Activity orientated rehabilitation following knee arthroplasty: feasibility study

Submission date	Recruitment status No longer recruiting	Prospectively registered		
20/11/2015		☐ Protocol		
Registration date	Overall study status Completed	Statistical analysis plan		
03/03/2016		[X] Results		
Last Edited	Condition category	[] Individual participant data		
12/04/2016	Surgery			

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)

Contact information

Type(s)

Public

Contact name

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Contact details

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s))

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 postop

Completion date

13/02/2013

Eligibility

Key inclusion criteria

Patients listed for total knee replacement for osteoarthritis

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

Study participating centre Southmead Hospital United Kingdom BS10 5NB

Sponsor information

Organisation

North Bristol NHS Trust (UK)

ROR

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

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
Participant information sheet	Participant information sheet	11/11/2025 11/11/2025	No	Yes