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What is the effect on independent recovery of using pedometers as a tool to prescribe exercise following total hip replacement?

Submission date 20/10/2014	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 25/02/2015	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 10/05/2021	**Condition category** Surgery	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Pedometers are portable devices, often attached by a belt worn on the waist. That counts every step a person takes by detecting hip movements. There is evidence to suggest that these devices promote physical activity and improve quality of life in the general population. It is also suggested that people generally don't increase their physical activity levels after undergoing hip replacement surgery. Here, we hope to use the pedometer to increase levels of physical activity in this group of patients and help them to recover from their surgery.

Who can participate?
Adults (at least 18 years old) who have a hip replacement operation scheduled for 2 weeks' time or later and are able to walk at least 10m without walking aids.

What does the study involve?
The participants are randomly allocated into one of two groups. Those in group 1 receive standard care following their surgery. Those in group 2 receive standard care and a pedometer-driven
walking intervention (treatment). Each person in this group will be given a target number of steps to walk each week using their pedometer.

What are the possible benefits and risks of participating?
The possible benefits of taking part in the study are that it is helping to understand if physical activity aids recovery following hip replacement. The additional risks on taking part in this study is that there is a slight increase in the risk of suffering a 'sports injury' as it is likely that participation in this study will result in participants being more physically active than usual.

Where is the study run from?
University of East Anglia (UK)

When is the study starting and how long is it expected to run for?
November 2014 to September 2016

Who is funding the study?
University of East Anglia (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1

Study information

Scientific Title
What is the effect on independent recovery of using pedometers as a tool to prescribe exercise following total hip replacement? A two arm randomised controlled trial

Acronym
HPA

Study objectives

1. Prescribed PA will significantly increase the overall amount of PA undertaken.
2. Prescribed PA will significantly improve quality of life.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cambridge south ethics committee, 20/10/2014, ref. 14/EE/1178

Study design
Two arm randomised controlled trial.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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
Total hip arthroplasty.

Interventions
Participants are randomly allocated into one of two groups.
Group 1: Receive standard care
Group 2: Receive standard care and walking based pedometer intervention

Intervention Type
Device

Phase
Not Applicable

Primary outcome measure
Oxford Hip Score

Measured pre-surgery and 4, 12 and 24 weeks post surgery.

Secondary outcome measures

1. Hip dislocation
2. Quality of life measured by self-completed questionnaire
3. Physical activity level through accelerometry.

Measured pre-surgery and 4, 12 and 24 weeks post surgery.

Overall study start date
01/11/2014

Completion date
30/09/2016

Eligibility

Key inclusion criteria
1. Patient is on the waiting list for primary elective unilateral THR
2. Patient is 18 years of age or older
3. Patient is able to walk at least 10m pre-operation without walking aids, if the patient is unable to walk pre-operation it is believed that the patient will be able to walk post-THR
4. Patients operation is scheduled to be at least 2 weeks away
5. Patients have no other prosthetic implants
6. The surgeon that is performing the operation performs operations in both the independent and NHS hospital

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
160

Key exclusion criteria
1. Patient is unable to give informed consent
2. Patient is having two different procedures combined together in one operation
3. Patients cannot comprehend English and do not have a friend, relative or care giver who is willing to translate for them
4. Patient is currently undertaking a custodial sentence
5. Patient already has a prosthetic hip in the other femur or patient is undergoing replacement of a previously implanted prosthetic hip
6. If the participants suffer an operative or perioperative complication they will be excluded from the study at this stage
7. Participants who suffer from any absolute or relative contraindication to exercise

8. For this this study partial proximal femur resection (PFR) will not be considered a form of THR
9. Patient lives in a care home
10. A reason for the patients to undergo THR is due to a form of cancer

Date of first enrolment
05/12/2014

Date of final enrolment
31/03/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of East Anglia
Room 1.23
School of Health Sciences
Queen's Building
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Sponsor information

Organisation
University of East Anglia

Sponsor details
Research and Enterprise Services West Office
Norwich
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Sponsor type
University/education

ROR
https://ror.org/026k5mg93

Funder(s)

Funder type
Research council

Funder Name
University of East Anglia

Alternative Name(s)
UEA

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

2017 results published in thesis: https://ueaeprints.uea.ac.uk/id/eprint/63758/1/Thomas_Withers_Thesis.pdf (added 10/05/2021)

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No