

Testing motion sensors, monitoring recovery, and exploring views on smart knee replacements in people having a total knee replacement

Submission date 16/10/2026	Recruitment status Not yet recruiting	☒ Prospectively registered ☐ Protocol
Registration date 27/10/2026	Overall study status Ongoing	☐ Statistical analysis plan ☐ Results
Last Edited 20/10/2026	Condition category Surgery	☐ Individual participant data ☒ Record updated in last year

Plain English summary of protocol

Background and study aims

Total knee replacement (TKR) is a very common operation. Most patients recover well after the operation; however, some may experience problems such as joint infection or stiffness. It is important for clinicians to identify these problems as early as possible.

Sensors could help patients and clinicians monitor how the knee is recovering and identify changes that may need further investigation. Knee sensors are small electronic devices that can measure how the knee moves during everyday activities and exercise.

A new knee sensor has been developed at the University of Leeds. In the future, this sensor may be placed inside knee replacement implants. These are known as "smart knee implants".

The first aim of this study is to find out how accurately the sensor measures knee movement when it is worn on the outside of the body.

The second aim is to understand how these measurements change as patients recover from their knee replacement operation.

The third aim is to find out what patients think about smart knee implants through interviews.

For this study, the sensor will not be implanted inside participants' knees. It will only be worn on the outside of the body.

Who can participate?

Patients aged 18 years or over who are waiting to have a total knee replacement operation

What does the study involve?

Participants will attend three sessions at the gait analysis laboratory: one before their knee replacement operation and two during their recovery.

At the first session, participants will complete a consent form.

At each session, we will ask participants to wear comfortable sports-style clothing, such as shorts and trainers. We will then ask them to complete two short questionnaires. We will collect some basic information and measurements, such as their age, gender, height, weight and leg length. We will then attach small reflective markers and sensors to their legs. These will measure

how their knees and legs move.

Participants will complete simple activities such as bending their knee, walking, using stairs, standing up from a chair and doing a squat. We may also ask them to complete some additional activities, depending on how they are feeling and what we need for the study. Participants can take breaks and stop any activity at any time.

At the end of each session, we will remove the markers and sensors.

Participants can also choose to take part in two optional interviews, one before and one after their knee replacement operation. During the interviews, a researcher will ask about their views on smart knee implants.

What are the possible benefits and risks of participating?

Participants may not benefit directly from taking part in this study. However, the study may help us understand how this new sensor could be used to monitor recovery after total knee replacement. Participants who take part in the optional interviews will also have the opportunity to share their views and experiences from their operation.

At the end of the study, we will send participants a summary of the results. This will be available in standard, easy read and large print formats.

We do not expect any major risks from taking part. Some of the physical activities, such as walking or using stairs, may involve a small risk of tripping or falling. We will take steps to reduce these risks and will only ask participants to complete activities that are safe for them.

Taking part in the study will not affect participants' usual care.

Where is the study run from?

Leeds Institute of Rheumatic and Musculoskeletal Medicine (LIRMM) (UK)

When is the study starting and how long is it expected to run for?

January 2027 to March 2028

Who is funding the study?

National Institute for Health and Care Research (NIHR) HealthTech Research Centre in Accelerated Surgical Care (UK)

Who is the main contact?

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Integrated Research Application System (IRAS)

370705

Study information

Scientific Title

Sensor validation, recovery tracking, and acceptability of smart implantable knee devices in patients undergoing total knee arthroplasty

Acronym

SKD_VATA

Study objectives

The aim of this study is to evaluate the performance and clinical relevance of algorithm-derived kinematic parameters obtained from a novel knee sensor, in patients undergoing total knee arthroplasty (TKA), and to explore patients acceptability of smart implantable knee devices.

Objectives:

1. To develop and evaluate algorithms for deriving kinematic parameters and recognising human activities from wearable accelerometer data in patients undergoing TKA, and to assess their accuracy, precision, and reliability
2. To evaluate whether the errors of the derived parameters are smaller than the minimal clinically important difference (MCID) thresholds reported in the literature, thereby assessing the clinical usefulness of the device and its implications for safe clinical decision-making
3. To assess whether the derived parameters can detect and quantify changes in patients' recovery across three time points (preoperative, 6 weeks postoperative, and 12 weeks)

postoperative)

4. To evaluate the relationship between the derived kinematic parameters and patient-reported outcome measures (PROMs), specifically the Oxford Knee Score and EQ-5D-5L, in patients undergoing TKA

5. To explore the perspectives of patients undergoing TKA regarding the acceptability of smart knee implants, and to identify the factors that contribute to making these devices more or less acceptable, in accordance with the Theoretical Framework of Acceptability (TFA) described by Sekhon et al.

6. To examine whether the experience of undergoing TKA influences patients' perspectives on the acceptability of smart knee implants

Ethics approval required

Ethics approval required

Ethics approval(s)

Not yet submitted

Primary study design

Observational

Secondary study design

Cohort study

Study type(s)

Health condition(s) or problem(s) studied

Patients undergoing total knee arthroplasty (TKA)

Interventions

This is an observational, longitudinal, single-arm cohort study involving 45 patients undergoing total knee arthroplasty (TKA). Participants will be recruited using consecutive sampling, whereby all eligible patients presenting during the recruitment period will be invited to participate.

Participants will attend three data collection sessions in a gait analysis laboratory equipped with a state-of-the-art motion capture system and force plates. Sessions will take place at the following time points:

T0: within 3 months before TKA surgery.

