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PEP-TALK: A study investigating whether having group discussions in addition to physiotherapy improves the amount of physical activity following hip and knee replacement

Submission date
15/10/2018

Recruitment status
No longer recruiting

Registration date
23/10/2018

Overall study status
Completed

Last Edited
17/11/2023

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Over 206,000 hip and knee replacements were performed in the United Kingdom (UK) last year. As well as joint pain, half of these people have other diseases such as high blood pressure, heart disease, diabetes and depression. Physical activity is known to improve these conditions. Before a hip or knee replacement, it can be difficult to be physically active because of pain and fatigue. It is hoped that after joint replacement, this improves so people can be more active. However, after hip or knee replacement, people are often no more active than before and, importantly, do not know how to be. They miss out on some of the health benefits which joint replacement can offer. The aim of this trial is to determine whether a group exercise and behaviour-change intervention targeted to increase physical activity participation can increase health related quality of life (HRQoL) and clinical outcomes following a total hip or total knee replacement.

Who can participate?
People who are expected to receive a hip or knee replacement and have one other disease such as high blood pressure, breath problems, circulating problems, previous stroke or cancer, anxiety or depression. Of these people, individuals who are safe to exercise will be allowed to participate if they so wish.

What does the study involve?
People wishing to participate would be allocate to either usual rehabilitation (physiotherapy) or usual rehabilitation (physiotherapy) and the behaviour change treatment (group discussion and phone calls).
People allocated to usual physiotherapy will attend rehabilitation sessions (physiotherapy) over 6 weeks – this will generally start at the latest within 4 weeks of their operation, and will be provided by your local physiotherapy team. Each rehabilitation session (physiotherapy) will last no longer than 30 minutes. As part of normal care, participants will also be given home exercises to continue to strengthen their legs between the exercise sessions. Those allocated to the group discussion group will receive, in addition to their rehabilitation sessions (physiotherapy),

and home exercises, a group discussion meeting before each physiotherapy group over the 6 weeks. Each group discussion will last for no longer than 30 minutes. In these discussion, we will talk to participants about things which may stop them being more physically active when they want to be. We will also help participants to find out ways to overcome these difficulties, to support them to be more physically active in their everyday lives. Once their rehabilitation sessions finish, participants' physiotherapist will telephone them 2, 4 and 6 weeks afterwards to see how they are getting on.

What are the possible benefits and risks?
There may not be any benefit to participants in taking part in this study. Research like this helps to continually improve the treatments and care provided to all patients now and in the future by collecting information on what may or may not help. There is a possible risk of feeling a little sore after exercising or being more active. However, participants will be guided by their physiotherapist whilst exercising in the classes and will be able to seek their opinions about bone, joint and muscle soreness during recovery after surgery, so activities can be modified if needed.

Where is the study run from?
The study is run from the Nuffield Orthopaedic Centre at the University of Oxford and will take place in 5 NHS hospitals (Norwich, Sunderland, Oxford and four in London (Orpington and St George's Tooting, Royal London Hospital and North Middlesex Hospital)

When is the study starting and how long is it expected to run for?
August 2018 to April 2021

Who is funding the study?
UK National Health Service (NHS) National Institute for Health Research (NIHR) under the Research for Patient Benefit scheme (UK)

Who is the main contact?
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Study website
https://rehabresearch.ndorms.ox.ac.uk/research/pep-talk-trial

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CPMS 39328

Study information

Scientific Title
A behaviour change physiotherapy intervention to increase physical activity following hip and knee replacement: a pragmatic phase III randomised controlled trial

Acronym
PEP-TALK

Study objectives
A group exercise and behaviour-change intervention targeted to increase physical activity participation (PEP-TALK) can increase health related quality of life (HRQoL) and clinical outcomes more than a group exercise intervention alone following a total hip replacement (THR) or total knee replacement (TKR)?

