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Targeted Rehabilitation to Improve Outcome after total knee replacement

Submission date
12/06/2013

Recruitment status
No longer recruiting

Registration date
25/07/2013

Overall study status
Completed

Last Edited
22/10/2020

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
This study is looking at how well patients with osteoarthritis (a condition that affects the joints) recover after knee replacement surgery [also known as Total Knee Arthoplasty (TKA)]. Currently around 20% of patients are not satisfied after TKA so we are looking to find out if we can identify who will not recover well at an earlier stage, so that we might be able to help them sooner. We will try to determine if doing intense physiotherapy with patients who are not doing well at the first review (6 weeks after their operation) can improve how well they have recovered at one year. We will also use questionnaires and saliva samples to see if certain traits (such as age, sex, attitudes towards surgery, genetic factors etc) can predict who will not recover well after surgery. We hope the information collected during the study will improve our knowledge of why some people do not recover as well as others after TKA and will enable us to help better recovery of patients in the future.

Who can participate?
If you are over 16 years old, undergoing TKA because of osteoarthritis in Aberdeen or Edinburgh and are able to complete the questionnaires, you will be invited to join the TRIO-POPULAR study. At any of the study centres, if you are over 18 and undergoing TKA because of osteoarthritis you will be asked to complete an Oxford Knee Score questionnaire 6 weeks after your operation. If the score shows you are not recovering as well as we would hope, you will be invited to join the TRIO-physio study.

What does the study involve?
For TRIO-POPULAR you will be asked to complete a questionnaire before your operation and at 6 weeks, 3, 6 and 12 months after your operation date. You will be asked once during the study if you would like to provide saliva samples for a few tests. If you have a poor Oxford Knee Score 6 weeks after your operation you will be asked to join the TRIO-physio study. We will put you into one of two groups at random to either (1) complete exercises from a worksheet at home or (2) go to physiotherapy sessions at hospital and complete exercises at home. Everyone will see a physiotherapist for an assessment and be taught exercises. If you are in the group that has to come to the hospital for physiotherapy sessions you will come once a week for 6 weeks and will also be asked to do exercises twice a week at home on your own. If you are in the group that completes exercises from the worksheet at home you will do these 3 times a week for 6 weeks.

No matter what group you are in, you will then come for a review at the hospital 14 weeks after your operation. You will be asked to complete questionnaires about your knee and do a Get-up-and-Go test with the Physiotherapist, which is a simple exercise where you are timed getting up from a chair and walking a short distance to check how well your knee is recovering. We will then post you questionnaires at 6 months and one year after your operation date to see how well you are recovering.

What are the possible benefits and risks of participating?
There are no additional risks in taking part in this study beyond those of having physiotherapy in general. You may experience some discomfort and/or swelling in the knee following exercise, but the therapist will guide you in performing the exercises and setting a correct intensity of exercise to help avoid this. We hope that the physiotherapy will help you recover better, but you may not directly benefit from taking part in this study. However, the knowledge gained from this study will benefit other people in the future by helping us to decide the best way to treat people who are recovering from TKA surgery.

Where is the study run from?
The study is being run by the Edinburgh Clinical Trials Unit in collaboration with the Universities of Edinburgh and Aberdeen. Aberdeen and Edinburgh are the main sites, with Oxford and Derby recruiting patients for the TRIO-physio study only.

When is the study starting and how long is it expected to run for?
The study will start in mid-July 2013 and is expected to run until July 2017. The recruitment period will last 18 months.

Who is funding the study?
Arthritis Research UK.

Who is the main contact?
Prof Hamish Simpson, (Professor of Orthopaedics and Trauma) University of Edinburgh
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Contact information

Type(s)
Scientific

Contact name
Prof Hamish Simpson

Contact details
Department of Trauma and Orthopaedics
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EH16 4SB

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT01849445

Secondary identifying numbers
20100

Study information

Scientific Title
Targeted Rehabilitation to Improve Outcome after total knee replacement: a multi-centre trial with an interventional and an observational arm