T1: 6 weeks (± 2 weeks) after TKA surgery.

T2: 12 weeks (± 2 weeks) after TKA surgery.

Participants who choose to take part in the optional qualitative component will also attend two semi-structured interviews, at T0 and T1.

After informed consent has been obtained, participants' demographic information (age and sex), relevant medical history and comorbidities will be collected from their medical records. At each data collection session, anthropometric measurements, including height, weight and leg length, will be recorded. Participants will also complete the Oxford Knee Score (OKS) and EuroQol 5-Dimension 5-Level (EQ-5D-5L) questionnaires.

Reflective markers and multiple inertial measurement units (IMUs), which are small motion sensors, will be attached to participants' legs and thighs. Participants will wear the IMUs and

reflective markers only for the duration of each data collection session, which will last approximately 2 hours.

During each session, participants will be asked to perform a series of physical activities, including:

1. Knee range-of-movement (ROM) tests while seated, standing or lying down
2. Walking a short distance (less than 10 m)
3. Single-leg standing with eyes open
4. Squatting
5. Transitioning from sitting to standing and from standing to sitting
6. Straight-leg raises
7. Double-leg bridges
8. Walking up and down stairs

Participants will also be asked to walk along a corridor and use adjacent stairs. Activities will be repeated as required, up to a maximum of 10 trials per activity. Feasibility data will also be collected for each activity.

Following each session, data collected using the IMUs will be processed and compared with data obtained from the motion capture system and force plates. Algorithms will be developed to recognise the activities performed and derive kinematic and spatiotemporal gait parameters. Their accuracy, precision and reliability will be evaluated. Longitudinal analyses will assess whether the sensor-derived parameters can detect changes across the three study time points and examine their relationship with the OKS and EQ-5D-5L scores. Sensor-derived parameters will also be compared with relevant minimal clinically important difference (MCID) thresholds reported in the literature to assess their potential clinical relevance.

For participants who choose to take part in the optional qualitative component, two semi-structured interviews will be conducted at T0 and T1 to explore their perspectives on the acceptability of smart knee implants. The interviews will be informed by the Theoretical Framework of Acceptability (TFA) described by Sekhon et al. and analysed using a framework analysis approach. Participants' responses will be compared between the pre-operative and post-operative interviews to explore whether their perspectives change following TKA.

Participants will complete their involvement in the study following the T2 data collection session, approximately 12 weeks after TKA surgery.

Intervention Type

Device

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

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Primary outcome(s)

1. Knee pain and function measured using the Oxford Knee Score (OKS) questionnaire (British English validated version) at baseline (pre-operation), 6 weeks (± 2 weeks) post-operation, 12 weeks (± 2 weeks) post-operation

2. Quality of life measured using the EQ-5D-5L questionnaire (British English validated version) at baseline (pre-operation), 6 weeks (± 2 weeks) post-operation, 12 weeks (± 2 weeks) post-operation
3. Tibia range of movement (ROM) from activities measured using Inertial Measurement Unit systems at baseline (pre-operation), 6 weeks (± 2 weeks) post-operation, 12 weeks (± 2 weeks) post-operation
4. Spatio-temporal gait parameters measured using Inertial Measurement Unit systems at baseline (pre-operation), 6 weeks (± 2 weeks) post-operation, 12 weeks (± 2 weeks) post-operation
5. Movement smoothness during activities measured using Inertial Measurement Unit systems at baseline (pre-operation), 6 weeks (± 2 weeks) post-operation, 12 weeks (± 2 weeks) post-operation
6. Smart knee implant technology acceptability measured using semi-structured interviews at baseline (pre-operation), and 12 weeks (± 2 weeks) post-operation

Key secondary outcome(s)

Completion date

31/03/2028

Eligibility

Key inclusion criteria

1. 18 years of age or older
2. Undergoing primary unilateral or bilateral TKA
3. Able to attend their first data collection session within three months before their TKA operation

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 Years

Upper age limit

120 Years

Sex

All

Total final enrolment

0

Key exclusion criteria

1. Unable to walk and climb stairs independently or with minimal assistance, including the use of walking aids such as walking sticks or crutches
2. Unable to transition from sitting to standing and from standing to sitting unaided, as well as to transition from getting up to lying down on a physiotherapy bed (and vice versa) unaided
3. Unable to perform basic lower limb rehabilitation exercises unaided or with minimal assistance
4. Pre-existing neurological or orthopaedic conditions, or any other pathologies that could impair the activities listed above
5. Undergoing partial knee replacement
6. Pregnant
7. Have any implantable electronic medical device (e.g., cardiac implantable electronic devices, cochlear implants, neural stimulators, infusion pumps, programmable hydrocephalus shunts)
8. Allergic to adhesives (e.g., sticky tape or plasters)
9. Not willing to wear appropriate clothing for the study sessions (sports clothing)
10. Have an active knee infection
11. Have an active cancer
12. Unable to provide informed consent
13. Have limited English language proficiency

Date of first enrolment

18/01/2027

Date of final enrolment

30/09/2027

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Leeds Teaching Hospitals NHS Trust

St. James's University Hospital

Beckett Street

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LS9 7TF

Sponsor information

Organisation

University of Leeds

ROR

<https://ror.org/024mrxd33>

Funder(s)

Funder type

Funder Name

National Institute for Health and Care Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available