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A randomized controlled trial of exercise to improve mobility and function after elective knee arthroplasty. Feasibility, results and methodological difficulties

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Objective: To assess the feasibility of comparing two types of exercise regime aiming to improve mobility and function following knee arthroplasty.
Design: A single-blind randomized controlled trial.
Subjects: Patients with primary, unilateral knee osteoarthritis undergoing elective knee joint replacement.
Intervention: Home-based traditional exercise group (TEG) or home-based functional exercise group (FEG) following discharge from hospital.
Outcome measures: These included goniometry; a knee-specific pain score, leg extensor power and a walking test. Patients were followed up at three, six and 12 months after surgery.
Results: Forty-seven patients met the study criteria, 24 were randomized to the TEG and 23 to the FEG. There were marked improvements in mobility, leg extensor power and pain in the year after surgery (MANOVA $p < 0.001$). There were no statistically significant differences between the two exercise groups. Knee flexion decreased during the follow-up period and had not recovered by 12 months. Retention of patients was a problem, with nearly 50% lost to follow-up at 12 months. These patients were assessed as having low motivation during inpatient rehabilitation ($p < 0.05$).
Conclusions: There were trends in favour of the FEG that were of clinical relevance. A definitive study would need a sample size of at least 100 patients in each arm. It is essential to develop strategies to combat loss to follow-up.

Introduction

Physiotherapy is an important component of the postoperative management of knee arthroplasty, and aims to maximize functional recovery by increasing range of movement and muscular strength. In recent years there has been a significant reduction in length of inpatient stay in the UK and there is a general trend towards early discharge from hospital to decrease pressure on hospital beds.[1,2] Consequently, reliance on home exercise regimes for rehabilitation is increasingly

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important although there are no clinical guidelines at present outlining the most effective exercise programme for the treatment of patients following knee replacement surgery. During 1994, before the study, the authors sent questionnaires to all 374 members of the Association of Orthopaedic Chartered Physiotherapists (AOCP). A response rate of 64% was achieved. The results suggested that exercise regimes incorporate predominantly static and isometric muscle contraction exercise; including static quadriceps exercise, dynamic quadriceps exercise between 0–30 degrees flexion, straight leg raise and active or active assisted flexion exercises. Similar exercises were described in a recently published trial comparing exercises with sliding boards and continuous passive motion for patients following total knee arthroplasty.[3] These exercises are generally considered as standard for patients with osteoarthritis,[4] despite the lack of evidence to support their use.

Research in healthy subjects has shown functional exercises, which mimic commonly used movements such as climbing the stairs, to be more effective in improving functional performance than static and dynamic quadriceps drills and straight leg raises.[5–9] These findings should be relevant for patients following knee arthroplasty and may be easier for patients to complete as they use normal movement patterns.

The objective of the study was to assess the feasibility of comparing traditional exercise regimes with a more functional and dynamic approach for patients following knee arthroplasty. We investigated the hypothesis that a home-based exercise regime based on the principles of functional training (functional exercise group (FEG)) would be more effective in improving walking ability, leg extensor power (LEP), knee flexion and pain, during the year following knee replacement, than traditional exercises (traditional exercise group (TEG)). The paper considers the methodological difficulties that were encountered and are likely to be experienced by researchers investigating rehabilitation after similar elective procedures.

Methods

The design of the study was a single-blind randomized controlled trial. Ethical approval was given by the Central Oxfordshire Research Ethic Committee. The plan of the study is set out in Figure 1. Patients with primary, unilateral osteoarthritis of the knee, who were on the waiting list for knee replacement surgery, were informed about the study at an orthopaedic preassessment clinic.

The criteria for inclusion were:

- Unilateral osteoarthritis of the knee undergoing knee joint replacement surgery
- Between 65 and 80 years.

Patients were excluded for the following reasons:

- Medical or other musculoskeletal problems that would affect ability to complete the objective tests
- Neurological problems (i.e. polio, muscle wasting disorders, Parkinson's disease, stroke)
- Patient referred for outpatient physiotherapy treatment following surgery.

