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Costs and effectiveness of pre- and post-operative home physiotherapy for total knee replacement: randomized controlled trial

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Abstract

Aims and objectives To assess the effectiveness of pre- and post-operative physiotherapy at home for unilateral total knee replacement (TKR). **Methods** In this pragmatic randomized controlled trial set in participants' homes (four primary care trust areas) and physiotherapy outpatients in a South Yorkshire teaching hospital trust, 160 osteoarthritis patients waiting for unilateral TKR were randomly allocated to intervention (home) group ($n = 80$) or control (hospital outpatient) group ($n = 80$). The intervention group had pre- and post-operative home visits for assessment and treatment by a community physiotherapist. Outcome measures were health-related quality of life (HRQoL), measured by the Western Ontario McMaster Osteoarthritis index (WOMAC) and the Short Form 36 health survey (SF-36) pre-operatively and at 12 weeks post-TKR operation; patient satisfaction; and NHS resource use. **Results** No significant differences were observed between the two treatment groups in the primary outcome measure, the WOMAC pain score, or any other HRQoL score. The home group had a significantly greater mean number of physiotherapy sessions than the hospital group [mean difference 5.2 sessions, 95% confidence interval (CI) = –6.3 to –4.1; $P = 0.001$]. There was no significant difference in the total NHS costs per patient between groups. However, home physiotherapy for TKR was significantly more expensive (mean difference –£136.5, 95% CI = –£160 to –£113; $P = 0.001$). Patients were equally satisfied with physiotherapy at home or in hospital; however, more of the home group would choose their location for physiotherapy again. **Conclusions** Although home physiotherapy was as effective and as acceptable to patients as hospital outpatient physiotherapy for unilateral TKR, it was more expensive. Additional pre-operative home physiotherapy did not improve patient-perceived health outcomes.

Introduction

The NHS Plan emphasizes the importance of cost-effective integrated 'whole patient care pathways' with near universal support for development of care closer to home (Department of Health 2000). However, in the case of severe osteoarthritis (OA) of the knee requiring total knee replacement (TKR) there is a gap between policy and practice. OA knee is a common disorder and approximately 20 per 1000 people over 55 years may benefit from a TKR (Tennant *et al*. 1995). Over 35 000 TKRs are performed each year in the UK but there are long waits for both specialist assessment and surgery during which patients often experience severe pain and disability (Moran & Horton 2000). Post-operatively, all rehabilitation usually takes place in a hospital setting. The current TKR and knee OA evidence base is dominated by studies assessing surgical and pharmaceutical interventions; whilst few published studies have assessed physiotherapy interventions (Tallon *et al*. 2000). Those which have demonstrate that primary care-based exercise interventions reduce pain and disability for people with knee OA (van Baar *et al*. 1999; O'Reilly *et al*. 1999; Thomas *et al*. 2002). Our review of the literature revealed that most studies comparing physiotherapy interventions for TKR lack statistical power, quality of life measures and health economic outcomes. This hinders the incorporation of new evidence-based practice into service development. Furthermore, the impact of TKR pre-operative physiotherapy on patient outcomes has not been established.

With regard to providing care closer to home, a recent systematic review highlights the lack of evidence comparing hospital to community settings in the UK for rehabilitation; specifically, the resource implications of transferring work from secondary to primary care have not been considered (Smith 2002).

Consequently, we designed a home-based physiotherapy rehabilitation programme to maintain activity before TKR surgery with follow-up by the same physiotherapist after hospital discharge. Patient-perceived health outcomes and NHS costs were compared with usual hospital outpatient post-operative physiotherapy in a pragmatic, randomized controlled trial.

Methods

Objectives

To assess the effectiveness of pre- and post-operative physiotherapy at home for unilateral TKR compared with usual hospital outpatient post-operative physiotherapy in terms of patient outcome, cost-effectiveness and patient satisfaction.

Study population and assignment

The North Sheffield Ethics committee gave ethical approval. A total of 160 participants residing in Sheffield were recruited over 16 months (1999–2000), from an NHS waiting list for unilateral TKR for OA (Sheffield University Hospitals Trust Orthopaedic Unit). Patients who fulfilled trial inclusion criteria (Table 1) were invited to participate by consultant letter, with a study information leaflet and a consent form enclosed. The research nurse opened returned consent forms sequentially and used an independently prepared computer block randomization sequence in opaque sealed envelopes to allocate consenting participants to a treatment group.

