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Activity orientated rehabilitation following knee arthroplasty: feasibility study

Submission date
20/11/2015

Recruitment status
No longer recruiting

Registration date
03/03/2016

Overall study status
Completed

Last Edited
12/04/2016

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
Total knee replacement (TKR) is a common operation in the UK for osteoarthritis of the knee. It involves replacing a damaged, worn or diseased knee with an artificial joint. Despite good pain relief after surgery, many patients continue to have ongoing functional difficulties that could be helped by exercise. The aim of this study is to determine whether a study comparing a physiotherapy exercise class with usual care could be carried at the Avon Orthopaedic Centre.

Who can participate?
Patients awaiting total knee replacement for osteoarthritis of the knee.

What does the study involve?
Participants are randomly allocated to receive either usual care or to attend a 6-week physiotherapy exercise class. Both groups complete questionnaires before surgery and at 2 weeks, 3 and 6 months after surgery. The rate of participant uptake, reasons for non-attendance at classes, patient satisfaction with the classes, patient-reported outcomes, timing and suitability of the exercises are recorded. The study also tests the methods to collect data for the cost analysis to assist in the development of a larger study.

What are the possible benefits and risks of participating?
Potential benefits of the group exercise class are increased knee function and activity participation and reduced pain. Potential risks of participating in the group exercise class include increased knee pain, although this was minimised by close supervision of exercise by two chartered physiotherapists.

Where is the study run from?
Southmead Hospital (UK)

When is the study starting and how long is it expected to run for?
October 2011 to February 2013

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Dr Neil Artz

Contact information

Type(s)
Public

Contact name
Dr Neil Artz

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Activity orientated rehabilitation following knee arthroplasty (ARENA): feasibility randomised control trial

Study objectives
Investigate the feasibility of conducting a randomised controlled trial comparing group-based outpatient physiotherapy with usual care after total knee replacement

Ethics approval required
Old ethics approval format

Ethics approval(s)
South West – Cornwall and Plymouth Research Ethical Committee, 21/12/2011, ref: 11/SW/0341

Study design
Feasibility randomized controlled trial

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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Total knee replacement for osteoarthritis

Interventions
Intervention group participate in a 6 week group-based functional and tailored exercise class starting at 6 weeks after surgery. Group-based physiotherapy exercise intervention will include six one-hour group exercise sessions for a duration of six weeks. Within this group, patients will also be provided with individual exercises targeted at individual functional goals.

Control group receive the usual care provided by the hospital after total knee replacement. Usual care given will be a knee replacement booklet given out at a pre-education class and contains information about discharge planning, the pre-operative period, the operation day, early and later stage post-operative exercises, performing everyday functional activities, returning to work and hobbies, discharge goals, precautions, expectations and potential problems.

Intervention Type
Behavioural

Primary outcome measure
As this is a feasibility RCT there were no primary outcome measures as such.
1. Rate of participant uptake
2. Reasons for non-attendance at classes
3. Patient satisfaction with the classes
4. Timing and suitability of the exercises

Secondary outcome measures
Patient-reported outcomes including:
1. KOOS = Knee Injury and Osteoarthritis Outcome Score – pre-op, 2 weeks, 3 months and 6 months post-op
2. LEFS = lower extremity functional scale - 2 weeks, 3 months and 6 months post-op
3. ABC scale = activities-specific balance confidence scale - pre-op, 2 weeks, 3 months and 6 months post-op
4. Pain VAS = pain visual analogue scale - pre-op, 2 weeks, 3 months and 6 months post-op
5. UCLA = UCLA activity score - pre-op, 2 weeks, 3 months and 6 months post-op

6. SER = self-efficacy for rehabilitation - pre-op, 2 weeks, 3 months and 6 months post-op
7. Ab-IAP = Aberdeen Measures of Impairment, Activity Limitation and Participation Restriction - pre-op, 2 weeks, 3 months and 6 months post-op
8. MYMOP = Measure Yourself Medical Outcome Profile – 6 weeks, 3 months and 6 months post-op

Overall study start date
05/10/2011

Completion date
13/02/2013

Eligibility

Key inclusion criteria
Patients listed for total knee replacement for osteoarthritis

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
46

Key exclusion criteria
1. Knee replacement for conditions other than osteoarthritis
2. Revision knee surgery
3. Inability to participate in exercise for any medical reason such as unstable cardiovascular or cardio-respiratory disease
4. Diagnosis of severe neurological disorders
5. Inability to provide informed consent
6. Inability to complete study questionnaires in the English language, as the study was using measures that had not all been validated in other languages

Date of first enrolment
23/07/2012

Date of final enrolment
13/02/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Southmead Hospital
United Kingdom
BS10 5NB

Sponsor information

Organisation
North Bristol NHS Trust (UK)

Sponsor details
Level 3
Learning and Research
Southmead Hospital
Southmead Road
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England
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/036x6gt55

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The results of the feasibility study have been submitted for publication and the manuscript is under review.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	10/07/2016		Yes	No