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RESEARCH PROTOCOL

Physical Activity Patterns after Knee Arthroplasty (PAPrKA)

Contents

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2) INTRODUCTION

Knee replacement is a treatment option for end-stage knee osteoarthritis, used when non-invasive and drug-based therapy does not work. This treatment alleviates pain and improves mobility. Patients typically experience pain reduction within three months following surgery. Patients, however, have unanswered questions about the extent to which their physical activity (mobility) will improve long-term, whether they can regain their previous level of physical activity, and the expected pattern of recovery of activity post-operatively.
To address these questions, this retrospective study will leverage data from the National Joint Registry (NJR), consumer fitness trackers and brief questions asked in a survey. The study will recruit participants who meet these criteria: (a) live in England, Northern Ireland, Wales, the Isle of Man or Guernsey; (b) have knee osteoarthritis and had knee replacement surgery before December 2023; (c) used a fitness tracker pre- and post their knee replacement surgery. Potential participants will have to complete and submit electronic informed consent prior to providing the study with research data (physical activity data and survey responses). The collected data will be combined with participant's knee replacement data in NJR. This dataset will be examined and analysed in de-identified form, on NJR's secure portal, using both descriptive statistics and statistical methods including latent class growth analysis and regression models.

Following the analysis of the data, the study is expected to generate insights into physical activity patterns before and after knee replacement surgery. The results will enable patients and clinicians to make more informed decisions: decisions based on anticipated future physical activity levels and an understanding of recovery patterns.

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3) BACKGROUND

Knee Osteoarthritis is a common condition that causes pain, disability, and other symptoms, which can lead to a reduced quality of life (1,2). The disease affects one in five adults over 50 in the United Kingdom, and 40% of adults over 70 worldwide (3,4). Knee replacement surgery is used to treat end-stage osteoarthritis when drugs and physical therapy do not improve the condition (5,6). As part of any surgical procedure, patients are informed about the procedure to be performed: risks, benefits, limitations, and expected recovery time. Prior research using patient reported outcomes indicates pain subsides within three months, with nine in ten people having a significant improvement in pain (7,8). Conversely, mobility has been described only as "improving" (7, 8). This leaves patients prior to the operation with questions pertaining to mobility/activity such as "will I be able to regain the ability to do certain activities? (For example, walk to the shops or run for buses)" and "when will I see an improvement in my physical activity?". Following surgery, patients want to know "is this level of physical activity to be expected this long after surgery?" (where 'this long' can be any time point after the surgery).

Prior research into patterns of physical activity pre- and post-knee replacement to answer patients' questions about physical activity recovery has used physical activity questionnaires, acknowledged as being subjective and prone to recall error (9–11). More recent studies have employed objective data collection using accelerometers (12–19). Limitations of these studies include: i) small numbers of participants, ii) the reporting of activity only at specific set time points after surgery, and iii) activity being reported using a single metric (like step count) where the metric may not be of interest to the patient pre-operatively. Taken together, this means the patient questions listed above remain unanswered.

In addition to questionnaires and research grade accelerometers, physical activity is now increasingly measured in large proportions of the public via their consumer devices, including smartphones and wearables (20). This data is stored on company servers, available for users to review their historical patterns of activity. Many past knee replacement patients will have tracked their activity in this way, either knowingly or unknowingly. This provides rich activity data pre- and post-knee replacement, available via Application Programming Interface (API) or other methods with the user's consent. Joining together this retrospectively collected consumer data with National Health Service (NHS) data stored in the National Joint Registry about past knee replacement surgery would allow us to understand patterns of physical activity following knee replacement, without the need to run an expensive, long prospective study.

4) STUDY OBJECTIVES

4.1 Primary Question/Objective:

Objective 1: In people with end-stage knee osteoarthritis, to what extent does step count increase after knee replacement surgery using physical activity data collected through consumer fitness trackers?

4.2 Secondary Question/Objective:

Secondary objectives are as follows:
Objective 2: In people with end-stage knee osteoarthritis, to what extent does physical activity improve after knee replacement, using a range of alternative physical activity metrics?

Objective 3: Explore the clustering of trajectories of post-operative daily physical activity.

Objective 4: Investigate factors contributing to variation in physical activity patterns and identify characteristics of individuals who have similar recovery patterns.

4.3 Tertiary Objectives:

The tertiary objectives are focussed on the evaluation of our novel study design, and are as follows:
Objective 5: Examine whether people who consent to participate in PAPrKA are representative of the whole NJR population of patients who had a knee replacement in the same study window

Objective 6: Explore the feasibility of linking digital patient-generated health data from consumer devices with routinely collected health data, including an evaluation of the sources of referral, eligibility of website visitors, recruitment rate, success in providing self-reported information, NHS number and access to sensor data, and completeness of the sensor data.

5) STUDY DESIGN & PROTOCOL

5.1 Participants

We aim to recruit 1000 or more people who have knee osteoarthritis, had knee replacement (total or partial) in any of these five places within the UK: England, Wales, Northern Ireland, Isle of Man, or Guernsey, between January 2017 and December 2023, and should be 18 years old or over at the time of the surgery. Participants need to have used one of the following fitness tracking systems, via their smartphone or a wearable device, to track their physical activity before and after knee replacement surgery: Fitbit, Apple (phone or watch), Garmin, and Oura rings.

5.2 Study Intervention and/or Procedures

We will advertise the study possibly via traditional and social media, posters, fitness tracking companies, National Joint registry, charity organizations and Patient and Public Involvement and Engagement (PPIE) groups (see section 6.3 for details). The adverts will direct potential participants to the study 'Physical Activity Patterns after Knee Arthroplasty (PAPrKA)' website. The PAPrKA website is hosted on RADAR-base by the Precision Health Informatics group, King's College London (KCL). Researchers at KCL (see section 10, table 10.1.1) are collaborating with the University of Manchester (UoM) researchers on this study. Potential participants will access the PAPrKA website by using a web browser link or scanning a QR-code obtained from the study adverts. The website will contain information about the study including the participant information sheet, and a button to participate in the study having confirmed eligibility. Users can contact the research team to seek clarifications and discuss the project prior to consenting. If they choose to join, users will need to fill out an electronic consent form on the website. During consent, participants may also enroll for the study's prize draw. After consent, participants will need to create a PAPrKA account and verify their identity by using the verification link that will be sent to their email address.

Following the verification of a user's identity and successful login to the PAPrKA's data collection portal , the user will proceed to complete the following tasks:

- Provide their personally identifiable information (their first name and last name, date of birth (DOB), NHS number, postcode, and sex to enable the National Joint Registry to associate their study data with their knee related surgical patient record, for the purpose of the study.
- Provide access to their physical activity information by completing a user authorization process with their consumer fitness data provider on the PAPrKA data portal, for non-iOS device users (Fitbit, Garmin and Oura ring). Participants using iOS (Apple iPhone and Apple

watch) devices will download a RADAR-base iOS app from Apple Store and grant access to their physical activity using this app.

