the University of Manchester, which is leading the study, and its partner Kings' College London. The joined *dataset* will be created and held securely at the National Joint Registry; the study team will work on it there with support from NJR researchers.

To take part in the study you will need to go to the [PAPrKA website](#). The website is held on a secure research platform called 'RADAR-base' which is managed by Kings College London. From the website you can:

1. [Check that you can take part.](#)
2. [Sign an electronic consent form.](#)
3. [Set up a study account.](#)
4. [Complete up to 4 tasks.](#)

Completing these steps will take approximately 35 minutes.

About the research

Who will do the research?

The study is part of a Medical Research Council funded program, and part of a doctoral (PhD) degree.

It is being done 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](#)

Why are we doing this research?

We are doing this study because we want to learn more about people's recovery and improvement after knee replacement so that in the future patients and doctors can make better informed decisions about knee replacement surgery. Knee replacement is most commonly 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.
- (c) what a 'normal' recovery of physical activity looks like for people like them.

Through our research we hope to answer some of these questions.

In addition, we want to help improve future research like this by learning about people's experience of taking part in the study and the quality of the data that we collect. Many people collect information about physical activity (for example step counts) using their own smartphones and fitness trackers. This data would be very helpful for research if only it could be linked with other health information once people provide their consent. Researchers do not yet have much experience of how to successfully conduct studies that link together these pieces of information. We want to understand how people progress through the stages of the website, as well as learning about the amount and quality of the information that we receive once people have given access to their activity data.

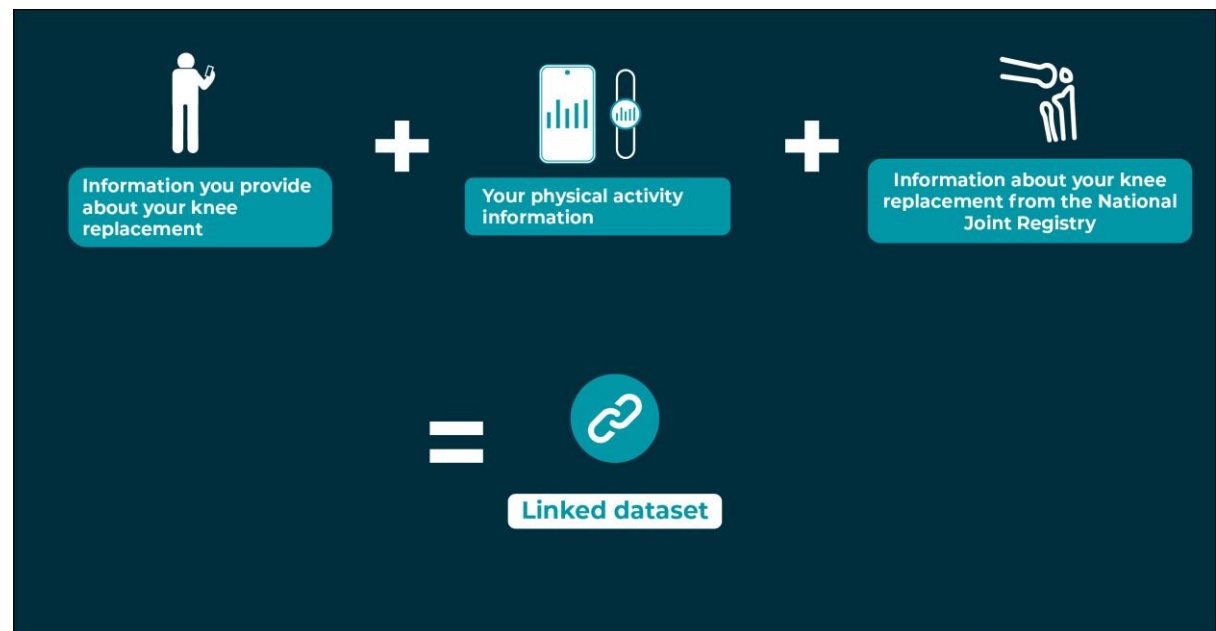
What types of information will we collect?

To learn more about recovery after knee replacement, we will join three pieces of information. They are

1. Information you provide to us about your knee replacement.
2. A one-off collection of your past physical activity information (obtained from your fitness tracker provider(s) for the period of 01.07.2016 – 31.12.2024 if available). This will help us understand how your activity changes following your knee replacement. Physical activities are any activity that uses energy. It includes activities such as walking, climbing stairs, housework, and gardening.