Randomization

The minimization method of stratified randomization was used as it is recommended in small randomized controlled trials.[10] Randomization was carried out using computer generated random numbers and stratified according to age, sex, type of knee replacement, range of knee flexion on discharge and the patients' perceived motivation to exercise. Motivation was scored by the physiotherapist treating the patient on a scale of 1–3 at the point of randomization (1 = poor motivation, 2 = average motivation, 3 = good motivation). This scale was based on the subjective view of the physiotherapist who treated the patient whilst in hospital.

Patients were randomized to either the functional exercise group (FEG) or the traditional exercise group (TEG).

Outcome measures

Leg extensor power (LEP)

LEP was measured using a rig that has been shown to be reliable for patients with osteoarthritic knees.[11] Details of the LEP rig are

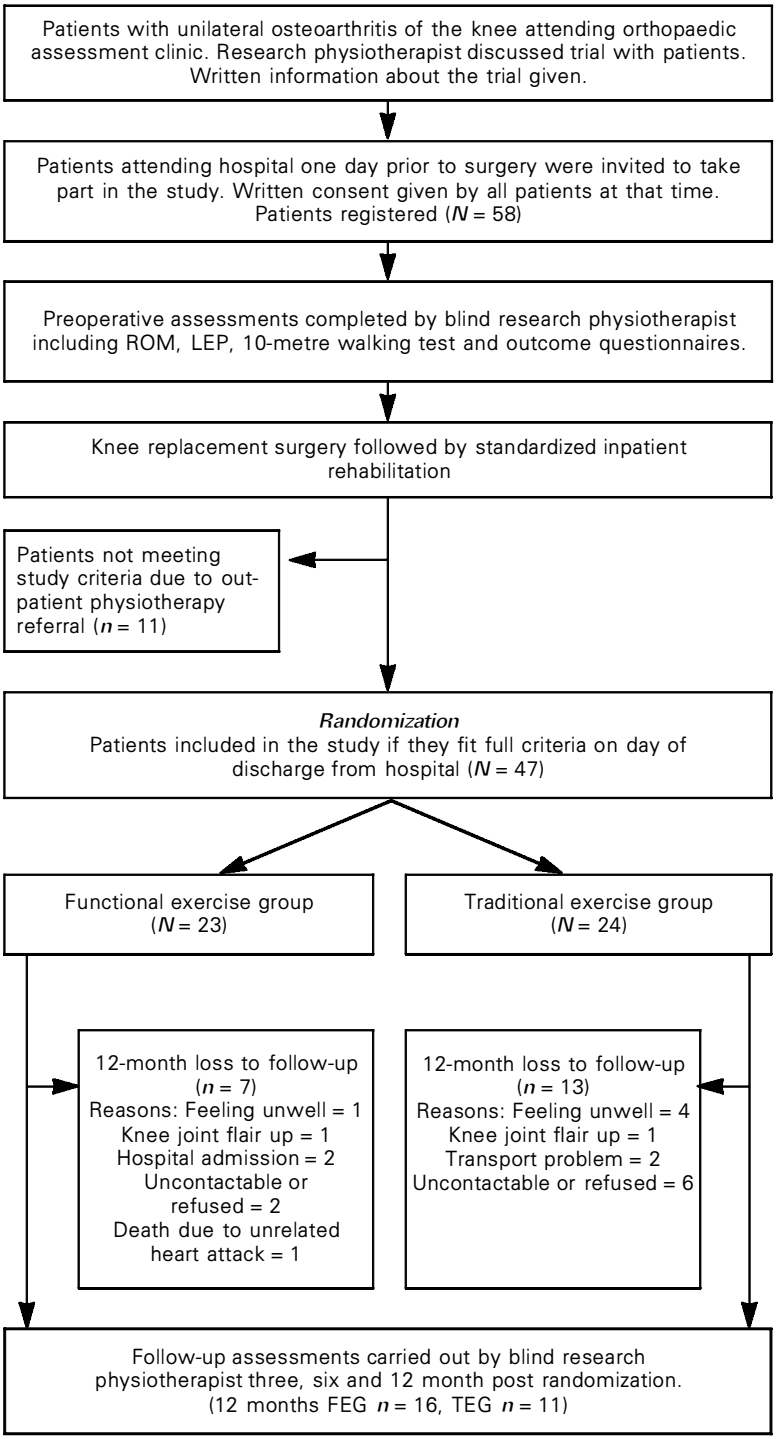

Figure 1 Flow diagram of plan of study.