Table 1 Inclusion and exclusion criteria

Inclusion criteria	*Exclusion criteria*
On waiting list for primary procedure for unilateral total knee replacement for osteoarthritis	Revision procedures, bilateral or unicondylar knee replacements, total knee replacement following severe trauma
Orthopaedic surgeon consent to referral of patients on their waiting list	Onset of serious comorbidity or terminal illness since patient placed on the waiting list, which necessitates cancellation or considerable delay in treatment
Patient address within Sheffield community physiotherapy service boundaries	Contra-lateral knee replacement within the preceding 12 months

Intervention and usual care

Senior hospital and community physiotherapists designed the home intervention with reference to a literature review and current practice. Four community physiotherapists, one per primary care trust (PCT) area, spent half a day observing inpatient TKR physiotherapy and visiting outpatient knee classes, in addition to two 1-hour in-house training sessions.

The home intervention involved individual treatment. There was a minimum of three pre-operative visits (starting within 8 weeks of joining the TKR waiting list) and up to six post-discharge visits. Pre-operative physiotherapy, based on an initial assessment, typically included pain relief, techniques to increase knee flexion and extension, gait re-education and home/functional adaptations. Post-operative physiotherapy additionally included techniques to reduce swelling and mobilize soft tissues.

Usual hospital physiotherapy was post-discharge only and comprised group exercises, and individual treatment, in knee classes of seven to 10 patients in the gymnasium; usually once or twice a week. Individual treatment sessions in the outpatient department were given at the physiotherapists' discretion. Treatments included techniques to increase knee flexion and extension, electrotherapy for pain relief and/or muscle stimulation; and gait re-education.

Outcome measures and follow-up

The primary outcome measure was the Western Ontario McMaster Osteoarthritis index (WOMAC) pain dimension scores 12 weeks post-operatively, the time by which patients have perceived the most improvement in their health status (Shields *et al*. 1999). Secondary outcomes included changes in stiffness and physical function as measured by the disease specific WOMAC (Bellamy *et al*. 1988; Brazier *et al*. 1999); changes on dimensions measured by the Short Form 36 health survey (SF-36) (Brazier *et al*. 1992); satisfaction with treatment and resource use. Questionnaires were posted to participants at trial entry and 12 weeks after TKR. Reminder questionnaires and telephone calls were used for non-responders and missing responses. Demographic and comorbidity data were collected from orthopaedic records, general practitioner (GP) and patient questionnaires.

Sample size and statistical analysis

Our sample size was 65 participants in each treatment group (80% power, two sided significance level $P = 0.05$) (Brazier *et al*. 1999), based on an expected mean difference of 1.5 between the two groups in their changes in WOMAC pain scores; this difference of 1.5 was taken to indicate clinical importance. Intention to treat analysis of quantitative data was blind to treatment group allocation, using SPSS statistical software. Patient-perceived health-related quality of life (HRQoL) scores (WOMAC and SF-36) were assumed to be continuous measurements and were analysed using a two independent samples *t*-test or by multiple linear regression analysis (where time to TKR differed significantly) with 12 week post-operative HRQoL as the outcome variable and pre-operative HRQol, pre-operative waiting time and treatment group as covariates. Demographic and comorbidity categorical data were compared using χ^2 test. A significance level of $P \leq 0.05$ was used.

Economic analysis

The economic evaluation compared costs and outcomes at 12 weeks post-TKR for the two treatment groups (Drummond *et al*. 1997). Costs were identified, measured and valued from an NHS perspective, using 2001/02 prices, for the period from 12 months before TKR until 12 weeks after TKR. Resource-use data were collected from GP, community physiotherapy and hospital records. Local cost estimates were included wherever possible. Otherwise national average costs were used (Netten *et al*. 2001). Secondary analysis compared personal expenditure by patients. Data for patient costs and transport use were collected from patient questionnaires and hospital physiotherapy notes (Table 2).