- Complete four questions: surgery date, education level, work status and satisfaction with their knee replacement. Answer three optional feedback questions to improve the study design .

Our expectation is that the entire process, including consent provision, will take no more than 50 minutes and may be completed in one sitting or in multiple sittings. When a user has consented and begun the data collection phase, but has not completed it, they will be reminded up to four times during the recruitment period. In the fourth reminder, we will ask the participants if they would be willing to answer a short survey to explore barriers to completing the data collection phase, which will help improve participation now and in future studies. A link to the survey will be included in the fourth reminder. The survey will be captured by a University of Manchester approved survey tool (i.e. Qualtrics or REDCap survey).

The identifiers, which include the NHS number obtained from the participants and the study generated study Identifier (ID), will be sent to the National Joint Registry by the KCL team. The data will be encrypted and sent via Secure File Transfer Protocol (SFTP). NJR will use this provided data to filter out knee replacement data (for example, the date and type of knee replacement, patient's demographics), for each participant. They will replace the participants' names and other identifying information with their study-ID and place the data on the NJR secure data access platform. The UoM team will pull all data captured on RADAR-base (by the KCL team) without the NHS number to secure data storages at the University of Manchester using a secure mechanism. The UoM study team will upload the participants' research data (physical activity and survey response) marked with study-ID to the NJR secure portal and link both datasets using the study-ID. All data analysis will take place on NJR portal. The resulting outputs will be vetted by NJR team before downloading them. The research dataset held at UoM, created to pre-process the study data prior to uploading it to the NJR environment, will include survey response and activity data as well as DoB, sex and social and economic status generated from postcode. We will ask participants if UoM can retain this valuable data for use in future research studies.

We will make explicit on the study website the need for participants to carefully enter their data to ensure that their identifiers are accurate for the National Joint Registry to establish a match. If no match in NJR or no physical activity data is available in their fitness trackers, we will notify those affected individuals via email and thank them for their interest in our study. We will not include those individuals where there is no match found in the NJR or no physical activity data found in their tracker in our data analysis, because of the lack of information needed to answer our research questions. We will delete the data already captured on those affected by following an agreed documented process. Table 5.2.1 shows the summary of the study procedure and timings in sequential order.

Lastly, clicks and digital behavior such as time spent on the study webpage and progress through each phase of data collection will be monitored using analytics tools such as Google Analytics. This is to measure and understand participant engagement with the study (see Objective 6 in Section 4).

Tracking this digital behavior requires web cookies. To aid participants' understanding of web cookies, we will use text refined with the PPIE group.

Table 5.2.1: Intended clinical intervention/procedure (I/P) in the PAPrKA study in sequential order.

I/P	**Total number of I/P**	**Total number of I/P outside research**	**Avg time taken per I/P (minutes, unless otherwise stated)**	**Who will conduct the I/P, and where it will take place**
Eligibility check	**1**	**0**	**2**	The PAPrKA team conducts the I/P through PAPrKA website.
Electronic Informed consent collection	1	0	15	The PAPrKA team conducts the I/P through PAPrKA website.
Register a PAPrKA account and verify email	1	0	5	The PAPrKA team conducts the I/P through PAPrKA website.
Study data collection from consented participants	1	0	25	The PAPrKA team conducts the I/P through PAPrKA website.
Provision of feedback for study (optional)	1	0	3	The PAPrKA team conducts the I/P through PAPrKA data portal.
Reminder to complete data collection	4	0	5	The PAPrKA team will notify the participants via email to complete the study's data collection on the PAPrKA data portal.
Barrier to data collection completion	1	0	4	The UoM PAPrKA team conducts this I/P through the UoM approved survey tool.
Notify of no match in NJR or no physical activity data and thank them.	1	0	1	The UoM PAPrKA team will notify the participants via email
Demographics, comorbidity, and knee related surgical data access, linkage with study obtained research data in NJR	1	0	1 hour	NJR collects and retains participants surgical data. KCL PAPrKA team sends the identifiers to NJR. NJR filters participants, replaces directly identifying data with studyID and grant PAPrKA

secure portal for the entire cohort				team access to the data access portal that has the data. PAPrKA team uploads the other research data to NJR, links the research data to the surgical data using the study-ID.
Data analysis of the linked dataset in NJR secure portal	1	0	1.5 Years	PAPrKA team with NJR access will perform the data analysis in NJR secure data access portal

Note: I/P: Interventions/procedures; Avg: Average

5.3 End of study

The completion of the successful data linkage process and subsequent analysis on the NJR platform for all participants marks the end of the study. This is expected to occur on or before the 31st December 2026 (See section 8 for more detail).

6) STUDY PARTICIPANTS

6.1 Inclusion Criteria:

A person:

- With knee osteoarthritis
- Who had a knee replacement, either total or partial:
    - between January 2017 and December 2023
    - in England, Wales, Northern Ireland, Isle of Man or Guernsey.
- Who was 18 years of age or over at the time of knee replacement.
- Who monitored their physical activity in the months before their knee replacement as well as in the year following the surgery via:
    - a smart phone application (Apple health*)
    - a wearable (which can be any of the following: Fitbit, Apple watch*, Garmin, or Oura ring)
- Can read and understand English or have support from someone who can.
- Who is willing to give us permission to access their physical activity data and link to their knee replacement information in the National Joint Registry.
- Who is able and willing to provide informed electronic consent.

* People with Apple devices (iPhone and Apple Watch), even if they have not actively installed a physical activity tracker on their smartphone or watch, have built-in activity tracking. iPhones come pre-installed with a health app and Apple watches have an activity app that automatically measures physical activity (21,22).

People who use more than one fitness tracking device or have switched between different fitness tracking manufacturers between their surgery period and December 2023, can participate in the study by either selecting one fitness device that best captures their physical activity before and after their knee replacement surgery, or by selecting multiple devices.

6.2 Exclusion Criteria:

A person:

- Does not have knee osteoarthritis.
- Did not undergo knee replacement in England, Wales, Northern Ireland, the Isle of Man or Guernsey between January 2017 and December 2023.
- Not 18 years or more at the time of knee replacement.
- Did not monitor their physical activity using a smartphone application (Apple health) or a wearable (Fitbit, Apple watch, Garmin, or Oura ring).
- Did not use a physical activity monitoring tracker at all before and after their knee replacement and do not have iPhone or Apple Watch that automatically tracks physical activity.
- Unable to read and understand English and does not have support from someone who can read and understand English.
- Unwilling to give us permission to access their physical activity data and link to their knee replacement information in the National Joint Registry.
- Unable and unwilling to provide informed electronic consent.