described elsewhere.[11,12] Power is the product of force and velocity of contraction. Subjects were seated in an upright position with arms folded. Comfortable extension at the knee (wearing flat shoes) in conjunction with full depression of a foot pedal determined the seat position. The unaffected knee (i.e. not for knee arthroplasty) was measured first and two warm-up trials were allowed before data were collected. All instructions were standardized. The patients were instructed to push the foot pedal as hard and as fast as possible after the count of three from the assessor i.e. verbal encouragement was limited to 1-2-3 push. A 15-second relaxation period was allowed between each attempt. Ten measures were taken and the maximum value recorded for the affected and normal leg. Body weight (kg) was measured using a calibrated bathroom type digital scale, placed on a firm surface. Patients were measured in the standing position, wearing light indoor clothing, but no heavy clothing items or shoes.

Walking speed

This was measured over a 10-metre walkway. Patients were asked to walk as normally but as quickly as they could to the end the walkway using a walking aid if necessary. The same shoes were worn each time. The time in seconds was recorded using a standard stopwatch. The walk was repeated twice with a rest period of five minutes between each of the walks or until the subject felt they had recovered. The fastest walking speed was recorded from the two tests.

Pain during walking

This was recorded using an item from a validated Knee Score.[13] Patients were asked, 'During the past four weeks, for how long have you been able to walk before pain from your knee became severe?' (with or without a stick). Responses were scored as 1 = no pain / more than 30 minutes, 2 = 16–30 minutes, 3 = 5–15 minutes, 4 = around the house only, 5 = not at all.

Knee flexion

This was measured with the subject in a supine lying position, with a pillow under their head, using a standard long arm goniometer.[14] Patients were asked to actively flex their knee with no assistance given from the assessor. The best of three attempts was recorded.

Inpatient rehabilitation

Following surgery, patients were treated in hospital with standard gait re-education using parallel bars or walking aids. Mobilizing and strengthening exercises were taught including active flexion exercises using a sliding board, isometric quadriceps, straight leg raises and inner range quadriceps exercise. Patients were also taught how to climb stairs safely before discharge from hospital.

Intervention

Intervention for the traditional exercise group (TEG) was based on the response of a survey of AOCP members working with orthopaedic inpatients. The TEG were given instructions by a physiotherapist to continue with the exercises they had been taught in hospital. They were given written instructions to perform the exercises three to four times daily for approximately 10–15 minutes.

The FEG were taught a warm-up exercise and three functional exercises aiming to increase general activity and improve function. The exercise for the FEG and the TEG are described in the appendix. Patients in both groups were given written instructions. The FEG were additionally given a record sheet to document the amount of walking they did each day. This record sheet was for personal use only and not part of the data collection. No further assistance was given to aid exercise compliance. Advice regarding stair-climbing, walking, rest, possible swelling, application of ice and elevation was also given.

Statistical analysis

All patients were analysed in the groups to which they were randomized. Data were checked for normal distribution using the Sharpiro Wilk test.[15] For normally distributed data, multivariate analysis of variance for repeated measures was used to test the statistical significance of observed changes over time, and between the two treatment groups. In addition the proportion scoring four or more (i.e. those with severest pain) was calculated and chi-square was used to test for

statistically significant differences in severe pain at each assessment interval. In order to assess the likely sample size requirements for future trials, the change in knee flexion, walking speed, LEP and pain during walking was calculated as the mean difference between baseline and 12 months. Sample size estimations were calculated according to Machin *et al.*,[16] assuming an alpha of 0.05, and beta of 80%, and using estimate of between-group differences and standard deviations observed in this trial.

To assess potential biases associated with loss to follow-up we:

1) examined baseline differences between people remaining in the trial at 12 months, and those who were not;
2) used a chi-square test to analyse associations between loss to follow-up and the clinical physiotherapist's assessment of the patients' motivation to exercise during hospital stay.

Statistical significance was claimed at the $p < 0.05$ or 95% level, and data analysis undertaken using the SPSS version 9 package.