3. Information about your knee replacement, obtained from the National Joint Registry¹ (NJR).

When we join all this information together, we will only use the physical activity data for 6 months before your surgery date and 1 year after.



To help researchers in the future run studies like PAPrKA and ensure that people joining them can do so easily we will:

1. Look at how many people wished to join the study, as well as how simple they found it to join and complete the study tasks. We will do this by using Google Analytics and a 'give us your feedback' survey.
2. Explore why people who started to join the study decided not to complete it. We will do this by sending an email inviting those people to answer a quick 'Survey of barriers to participation in PAPrKA' feedback survey.
3. Look at the amount and quality of the physical activity information we obtain from your fitness tracker (iPhone/Fitbit/Oura ring).

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.

¹ The NJR collects and manages joint replacement information in United Kingdom.

Can I take part?

You can take part in the study if you can answer yes to the five statements in Table 1.

Table 1: Am I suitable to take part

1	I had knee osteoarthritis and had a knee replacement (total or partial) between 01 st January 2017 and 31 st December 2023, either through the NHS or a private healthcare provider
2	I was aged 18 years or older when I had my knee replacement and living in England, Wales, Northern Ireland, the Isle of Man or Guernsey.
3	I used a Fitbit, iPhone 6s or above, Apple Watch or Oura Ring to track my activity for at least six months before my knee replacement and one year or more after
4	I am willing to give permission for the research team to access my past physical activity information from my fitness tracker(s) and link to my knee replacement information in the National Joint Registry.
5	I can read and understand English or have support from someone who can.

***Please note:** If you use Apple devices (iPhone and Apple Watch), you have automatic tracking of your physical activity. The iPhone and Apple watch come pre-installed with a health app called Apple Health that automatically measures physical activity. Apple Health captures physical activity information from your iPhone and Apple Watch (if you have one) as well as any other fitness tracking devices or apps (such as Strava, Garmin, Polar etc.) *that you have already connected to your iPhone's Apple Health app.* Fitbit and Oura ring similarly enable users to connect to other fitness tracking devices and apps to share data.

What would my involvement be?

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

To take part, you will:

1. [Sign an electronic consent form.](#)
2. [Set up a study account.](#)
3. [Complete up to four tasks on the PAPrKA website.](#)

You can do this on any electronic devices (for example, smartphone, tablet (e.g. iPad), laptop, or desktop computer).

What you need to help you to take part

Table 2: What I need to help me take part in the study

What information you need	What you need it for
---------------------------	----------------------

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Email address	To set up a study account
Month and year of your knee replacement	To complete questions about your knee replacement
NHS number (we tell you how to find this on the study website)	To enable the study team to join the information you provide with information about your knee replacement.
For Fitbit and/or Oura ring: your device account information	To share your Fitbit, and/or Oura ring physical activity data
For iPhone users: pen and paper to write down 3 pieces of information: <ul style="list-style-type: none"> i. Study name: PAPrKA ii. The email address you set up the study account with iii. Password you used when setting up your study account. 	To share your Apple physical activity data

On the website we provide step-by-step guides on how to complete each task.

How to take part – step by step guidance

Step 1: *Read and sign the consent form on the website:*

You can sign the consent form by either drawing your signature or typing your name. We will email you a copy of your signed consent form and a copy of the Participant Information Sheet for your records once you have completed **Step 2: Register an account.**

Step 2: *Register an account*

The next step is for you to set up an account for the study. To set up the account you will need to add an **email address and create a password.**

Once you click submit, a new page will open requesting a ‘verification code.’ This verification code will have been sent to your email address after you entered your email address and created a password. You can copy this code from your email and enter it as the ‘verification code’ in the open page and click submit. [This is the end of the registration step.](#)

Please note, the verification code is valid for [60 minutes](#). If your verification code expires you can click ‘resend code.’

Forgot your account password: You can set a new password by clicking on ‘forgot password’ on the bottom left corner of the “Sign In” page. A link to change your password will be sent to your email address.

Email address: It is important that you always use the email address you set the account up with to change your password and or to contact the study team.

