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Joint PREP: Joint PRehabilitation with Exercise and Protein

Submission date
22/09/2022

Recruitment status
No longer recruiting

Registration date
29/09/2022

Overall study status
Completed

Last Edited
26/09/2024

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
One-third to one-half of people waiting for hip/knee replacements are frail (which generally means they have poor strength and function) or are at risk of becoming frail ('pre-frail') and may not recover as well after surgery as those who are not. They may experience more complications and longer hospital stay. Studies have looked at ways to help people to prepare before their surgery, to increase their chances of an easier recovery. An improved diet with extra protein and pre-operative exercise may lead to fewer post-operative complications and faster recovery. However, few studies have included frail people, and none have looked at pre-operative protein and exercise in this group waiting for hip or knee replacement in the NHS. A large study is required to see if frail patients undergoing hip or knee replacements, have improved outcomes if they consume more protein and exercise daily in the weeks leading up to their operation. First, we want to see if people are willing to do this by running a small study. If they are, we will design a larger study to test whether this can improve recovery from surgery.

Who can participate?
Frail patients who are aged 65 years or older, scheduled for total hip or knee replacement surgery with at least 12 weeks until their intended date of operation.

What does the study involve?
Participants will be randomised to one of two groups using a computer-based tool. One group will follow usual care and will not receive any additional advice or treatment to that provided routinely by the NHS. The other group will be given a daily protein supplement to add to their diet and will be asked to follow a home-based, tailored daily exercise programme for up to 12-weeks before their operation.
All participants will complete questionnaires about health and quality of life soon after recruitment to the trial and at 12 weeks (or just before surgery).

What are the possible benefits and risks of participating?
We do not know if increasing protein intake and exercise in the weeks leading up to joint replacement surgery will help improve recovery in frail patients. Although participants may not receive any measurable benefit from taking part in this trial, research like this helps to continually improve the care and treatments provided to all patients now and in the future.

There are only minimal risks involved in this research. Potential side effects of exercise include a temporary ache in muscles and joints, similar to that commonly experienced after unaccustomed exercise. However, these effects are normally mild and will resolve themselves following a short period of rest. Participants in the intervention arm will be given a tailored exercise program based on their individual ability and will be carefully trained on how to perform and progress the exercises to minimise these risks. They will also be encouraged to take adequate rest periods in between to prevent aggravating symptoms.

Where is the study run from?
North Bristol NHS trust (UK)

When is the study starting and how long is it expected to run for?
January 2022 to December 2023

Who is funding the study?
NIHR Research for Patient Benefit Programme (UK)

Who is the main contact?
Dr Tanzeela Khalid, t.khalid@bristol.ac.uk

Study website
https://www.bristol.ac.uk/translational-health-sciences/research/musculoskeletal/orthopaedic/research/joint-prep-study/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
312883

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 53511, Grant Codes: NIHR202289, IRAS 312883

Study information

Scientific Title
A randomised controlled feasibility trial of a prehabilitation intervention in frail older people undergoing total hip or knee replacement

Acronym
Joint PREP

Study objectives
Pre-operative exercise and protein supplements may lead to fewer post-operative complications and faster recovery in frail individuals undergoing total hip or knee replacement. However, it is not known whether it is possible to recruit people scheduled for total joint replacement surgery in the NHS at the right time to allow for successful implementation of the planned intervention, or whether participants would be able to adhere to the intervention. Therefore, we aim to test the feasibility of a daily program of exercise and protein supplementation in the 12 weeks prior to surgery in frail individuals undergoing total hip or knee replacement in the NHS.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 30/08/2022, East of Scotland Research Ethics Service (Ninewells Hospital & Medical School, Tayside Medical Science Centre (TASC), Residency Block, Level 3, George Pirie Way, Dundee, DD1 9SY, UK; +44 (0)1382 383871; tay.eosres@nhs.scot), ref: 22/ES/0033

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Other

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

Health condition(s) or problem(s) studied
Total hip or knee replacement surgery

Interventions
Patients who are ≥65 years of age and frail will be randomised on a 1:1 allocation to either the Joint PREP intervention or usual care.
Intervention group: Participants will be given a daily protein supplement to add to their diet and will be asked to follow a home-based, tailored daily exercise programme for up to 12-weeks before their operation. All exercises will be demonstrated by a physiotherapist either in-person at a hospital appointment, online or using a hybrid model. Appropriate starting levels will be based on individual physical capacity and risk assessment, and participants will be supported to gradually increase their levels of moderate physical activity throughout the weeks leading up to their surgery through regular telephone/videocalls from a physiotherapist.

Usual care group: Participants will receive usual care for the duration of the study.