Results

Forty-seven patients were randomized between 1995 and 1996. Twenty-four patients were randomized to the TEG, and 23 to the FEG. The groups were well-matched in terms of age, gender, intensity of symptoms, walking speed, knee flexion, LEP and pain prior to surgery (Table 1). One participant had a unicompartmental prosthesis, all others had a total condylar prosthesis.

As the study progressed, the number of patients who did not attend the follow-up appointments increased and was nearly 50% at one year.

Knee flexion, leg extensor power, mobility, pain and motivation scores

Table 2 shows knee flexion, walking speed, leg extensor power, pain during walking and motivation scores at baseline and at the follow-up assessments. Data are shown for all patients who were randomized to the study and for the subgroup who completed the trial. Overall, the general trend was of good improvement in leg extensor power, walking speed and stair-climbing time during the 12 month follow-up. There were no statistically or clinically significant differences between the two groups. Knee flexion decreased in the postoperative period, and even by 12 months had not reached preoperative levels (MANOVA within-subject change $p < 0.001$). There was a trend suggesting that loss of range was less in the FEG, but there were no statistically significant differences between the groups (MANOVA $p > 0.05$). Table 2 shows that pain during walking decreased significantly during the follow-up period, but there were no statistically significant differences between the groups. Likewise there was no statistically significant difference between the groups in terms of the walking aids used at each assessment interval.

Mean change

The mean change (difference baseline to 12 months) in key outcomes is shown in Table 3, as well as estimations of the required sample sizes to demonstrate a statistically significant differences assuming as alpha of 0.05 and beta of 80%.

Table 1 Comparison of presurgery characteristics of the patients randomized to the traditional and functional exercise groups. There were no statistically or clinically significant differences between the two groups

	Traditional ($n = 24$)	Functional ($n = 23$)
Age (years) – mean (SD)	71.1 (5.6)	71.5 (5.4)
Females	$N = 12$	$N = 11$
Good motivation	$N = 18$ (73%)	$N = 15$ (67%)
Pain severity during walking – mean (SD)	4.3 (0.9)	4.2 (0.5)
LEP (W/kg) – mean (SD)	1.05 (0.55)	1.05 (0.5)
ROM (degrees)	108 (15)	104 (19)
Walking speed (m/s) – mean (SD)	1.2 (0.47)	1.1 (0.46)

Table 2 Absolute values of flexion, LEP, walking speed, pain and motivation for patients who attended for all follow-up appointments (completers) and those who were lost to follow-up (all data)

	Baseline Mean (SD)	3 months Mean (SD)	6 months Mean (SD)	12 months Mean (SD)
Flexion (degrees)				
TEG – all data	113 (14.7)	95 (15.2)	102 (14.4)	103 (16.2)
TEG – completers = 11	115 (14.5)	99 (13.1)	100 (15.3)	102 (16.2)
FEG – all data	111 (20.0)	97.3 (12.3)	102 (9.8)	103 (9.3)
FEG – completers = 16	108 (22.1)	97 (9.5)	102 (9.3)	102 (9.3)*
LEP (W/kg)				
Operated knee				
TEG – all data	0.9 (0.5)	1.2 (0.47)	1.3 (0.61)	1.6 (0.71)
TEG – completers = 11	0.9 (0.5)	1.2 (0.47)	1.3 (0.60)	1.7 (0.67)
FEG – all data	0.8 (0.47)	1.2 (0.56)	1.4 (0.63)	1.7 (0.81)
FEG – completers = 16	0.8 (0.53)	1.2 (0.56)	1.5 (0.62)	1.7 (0.64)**
LEP (W/kg)				
Normal knee				
TEG – all data	1.2 (0.76)	1.3 (0.78)	1.5 (0.86)	1.6 (0.79)
TEG – completers = 11	1.3 (0.8)	1.4 (0.75)	1.5 (0.84)	1.6 (0.80)
FEG – all data	1.2 (0.67)	1.4 (0.63)	1.6 (0.74)	1.8 (0.64)
FEG – completers = 16	1.2 (0.64)	1.5 (0.63)	1.7(0.71)	1.8 (0.64)†
Walk speed (m/s)				
TEG – all data	1.18 (0.45)	1.39 (0.39)	1.57 (0.04)	1.49 (0.40)
TEG – completers = 11	1.22 (0.27)	1.46 (0.33)	1.62 (0.34)	1.49 (0.40)
FEG – all data	1.14 (0.46)	1.42 (0.39)	1.60 (0.52)	1.63 (0.56)
FEG – completers = 16	1.15 (0.51)	1.47 (0.42)	1.67 (0.43)	1.65 (0.55)††
Pain (1–5 scale)				
TEG – all data	4.3 (0.99)	2.8 (1.07)	2.0 (1.13)	1.5 (0.93)
TEG – completers = 11	4.2 (1.16)	2.6 (0.9)	1.9 (1.14)	1.5 (0.93)
FEG – all data	4.2 (0.52)	2.5 (1.06)	2.1 (1.08)	1.8 (0.99)
FEG – completers = 16	4.2 (0.54)	2.6 (1.0)	2.0 (0.8)	1.6 (0.8)*
Percentage scoring > = 4				
TEG – all data	91.7%	35.2%	13.3%	9.1%
TEG – completers = 11	90.9%	18.2%	9.1%	9.1%
FEG – all data	95.7%	18.2%	11.1%	0%
FEG – completers = 16	93.8%	18.8%	6.3%	0%***