6.3 Recruitment:

Again, we will recruit participants via the following potential channels:

- Direct to public advertising via traditional and social media platforms: television, radio, posters, LinkedIn, X (formerly Twitter), Instagram, YouTube, and Facebook.
- Possible advertisement of the study to Fitbit or other consumer fitness tracking providers users through push notifications or/and in-app messages.
- Possible advertisement through the National Joint Registry in partnership with High Quality Improvement Partnership (HQIP), posters, possibly through charity organizations (for example Versus-Arthritis, ESCAPE-pain), and study adverts at PPIE group meetings.

As described in section 5.2, interested participants will, via the advertised QR code or website link in the invitation, access the PAPrKA study website << insert PAPrKA website >>. Once on the website, they will be directed to read the participant information sheet. They will have as long as they wish to review the study information on the study webpage and to contact the research team, using the study's mailbox << insert study email address >> and/or study's Teams account << insert study phone number >>, with any questions before completing the online informed consent form. To allow quick response, the study has a prepared question and response document for frequently asked questions.

People who expressed an interest after reading the participant information sheet and are eligible will be asked to fill out and sign an informed electronic consent (e-consent) form. This e-consent form would include the participant's name and signature. It will be captured via PAPrKA website (hosted on KCL's RADAR-base). If participants decide not to take part, they do not need to take any further action. Participants who provide their consent will be informed that completing the electronic consent is the same as signing a physical copy of the consent form.

Once a potential participant fills in the electronic consent form, digitally signs and submits it, they will receive an email with a copy of their signed informed consent. The PAPrKA study file also gets a copy of this signed informed consent. Participants can also download the completed copy in PDF format from the completion screen. Once the PAPrKA team receives the signed electronic informed consent form, the study team will automatically assign the participant a randomly generated unique study identification (ID), and a participant-ID. These IDs will be used to identify the participants instead of their names. This participant-ID is a secondary key to the main study-ID (see section 8). The Study-ID is the main key to directly identify the participants' personal data. The completed signed electronic consent form will be stored in KCL's RADAR-base and a copy sent to UoM via a PGP encrypted Amazon S3 bucket. The RADAR-base also uses AWS CloudTrail to keep track of all events on the platform (data access, modification, login and activity) for research transparency.

It should be noted that it is not within the study budget to provide translations, either in Welsh or other languages that are not English. However, those who can access support with reading and understanding the study materials will be able to participate. Lastly, we will produce guides to support participants' use of the PAPrKA website. The guidance is in development and will involve a series of PPIE workshops to refine the content into digestible, easy-to-follow instructions for participants.

6.4 Participants who withdraw consent [or lose capacity to consent]:

Participants can withdraw consent to take part in the study at any time without giving a reason, as participation in the research is voluntary, without their care or legal rights being affected. Participants can do so by contacting the study team and providing their unique participant-ID. Request from participant to delete data will be considered on a case-by-case basis and in accordance with university policy up until the point that the 'key' that links participant's identifiers with their participant and study ID is broken. At this point, it will not be possible to remove participants data from the dataset. This will not affect their data protection rights. This is made explicit in the participant information sheet and the consent form.

7) OUTCOME MEASURES

The study will examine objective measures of physical activity from consumer fitness tracking devices.

Primary outcome

Daily step count before and after the knee replacement surgery. The outcome will be measured daily (where available) for a period of 18 months: six months before and twelve months after the knee replacement surgery. We chose these time points to account for effect of seasons on data, as well as examine the recovery phase, which is documented in research to occur within the first 12 months after knee replacement.

Secondary outcome

This may include daily measures of duration of moderate-to-vigorous physical activity (MVPA), sedentary behaviour, heart rate, walking speed, distance, activity duration, cadence, and other relevant physical activity metrics, for a duration of 18 months (six months before and one year after the knee replacement surgery). Patient and public involvement work will help inform the selection of the most appropriate secondary outcome metrics relevant to people living with knee osteoarthritis.

Tertiary outcome

Demographics and socioeconomic status will be compared between our study population and the whole NJR population. Website engagement data via Google Analytics and participant feedback will allow examination of engagement with the study platform.

8) DATA COLLECTION, SOURCE DATA AND CONFIDENTIALITY

Following consent, as described in section 6.1, all participants will be identified using their participant-ID (participants version of the study-ID). Also, a copy of the identifying information held on RADAR-base (i.e. participant's name, email address, participant-ID, and study-ID, sex, DoB and postcode) will be encrypted and transferred to UoM via a secure Amazon Web Service (AWS) S3 bucket, (figure 8.2.4). Access to the identifying information will be restricted to the PAPrKA team members only and with approval from the CI. From the identifying information the PAPrKA team will create a participant list (study and participant ID, name, email address). At the end of the study (see section 5.3) the participant list will be destroyed.

This section would explain more on other study activities as well as data management strategies.

8.1 User authentication

Once the participant submits their electronic consent, they will receive an email with their completed consent attached, and a link to register an account for the data collection. The link sent to their registered email is automatically generated and personalized for each user. It acts to support the verification of a user's identity. To start the study's data collection phase (described in section 8.2) participants will click on the link sent to their email address, register their account, verify their account using a verification link emailed to them, and login to the data portal.

8.2 Data Collection Process

The data collection phase has four tasks: three mandatory and one optional. First, participants will fill in their NHS number and other identifiers. Second, they will fill in other participant data (education level, surgery date, and work status) and, answer a question about satisfaction with the knee replacement surgery. Participants who have undergone more than one knee replacement surgery are asked to complete the surgery date and satisfaction question based on their most recent knee replacement surgery. Also, participants with left and right knee replacements are asked to report surgery dates for both knees. Third, participants will authorize access to their physical activity data. The remaining optional task asks interested participants to provide response to three feedback questions. An overview of the participant's journey from expression of interest to submission is provided in Figure 8.2.1.

Figure 8.2.1: Participants journey through the study.

8.2.1 Collection of NHS identifier and other participant data

Once a user is verified via user authentication as discussed in 8.1, they proceed to the PAPrKA data portal. As described in 8.2, participants will provide their NHS identifiers (Date of birth, Gender, First name, Surname, NHS number and Postcode) to allow linkage to data in the National Joint Registry. Users who do not know their NHS number can get it from the 'Find Your NHS Number' service and will be directed via the following link: https://www.nhs.uk/nhs-services/online-services/find-nhs-number/https://www.nhs.uk/nhs-services/online-services/find-nhs-number/ .
In the web form section for obtaining this information, we ask participants to supply accurate information so that a match can be secured in the National Joint Registry for the study.

The NHS identifiers obtained will be stored separately from the research data in a secured KCL's AWS S3 bucket as shown in Figure 8.2.4.

As part of the mandatory sections, participants are also asked about their surgery date(s), education and work status. This will enable the study to understand patterns that emerge from the study and determine how these factors influence those patterns. The responses to these three questions will be stored separate from the identifying information in a separate KCL's AWS S3 bucket section (See figure 8.2.4).

