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

Submission date	Recruitment status No longer recruiting	Prospectively registered		
20/10/2014		Protocol		
Registration date	Overall study status	Statistical analysis plan		
25/02/2015	Completed Condition category	Results		
Last Edited		[] Individual participant data		
10/05/2021	Surgery	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? Mr Tom Withers t.withers@uea.ac.uk

Contact information

Type(s)

Scientific

Contact name

Mr Tom Withers

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Contact details

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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 Norwich United Kingdom NR4 7TJ

Sponsor information

Organisation

University of East Anglia

Sponsor details

Research and Enterprise Services West Office Norwich England United Kingdom NR4 7TJ

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