Effectiveness and cost-effectiveness of pre- and post-operative physiotherapy at home for osteoarthritis patients undergoing unilateral total knee replacement: a randomised controlled trial.

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SUMMARY MD Thesis **Dr Caroline Mitchell**

Costs and effectiveness of pre- and postoperative home physiotherapy for total knee replacement: a randomised controlled trial.

Total knee replacement (TKR) is a common effective intervention for knee osteoarthritis (OA) with potential to further improve patient outcomes. There is a lack of evidence assessing physiotherapy within the TKR care pathway; previous studies lack statistical power and measures of health related quality of life (HRQoL). Pre- and postoperative home physiotherapy rehabilitation for TKR has not previously been evaluated as an alternative to NHS hospital outpatient rehabilitation.

Objective

To assess the costs and effectiveness of pre- and postoperative physiotherapy at home for unilateral total knee replacement (TKR).

Design

This was a pragmatic RCT comparing patient reported HRQoL, and NHS costs of home physiotherapy pre- and postoperatively for TKR with usual hospital outpatient postoperative physiotherapy.

Setting

160 Sheffield knee OA patients awaiting TKR, randomly allocated to an intervention (home care) group (n=80) or a control (usual care) group (n=80).

Intervention

Individual home physiotherapy assessment and treatment; 3 sessions preoperatively, continuing for maximum 6 sessions postoperatively, supplemented by advice on self-directed exercise routines.

Usual Care

8 to 10 knee classes postoperatively; average 10 patients with 2 physiotherapists and one assistant, individual treatments for up to 15 minutes and an exercise circuit in the outpatient gym, supplemented by advice on self-directed exercise routines.

Outcome Measures (OCM)

Western Ontario McMaster Osteoarthritis index (WOMAC) and Short Form 36 health survey (SF-36) questionnaires measured at trial entry and 12 weeks post TKR.

Primary OCM; WOMAC pain dimension scores. A patient satisfaction questionnaire was used and NHS resource use also assessed.

Results

116 participants completed follow up, well matched by group with a 98% questionnaire response rate. 45 (28.1%) participants withdrew, 24 (15%) due to TKR cancellation, 2 patients died. There was no significant difference in primary OCM post TKR between groups ($p = 0.53$) or in any other dimension of the WOMAC or SF-

36. Participants were equally satisfied with physiotherapy in both groups (86%). The home group had a significantly greater mean number of physiotherapy sessions (8.7 sessions vs 3.5 sessions, $p = 0.001$). Home physiotherapy for TKR was significantly more expensive per patient than hospital outpatient physiotherapy (£197.9 vs £61.5, mean difference = -£136.5; $p = 0.001$) The hospital group had additional transport costs, (mean £38.7). There was no significant difference in consumption of other NHS services or in total NHS costs per patient between groups; £5,376 (intervention group) vs £5,372 (control group).

Conclusions

This study demonstrated the effectiveness of home physiotherapy for TKR, but home care was more intensive and expensive than usual hospital care; additional preoperative home physiotherapy did not improve patient outcomes. The cancellation rate for TKR was high and supports the need for clearer selection criteria with greater consideration of co-morbidity and willingness to undergo surgery. Investigation of whether a less intensive individualised physiotherapy intervention at home would deliver expected patient group outcomes and individual rehabilitation goals is important if a more cost-effective home physiotherapy programme were to be provided for TKR patients.

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1 BACKGROUND TO THE STUDY

1.1 A patient scenario

Mrs B, aged 79 years, lives alone in a warden supervised flat. She has bilateral knee osteoarthritis, worse in her right than her left knee. She has gradually become less active and gained weight. She applies topical non-steroidal inflammatory (NSAID) cream to her knees, takes analgesics regularly (paracetamol /codeine), which cause constipation (for which she takes laxatives), and is unable to tolerate oral NSAIDs. She was assessed by a physiotherapist some time ago, but this short term contact has long since ceased, although she still uses her stick. She now finds it difficult to get out of her flat for a weekly visit to church. She is unable to do her own shopping but manages to self care and cook for herself.

A new GP encourages her to consider a knee replacement and she reluctantly agrees to referral. She waits 10 months for orthopaedic assessment and a further 18 months for unilateral total knee replacement (TKR); during which time her pain and disability has increased.

Following surgery she has weekly ambulance trips to the hospital for physiotherapy in small groups in the gym. She has to be up and ready early in the morning, finds the travel uncomfortable and the round trip takes up most of her day. Her pain is improved but she now has mild angina and six months after surgery, her social isolation and mobility outside of the flat has changed little. She is not keen on having a knee replacement in her other affected knee, which the surgeon suggested as an interval procedure. She wonders whether she should have ever had knee surgery, her GP speculates about earlier interventions to improve outcome and how to improve the pre- and post-operative care pathway for total knee replacement.

1.2 Knee Osteoarthritis- A common problem

Osteoarthritis (OA) is the single most important cause of disability and limitation of activity for older people in the UK [1]. The number of people experiencing severe knee pain is likely to rise substantially as our population ages and there are rising levels of obesity, linked to incident OA knee [2],[3]. McAllindon et al (1992) conducted a community survey in Bristol and found that knee pain had a prevalence of 28% in people aged over 55 years [4]. A more recent population study by Jinks et al (2004) of around 9000 people over 50 years found that 1in 4 people aged 50 yrs or over had chronic knee pain and over half of these had severe pain or disability [5]. At present the national annual rate of total knee replacement is approximately one third that of hip replacements performed, but the gap is decreasing, especially in the elderly [6]. Total knee replacement (TKR) is now one of the most common surgical procedures in the UK; around 41,000 total knee replacements are performed each year[7]. Dixon et al examined trends in primary and revision joint (hip and knee) replacement in England between 1991 and 2000. The incidence of primary TKR doubled, with revision TKR increasing by 300%. If current trends continue there would be almost 54 000 primary knee operations annually by 2010 [8].

In a further population based study undertaken by Jinks et al (2003), less patients reported improvement after TKR than following total hip replacement (THR) and the authors suggest that further research is needed to improve patient selection, the timing of surgery and improve the TKR rehabilitation evidence base [9].

1.3 Access of OA knee patients to total knee replacement (TKR) and outcomes

Tenant et al (1993) designed a survey to enable a North Yorkshire purchasing authority to estimate the numbers of people aged 55 years and above who report knee pain such that they might benefit from knee arthroplasty[10]. A short questionnaire was sent to 18,827 eligible participants (86% response rate) and a detailed questionnaire was sent to 1277 participants who reported knee problems (78% response rate). An estimated 20 per 1000 of the population of North Yorkshire over 55 years have symptom severity such that total knee replacement would be beneficial and four per thousand have severe disability (assessed by Lequesne ostaeoarthritis index and the Short Form 36). In women over 74 years the prevalence is 43 per thousand. These estimates exclude participants with Parkinson's disease, stroke, heart disease, dementia and a body mass index >32. Almost all patients with extremely severe or extreme pain and disability had seen their GP within the previous year. However, most of those aged over 75 years who might benefit from

knee surgery, had not been referred to hospital and hardly any were on the waiting list for surgery. Care by a hospital specialist occurred in two thirds of those aged 55 -65 years, but 24% of those aged over 75 years. In the younger age group with extreme pain and disability, 26% were listed for surgery, but no one over 75 years was on a waiting list. Only 2% of those over 75 years in the extremely severe group were listed for knee surgery, yet almost half the potential need was within that group. The study highlighted poor access by patients over 75 years to rheumatology or orthopaedic services. The authors speculated that this might reflect reluctance of GP's to refer older patients for surgery. In 1993, two thirds of the GP's were fundholders and the researchers estimated that meeting extreme need for knee replacement would consume 15-20% of an average practice annual inpatient budget. This was a primary care based study, with a high response rate, which linked epidemiological data to an assessment of health need. The study focused on a single health authority and the authors acknowledged the variation in disability by locality which could limit the generalisablity of the data.

Dieppe et al (1999) investigated the effectiveness, practice variations, indications and possible determinants of utilisation of TKR for OA [11]. Firstly a systematic review of the literature was undertaken. Secondly, two European multidisciplinary consensus panels (primary care physicians, epidemiologists, rheumatologists, physiotherapists, orthopaedic surgeons, psychologists and sociologists) met on four separate occasions, to examine problems associated with the use of TKR in management of OA knee.

A hypothetical model was constructed which assumed that the pathway to TKR involved passage via a 'gatekeeper' (usually a primary care doctor) to the surgeon. Three main decision points were identified; 1) the patient's decision to seek help from a doctor, 2) the decision of a medical gatekeeper to refer to a surgeon and 3) the decision of the surgeon to carry out a TKR.

The systematic review confirmed the effectiveness of TKR in the treatment of OA knee in seven observational studies and two meta-analyses, using some patient perceived outcome measure (pain or disability). There were very few published randomised controlled trials (RCTs) comparing TKR with any other interventions, most studies were observational and many used survival of the prosthesis as the main or only outcome measure. The number of TKR's continues to increase but there is a wide discrepancy in the rates of TKR per head of the population in different countries and communities from around 0.5-0.7 in the UK and Canada to > 2/1000 in the USA.

There were no evidence-based indications for TKR in knee OA but three recently published reports, based on consensus between health care professionals, were summarised in this paper. A postal survey of orthopaedic surgeons (1996 Manusco et al) reported no clear consensus but most agreement on severe daily pain, X-ray evidence of

loss of joint space and an absence of relative contraindications to surgery (co-morbidities, technical difficulties). Naylor and Williams used a Delphi consensus technique, presenting 120 scenarios to health professionals. The aim of this study was to develop algorithms for TKR and total hip replacement in which pain at rest, severity of functional impairment; problems with care-giving and perceived likely improvement in function were the key determinants to prioritise surgery. Hadorn and Holmes (1997) used a Delphi consensus method to derive surgical priorities in New Zealand [12],[11]. The New Zealand priority criteria for major joint replacement are summarised in Table 1.

Table 1 New Zealand priority criteria for major joint replacement (Hadorn & Holmes) *

Priority Criteria	
Pain 40%	Pain severity scored 0-20 Pain duration scored 0-20
Function (20%)	Walking difficulty 0-10 Other functional impairment 0-10
Joint damage (20%)	Pain on active/ passive motion 0-10 Other abnormalities, including loss of movement & radiographic change 0-10
Other factors (20%)	Other joints affected 0-10 Ability to work, act as a caregiver and live independently 0-10
*patients scored from 0-100 on a scale that describes different levels of severity in four domains: pain, function, joint damage and other factors, adapted.	

The European multidisciplinary consensus panel referred to health psychology and sociology literature and the experiences of the panel members to identify three types of characteristics, which might affect how people with OA access health care. These characteristics were 'pre-disposing factors' such as social class, ethnicity, general health beliefs, lay referral and social structures, 'enabling factors' such as personal and family beliefs, ease of access to and relationship with gatekeeper and 'need' including functional status and co-morbidity. Potential patient barriers to consultations with a gatekeeper and gatekeeper factors influencing referral to an orthopaedic surgeon are summarised in Table 2.

Table 2 Potential patient and gatekeeper barriers in the referral pathway to orthopaedic surgeons for OA knee

Potential patient barriers to consultations with a medical gatekeeper *	Factors likely to determine whether OA knee patients are referred to an orthopaedic specialist for TKR*
High prevalence of negative attitudes to OA and TKR Resignation to pain and disability Belief that joint pain is part of the normal ageing process Fear of painful examination and investigations Previous unsatisfactory experiences with doctors Previous bad experiences of relatives or friends Message that 'nothing can be done' from doctors Plausible options offered by alternative practitioners	Gatekeeper's ability to make a correct early diagnosis Experience, interests and seniority of the gatekeeper Severity of the problem Ability of gatekeeper to assess severity Attitude of gatekeeper towards TKR / orthopaedic surgery Relationship of gatekeeper with local surgeons Access to surgery Access to alternatives including physical therapy Presence or absence of referral guidelines Costs

**adapted from Dieppe et al [11].*

This report combined a systematic literature review with multidisciplinary consensus panels to appraise the evidence. Furthermore the consensus panels included primary care physicians and physiotherapists, in addition to the relevant hospital specialities, which enabled a perspective focused on the whole patient care pathway. Several gaps were highlighted within the current research evidence base; namely, a lack of simple tools to assess the severity and impact of OA knee, applicable to a community setting; there are no evidence-based indications for TKR and no studies, of sufficient quality or size, comparing the efficacy of TKR with that of non-surgical interventions. The consensus panels reported a concern that persistent negative attitudes to OA in general and towards TKR are widely prevalent amongst the public and primary health care professionals.

Hawker et al (1998) performed a US based cross sectional survey of a random sample of 1750 of 242,311 Medicare recipients, divided into three samples (a national and 2 regional groups) and then stratified by ethnicity, age, residence (urban or rural), and the year of the procedure [13]. This was the first large-scale community-based study of the outcome of knee replacement. The patients had undergone primary or revision knee replacement (unilateral or bilateral) between 1985 and 1989. The main outcome measures were a general health status measure, the Short Form-36 (SF36), the Western Ontario

and McMaster Universities Osteoarthritis Index (WOMAC) measure of knee pain and physical function and patient satisfaction two to seven years after the knee replacement. The self –administered questionnaire also asked for demographic information, to include age, gender, occupation, living status and co-morbidities. 1486 patients were eligible for inclusion in the survey and there was an 80.3% response rate, 71% of respondents were women, the mean age of respondents was 72.6 years. Satisfaction with knee replacement was high (85.2 %) and patients reported significant (p = 0.0001) persistent relief of pain and improved physical function two to seven years postoperatively. After adjustment for potential confounding variables, predictors of better physical function after the replacement were an absence of problems with the contra-lateral knee, primary knee replacement (rather than revision), and a lower body-mass index. Age did not have a negative impact on patient-relevant outcomes (pain and physical function). Obesity (BMI >32) was not a significant predictor of pain or the need for revision surgery up to 7 years after primary TKR [13]. The main limitation of this study was that baseline data were collected at the same time as current health status. Patients were asked to recall their knee symptoms and general health for the 4 weeks prior to surgery (up to 2-7 years previously). The second part of the survey asked about health status and knee symptoms in the previous 4 weeks to assess post-operative knee function. Therefore the changes in WOMAC and SF-36 scores were based on retrospective participant-recalled data.

Moran, in a BMJ editorial 'Knee Replacement, the joint of the decade', summarised the evidence of other large outcome studies, which have also confirmed that TKR results in a significant and sustained improvement in all dimensions of health, including pain, disability, well being and emotional status for the majority of patients who have the procedure, including older adults. Changes in surgical techniques have increased the life expectancy of knee joints to that comparable with hip replacements. Although TKR is one of the commonest surgical procedures in the UK, there is still a large unmet need [2;7]. There is also evidence from the population survey undertaken by Dixon et al (2004) that the 'inverse care law' may apply, since the most deprived fifth of the population experienced significantly lower rates of total hip replacement and TKR [8]

The 1996 Trent Regional five year study of the 1990 cohort outcomes of total hip replacement (THR) and TKR summarises referral and demographic data alongside outcomes of arthroplasty by orthopaedic unit and grade of surgeon across the region [14]. Arthroplasty rates varied between districts, from <0.2/1000 to 1/1000. Around 80% of these procedures were for knee OA, 18% for rheumatoid arthritis and 1-2% for other reasons (e.g. trauma). More women then men have total knee replacement (62% female, 38% male). The age range at time of knee replacement was 20 to 102 (mean 70 years). An overall increase in total knee replacements of around a third, between 1990 and 1994

reflects national trends for TKR. Patient satisfaction with TKR was reported at around 82% compared to 88% for total hip replacement (THR), a more established surgical procedure. A simple satisfaction tool was used; 'are you pleased?' with responses yes, unsure or no. This was compared to patient responses to the Nottingham generic health profile scores which demonstrated increased scores where the response was 'no', compared to scores within normal limits for those who responded yes. There were no statistical tests of significance reported with this comparative data. There was no significant difference in patient satisfaction relating to grade of surgeon. Analysis of patient satisfaction by volume of TKR, showed slightly higher satisfaction with surgeons who performed >30 TKR's per year, however no tests of statistical significance were provided. Lower satisfaction rates were reported for un-cemented knee and hip replacements.

The variation in referral rates could be related to proximity to orthopaedic units and cross boundary referrals out of Trent, longer waiting times in certain hospitals, or other secondary care factors not explored within the study. However, screening for symptom severity is not systematic in primary care and the variation in population rates of arthroplasty might also be influenced by local GP referral patterns [8],[14],[7]

1.4 NHS Policy

The NHS Plan emphasises the importance of cost-effective integrated 'whole patient care pathways' with near universal support for development of care closer to home and closer collaboration between multidisciplinary teams in primary and secondary care [15]. Despite the emphasis on providing care within the community, there is little evidence that schemes such as 'hospital at home', can reduce costs without adversely affecting quality or outcomes of treatment [16],[17],[18]. The NHS plan also emphasises the need for patient care pathways to be designed for conditions or client groups, rather than for organisations. Patient care pathways are well developed for certain conditions and patient groups e.g. national guidelines for stroke care, ischaemic heart disease, diabetes and cancer care, but have not been widely developed for knee osteoarthritis and total knee replacement [15],[2]. Central to the new NHS strategy is an increase in patient choice and health care capacity by plurality of service provision within NHS teaching hospitals, private and independent treatment centres (ITC's, formally known as diagnostic and treatment centres) [19]. This diversification of inpatient facilities may disrupt existing care pathways for knee replacement and alternative community models for physiotherapy rehabilitation will need to be developed if inpatient care is distant from a patient's home.

1.5 Definition, location, outcomes and costs of rehabilitation interventions

The Kings Fund research unit published two systematic reviews in1998, on behalf of the Audit Commission; 'Effective Practice in Rehabilitation' and 'Trends in Rehabilitation Policy'. These reviews highlighted the lack of high quality evidence assessing rehabilitation interventions [20],[21]. Most physiotherapy intervention studies were under-powered and have concentrated on a limited range of therapy outcome measures; measures of patient perceived health related quality of life, patient satisfaction and carer outcomes were rarely used. Previous studies have also focused on institutional provision of rehabilitation care and the potential of other settings in primary and community care were underdeveloped. Sinclair and Dickenson (1998) describe the inclusion of costing and health economics within outcome measures of rehabilitation studies in general, as 'very weak' [20].

The broad literature review demonstrated very few economic evaluations associated with physiotherapy interventions in the TKR or knee OA care pathways. All economic evaluations were of poor quality, with no statistical tests of significance or sensitivity analyses performed. Most studies used hospital length of stay as a proxy measurement for resource use and patient costs were not reported. Where costs were quoted to compare models of care, this was within the North American Health care system and comparisons with NHS resource use were not possible.

A lack of high quality evidence stifles innovation in service development and organisation thus it is difficult to determine how finite NHS rehabilitation resources should be used. A shift in NHS service development towards institutional provision of surgical procedures, with outreach and community based services may encourage the transfer of care from hospitals before assessment of effectiveness and comparative resource use occurs [18].

Community physiotherapists are increasingly closely integrated into the UK primary care team; many GP practices have on-site physiotherapy clinics and the same local team visiting practices usually provides the domiciliary physiotherapy visits. There is potential to extend physiotherapist roles to become the lead health care professionals in the management of musculoskeletal problems from presentation and treatment in primary care to screening orthopaedic referrals[22],[23],[24],[25]. Furthermore, there is a growing evidence base supporting exercise based physiotherapy treatments in primary care for knee osteoarthritis[26],[27],[28],[3]. Referral of knee OA patients to community physiotherapists is inconsistent and evidence based exercise treatments for OA knee are not widely available in primary care. Specialist orthopaedic physiotherapy rehabilitation usually takes place in hospital outpatient clinics or during in-patient episodes of care.

1.6 Consumer perspectives

Sanders (2004) conducted a qualitative, interview based study with 27 participants who had severe hip/knee pain and disability (according to New Zealand scores) to investigate barriers to treatment. Three types of barriers were identified: people's own perception of need and reluctance to seek treatment, perceptions and experiences of primary care and experiences of treatment in secondary care. Older adults were pessimistic about availability of treatments and were concerned about effectiveness and risks of surgery. This group were reluctant to seek medical help and their views were often reinforced by general practitioners and orthopaedic specialists [29].

Woolhead et al (2002) interviewed 25 patients three months before TKR to explore their views on who should have priority for TKR. In-depth, semi-structured interviews were conducted, recorded and transcribed. Data were independently analysed by three researchers using constant comparison methods. Common themes were identified and coded using Atlas.ti software. Descriptive accounts were discussed by the authors to check credibility (internal validity), plausibility (reliability) and clinical relevance of the findings. Participants thought that priority for TKR should be based on length and degree of suffering, pain severity, and immobility, paid employment, dependants and National Insurance contributions. However, they felt that actual prioritisation depended on age, weight, excessive complaining and access to private practice. Participants agreed with previously published consensus views of health professionals, namely that pain and disability are the most important criteria for the prioritisation of people for TKR [30].

Tallon et al (2000) reported a mismatch between the research agendas of the research community and the research consumer (patients and professionals) within a systematic review of the published and unpublished studies of interventions for the treatment of osteoarthritis of the knee joint [31]. Studies were searched to assess the structure of the evidence base demonstrating that it was 'massively' dominated by studies of pharmaceutical and surgical interventions. Physiotherapy and exercise treatments for osteoarthritis comprised 6% of all studies, 2% of which were commercially funded. Injected and oral drug treatments however were represented by 60% of all intervention studies evaluated and 89% of these studies were commercially funded. This paper further addressed the information needs of patient and professional consumers of research using patient surveys and professional focus groups. Patients favoured conservative treatments such as physiotherapy and complementary medicine and wanted more research on education and self-help. Physiotherapists were concerned about the relative dominance of

drug trials and wished physiotherapy research to be of higher quality and address clinically relevant questions.