*MANOVA $p < 0.0001$ for within-subject change; $p = 0.68$ for between-group comparisons.
**MANOVA $p < 0.0001$ for within-subject change; $p = 0.89$ for between-group comparisons.
†MANOVA $p < 0.0001$ for within-subject change; $p = 0.72$ for between-group comparisons.
††MANOVA $p < 0.0001$ for within-subject change; $p = 0.58$ for between-group comparisons.
Percentage of patients scoring > = 4 on the pain scale (1 = no pain, 5 = severe pain on walking)
***MANOVA $p < 0.0001$ for within-subject change; $p = 0.57$ for between-group change.

Loss to follow-up

There were no statistically or clinically significant differences in the preoperative characteristics of people who attended follow-up appointment and those who did not. However, people who were judged by the clinical physiotherapists as having poor motivation to exercise were more likely not to attend the six-month follow-up appointments (chi-square $p < 0.02$).

Discussion

The study suggests that there may be some benefits in using functional exercises as opposed

Table 3 Mean change between baseline and 12 months in key outcome variables

	Mean change	SD	Difference between groups	Sample size required per group
Pain during walking				
TEG	2.7	1.3	0.3	545
FEG	2.4	0.9		
Flexion (degrees)				
TEG	12.4	22.2	7.1	298
FEG	5.3	18.6		
Walk speed (m/s)				
TEG	0.23	0.26	0.21	100
FEG	0.42	0.53		
LEP (W/kg)				
TEG	0.65	0.42	0.41	357
FEG	0.79	0.53		

to traditional strength training for patients following knee arthoplasty, but a large randomized controlled trial would be needed to draw any firm conclusions. The differences between groups are likely to be of moderate size[17] and this would be the case for any trial comparing exercise regimes of similar intensity. However, the clinical relevance of finding even small differences between exercise regimes are likely to be of importance, as home-based treatments are cheap and easy to implement.

A trial with only small numbers of patients carries a risk of failing to demonstrate a treatment effect when one is present, i.e. small trials have large type II errors. Therapy trials are often too small to demonstrate differences between groups and it has been suggested that a considerable amount of clinical research remains futile since it lacks the resources to answer the questions being posed.[10] This trial, although small, was considered as a feasibility study and has generated data for power calculations. The difference in gain in walking speed between the traditional and functional groups was of clinical interest, and the confidence interval was approaching unity. These indicate that walking speed over 10 metres was the most sensitive outcome measure chosen but at least 100 patients would be required in each group to show a statistically significant difference between groups. This suggests that a multicentre trial would be preferable to overcome the problem of slow recruitment from a single centre.

Clinical messages

- There was a trend in favour of functional exercises compared with traditional exercises for patients following knee replacement surgery but these differences were not statistically significant.
- Loss of knee flexion is a particular problem during recovery and preoperative range was not regained 12 months post surgery.