8.2.2 Collection of participants' physical activity data

KCL's RADAR-base will be used to collect the physical activity data from the participants when they click the 'connect device' task on the PAPrKA data portal. The RADAR-base is an open-source solution designed for collection of mobile health data. The solution is built using open-source software such as Apache Kafka, PostgreSQL. The platform also has costume-built components like study management portal and smartphone study application. The study's approach to collecting physical activity information from each user is further delineated below.

There are four fitness tracker manufacturers included in the study: Apple, Fitbit, Garmin, and Oura ring. This list of fitness providers was initially obtained by merging device manufacturers from PubMed studies published between 2015 and 2021 looking at fitness trackers in healthcare (23–29). The study selected devices with entry dates of before 2015 into the consumer market and an exposed interface for accessing data for example, API. The list was then limited to the stated four devices because of RADAR-base's capacity to extract data from only these devices. In the PAPrKA data portal, once participants click on their device name, if the device is Fitbit, Garmin, and Oura ring users will authenticate with their device manufacturer's portal and provide authorization for their physical activity to RADAR-base

The authorization page will look like Figure 8.2.2. The user will grant PAPrKA study access to pre-selected information corresponding to their physical activity data through this webpage by choosing 'Allow' or 'Authorize'. Once that is done, users will be redirected to this data portal to complete the remaining tasks.

When a user selects Apple (Apple watch or iPhone) as the device to connect, the user will be directed to download a RADAR-based iOS app <<insert name of app>>. After downloading the app, each user will register an account with the app, login, and grant access to their physical activity data. This process is needed for Apple devices because Apple does not have an exposed external API that allows data collection from a cloud server. This means to collect data from an Apple device we are required to do so through an app that interfaces with Apple servers.

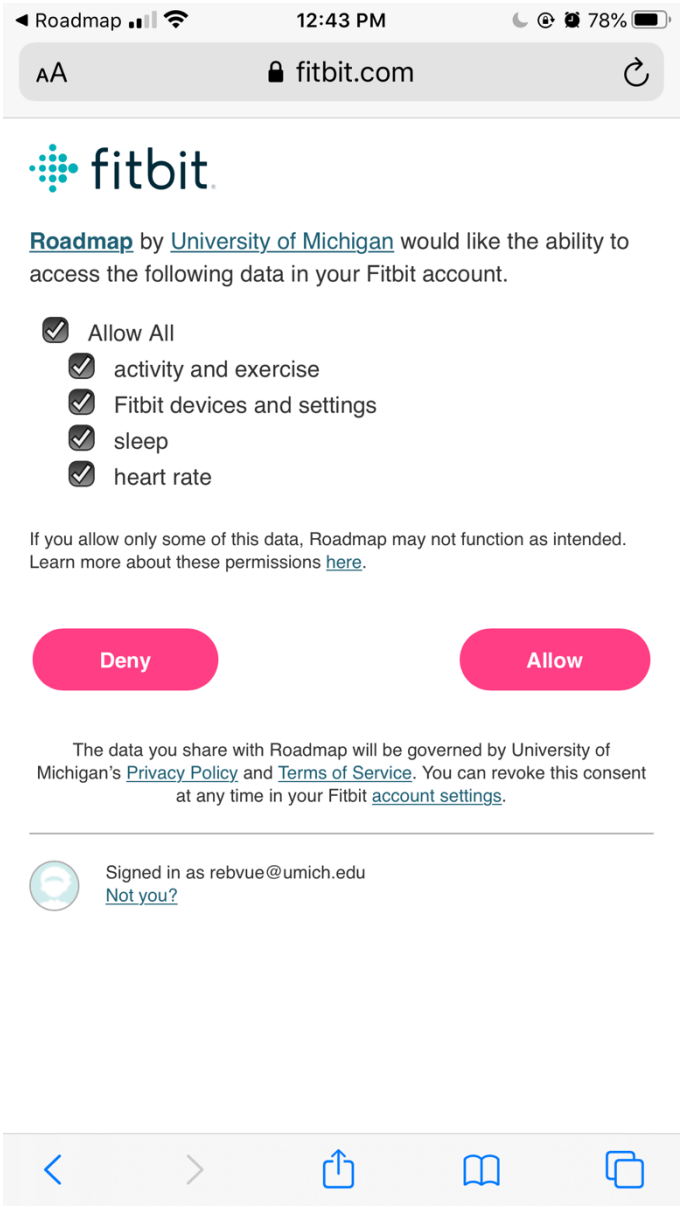
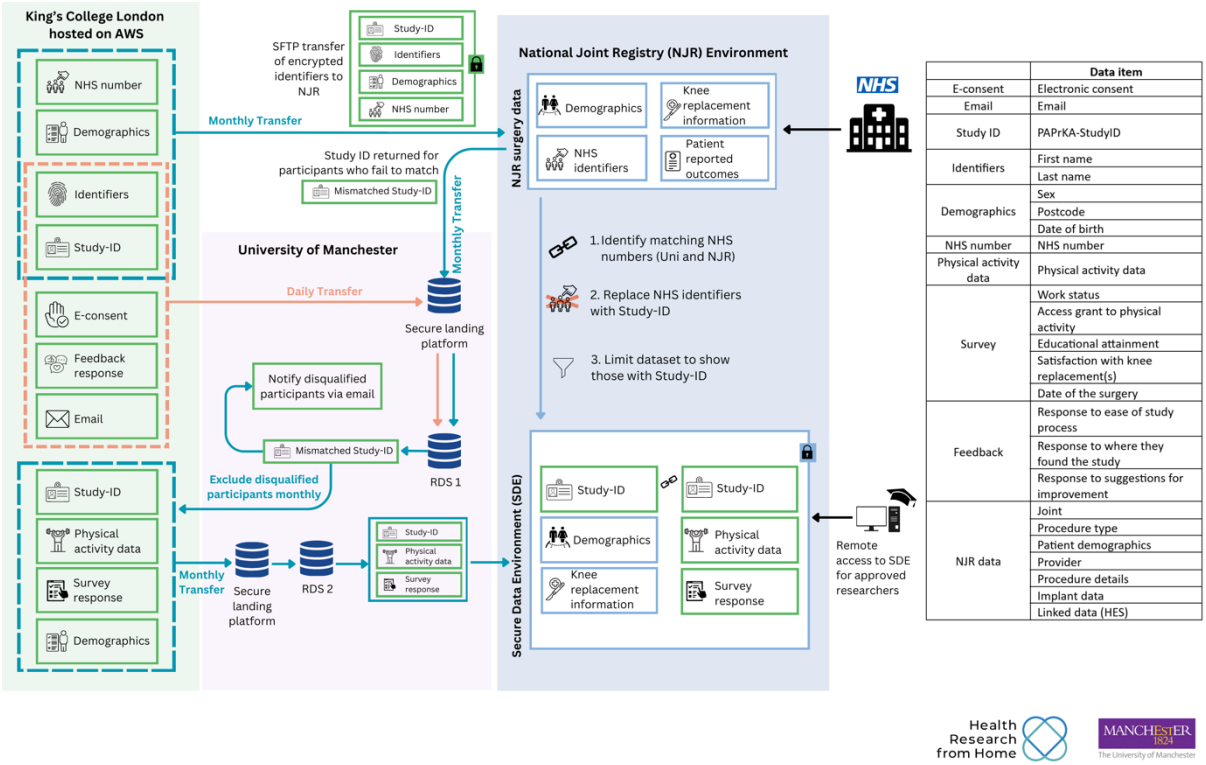


Figure 8.2.2: Example of how an authorization access page from fitness tracker provider (FitBit) looks like) (30).