1.7 Referral for total knee replacement: the Sheffield model:

The Sheffield model for referral of OA knee patients to a hospital specialist is a typical UK NHS referral pathway. There are no widely disseminated and agreed guidelines for assessment and referral of patients with OA knee to specialist services. The referral pathway and the overlap with primary care are presented in Figure 1.

Figure 1: The Sheffield model of referral and follow up for OA knee and TKR

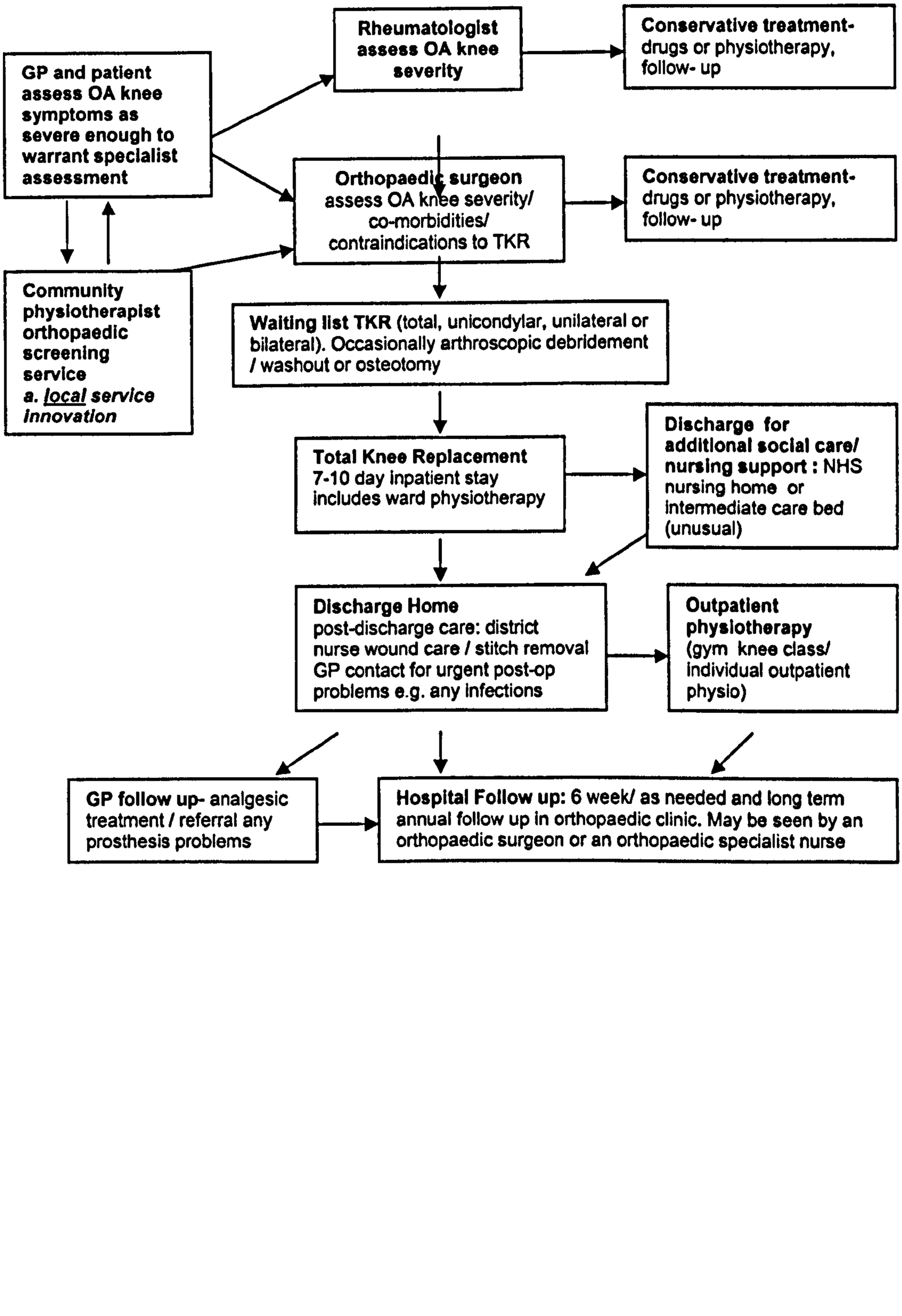
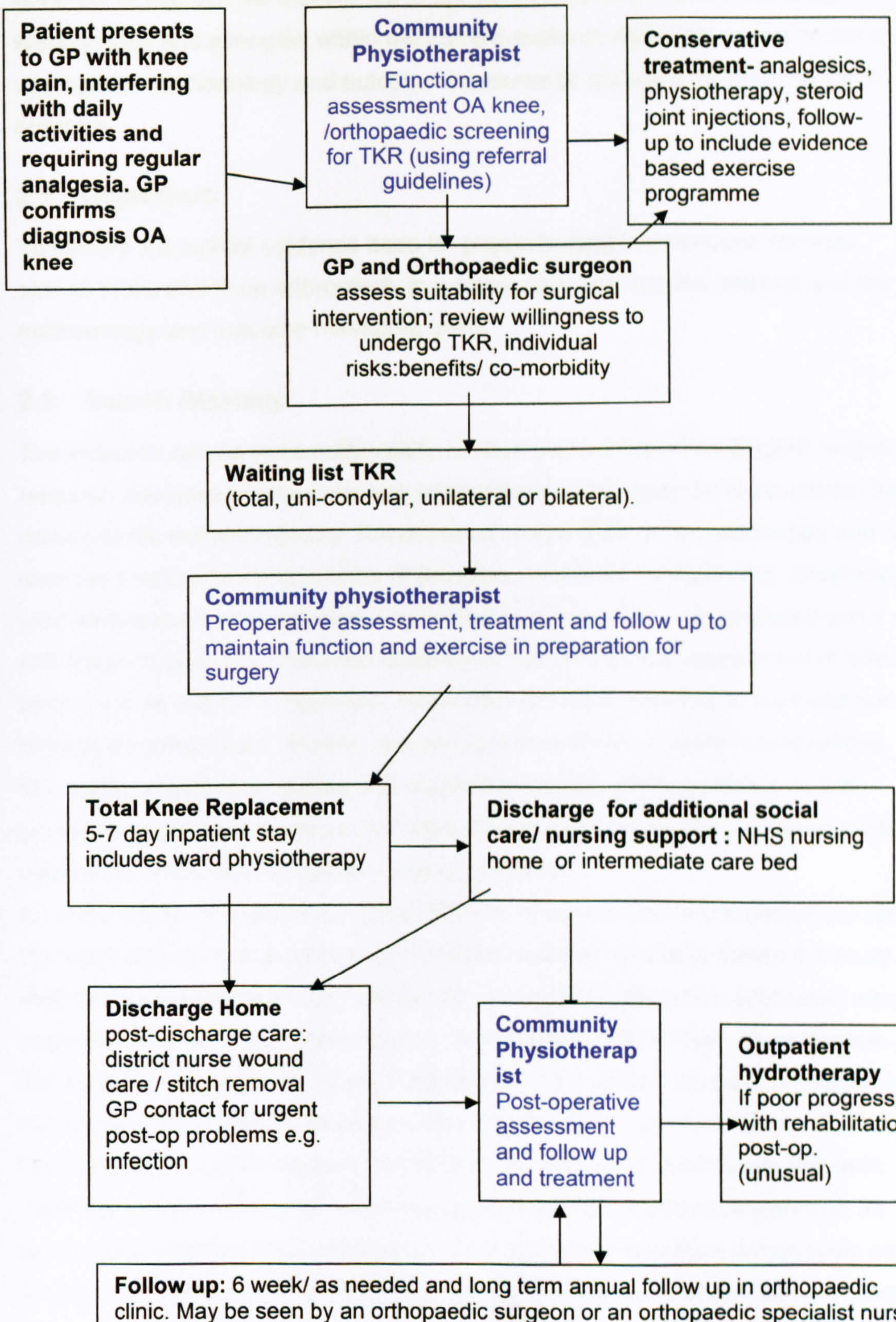


Figure 2 An alternative model for a care pathway for OA knee and TKR, incorporating community physiotherapist assessment and treatment:



2 THE LITERATURE REVIEW

A variety of sources were searched to critically appraise the published literature, identify gaps and strengths within the current research database, to define the most appropriate methodology and outcome measures to answer a focused research question.

2.1 Objectives

To identify the current evidence base for physiotherapy interventions for knee osteoarthritis and knee arthroplasty in primary care and hospital settings and the methodology and outcome measures used.

2.2 Search Strategy

The inclusion criteria were deliberately open to capture the entire English language research database of physiotherapy interventions (see appendix re keywords) for knee osteoarthritis and arthroplasty. Randomised clinical trials on physiotherapy and or exercise therapy for osteoarthritis of the knee, total knee replacement, rehabilitation for joint replacement were selected if treatment had been randomly allocated and if pain, self-reported disability, observed disability or patient's global assessment of effect had been used as outcome measures. Resources were not available to translate non-English language texts. Studies comparing resource use, economic evaluations, descriptive prevalence studies and qualitative studies, where participants had undergone total knee replacement, were also included to assess published evidence relevant to costs, service delivery and organisation.

An initial literature search in October 1998, was used to define the breadth of published literature and refine a search which could be repeated quarterly during the study. Three methods were used to identify articles for review. First, electronic databases were searched to identify published articles; Ovid Medline (1965-2004), Ovid Embase (1980-2004), BIDS Institute for scientific Information (1981-2004), Cinahl (Cumulative Index to nursing and Allied Health literature 1982-2004) and the Cochrane library. Second, the UK National Research register, the PEDro international physiotherapy research database and e-mail and personal discussions with an academic supervisor, an academic consultant rheumatologist and an academic consultant orthopaedic surgeon. Thirdly, a manual search of the bibliographies of review articles for relevant studies was performed. Reviews already known to me or identified by electronic searches were obtained and reference lists searched. All relevant articles were collated using a widely available electronic reference management system ('Reference Management 10' software package).

2.3 Data extraction

There were four stages of data extraction involving the assessment of eligibility, quality, study characteristics and study results.

Data were extracted from each study using a pre-defined protocol and data extraction form, which included:

- Research reference
- Population / Patient / Condition
- Study methodology
- Study treatment/ intervention
- Study outcome measures
- Comparison: standard practice/ any comparison
- Results

Early on in the literature search process, the paucity of high quality research in this area was apparent. Grey literature, descriptive case studies of teamwork and physiotherapy or educational interventions and audits were therefore also critically appraised to maximise knowledge and understanding of this area. These additional literature sources included examples of successful alternative models of service delivery and organisation and the design of complex physiotherapy interventions in the care pathway for total knee replacement. The studies, reviews and reports critically appraised are summarised in Table 3.

Table 3 Summary of physiotherapy and pre-operative intervention studies for TKR and knee osteoarthritis

Research reference	Population / Patient / Condition/ sample size	Study methods	Treatment/ Intervention	Outcome measures (OCM)	Comparison	Results	Limitations/ implications
[33] D'Lima et al 1996	North America, single centre (New York), 30 patients > 55 years, primary TKR for osteoarthritis (OA) n=25 or Rheumatoid arthritis (RA) n=5	RCT	Group 2 pre-operative physiotherapy (n=10) Group 3 cardiovascular conditioning programme (n=10)	Follow up at 3, 12, 24 and 48 weeks post-operatively Hospital for special Surgery Knee rating Arthritis Impact Measurement Scale Quality of Well Being instrument	Group 1 control (n=10)	No significant differences in length of hospital stay, pain or function at follow up points	Very small study, minimal demographic data to compare groups (age), single surgeon (? generalisability). No participant flow diagram OCM's not now considered to the most appropriate for assessment acknowledged by authors (WOMAC now usually recommended) No economic evaluation
[34]Weidenheim et al 1993	1993 Swedish single centre 39 knee osteoarthritis patients listed for unilateral total knee replacement	RCT	Hospital outpatient physiotherapy in groups of 3 to 4 (cycling, mobilty exercises, muscle strengthening) x3/ wk, total 15 sessions + home exercises. No data re post-operative physiotherapy received	Measured @ 3 months pre-op., pre-surgery, 3 months pre-op. No primary OCM defined Clinician assessment of: Pain (10 grade scale) Knee muscle strength (Cybex II dynamometer) Walking speed (peedometer) O2 cost of walking	No pre-operative physiotherapy No data re post-operative physiotherapy received	No significant differences in any of OCM's	Small sample No sample size calculation No economic evaluation Drew 'lots' for randomisation No data collection re post-operative physiotherapy No functional asessments Outcome measures all clinician derived No patient perceived HRQol or functional outcome measures No benefit of pre-operative physiotherapy if aim is increased muscle strength
[35] Turner et al 1999	63 TKR patients in 5 hospitals in England	Retrospective audit of physiotherapy notes	n/a	Quality and consistency of recording of- Initial assessment, problem and goal lists, discharge summary, treatment plan	n/a	Audit suggests that standard of recording is of poor quality for a range of treatment parameters	Research reference

Research reference	Population / Patient / Condition/ sample size	Study methodology	Treatment/ Intervention	Outcome measures (OCM)	Comparison	Results	Limitations/ implications
[36]Worland et al 1998	Single North American centre 114 primary TKR's in 91 osteoarthritis patients ; 23 bilateral TKR's, 68 unilateral TKR's	Prospective RCT	Same inpatient physiotherapy programme Post-discharge self administered home Continuous Passive Motion machine (CPR) + home exercises	Hospital for Special Surgery Scoring system (clinician assessment) Primary OCM: Knee Flexion / flexion contraction	PT group: Physiotherapist visits at home (x3 /week) for 2 weeks / home exercises	22 patients excluded 80 patients (103 TKR's) followed up at 2 weeks/ 6weeks/ 6 months No significant differences in primary OCM apart from increased flexion contraction at 2 weeks, not felt to be clinically significant by authors Costs lower per patient $286 (CPR) vs $558 (PT)	OCM's clinician derived No patient perceived HRQol[1] measures Well matched groups for patient characteristics Consistent surgical approach No flow diagram/ intention to treat analysis of data Contra lateral knee data excluded 'randomly' for bilateral TKR. Patient views re CPR sought Limited economic evaluation
[37]Rodgers et al 1998	Single centre, North America 20 osteoarthritis patients awaiting primary unilateral TKR	Prospective RCT	6 weeks pre-operative outpatient physiotherapy (n=10) + usual post-operative care (either home physiotherapy or inpatient rehabilitation)	Hospital for Special Surgery Scoring system + clinician assessment ROM[2], walking speed, thigh circumference, Cybex isokinetic testing (flexion / extension) Hospital length of stay No. of post-op. physiotherapy sessions	Control group- no pre-operative physiotherapy + usual post-operative care	Baseline and follow up data at 6 weeks & 3 months No difference in primary or secondary outcome measures, hospital stay or need for post-operative physiotherapy Patients felt pre-operative physiotherapy helpful	OCM's clinician derived No functional / patient perceived HRQol measures Small sample size / underpowered Limited comparison baseline patient characteristics (no co-morbidity) No flow diagram or intention to treat analysis Limited economic evaluation; no costs assessed

[1] HRQol : Health related quality of life measure
[2] ROM: range of movement

Research reference	Population / Patient / Condition/ sample size	Study methodology	Treatment/ Intervention	Outcome measures (OCM)	Comparison	Results	Limitations/ implications
[38]Leininger et al 1998	35 TKR patients in a single North American hospital	Before and after audit of TKR outcome data	Revised multidisciplinary home care pathway Included pre- and post-operative physiotherapy and functional home assessment	ROM Functional mobility	Retrospective data collection from a 'random' TKR patient group who had a previous home care pathway which involved post-operative team care only	Decreased length of hospital stay and decreased physiotherapy visits, improved function	Retrospective data collection Useful description of processes of care and team working North American health care system (differing roles of key health care professionals)
[39]Trousdale et al 1999	North America 266 patients from a large tertiary institution and a moderate sized group practice, 4 consultants, listed for hip or knee arthroplasty cx	Cross sectional survey	Hip or knee arthroplasty	Pre-operative concerns and anxiety 54 item survey specific questionnaire , visual analogue scale, concern ranked by mean responses(1 not concerned, 2 somewhat concerned,3 very concerned, 4extremely concerned)	Age Gender Knee or hip arthroplasty	Responses to 6 items scored 1.9 or>; pain after surgery (2.07), length of recovery (2.07), ability to walk as much as you wish (2.03), ability to return to recreational activities (1.97), ability to go up & down stairs (1.94), risk of getting AIDS form blood transfusion (1.92) Older patients (>65yrs) less concerned than younger patients.Women more concerned than men in 19/54 questions asked	No info. re exclusion criteria applied No questionnaire response rate or missing values reported No pilot study/ validation of questionnaire reported. Useful for design of pre-operative physiotherapy intervention.

Research reference	Population / Patient / Condition/ sample size	Study methodology	Treatment/ Intervention	Outcome measures (OCM)	Comparison	Results	Limitations/ implications
[28]1982 Chamberlain et al	42 Knee osteoarthritis patients referred to hospital outpatient physiotherapy Stabilised on analgesics for 3 weeks, intra-articular steroids Excluded patients unfit for exercise, more than 15 degrees fixed flexion	Prospective RCT Participants stratified by age (< 70yrs, >70yrs)	n=15 3 teaching sessions at outpatient physiotherapy dept., then self-directed exercise programme at home to increase strength & endurance of knee extension Loaned weights from dept.	'Physiotherapist assessments, 'blind' to treatment allocation, at 4,6 &12 weeks of: Pain Function ROM Maximum weight lift (MWL) Endurance Exercise diaries to record home activity	n=21 x3/ week for 4 weeks, short wave diathermy, followed by exercises in outpatients to be repeated x2 daily at home Loaned weights from dept.	13 patients withdrawn Home and hospital groups showed improvement and both treatments were equally effective. Monitoring of patient progress and adherence to exercise at home was important. Subgroup analysis of those who had a follow up appointment to assess progress showed significantly greater adherence to home exercises (and significantly reduced pain) compared to those not sent an appointment until 1 week prior to assessment.	No sample size calculation No description of method of randomisation Little data re baseline assessment patient characteristics such as co-morbidity. Less physiotherapy resources were needed for the home treatment group.
[40]1993 Scott,D. et al	UK 1993 Guidelines for the Diagnosis and Management of OA of the hip & Knee	Literature review & report of the Joint working group of the British Soceity for Rheumatology & the research unit of the Royal College of Physicians	n/a	n/a	n/a	Paucity of evidence relating to non-pharmacological interventions Exercise therapy recommended No significant advantage of NSAIDS over paracetamol	Working group almost exclusively academic physicians and surgeons, 1 occupational therapist and 1 GP. No physiotherapist Lack of pain/ functional assessments as OCM's Greater definition of progression of disease and factors/ interventions influencing this

Research reference	Population / Patient / Condition/ sample size	Study methodology	Treatment/ Intervention	Outcome measures (OCM)	Comparison	Results	Limitations/ implications
[26]1998 Van Baar et al	201 patients aged 40-85 years with hip or knee OA, primary care settings (4 centres),The Netherlands. Excluded: <30days symptoms, physiotherapy in<6months ago, ref. for THR or TKR	Prospective single blind RCT (participants and physiotherapists could not be blinded)	Primary Care usual treatment of education +/- medication and Exercise therapy from a primary care physiotherapist- 30 min sessions- to improve muscle strength, ROM, reduce pain and improve walking.	Measurements at baseline /12 weeks. Blinded researcher assessed- Primary OCMs: Pain in last week (Visual Analogue Scale), use of NSAIDS, video observed standardised tasks (adapted 'Keefe') Secondary OCM's; Pain at assessment (VAS), Pain & disability assessed by 'use of paracetamol, dynamometer muscle strength, goniometer measure of hip & knee ROM, Questionnaires: Influence of rheumatic disease on health & lifestyle' (IRGL), Fear Avoidance beliefs, rising/ sitting down	Primary care treatment of education +/- medication	POCM significantly improved in intervention group, compared to control (p<0.001)- medium effect on pain and small effect on observed disability. No effect on use of NSAIDS Secondary OCM's significantly improved overall for intervention group ((p<0.001)- beneficial effects on 2 further pain measures, reduction paracetamoll use and muscle strength of hip Increased GP consultations in control group (p=0.003), Mean no. of physiotherapy sessions = 16.8, compared to control (0.6). OCM's unaffected by site of OA	CONSORT standards for reporting achieved, high participant follow up despite high outcome measure burden. Well described and justified complex intervention designed to be easily replicated in other healthcare settings. High physiotherapy resource use- ? generalisable to NHS setting.