In this study we chose to exclude patients who were referred for outpatient physiotherapy treatment after discharge as the treatment would have affected outcome. At the same time we wanted to be able to assess the patients before their operation. Therefore, patients were registered and assessed before surgery and randomized on the day before they returned home. Timing of randomization can be a problem in clinical trials where waiting lists and other organizational issues take preference over the running of the trial. These issues should be seriously considered when planning trials to allow randomization to occur at the optimum time.

There was evidence to suggest a systematic difference between people who completed the trial and those who did not, notably in the measure of motivation to exercise made by physiotherapists at the time patients were discharged. Physiotherapists' subjective assessment of patients'

motivation during hospital stay has previously been reported to predict well-being and fatigue six months after discharge.[18] Assessment of patients' motivation may be an important covariante measure for future trials of exercise. A particular problem with retention of patients after elective surgery is that some travel long distances to attend hospital appointments, and the time and effort required to travel into the hospital can be daunting. Domiciliary examinations or the use of postal questionnaires should be considered to minimize the number of drop-outs.

There was no evidence in this study to suggest that pain was exacerbated by either exercise regime. In keeping with previous reports of recovery after knee replacement, pain gradually diminished during the follow-up year.[19]

The overall loss of range of flexion at 12 months is of interest and has been reported previously by patients with osteoarthritis of the knee.[20] The most important factors in regaining range of motion after knee arthroplasty are preoperative range of flexion and the body weight of the patient.[21,22] The type of knee replacement also affects postoperative flexion, unicompartmental knees tend to result in better postoperative flexion than total knee replacements.[22] Although pain is the most important outcome of knee replacement surgery, function is also important and some patients may not be gaining maximal benefit from knee surgery. Ritter and Campbell[23] reported that the amount of postoperative flexion had a statistically significant effect on walking and stair-climbing ability. At present, it is not known whether loss of flexion can be recovered for this group of patients.

A limitation of the study is the lack of information regarding compliance with the exercise regimes. Future studies should plan to monitor exercise adherence and include qualitative research nested within randomized controlled trials to address this issue. Other factors apart from exercise compliance also confound the results. These include the success of the surgical procedure, pain, fatigue and psychological outlook.[24]

The results of this trial are of value to others setting up postoperative exercise trials and could be used for future meta-analysis of rehabilitation following joint arthroplasty. The methodological issues highlighted in this study should be considered when planning future randomized controlled trials of physiotherapy following knee arthroplasty.

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Appendix – Home-based treatment intervention

Traditional exercise group	Functional exercise group
Static quadriceps in long sitting, push knee straight, tighten quadriceps muscle and hold for a count of five seconds	**Warm up-exercise**. Sit on sturdy chair, straighten and bend your knee slowly. Repeat ten times
Straight leg raising. Repeat static quadriceps exercise and lift whole leg straight. Hold for five seconds	**Chair rise**. Slowly rise from a chair and return to a sitting position. Baseline number given by a physiotherapist and increased every alternate day up to two minutes. Following two-minute target, repeat up to three times daily
Inner range quadriceps. In long sitting with rolled up towel beneath knee, straighten knee and hold for five seconds	**Walking**. Walk continuously for one minute at normal pace. Increase time by 30 seconds each day. When walking for ten minutes stop increasing and repeat exercise 2–3 times a day
Knee bending exercise in lying. Sit or lie with leg straight. Slide your heel back towards your bottom and allow knee to bend. Slide heel back down again and straighten knee	**Leg lifts**. Lift your foot onto a step or thick book using a handrail or wall for support. Do not swing leg out but bend knee as far as possible. Baseline set. Increase by one lift each day. After reaching a time of two minutes stop increasing and repeat exercise 2–3 times a day
Knee-bending exercise in standing. Standing with support, bend knee by taking heel towards bottom. Hold for five seconds and lower heel slowly	**Daily records**. An exercise record sheet was supplied for patients to complete each day. Patients were asked to record the time they spent exercising and the number of repetitions. No further intervention was used to assist compliance
Long arc quadriceps exercise. Sit on sturdy surface or chair. Straighten knee as far as possible. Hold for three seconds and lower leg slowly	