Upon the user granting access to their physical activity data, the user's fitness data provider supplies the RADAR-base with an access token. This access token identifies the user's device, confirms authorization, and allows retrieval of physical activity data about the user. The RADAR-base will use these access tokens to retrieve physical activity data for each user from the tracking device's cloud platform. The data to be retrieved will be previously collected data by the fitness tracker. This data will comprise of daily activity metrics measured (where available) between July 2016 and December 2024 to match the study period. The physical activity data may include step count, duration of moderate-to-vigorous physical activity (MVPA), sedentary behaviour, heart rate, walking speed, distance, activity duration, cadence, and other relevant physical-activity-related metrics. The data will not include GPS data, or location-related data (latitude, longitude) that can identify participants' address. Step count is the number of steps taken at a time; duration of MVPA is the time spent in activity that demands high energy expenditure but allows for conversation; sedentary behaviours are activity that requires staying in a specific position; heart rate is the number of heart beats per minute; speed is the velocity when walking on flat ground; activity duration is time spent performing a particular activity; cadence is steps taken per minute; and distance is the total of how far someone has moved. The data extracted will be saved to a KCL's secure AWS S3 bucket, separate to the storage of any identifying information captured by the study, and indexed against the study-ID. The study-ID is the same study-ID that identifies each user and is automatically obtained as the user gains access to the PAPrKA data collection portal. Although we think the risk of this is low, in cases where the participant provides more information than we need, the data will be deleted and will not form the research dataset.

8.2.3 Collection of patient's satisfaction with the knee replacement

As part of the mandatory sections, participants will be asked to complete a question about their current (post-operative) satisfaction level with the knee replacement they had. Individuals who have undergone multiple knee replacements between 2017 and 2023 are asked to answer the question based on their most recent knee replacement procedure. The response to the question is on a four-point Likert scale ranging from very satisfied to very dissatisfied. This satisfaction question was taken from the validated self-administered 'Patient Satisfaction Scale for Primary Hip and Knee Arthroplasty questionnaire' (Question 1)(31). This questionnaire has high internal consistency (Cronbach Alpha 0.86 to 0.92).



	Data item
E-consent	Electronic consent
Email	Email
Study ID	PAPrKA-StudyID
Identifiers	First name
	Last name
Demographics	Sex
	Postcode
	Date of birth
NHS number	NHS number
Physical activity data	Physical activity data
Survey	Work status
	Access grant to physical activity
	Educational attainment
	Satisfaction with knee replacement(s)
	Date of the surgery
Feedback	Response to ease of study process
	Response to where they found the study
	Response to suggestions for improvement
NJR data	Joint
	Procedure type
	Patient demographics
	Provider
	Procedure details
	Implant data
	Linked data (HES)

Health Research from Home

Figure 8.2.4: Diagram showing the collected data, where they are stored and the flow to National Joint Registry. E-consent: Electronic consent; SDE: Secure Data Environment; NHS: National Health Service; NJR: National Joint Registry.

8.2.4 Optional data obtained to improve participation and the study approach.

Participants can also complete an optional task: answer three feedback questions. The feedback questions will be collected via PAPrKA data portal, and it will explore participants' perception of how easy the process was, where they found the study, and collect any suggestions to improve our data collection process. Participants who do not wish to respond to the optional section can opt to submit the data collection form by clicking ‘finish’. Completing the mandatory task then clicking finish for all tasks marks the end of participant data collection. The questionnaire that has all the questions for all the tasks is attached as "333659_PAPrKA_Study Questionnaire.docx".

8.3 Possible Compensation

All participants who indicate an interest in entering a prize draw during consent, to win one of the ten £25 Amazon vouchers as a thank you, will be entered into a prize draw. In the draw, ten winners will be selected at random using a random number generator/picker.

8.4 Working with National Joint Registry's Data

The NJR data is essential to allow us to answer the main research question given physical activity data from fitness trackers lacks the necessary medical information about the joint replacement surgery. To access NJR's data for analysis on their secure environment we will do the following (also see figure 8.2.4 and 8.4.1):

Step 1:

The KCL PAPrKA research team will send a copy of the 'NHS Identifiers' containing date of birth, sex, first name and last name, NHS number and postcode and study-ID to NJR. This will be sent from the KCL servers to the NJR using an encrypted file, and, through Secure File Transfer Protocol (SFTP) – an extension of Secure Shell (SSH).

Step 2:

UoM PAPrKA team will pull all data captured on RADAR-base by KCL collected without the NHS data to UoM via a secure mechanism. The team will pull identifying data to Research Data Storage for identifying data (account 1) and the research data to Research Data Storage for research data (account 2). The identifying data will contain name, email address, postcode (to be converted to social Economic Status and then deleted), study and participants IDs and signed informed consent. The research data will be indexed by Study-ID and include physical activity data from Apple devices, Gramin, Fitbit and Oura ring (as available) and mandatory survey information (date of surgery, satisfaction with knee operation, education attainment and work status). We will also pull other non-mandatory information stored (feedback response) to account1 - identifying RDS.

Step 3:

NJR will use the received key identifiers to do the following: (a) filter out surgical data for the participants; (b) remove participants' directly identifying details and replace them with the study-ID; (c) Place the resultant pseudonymised data on their secure research portal; and (d) grant the PAPrKA team access to the secure research portal with the pseudonymised data. The pseudonymised data will include joint side, Body Mass Index (BMI), date of procedure, procedure type, American Society of Anaesthesiologists (ASA) score, Surgical Unit/consultant, surgeon grade, approach/minimally invasive technique, adverse events, manufacturer, comorbidity, demographic information (age, gender, ethnicity category, index of multiple deprivation, county of residence, and health authority of residence) for the participants. NJR will also provide age, sex and socioeconomic data for all knee replacements in the study period (January 2017 – December 2023) to enable an evaluation of the representativeness of our consented PAPrKA study population.

Step 4:

The UoM PAPrKA research team will upload the pseudonymised research data (physical activity and survey response with the study-ID) to NJR secure research portal. After this, the team will combine pseudonymised NJR data on the portal with the uploaded pseudonymised research data using study-ID.

Step 5:

Once linkage is verified to be correct through a count of the matched study_IDs, the study team will use the surgery date for each participant to censor their physical activity data to 18 months data (6 months prior and 12 months after surgery, as available). Then, the study team will commence the study's planned analysis (see section 9). Analyses for objective one to five will be conducted in NJR's data access portal. The aggregated results generated will be vetted (output checked) by the National Joint Registry to maintain individual participants' anonymity before download.