Research reference	Population / Patient / Condition/ sample size	Study methodology	Treatment/ Intervention	Outcome measures (OCM)	Comparison	Results	Limitations/ Implications
[41]1998 Daltry et al	North American, 8 orthopaedic surgeons, single teaching hospital 222 elderly patients undergoing total knee or hip arthroplasty. Broad inclusion criteria included RA & OA, bilateral and unilateral surgery.	Prospective RCT of two interventions , information and relaxation training, in a 2x2 factorial design. Participants stratified by joint (hip or knee) and age(18-70yrs, 71yrs+)	Information intervention (EI gp): 12 min. audiotape/ slide programme the day before surgery + a patient leaflet. Relaxation intervention (RI gp) – Benson's relaxation response. Day before surgery, provision of oral and written instructions with an 18 minute audiotape and tape player. Technique reinforced post-operatively Combined intervention (CI gp)- information followed by relaxation teaching.	Primary OCM length of stay to discharge or second surgery. Secondary OCM's were : Charted pain medication in 4 days after surgery. Speilbergers Anxiety inventory Mini-Mental State Exam. Post-operative complications Use of CPR machine Patient feedback Primary nurse / Physiotherapist feedback	Control group - no intervention	216 patients followed up, groups well balanced for baseline characteristics 99% adherence to information intervention protocol, with positive patient feedback 9% adherence to relaxation intervention protocol; patients did not have time to become familiar with the technique or practice it usefully- this group of patients excluded from the final analysis. Study sample as a whole, information intervention did not improve primary OCM.	RI gp- only 9% adhered to the Rx protocol and this did not influence post-op OCM;s EI had no effect on post-op. or length of stay for the whole group. The EI reduced length of stay and pain medication use for patients who exhibited most denial (tendency to avoid thinking about unpleasant events) and pain medication and reduced post-operative anxiety and cognitive errors on the MMSE for patients with least baseline anxiety. Good e.g. RCT assessment of a complex intervention for TKR patients, CONSORT standards for reporting mainly reached (lbut no flow diagram) Useful in the design of a pre- and post-operative intervention for TKR
[1]Brazier et al (1996) and 1999[1]	118 knee osteoarthritis patients on a single hospital (UK) waiting list for TKR	Comparison of patient-perceived health status using 4 different measures and the surgery outcome	TKR	Patient-perceived Condition-specific: WOMAC & HAQ Generic: SF36, Euroqol	112 knee osteoarthritis patients, rheumatology outpatients	WOMAC is the instrument of choice for measuring outcome after TKR, supplemented by the generic SF36	Large sample size study, good questionnaire response rates (83%), control group all hospital outpatients/ no primary care group, guidance re appropriate OCM's for knee OA interventions

Research reference	Population / Patient / Condition/ sample size	Study methodology	Treatment/ Intervention	Outcome measures (OCM)	Comparison	Results	Limitations/ implications
[42]Chard et al (2000)	n/a	Systematic literature search to examine the epidemiology of research base for interventions for OA knee Study aim to assess published research base for OA knee & identify areas for further research	n/a	Study treatment Justification for study Methodology Statistics Conclusions Funding source & year of publication	n/a	930 articles analysed Rapid growth overall in OA knee research 1964-1995 of interventions assessed, Drug & surgical >84%, physiotherapy 6.5% 1995-1998 71% drug & surgical interventions, 14.1% exercise interventions 94% reported 'support' for studied intervention	Review demonstrates commercial, researcher % publication bias in the OA knee evidence base Research needed in 3 areas: Conservative vs surgical interventions, interventions appropriate to different stages of disease process, more RCT evidence in non-drug interventions
[27]1998 O'Reilly et al	191 people with knee pain aged 40 to 80 years, from 2 general practices in Nottingham Excluded inflammatory arthropathy, previous TKR, serious surgery, refered pain from back or hip	Prospective RCT Block randomisation, stratified by 4 age bands	Exercise group: strengthening graded exercise programme, daily for 6 months n= 113	Measurements at baseline and at 6 months Primary OCM – change in WOMAC knee pain score Secondary OCM's included visual analogue scales (VAS) for pain on stairs and walking, WOMAC physical functioning scores, clinician observed isometric quadriceps strength and activation SF36 Hospital Anxiety & Depression scale Weight Self reported analgesic usage per day	Control group, no intervention, n= 78	At a significance level <0.05, WOMAC pain score significantly reduced by 22.5% in the exercise group and by 6.2% in the control group VAS scores significantly reduced in exercise group, WOMAC physical function scores were significantly reduced by 17.4% in the exercise group and were unchanged in the control groups	CONSORT standards for reporting achieved Well matched groups for baseline characteristics A power of 80% was not achieved as the SD was wider than in previous hospital trials. More marked improvements in pain and strength (except total pain score), the closer the self reported adherence to home exercise in the intervention group. 70% of patients completed 75% of the programme. Simple programme of quadriceps exercises significantly improved self reported knee pain and function.
[40]1993 Scott,D. et al	UK 1993 Guidelines for the Diagnosis and Management of OA of the hip & Knee	Literature review & report of the Joint working group of the British Soceity for Rheumatology & the research unit of the Royal College of Physicians	n/a	n/a	n/a	Paucity of evidence relating to non-pharmacological interventions Exercise therapy recommended No significant advantage of NSAIDS over paracetamol	Working group academic physicians and surgeons, 1 occupational therapist and 1 GP. No physiotherapist Lack of pain/ functional assessments as OCM's Greater definition of progression of disease and factors/ interventions influencing this

2.4 Physiotherapy Interventions for TKR

D'Lima et al (1996) recruited 30 patients awaiting TKR (25 with OA knee, 5 with Rheumatoid arthritis) in a single centre US study [33]. Patients were randomised to a control group 1 who received no pre-operative physiotherapy intervention (usual care) for TKR or one of two intervention groups (groups 2 and 3). Group 2 received a pre-operative physiotherapy programme; group 3 received a pre-operative cardiovascular conditioning programme. The TKR was performed by the same surgeon and each group received the same post-operative physiotherapy programme. Primary outcome measures were the 'Hospital for special surgery knee rating Arthritis Impact Measurement Scale' and a 'Quality of Well Being' instrument. A secondary outcome measure was length of hospital stay. Participant follow up was at 3, 12, 24 and 48 weeks post-operatively. This was a poor quality small study with minimum baseline demographic data to compare groups and insufficient explanation of statistical analysis (particularly since repeated measurements were made). Generalisablity was limited by single centre/ single surgeon recruitment and there was no participant flow diagram or economic evaluation. The authors acknowledged that the outcome measures used for assessment had been superseded by WOMAC, as the 'instrument of choice'.

In 1993, Weidenheim et al recruited 39 participants with knee osteoarthritis, awaiting unilateral TKR from a single Swedish centre[34]. Participants were randomised by 'drawing lots' into a control , usual care group who received no pre-operative physiotherapy and an intervention group who received pre-operative hospital outpatient physiotherapy in groups of three or four (cycling, mobility exercises, muscle strengthening) three times per wk (total 15 sessions) and home exercises. There was no data available comparing post-operative care between groups. There was no defined primary outcome measure from which a sample size had been calculated. All outcomes measures were clinician derived namely assessment of: pain (10 grade scale), knee muscle, strength (Cybex II dynamometer), walking speed (pedometer) and oxygen cost of walking. There was no significant difference or changes in outcome measures were at 3 months pre-operative, immediately pre-surgery and 3 months post-operative. This was a poor quality trial with inadequate statistical information provided and inappropriate randomisation technique. Pre-operative physiotherapy did not increase muscle strength.

Worland et al (1998) recruited 91 osteoarthritis patients undergoing 114 primary TKR's from a single North American centre (23 bilateral TKR's, 68 unilateral TKR's) to a prospective RCT [36]. The control physiotherapy group had usual care which comprised physiotherapist visits at home (three times per week) for 2 weeks and home exercises.

The intervention group had the same inpatient physiotherapy programme but post-discharge self administered the home Continuous Passive Motion machine (CPR) supplemented by home exercises. The primary outcome measures were knee flexion / flexion contraction and the Hospital for Special Surgery Scoring system (clinician assessment) with follow up at 2 weeks, 6 weeks and 6 months. Groups were well matched for patient characteristics but there was no flow diagram or intention to treat analysis of data There were no significant differences in outcome measures apart from increased flexion contraction at 2 weeks (clinically insignificant). Although costs were lower per patient $286 (continuous passive motion) vs. $558 (physiotherapy), this study was small and no sensitivity analysis or statistical tests of significance were reported for the economic evaluation.

Rodgers et al (1998) recruited 20 knee OA patients awaiting primary unilateral TKR from a single centre in North America to a prospective RCT [37]. The control group (n=10) received no pre-operative physiotherapy (usual care). The intervention group received 6 weeks pre-operative outpatient physiotherapy (n=10). Both groups received usual post-operative care (either home physiotherapy or inpatient rehabilitation). The clinician derived outcome measures were the Hospital for Special Surgery Scoring system, clinician assessment of range of movement, walking speed, thigh circumference, Cybex isokinetic testing (flexion / extension), hospital length of stay and number of post-operative physiotherapy sessions. Follow up at 6 weeks and 3 months showed no difference in primary or secondary outcome measures, hospital stay or need for post-operative physiotherapy. Patients felt that pre-operative physiotherapy was helpful. This study was of limited value since it was underpowered, there were inadequate baseline patient demographic data (no co-morbidity) and there was neither a flow diagram nor intention to treat analysis of follow up data. There was no economic evaluation.

Two published clinical audits were identified. Leininger (1998) described the development of a multidisciplinary team in a single US centre, providing an integrated home care pathway for TKR[38]. This new care pathway included pre- and post-operative physiotherapy and functional home assessment. Retrospective outcome data were collected from a random group of TKR patients who received the preceding care pathway, which involved post-operative care only. This study demonstrated a promising trend in reduced length of hospital stay and the reduction of total physical therapy visits after a pre-operative education and physiotherapy visit was introduced, but only 18 patients were involved in the new care pathway arm of the study. Despite methodological shortcomings which meant that the significance of these findings could not be determined or generalised, the study provided useful insight into the processes of home care and multidisciplinary team working

in a different healthcare system. Turner et al (1999), in a retrospective audit of 63 TKR patient physiotherapy notes in 5 UK hospitals suggested that the quality of recording is of poor quality and consistency for a range of treatment parameters (initial assessment, problem and goal lists, discharge summary and treatment plan) [35]. This was a useful reference for quality standard setting in the design of a physiotherapy intervention for TKR.

2.5 Physiotherapy Interventions for Knee Osteoarthritis

Interventions for knee OA alone were reviewed where a new complex home physiotherapy intervention had been assessed by RCT, where home and hospital physiotherapy settings for OA knee were compared and to compare outcome measures and effect sizes (disease specific and generic) for interventions for knee OA. In contrast to research publications of physiotherapy interventions in the TKR care pathway; studies were of much higher quality. Overall, sample sizes were larger and in two studies, CONSORT standards for reporting of RCT results were achieved[43;44]. These two studies provided physiotherapy treatment in patients own homes, there was a high adherence to the treatment protocol and patient perceived health related quality of life measures (HRQol) were used in addition to clinician observed outcome measures.

Van Baar et al (1998) recruited 201 patients aged 40-85 years with hip or knee OA, from four primary care centres in the Netherlands, to a prospective single blind RCT. People with less than 30 days of symptoms, physiotherapy in the preceding 6 months or referral for THR or TKR were excluded[26]. The control group received primary care treatment of education with or without medication (usual care). A control group received exercise therapy from a primary care physiotherapist; 30 minute sessions to improve muscle strength, ROM, reduce pain and improve walking. Follow up of baseline assessments was at 12 weeks post-completion of the intervention. Primary outcome measures were pain in last week (Visual Analogue Scale), use of NSAIDS, video observed standardised tasks (adapted 'Keefe') There were an extensive range of secondary outcome measures; pain at assessment (VAS), pain & disability assessed by 'use of paracetamol, dynamometer muscle strength, goniometer measure of hip & knee ROM, and three patient questionnaires ('Influence of rheumatic disease on health & lifestyle' (IRGL), 'Fear Avoidance beliefs', 'Rising/ sitting down'). The primary outcome measure significantly improved in the intervention group, compared to the control group ($p<0.001$). There was a medium effect on pain, a small effect on observed disability and no effect on the use of NSAIDS. Secondary outcome measures significantly improved overall for the intervention group (($p<0.001$); there were

beneficial effects on 2 further pain measures, a reduction in paracetamol use and fewer GP consultations than in the control group (p=0.003). The mean number of physiotherapy sessions was 16.8, compared to the control group (0.6). The outcome measures were unaffected by the site of OA. CONSORT standards for reporting were achieved and there was high participant follow up despite a heavy patient outcome measure burden. This was a well defined complex intervention, designed to be easily replicated in other healthcare settings. However, in view of the intensive physiotherapy resource use involved in the programme, this may well not be generalisable to an NHS setting.

O'Reilly et al (1998) recruited 191 people with knee pain aged 40 to 80 years, from 2 general practices in Nottingham to a prospective RCT evaluating a physiotherapy exercise intervention, with six month follow up [27]. People were excluded if there was evidence of inflammatory arthritis, previous TKR, serious surgery or referred pain from their back or hip(s). Participants were allocated by block randomisation, stratified by 4 age bands. The control group received no intervention (n= 78), the exercise group performed a strengthening graded exercise programme daily for 6 months, taught and followed up by a physiotherapist (n= 113). The primary outcome measure was the change in WOMAC (Western Ontario and McMaster University Osteoarthritis Index), knee pain score, a disease specific patient perceived health outcome measure. Secondary outcome measures included visual analogue scales (VAS) for pain on stairs and walking, WOMAC physical functioning scores, clinician observed isometric quadriceps strength and activation, Hospital Anxiety & Depression scale, elf reported analgesic usage per day, weight and SF36. This simple home programme of quadriceps exercises, taught by a physiotherapist, significantly improved self reported knee pain and function. The closer the self reported adherence to home exercise in the intervention group the more marked the improvements in pain and strength (except total pain score); 70% of patients completed 75% of the programme. However, a power of 80% was not achieved as the standard deviation was wider than in previous hospital trials.

2.6 Qualitative studies

Campbell et al (2003) reported a qualitative study 'nested' within a randomised controlled trial evaluating a physiotherapy intervention for OA knee[45]. The primary quantitative outcome measure for the study was the WOMAC. The WOMAC outcome measure was developed using qualitative interview methodology and the validity and reliability of the questionnaire has been rigorously assessed in North America[46;47]. The

WOMAC index is designed as a self-completion questionnaire, and is currently the most commonly used outcome measure internationally for studies assessing treatments for OA knee[48]. In the randomised controlled trial reported, the WOMAC questionnaire was administered in an outpatient setting, by a clinician who also recorded objective examination assessments of outcome. A maximum variety, purposive sample of respondents was then approached to participate in a qualitative interview study to explore the impact of knee osteoarthritis on pain and disability for individuals and their views about the treatment processes. The authors describe a significant difference between expression and description of pain and disability between individual responses to WOMAC and soon after within an interview setting in their own home. Individuals had tended to minimise their symptoms when asked closed WOMAC questions by the clinician. The authors suggest that clinician face-to-face administration of WOMAC in a healthcare setting could introduce bias. Conversely, there is a danger in interpreting individual responses to an outcome measure designed to assess group outcomes.

Daltry et al (1998) conducted a prospective randomised controlled trial of three interventions, relaxation training, educational information and individual relaxation training and an educational information intervention in a 2x2 factorial design with a control group with no intervention[41]. Broad inclusion criteria included RA & OA, bilateral and unilateral surgery. The relaxation intervention (RI) used the technique 'Benson's relaxation response'. The educational intervention (EI) was the provision of oral and written instructions with an 18 minute audiotape and tape player, the day before surgery. A combined intervention (CI) provided information followed by relaxation teaching. The relaxation technique was reinforced post-operatively. Patient, primary nurse and physiotherapist feedback data were collected as well as quantitative outcome data. 216/222 patients were followed up with 99% adherence to the information intervention protocol, with positive patient feedback. However there was only 9% adherence to the relaxation intervention protocol since patients did not have time to become familiar with the technique or practice it usefully, nor was there sufficient health professional time to support the intervention; this group of patients was excluded from the final analysis. The incorporation of patient and health professional feedback within the study design illuminated strengths and potential weaknesses in the design of randomised controlled trials evaluating complex interventions for TKR patients and, of course, the importance of the pilot phase.

2.7 The Evidence Gap

The process of structured critical appraisal of the evidence outlined above was used to identify the evidence gap, refine the research question, define primary and secondary outcome measures and design the research study and define a complex home physiotherapy intervention.

In summary;

- Three randomised controlled trials were identified which assessed the impact of pre-operative physiotherapy on TKR. A fourth study assessed a post-operative home CPR machine and exercise treatment schedule as an alternative to post-operative hospital outpatient physiotherapy.
- No studies had been published assessing a physiotherapy intervention in the NHS care pathway for TKR. All studies were based in different healthcare settings to the NHS (either North America or Sweden), most were hospital based interventions.
- The four clinical trials identified would not fulfil current CONSORT standards for publication (Consolidation of Standards for Reporting Trials) [43],[44]. Methodological flaws included a lack of participant flow diagram, no blinded outcome assessment, insufficient power (very small sample sizes and often no power calculation made) and clinician reported outcome measures rather than patient perceived health status and health related quality of life.
- There were no economic evaluations comparing physiotherapy interventions for TKR or knee osteoarthritis.

Qualitative studies evaluating physiotherapy care were of poor quality.

3 THE RESEARCH QUESTION

A well- defined research question allows the generation of a research hypothesis and aims and objectives for the research. The researcher then defines concepts and indicators, identifies the population of potential participants, designs the study and determines the method of statistical analysis to achieve the aims and objectives of the study. The systematic literature review confirmed a gap in published evidence about pre- and post-operative physiotherapy for TKR, which is addressed by the following research questions:

3.1 The Research Questions

1) Does pre- and post-operative home assessment and treatment by a community physiotherapist improve patient outcome after unilateral TKR for people with knee OA, compared to usual post-operative hospital out-patient physiotherapy care alone?
The Independent variables are pre-and post-operative home physiotherapy and post-operative hospital outpatient physiotherapy. The Dependent variable is patient outcome after TKR

2) Is pre and post -operative physiotherapy at home more cost-effective than usual hospital outpatient post-operative physiotherapy for OA patients having unilateral total knee replacement?
The Independent variables are pre-and post-operative home physiotherapy and post-operative hospital outpatient physiotherapy. The Dependent variable is cost-effectiveness after TKR

3) Does pre and post -operative physiotherapy at home increase patient satisfaction after TKR compared to usual hospital outpatient post-operative physiotherapy?
The Independent variables are pre-and post-operative home physiotherapy and post-operative hospital outpatient physiotherapy. The Dependent variable is patient satisfaction after TKR

3.2 The Research hypothesis

The research hypotheses are:

- Pre- and post-operative physiotherapy at home improves patient outcomes following TKR when compared with patient outcomes after usual post-operative physiotherapy in the hospital outpatient clinic following TKR.

- Pre- and post-operative home physiotherapy for unilateral TKR is a cost effective and acceptable model of physiotherapy for TKR when compared with usual post-operative physiotherapy in the hospital outpatient clinic.

3.3 The Null hypothesis

The null hypothesis is:

- There is no difference in patient outcomes and cost outcomes, after unilateral TKR, between a group of OA knee patients receiving pre- and post-operative physiotherapy at home and a group of patients receiving usual hospital outpatient physiotherapy post-operatively only for TKR.

3.4 Concepts and operationalising the hypothesis

3.4.1 Concepts

A concept is a mental construct, an abstraction from an event or aspect of the world around us identified early in the research process from the research question. Concepts are further defined to enable the researcher to identify indicators, which represent these concepts in the real world. The definitions of the concepts generated by the research hypothesis for this study, are summarised in Table 4.

Table 4 The definition of concepts

Concept	Definition
Pre-operative physiotherapy	Pre-operative physiotherapy treatment schedule for TKR
Post-operative physiotherapy at home	Post-operative physiotherapy schedule at home after hospital discharge following TKR
Post-operative physiotherapy in a hospital outpatient clinic	Usual post-operative physiotherapy schedule in hospital outpatient clinic after hospital discharge following TKR.
Home care	Treatment provided to individual TKR patients in their own home, by a community physiotherapist
Hospital outpatient care	Treatment provided to individual or groups of TKR patients in the hospital outpatient clinic, by an orthopaedic hospital physiotherapist
Patient outcomes after TKR	Pain, stiffness and function of the affected knee joint Health related quality of life Post-operative complications and morbidity Patient satisfaction
Costs	NHS resources consumed by patient care Patients' and carers personal costs associated with treatment

3.5 Indicators and the Index

3.5.1 Indicators

Indicators indicate concepts; other terms which are used include *measures*, which attach a value to the indicators of concepts or *operations* which generate data which the researcher is satisfied reflect the concept. The process of turning concepts into indicators is known as operationalization. The indicators used for the concepts are summarised in Table 5.