Step 3: *Filling in the information on the study website*

We need you to do up to four things in total, three of which are needed to take part. For the 4th task you have a choice. We will ask you to:

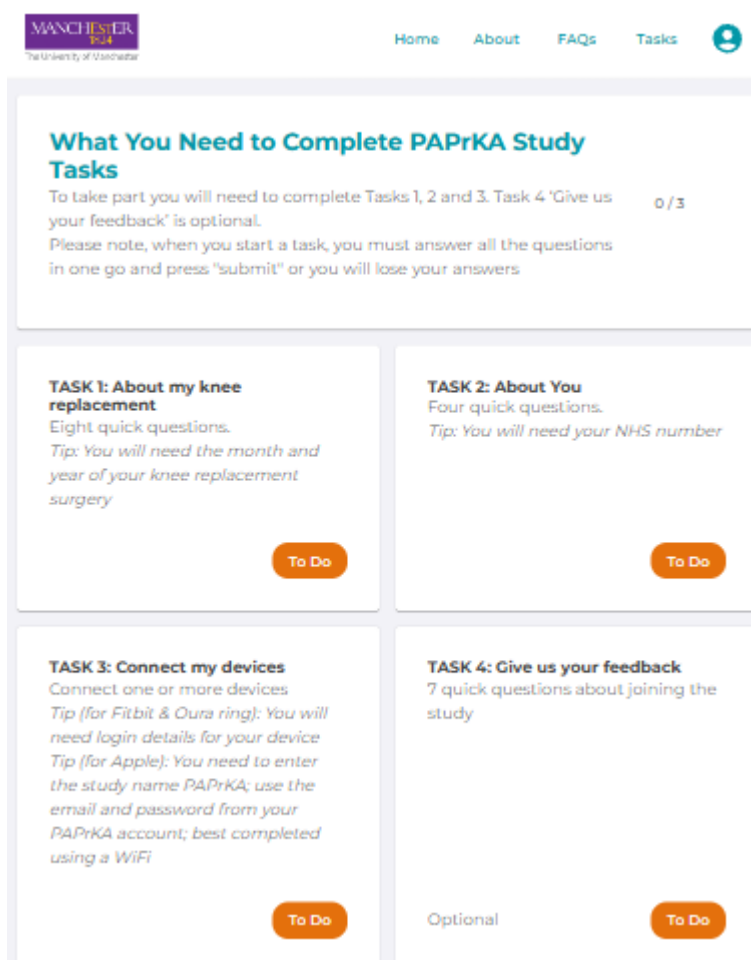
Task 1: Need to do: answer questions about your knee replacement including the month and year of your surgery.

Task 2: Need to do: answer questions about you, including your date of birth, postcode, and NHS number. If you do not know your NHS number, we will give you help to find it.

Task 3: Need to do: Give the study team permission to access your physical activity information from your fitness tracker(s). On the website, we will give you clear instructions on how to allow access to this information.

Task 4: Optional: Answer the ‘give us your feedback’ survey.

Diagram 1 below shows you the process.



The screenshot shows the PAPA Study website interface. At the top, there is a navigation bar with links for Home, About, FAQs, and Tasks, along with a user profile icon. The main heading is "What You Need to Complete PAPA Study Tasks". Below this, a progress indicator shows "0 / 3". A note states: "To take part you will need to complete Tasks 1, 2 and 3. Task 4 'Give us your feedback' is optional. Please note, when you start a task, you must answer all the questions in one go and press 'submit' or you will lose your answers".

The tasks are listed in a grid:

- TASK 1: About my knee replacement**
Eight quick questions.
Tip: You will need the month and year of your knee replacement surgery
To Do
- TASK 2: About You**
Four quick questions.
Tip: You will need your NHS number
To Do
- TASK 3: Connect my devices**
Connect one or more devices
Tip (for Fitbit & Oura ring): You will need login details for your device
Tip (for Apple): You need to enter the study name PAPA; use the email and password from your PAPA account; best completed using a WiFi
To Do
- TASK 4: Give us your feedback**
7 quick questions about joining the study
Optional
To Do

As you complete each task, the 'To Do' button on the Task Tab, will change to 'Done.' Once you have completed Tasks 1, 2 and 3 you will see a message on the website confirming that you have completed the study, in addition we will send you a thank you email. We will ask you, if you have not already done so and can spare the time, to please complete Task 4 to provide feedback on taking part in the study.