Patient views

A patient questionnaire was designed and piloted by the study team then posted to participants 12 weeks after TKR. Questions were largely open but closed questions were included to ascertain satisfaction

Table 2 Important costs identified for each group

Important costs	*Intervention group*	*Control group*
NHS		
Pre-operative care	Community physiotherapy sessions	
	GP consultations	GP consultations
Post-operative care	Hospital services: operation and length of stay	Hospital services: operation and length of stay
	GP consultations	GP consultations
	Hospital physiotherapy sessions	Hospital physiotherapy sessions
	Community physiotherapy sessions	NHS transport
	NHS transport	
Patient costs		
Transport costs	Costs incurred by patients	Costs incurred by patients
Other costs	Other out-of-pocket costs associated with having physiotherapy sessions	Other out-of-pocket costs associated with having physiotherapy sessions

GP, general practitioner.

with, and preferred site of, physiotherapy treatment. Quantitative data were analysed using SPSS software (χ^2 test). The qualitative data will be presented in a separate paper.

Results

Recruitment and participant flow

Figure 1 illustrates a 63.7% recruitment rate (160/251) from the waiting lists of nine out of 13 consultants who regularly performed TKR. There were 45 (28.1%) withdrawals from the study, 24 of whom (15.1%) had their surgery cancelled. There was no evidence that study withdrawal varied by group or WOMAC dimension scores. However, withdrawn patients had significantly poorer scores on the SF-36 General health ($P = 0.037$), Energy ($P = 0.004$) and Mental health ($P = 0.054$) dimensions and were also significantly more likely to report heart problems ($P = 0.012$) and stroke/transient ischaemic attack (TIA) ($P = 0.011$). Two patients died pre-operatively.

Baseline comparability

Baseline characteristics were similar in the two groups (Table 3). Patients in the home care group had a significantly longer mean pre-operative waiting time than patients in the hospital group [$P = 0.036$, mean difference 5.2 weeks, 95% confidence interval (CI) = 0.4 to 10.1 weeks].

HRQoL outcome measures

The post-operative WOMAC and SF-36 questionnaire response rate was 98% (114/116). No significant differences were observed between the groups in post-operative WOMAC and SF-36 mean scores including the primary outcome measure, the WOMAC pain dimension (Table 4).

Physiotherapy outcomes and patient satisfaction

Physiotherapy data were missing for 9/114 patients because of missing hospital notes and non-returned questionnaires. The mean wait to first post-operative physiotherapy appointment after hospital discharge was significantly longer for the hospital outpatient physiotherapy group (18.6 days) compared to the home physiotherapy group (3 days) ($P < 0.001$; mean difference 15.5, 95% CI = 10.82 to 20.17). The home physiotherapy group had a mean of 8.4 home treatment sessions (includes a mean of 2.8 pre-operative sessions) compared to a mean of 3.5 post-operative outpatient sessions for the hospital group. Four home group patients also had hospital outpatient sessions, bringing the group's total mean number of treatment sessions to 8.7, the difference between the two groups (5.2 sessions) was statistically significant ($P = 0.001$; 95% CI = –6.3 to –4.1). Physiotherapy treatment outcomes, by group, are summarized in Fig. 1.

Satisfaction with physiotherapy for TKR was equally high (86%) in both treatment groups; how-

