# 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
Registration date
23/10/2018
Completed
Condition category

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

Musculoskeletal Diseases

## Plain English summary of protocol

Background and study aims

17/11/2023

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? Dr Scott Parsons pep-talk@ndorms.ox.ac.uk

## Contact information

## Type(s)

Scientific

#### Contact name

Dr Toby Smith

#### **ORCID ID**

https://orcid.org/0000-0003-1673-2954

#### Contact details

Botnar Research Centre University of Oxford Nuffield Orthopaedic Centre Windmill Road Oxford United Kingdom OX3 7LD +44 (0)1865 227224 toby.smith@ndorms.ox.ac.uk

## Type(s)

Public

#### Contact name

**Dr Scott Parsons** 

#### Contact details

Botnar Research Centre
University of Oxford
Nuffield Orthopaedic Centre
Windmill Road
Oxford
United Kingdom
OX3 7LD
+44 (0)1865 227224
pep-talk@ndorms.ox.ac.uk

## Additional identifiers

## Protocol serial number

**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

## Study type(s)

Treatment

## 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(s)

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

## Key secondary outcome(s))

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

## 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** 

## Healthy volunteers allowed

No

## Age group

Adult

### Lower age limit

18 years

#### Sex

All

#### 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** United Kingdom

England

Study participating centre
Nuffield Orthopaedic Centre
Windmill Road
Oxford
United Kingdom
OX3 7HE

Study participating centre
Norfolk and Norwich University Hospital
Colney Lane
Norwich
United Kingdom
NR4 7UY

Study participating centre
St George's Hospital
Blackshaw Road
Tooting
London
United Kingdom
SW17 0QT

Study participating centre Sunderland Royal Hospital Kayll Road Sunderland United Kingdom SR4 7TP

## Study participating centre Orpington Hospital

Sevenoaks Road Orpington United Kingdom BR6 9JU

## Study participating centre Royal London Hospital

Whitechapel Road London United Kingdom E1 1FR

## Study participating centre North Middlesex Hospital

Sterling Way London United Kingdom N18 1QX

## Sponsor information

## Organisation

University of Oxford

#### **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**

## 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?
Results article		31/05/2022	08/06/2022	Yes	No
Protocol article	protocol	19/07/2020	22/07/2020	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Statistical Analysis Plan		20/07/2021	17/11/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes