ISRCTN18394084 https://doi.org/10.1186/ISRCTN18394084

Tracking physical activity after total knee replacement

Submission date
08/12/2020

Recruitment status
No longer recruiting

Registration date
04/02/2021

Overall study status
Completed

Last Edited
20/06/2024

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Total knee arthroplasty surgery, also known as total knee replacement, is recognised as a successful procedure. However some patients find recovery more difficult than others. At present there is little evidence on the best type of exercise recovery plan to give patients following surgery. We think it likely that recovery strategies can be targeted more effectively if they take into consideration participant information that can be collected before surgery, such as expectations regarding recovery, pain, and psychological status.

Who can participate?
Adults over 18 years, scheduled for total knee arthroplasty for osteoarthritis.

What does the study involve?
In this study we ask participants undergoing surgery to wear an activity monitor, worn on the wrist like a watch for a week in the month preceding surgery, and then for six weeks following surgery. We will also collect data prior to surgery on:
• ability to do everyday tasks (using a validated questionnaire);
• functional tests (40m walking test, climbing 9 steps, and number of times participant can do sit-to-stand in 30s);
• pain levels measured on visual analogue scale;
• analgesic use;
• inflammation using level of C-reactive protein in blood (measured again day following surgery)
• pre-operative characteristics –socioeconomic data; expectations of surgery and pain; mental health status; frailty level; number of falls in last 3 months
• osteoarthritis classification (measured on routine x-rays)
Participants will be called once a week following surgery to record their pain level and analgesic use, and to check they are happy wearing the activity monitor. At six weeks, data will again be collected on the ability to do everyday tasks; functional tests; analgesic and resource use and pain.
In the analysis, changes in the primary outcome measure of activity over time, and distinct subtypes amongst TKA recovery trajectories will be examined using statistical modelling.

What are the possible benefits and risks of participating?
We cannot promise the study will help you but we hope that the information we obtain from this study will help improve treatment for patients having total knee replacement surgery in the future. The possible risks and/or discomforts associated with the knee replacement operation are as for a routine knee replacement operation. There is no increased surgical risk if you take part in this study. You will have study visits before surgery and at 6 weeks which should take place on the same day as your routine visits, and we will give you a phone call every week up to the 6 weeks following surgery, to monitor your pain levels and your use of painkillers.

Where is the study run from?
This study is a collaboration between Northumbria Healthcare NHS Foundation Trust and the Orthopaedic Research Institute (ORI) at Bournemouth University (UK).

When is the study starting and how long is it expected to run for?
January 2020 to September 2022

Who is funding the study?
Zimmer, Inc. (USA)

Who is the main contact?
Tom Wainwright (scientific), twainwright@bournemouth.ac.uk
Tikki Immins (public), timmins@bournemouth.ac.uk

Contact information

Type(s)
Scientific

Contact name
Mr Tom Wainwright

ORCID ID
http://orcid.org/0000-0001-7860-2990

Contact details
Orthopaedic Research Institute
Bournemouth University
89 Holdenhurst Road
Bournemouth
United Kingdom
BH8 8EB
+44 (0)1202 961656
twainwright@bournemouth.ac.uk

Type(s)
Public

Contact name
Mrs Tikki Immins

ORCID ID

http://orcid.org/0000-0002-9797-6098

Contact details
Orthopaedic Research Institute
Bournemouth University
89 Holdenhurst Road
Bournemouth
United Kingdom
BH8 8EB
+44 (0)1202 961656
timmins@bournemouth.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
274998

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 44153, IRAS 274998

Study information

Scientific Title
Tracking physical activity after total knee arthroplasty

Study objectives
This study aims to identify and differentiate high and low physical activity responders in the early recovery stage following total knee arthroplasty (TKA). This will enable further studies of interventions designed for groups of patients at risk of a poorer recovery of physical function, unlike earlier studies undertaken with “average patients” which have had a limited effect on postoperative recovery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/03/2020, North of Scotland Research Ethics Committee (Summerfield House, 2 Eday Road, Aberdeen, AB15 6RE, UK; +44 (0)1224558458; nosres@nhs.net), ref: 20/NS/0035

Study design
Observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Physical activity after total knee arthroplasty

Interventions
This is a prospective cohort study recruiting 120 participants from patients undergoing total knee arthroplasty surgery as part of their routine care at Northumbria Healthcare NHS Foundation Trust.
Participants will be assessed at baseline up to one month prior to surgery, and be asked to wear an activity monitor for 7 consecutive days prior to surgery. The activity monitor is an Actiwatch (CE marked. Phillips Respironics Murrysville, PA, USA). After routine surgery, at discharge, participants will be asked to again wear the activity monitor continuously for the six weeks following surgery, when they will be assessed again. They will be rung once each week up to 6 weeks to check on pain levels on activity, and on analgesic use.