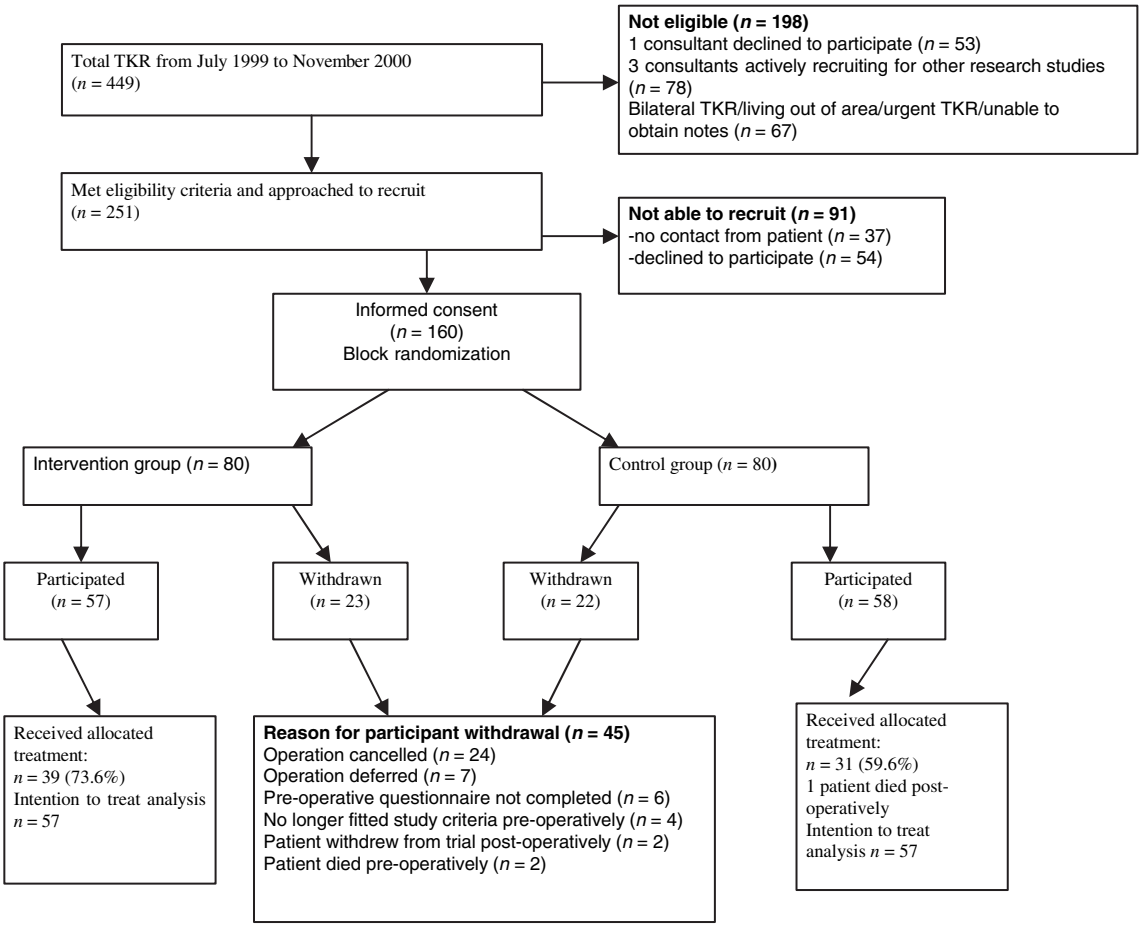

Figure 1 Participant flow (TKR, total knee replacement).

ever, more of the home group (64.9%, compared with 47.4% of the hospital group) would choose their location for physiotherapy again; however, this was not statistically significant ($P = 0.13$).

Economic evaluation

The mean total costs of pre- and post-operative NHS services were almost identical for both groups: £5376 and £5372 for the home and hospital groups respectively (mean difference –£4.7, 95% CI = –£334 to £324; $P = 0.978$) (Table 5). However, physiotherapy services for the intervention group were significantly more costly than for the control group: £197.9 compared to £61.5 (mean difference = –£136.5, 95% CI = –£160 to –£113; $P = 0.001$). The hospital group also had transport costs, a mean of £38.7 per patient. There was no evidence that the intervention group patients consumed more or fewer NHS services in terms of length of stay in hospital, GP contacts and prescriptions.

A sensitivity analysis measured the impact on physiotherapy costs of reducing community visits by one third. The total mean cost difference per patient between the two groups for physiotherapy services overall would reduce to £76.50. However, this would still be significantly more costly ($P = 0.001$, 95% CI = –£95.1 to –£57.8).