Table 5 The Index

Concept	Indicator
Pre-operative physiotherapy	A complex intervention, designed by the research team, which defines the pre-operative physiotherapy treatment schedule for TKR (see appendix)
	Number and length of treatment sessions
	Number and length of telephone contacts
	Grade of physiotherapist
Post-operative physiotherapy at home	A complex intervention, designed by the research team, which defines the post-operative physiotherapy schedule at home after hospital discharge following TKR (see appendix)
	Number and length of treatment sessions
	Number and length of telephone contacts
	Grade of physiotherapist
	Referral to hydrotherapy
Post-operative physiotherapy in hospital outpatient clinic	Usual post-operative physiotherapy schedule in hospital outpatient clinic after hospital discharge following TKR, described by the research team (see appendix)
	Group treatment sessions
	Individual treatment sessions
	Number and length of treatment sessions
	Grade of physiotherapist
	Referral to hydrotherapy
Home care	Record of deviation from treatment protocol for site of treatment
Hospital outpatient care	Record of deviation from treatment protocol for site of treatment

Concept	Indicator
Patient outcomes after TKR	Pain, stiffness and function of the affected knee joint: Validated osteoarthritis specific health outcome measure
	Health related quality of life: validated general health outcome measure
	Post-operative joint complications; infections, readmission to manipulate joint,
	Change in severity of or new co-morbidity e.g.pulmonary embolus, respiratory or cardiac problems
	Patient satisfaction questionnaire
Costs	NHS resources consumed by patient care:
	Physiotherapy & hospital data collection forms , patient survey questionnaire
	Number, site and timing of physiotherapy sessions, grade of physiotherapist; define prices and cost per patient for physiotherapy sessions in the community and hospital settings to the defined end point of rehabilitation according to the discharge criteria or at 12 weeks.
	Number and cost of hydrotherapy sessions
	No. of out-patient orthopaedic consultations pre- and post-operatively (in-patient and out-patient)
	Transport costs per patient ambulance/ medicar
	No. of GP consultations pre- and post-operatively
	Other primary care resource use (analgesic prescribing, practice or district nurse attendance).
	Patients' and carers personal costs associated with treatment: patient questionnaire
	Patient transport costs (includes parking)
	Distance travelled
	Any other reported patient or carer costs

3.6 Confounding variables

The literature review demonstrated a number of independent variables that cannot be controlled for (without restricting participation so much that results could not be generalised) but may influence outcome after TKR. These confounding variables, such as co-morbidity also may affect the osteoarthritis specific health status and health related quality of life measures. A prospective study design, which randomly allocates participants to control and intervention groups, ensures that any confounding variables equally influence both groups, providing the sample size is large. The usual practice is to measure these important patient characteristics at baseline and at follow up, since statistical tests can be used to assess whether the two treatment groups are well matched, i.e. do not differ significantly from each other apart from the intervention being assessed. Such pre-defined important patient characteristics should also be compared for eligible patients who do not consent to participate in the study and for participants who withdraw from the study. This is to ensure that the participant population does not differ significantly from the eligible population of patients, for whom the study results should be generalisable. Data collection for the following confounding variables is also incorporated into the study methodology (Table 6).

Table 6 Summary of confounding variables

Age at surgery	Patient co-morbidity:
Length of wait for surgery	cereberovascular disease
Gender	ischaemic heart disease
BMI	chronic obstructive airway disease
Lives alone	diabetes
Consultant code	'other' significant health problem

4 RESEARCH METHODS

4.1 What is the most appropriate methodology to evaluate a physiotherapy intervention for TKR?

Health services research aims to determine whether a treatment is effective and also to estimate the benefits and costs of providing a new treatment or implementing a new policy or care pathway. Benefits and costs are a measure of the impact of a new treatment from clinical, health service, social and economic perspectives. Evidence based health care uses information from clinical trials, non-experimental observational studies and qualitative studies, ideally with input from a broad range of academic and clinical disciplines[16]. The choice of methodology for this study was determined by critical appraisal of the methodology and outcomes of relevant studies identified by the literature review and the purposive rejection of methodologies unsuitable to answer the research questions:

1. Does pre- and post-operative home assessment and treatment by a community physiotherapist improve patient outcome after unilateral TKR for people with knee OA, compared to usual post-operative hospital out-patient physiotherapy care alone?
2. Is pre and post -operative physiotherapy at home more cost-effective than usual hospital outpatient post-operative physiotherapy for OA patients having unilateral total knee replacement?
3. Does pre and post -operative physiotherapy at home increase patient satisfaction after TKR compared to usual hospital outpatient post-operative physiotherapy?

4.1.1 Meta-Analysis

Meta-Analysis is the quantitative synthesis of the results of a systematic review of previous studies. All the available evidence on a particular research question is collated and analysed in a systematic way. The validity of the method depends on an unbiased and systematic selection of previous studies conducted within a specific research area. However publication, citation and funding bias mean that positive results are more likely to be published and cited by other researchers. Chard et al (2000) analysed 930 articles reporting research about knee osteoarthritis. This systematic review demonstrated that 94% of studies reported support for the studied intervention (publication bias) and 71% of studies reported drug & surgical interventions, suggesting both researcher and commercial bias[42] In the area of physiotherapy for TKR there is such a paucity of high quality evidence

and a wide variety of outcome measures, that this methodology is currently unsuitable to answer these research questions.

The research methodologies summarised below, were considered the most appropriate and feasible to answer the three research questions.

4.1.2 Randomised controlled trials

Randomised controlled trials are the 'gold standard' of evidence-based medicine[16;49,50].

The Randomised controlled trial is a prospective study design, which randomly allocates participants to control and intervention groups, ensuring that any confounding variables equally influence both groups, providing the sample size is large. Thus if an adequately powered study detects an important difference between an intervention and a 'usual' care treatment group, this difference can be attributed to the impact of the intervention.
Randomisation is a process of treatment allocation applied to a whole target population of people who fulfil the eligibility criteria for the study (e.g. OA knee, listed for unilateral knee replacement) and who consent to participate. The allocation of treatment is entirely by chance, usually using a computer generated random allocation sequence which ensures similar numbers in each treatment group, but does not allow researchers to predict which group a person will be allocated to when they consent to the study. The study is protected from researcher bias by concealing treatment allocation e.g. by sequential opening of sealed envelopes containing the randomised treatment code or by using an independent telephone randomisation service[51;52].
Data should be collected, describing reasons for exclusion and characteristics (e.g. age, gender) of people who withdraw from the study or who fail to consent to participation in order to determine both the generalisability of the results and the acceptability of the treatment allocation to the total population. Thus, a high participation rate, a low withdrawal rate and participants with similar characteristics to the total population reflect a study and intervention whose findings are likely to be more generally applicable and acceptable if repeated elsewhere. All potential participants from the total population of eligible individuals are approached for this study design, unlike a large random sample of a target population whereby important variation in patient characteristics within the random sample reflects the variation of these characteristics (or confounding variables) within the whole target population. The CONSORT guidelines for the reporting of randomised controlled trials reflect internationally agreed quality assessment criteria for Randomised controlled trials and provide a series of headings used to guide the research protocol and disseminate results [43],[44].

A randomised controlled trial was chosen as the most robust and appropriate methodology to answer this research question and was also feasible within the timescale and the research resources available. However, some limitations are recognised with this method, namely, randomised controlled trials do not easily assess long-term outcomes or rare events and there may be ethical difficulties in identifying a control group and concealing treatment allocation for non-pharmaceutical interventions[16,52].

4.1.3 Qualitative methodology

Qualitative methodology is used to explore the reasons why individuals or organisations behave as they do. This method is most appropriate if the objective of a study is to explore, interpret or obtain a deeper understanding of a health care issue. Observational techniques, focus groups, individual in-depth interviews are all techniques used widely. Qualitative methodology is the usual starting point in the development of quantitative patient perceived health outcome measures, where interviews with people with or without illness, explore how health and ill-health affect individuals. These processes can operationalise concepts such as quality of life[53;54].

Quantitative methodologies may be criticised for an overly superficial approach whereas qualitative methodology always involves relatively small numbers of participants and may be criticised as less 'scientific', more subject to researcher bias and of producing findings less easily generalised to other health care settings. However, the use of a true theoretical sampling framework increases the generalisability of results over a convenience sample [53]. The rigour of qualitative research, as with quantitative research, may also be assessed by published guidelines[54;55] although the field of critical appraisal of qualitative literature is controversial[56;56]. The studies identified in the literature review (Chapter 2) would not fulfil current criteria for the conduct and reporting of health services qualitative research, with the exception of Woolhead et al (2002) who conducted a study of the views of respondents awaiting TKR about eligibility for TKR (Table 3) [30] .

Laboratory work usually defines how a drug treatment works before a RCT assesses clinical effectiveness of a pharmaceutical intervention. The RCT evaluation of complex interventions, for example packages of rehabilitation care, may demonstrate effectiveness but not explain why the intervention has worked from patient, carer and other stakeholder perspectives. The factors influencing positive and negative outcomes can be monitored and described by a parallel observational qualitative approach. Qualitative studies 'nested' within randomised controlled trials can illuminate the processes determining how a complex intervention works and why, thereby increasing the generalisablity of the results to other health care settings[57]. Qualitative methodology would usefully complement

quantitative outcome measures in the proposed study by exploring patient, carer and professional perspectives about the processes of physiotherapy rehabilitation care for TKR e.g. location and intensity of physiotherapy rehabilitation, the logistics of service delivery and to invite feedback about the overall care pathway for TKR from consumers and professional stakeholders.

4.1.4 Economic evaluation

Increasingly health service commissioners, research-funding organisations and peer reviewed journals expect an assessment of costs and benefits to be provided alongside clinical outcome data [58]. Rationing, prioritisation and control of costs are important in all health care systems especially as new technologies and drugs are introduced and consumer expectations of services change. An economic evaluation considers not only the costs of a treatment but also the opportunity costs of selecting one treatment or one patient group over another to inform health policy makers.

4.1.5 The research design

The research question identified is concerned with quantity primarily in that the impact of a new technology on patient outcomes after TKR is to be assessed. The study is experimental as the home physiotherapy intervention can be defined and outcomes of an intervention group can be compared to a 'control' group of participants. There is no need to control for a pre-test and nor can all groups be exposed to both an intervention and control treatment. Therefore, the most appropriate study design is a parallel randomised controlled trial. This study is an open design, since it would not be possible to conceal treatment allocation from either participants or health professionals as in a double-blind trial. However, it is possible to conceal treatment allocation to the researcher at the point of statistical analysis of the primary outcome measure by providing anonymised coded data for example describing data outputs only as group 1 and group 2.

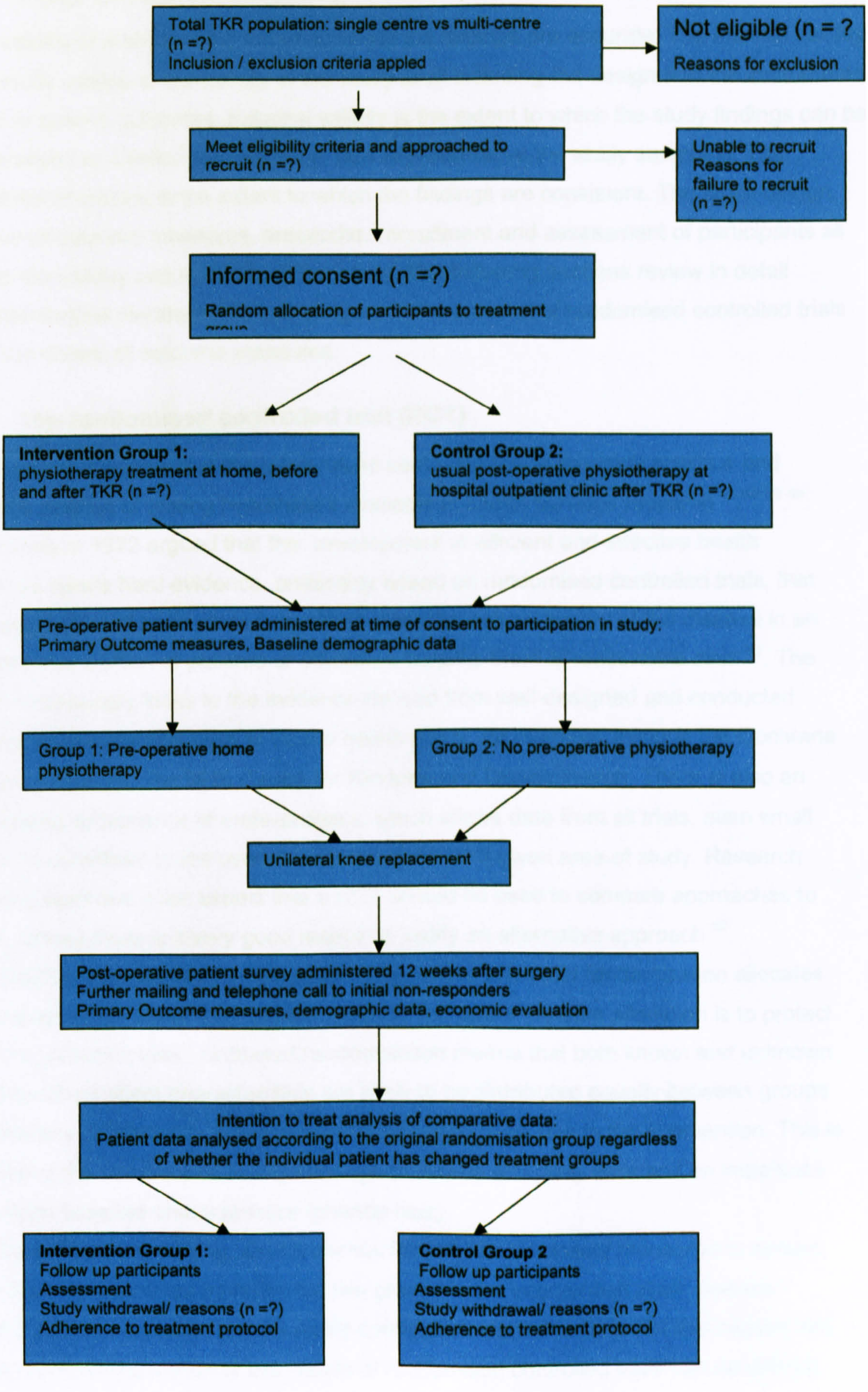
4.1.6 Overview of alternative study methodologies

Table 7 summarises several study designs which were considered, but rejected as less scientifically robust or unsuitable to answer these research questions.

Table 7 Summary of other research methodologies used in health services research [59]

Methodology	Description	Advantages	Disadvantages	Example
Case control studies	Observational, non-experimental techniques. Describe population and information about factors influencing health and well being	Larger sample sizes, analysis of rare events, assessment long term outcomes and trends	Researcher cannot influence nature & duration of the intervention nor quality of retrospective data collection Selection bias more likely with a control group retrospectively selected to control for confounding variables. Inappropriate to assess new therapies	Relationship between smoking and lung cancer
Comparable experimental design.	For example, group A receive one service, group B receive another service at another site/ another time	Pragmatic; reflects local variability in health service practice, cheaper, quicker than RCTs	no control group, difficult to know whether differences in outcomes are due to unknown differences between the participants, data may be retrospectively collected, difficult to maintain adherence to intervention protocols	Health service evaluation e.g. Leninger et al retrospective process and outcome data comparison; group 1 patients received a previous, different care pathway, group 2 a new, intervention care pathway [38]
Self assigned experimental group study (quasi-experimental)	Group 1 follow a particular care pathway, outcomes compared to 'control' group 2 (participants 'matched' for key characteristics e.g. age, sex, disease severity)	Pragmatic, quicker, cheaper to carry out than RCT's	Researcher no control over who receives an intervention and who does not, difficult to forecast which key characteristics are important in the assessment of outcomes after a particular intervention, matching may be inadequate.	Service delivery and organisation
Uncontrolled before and after studies	Participants are assessed before and after an intervention	Observational data, can be used to pilot and modify an intervention	no control or comparison groups cannot control for the significance of events over time, outside the intervention itself	Service delivery and organisation Clinical audit

Figure 3 The Research Design



4.2 Study validity and reliability

The validity of a study is the extent to which the findings are accurate. The internal validity of a study relates to the validity of the study itself including the design and the instruments used to assess outcomes. External validity is the extent to which the study findings can be generalised to a wider population i.e. how representative the study sample is. The reliability of a study is the extent to which the findings are consistent. The study design, choice of outcome measures, researcher recruitment and assessment of participants all affect the validity and reliability of the study. The following sections review in detail methodological literature relevant to rigour in the conduct of randomised controlled trials and the choice of outcome measures.

4.3 The randomised controlled trial (RCT)

Consensus suggests that the randomised controlled trial is the most rigorous and reliable method of testing hypotheses available in health services research [49,50,59,60]. Cochrane in 1972 argued that the 'development of efficient and effective health services needs hard evidence, preferably based on randomised controlled trials, that the application of each procedure either alters the natural history of the disease in an appreciable portion of patients or otherwise benefits them at reasonable cost' [61]. The NHS increasingly looks to the evidence derived from well-designed and conducted randomised controlled trials to inform health policy, for example, through the Cochrane Collaboration and the NHS Centre for Reviews and Dissemination. There is also an increasing acceptance of meta-analysis, which allows data from all trials, even small trials, to contribute to the overall evidence base for a given area of study. Research funding agencies often expect that a RCT should be used to compare approaches to care, unless there is a very good reason to justify an alternative approach [62].

The RCT is a prospective longitudinal study, where unbiased randomisation allocates participants into 'study' and 'control' groups. The aim of random allocation is to protect against selection bias. Unbiased randomisation means that both known and unknown confounding patient characteristics are likely to be distributed equally between groups so that any difference in outcome can be assumed to be due to the intervention. This is providing the sample size is large enough to reduce sampling error and an imbalance in patient baseline characteristics (chance bias).

Within a laboratory setting, environmental factors can be closely monitored to ensure that the only difference between the two groups is the intervention itself, however health services research cannot easily control for external factors. For this reason, the design and interpretation of the results of randomised controlled trials can be difficult,

particularly where the intervention is a complex healthcare package rather than a single drug treatment [50],[62]. An editorial by Roland and Torgerson (1998) summarises the differences in methodological approaches between 'explanatory' trials and 'pragmatic' trials. The explanatory approach aims to further scientific knowledge by 'recruiting a homogeneous population and delivering treatments in a controlled environment'. By contrast, a pragmatic trial recruits a more heterogeneous group of individuals, reflecting the characteristics of the patient population to whom the treatment will be applied, so that the results of the study are generalisable to real clinical settings. In a pragmatic trial it is accepted that clinician and patient biases are a usual response to treatments and that it is usually not possible to conceal treatment allocation from patients using placebos. The treatment response in a pragmatic trial is the difference between two treatments and includes both treatment and placebo effects, which reflects the likely clinical response in practice [52].

In a pragmatic trial participants may not necessarily complete the trial in the treatment group to which they are allocated. Participants are always analysed according to their original treatment group allocation (intention to treat analysis), even if they withdraw from the study or change treatment [52].

Prescott et al (1999), within a systematic review of published randomised controlled trials, provided a detailed analysis of factors that limit the quality, number and progress of randomised controlled trials for the Health Technology Assessment (HTA) NHS programme [62]. Around half of all randomised controlled trials have recruitment difficulties, leading to abandonment or reduced size and loss of statistical power. Many randomised controlled trials are presented only at conferences and around 10% of studies are unpublished. Randomised controlled trials are less likely to be published if they are small or show non-significant treatment effects. The team emphasised that a randomised controlled trial should be designed following a systematic review to define a well-formulated research question which specifies participants, interventions and outcomes. The recommendations of the group were summarised under several headings; design, barriers to participation, conduct and structure, analysis, reporting and costs. These detailed recommendations provide a framework to write a study protocol, designed to minimise bias, maximise recruitment and generalisablity of results, determine appropriate outcome measures and sample size and maintain quality standards by reference to steering and data monitoring committees. This guidance complements the Medical Research Council (MRC) 'Framework for the randomised controlled trial evaluation of complex interventions' [60],[63] and the CONSORT guidelines on the reporting of randomised controlled trials [43].