Ethics approval required
Old ethics approval format

Ethics approval(s)
NHS South Central-Oxford B Research Ethics Committee, 23/10/2018, ref: 18/SC/0423

Study design
Randomised; Interventional; Design type: Treatment, Psychological & Behavioural, Rehabilitation

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Physical activity after hip or knee replacement

Interventions
Participants will be enrolled onto the trial for 12 months, and will be screened to see if they meet the inclusion criteria for the trial prior to their hip or knee replacement surgery. If they meet the inclusion criteria they will be approached to discuss entering the trial and provided with the appropriate documentation to allow them to make and informed decision regarding whether they wish to participate, and if so informed consent will be taken prior to surgery. After surgery consented participants will be checked to see if they meet the eligibility criteria and randomised accordingly prior to hospital discharge. Participants will be randomised to either the experimental intervention or usual care. They will be notified of the group they have been allocated to.
Participants randomised to usual care will receive six 30 minute group-based exercise sessions. Those randomised to the experimental intervention will receive six group-based behaviour change intervention sessions (30-minute duration) immediately followed by the control intervention of 30-minutes of group-based exercise. Both group interventions will commence within the initial 4 weeks post-surgery and continue weekly for six weeks.
Information will be collected at baseline (the date when the consent was taken before the operation), six months and 12 months form the randomisation date. The baseline information will be collected face-to-face by researchers at the hospital. All other information collected at the further time-points will be self-reported by the participant by either postal questionnaire or through a online survey.

Intervention Type
Behavioural

Primary outcome measure
Physical activity, assessed using the University of California Los Angeles (UCLA) Activity Scale at the baseline and after 6 and 12 months

Secondary outcome measures
The following will be assessed at the baseline and after 6 and 12 months unless otherwise stated:
1. Lower limb function, assessed using the Lower Extremity Functional Scale (LEFS)
2. Hip and knee-specific disability, assessed using the Oxford Hip Score and Oxford Knee Score respectively
3. Pain, assessed using the Numerical Rating Scale for Pain
4. Self-efficacy, assessed using the Generalized Self-Efficacy Scale (GSE)
5. Fear of movement, assessed using the Tampa Scale for Kinesiophobia (TSK)
6. Psychological distress (anxiety and depression), assessed using the Hospital Anxiety and Depression Scale (HADS)
7. Health-related quality of life, assessed using the EQ-5D-5L
8. Complications and adverse events, assessed using self-reported questionnaire complications and an adverse event questionnaire
9. Self-reported health-resource use questionnaire, assessed after 6 and 12 months

Overall study start date
01/08/2018

Completion date
27/04/2021

Eligibility

Key inclusion criteria
1. People following primary (first-time) unilateral total hip replacement (THR) or total knee replacement (TKR) where the indication for surgery is degenerative joint pathology (not trauma). Participants post-THR and TKR will be recruited given that there is no difference in physical activity participation between the two cohorts. Both have similar barriers to physical activity engagement which the intervention could address.
2. People who do not meet physical activity levels to benefit health (using the General Practice Physical Activity Questionnaire (GPPAQ))
3. Aged 18 years or older
4. Charlson Comorbidity Index (CCI) of one point or above
5. Capacity to provide written informed consent as determined by the approaching researcher at screening through an assessment using the AMTS

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 260; UK Sample Size: 260

Total final enrolment
230

Key exclusion criteria
1. Absolute contraindication to exercise such as severe cardiovascular or pulmonary disease (New York Heart Association III-IV)
2. Undergo revision (second-time) joint replacement given that surgery and recovery of this population is more complicated.
3. Living in a care home
4. Enrolled onto another trial investigating interventions on physical activity or exercise adherence or behavioural therapy interventions
5. Cannot read and/or comprehend English
6. Do not have access to a working telephone

Date of first enrolment
27/03/2019

Date of final enrolment
31/03/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Nuffield Orthopaedic Centre
Windmill Road
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Study participating centre
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Sponsor type
University/education

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: PB-PG-1216-20008

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal, intending to publish within one year after the overall trial end date

Intention to publish date
27/04/2022

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made 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?
Protocol article	protocol	19/07/2020	22/07/2020	Yes	No
Results article		31/05/2022	08/06/2022	Yes	No
HRA research summary			28/06/2023	No	No
Statistical Analysis Plan		20/07/2021	17/11/2023	No	No