Discussion

Summary of main findings

No significant differences were observed between the two treatment groups in patient-perceived health outcomes. This study compared an individually

Table 3 Baseline patient characteristics, WOMAC and SF-36 scores according to randomization group

Characteristics	**Hospital group $n = 57$**	**Home group $n = 57$**
Mean age at TKR – years (SD)	70.6 (8.2)	70.0 (7.2)
Mean pre-operative waiting time – weeks (SD)	25.3 (12.9)	30.7 (13.17)
	No (%)	**No (%)**
Women	30 (52.6)	36 (63.2)
Heart problems	10 (18.9)	8 (16)
Chest problems	7 (12.7)	6 (11.5)
Stroke/TIA	1 (1.80)	
Previous knee surgery	14 (26.4)	9 (15.8)
Diabetes	6 (11.1)	6 (11.5)
Raised blood pressure	21 (37.5)	23 (46.3)
Mean pre-operative waiting time – weeks (SD)	25.3 (12.9)	30.7 (13.17)
Health status measure	**Mean (SD)**	**Mean (SD)**
WOMAC*		
Pain	12.0 (3.1)	12.4 (3.4)
Stiffness	5.2 (1.4)	5.4 (1.4)
Physical function	40.6 (11.2)	40.0 (10.9)
SF-36†		
SF-6D: preference-based measure of health	0.51 (0.10)	0.52 (0.09)
General health	56.9 (20.3)	57.0 (21.4)
Mental health	70.4 (15.7)	69.3 (18.9)
Bodily pain	27.7 (15.6)	29.2 (17.5)
Physical function	27.0 (17.8)	21.8 (17.5)
Role emotional	39.8 (45.6)	43.9 (44.2)
Role physical	12.3 (26.4)	10.1 (23.6)
Social functioning	59.3 (29.2)	52.6 (28.6)
Energy	44.2 (18.3)	42.1 (18.4)

TKR, total knee replacement; SF-36, Short Form 36 health survey; TIA, transient ischaemic attack, WOMAC, Western Ontario McMaster Osteoarthritis index.

*WOMAC dimension scores range 0–20 (pain), 0–8 (stiffness) and 0–68 (physical function); a higher score indicates increased pain or stiffness or worse physical function.

†SF-36 dimension scores range 0–100: a higher score for each dimension indicates better health-related quality of life. The SF-6D scores range 0.3–1.0 (good health).

focused home physiotherapy programme with hospital physiotherapy delivered in groups. The physiotherapy rehabilitation programmes differed in timing (pre-operative programme and post-operative vs. post-operative only), intensity (home one-to-one vs. hospital group therapy with less one-to-one treatment) and in the total number of sessions. However, although the hospital group had fewer physiotherapy sessions than recommended by senior physiotherapists at the outset of the study, this does not appear to have adversely affected health outcomes.

The community physiotherapists saw knee replacement patients significantly more quickly post-operatively than their hospital counterparts. This could reflect the enthusiasm associated with a new service, although this access measure was unchanged over the 30 months of the study. As well as quicker access, community physiotherapists provided the advantage of continuity of care before and after TKR; whereas hospital physiotherapy provided access to gym equipment and group work.

There was no significant difference in the total NHS costs per patient between groups for similar health outcomes. The control group made significantly more use of NHS patient transport services, but the intervention group physiotherapy treatment cost significantly more per patient. The latter was because of factors such as their greater number of sessions (including pre-operative physiotherapy) and home physiotherapy being delivered on a one-to-one

Table 4 Mean Scores and results of multiple linear regression analysis of post-operative WOMAC and SF-36 according to randomization group

Dependent variable	*Hospital group mean score (SD)* n = *57 (*n = *56)*	*Home group mean score (SD)* n = *57 (*n = *56)*	n†	*Regression Coefficient*‡ *(95% CI)*	P-*value*	R^2
WOMAC§						
Physical function	26.4 (14.9)	24.9 (13.4)*	108	–1.0 (–5.9 to 3.8)	0.677	0.24
Pain	6.9 (4.3)	6.8 (3.7)	111	–0.5 (–2.0 to 1.0)	0.530	0.086
Stiffness	3.6 (2.1)	3.5 (1.4)	111	–0.2 (–0.9 to 0.4)	0.496	0.018
SF-36¶						
SF-6D	0.56 (0.12)*	0.57 (0.09)*	109	0.002 (–0.034 to 0.039)	0.897	0.225
General health	61.0 (22.9)	61.0 (23.4)	111	–0.2 (–7.0 to 6.7)	0.964	0.434
Mental health	71.2 (20.0)	68.0 (20.4)	111	–2.9 (–9.3 to 3.5)	0.368	0.342
Bodily pain	48.5 (26.8)	46.6 (20.6)	111	–3.4 (–12.0 to 5.2)	0.432	0.129
Physical function	43.3 (27.6)	41.6 (22.2)	111	2.5 (–6.3 to 11.3)	0.579	0.211
Role emotional	45.6 (44.8)	48.0 (46.7)	111	4.1 (–10.9 to 19.0)	0.592	0.285
Role physical	23.2 (36.2)	27.6 (37.1)	111	7.8 (–5.6 to 21.2)	0.249	0.103
Social functioning	60.8 (33.1)	64.1 (26.6)	111	6.7 (–3.4 to 16.7)	0.193	0.271
Energy	48.2 (23.7)	50.7 (19.5)	111	3.4 (–3.5 to 10.3)	0.330	0.343

