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COmmunity-based Rehabilitation after Knee Arthroplasty (CORKA)

Submission date
26/01/2015

Recruitment status
No longer recruiting

Registration date
12/02/2015

Overall study status
Completed

Last Edited
01/09/2021

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
The number of knee replacements taking place in the UK is continuing to rise. Part of the reason for this increase is that knee replacements are increasingly being performed for patients who are older and with other health conditions in addition to their osteoarthritis. It is known that age is not a barrier to having a good outcome from knee replacement, with reports of successful outcome in patients aged over 90 years. However, it is also known that around 15% of patients do not report a good outcome from their knee replacement and have continuing pain and mobility problems that limit or prevent them from being able to do the activities they would like to be able to do after their knee replacement. It is thought that factors such as the amount of pain and limitation of balance and muscle strength may contribute to poorer outcome. Currently it is normal practice for patients to receive a short course (between 4-6 sessions) of post-operative physiotherapy after their surgery. This is usually delivered in a physiotherapy outpatient clinic setting. Previous research has shown that this short course of physiotherapy is not needed by all patients to help them recover after their operation. Given the increasing number of knee replacements, the relatively limited physiotherapy resources available and the increasing age and frailty of patients receiving joint replacements, it is important that we concentrate our rehabilitation resources on those patients who most need help to avoid poor outcome.

Who can participate?
Patients aged 55 or over undergoing knee replacement surgery and deemed to be at risk of poor outcome.

What does the study involve?
First, we will develop a screening tool that will help us to identify those patients who are most at risk of poor outcome after their joint replacement. Second, we will develop and test a rehabilitation exercise intervention designed to improve the function of ‘at risk’ patients and their participation in activities. Patients deemed at risk of poor outcome will be randomly allocated to either the intervention or the control group. Both groups will receive the same treatment whilst in hospital and the same advice about exercise on discharge. Those in the control group will receive standard post-operative care which may include outpatient physiotherapy. Those in the intervention group will receive a home-based exercise programme.

We will measure patients' progress at 6 months and one year after their surgery. We will assess whether this new intervention improves patient's functional abilities, quality of life and their taking part in social activities. We will use information from diaries kept by patients about their visits to their GP, district nurse, physiotherapy, occupational therapy, any hospital visits and medication and equipment to perform an analysis of the costs and benefits of the new intervention compared to usual care. We will also interview patients, carers and therapists to gain their perspectives about our intervention.

What are the possible benefits and risks of participating?
We do not expect any particular benefits from taking part in the study for individual participants. The information we get from this study will help us to treat future patients with knee replacement. However, it is known that rehabilitation can improve outcomes after knee replacement. There are no new treatments included in this study. The treatments are those already used with patients after knee replacement. There should be no more risk in the community-based rehabilitation group as in standard care.

Where is the study run from?
Nuffield Orthopaedic Centre (UK)

When is the study starting and how long is it expected to run for?
August 2014 to January 2019

Who is funding the study?
NIHR Health Technology Assessment Programme - HTA (UK)

Who is the main contact?
Karen Barker
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Study website
http://corka.octru.ox.ac.uk/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 12/196/08

Study information

Scientific Title
COmmunity-based Rehabilitation after Knee Arthroplasty (CORKA): a prospective individually randomised two-arm randomised controlled trial

Acronym
CORKA

Study objectives
Aims and objectives:
1. To analyse data from the KAT study (outcomes in arthroplasty) to develop an algorithm to be used at the pre-operative assessment to identify patients likely to be at risk of poor outcome after knee replacement
2. To develop a treatment intervention that can be delivered in patients' own homes by rehabilitation assistants supervised by qualified therapists
3. To compare the clinical outcomes of this new rehabilitation protocol vs. usual care of outpatient-based post-operative physiotherapy
4. To assess the safety and serious adverse events associated with the treatment programme
5. To assess the acceptability and adherence to the treatment programmes for patients and therapists using a RCT with a nested qualitative study
6. To assess the cost effectiveness of the different treatment strategies

More details can be found at http://www.nets.nihr.ac.uk/projects/hta/1219608
Protocol can be found at http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0019/130663/PRO-12-196-08.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South Central Oxford B – provisional opinion given 20/01/2015, ref: 15/SC /0019

Study design
Prospective individually randomised single-blinded 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 contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Knee osteoarthritis

Interventions
A two-stage study is proposed. Firstly, we will perform analysis of factors associated with poor outcome to develop a screening algorithm. Methods to identify people at high risk are uncertain, but general principles of older people with generalised frailty and significant global function /cognitive impairment prior to surgery are widely accepted. We aim to identify patients at risk of poor outcome using two methods:
1. We will systematically review the literature and use expert opinion from rehabilitation clinicians to identify factors associated with poor outcome after knee arthroplasty.
2. We will examine data from a large study cohort of patients from the KAT study.