Intervention Type
Mixed

Primary outcome measure
1. Eligibility rate (i.e. proportion of all on list >=65 who are frail)
2. Recruitment rates, calculated as the percentage of eligible patients recruited each month, as recorded in the recruitment logs at each site
3. Retention rates, calculated as the number of participants who complete data collection measures and/or the intervention
4. Adherence to intervention, assessed by analysis of the self-reported log on exercise and protein supplement consumption.
5. Acceptability of the trial and the intervention, evaluated through qualitative semi-structured interviews with a sample of the trial participants
6. Data completion rates, assessed by calculating data completeness for all measures
7. Data to estimate sample size required for a definitive trial

Secondary outcome measures
Current secondary outcome measures as of 13/03/2023:
1. Frailty measures determined from use of the Groningen Frailty Index and Clinical Frailty Scale at the screening stage and during the pre-operative assessment
2. Protein adequacy of usual diet measured using Protein screener 55+ during screening stage
3. Usual physical activity levels measured using the Global Physical Activity Questionnaire at baseline and at the end of the intervention period
4. Patient reported outcomes (including WOMAC, EQ-5D-5L, and ICECAP-O). These will all be measured at baseline and pre-operatively.
5. Operative and post-operative data (e.g., length of hospital stay, complications, mobilisation

and physiotherapy protocol). This data will be collected from patient notes or medical records when the patient is 1-2 months post-operative.
6. Qualitative assessment of the acceptability of the study.

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Previous secondary outcome measures:
1. Frailty measures determined from use of the Groningen Frailty Index and Clinical Frailty Scale at the screening stage and during the pre-operative assessment
2. Protein adequacy of usual diet measured using Protein screener 55+ during screening stage.
3. Usual physical activity levels measured using the Global Physical Activity Questionnaire at baseline and at the end of the intervention period.
4. Patient reported outcomes (including WOMAC, EQ-5D-5L, and ICECAP-O). These will all be measured at baseline, pre-operatively and 12 weeks post-operatively.
5. Operative and post-operative data (e.g., length of hospital stay, complications, mobilisation and physiotherapy protocol). This data will be collected from patient notes or medical records when the patient is 1-2 months post-operative.
6. Complications, readmissions, primary care contacts, and physiotherapy appointments attended to week 12 post-operation collected on the post-operative questionnaire.

Overall study start date
01/01/2022

Completion date
31/12/2023

Eligibility

Key inclusion criteria
1. Scheduled for elective primary total hip or knee replacement
2. >=12 weeks until intended date of operation
3. >=65 years of age
4. Frail according to self-report Groningen Frailty Indicator (score of >4)

Participant type(s)
Patient

Age group
Senior

Lower age limit
65 Years

Sex
Both

Target number of participants
Planned Sample Size: 60; UK Sample Size: 60

Total final enrolment

Key exclusion criteria
1. Unable or unwilling to provide informed consent
2. Participating in another study that may affect the outcomes of this feasibility study or that does not permit co-enrolment in another study or where co-enrolment would be burdensome to the patient.
3. Contraindications to following trial treatments (e.g., following a low protein diet or co-morbidities which preclude participation in physical exercise)

Date of first enrolment
21/11/2022

Date of final enrolment
31/08/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Southmead Hospital
Southmead Road
Westbury-on-trym
Bristol
United Kingdom
BS10 5NB

Study participating centre
University Hospital Llandough
Penlan Road
Llandough
Penarth
United Kingdom
CF64 2XX

Study participating centre
Princess Elizabeth Orthopaedic Centre
Royal Devon & Exeter Hospital
Barrack Road

Exeter
United Kingdom
EX2 5DW

Sponsor information

Organisation
North Bristol NHS Trust

Sponsor details
Southmead Hospital
Southmead Road
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United Kingdom
BS10 5NB
+44 117 414 9330
ResearchSponsor@nbt.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.nbt.nhs.uk/

ROR
https://ror.org/036x6gt55

Funder(s)

Funder type
Government

Funder Name
Research for Patient Benefit Programme

Alternative Name(s)
NIHR Research for Patient Benefit Programme, RfPB

Funding Body Type
Government organisation

Funding Body Subtype

National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Open access publication in a peer-reviewed journal, final report to funder, presentations at scientific conferences, plain language summaries of findings for participants and the public.

Intention to publish date
01/10/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository. Anonymised data will be stored indefinitely on the University of Bristol's secure online Research Data Storage Facility. In accordance with the University's policy for sharing of anonymised research data, participants will be asked for their consent to make the anonymised data available to other researchers for whom this data may help facilitate the answering of their research question. Data will only be accessible to members of the study research team but may also be made available to other research teams who request the data to answer their own research questions.

IPD sharing plan summary
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Protocol article		07/08/2023	09/08/2023	Yes	No
Results article		17/09/2024	26/09/2024	Yes	No