How long will it take to complete the required tasks

Table 3: How long it will take

Completing all the tasks will take up to 35 minutes. How long it will take you to complete the individual tasks is shown below.

Steps and tasks	Time to complete
To sign the consent form and set up an account and complete the 4 tasks	Up to 35 minutes
Step 1: To read and sign the consent form	Up to 8 minutes
Step 2: To set up an account	Up to 5 minutes
Step 3: Task 1: to complete the study survey	Up to 5 minutes
Step 3: Task 2: to provide your details [this will help us find your record in the NJR]	Up to 3 minutes
Step 3: Task 3: to authorise access to your physical activity data for a Fitbit and/or Oura	Up to 4 minutes
Step 3: Task 3: to authorise access to your physical activity data for an Apple iPhone/watch	Up to 8 minutes
Step 4: Task: to complete a 'give us your feedback' survey	Up to 4 minutes

We will contact you by email:

- To send you your consent form and a copy of the Participant information Sheet. **Please note** we can only do this if you set up a study account.
- To thank you for completing the study.
- To send you a reminder, if you have signed the consent form and set up an account but not completed the three required study tasks (**Step 3**). We will send you up to **4 reminders** on **day 3, 7, 10 and 14** after you create your account. In the 4th reminder (day 14), we will invite you to take part in a short '*Survey of barriers to participant in PAPrKA*' to help us better understand why people may not wish to continue with the study.
- If your record cannot be found in the National Joint Registry.
If we email you because we cannot find your record in the NJR, we will explain that we are *not able to include your (research) data in the research database* for analysis. We will delete the information² we hold on you at the end of the study. We will not ask you to do anything else.

Will I be compensated for taking part?

You will not receive any payment for taking part in this study. However, when completing the consent form you can opt into the study's prize draw. This will give you a chance to win one of ten

² With the exception of consent forms which are kept for 5 years. If you consented to take part in the prize draw and win your name and email will be kept by the Finance team at the University for 7 years.

£25 Love to Shop 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, you can download and save a copy of this participant information sheet (PIS) to keep. You will be asked to sign an informed consent form. Once you set-up a PAPrKA study account, we will send you a copy of your consent form and the PIS. 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 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?

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
- First name and last name
- Electronic consent forms (including full name and signature)
- Date of birth
- Postcode
- Email address

We will also collect the following research data:

- Your educational qualifications
- Current work status

- Your current satisfaction with your most recent knee replacement
- Knee replacement information including:
 - Date and type of knee replacement, which knee side, whether it is a 1st or 2nd joint replacement
 - Information from NHS England provided to NJR (under sublicence)
 - Your age, sex, body mass index (BMI), socio-economic status, ethnicity, county, and health authority of residence
 - Health conditions that you live with
- Past Physical activity information includes:

From Apple Health

1. Active Energy
2. Exercise Minutes
3. Flights Climbed
4. Heart Rate
5. Steps
6. Walking + Running Distance
7. Cycling Distance
8. Workouts

Form Oura:

1. Sleep, Readiness, and Activity Data
2. Heart Rate Data
3. Workout Data

From Fitbit:

1. Heart Rate
2. Activity and Exercise

Things to know about sharing physical activity information

- *If you have connected your iPhone/Fitbit/ Oura ring to other fitness tracking devices and apps the same information (listed above) from those other devices and apps will be collected and used in our research.*
- *If you agree to share Fitbit or Oura ring information: Once you have provided permission to share your information, you do not need to do anything further.*

For your information: It takes approximately 9 days for the research team to receive your physical activity information from Fitbit/Oura. In some circumstances, e.g. if there is a connection issue, it may take up to 4 weeks for the team to receive your data. This is because Fitbit/Oura will send the information to us in small chunks rather than all in one go. If there are gaps in the physical activity data we receive from Fitbit/Oura, we will make one further request to Fitbit/Oura to download your data.

