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Comparison of post-discharge physiotherapy versus usual care following total knee replacement: a randomised clinical trial

Submission date 30/09/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/09/2004	**Overall study status** Completed	
Last Edited 10/09/2012	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N0176127673

Study information

Scientific Title

Study objectives
Please note that as of 02/07/2008 this record was extensively updated due to service structure changes. All updates can be seen under the relevant field, under the update date of 02/07/2008. The previous title of the trial was Is the intervention of primary care physiotherapy effective in improving mobility and function after elective joint surgery in a Diagnostic and Treatment Centre? The current target number of participants has also been changed to 107 patients; the previous target number of participants was 250 patients.

Current hypothesis as of 02/07/2008:
The study will evaluate the intervention of an innovative physiotherapist for patients undergoing elective primary total knee arthroplasty for osteoarthritis; the ability to improve mobility and enhance functional activity compared with standard care. The study will also document the effect of the intervention on health resource utilisation and include an economic evaluation.

Previous hypothesis:
The study will evaluate the intervention of a community physiotherapist for patients undergoing arthroplasty specifically; the ability to improve mobility and enhance functional activity compared with standard care. The study will also document the effect of Diagnostic and Treatment Centre surgery on primary care resource use and include an economic evaluation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from The Oxford Local Research Ethics Committee on the 20th August 2003 (AQREC No: A03.018). Trial amendments were approved via substantive amendment (amendment 1 date = 23/05/2005, amendment 2 date = 18/10/2006). Date of approval runs from 20th August 2003 until 30th April 2009.

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Surgery: post-operative care

Interventions
Current interventions as of 02/07/2008:
The intervention group patients received two physiotherapy home visits. The first visit took place within two weeks of discharge and the second visit was 6 - 8 weeks post-operatively. The intervention consisted of these two home visits. During each visit the physiotherapist assessed the participants function and progressed each participants rehabilitation programme as appropriate. Objective reassessment of range of movement, muscle strength and observation of

functional activities (including transfers, gait, posture and balance) occurred to enable this progression of treatment. Gait re-education and progression/removal of walking aids, task specific training and a daily home exercise programme were included. The exercises were defined following a systematic review.

The control arm received the usual care currently provided by the hospital with no additional input. Usual care includes no routine physiotherapy organised post discharge.

All trial participants (both arms) received a knee advice booklet presently used by the hospital to standardise the advice provided. The advice and exercises contained in these booklets are essentially similar to those used as controls in previous trials. The exercises include non weight bearing exercises to regain range of movement plus isometric strengthening exercises and several exercises in weightbearing

Previous interventions:
Community physiotherapist versus standard care.

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome(s)
Current primary outcome measures as of 02/07/2008:
Oxford Knee Score.

Trial patients underwent reassessment, using all outcome measures, at three and twelve months post-operatively by a physiotherapist blind to trial arm allocation. Patients were also followed up at six months post-operatively by postal questionnaire containing Oxford Knee score, the Knee injury and Osteoarthritis Outcome Score (KOOS) and the EuroQol.

Previous primary outcome measures:
Changes in Oxford Hip and Knee and Iowa Level of Assistance Scores, timed sit-to-stand, EuroQol and resource use diaries.

Key secondary outcome(s))
Added as of 02/07/2008:
1. The Knee injury and Osteoarthritis Outcome Score (KOOS)
2. The timed sit-to-stand test
3. The timed walk test
4. The Leg extensor press
5. Joint range of motion
6. The EuroQol questionnaire (EQ-5D)
7. Patient diaries to collect heath resource utilisation

Trial patients underwent reassessment, using all outcome measures, at three and twelve months post-operatively by a physiotherapist blind to trial arm allocation. Patients were also followed up at six months post-operatively by postal questionnaire containing Oxford Knee score, the Knee injury and Osteoarthritis Outcome Score (KOOS) and the EuroQol.

Completion date
01/04/2009

Eligibility

Key inclusion criteria
Added as of 02/07/2008:
Age range and gender was unspecified; all patients undergoing an elective primary total knee arthroplasty for osteoarthritis and who reside within the community of Oxfordshire were eligible.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
All

Key exclusion criteria
Added as of 02/07/2008:
1. Patients undergoing bilateral arthroplasty
2. Minimally invasive surgery and metal-to-metal implants
3. Patients where further joint surgery is planned within the next twelve months
4. Patients with inflammatory arthritis
5. Patients whose existing co-morbities prevent them from participating in the proposed treatment intervention
6. Patients who are unable to provide informed consent

Date of first enrolment
20/08/2003

Date of final enrolment
01/04/2009

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

Physiotherapy Research Unit
Oxford
United Kingdom
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Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Government

Funder Name
Oxford Radcliffe Hospitals NHS Trust (UK)

Results and Publications

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	01/07/2012		Yes	No