SF-36, Short Form 36 health survey; CI, confidence interval.

†The maximum sample size for the multiple regression analysis was 111 as three patients did not have pre-operative waiting times or health-related quality of life (HRQoL) scores.

‡The regression coefficient for study group represents the effect on post-operative HRQoL of moving from Group 1 (Hospital) to Group 2 (Home) after adjusting for pre-operative HRQoL and pre-operative waiting time.

§WOMAC dimension scores range 0–20 (pain), 0–8 (stiffness) and 0–68 (physical function); a higher score indicates increased pain or stiffness or worse physical function.

¶SF-36 dimension scores range 0–100: a higher score for each dimension indicates better health-related quality of life. The SF-6D scores range 0.3–1.0 (good health).

basis, whereas in hospital the patient: physiotherapist ratio was lower. Even when a sensitivity analysis reduced the number of home sessions by a third, home physiotherapy for TKR was significantly more expensive than hospital outpatient physiotherapy.

TKR patients were equally satisfied with physiotherapy at home or in hospital; however, more of the home group would choose their location for physiotherapy again.

Strengths and limitations of this study

This was a pragmatic trial and illustrates the fact that 'usual care' within the NHS may change during long-term studies, despite the highest level of collaboration at the outset in defining the treatment protocol. The WOMAC and SF-36 may have been too insensitive to detect change or distinguish differences in outcomes between the two groups. However, WOMAC is deemed to be the instrument of choice for evaluating the outcome of knee replacement surgery in OA (Brazier *et al*. 1999).

We recruited fewer patients than planned, therefore, a major limitation of this study is that the analysis was inadequately powered to detect the minimum important difference of 1.5 points in the primary outcome (WOMAC pain score) between the groups. However, the observed changes in WOMAC pain scores were small, a mean difference of –0.5 (95% CI = –2.0 to 1.0) and, although low power can explain the lack of significance, and the width of the CIs, it cannot explain the size of the observed effect. Overall, it is unlikely that the study failed to detect changes of 2 points or more in WOMAC pain scores, although differences of 1.5 points or less remain a possibility.

There is potential for trial bias, because it was not possible to conceal allocation of treatment from the patients and physiotherapists. However, the researchers were 'blinded' at the point of analysis of

Table 5 NHS resource use and costs at 12 weeks post-TKR, according to randomization group