Other important things to note on the linkage:

The participants NHS linkage identifiers that would be sent to NJR (see step 1 above) will be prepared by KCL PAPrKA team member with consent from participants and approval from the CI. This data will be shared with participants' consent. This list will be stored in KCL AWS S3 bucket separate from the other pseudonymised research data. Access to the list would be through approval from CI, and it would be deleted (destroyed) at the end of the study.

If there is no match between the consented participants and NJR Registry patients, these participants will be contacted to notify them and thank them for their interest in the study. Their data will be deleted following an agreed and documented process. The data linkage in step 4 will exclude a participant if NJR cannot secure a match. This is because their health data will not be available for linkage to the other research data as described in step 4 above.

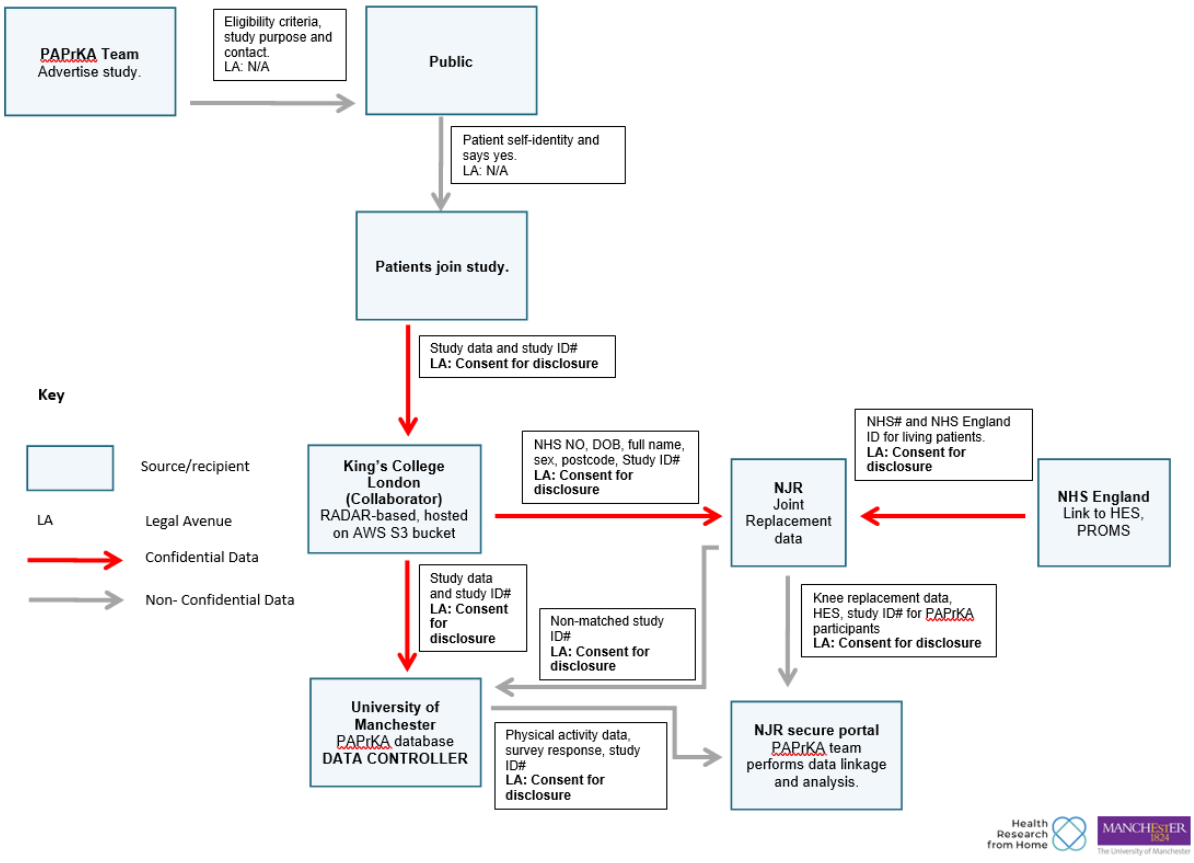


Figure 8.4.1: Data flow diagram for the study

8.5 Individuals who will have access to participants personal data during the study.

The following group of people will or may access participants personal data during the study (see figure 8.4.1).

a) UoM and KCL PAPrKA Research Team:

The research team will have access to personal data provided by participants, with their consent.

b) National Joint Registry (NJR):

NJR will have access to the study collected participants' personal data, with participants' consent. NJR collects surgical information and always retains it (See section 8.4 and figure 8.4.1).

c) The University of Manchester.

Study data and material may be looked at by individuals from the University of Manchester, from regulatory authorities National Joint Registry, or from the NHS Trust, for monitoring and auditing purposes, and this may well include access to personal information.

8.6 Data management: preservation and archiving

At the end of the study, once UoM validates that all the research data obtained for the study now resides in the UoM RDS, the PAPrKA team will confirm this with the KCL team and request they delete all the collected data from the RADAR-base. The KCL team will provide proof that the data has been deleted from their server. Once KCL deletes the data, the study data (with the exception of NJR data) will now reside with UoM for archiving. The electronic consent form (including participants' name and signature) will be retained separately from the research data for five years on the University of Manchester Research Data Storage. It is retained as evidence of the patient's consent to participate as well as for audit purposes. On the e-consent form, we will also ask participants' permission to keep their contact details on file. This is to contact them about future studies in accordance with the University of Manchester's Research Privacy Notice and with their consent. Participants who provide consent for this, their details will be safely stored on University of Manchester's servers in a digital folder for ten years accessible to the University of Manchester PAPrKA study team and used only for the purposes described above.

In addition, research data collected about participants' physical activity, self-reported surgery date, education level, work status and current satisfaction with their knee replacement will be stored in de-identified form on the RDS research folder at UoM. Again, the key to re-identifying the participants (first name, and last name) will be deleted, thereby making the research dataset de-identified. Sex, date of birth, self-reported surgery date and socioeconomic status derived from postcode would be retained as demographic data and form part of research data. We retain these

demographic data because they are needed to identify and interpret trends and associations in population research. This research data will be stored in the RDS for ten years. Access to Research Data Storage will be through the PAPrKA's CI, data manager, and data custodian We will store a metadata record that summarizes the data and explains how to request access to the data in an open data repository, Figshare at the UoM Library, for the same period. Researchers at other institutions, and others, can access the metadata directly from the repository. If they have an interest, they can request access to the research dataset from the PAPrKA's CI to use for further research or to check our analysis and results.

The full names and email addresses of the ten participants who win the £25 shopping/Amazon vouchers will be securely retained by Finance for a period of up to 7 years for audit purposes only and then destroyed. It will not be used for them for any other purpose. The PAPrKA team will hold the prize draw data in the UoM RDS and would destroy it at the end of study (see section 5.3).