- Participant's permission to share physical activity data will stay in place for approximately 10 months, until people stop joining the study, after which we will delete participant's permission.
- We work within strict ethical guidelines meaning **we will only** collect the information you have agreed to share with us. If you would like to know more about how we manage your information, please read our [FAQs](#) or contact us on PAPrKA@manchester.ac.uk.
- *If you agree to share information from an Apple watch* and have family sharing: under certain circumstances e.g. use of subscription services, your forename maybe associated with the device name. If we receive your forename with the name of your device, we will delete it as soon as possible.
- **Other optional information we will collect:**
 - [Feedback](#) surveys 'give us your feedback' and 'Survey of barriers to participant in PAPrKA.'
 - [Google Web analytics](#) from the study website

What information we share

To create the joined research dataset, we will securely send to the National Joint Registry (NJR) your identifiable information:

- NHS number, full name, date of birth, sex, and postcode with your unique participant ID
- This information will be used by the NJR to find your record with your knee replacement information.
- Your knee replacement information with your participant ID (no identifiable information) will be placed in the NJR's secure data environment.
 - The research team will be given access to NJR's secure environment to join the information they have collected from you and your fitness tracker providers with your knee replacement information.

- The final analysis will be done using the data from people who have sufficient physical activity data either side of their surgery date.

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](https://documents.manchester.ac.uk/dislay.aspx?DocID=37095). Link: (<https://documents.manchester.ac.uk/dislay.aspx?DocID=37095>).

If you would like more general information on how researchers use data about patients, please visit <https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/template-wording-for-generic-information-document/>

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 research study. 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 King's College London (PAPrKA team collaborators) on a secure research platform called 'RADAR-base'. Your identifiable information, survey data and physical activity data is stored in RADAR-base.
- The King's College London PAPrKA team will securely sends to:
 - The National Joint Registry a copy of your participant ID, full name, DOB, sex, postcode, and NHS number.
 - The University of Manchester a copy of your participant ID, full name, year of birth, sex, socio-economic status, email address and consent form as well as your survey data and physical activity information (from 01st July 2016-31st Dec2024). If your fitness tracker provider sends us more information than asked for, this additional information will be deleted).
- The UoM PAPrKA team will upload a copy of your physical activity information and survey data to a dedicated area in NJR's secure environment. This information will be joined with your knee replacement information. When we join the information together will trim your physical activity information to 6 months before your hip replacement and 1 year after.
- 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 participant ID to both your identifiable information and research data; this is called a 'key.' We will destroy the 'key' i.e. the link between your identifiable information and research data at the end of the study. We (PAPrKA team at University of Manchester) may still hold your name and contact details if you have agreed to future contact in the consent form, but those details will not be associated with your participant ID or research data. It will also not be used to make decisions about future services available to you.
- With your consent, your research information held at the University of Manchester may be shared for research and educational purposes. This research information will consist of your participant ID, survey data, and physical activity data from 01st July 2016-31st Dec 2024. We will only share deidentified information 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. The information will be share 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/>

- At the end of the study UoM will,
 - Check they have a complete dataset and instruct Kings College London to delete its copy of the PAPrKA study's data.
 - Delete from the copy of the data it holds, all information (with the exception of consent forms) on participants who did not have a record in the NJR.
- Consent forms will be held securely for five years, at the University of Manchester.
- If you win the prize draw: so that we can provide you with the £25 Love to Shop 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.
- At the end of the project, we will archive for 10 years the:
 - Joined research dataset (i.e. physical activity data and survey data and knee replacement data) at the National Joint Registry.
 - Research data you provided (i.e. physical activity data and survey data) at the University of Manchester.
- Information about the study and how one might make an access request will be added to an open data repository, Figshare at the University of Manchester Library.
- **Please note** 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.
- Google analytics used on the website will look at how interested people use the study website. For example, whether they clicked through to the study from another website, how long people spend on the webpage, what study tasks they look at, and how well they progress through the study tasks. Google analytics uses cookies: the cookie statement on the website will be clear so that you understand what you are agreeing to when you select or decline cookies.

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 dissertations. The [PAPrKA study webpage](#) 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 you would like to receive the study's newsletter, and a summary of our findings 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 (REC) 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 Northeast - 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@manchester.ac.uk or Call 0161 306 2719.

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 email: research.complaints@manchester.ac.uk or by telephone 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 for the research team

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:

PAPrKA@manchester.ac.uk

0161 306 2719 If you are ready to take part, and do not have any questions or concerns, please click [Join PAPrKA Study](#) or copy this link <https://bit.ly/PAPrKA> into your browser, load the page and click on "Join Study".

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