Screening and consent
The clinical team will identify patients who are suitable to take part in the study. During a routine appointment a member of the clinical care team will explain the purpose of the study and invite potential participants to discuss the study with a member of the research team. The research team member will explain the purpose of the study, the procedures and the duration to the patient. If they would like to proceed they will be asked to complete an informed consent form. The research team member will ensure that the patient has sufficient time to consider taking part in the study before taking consent, in line with GCP guidelines.

Visit 1 – baseline assessment, up to one month before surgery
Participants will be given an activity monitor to wear for seven consecutive days before surgery. Data on demographics, medical history, physical examination (to include height and weight), current medication, name of GP, American Society of Anaesthesiologists classification will be recorded for the study. X-rays taken as part of routine care will be assessed for level of osteoarthritis using the Kellgren and Lawrence classification; and blood taken prior to surgery as part of pre-assessment testing, will be tested for C-reactive protein level (CRP).Participant s will be asked to rate their pain on activity, and undertake functional tests – how many sit-to-stands they can perform in 30s, walk fast-paced for 40m, and a stair climb test. The will also be asked to complete questionnaires on how they find their pain and ability to do everyday activities, their expectations of surgery, their frailty level, how they perceive their pain will be following surgery, levels of anxiety and depression, use of analgesics, and number of falls in the past three months.
Visit 2 – the day following surgery, the CRP protein level will be measured again, along with pain on activity level, and changes in analgesic use and other medications. At discharge, participants

will be asked to wear their activity monitor again until they return for their 6 weeks follow-up visit. They will be asked to wear it continuously, except if they have hydrotherapy or go swimming.
Visit 3 – from discharge to 6 weeks, participants will be rung each week to check they are happy with the activity monitor, and to check their pain on activity level, changes in analgesic use and other medications. Visit 4 – 6 weeks following surgery. Participants will return their activity monitor. Their length of hospital stay will be recorded, and the reasons if the stay is over 4 days. Changes in analgesic use and pain level on activity will be recorded. Participants will be asked to repeat the functional tests; and to complete again a questionnaire on they find their pain and ability to do everyday activities.

Intervention Type
Behavioural

Primary outcome measure
Physical activity, as measured using an Actiwatch device (Philips Respironics, Murrysville, PA, USA) from baseline (pre-surgery) to 8 weeks post-surgery

Secondary outcome measures
At baseline and 8-weeks post-surgery (unless otherwise stated):
1. Physical performance (PBOMs): 40m paced walk test, 30s sit-to-stand, 9 step stair-climb
2. Pain and function daily living subscales from Knee Injury and Osteoarthritis Outcome Score (KOOS)
3. Analgesic use measured using self report
4. Pain levels on activity measured using a numerical rating scale at baseline, and each week post-surgery until 8 weeks
5. C-reactive protein (CRP) measured using ... from baseline to one day following surgery (or at discharge if discharged on day of surgery)
6. Patient expectations (HSS Knee Replacement Expectation Survey) at baseline
7. Anxiety and depression measured using the Hospital Anxiety and Depression Score (HADS) at baseline
8. Pain catastrophizing measured using the Pain Catastrophizing Scale (PCS) at baseline
9. Frailty measured using the Edmonton Frail Scale at baseline
10. Number of falls in the past three months measured using self report at baseline
11. Classification of osteoarthritis measured using the Kellgren and Lawrence system at baseline

Overall study start date
01/01/2020

Completion date
30/09/2022

Eligibility

Key inclusion criteria
1. Participants capable of giving informed consent
2. Scheduled for primary unilateral total knee arthroplasty for osteoarthritis
3. Aged 18 years and over

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 120; UK Sample Size: 120

Total final enrolment
120

Key exclusion criteria
Unable to complete follow-up (insufficient English, lives overseas, unable to return easily).

Date of first enrolment
12/04/2021

Date of final enrolment
30/04/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
North Tyneside General Hospital City
Northumbria Healthcare NHS Foundation Trust
Rake Lane
North Shields
United Kingdom
NE29 8NH

Sponsor information

Organisation
Bournemouth University

Sponsor details
M402, 4th floor
Melbury House
1-3 Oxford Road
Poole
England
United Kingdom
BH8 8ES
+44 (0)1202 961208
jnortham@bournemouth.ac.uk

Sponsor type
University/education

Website
https://www1.bournemouth.ac.uk/

ROR
https://ror.org/05wwcw481

Funder(s)

Funder type
Industry

Funder Name
Zimmer; Grant Codes: IRE2020-06CH

Alternative Name(s)
Zimmer, Inc., Zimmer Biomet

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
31/10/2024

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			26/07/2023	No	No