The feedback questions' response collected by the PAPrKA team, and study engagement results from the analytic tool, both obtained for the purpose of improving our study process, will be retained on University of Manchester research data RDS for ten years after the study ends. This is for potential reuse.

All this information is provided in the participant information sheet.

9) STATISTICAL CONSIDERATIONS

9.1 Statistical Analysis

Objective 1: In people with end stage knee osteoarthritis, to what extent does step count increase after knee replacement surgery using activity data collected through consumer fitness trackers?
To investigate the changes in step count between six months, three months, and a month pre-surgery and after surgery at different intervals: one month, three months, six months, and one-year post-surgery, first, we will compute the average of the daily step count within each month before surgery and the average of the daily step count within the specified interval after surgery. We will employ descriptive statistics to describe pre-surgery and post-surgery averages. After that, we will test for normality using the Shapiro-Wilks test. If the data distribution is normal, we will conduct a paired t-test evaluated at aforementioned time intervals and if not, we will use appropriate non-parametric equivalence of the paired-test. In addition, we will employ appropriate correction criteria such as Bonferroni correction to account for the multiplicity issue arising from multiple tests.

Objective 2: In people with end stage knee osteoarthritis, to what extent does physical activity improve after knee replacement, using a range of alternative physical activity metrics?

The methods for Objective 2 will follow those of Objective 1 but using the alternative physical activity metrics such as speed, activity duration, cadence, distance, heart rate as described in Section 7.0 and 8.2.

Objective 3: Explore the clustering of trajectories of post-operative daily physical activity.

To identify unknown (latent) subgroups with distinct post-operative physical activity patterns (trajectories), we will employ a latent class growth modelling (LCGM) approach (32). For this the following steps will be taken. First, a latent growth curve model (LGM), with daily step count as an outcome and time since knee replacement surgery as a predictor, will be applied to identify the best-fit growth model that will describe the longitudinal physical activity trajectories at the population level. Three growth models with linear, quadratic, and cubic-spline specifications for the longitudinal physical activity trajectories will be compared. Lower Bayesian information criteria (BIC) values will identify the best-fit growth model. In the second stage, the best fitting LGM model specified in the first stage will be extended to LCGM to identify latent subgroups with distinct post-operative physical activity patterns. The elbow method will determine the number of distinct latent subgroups using BIC as a goodness of fit measure. The process starts with a one-class model and then adds classes until we identify the model with the best fit (for example, lower BIC value and no significant reduction in BIC from adding further classes). Both domain knowledge and statistical criteria will be employed to examine the validity of the final model. Once we identified the final LCGM, participants will be assigned to a specific class based on their posterior class membership probabilities.

Objective 4: Investigate factors contributing to variation in physical activity patterns and identify characteristics of individuals who have similar recovery patterns.

To examine the correlates of latent subgroups, we will employ a multivariable multinomial logistic regression model in which the latent subgroups identified in objective three are regressed on the set of baseline covariates. The following baseline covariates will be considered: surgical information (see section 8.4), satisfaction level, participant characteristics (e.g., age, gender, and socioeconomic status), comorbidity, and pre-surgery daily physical activity levels. We will then report odds ratios (OR) along with 95% confidence intervals of being in a particular subgroup.

Objective 5: Examine whether people who consent to participate in PAPrKA are representative of the whole NJR population

We will compare the demographics and socioeconomic status of our participants to that of all people in the National Joint Registry who have had a knee replacement in the study period. We will carry out an appropriate statistical test for comparison, for example multiple analysis of variance (MANOVA) if the data is normal distributed or multivariate kruskal-wallis test (MKN) or other appropriate statistical test if the data is distribution free.

Objective 6: Explore the feasibility of linking digital patient-generated health data from consumer devices with routinely collected health data

We will use descriptive statistics and appropriate graphics to summarise the many steps within the participant flow, including i) sources of referral (from Google Analytics and feedback survey), ii) a count of completed eligibility checks (the number and proportion who are or not eligible), iii) the cumulative recruitment rate, iv) the proportion of consented participants who successfully provide self-reported information, NHS number and access to sensor data, and v) completeness of the sensor data, summarised in episodes in the pre-operative and post-operative periods.

9.1.1 Statistical power

We have a target of recruiting 1000 or more participants as we are interested in demonstrating the feasibility of recruiting at scale for a retrospective cohort that links existing consumer data to National Joint Registry data. It is nevertheless important to show that we have the statistical power to detect the primary outcome.

9.2 Sample Size:

Previous literature from Lützner (19) estimates an increase in average daily step count of approximately 1200 steps one year following knee replacement when compared with pre-operative average daily step count (standard deviation ~3000). If we wish to demonstrate an improvement in step count of half as big as what the study estimated with confidence, we will need to have data on 608 participants. The null hypothesis is that the improvement in average daily step count at one year following knee replacement is less than 600. Using a significance level of α = 0.05, Effect size δ = 600, standard deviation = 3224, and power: β = 0.90, assuming normality of the data, and using a two-sided t-test with a two-sided hypothesis, we will need 608 participants. The result is generated using the power.t.test using RStudio 2022.02.3.

Therefore, we can be confident that the target sample size of 1000 has adequate power to detect the expected change of 600 daily steps counts or greater at one year and allows for incomplete data in around 40% of the cohort.

10) MONITORING AND QUALITY ASSURANCE

Two things are described within this section: the project team and the plans for quality assurance.

10.1 Study team and responsibility

This section describes each of the PAPrKA study team and their respective responsibilities in the project, and it is presented in Table 10.1.1.

Table 10.1.1: Role and responsibilities of the study team.

Name	Role	Main responsibilities
Will Dixon	Main Supervisor	CI, Supervision, and mentorship
Sabine Van der veer	Co supervisor	Supervision
David Wong	Co supervisor	Supervision
Shuai Shao	Post-doctoral research associate	Analysis methods
Amos Folarin	'Health Research from Home (HRfH)' collaborator	Technical expertise
Richard Dobson	HRfH collaborator	Technical expertise
Mark Wilkinson	NJR Collaborator	Technical expertise with NJR

Andrew Judge	NJR Collaborator	Statistical methods and technical expertise with NJR
Michael Whitehouse	NJR Collaborator	Technical expertise with NJR
Ayobami Olanrewaju	PhD student	Conduct the study (coordinate data collection, linkage, analyse the data, and write up the results for publication)
Elaine Mackey	Information and data governance manager	Information governance
Rachel Nagy	Programme Manager	Providing support for the conduct of the study
Coral Stevenson	Programme Administrator	Providing support for the conduct of the study

More information on the roles and responsibilities of the NJR and HRfH collaborators

- The NJR internal collaborator is a co-applicant and part of the research team. Their expertise is in the interpretation of the NJR dataset. Their role also involves a guarantor role ensuring the appropriate handling of data linkage and analysis. For this project they will be mainly engaged for insights into the data interpretation of the wearables data given their PROMs links/interest, as well as acting as the NJR internal co-applicant (a requirement of NJR access).
- Health Research from Home is an MRC partnership grant about the use of smartphones and wearables for population health research. The HRfH collaborators are part of the research team with expertise in working with wearable technology, API design, development and deployment, as well as in the analysis and interpretation of findings from such studies. In this project, they will be consulted for insight into the interpretation of results, as well as technical aspects relating to acquiring data from smartphones and wearables.

