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What are the effects of balance exercises in patients' following total knee replacement ability to perform every day life activities?

Submission date
11/03/2017

Recruitment status
No longer recruiting

Registration date
14/03/2017

Overall study status
Completed

Last Edited
26/04/2023

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Osteoarthritis of the knee is a type of arthritis that is caused by the wear and tear of the cartilage lining the knee joint. This causes pain, stiffness and a loss in mobility (movement). The best treatment option for knee osteoarthritis is to have a total knee replacement (TKR) surgery. TKR is a common procedure where the weight bearing surfaces of the knee joint are replaced with metal and plastic components. This is done to relieve pain and disability. The main complaints of patients who are undergoing TKR due to osteoarthritis are the difficulties performing everyday tasks (such as going up a staircase or walking on uneven roads) and the increased risk of falling. Usual care after a TKR is to undergo rehabilitation that is aimed to increase the muscle and improve the motion of the knees. However, this does not address patient's difficulties performing daily tasks. Research has shown that rehabilitation that includes specific techniques aimed at increasing balance, managing pain, and improving daily function can reduce the risk of falling and improve surgery outcomes. Despite this knowledge, there are no guidelines as to what type of rehabilitation is the best practice. Following a TKR surgery, patients still have difficulties doing their normal daily activities. Therefore, the aim of this study is to investigate the effects of a self-managed rehabilitation programme targeted to improve balance has on improving patient's daily function.

Who can participate?
Adults aged 65-80 who have osteoarthritis and require a total knee replacement

What does the study involve?
After undergoing total knee replacement surgery, participants are randomly allocated to one of two groups. Those in the first group undergo standard rehabilitative exercises but also undergo self-managed exercises that are aimed at improving balance. This involves daily exercise (including walking) for around 10-20 minutes (building up to 34-40 minutes with time) for 12 weeks. Those in the second group continue with routine rehabilitation care. The same number of exercises are performed by both groups. Participants are assessed to see how well their knee works before the surgery and at eight and 14 weeks post-surgery.

What are the possible benefits and risks of participating?
Participants may benefit from the rehabilitation programmes. There are no notable risks with participating, however participants may experience some discomfort during the exercise training.

Where is the study run from?
University Hospital of Rion (Greece)

When is the study starting and how long is it expected to run for?
September 2011 to August 2015

Who is funding the study?
1. Queen Mary University (UK)
2. Musculoskeletal Association of Chartered Physiotherapists (UK)

Who is the main contact?
1. Mrs Maria Moutzouri (Scientific)
2. Professor Nigel Gleeson (Scientific)

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
1945

Study information

Scientific Title
What are the effects of enhanced sensori-motor rehabilitation on indices of functional performance associated with patients following total knee replacement?

Acronym
ESMET

Study objectives
Sensori-motor rehabilitation training is better that usual care functional exercise training in patients' following knee replacement functional performance.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. The Institutional Committees of University Hospital of Patras, 22/08/2011 (Greece)
2. Queen Margaret University Edinburgh, 22/05/2012, ref: 7052/4-7-2011 (UK)

Study design
Single-centre interventional single blind prospective randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Osteoarthritis

Interventions
After a total knee replacement, participants are randomly allocated to either the intervention rehabilitation group or the control rehabilitation group. Randomisation is done using a computer generated programme.

Intervention group: Participants undergo the early initialised, self-managed, enhanced sensori-motor programme as well as the standard rehabilitation. This includes participants being prescribed to perform the same number of exercises daily for 35-45 minutes which includes walking (progressively for 10-20 minutes) for six weeks. This is followed by a further six weeks of training (three times weekly for 45 minutes). Participants are taught by a physiotherapist all the required exercises that they should be doing and they are provided with a booklet that contains

instructions. Participants who report signs of effusion or discomfort are given clinical help. Participants received support during the programme including encouragement to continue with the self-managed exercises.

Control group: Participants receive the usual level of care which consists of 15 exercises, focusing on improving knee motion and muscle strengthening. The same principles are followed in the case of discomfort or participants need clarification about exercises.

Participants in both groups are supervised by regular weekly phone-calls with a physiotherapist and/or orthopedic surgeon. Follow up includes a clinical evaluation at the end of the exercise programme, which is 14 weeks post-surgery. Another follow-up is planned for two years from the surgery and includes self-reproted questionnaires (KOOS, KOS- ADLS and SF-12) and takes place over the telephone.

Intervention Type
Other

Primary outcome(s)
1. Function is assessed using the Timed Up and Go Test at baseline, eight and 14 weeks post-surgery
2. Pain is measured using Visual Analogue Scale (VAS) at baseline, eight and 14 weeks post-surgery

Key secondary outcome(s))
1. Balance is measured using Biodex balance system at baseline, eight and 14 weeks post-surgery
2. Knee proprioception is measured using joint position error with a bubble inclinometer at baseline, eight and 14 weeks post-surgery
3. Muscle strength is measured using quadriceps maximum voluntary isometric contraction at 60 degrees of knee flexion with Primus Isokinetic dynamometer at baseline, eight and 14 weeks post-surgery
4. Muscle size is measured using rectus femoris cross sectional area with real time ultrasound at baseline, eight and 14 weeks post-surgery
5. Range of knee motion is measured using a goniometer while the patient is sitting at baseline, eight and 14 weeks post-surgery
6. Peak force of quadriceps with Spike electromyographic EMG during isometric contraction on the dynamometer at baseline, eight and 14 weeks post-surgery
7. Daily living function and quality of life are measured using the Knee injury and Osteoarthritis Outcome Score (KOOS), Knee Outcome Survey: Activities of Daily Living Scale (KOS-ADL)and the Short-Form 12 (SF1-2) at baseline, eight, 14 weeks and two years post-surgery

Completion date
30/08/2015

Eligibility

Key inclusion criteria
1. Ambulatory patients with osteoarthritis (clinical and radiological findings of advanced osteoarthritis, 6-12 months length of wait for surgery)
2. Undergoing primary standardized cemented total knee replacement by the same surgeon
3. Aged 65-80 years old

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
52

Key exclusion criteria
1. Infection, or complications after total knee replacement (TKR)
2. Scheduled for TKR revision surgery
3. Having had any surgery in their lower limbs affecting their gait
4. Cardiovascular diseases, high blood pressure not controlled with medication
5. Neurological/ neuromuscular problems
6. Medical or other musculoskeletal problems that could affect ability to complete objective assessments

Date of first enrolment
20/05/2012

Date of final enrolment
30/05/2014

Locations

Countries of recruitment
Greece

Study participating centre
University Hospital of Rion
Orthopedic Department
Rio 265 04
Patras
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26504

Sponsor information

Organisation
Queen Margaret University

ROR
https://ror.org/002g3cb31

Funder(s)

Funder type
University/education

Funder Name
Queen Margaret University

Alternative Name(s)
Queen Margaret University, Edinburgh, QMU

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Funder Name
Musculoskeletal Association of Chartered Physiotherapists

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository at the Technological Education Institute of Western Greece and can be accessed after the an application and approval from the Institute and from Queen Margaret University.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2018		Yes	No

Other publications	Secondary analysis	17/05/2019	26/04/2023	Yes	No
Participant information sheet	Participant information sheet	14/03/2017	15/03/2017	No	Yes
Participant information sheet		11/11/2025	11/11/2025	No	Yes