In the second stage we will conduct a prospective individually randomised single-blinded two-arm RCT. Patients deemed at risk of poor outcome will be randomised to either the intervention or the control arm. Both arms of the trial will receive the same treatment whilst in hospital and the same advice about exercise on discharge. Those in the normal care arm would receive standard post-operative care which may include outpatient physiotherapy; those in the intervention arm will receive a home-based exercise programme. We will measure patients' progress at 6 months and one year after their surgery.

Intervention Type
Procedure/Surgery

Primary outcome measure
Late Life Function and Disability Instrument (LLFDI) score, collected at baseline, 6 and 12 months after randomisation. Primary endpoint:12 months post-surgery

Secondary outcome measures
Current secondary outcome measures as of 25/06/2021:
Questionnaires and physical measures at baseline, 6 months, and 12 months unless otherwise indicated:
1. Functional Co-morbidities Index (baseline measure only)
2. Oxford Knee Score
3. Physical Activity Scale for the Elderly (PASE)
4. EQ-5D-5L
5. KOOS, Quality of Life Sub-scale

6. Figure of 8 walk test where participants are asked to walk in a figure of 8 around two cones. This test is timed, the number of steps taken is counted, in addition to accuracy (if a participant stays with in boundary of the test) being recorded.
7. 30 Second Chair Stand Test where the participant starts sitting on a chair which has a seat high of 17 inches, the participant is asked to complete as many full stands in 30 s, the participant sits in between each stand. The number of full stands a person can complete is recorded.
8. Single leg stance where the participant is asked to stand and lift one leg without using any other support, they will be timed standing on one leg. The participant will be stood with a chair in front of them should they require support.

Previous secondary outcome measures:
Questionnaires at baseline, 6 months and 12 months:
1. Oxford Knee Score
2. Physical Activity Scale for the Elderly (PASE)
3. EQ-5D-5L
4. Functional Co-morbidities Index

Physical measures at baseline, 6 months and 12 months:
1. Figure of 8 walk test - participants are asked to walk in a figure of 8 around two cones, this is timed, the number of steps taken is counted, in addition to accuracy (if a participant stays with in boundary of the test) being recorded.
2. 30 Second Chair Stand Test - the participant starts sitting on a chair which has a seat high of 17 inches, the participant is asked to complete as many full stands in 30 seconds, the participant sits in between each stand. The number of full stands a person can complete is recorded.
3. Single leg stance - the participant is asked to stand and lift one leg without using any other support, they will be timed standing on one leg. The participant will be stood with a chair in front of them should they require support.

Overall study start date
01/08/2014

Completion date
31/12/2019

Eligibility

Key inclusion criteria
1. Participant is willing and able to give informed consent for participation in the study
2. Male or female, aged 55 years or above
3. Primary unilateral KR as a scheduled procedure
4. Deemed by study screening tool developed to be at risk of poor outcome
5. Happy to allow physiotherapy teams to attend their home to deliver the intensive rehabilitation programme if randomised to the intervention arm

Participant type(s)
Patient

Age group
Senior

Sex

Both

Target number of participants
635

Total final enrolment
621

Key exclusion criteria
1. Any absolute contraindications to exercise
2. Severe cardiovascular or pulmonary disease (New York Heart Association III-IV)
3. Severe dementia, assessed using the hospital dementia screening tool
4. Rheumatoid arthritis
5. Further lower limb arthroplasty surgery planned within 12 months

Date of first enrolment
01/03/2015

Date of final enrolment
01/01/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Nuffield Orthopaedic Centre
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Sponsor information

Organisation
University of Oxford

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Sponsor type
University/education

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date
30/06/2020

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?
Protocol article	protocol	13/10/2016		Yes	No
Statistical Analysis Plan	statistical analysis plan	19/11/2018		No	No
Results article	results	01/11/2020	01/12/2020	Yes	No
Results article		27/08/2021	01/09/2021	Yes	No
HRA research summary			28/06/2023	No	No