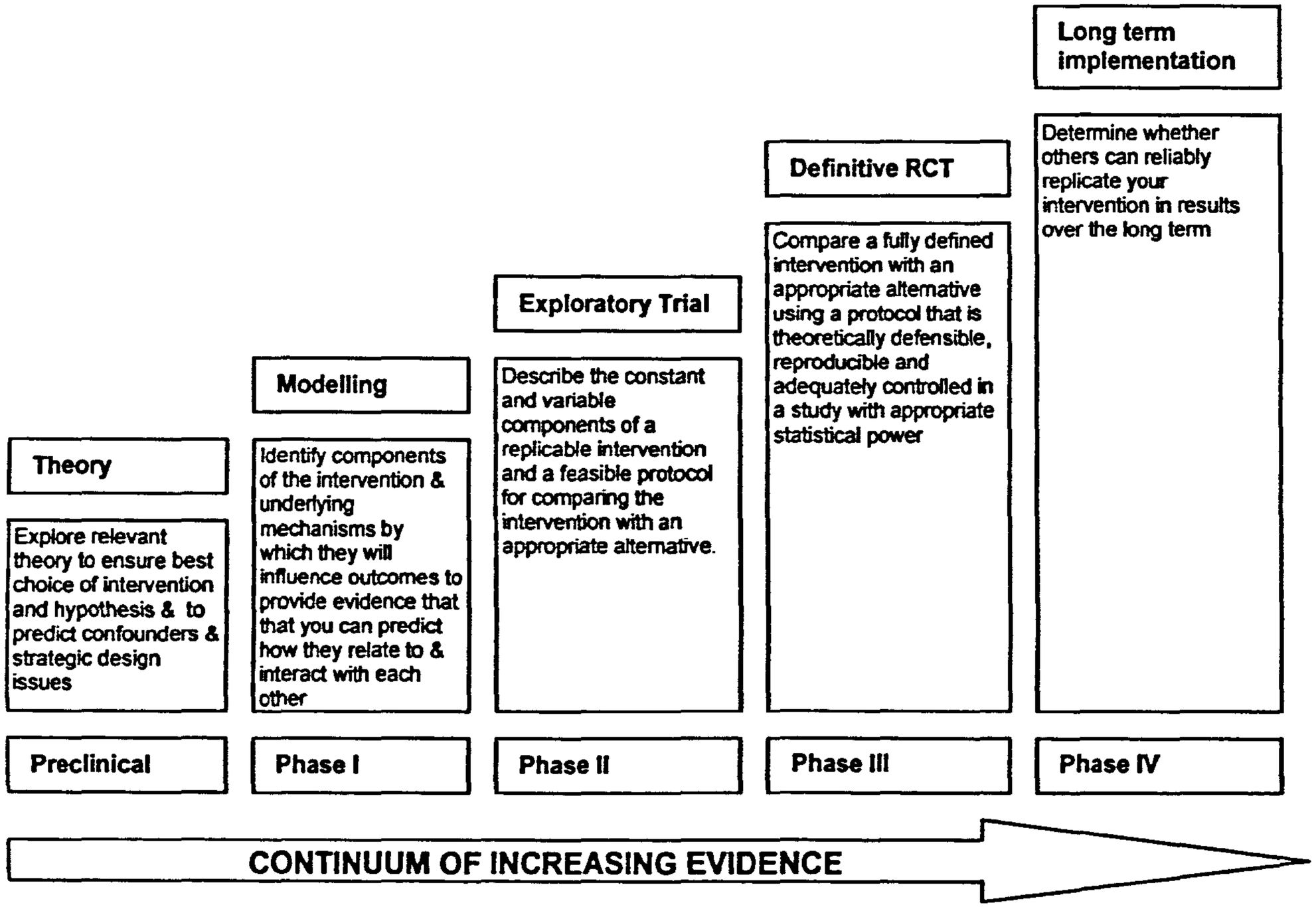
4.4 Randomised controlled trial evaluation of a complex intervention to improve health

The MRC 'Framework for development and evaluation of randomised controlled trials for complex interventions to improve health' (2000) addresses the difficulties associated with this methodology and provides guidance on best practice in study design [60],[63]. A health services research viewpoint considers that a treatment evaluated by a RCT is successful if the outcome improves quality of life (and may extend life), and patient satisfaction and does so without being significantly more expensive. Complex interventions contain several components and are difficult to evaluate as there are problems identifying, documenting and reproducing the intervention.

The experimental evaluation of a complex intervention is more difficult than a comparison between a single drug and placebo because it requires the definition of a number of 'active ingredients' of the intervention itself. A package of physiotherapy care for total knee replacement may be defined as 'a series of exercises performed in a set order, this frequently, for this long, with changes at these stages'. However the physiotherapist also has a less easily defined role. A physiotherapist also provides education, advice, support, home functional assessment, confidence building and motivation of patients and carers. Within a TKR pathway of care, the physiotherapists is a member of a multidisciplinary team including nurses, doctors and other health and social care workers working in different organisations, alongside patients and their carers.

The MRC guidelines recommend a phased approach to the development and evaluation of complex interventions represented in Figure 4:

Figure 4 MRC Sequential phases of developing randomised controlled trials of complex interventions [63]



This MRC report also emphasises the need to use both qualitative and quantitative evidence, in an iterative process, to design randomised controlled trials of complex interventions. During a modelling phase or an exploratory trial, consumer and stakeholder feedback may demonstrate that the intervention is unacceptable to participants or impractical to deliver in the health care setting proposed.
A good example illustrating the importance of phases I and II is described in the literature review. Daltry et al (1998) used a 2 x 2 factorial design to compare two intervention groups pre-operative education/ information or pre-operative relaxation training (Benson's technique) with a control group receiving no pre-operative intervention prior to hip or knee arthroplasty (Table 3)[41] This RCT assessment of a complex intervention for TKR patients mainly achieved CONSORT standards for reporting, except for the absence of a flow diagram and intention to treat analysis of data. However, in the pre-operative relaxation group, only 9% adhered to the treatment protocol since patients did not have time to become familiar with the technique or practice it usefully pre-operatively; this group of patients was excluded from the final analysis. There was 99% adherence to the educational/information intervention protocol, with positive patient feedback.

4.5 Designing a Complex Physiotherapy Intervention to answer the research question

The principles outlined in the MRC guidelines [63] were incorporated into the design of the complex home physiotherapy intervention. A number of factors, summarised in Figure 5, are important to consider in the design and definition of a complex intervention.

Table 8 Factors influencing the definition of a complex intervention

- Method of delivery of intervention:
- Setting; home/ hospital/ intermediate care
- Communication; face to face/ telephone/ written
- Health professional; experience/ grade, training/ learning curve in trial
- Individualisation in method of delivery; assessment of & tailored response to individual need
- Content of Intervention
- Frequency
- Quantity: length of contact, intensity (e.g. 1 therapist to three patients or one to one)
- Individualisation in method of delivery (e.g. functional home assessment)
- Specific treatment(s) used, for how long, how often
- Communication; written advice/ instructions/ standard leaflets
- Health professional: experience/ grade, training/ learning curve in trial

Exploratory trials can assess the questions 'how much' and 'how often' to test variations of an intervention for a full scale trial. However, an intervention in a randomised controlled trial should not evolve over time as the results of the randomised controlled trial are invalidated if earlier participants receive a different treatment package to those recruited later into the trial [63]. This is a disadvantage of studies where recruitment and treatment phases are prolonged (as in the study proposed) as the influence of external factors e.g. risk of staff changes are increased. Training and preparation of practitioners to deliver a complex intervention is critical to the consistent delivery of a complex intervention over time. The results of exploratory trials can be used to define the parameters for acceptable deviation from treatment protocols and any such deviations must be reported and

monitored [63]. The literature review did not report any evidence that variation in skills between physiotherapists could affect outcomes of rehabilitation after TKR. The intervention should be based on established professional standards of physiotherapy practice training and expertise, recording of treatment and monitoring of treatment progress. [35]. Chamberlain et al (1982) demonstrated that review by an independent physiotherapist increased adherence to the trial protocol [28]. Methods such as booster training, supervision, random assessment by an independent reviewer during the trial can maintain and monitor the consistency of delivery of the intervention throughout the study

4.5.1 Defining usual and intervention physiotherapy treatment for the study

Within a field of health care such as physiotherapy it is important to practitioners that rehabilitation is tailored to the needs of the individual patient. This was confirmed in the earliest stages of consultation with local physiotherapists in Sheffield. The community physiotherapists routinely incorporate an individual functional home assessment for housebound disabled people into their assessment and treatment plans. Functional goals are also set within hospital outpatient clinics and gym sessions (e.g. climbing stairs), but achievement of these goals once patients are at home is not observed or assessed by hospital based physiotherapists. Ultimately interventions need to be both feasible within the health service and acceptable to other health care professionals. A degree of individualisation of a treatment package is acceptable within a pragmatic randomised controlled trial which aims to mimic 'real world' health care conditions; a degree of flexibility enhances generalisablity both to other health professionals and other settings. However, the boundaries of individualisation of treatment must be clearly defined at the outset and incorporated into the training programme for practitioners delivering the intervention and the researcher assessing the programme.

'Usual' care must also be defined at the outset. The senior hospital and community physiotherapist defined the usual total number (up to nine sessions) and content of hospital treatment sessions at the outset of the study. The resources to plan the home physiotherapy package were based on this total number of nine hospital sessions of physiotherapy provided as a home care package comprising 3 pre-operative physiotherapy sessions, starting within six weeks of joining the TKR waiting list and a maximum of 6 post-operative physiotherapy sessions, to agreed common discharge criteria. Observation and field notes described and defined the elements of 'usual' hospital TKR physiotherapy treatment illustrating the importance of using complementary qualitative methodology.

Senior hospital and community physiotherapists and the general practitioner researcher designed a standardised home physiotherapy intervention package, referring to local guidelines, a review of the literature and usual local hospital exercise routines and care. The hospital gym and knee class based care package was adapted to an individual physiotherapy treatment programme at home before and after surgery. The treatment schedule for the complex physiotherapy intervention specified how often treatment was to be delivered, for how long, and the content of the treatment programme. Standardised training and monitoring procedures for the service were defined by a senior community physiotherapist to ensure that the four community physiotherapists delivered the home intervention consistently. The training schedule is summarised in the appendix, alongside the treatment schedule and discharge criteria for both the intervention and 'usual physiotherapy care packages. Four community physiotherapists spent half a day observing inpatient TKR physiotherapy and visiting outpatient knee classes, in addition to two one-hour in-house training sessions. An in-house booster training session took place once during the study to ensure skills were maintained.

Each physiotherapist worked within one of four Sheffield Primary Care Trusts (with cross cover across PCT boundaries for absence). An identifying code was given to each physiotherapist and a data sheet was designed to record clinical and research details of physiotherapy sessions for each patient. The community physiotherapists provided continuity of care during the wait for surgery, and developed new patient triggered contact systems to ensure an early post-operative visit after hospital discharge. The community physiotherapy team had defined monitoring procedures for patient response to treatment, any complications of surgery and also to communicate their findings to the relevant clinicians e.g. the GP or orthopaedic surgeon.

The end point, (discharge criteria), of treatment was defined with reference to hospital practice but would also be no later than 12 weeks post-operatively. At this point if patients needed further rehabilitation input, this was to be determined according to usual hospital practice and after assessment by the orthopaedic surgeon, either within the community or hospital setting. Patients could be referred for hospital based hydrotherapy from both treatment groups according to standard referral criteria. The physiotherapists met with the research nurse and GP 6-8 weekly during the study to report any difficulties, critical incidents and to monitor how the service was delivered. The minutes from each of these meetings were circulated to the research team and academic supervisors, to monitor how the service was delivered, ensure the intervention could be replicated, and to report any serious adverse events which would trigger review of the trial protocol or stopping of the study.

4.6 Identification of potential bias in the recruitment and randomisation of participants

To maximise recruitment, the research should address a question which is important to both clinicians and patients, minimise demands on health professionals and patients in terms of the protocol and data collection and fulfil best practice research governance and ethical procedures for information and consent [64],[65]. A high participation rate in a study suggests that the treatment offered is more likely to be acceptable to patients and more generalisable to other NHS settings. However, some studies fail to recruit their target population efficiently and poor planning, consent and information procedures, alongside unrealistic time schedules can contribute to this [62]. Prior planning and piloting of the trial recruitment strategy identifies the research support needed for clinicians and participants.

Selection bias is minimised by the use of telephone or computer based randomisation (with pre-prepared sealed opaque envelopes) independently of the research team. The latter method was chosen, as this was the most efficient way of organising the study within the available resources. Intention to treat analysis, according to treatment group allocation also minimises selection bias. Open allocation of treatment meant that it was not possible to eliminate performance bias; participants were aware of the alternative treatment options and this may influence their response to treatment, whilst physiotherapists were aware of the research process which might have influenced their performance in delivering the treatment. Treatment policies which were outside the treatment protocol, e.g. hydrotherapy referral, were specified and monitored.

Other study bias (detection and attrition) is minimised by outcome assessment 'blind' to treatment allocation and also follow up of all patients randomised, in the treatment groups to which they were randomised ('intention to treat' analysis of outcome data). Intention to treat analysis of outcome data provides an unbiased estimate of treatment effects within the two groups, whilst follow up of all randomised participants, to include monitoring of actual treatment received, describes compliance (and also acceptability) with the treatment protocol.

Obtaining prior permission from a maximum number of orthopaedic consultants for this study and the general principle of obtaining signed letters from each lead clinician responsible for the patient has been shown to improve recruitment [66],[67],[68],[69]. Wide patient eligibility criteria produce more generalisable results and also facilitate recruitment [52]. In this study consultation with the orthopaedic specialists determined that the study should include unilateral rather than bilateral TKRs, and knee osteoarthritis only, excluding people with knee pain and disability secondary to trauma or rheumatoid arthritis. The additional

disability associated with patient characteristics such as traumatic, inflammatory or bilateral knee surgery would have a more unpredictable effect on rehabilitation outcomes compared to greater homogeneity of disability of people with knee osteoarthritis. Recruitment of participants from more than one provider site (multi-centre studies) improves the generalisability of the study by representing a diversity of healthcare settings which most accurately reflect the range of NHS provider characteristics e.g. teaching hospital, district general hospital, large and small orthopaedic units, urban and rural community physiotherapy rehabilitation. The disadvantages of multi-centre trials include expense and time to set up a study across several geographically dispersed locations, maintaining communication between research and clinical professionals, monitoring recruitment targets and adherence to or deviation from the trial protocol. This research study was not resourced to recruit and follow up participants from multiple centres and therefore the findings are likely to be more applicable to large volume orthopaedic units, similar to the Sheffield University Hospitals Trust. In the case of joint arthroplasty, this is now most commonly undertaken in large 'high volume' specialist arthroplasty units. 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 or location of surgery [14]

4.7 Open or closed allocation of treatment?

Treatment allocation in this study was open since it was considered neither ethical nor possible to conceal treatment allocation from the control group. A study design involving 'randomised consent' commonly known as 'Zelen's' design can be used to reduce bias due to open treatment allocation of control group participants [70]. This design was developed to address a concern that recruitment and follow up of participants would be compromised by participants' knowledge of the different treatment options under comparison in a clinical trial [7;71]. This method involves asking trial participants' consent to receive the treatment they have been randomised to and not to randomisation itself. This method is tempting for a researcher keen to target recruitment resources for 'informed' consent to the intervention group to provide detailed explanation of the 'new' treatment. The 'control' group in this study would only have been consenting to baseline and follow up assessments to evaluate outcomes. Another argument for the use of this design is the potential for 'control' group participant bias as they know about the 'new' treatment they are unable to receive. Zelen's design however is scientifically inferior to standard randomisation design when more people refuse the 'new' treatment, which may produce 'crossover' back to usual care. This crossover dilutes the treatment effect and reduces the

power of the study to detect a difference. This means that special consideration of the potential refusal rate is needed when calculating the sample size needed for the study. Best practice guidelines for informed patient consent recommend that patients should always be fully informed about the full scope of the trial and this is certainly the view of the Sheffield Local Ethics Committee who do not usually now accept Zelen's design.
A disadvantage of the open allocation of a physiotherapy intervention which has both behavioural and psychosocial components is that there is potential for resentment or demoralisation within the control group. The chances of control group participant bias are more likely if usual care falls short of individual expectations [51]. In either group, participants' perception of response to treatment may be improved by the additional attention by the researchers and this may influence an individual's response or attitudes towards rehabilitation. Incorporation of a measure of patient satisfaction and opportunity to feedback about individual experiences of the different packages of care can monitor the influence of these factors on outcomes where there has been 'open' allocation of treatment. Roland and Torgerson acknowledge the bias introduced by open allocation in randomised controlled trials, however in a pragmatic trial the treatment response which includes a placebo effect, is likely to reflect clinical response in practice.[52]

4.8 Outcome Measures

Outcome measures need to be clinically and socially relevant, valid, sensitive to important change, and measured at appropriate follow up intervals. Traditionally morbidity, mortality and the data derived from clinical, radiological and laboratory tests have been used to assess outcomes of clinical trials of medical and surgical treatments. However, these measures are often seen as impractical or too rare to be used as primary outcome measures for health care evaluations comparing service settings such as home or hospital treatment. Health service research is more often concerned with addressing outcomes based on the assessment of health, illness and benefits of health interventions from a patient perspective. Specifically there has been a move away from clinician derived and observed outcome measures in recent years. Alternative clinician derived outcome measures for interventions for knee osteoarthritis include, for example, knee muscle strength (Cybex II dynamometer)[34;37] walking speed (pedometer) and oxygen cost of walking[34], the Hospital for Special Surgery Scoring system [36;37] and clinician assessment of knee flexion / flexion contraction, range of movement, walking speed and thigh circumference [37]. The use of patient perceived health outcome measures has been restricted, in previously undertaken studies of physiotherapy for TKR, to self assessment of pain, for example, a 10 grade scale[34] although D'Lima et al supplemented the 'Hospital

for special surgery knee rating Arthritis Impact Measurement Scale' with a 'Quality of Well Being' instrument [33].

4.8.1 Patient based outcomes measuring health status and quality of life

Evaluating health care by incorporating subjective viewpoints of patients as outcome measures provides a relevant and accurate assessment of individual and population health and the benefits and harm associated with medical treatments. For example Leigh and Fries (1991) demonstrated that patient perceived health status was more accurate than traditional measures of health state in predicting long term mortality and morbidity in rheumatoid arthritis [16]. The trend towards increased use of patient based outcome measures is also associated with the importance of improving or maintaining overall general health and function of people with chronic conditions such as musculoskeletal, cancer, cardiovascular, neurological and respiratory diseases. The ideal outcome of treatment would be a return to normal or usual quality of life for a given age or medical condition. Alongside evidence-based health care, NHS policy promotes greater patient participation in decisions relating to their health care [15]. Patients therefore also need relevant and accessible evidence about how illnesses and their treatments will affect them.

Patient based outcome measures assess research constructs such as health related quality of life (HRQol), subjective health status and functional status. However, there are many definitions of 'health' and 'quality of life' (Qol); for example;

- WHO (1947*): Health is a 'state of complete physical, mental and social well-being and not merely the absence of disease or infirmity'* [72]
- WHO Quality of Life Group (1993): *'Quality of life is an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns'.*[73]
- Calman (1984); *'Quality of life measures the difference or the gap, at a particular period of time, between the hopes and expectations of the individual and that individual's experiences'* [74]

Muldoon et al (1998) present a framework that describes the elements of quality of life related to health and use this to evaluate quality of life measurement. The authors acknowledge the limitations of measures of disease status alone in the assessment of the burden of illness. The measurement of health related quality of life incorporates two operational definitions, namely objective functioning (e.g. ability to climb stairs) and subjective wellbeing (e.g. does your health problem interfere with your social life?) which present different problems in terms of validation. Whilst self-reporting of

functioning can be validated against measures of directly observed performance, psychological factors, unrelated to health may significantly influence subjective appraisal of wellbeing[75].

Patient based outcome instruments address the patient's subjective experience of health and illness by asking the respondent to report views and feelings and experiences. Clinical scores and scales differ in that they usually reflect the subjective judgement of health professionals. Questionnaire items may request information about measurable behaviours such as distance walked or use of aids, which in principle can be observed by health professionals or carers. However, in practice this type of observation is resource intensive, time consuming for participants and still incorporates subjective assessment. The choice of patient based measures usually explicitly precludes 'objective' verification of these experiences. Concerns about the robustness and scientific value of patient based measures should therefore be addressed and justified in the choice of instrument for clinical trials.

Fitzpatrick et al (1998) identified seven major types of patient based instruments in a systematic review of the literature; disease specific, site specific, dimension specific, generic, summary item, individualised and utility [76]. The authors of this report recommended eight criteria and questions to guide researchers in the choice of patient based outcome measures, summarised in Table 9 below:

Table 9 Criteria and questions that need to be addressed in relation to a patient based outcome measure being considered for a clinical trial*

- **Appropriateness:** Is the content of the instrument appropriate to the questions, which the clinical trial is intended to address?
- **Reliability:** Does the instrument produce results that are reproducible and internally consistent?
- **Validity:** Does the instrument measure what it claims to measure?
- **Responsiveness:** Does the instrument detect changes over time that matter to patients?
- **Precision:** How precise are the scores of the instrument
- **Interpretability:** How interpretable are the scores of the instrument
- **Acceptability:** Is the instrument acceptable to patients?
- **Feasibility:** Is the instrument easy to administer and process?

**adapted from Fitzpatrick el* [76]

4.8.2 Disease specific instruments

A disease specific instrument is developed to measure a patients perception of a disease or health problem e.g. for rheumatic diseases, the self-administered questionnaire; the 'Arthritis Impact Measurement Scale' [77]. This type of measure is clinically relevant and assesses the impact of an intervention on known and anticipated important consequences of that specific health problem e.g. pain and functional disability. However it is not possible to use the measure to compare health status with people who do not have the condition. Thus, these measures cannot compare outcomes of different treatments for patients with different health problems to provide a broader policy perspective to clinical trials. Site-specific instruments have also been developed to focus on a particular part of the body e.g. hip or knee. The Oxford Hip score was designed to assess outcome after total hip replacement surgery (Dawson et al 1996) [6]. This instrument helps detect differences that are relevant to hip replacement surgery rather than just pain associated with generalised osteoarthritis. In general, the narrower the focus of the instrument, the less useful it will be in assessing the broader aspects of health or quality of life.

4.8.3 Generic instruments

Generic instruments assess a broad range of aspects of health and the consequences of illness and are more relevant to a wider group of patient groups. These instruments can compare health status between samples of people with a specific condition and the general population and assess comparative effectiveness of different interventions. A disadvantage is that the broad approach to health status implies less detail relevant to specific illnesses. Thus within a clinical trial fewer items are strictly relevant to specific conditions and the instrument is less sensitive to changes resulting from a disease specific intervention.

Advocates of subjective health status measurement often recommend using both disease or site specific and generic measures of quality of life. The main justification is that this approach will provide complementary evidence from the two measures. The disease specific measure is likely to be the most responsive and clinically relevant to the intervention and more acceptable to patients as there would be few, if any irrelevant items to complete. A generic measure produces comparative information, more relevant to the health community (e.g. for needs assessment), reflects co-morbidity and may also detect unexpected positive or negative effects of the intervention. Disadvantages of this approach include the respondent burden associated with longer questionnaires and additional statistical analyses, which increase the risk of

significant events occurring by chance. Selecting questionnaire items from different types of measures, rather than whole scales can reduce unnecessary repetition of similar questions and respondent time burden. However, this compromise may affect the validity and reliability of individual measurement properties, by removing items from validated reliable whole instruments.

