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Multidisciplinary rehabilitation after primary total knee arthroplasty

Submission date	Recruitment status	[_] Prospectively registered
01/06/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/06/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
22/03/2012	Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Multidisciplinary rehabilitation after primary total knee arthroplasty: a randomised, controlled trial

Study objectives
The principal questions of the study were:
1. To examine the attributes of disability in end-stage knee osteoarthritis (OA)
2. To examine the effectiveness of a multidisciplinary outpatient rehabilitation program (MRP) on functional recovery, health-related quality of life (HRQoL), and rehabilitation service utilisation following total knee arthroplasty (TKA)
3. To assess predictive factors for functional outcome of primary TKA
4. To assess costs and cost-effectiveness of the MRP following primary TKA

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Ethics Committee of the Oulu University Hospital on the 17th December 2001.

Study design
Single-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Rehabilitation after primary total knee arthroplasty in knee osteoarthritis patients

Interventions
Patient information was provided according to the Declaration of Helsinki. The patients were first informed about the study by letter and then contacted by telephone by the head investigator or by the chief physician of the Department of Physical Medicine and Rehabilitation of the Oulu University Hospital.

The participants were randomly assigned to two groups on the day of their discharge. The active group (AG) participated in the MRP 2 - 4 months after TKA, and the control group (CG) followed usual orthopaedic care. Follow-up assessments were performed in both groups at 2, 6 and 12 months after TKA.

1. Usual orthopaedic care:
All the participants received usual orthopaedic care. Preoperative exercises (use of crutches; simple mobility exercises for the lower limbs; maintenance of cardiovascular fitness) were recommended to all the participants by a physiotherapist when the decision of surgery was made. An outpatient control visit to an orthopedic surgeon was made 2, 6 and 12 months after TKA. The need for further rehabilitation was assessed at each control visit. No attempt to interfere with usual care was made. Thus, a series of outpatient physiotherapy or other rehabilitation interventions might have been included in the usual care during the study period.

On the surgical ward, an exercise program tailored to the needs and status of the patient was taught perioperatively to all the participants by a physiotherapist. The programme was comprised of simple exercises to retrain lower-limb strength and lower-limb joint mobility. Advice on ice application was given. Functional exercises included transfers, gait training, and stair climbing. A subsequent exercise program was recommended to each outpatient by a physiotherapist at the 2-month outpatient control visit. It was comprised of walking without sticks, further lower-limb strengthening, and joint mobility exercises.

2. Multidisciplinary rehabilitation program:
The MRP in the Department of Physical Medicine and Rehabilitation at the Oulu University Hospital was completed as an outpatient course lasting 10 days. Each course consisted of up to 8 participants. The aim of the MRP was to improve the participants' coping with the activities of daily living, including improvement of lower-limb strength, increase of lower-limb joint mobility, improvement of endurance and cardiovascular fitness, and reinforcement of coping strategies. Further objectives were motivating the participants to carry out a regular exercise programme and weight control or weight reduction. The final aim of the MRP was psychosocial recreation, especially through peer support.

On the first day of the MRP the physiatrist verified each participant's eligibility in the course. Two physiotherapists supervised the participants in all the courses, and each participant was also individually assessed (30 and 45 minutes). Three group sessions (45 minutes/session), which included supervision of strengthening exercises for the lower limbs and focused on knee and ankle extensors and flexors, were included in the first week. Two similar sessions were included in the second week. In the first week there were two water gymnastic sessions (30 minutes /session), including supervision of stretching and mobility exercises for the lower limbs, with functional exercises focused on walking. Three similar but longer-lasting (40 minutes) sessions were included in the second week. Stretching exercises were supervised in a daily group (30 minutes/session). Nordic walking, representing functional exercises, was supervised twice a week in an outdoor activity group (30 minutes). Four supervised group rehearsals of relaxation strategies were included (30 minutes/session) in the MRP.

Two group sessions (90 minutes/session; 1 session/week) supervised by a psychologist were included, and in the second week each participant visited a psychologist. The aim of the sessions was to support the participants' coping strategies. In the first week a social worker gave a lecture (60 minutes) concerning social benefits and community services, and a nutritionist gave a lecture (90 minutes) concerning healthy nutrition and weight control. In the second week an orthopaedic surgeon lectured (45 minutes) about TKA and clinically assessed each participant (15 minutes).

MRP courses following the protocol described above have been used as an intensive rehabilitation intervention for selected patients with a high risk of poor outcome after TKA or total hip arthroplasty (THA) at the Oulu University Hospital since 2000.

Of the 144 patients, 88 patients were selected to proceed in the 12-month follow-up. The total duration of follow-up was 12 months.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Self-reported functional ability and pain, assessed with the arthritis-specific Western Ontario McMaster Universities Osteoarthritis Index (WOMAC) composite score and subscale scores of pain, stiffness and function in both groups preoperatively and at the 2, 6 and 12-month follow-ups.

Secondary outcome measures
The following were assessed preoperatively and at 2-, 6- and 12-month follow-up:
1. HRQoL was measured with the generic 15D and the Rand 36-Item Health Survey 1.0 (Rand-36)
2. Demographic characteristics and surgical backgrounds were obtained preoperatively
3. Utilisation of rehabilitation services, assessed by a self-administered questionnaire at 2, 6 and 12 months after TKA
4. Physical performance tests:
4.1. Physical performance, objectively measured with a 15 metre (15 m) walk test and a stair test
4.2. Isometric strength of the knee was measured with the Lido Active Multijoint Rehabilitation System (Loredan Biomedical, USA)
4.3. Active knee flexion range of motion (ROM), measured with a standard long-arm goniometer

Note: The physical performance tests were administered by five experienced physical therapists and two exercise physiologists, all of whom adhered to the protocol that included patient positioning, patient instructions, and evaluation of the results. The order of the tests remained constant throughout the study.

Overall study start date
23/01/2002

Completion date
11/12/2006

Eligibility

Key inclusion criteria
Patients scheduled for primary unilateral TKA in the Department of Surgery at the Oulu University Hospital were recruited from the surgical waiting list. The inclusion criteria were:
1. Diagnosis of primary OA of the knee
2. Both males and females, 60 - 80 years of age
3. Primary unilateral TKA as a scheduled procedure
4. Voluntary participation in the study

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
144

Key exclusion criteria
1. Severe cardiovascular or pulmonary disease (New York Heart Association [NYHA] III - IV)
2. Severe dementia (Mini-Mental State Examination [MMSE] less than 18)
3. Rheumatoid arthritis
4. Primary TKA scheduled as a treatment of an acute trauma of the knee
5. Planned use of a special endoprosthesis

Date of first enrolment
23/01/2002

Date of final enrolment
11/12/2006

Locations

Countries of recruitment
Finland

Study participating centre
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Sponsor information

Organisation
Oulu University Hospital (Finland)

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/045ney286

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Oulu University Hospital (Finland)

Funder Name
Uulo Arhio Foundation (Finland)

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?
Results article	results	01/08/2009		Yes	No
Results article	results	01/05/2010		Yes	No
Results article	results	01/03/2011		Yes	No