10.2 Plans towards Quality Assurance

Here are the ways the study plans to ensure quality assurance. The University of Manchester Data Management Plan Team has reviewed these approaches and has determined that they are sufficient for our research.
The approaches are listed below. The study will:

1) Adopt a clear, consistent file structure.
   The study team will adopt the FBMH file folder structure (item 7, template study file index) for organising the data. This is to ensure ease of location of all the project files.
2) Have each file version controlled.
   The study will adopt a version control strategy that uses integers and the last-update date. This information will be written within the document, for example, 'Version X.X, Date: ddmmmyyyy'.
3) Adopt a naming convention for all documents.

There will be a naming convention for all documents which will take this format, unique_number_Study name_document name_ddmmmyyyy. For example, 333659_ PAPrKA Study_Protocol_24Nov2023.

4) Documentation of each phase of the projects
   Each phase of the project will be documented. this will include minutes of meeting with action plans and email communications. This will help people understand how the project has developed.
5) Use of standardised methods and protocols for data capture.
   The study will adopt where necessary standardised methods and protocols to allow repeatability and a way to allow recheck.
6) Adoption of controlled vocabulary, code lists and choice lists in data collection.
   To prevent confusion or mixed up in our data, we will adopt controlled vocabularies where necessary.
7) Taking notes and documenting data properly
   The data will be documented properly. For example, the information about the data will include the following: how the data was retrieved, when it was obtained, transformation carried out, the reason for each action and logging any changes made to the original data (this will includes corrections or redactions).
8) Adoption of peer data review.
   We will adopt a peer data review so that errors, biases, and inconsistencies is identified and fixed.

11) PEER REVIEW

This protocol has undergone thorough reviews within the research team, within our organisation and by independent external reviewers.

a) Review by educational supervisor and within the research team.
PAPrKA study team members have reviewed the document several times and provided tracked changes and suggestions, all of which have been incorporated after deliberation and agreement.

b) Within the Chief Investigator's institution or host organisation
This study protocol has been reviewed by the Faculty of Biology Medicine and Health Information Governance team, which oversees the project and provides guidance. In addition, the University of Manchester (sponsor) has carefully reviewed the project and agree to act as sponsor for the study (Reference: NHS002146).

c) Independent external reviewer
An expression of interest of the project was submitted to NJR and approved (NJR Reference: RSC2022/17) by them. A full ethics was submitted to NJR in July 2024 and approved in September 2024. The study was also described in brief as part of an MRC Partnership Grant 'Health Research from Home', which was subject to external peer review and awarded in July 2023 (Grant number: MR/Y003624/1). Also, the patient facing documents of the study have had PPIE input from the PPIE

group at the UoM Musculoskeletal Network and a subsequent review by a public contributor in 'Health research from Home'.

12) ETHICAL and REGULATORY CONSIDERATIONS

12.1 Approvals

NHS Research Ethics Committee and Health Research Authority approval will be obtained before commencing the proposed research. The study will be conducted in full conformance with all relevant legal requirements and the principles of the Declaration of Helsinki, Good Clinical Practice (GCP) and the UK Policy Framework for Health and Social Care Research 2017.

Other approvals that are needed for the study are explained below.

- **National Joint Registry**

There are two parts to the National Joint Registry approval. The first is an expression of interest submitted before the start of this project which has already been approved (NJR Reference: RSC2022/17). The second is a full NJR application to request data access which can only be submitted following NHS ethics approval. This second part has been submitted and approved but will be amended after this amendment is approved. More information about the National Joint Registry approvals can be found in the link below.
https://www.njrcentre.org.uk/healthcare-providers/data-access-requests/

12.2Risks

The main risk to participants is a breach of data confidentiality.

To mitigate this risk, we have mapped out the dataflow in the planning phase of the project, working with both internal and external teams involved in the processing of the project's data. We have mapped out each phase of the data under each of these four key processes.

1) **Data captured and final storing at UoM:**

For data captured and final storing at UoM by the PAPrKA team, we will:

- Use a RADAR-base a software platform hosted on AWS and stored in AWS S3 bucket to collect the survey response and physical activity data. The platform has AWS CloudTrail that logs all events that occurs when using RADAR-base.
- The identifying data will be asymmetrically encrypted using PGP encryption by KCL team.
- The UoM team will pull encrypted identifying and non-identifying data from RADAR-base into two different UoM RDS folders (the folder for identifying data, and the other for research data).
- Access to the RDS folders will be restricted. Permission to access the folders must be approved by the CI.
- Researchers accessing research and research-related project data will be required to use a university-approved device with a password login, after connecting to the University's Virtual Private Network (VPN).

2) Data transfer to the NJR:

- KCL will transfer the 'NHS identifiers' needed for first part of the data linkage to NJR via a Secure File Transfer Protocol (SFTP) (with TLS 1.2), an extension of Secure Shell (SSH).

3) Data linkage:

- NJR will create the first part of the *'research dataset'* by filtering out knee replacement surgical data for matching participants in our study and replacing their identifying information with our study-ID (See figure 4, section 8).
- The '*research dataset'* will be made available to the research team within the NJR's secure environment.
- To the '*research dataset'* the PAPrKA team will upload the survey response and physical activity data from the RDS to NJR data access portal to form the full research dataset.

4) Management of research data:

- A copy of the survey, demographics, and physical activity tracking data will be held securely at UoM. For the copy of the research data held at UoM participant will be asked if they agree to the reuse of this data to answer research questions over and above those for the PAPrKA study; on the basis that only pseudonymised data will be shared and where there are data protection measures in place to ensure the confidentiality of the data.
- The PAPrKA team will analysis the full research dataset within NJR's secure environment.
- Research results derived from data analysis will be checked and approved for download by the National Joint Registry team.

There are no risks to the researchers.

13) STATEMENT OF INDEMNITY

The University has insurance available in respect of research involving human subjects that provides cover for legal liabilities arising from its actions or those of its staff or supervised students. The University also has insurance available that provides compensation for non-negligent harm to research subjects occasioned in circumstances that are under the control of the University.

14) FUNDING and RESOURCES

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).

15) PUBLICATION POLICY

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 will host a plain language summary of the results. In addition, the webpage will provide links to research publications of the results. Additionally, when participants provide their informed consent, we will ask if we may keep their contact information to allow us to provide them with a summary of our findings. If they show interest, we will provide the summary to them by email once it is available. The results are anticipated to be available at the end of 2026. This information is in the participant information sheet.

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