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ARENA study: effectiveness and cost-effectiveness of outpatient physiotherapy after knee replacement

Submission date
11/02/2015

Recruitment status
No longer recruiting

Registration date
11/02/2015

Overall study status
Completed

Last Edited
01/08/2019

Condition category
Musculoskeletal Diseases

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Knee replacement is a common operation for patients with osteoarthritis. It is a major operation with a long recovery period. Physiotherapy is an important part of the recovery process because it can help improve strength and movement in the replaced knee and allow people to gain the maximum benefit from the operation. However, not all hospitals offer physiotherapy to patients once they have been discharged after their knee replacement operation. In this study, we will find out whether it is helpful to offer exercise classes to patients following knee replacement.

Who can participate?
Adult (aged at least 18) NHS patients about to have a total knee replacement due to osteoarthritis at Southmead Hospital or Emersons Green Treatment Centre (UK).

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 receive usual care after their knee replacement where they are given a leaflet about exercise and referred to outpatient physiotherapy on a needs only basis i.e. if they have poor mobility. Those in group 2 are invited to attend an exercise class, in addition to receiving 'usual care'. This class is run every week for six weeks, starting at six weeks after knee replacement surgery. In the class, patients practice task related exercises such as walking, stair climbing, and kneeling. Each patient is also given two individualised exercises, designed by the physiotherapist, to help address specific goals. We ask everyone in the study to complete questionnaires during the first year after surgery to see if the exercise classes improve their mobility. We also collect information to compare the cost of providing both treatments. The findings from this study will help us to know if providing outpatient exercises classes can improve patient's mobility up to one year after knee replacement surgery and is good value for money to invest NHS resources.

What are the possible benefits and risks of participating?
Patients participating in the exercise class may gain some functional benefit from regular specific exercises. However we do not know whether the exercise class will provide any benefit over usual care

Risks include the physical risks of undertaking exercise. Many patients will continue to have some ongoing pain and functional limitations in the first 3 months after their knee replacement. Participation in the exercise class has the potential to cause further pain and tissue injury or exacerbate existing pain. Although these risks are likely to be small, every attempt to minimize these risks will made. Participants in the exercise class will be monitored throughout the duration of the class and all adverse events will be documented. All exercises will be demonstrated and participants will be advised on how to exercise safely. If the physiotherapists are concerned about a participant then they will contact the participant's consultant orthopaedic surgeon following discussion with the participant.

Where is the study run from?
Southmead Hospital and Emersons Green Treatment Centre (UK)

When is the study starting and how long is it expected to run for?
March 2015 to May 2018

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

Who is the main contact?
Dr Vikki Wylde
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

18286

Study information

Scientific Title
Effectiveness and cost-effectiveness of outpatient physiotherapy after knee replacement: a randomised controlled trial

Acronym
ARENA

Study objectives
The aim of this study is to find out whether it is helpful to offer exercise classes to patients following knee replacement.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South West – Central Bristol, 19/01/2015, ref: 14/SW/1144

Study design
Randomised; Interventional; Design type: Not specified

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 contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Surgery; Subtopic: Surgery; Disease: All Surgery

Interventions
Outpatient physiotherapy: Six week group-based outpatient physiotherapy course consisting of task-related and individualised exercises, starting 6 weeks after total knee replacement surgery.

Intervention Type
Other

Primary outcome measure

Lower Extremity Functional Scale (LEFs) at 12 months after surgery

Secondary outcome measures
1. EQ-5D-5L at 2 weeks, 3 months, 6 months and 12 months after surgery
2. LEFS at 3 months and 6 months after surgery
3. Knee Injury and Osteoarthritis Outcome Score (KOOS) at 3 months, 6 months and 12 months after surgery
4. Self-Administered Patient Satisfaction Scale for Primary Hip and Knee Arthroplasty at 3 months, 6 months and 12 months after surgery
5. Likert-type scale for satisfaction with physiotherapy treatment received at 3 months, 6 months and 12 months after surgery
6. Hospital Anxiety and Depression Scale at 3 months, 6 months and 12 months after surgery

Overall study start date
01/11/2014

Completion date
09/05/2018

Eligibility

Key inclusion criteria
1. NHS patients listed for primary total knee replacement due to osteoarthritis at Southmead Hospital or Emersons Green Treatment Centre
2. Male & Female
3. Lower Age Limit 18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 256; UK Sample Size: 256

Total final enrolment
180

Key exclusion criteria
1. Patients listed for total knee replacement for reasons other than osteoarthritis
2. Patients listed for revision total knee replacement
3. Patients unable or unwilling to attend physiotherapy classes if randomised to the intervention group

4. Inability to participate in exercise for medical reasons such as unstable cardiovascular or severe neurological conditions
5. Unable or unwilling to provide informed consent
6. Inability to understand English because not all the questionnaires have been translated and validated into other languages
7. Post-operative complication(s) within the first two weeks of surgery which would preclude participation in the physiotherapy class e.g. prosthetic joint infection, manipulation under anaesthetic

Date of first enrolment
01/03/2015

Date of final enrolment
01/03/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Southmead Hospital
Southmead Road
Westbury-On-Trym
Bristol
United Kingdom
BS10 5NB

Study participating centre
Emersons Green NHS Treatment Centre
The Brooms
Emersons Green
Bristol
United Kingdom
BS16 7FH

Sponsor information

Organisation
North Bristol NHS Trust

Sponsor details

Research & Innovation
Floor 3 Learning & Research Building
Southmead Hospital
Bristol
England
United Kingdom
BS10 5NB

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 trial protocol will be submitted for publication in an open-access journal by Spring 2015. After the trial is complete, manuscripts presenting the clinical and cost-effectiveness results will be submitted to relevant peer-review journals. Results will also be submitted for presentation at a national or international conference.

Intention to publish date

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a publically available repository, the University of Bristol Research Data Repository (https://data.bris.ac.uk/data/). Data will be available 6 months following publication. Access to the data will be restricted to ensure that data is only made available to bona fide researchers for ethically approved research projects, on the understanding that confidentiality will be maintained and after a Data Access Agreement has been signed by an institutional signatory. Consent from participants was obtained for sharing of anonymised data.

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	13/06/2016		Yes	No
Results article	results	01/06/2020	01/08/2019	Yes	No
HRA research summary			28/06/2023	No	No