4.8.4 Disease specific and generic patient perceived health outcome measures for OA knee

This study is an evaluation of a complex physiotherapy intervention and compares hospital to home treatment. A patient based, disease specific health outcome measure is the most appropriate assessment tool for the primary end point of the trial, supplemented by a generic health outcome measure as a secondary outcome measure. The primary outcome measure forms the basis for the calculation of sample size for an adequately powered study, based on data from previous clinical trials recruiting participants with OA knee (standard deviation, mean and effect sizes). The choice of primary and secondary patient based outcome measures was informed by the criteria outlined in Table 9.

Assessment of the reliability and validity of health outcome measures for people with knee OA is a fairly recent field of research in the UK, in contrast to rheumatoid arthritis [1]. The Lesquesne Index measures severity of OA of the hip and knee [10;46;46]The Arthritis Impact Scale (AIMS) was originally developed for all arthritis patients but has mainly been used as a health outcome measure for rheumatoid arthritis[78]. The most internationally widely used outcome measure is the WOMAC Osteoarthritis Index (Western Ontario and McMaster University Osteoarthritis Index). The WOMAC is a osteoarthritis, patient based outcome measure originally developed and validated in North America [47],[46].

The rationale for combining a disease specific patient based health outcome measure with a generic health status measure has been discussed above. The Short Form-36 [79] has been used with a wide range of patient groups in the UK and the USA [80,81],[82]. Brazier et al (1992) demonstrated that the SF-36 was more reliable, valid and more sensitive than the commonly used Nottingham Health profile[80]. A single index measure of health is necessary for an economic evaluation. The Euroquol health questionnaire (EQ) has been developed for this purpose. A preference-based single index can also be derived from the UK SF-36 survey to assess the cost-effectiveness of health technologies, but this is a less established use of the SF36[81]. Brazier et al (1996) recruited 118 knee osteoarthritis patients from a single Sheffield hospital waiting list for

TKR and 112 knee osteoarthritis patients from a rheumatology outpatient clinic to compare patient-perceived health status using four different measures and the surgery outcome TKR [1]. The measures used were:

Two disease specific patient based health status questionnaires:

- The WOMAC osteoarthritis index (Western Ontario and McMaster University Osteoarthritis Index, Bellamy 1995)
- The HAQ (Health Assessment Questionnaire), modified for British patients (Kirwan and Reeback 1986)

Two generic patient based health status questionnaires

- The Short Form-36 questionnaire (SF-36, Ware et al 1992)
- The EQ-5D questionnaire (Euroqol Health Questionnaire, the Euroqol Group 1990- The Euroqol Group. A new facility for the measurement of health related quality of life. *Health Policy*. 16(3): 197-208)

The dimensions and number of items for the four instruments are summarised in Table 10:

Table 10 **Comparison of dimensions and number of items (n) for four patient based health status measures; WOMAC, HAQ, SF-36, EQ** ***(adapted from Brazier et al [1])***

WOMAC	HAQ	SF-36	EQ
Physical function (17)	Dressing & grooming (2), Rising (2), Eating (3), Walking (2), Hygeine (3), Reaching (2), Grip (3), Activities (3)	Physical functioning (10)	
	Aids and assistance (20)	Social functioning (2)	
		Role limitations (physical) (4)	
		Role limitations (emotional) (3)	
Pain (5)	VAS pain (1)	Pain (2)	
		Mental Health (5)	
		Energy (4)	
		General Health perception (5)	Rating Scale (1) Single Index (5)
		Health Change (1)	
Stiffness (2)			

All health questionnaires were administered by postal survey. Baseline assessment included sociodemographic information, the Lesquesne index,[78] HAQ, WOMAC, SF-36 and EQ, supplemented by clinician assessment by routine medical data and X-Ray. The assessment was repeated at 6 months, with a re-test on a sample of 50 patients two weeks later.

There were excellent response rates in the surgical group (79%) and in the medical group (90%). Completion rates of all questionnaires were greater than 90%. The WOMAC questionnaire was the instrument of choice for measuring outcome after TKR for OA knee patients, with high levels of responsiveness or all dimensions. WOMAC also discriminated clearly between levels of disease severity, within the medical group, such that it would also be an appropriate instrument to evaluate treatments for OA knee. The HAQ questionnaire covered too wide a range of arthritic symptoms; the total score and pain were responsive but other dimensions such as Grip and Eating are unlikely to be relevant to knee pain. The authors recommended that the index should be supplemented with a generic instrument to provide wider scope. The EQ is convenient, particularly for economic evaluations within a clinical trial but it lacked the qualitative detail of SF-36. The SF-36 would be more useful for health status assessment in OA if certain dimensions were extended to cover extreme disability.

The Brazier et al study was a key reference in that the study population was the same as that proposed for this research question. The postal survey had excellent response and completion rates and the study demonstrated the feasibility of recruiting knee osteoarthritis patients from TKR waiting lists. The WOMAC mean and standard deviations derived form the study data were available to inform sample size calculation to assess the home physiotherapy intervention for TKR.

The WOMAC OA Index pain score was chosen as primary outcome measure, supplemented by SF-36 as a secondary outcome measure. This decision was based on Brazier et al's study [1;83] and the literature review, which confirmed the widespread current use of WOMAC and SF-36 as outcome measures in the assessment of treatments for OA knee and outcomes after TKR. The use of commonly accepted outcome measures also enables meta-analysis of randomised controlled trial results.

4.9 The Western Ontario and McMaster Universities Osteoarthritis Index

The Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Index is a three-dimensional, disease specific, self-administered, health status measure which was developed by Bellamy et al (1988) by interviewing 100 patients with knee osteoarthritis [46]. Forty-one items were identified on 5 dimensions (pain, stiffness, physical function, social function and emotional function). The construct validity was further tested in a study, which recruited 57 participants. The study used the following secondary outcome measures, selected to validate the 5 different WOMAC dimensions:

- Pain: joint tenderness (modified Doyle Index for hip and knee and Lesquenne Index)
- Stiffness: Lesquenne Index
- Physical function: Lesquenne Index,
- Emotional function: Bradburn index of well being
- Social Function: the social component of the McMasters Health Index questionnaire (MHIQ)

The efficiency of the WOMAC questionnaire was assessed against traditional clinician observed measures: 50 foot walking time, total range of movement, intermalleollar straddle. The social component of WOMAC did not correlate with the MHIQ social component and was excluded from the Index. The emotional component fulfilled construct validity criteria and most items were reliable and responsive, however the removal of the social component led to a review of the instrument by the researchers. The final index consists of 24 questions (5 pain, 2 stiffness and 17 physical function) each with five response categories (scored as 0 = none, 1 = mild, 2 = moderate, 3 = severe, 4 = extreme); summarised in Table 11 below. A subscale score for each WOMAC dimension is calculated by simple summation of the assigned values scored on the component items. Thus, the range of possible subscale scores for the three dimensions are Pain (0 -20), Stiffness (0-8) and Physical Function (0-68). A high score for the dimensions represents a high level of symptoms and low or poor level of functioning

Table 11 WOMAC OSTEOARTHRITIS INDEX

Dimension	ITEMS
Pain	Walking Stair Climbing Nocturnal Rest Weight bearing
Stiffness	Morning stiffness Stiffness occurring later in the day
Physical Function	Descending stairs Ascending stairs Rising from sitting Standing Bending to floor Walking on flat Getting in/ out of car Going shopping Putting on socks Rising from bed Taking off socks Lying in bed Sitting Getting on/ off toilet Heavy domestic duties Light domestic duties

4.10 The Short Form-36

The self administered short form-36 health survey was adapted from an instrument comprising 149 health status questions and then developed and tested on a population of over 22000 participants as part of the US Medical Outcomes Study. The instrument was developed to assess how specific parts of the American Healthcare system affected patient perceived health related quality of life for different medical problems but it has been anglicised and widely used in the UK [79],[84],[85],[82], [81]. The instrument contains 36 questions measuring health across eight dimensions - physical functioning (PF), role limitation because of physical health (RLP), social functioning (SF), vitality or energy (V), bodily pain (Pain), mental health (MH), role limitation because of emotional problems (RLE) and general health (GHP). Responses to each question within a dimension are combined to generate a score from 0 to 100, where 100 indicate "good health". Two further summary components, the Mental Component Summary (MCS) and Physical Component Summary have also been derived from the eight dimensions using factor analysis [86]. The PCS and MCS scales of the SF-36 are standardised such that a mean score of 50 (standard deviation 10) reflects the mean score of a standard population. The dimensions and scales and items are summarised in Table 12.

Table 12 SF-36 health survey dimensions and items

SF-36 Dimensions	Scales (number of items)	Items
Functional status	Physical Functioning (10)	Bathing & dressing, walking 100 yds, walking ½ a mile, walking>1 mile, bending, kneeling or stooping, climbing 1 flight of stirs, climbing several flights of stairs, lifting or carrying groceries, moderate activity, vigorous activity
	Social Functioning (2)	Extent to which physical, health, emotional problems interfere with normal social activities
	Role Limitation (physical problems) (4)	reduction time on work/ activities, accomplished less, limited in kind of work/ other activities, difficulty performing work/ other activities
	Role limitation (emotional problems) (3)	reduction time on work/ activities, accomplished less, didn't do work as carefully as usual
Well-being	Mental Health (5)	Nervousness, feeling happy, feeling calm, downhearted and low, worn out
	Energy (4)	full of life, a lot of energy, tired, limited social life by health
	Pain (2)	Amount of pain, interference with normal work
Overall evaluation of health	General Health perception (5)	Current general health , ill more easily than others, healthy as others, expect health to worsen, excellent health
	Health Change (1)	Change in general health compared to 1 year ago

4.10.1 The SF-6D Health State Classification

The SF-36 has been revised into a six dimensional health state classification called the SF-6D. Brazier et al derived this preference based single index (or utility measure) from the UK SF-36 health survey to reduce all the outcomes to a single summary measure for use in economic evaluations [81]. The six dimensions (Physical, Role, Social, Pain, Mental and Vitality) each have between four and six levels. An SF-6D health state is defined by selecting one statement from each dimension. A total of 18000 health states can be defined in this way. A sample of 249 states defined by the SF-6D has been valued by a representative sample of 611 members of the UK general population. Econometric modelling was used to estimate health state valuations for all 18,000 states defined by the SF-6D and to derive a scoring algorithm. All responders to the original SF-36 questionnaire can be assigned to the SF-6D provided the 11 items used in the six dimensions of the SF-6D have been completed. The SF-6D preference-based measure can be regarded as a continuous outcome scored on a 0.29 to 1.00 scale, with 1.00 indicating "full health".

4.11 Summary of assessment of criteria of suitability of WOMAC and the Short Form-36 as outcome measures for a study comparing treatments for OA knee

The eight criteria [76] of suitability of WOMAC and SF-36 as outcome measures for this clinical trial were formally assessed referring to the results of the study conducted by Brazier et al (1996) [1], Shields et al (1999) [82], Bellamy et al [46] and Ware and Gandek [79].

4.11.1 Appropriateness: Is the content of the instrument appropriate to the questions, which the clinical trial is intended to address?

WOMAC is a disease specific patient based outcome measure. The development of the tool using qualitative methodology demonstrates that the dimensions and items are important to patients who have OA knee. The ability of SF-36 to assess co-morbidity makes it a useful general health status measure for an elderly patient group where co-morbidity is more prevalent. The dimensions and items of both WOMAC and SF-36 are also meaningful to clinicians. The current widespread use of WOMAC, supplemented by SF-36 enables the trial results to be compared with results from other clinical trials in this field [1,46,76].

4.11.2 Reliability: Does the instrument produce results that are reproducible and internally consistent?

The complete comparative data set of all four instruments was assessed by Brazier et al to examine internal consistency; Cronbach's alpha coefficients for HAQ and WOMAC were adequate (using standard criteria of 0.8). The alpha coefficients were variable for SF-36, with the most relevant, for Physical Functioning and Pain, being equivalent to WOMAC. This study also demonstrated two week test-retest reliability by calculating score differences for participants who said their health hadn't changed. There were no significant differences between the test and retest scores for all three dimensions of WOMAC [1].

4.11.3 Validity: Does the instrument measure what it claims to measure?

The correlation values in the matrix of the complete comparative data set, demonstrated convergent validity of the dimensions of the four instruments (Brazier et al, 1996). Spearman's rank correlation coefficients for WOMAC and HAQ, were in the predicted direction between dimensions scores for each questionnaire. The functioning dimensions of the SF-36 correlated more highly with Physical Function than with WOMAC Pain and Stiffness, although , as expected correlations of Mental Health and Vitality with WOMAC dimensions were low [1].

Brazier et al compared data from a contrasting medical and surgical group of OA patients. The interventions for the medical group were minimal so an independent measure of clinical severity was used to estimate construct validity. The results were compared for patients by severity of osteoarthritis and by co-morbidity other than musculoskeletal health problems. Highly significant score differences between patients with mild/ moderate and severe OA were demonstrated for all 3 dimensions of WOMAC. Six dimensions of the SF-36 discriminated clearly between patients with mild/moderate or severe OA, but there was no significant difference for the Mental Health dimensions. The SF36 distinguished between patients on the basis of the presence or absence of significant co-morbidities, but WOMAC did not. For participants soon to undergo TKR, the SF36 discriminated for Physical Function, Pain and General Health for patients with or without co-morbidity [1].

4.11.4 Responsiveness: Does the instrument detect changes over time that matter to patients?

All dimensions of WOMAC and six out of eight dimensions of the SF-36 were able to detect actual change in patients who reported worse or improved health.

In the surgical group of patients health perceived health was significantly related to score differences for WOMAC and Pain and Physical Functioning dimensions of SF-36.

The absolute standardised response means (SRM's) were calculated to indicate the responsiveness of WOMAC and SF-36 to health change. Standardised response means are considered large when ≥0.8, moderate when between 0.5-0.79 and small when <o.5>0.2. The standardised response means for all dimensions of the WOMAC and most dimensions of the SF-36 were large.

4.11.5 Precision: How precise are the scores of the instrument?

The form in which respondents are able to give their answers influences the precision of an instrument. Binary response categories such as 'yes' or 'no' are simple but do not express degrees of difficulty or severity. Most instruments allow a graded response in the form of Likert scales e.g. none, mild, moderate, severe, extreme. The use of seven rather than five response categories on a Likert scale may increase precision, but there is no evidence of advantage above seven response categories. Visual analogue scales in theory offer more precision by allowing respondents to mark any point on a continuous line to reflect their experience e.g. of pain. However, the task takes longer, is less acceptable to respondents and no significant advantage has been demonstrated over the Likert scale [78]. WOMAC has five response categories for each item. SF-36 has five response categories for eight items, six response categories for eleven items, three response categories for ten items and binary response categories for seven items. The scoring systems for the SF-36 is described by Wave and Gandek (1998, [79]) and the scoring system for WOMAC by Bellamy (1995, [47]).

4.11.6 Interpretability: How interpretable are the scores of the instrument?

Absolute scores for SF-36, presented as mean deviations from the general population allow comparisons between patient groups and the general population for each individual SF-36 scale. Line graphs of standard scores allow comparisons by patient group and the general population across the whole SF-36 profile. High values for each SF-36 score indicate good health {48,273}. Low scores for the WOMAC index indicate good health and as the instrument has become more widely used, score comparisons are readily available within the literature [1].

4.11.7 Acceptability: Is the instrument acceptable to patients?

Researchers need to be aware of respondent burden, indicated by piloting of time to complete the questionnaire in the relevant patient group and the response and completion rates reported within the literature. Standard methodological approaches are used to maximise response rate e.g. stamped addressed envelopes, personal communication from the clinician caring for the patient, follow up of non-respondents by telephone or repeat mailing, optimising questionnaire design and layout and the availability of researcher support to deal with patient concerns or difficulties with questionnaire completion. Response rates to postal surveys for both SF-36 and WOMAC are widely reported as very good, with response rates over 75% the norm for both WOMAC and SF-36, either alone or in combination in both hospital and community populations of patients {29, 87,141, 165,167}. Self completion of the SF-36 has been reported as around 12 minutes, compared to around 10 minutes by interview or telephone [76]. Completion rates of 90% have been reported for both WOMAC and SF-36 questionnaires [1].

4.11.8 Feasibility: Is the instrument easy to administer and process?

The administrative details of clinical trials are rarely easily available but researcher and /or clinician burden can adversely affect the use of patient based health status measures [76], [62]. WOMAC and SF36 have been used as postal surveys both in small populations and in large community studies with excellent response rates [1],[87],[27], [13]. Computer programmes such as SPSS statistical software are available universally to process and analyse data.

4.12 Secondary outcome measures

Secondary outcome measures derived from the concepts and indicators are:

4.12.1 An economic evaluation

An economic evaluation assessing the average cost per patient of physiotherapy intervention between the two groups (cost consequence analysis). Resource use was compared between the groups in order to attribute cost per patient for the two models of physiotherapy care, as measured by data extracted from hospital physiotherapy notes and community physiotherapist and patient responses on self-completion questionnaires:

- length of hospital stay
- transport costs
- attributed costs of physiotherapy sessions
- other patient costs

4.12.2 Patient satisfaction

The proportion of patients expressing satisfaction with the physiotherapy intervention and themes identified from patient feedback about the processes of care (open comments), measured by self-completion questionnaires.

4.12.3 Postoperative complications

The proportion of patients with post-operative complications and morbidity as measured by data extracted from orthopaedic notes and patient responses on self-completion questionnaires.

4.13 Economic outcomes and evaluation

The aim of the economic evaluation was to determine whether providing pre- and postoperative community physiotherapy was a cost-effective use of NHS resources. In this trial, the main purpose of the economic analysis was to compare total costs and benefits for the intervention and control groups at 12 weeks post-operatively and report any differences. The technique for performing the economic analysis (cost-effectiveness, cost-minimisation or cost-utility analysis) can only be chosen once costs and health outcomes for both the intervention and control group are known [88].

The main cost burden of providing services for the intervention and control group were thought to fall on the health service. However, resource-use data were also collected to provide service commissioners with information about costs from the perspective of the patients in the trial. The main cost categories were therefore:

- costs to the NHS
- costs incurred by the patients in the trial

The important costs identified for each group are summarised in Table 13

Table 13 Important costs identified for each group

4.13.1 Important costs	4.13.2 Intervention group	Control group
4.13.3 NHS Pre-operative care	Community physiotherapy sessions GP consultations	GP consultations
Post-operative care	Hospital services: operation and length of stay GP consultations Hospital physio sessions Community physio sessions NHS transport	Hospital services: operation and length of stay GP consultations Hospital physiotherapy sessions NHS transport
4.13.4 Patient costs Transport costs Other costs	Costs incurred by patients Other out-of-pocket costs associated with having physiotherapy sessions	Costs incurred by patients Other out-of-pocket costs associated with having physiotherapy sessions

4.14 Patient Satisfaction

Incorporating consumer perspectives, alongside other methods of quality assessment and assurance is an important focus of the 'modernising' agenda for the NHS {286,288}. The methodological approach of 'Patient Satisfaction' surveys is often criticised as such surveys tend to address structural aspects of secondary care, such as hospital based amenities, rather than encouraging patient feedback to influence processes of care[89-91]. Furthermore published patient satisfaction surveys invariably report 'satisfaction' rates with NHS services at over 80% in older adult groups. The systematic review of the literature did not provide any published reports of patient satisfaction with physiotherapy care and nor was a validated service specific survey instrument found.

Patient satisfaction can be measured with validated generic quantitative survey instruments such as the GHAA questionnaire (Davies and Ware), [92],[93] The GHAA allows comparisons to be made between intervention and usual care groups of participants' overall satisfaction with several elements of the service provided; namely access, technical quality, communication, interpersonal care, outcomes and patient attitudes towards care from the health professional. This generic satisfaction measure offers the advantage of allowing comparisons between different kinds of services for the same group of patients, or even a comparison between different groups of patients. However, participant burden in the completion of questionnaires needs to be considered where the research study already takes a wide perspective with a large number of secondary outcome measures. Simply expanding the amount of information collected may result in lower questionnaire completion rates and missing data.

Fitzpatrick (1991) reviewed the extensive patient satisfaction literature and provided a comprehensive framework for the design of a survey instrument, which could incorporate patient perceptions of the processes of care. The use of qualitative methodology in the development of patient satisfaction questionnaires was considered to be very important [94],[92]. In-depth qualitative methodology may be more appropriate to encourage constructive negative feedback to improve care pathways. This however is resource intensive, the study resources may not be sufficient to ensure qualitative methodological rigour and only a small number of study participants could be included.

A short study specific questionnaire referring to guidelines for the development of patient satisfaction tools to be sent to all participants[92]. A group comprising physiotherapists, a GP, a primary care nurse and a primary care research facilitator were consulted to define the dimensions of physiotherapy care, which were felt to be useful to compare home and hospital treatment from a service provider perspective. A questionnaire was piloted amongst elderly and osteoarthritis patients from a single general practice and feedback

was incorporated into the final service specific questionnaire. The eight-item postal questionnaire included both closed and open questions about recent and previous experiences of care, preferences for the location of physiotherapy care, feedback about how physiotherapy could be improved for knee replacement patients as well as space for additional comments. The questionnaire was designed to encourage respondents to define issues of importance to them. Resources were not available for more rigorous testing of the validity and reliability of this survey instrument.