Acronym
TRIO

Study objectives
Interventional arm (TRIO-physio) To determine if intense physiotherapy for patients performing poorly at their first post-operative review at 6 weeks can improve their outcome at one year. Observational arm (TRIO-POPULAR)- To investigate predictors of unfavourable outcome following total knee arthroplasty (TKA) in order to further examine the combined effects of individual, clinical, psychosocial and biological markers in predicting poor outcome.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. The TRIO-physio study was approved by the South East Scotland Research Ethics Committee 01 on 17/04/2013, ref: 13\SS\0051
2. The TRIO-POPULAR study was approved by the Health and Social Care Research Ethics Committee 3 (HSC REC 3), 19/07/2013, ref: 13/NI/0101

Study design
Multi-centre trial with an interventional and observational arm. The interventional arm is a randomised controlled trial, the observational arm is an observational cohort study.

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
Osteoarthritis of the knee

Interventions
1. TRIO-POPULAR: Questionnaire at pre-operation, baseline, 6 weeks and 3, 6 &12 months post-operation. One-off saliva samples for cortisol and genetic analysis.
2. TRIO-Physio: Intervention is either completion of exercises from a worksheet at home or physiotherapy sessions at hospital and completion of exercises at home by participant. The group going to hospital for physiotherapy sessions will do so once a week for 6 weeks and will also be asked to do exercises twice a week at home. The group that completes exercises from the worksheet at home will do these 3 times a week for 6 weeks. A timed Get-up-and-Go test will be completed with the physiotherapist by all participants before and after the intervention. An Oxford Knee Score, EQ-5D, health economic questionnaires will be completed at baseline, 14 weeks, 6 months and 1 year. In addition satisfaction questionnaires will be collected at 6 months and 1 year.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Oxford Knee Score at 52 weeks

Secondary outcome measures
TRIO-Physio study only:
1. Assess patient satisfaction with knee arthroplasty, pain relief and functional ability.
2. Patient functional improvements following physiotherapy (Timed-get-up-and-go test)
3. To evaluate the cost effectiveness of enhanced targeted physiotherapy.

TRIO-POPULAR study only:
Questionnaires to collect EQ5D, demographics, Hospital Anxiety and Depression Scale (HADS), social support, attitudes and concerns about illness, patient expectations about outcome, Pain Catastrophising Scale, Short-form Tampa Scale of Kinesophobia, Sleep Problem Scale, Prior health seeking behaviour, Pain Manikins, Co-morbidities, General Health (PROMIS), HPA, DNA collection, Brief Pain Inventory.

Overall study start date
15/07/2013

Completion date
15/07/2017

Eligibility

Key inclusion criteria
1. Undergoing primary total knee arthroplasty for osteoarthritis.
2. Patients are able to consent and willing to comply with the study protocol
3. TRIO-physio only: Defined poor outcome (Oxford Knee Score less than or equal to 26) at first post-op review (6
weeks).
4. TRIO-POPULAR only: Patients are eligible for inclusion if they are adults aged 16 years and over and understand oral and written English

Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Sex
Both

Target number of participants
TRIO-Physio: 440. TRIO-POPULAR: 750

Key exclusion criteria
1. Patients undergoing revision knee arthroplasty or fully constrained knee arthroplasty
2. Knee replacement for a diagnosis other than osteoarthritis
3. TRIO-Physio only: Patients unable to attend the study physiotherapy intervention centres.
4. TRIO-Physio only: Patients subjected to procedures done purely for pain relief (such as for patients with no walking capacity)

Date of first enrolment
15/07/2013

Date of final enrolment
15/07/2017

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Department of Trauma and Orthopaedics
Edinburgh
United Kingdom
EH16 4SB

Sponsor information

Organisation
University of Edinburgh/NHS Lothian (UK)

Sponsor details
The Queens Medical Research Institute
47 Little France Crescent
Edinburgh
United Kingdom
EH16 4TJ

Sponsor type
Other

Website
http://www.accord.ed.ac.uk/index.html

ROR
https://ror.org/01nrxwf90

Funder(s)

Funder type
Charity

Funder Name
Arthritis Research UK (Reference No. 20100)

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

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?
Protocol article	protocol	01/02/2014		Yes	No
Results article	results	01/07/2018		Yes	No
Results article	results	13/10/2020	22/10/2020	Yes	No
HRA research summary			28/06/2023	No	No