	Quantity of resource used				*Cost of NHS resource used per patient (£)*			
Resource	*Home n = 56 Mean (SD)*	*Hospital n = 55 Mean (SD)*	*Mean difference (95% CI)*	*P-value	*Home n = 56 Mean (SD)*	*Hospital n = 55 Mean (SD)*	*Mean difference (95% CI)*	*P-value
	Pre-operative resource use				**Pre-operative costs**			
Community physio visits	2.8 (1.0)				65.6 (15.0)			
GP consultations	6.8 (4.4)	6.8 (4.6)	–0.08 (–1.8, 1.6)	0.929	130.0 (83.1)	128.5 (87.3)	–1.4 (–33.5, 30.6)	0.929
	Post-operative resource use (12 weeks)				**Post-operative costs (12 weeks)**			
Inpatient stay (days)	9.2 (3.4)	9.6 (3.0)	–0.4 (–0.8, 1.6)	0.550	4993 (906)	5089 (785)	97 (–222, 416)	0.550
GP consultations	2.6 (2.0)	2.8 (2.1)	0.3 (–0.5, 1.0)	0.504	48.9 (37.5)	53.9 (41.5)	5.0 (–9.8, 19.9)	0.504
Hospital physio								
Knee classes	0.1 (0.3)	2.3 (2.7)	2.3 (1.6, 3.0)	0.001	0.8 (4.6)	36.0 (42.0)	35.2 (24.0,46.3)	0.001
One to one	0.3 (1.4)	1.2 (2.7)	0.9 (0.1, 1.7)	0.029	4.4 (23.7)	19.2 (43.8)	14.8 (1.6, 28.0)	0.029
Hydrotherapy	0.0 (0.1)	0.1 (0.3)	0.1 (–0.0, 0.1)	0.166	1.5 (11.5)	6.3 (22.5)	4.7 (–2.0, 11.4)	
Community physio visits	5.6 (2.8)				125.5 (67.9)			
Total post-operative physio costs					132.2 (60.8)	61.5 (57.1)	–70.8 (–93.0,-48.6)	0.001
Ambulance journeys	0.1 (0.5)	1.3 (3.3)	1.3 (0.3, 2.0)	0.010	1.9 (8.9)	23.0 (59.2)	21.0 (5.2, 36.9)	0.010
Medicar journeys	0.3 (1.5)	1.0 (1.8)	0.6 (–0.0, 1.3)	0.066	5.2 (27.9)	15.7 (32.0)	10.6 (–0.7, 21.9)	0.066
Total pre- and post-operative physio costs					197.9 (65.9)	61.5 (57.1)	–136.5 (–160, –113)	0.001
Total pre- and post-operative costs					5376 (916)	5372 (832)	–4.7 (–334, 324)	0.978

TKR, total knee replacement; GP, general practitioner.
Costs are estimated at 2001/02 prices (£).
*Two-independent samples t-test.

primary outcome measure and withdrawal rates were equal in both treatment groups. This was a single centre study, however, long-term hip and knee arthroplasty outcome data collated across the Trent region (97 consultants) demonstrates consistently high patient satisfaction with TKR across the units, regardless of the grade of surgeon (Harper W.M. unpubl. report: *Outcome of total hip and knee replacement*, 1997). The majority of consultants in this single orthopaedic provider unit supported patient recruitment, which, together with a high patient participation rate in the study, suggests that home physiotherapy for TKR is applicable to other NHS sites.

Agreement/disagreement with existing literature

The similarity in HRQoL outcomes between the home and hospital groups reflects the findings of two recent Canadian studies (Mahomed *et al*. 2000; Kramer *et al*. 2003). However, the interventions in these studies were markedly different from ours, involving telephone contacts as the home intervention in the former and inpatient rehabilitation clinics in the latter, resulting in home-based rehabilitation being their cheaper option. Our study also supports the findings of previous smaller studies in that there was no additional benefit of pre-operative physiotherapy on post-operative outcomes for TKR (Weidenhielm *et al*. 1993; D'Lima *et al*. 1996; Rodgers *et al*. 1998). The high satisfaction rates within both treatment groups reflect the tendency of NHS patients, particularly older adults, to be highly satisfied with care in most published literature (Fitzpatrick 1991).

Implications for research and clinical practice

The NHS Plan promotes enhanced access, patient-centred care pathways and increasing flexibility in NHS waiting list management to allow the purchase of surgical procedures from other NHS and private providers both in the UK and Europe. This may fragment the TKR care pathway from the patient's perspective. However, community physiotherapists can provide continuity of care in patients' own homes before and after TKR, regardless of the location of surgery, whilst maintaining current standards of hospital-based physiotherapy and providing patients with quicker access to physiotherapy. This study suggests that the introduction of pre- and post-operative home physiotherapy rehabilitation for TKR is likely to be more expensive than usual hospital post-operative physiotherapy treatment in knee classes and would therefore require appropriate resources. That the two groups of patients had similar outcomes with very different amounts of rehabilitation input suggests further research is needed to determine the optimum level of input for such patients.

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