In addition to the semi-structured questionnaire, observational techniques were used to describe and monitor the physiotherapy intervention and usual care. In-depth interviews were proposed with a small maximum variety sample of participants, their carers and physiotherapists from both the community and hospital services to explore their perceptions of the processes of physiotherapy care for TKR.

4.15 Piloting of study data collection forms and treatment protocol

A patient information leaflet and data collection forms for secondary outcome measures, demographic and co-morbidity data were designed (Appendix). These data collection forms were piloted within a single general practice on home visits to elderly patients, patients with osteoarthritis, opportunistically in consultations and within a social group for the elderly. Professional stakeholders were also consulted; this group included a GP, physiotherapists, a nurse, a health economist, a primary care research facilitator and a GP academic).

The piloting of the data collection instruments ilicited patient feedback re content, legibility, layout, comprehension, ease of completion and time to complete (to assess potential participant burden). The multi-disciplinary group gave feedback about the content, layout and relationship to concepts and indicators. The feedback from these patient and professional groups was incorporated into the final version of the forms to provide external validity of these data collection instruments. Clinician-confirmed patient reported co-morbidity data were collected, by including co-morbidity questions on the patient questionnaire and from GP and hospital orthopaedic notes.

Home physiotherapy following total knee replacement is not usual practice, however, occasionally as a result of co-morbidity or carer needs, rehabilitation had exceptionally been provided in patients own homes. Senior physiotherapists involved in the design of the study had experience of this and incorporated their own specialist knowledge of post-operative home physiotherapy and physiotherapy treatments for advanced knee OA in the community into the treatment protocol. The literature search also supported the acceptability of a home physiotherapy programme in small published pilot studies (refs).

Additionally there was a lack of resources and time for a prolonged peri-operative pilot treatment phase. Thus the treatment protocol was piloted only with the health professionals delivering the intervention and not with patients, prior to study commencement.

4.16 Ethical issues in the conduct of a randomised controlled trial

The dignity, rights, safety and well-being of participants are a primary consideration in any research study. Since 2001, the principles of *Research Governance* must be adhered to by all professionals who participate in research, host research in their organisation, fund research, manage research and undertake research. The NHS Research Governance Framework (2001) sets standards for NHS researchers and organisations, defines mechanisms to deliver these standards and also describes monitoring and assessment procedures. In addition to ethical approval processes, research governance aims to improve research quality and safeguard the public by enhancing ethical and scientific quality, promoting good practice, reducing adverse incidents, ensuring lessons are learned and by preventing poor performance and misconduct [95]. The framework also provides web-based links to important sites such as the Medical Research Council, European Community directives and Research Ethic Committees. The study design, consent and data access procedures were reviewed early in the research process referring to MRC guidelines (1998) on the conduct of clinical trials [96], Caldicott guidance on the use of patient information[97] and the HTA systematic review 'Ethical Issues in the design and conduct of randomised controlled trials' (Edwards et al,1998) [64].

4.17 Summary: Methodology

Critical appraisal of the literature reporting physiotherapy interventions for TKR and OA knee confirmed the evidence gap and provided qualitative evidence of the acceptability and feasibility of a home physiotherapy intervention and process outcome measures for OA knee patients and professional stakeholders [36],[38],[35;98;99].

The randomised controlled trials evaluating pre-operative physiotherapy in addition to usual post-operative physiotherapy for TKR were small and would be considered, referring to the MRC Framework, to be *exploratory trials* providing phase II evidence. A definitive randomised controlled trial evaluating[34] a pre- and post-operative home physiotherapy programme on patient perceived outcomes after TKR providing Phase III evidence was not identified [63]. There is also no evidence of any economic evaluation comparing physiotherapy interventions for TKR in the UK.

Quantitative evidence of selection criteria, outcome measures, effect sizes on which to base sample size calculations and follow up schedules were derived from small exploratory trials, systematic reviews and systematic comparisons of patient perceived health status measures for OA knee patients undergoing TKR [33;36;37],[100],[1;27;42].

5 THE RESEARCH PROTOCOL

5.1 Research ethics

Ethical approval was granted by the North Sheffield Local Ethics Research Committee (LREC). Standardised forms for ethical approval included signatures from a senior clinician responsible for hospital care of the participants and the risk managers from each of the trusts where health professionals cared for the participants (in this case a community trust and an acute hospital trust).

The research process considered specific ethical issues relevant to the conduct of this study namely:

- Risks vs. benefits for participants and society
- Consent
- Data protection and confidentiality, trial documentation
- Quality Control for the intervention

5.1.1 Risks vs. benefits for participants and society

Systems were designed for participant recruitment to ensure that all patient identifiable data were accessed only by primary care or hospital staff, or named researcher(s) within the team to ensure that patient autonomy and confidentiality were respected. The study addressed important questions from the perspectives of patients, clinicians and the wider NHS community. In this case, there has been no previous research conducted in a UK setting to answer the research question. Since it is not currently known whether this programme of physiotherapy is effective, it is ethical to assess the treatment in a RCT.

The research intervention was not expected to be harmful to participants and this was confirmed by formal assessment by the risk managers of both the acute and community trusts. The study team, with consumer feedback, designed an intervention to be as convenient to participants as possible and to minimise participant time burden in completion of baseline and outcome assessments (in this case postal questionnaires). A monitoring procedure for adverse events / 'critical incidents' relating to the intervention or complaints about clinical treatment was set up to enable appropriate use of the NHS clinical complaints procedures and feed back events to the academic steering group. All participants were covered for clinically negligent harm by the NHS

indemnity scheme and additionally research indemnity was provided by the university employing the researcher.

5.1.2 Consent

A patient information sheet and postal consent form were drawn up with reference to 'best practice' guidelines issued by the local ethics committee.(see appendix). The information leaflet and consent form was piloted within a primary group of patients with and without OA in surgery consultations and on home visits and within a social group for the elderly (as with the study data collection tools). The aim of this process was to try to ensure that the information leaflet was easy to understand and addressed potential concerns of patients. The information leaflet and consent form were also piloted within a small multidisciplinary group comprising a GP academic, physiotherapists and a primary care research facilitator. Feedback from this stage was incorporated into the final version leaflet and consent form.

The consent form included signed consent to access to that person's medical and physiotherapy notes for fully anonymised data for the study. All patients participating in the trial consented to data access. Each consent form was kept with all patient data in a locked cabinet and when the multiple data source holders were approached for information from patient records, a copy of the signed consent was sent for each patient. Upon receipt of the participant's consent form, each individual GP and Orthopaedic surgeon was sent a letter, research office telephone number and information sheet to inform him or her of the person's agreement to participate in a trial.

All researchers completed training in the ethics of informed consent with written consent from all participants. Before consent was obtained, all participants had a minimum of a week to read detailed information leaflets and opportunity to discuss the study with a researcher. The time 'burden' of questionnaires and physiotherapist assessment visits were fully discussed with participants, with reassurance that clinical care would not be affected by refusal to participate in or withdrawal from the trial at any point.

5.1.3 Data protection and confidentiality, trial documentation

All research and clinical staff involved in research had a confidentiality clause within their employment contracts. All participant data was made confidential at computer data entry and written questionnaires, randomisation details and any personal patient information were kept in locked cabinets within a locked office.

Access to computer databases was password protected. Records were kept describing the methods and conduct of the trial, factors affecting the trial and action taken, ethics approval, consent forms, relevant letters and the final report. The Research protocol provides precise detail of the methodology and conduct of the trial and is provided as an appendix. This was not amended in content for the duration of the study. Data would usually be destroyed five years after publication of the findings.

5.1.4 Quality Control for the Intervention

The standardised training and written information for health professionals providing the intervention were described in the trial protocol. The community physiotherapists had a structure to support the standardised intervention programme, which included both designated clinician management support and regular links with the research team to monitor and record any difficulties in delivering the intervention, deviations from the protocol and any critical incidents. Training and supervision to monitor the intervention occurred during the study with documentation of any deviations from the trial protocol

5.1.5 Research Monitoring

Steering and data monitoring committees are recommended by research funding agencies and ethical committees to monitor quality control within RCT's. This includes adherence to project timetables and the study protocol and would also include interim reporting of important trial data, for example adverse effects. Originally a steering group of academics and clinicians was organised, but conflicting work commitments for the orthopaedic, senior physiotherapy managers and academic stakeholders meant that feedback to this group was structured by individual or small group meetings, newsletters and minutes of six weekly project team meetings with the physiotherapists delivering the intervention. The advisory group of academic and clinician supervisors included a senior primary care research clinician, two senior statisticians, a health economist, an orthopaedic surgeon and a primary care research facilitator, all of whom were experienced in the conduct of clinical trials. Six weekly personal academic supervision and mentorship for the lead researcher continued throughout the study.

5.2 The Research Team

The research team comprised a lead GP principal investigator, a research practice nurse and a research associate, with statistical and economic advice and

supervision provided by an academic advisory group based within the Sheffield School of Health and Related Research (ScHARR), Sheffield University.

5.3 Study Methodology

The methodology of the study is presented using the CONSORT guidelines for the reporting of randomised controlled trials according to the headings in Table 14:

Table 14 Consort structured reporting of the methodology of RCTs (adapted*)

Study population: Eligibility criteria for participants, settings and locations where the data were collected
Randomisation:- Sequence generation: method used to generate the random allocation sequence, including details of any restriction (e.g., blocking, stratification). Allocation concealment: Method used to implement the random allocation sequence (e.g., numbered containers or central telephone), clarifying whether the sequence was concealed until interventions were assigned. Implementation: Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups.
Interventions: Precise details of the interventions intended for each group and how and when they were actually administered.
Blinding (masking): Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment. When relevant, how the success of blinding was evaluated
Outcomes: Clearly defined primary and secondary outcome measures and, when applicable, any methods used to enhance the quality of measurements (e.g., multiple observations, training of assessors).
Sample size: How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules
Statistical Methods Methods used to compare groups for primary outcome(s) Methods for additional analyses, such as adjusted analyses and sub-group analyses

*43

5.4 Study population

The setting was a single National Health Service provider unit within the Sheffield University Hospitals Trust. Fifteen orthopaedic consultants regularly performed total knee replacements during the recruitment phase within the hospital unit. The project and protocol were discussed in detail with an orthopaedic consultant, who approached other colleagues within the orthopaedic department with a written leaflet and personal letter from the principal investigator. Further face to face discussion of the project was arranged with three further consultants to discuss queries and concerns. These three consultants agreed to support study recruitment however, a pre-existing commitment to a different research study investigating knee and hip arthroplasty, patients under their care could not be approached for the duration of the recruitment phase. One consultant refused participation within the trial. This consultant differed from the other 15 consultants in that he recommended a specific, different model of physiotherapy to the other surgeons and also performed un-cemented knee arthroplasty. Eleven consultants agreed to actively support study recruitment.

The patient throughput for knee arthroplasty at the Northern General Hospital between 1999 and 2000 remained fairly constant at about 450 (Sheffield Health Authority pooled data) but this included all types of knee replacements including revisions/ complex trauma cases and bilateral knee replacements. The estimated maximum wait from the point at which patients were added to the waiting list, to TKR, was about 14 months for the duration of the study. The inclusion and exclusion criteria were determined by discussion with the Orthopaedic Surgeon supporting the trial, the community and hospital physiotherapists and current literature referring to the post-operative care of knee replacement patients. The orthopaedic waiting list administrator identified new patients added to the single hospital TKR every six weeks. The research nurse consulted individual orthopaedic notes to check against the inclusion and exclusion criteria in order to produce a list of eligible patients (Table 15).

Table 15 Study Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
On the waiting list for a 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 co-morbidity 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

5.5 Randomisation

Patients who fulfilled trial inclusion criteria were invited to participate by consultant letter, with a study information leaflet, research nurse contact details and consent form enclosed. All patients were sent an explanatory letter signed by the orthopaedic consultant, an information sheet and consent form to invite participation in the project (Appendix). Researcher time was protected by inviting postal consent but a telephone contact number was given for further information about the project, and an offer of a home visit, should they wish to discuss the project 'face to face'. 160 participants were recruited over 16 months (1999-2000) from this NHS waiting list for unilateral TKR for osteoarthritis

5.5.1 Sequence generation

Concealed block randomisation was used. Patients were randomised in blocks of 8 or 10, to an intervention or control group according to a list drawn up by a senior statistician. The randomisation code was developed using a computer random number generator to select random permuted blocks. The block lengths were 8 and 10, varied randomly.

5.5.2 Allocation concealment:

An independent administrator inserted intervention and control cards into 160 sealed envelopes. The randomisation list was then sealed in an envelope, dated and kept securely and separately to the cards. The researcher did not have access to this randomisation list to 'conceal' the allocation process.

5.5.3 Assignment to group

The research nurse opened returned consent forms sequentially and used an independently prepared computer block randomisation sequence in opaque sealed envelopes to allocate consenting participants to a treatment group. After allocation to treatment, the research nurse phoned all participants to explain the physiotherapy treatment and to offer a home visit, if they wished. This contact was followed up with a letter confirming treatment allocation and the baseline questionnaires. Thus although the allocation sequence was concealed from the researcher, participants were then made aware of the treatment group to which they were allocated ('open' allocation).

5.6 Intervention and usual care

Senior hospital and community physiotherapists designed the home intervention and physiotherapists' training programme with reference to a literature review and current

practice and defined usual postoperative physiotherapy rehabilitation. Participants were randomised to receive either the usual hospital-based, outpatient physiotherapy post-operatively (control group) or a new, home -based physiotherapy service, pre- and post-operatively (intervention group).

5.6.1 Hospital outpatient physiotherapy rehabilitation (Usual care)

A typical knee class was observed and described during the pre-protocol phase of the study. An expected attendance for 8-10 postoperative outpatient physiotherapy sessions after TKR was defined as usual care by the senior hospital physiotherapists. Usual hospital postoperative physiotherapy comprised exercises, and individual treatment, in knee classes of seven to twelve patients in the gymnasium; once or twice a week, or fortnightly, as deemed appropriate by the physiotherapist.

Two physiotherapists and one technical assistant supervised the knee classes and provided individual treatments as necessary. One-to-one treatment sessions in the outpatient department were given at the physiotherapists' discretion. Treatments included techniques to increase knee flexion and extension such as mobilisations; muscle stretches and proprioceptive neuromuscular facilitation techniques, electrotherapy for pain relief and/or muscle stimulation; and gait re-education. The patients were also to be given advice and written information. The hospital outpatient group did not routinely have access to either pre-operative physiotherapy or a home physiotherapy assessment.

5.6.2 Hospital inpatient physiotherapy

During the pre-protocol phase of the study, the senior inpatient orthopaedic physiotherapist was interviewed and an individual inpatient post-operative physiotherapy rehabilitation session for TKR was observed and described (see Appendix 1). Both physiotherapy treatment groups had the same inpatient postoperative physiotherapy.

5.6.3 Home physiotherapy rehabilitation (Intervention)

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 an initial and then a booster one-hour in-house training session, 12 months into the study. The four intervention group physiotherapists met six weekly with the research nurse and GP researcher during the intervention phase of the study. The purpose of these regular meetings was to

monitor adherence to the treatment protocol, record and respond to any significant events, record any problems encountered delivering a home based physiotherapy rehabilitation treatment and to encourage high community physiotherapy data collection rates. Field notes were taken at each meeting.

The home physiotherapy rehabilitation programme involved a minimum of three preoperative visits (starting within eight weeks of joining the TKR waiting list) and up to six postoperative visits. Preoperative physiotherapy, based on an initial assessment, typically included pain relief e.g. electrotherapy or cold therapy, techniques to increase knee flexion and extension such as mobilisations; muscle stretches and proprioceptive neuromuscular facilitation techniques, techniques to improve muscle strength at any or all of the lower limb joints, gait re-education and home functional adaptations. Postoperative physiotherapy additionally included techniques to reduce swelling and mobilise soft tissues. Although standard treatment techniques were used by the physiotherapy team, the home physiotherapy intervention was designed to offer a patient centred, functional focus to treat OA symptoms and maximise function prior to surgery, prepare for surgery and to continue that individual physiotherapy rehabilitation programme postoperatively. The home physiotherapy group did not have access to gym equipment or group activities.

5.6.4 Hydrotherapy

Patients in both treatment groups who made unsatisfactory progress could also be referred to hydrotherapy, according to standard referral criteria (appendix). Groups of seven to eight patients exercise in a pool, supervised by two senior-grade-2 physiotherapists, one senior-grade-1 physiotherapist and one half of a whole-time-equivalent assistant physiotherapist.

5.6.5 Comparison of usual and intervention physiotherapy treatments

In summary, the differences between the two groups were that the hospital group did not have access to pre-operative physiotherapy and would not normally have a home-based, functional assessment; the home care group would not have access to gym equipment. Both treatment groups could be referred for hydrotherapy. Table 16 compares the intervention with usual care.

Table 16 Comparison of content of 'usual' hospital outpatient physiotherapy and home physiotherapy

Hospital outpatient physiotherapy (Usual care)	Home physiotherapy care (Intervention)
No preoperative physiotherapy assessment or treatment.	Preoperative functional assessment and treatment.
Group work in knee classes based on standard exercise routines and individual physiotherapy	Standardised individual home treatment, by one of four community physiotherapists
Patients used outpatient gym equipment.	No access to gym equipment
Maximum 9 postoperative physiotherapy sessions	Maximum 9 pre- and postoperative sessions, started within 8 weeks of addition to TKR waiting list

5.7 Blinding

It was not feasible for the allocated treatment to be concealed from patients and physiotherapists, although the randomisation treatment sequence was concealed from the researcher by sealed envelope. The block randomisation sequence generated by computer software and independently inserted into sealed envelopes ensured that although overall the numbers allocated to the treatment groups would be equal, it was not possible for the researcher to predict the treatment allocation sequence.

The self-completion survey instruments assessed patient perceived health outcome measures, patient satisfaction and experiences of the two physiotherapy rehabilitation care pathway. Independent clinician observed measures of patient outcome, 'blind' to treatment allocation were not included in this study as those available are time-consuming for both researcher and patient, difficult to reproduce consistently, involve patient assessment in a clinic setting, and often measure outcomes which do not accurately reflect constructs such as health related quality of life. The efficiency of the WOMAC questionnaire has been assessed as part of the validation process, against traditional clinician observed measures; 50 foot walking time, total range of movement, and intermalleollar straddle (McConnel et al 2001)[48].

The lead GP researcher used Access computer software to create a relational database which included a number of separate tables for each of the core datasets. Each of these tables was linked by a unique patient number (UPN). A single table, which was protected with an additional password, contained complete essential personal data for the purpose of patient tracking only. Treatment group allocation was described only as 1 or 2 and anonymised, cleaned primary and secondary outcome data (WOMAC, SF-36 and resource use data) were provided as a separate output for preliminary analysis. This preliminary analysis of WOMAC, SF-36 and resource use data was undertaken blind to group assignment by a statistician and a health economist independent of data collection and input and then verified and interpreted by the lead researcher.

5.8 Outcome measures and follow up

The outcomes measured were:

- Patient reported health-related quality of life at trial entry and 12 weeks post TKR
- Patient satisfaction
- NHS resource use
- Patient costs

5.8.1 Main health related quality of life (HRQoL) outcome measures

The Western Ontario McMaster Osteoarthritis index (WOMAC) was the disease specific outcome measure chosen, supplemented by the generic instrument, the Short Form-36 health survey (SF-36). The **primary outcome measure** (POCM) for this study was a comparison of the differences in the mean WOMAC pain scores between the two treatment groups 12 weeks after TKR.

5.8.2 Western Ontario and McMaster Universities Osteoarthritis Index

The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) assesses three patient reported dimensions: pain, physical function and stiffness. The WOMAC index consists of 24 questions (5 pain, 2 stiffness and 17 physical function) each with 5 response categories (scored as 0=none, 1=mild, 2=moderate, 3=severe, 4=extreme). The ranges of subscale scores for the three dimensions are pain: 0-20; stiffness: 0-8; and physical function: 0-68. A high score for the dimensions represents a high level of symptoms and poor level of functioning.

5.8.3 SF-36

The SF-36 measures health across eight dimensions: physical functioning (PF), role limitation because of physical health (RLP), social functioning (SF), vitality or energy (V), bodily pain (Pain), mental health (MH), role limitation because of emotional problems (RLE) and general health (GHP). Responses to each question within a dimension are combined to generate a score from 0 to 100, where 100 indicates "good health". The SF-36 can be used to compare patient perceived, health related quality of life for different health problems.

The SF-36 has been revised into a six dimensional health state classification called the SF-6D. Brazier et al[5] derived this preference based single index (or utility measure) from the UK SF-36 health survey to reduce all the outcomes to a single summary measure for use in economic evaluations. The six dimensions (Physical, Role, Social, Pain, Mental and Vitality) each have

between four and six levels. An SF-6D health state is defined by selecting one statement from each dimension. The SF-6D preference-based measure can be regarded as a continuous outcome scored on a 0.29 to 1.00 scale, with 1.00 indicating "full health".

5.8.4 Baseline assessment and follow up

Participants completed postal questionnaires (WOMAC, SF-36 and patient demographic data) at trial entry, within 8 weeks of addition to the waiting list for TKR. This baseline assessment was repeated for WOMAC & SF-36 at 12 weeks after TKR.

An additional patient questionnaire was designed and piloted to measure patient satisfaction with treatment; the number of private transport journeys made to the hospital physiotherapy outpatients department; the number of miles travelled and any other costs at 12 weeks post TKR.

Also, at 12 weeks post TKR demographic, co-morbidity and postoperative event data were collected from orthopaedic and GP records. NHS resource use was measured by data collected from orthopaedic, hospital physiotherapy outpatients' and GP notes and from questionnaires returned by community physiotherapists.

Reminder questionnaires and telephone calls were used for non-responders and missing responses.

5.8.5 Secondary Outcome measures

Secondary outcome measures were:

1. An economic evaluation assessing the average cost per patient of the physiotherapy intervention between the two groups. Resource use was compared between the two groups, in order to attribute cost per patient for the two treatment groups, as measured by data collection from hospital physiotherapy notes and community physiotherapist and patient responses on self-completion questionnaires; length of hospital stay, transport costs, attributed costs of physiotherapy sessions. Data were also collected from general practioner notes to assess number and type of analgesic prescriptions used by participants.
2. The proportion of patients expressing satisfaction in the two treatment groups and themes identified by patients about the processes of care (open comments), measured by self-completion questionnaires.

3. The proportion of patients in the two treatment groups with co-morbidity and post-operative complications as measured by data extracted from GP and orthopaedic notes and patient responses on self-completion questionnaires

Primary and secondary outcome measures, data collection tools and timing of data collection are summarised in Table 17.

Table 17 Outcome measures, data collection tools and timetable

Outcome measures data collection	Data collection Tool	Baseline	12 weeks postoperatively
HRQoL (WOMAC/ SF-36)	Patient questionnaire	√	√
Demographic data; age, gender, home status, carer, lives alone	Patient questionnaire	√	√
Co-morbidity	Patient questionnaire GP & orthopaedic notes data collection forms	√	√
Primary care resource use; GP consultations and prescriptions	GP data collection form		√
Orthopaedic resource use, post-operative events	orthopaedic notes data collection form		√
Physiotherapy resource use	Community physiotherapist data collection form Outpatient physiotherapy notes data collection form		√
NHS transport use	Outpatient physiotherapy notes data collection form Patient resource use questionnaire		√
Patient feedback, satisfaction & resource use	Patient views questionnaire Patient resource use questionnaire		√

5.9 Sample size

There are no published large scale randomised controlled trials comparing physiotherapy rehabilitation treatments for TKR using WOMAC as a primary outcome measure. Brazier et al demonstrated a mean difference of 4 and standard deviation of 4.3 in WOMAC pain dimension scores (0-20) when comparing two groups of patients with OA: one, surgical, group before and after TKR; the other group over the same time period in a medical outpatient clinic[1]. Thus, TKR as an intervention had a large impact on pain scores in a group of patients severely disabled by OA knee; however, physiotherapy rehabilitation as part of the TKR pathway would be expected to have a smaller additional effect. The sample size calculation is 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. The number calculated to detect this difference was 65 participants undergoing TKR in each physiotherapy treatment group (80% power, two sided significance level p=0.05). The recruitment sample size was increased to 80 in each group to allow for in excess of 15% patient withdrawals.

5.10 Statistical methods

Intention to treat analysis of quantitative data was blind to treatment group allocation, using SPSS statistical software i.e. patient data was analysed according to the original randomisation group regardless of whether the individual patient has changed treatment groups. All tables had the groups labelled as "Group 1 and Group 2" until the final analyses were complete. These output tables have been changed in the results section to reveal the treatment group, for clarity of presentation. Statistical tests are two-tailed with a p-value <= 0.05 regarded as "statistically significant".

Patient perceived health status scores (WOMAC and SF36) were assumed to be continuous measurements and were analysed using t test or by multiple linear regression analysis (where time to TKR differed significantly). Demographic and co-morbidity categorical data were compared using χ^2 test.

5.11 Economic Analysis

The aim of the economic evaluation was to determine whether providing pre- and post-operative community physiotherapy was a cost-effective use of NHS resources. In this trial, the main purpose of the economic analysis was to compare total costs and benefits

for the intervention and control groups at 12 weeks post-operatively and report any differences. The technique for performing the economic analysis (cost-effectiveness, cost-minimisation or cost-utility analysis) can only be chosen once costs and health outcomes for both the intervention and control group are known [88]. Where possible, all costs were identified, measured and valued from the perspective of the NHS using 2001/2002 prices, referring to local service providers or national data sources. The main cost burden of providing services for the intervention and control group were thought to fall on the health service. However, resource-use data were also collected to provide service commissioners with information about costs from the perspective of the patients in the trial.

The main cost categories were therefore:

- costs to the NHS
- costs incurred by the patients in the trial

NHS resource use was measured for 12 months prior to TKR and for 12 weeks after TKR. Secondary analysis compared personal expenditure of patients. Data were collected from GP, hospital physiotherapy and orthopaedic records. Community physiotherapists recorded number and length of visits to patients in the intervention group. Patient questionnaires and hospital physiotherapy notes assessed physiotherapy-related patient cost data and transport use. Important costs are summarised in Table 18.

Table 18 Important costs identified for each group

5.11.1 Important Costs	5.11.2 Intervention group	Control group
NHS	Community physiotherapy sessions	GP consultations
Pre-operative care	GP consultations	
Post-operative care	Hospital services: operation and length of stay	Hospital services: operation and length of stay
	GP consultations	GP consultations
	Hospital physio sessions	Hospital physiotherapy sessions
	Community physio sessions	NHS transport
	NHS transport	
5.11.3 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

5.12 Economic Data Costing Methods

5.12.1 Physiotherapy Costs

Costs of physiotherapy (community, hospital and hydrotherapy) treatment sessions were calculated using the number of minutes in each session multiplied by the physiotherapist's salary, taken to be the midpoint on the local salary scale. Added to this were employer on-costs direct, indirect and capital overheads per year. Indirect time spent on patient contacts, such as travel, administration etc were added to time spent on direct patient contact using nationally estimated ratios of direct to indirect time in hospital and community settings. Working time, allowing for holidays and sickness absence, was also taken from national estimates. Adjustments were made for individual and group treatment sessions to provide a cost per patient.

5.12.2 Community physiotherapy costs

Based on the above calculations the estimated cost per minute of community physiotherapists' time for home visits was £0.64. Training costs for the four intervention group physiotherapists were spread over the expected working lifetime of the physiotherapists within a community post of 10 years. The estimated cost of this training was £0.35, per home visit.

5.12.3 Hospital physiotherapy costs

Control group patients received post-operative hospital-based physiotherapy sessions in the form of knee classes and one-to-one sessions with a physiotherapist. A small number of intervention group patients also received hospital-based physiotherapy, post-operatively. Hospital records were reviewed to estimate the number of knee classes attended. Groups of 7-12 patients attended sessions run by two physiotherapists and one assistant. The unit cost of a knee class has two components: the average cost per patient for the one hour exercise circuit and, in addition, the 15 minutes spent with a physiotherapist one to one at the end of the gym session. The average cost of an hour's knee class came to £7.73 per patient. Added to this was the cost of 15 minutes per patient spent with either a senior-grade-1 or senior-grade-2 physiotherapist: making the total average cost of a knee class £15.46 per patient. Patients, who did not progress, had individual outpatient physiotherapy sessions. A typical session one-to-one lasts approximately 30 minutes and costs £16.5.

5.12.4 Hydrotherapy

Patients in both treatment groups who made unsatisfactory progress were referred to hydrotherapy where groups of 7 to 8 patients exercise in a pool, supervised by two senior-grade-2 physiotherapists, one senior-grade-1 physiotherapist and one half of a whole-time-equivalent (WTE) assistant physiotherapist. Information was only available about hydrotherapy referrals, not the number of sessions attended. It was assumed that patients usually attended six times (local NHS trust data) and therefore a typical total hydrotherapy cost is £85.98 (£14.33 x 6).

5.12.5 GP consultation costs

GP consultation data were collected, retrospectively from the patient notes from 12 months prior to TKR to 3 months after TKR. Consultations were costed using a national estimate of the cost per surgery consultation lasting 9.36 minutes (£19).

5.12.6 Prescriptions

In addition, data on the number of prescriptions for analgesics, non-steroidal anti-inflammatory drugs, antidepressants and night sedation were collected for each patient through a review of GP notes. This covered the 12 month period prior to the TKR operation and the 3 month period immediately after the operation. A comparison of numbers of prescriptions between the intervention and control group was undertaken. However, costing was not possible because of the lack of named drugs in each category.

5.12.7 Hospital services: operation and length of stay costs

The cost of a TKR operation was £2574 (local NHS trust data) and the cost per day spent in hospital was £263. Patient data on length of stay was collected from patient records and combined with these costs to estimate a cost per inpatient episode.

5.12.8 NHS transport costs

Patients questionnaire data were used to assess the number of NHS ambulance and car journeys to hospital. Local NHS patient transport services estimated the average cost of a one-way journey to be £9.02 (ambulance or NHS car). Cost per patient was calculated by multiplying the number of return journeys by £18.04.

5.12.9 Patient transport costs

Patient questionnaire data were used to assess the number of private transport journeys that were made to hospital outpatients department. In addition, patients estimated the number of miles travelled. The cost of private transport was calculated by multiplying number of return journeys by number of miles per round trip by an average cost per mile (Automobile Association reference).

5.13 Patient satisfaction and views

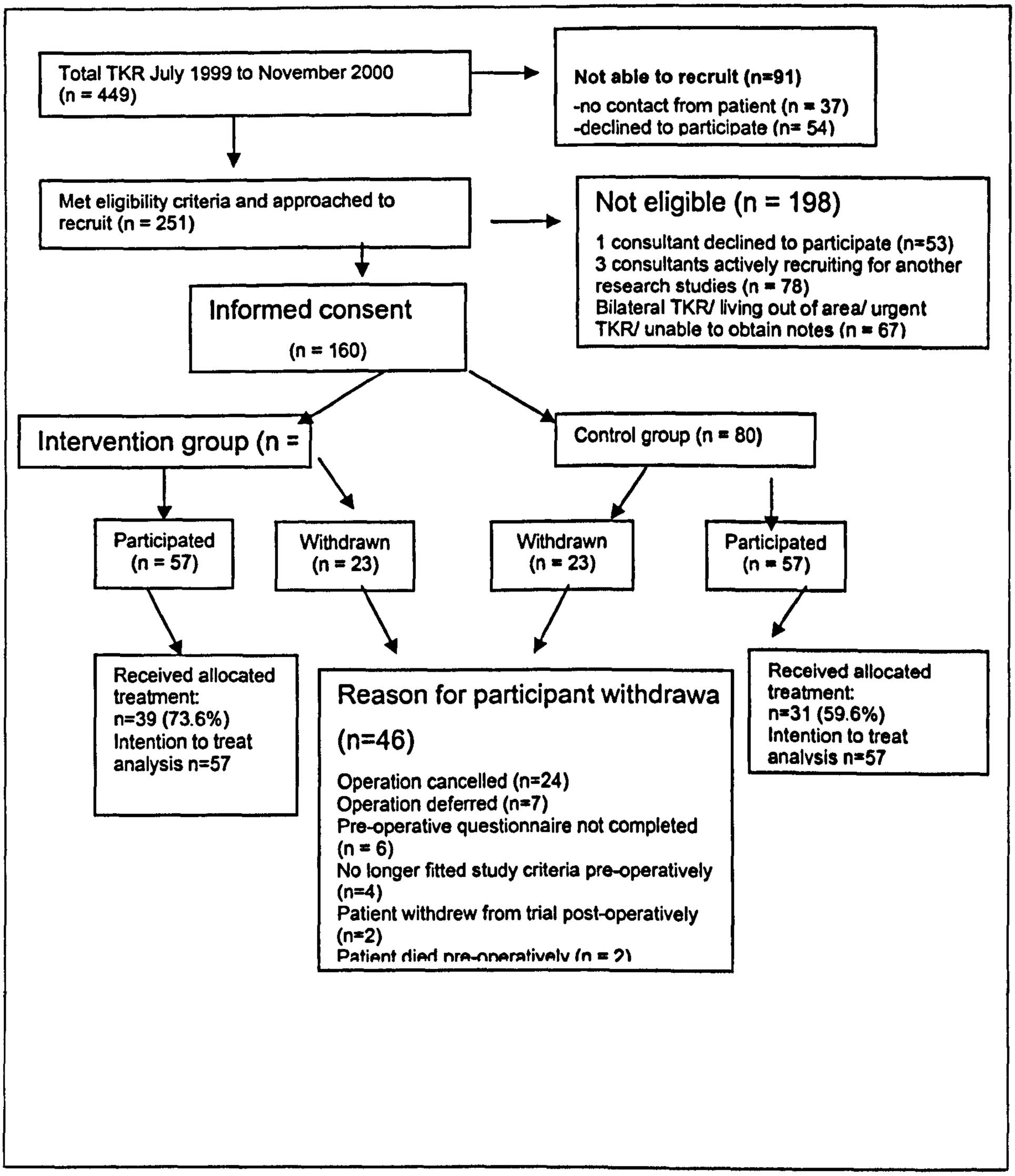
Closed question responses were tabulated and presented both by treatment group and as a whole patient group. Quantitative data were analysed using (χ^2 test) to compare treatment groups (SPSS statistical software). Free text comments were transcribed verbatim and independently coded and analysed by the principal investigator and a second researcher using Atlas-ti software. Themes were identified using an iterative process whereby constant comparisons were made between developing concepts and the raw data, including a search for contrasting observations. An academic partner undertook independent analysis and verification of the identification of emergent themes to minimise bias. A response framework was constructed to compare the frequency of participant responses, by theme.

6 RESULTS

6.1 Recruitment and participant flow

Participants were recruited from the waiting lists of 9 out of 13 consultants, who regularly performed TKR. Three further consultants agreed to refer TKR patients, but continued recruitment to a separate arthroplasty research study meant these patients were ineligible. A fourth non-referring consultant declined to participate but was also atypical since he recommended a specific physiotherapy programme, which differed from usual outpatient care. 160/251 (63.7%) of patients fulfilling all eligibility criteria consented to participate in the study. Figure 5 illustrates recruitment data and participant flow during the study.

Figure 5 Participant flow diagram



6.2 Study Withdrawal

The overall withdrawal rate from the study was higher than anticipated; 46/160 (28.8%). However, 24/160 (15%) of all participants withdrew from the study when their TKR was cancelled. 8/160 (5%) of participants were withdrawn from the study either due to failure to complete the pre-operative questionnaire or post-operative withdrawal from the study by participant request (Figure 1). Three participants died during the study; one participant who died post-operatively is included in the data analysis of withdrawn participants. Overall, the majority of study withdrawals were due to factors external to the study prior to TKR. There was no evidence that study withdrawal varied by group (p=1.0); Table 19.

Table 19 Comparison of patients by withdrawn status and treatment group

Withdrawn * Study group Crosstabulation

			Study group		
			Group 1	Group 2	Total
Withdrawn	No	Count	57	57	114
		% within Study group	71.3%	71.3%	71.3%
	Yes	Count	23	23	46
		% within Study group	28.8%	28.8%	28.8%
Total		Count	80	80	160
		% within Study group	100.0%	100.0%	100.0%

Chi-Square Tests

		Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square		.000[b]	1	1.000
Continuity Correction	[a]	.000	1	1.000
N of Valid Cases		160		

a. Computed only for a 2x2 table

b. 0 cells (.0%) have expected count less than 5. The minimum expected count is 23.00.

6.2.1 Comparison of baseline demographic characteristics by withdrawn status

Baseline comparison by gender, and history of previous knee replacement, hip surgery or knee surgery demonstrated no significant difference for each of these characteristics between participants and withdrawn patients (Table 20). Withdrawn patients were significantly more likely to report heart problems (p=0.02) and stroke/TIA (p=0.01).There were no significant differences between withdrawn patients and participants in other patient reported co-morbidities. (Table 21)

6.2.2 Comparison of primary health related quality of life (HRQoL) measures WOMAC and SF-36 by withdrawn status

There was no evidence to suggest that pre-operative WOMAC dimension scores differed between those patients who completed the study and those patients who withdrew (Tables 22 and 25). Comparisons of study withdrawal status by all SF-36 dimensions and SF-36 Summary measures are summarised in Table 23, 24 and 25. Withdrawn patients had significantly poorer scores on the General Health (p=0.037), Energy (p=0.004) and Mental Health (p =0.054) dimensions of the SF-36. The significance levels and confidence intervals for all WOMAC and SF-36 dimensions are summarised in Table 25.

6.2.3 Summary of significant differences between participating and withdrawn patients

There was no evidence that study withdrawal varied by group or WOMAC dimension scores. However, withdrawn patients had significantly poorer scores on the General Health (p=0.04), Energy (p=0.004) and Mental Health (p=0.05) dimensions of the SF-36 (Table 26) and were also significantly more likely to report heart problems (p=0.02) and stroke/TIA (p=0.01), (Table 21).

Table 20 Baseline demographic characteristics by study withdrawal status

Dependent Variable *(no. of patients)*	Participated n= (%)	Withdrawn n= (%)	P-value *χ2 test*
Male	48/114 (42.1)	17/46 (37.0)	0.673
Female	66/114 (57.9)	29/46 (63.0)	
Previous knee / hip surgery	63/113* (55.8)	23 /37* (62.2)	0.622

**missing data from incomplete questionnaires*

Table 21 Baseline co-morbidities for withdrawn and participating patients

Co-morbidity	Participating patients			Withdrawn patients			*P* value *χ2 test*
	Yes	No	6.2.4 Total	Yes	No	Total	
	n *(%)*	n *(%)*		n *(%)*	n *(%)*		
Heart problems	18 *(17.5)*	85 *(82.5)*	103	13 *(38.2)*	21 *(61.8)*	34	0.02
Stroke or Transient Ischemic attack	1 *(0.9)*	108 *(99.1)*	109	4 *(11.8)*	30 *(88.2)*	34	0.01
Chest problems	13 *(12.1)*	94 *(87.9)*	107	9 *(27.3)*	24 *(72.7)*	33	0.07
Diabetes	12 *(11.3)*	94 *(88.7)*	106	2 *(6.5)*	29 *(93.5)*	31	0.74
Raised blood pressure	46 *(41.8)*	64 *(58.2)*	110	13 *(37.1)*	22 *(62.9)*	35	0.77

Table 22 Baseline WOMAC dimension scores by study withdrawal status

WOMAC dimensions		No	Yes
Pre-operative WOMAC Pain Dimension	n	n=114	n=35
	Mean	12.2	11.2
	Std Deviation	(3.3)	(3.2)
	Median	12.0	12.0
	Minimum	5.0	5.0
	Maximum	20.0	17.0
Pre-operative WOMAC Stiffness Dimension	n	n=114	n=36
	Mean	5.3	4.9
	Std Deviation	(1.4)	(1.2)
	Median	5.0	5.0
	Minimum	2.0	2.0
	Maximum	8.0	8.0
Pre-operative WOMAC Physical Function	n	n=112	n=35
	Mean	40.3	39.4
	Std Deviation	(11.0)	(11.8)
	Median	41.0	39.0
	Minimum	11.0	11.0
	Maximum	68.0	60.0

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

A higher WOMAC score indicates poorer health related quality of life (HRQoL.)

Table 23 Baseline SF-36 Scores for withdrawn and participating patients

SF-36 Dimension	Participating patients *n=114*	Withdrawn patients *n=37*	*P* value (95% CI) *t-test (2-tailed)*
	Mean score (SD)	Mean score (SD)	
General Health	57.0 (20.8)	47.8 (23.2)	0.04 (0.6 to 17.7)
Mental Health	69.9 (17.3)	61.6 (23.4)	0.05 (-0.2 to 16.6)
Energy	43.2 (18.3)	32.1 (19.4)*	0.004 (3.6 to 18.4)
Bodily Pain	28.5 (16.5)	30.9 (20.1)	0.50 (-9.8 to 4.9)
Physical Function	24.4 (17.8)	24.1 (18.5)	0.91 (-6.6 to 7.3)
Role Emotional	41.8 (44.7)	42.3 (48.2)	0.95 (-18.5 to 17.4)
Role Physical	11.2 (24.9)	22.5 (34.3)	0.07 (-23.6 to 0.9)
Social Functioning	55.9 (29.0)	51.1 (34.9)	0.44 (-7.8 to 17.6)

1. ** n=35. Note the 95% CI are for the mean difference.*
2. *The eight dimensions of the SF-36 are scored on a 0 (poor health) to 100 (good health) scale; a higher score for each summary measure indicates better health related quality of life.*

Table 24 SF-36 Summary Measures at pre-operative assessment by study withdrawal status

Baseline SF-36 summary measures		Withdrawn	
		No	Yes
Pre-operative SF-36 MENTAL COMPONENT SCALE (MCS)	n	n=114	n=35
	Mean	3.71	-9.08
	Std Deviation	(33.06)	(39.99)
	Median	.48	-7.13
	Minimum	-73.82	-77.89
	Maximum	82.04	82.23
Pre-operative SF-36 PHYSICAL COMPONENT SCALE (PCS))	N	N=114	N=35
	Mean	-34.65	-40.60
	Std Deviation	(28.70)	(34.59)
	Median	-36.24	-48.64
	Minimum	-93.75	-97.24
	Maximum	56.62	25.55
Pre-operative SF-6D preference-based measure of health	n	n=114	n=32
	Mean	.52	.49
	Std Deviation	(.09)	(.11)
	Median	.51	.49
	Minimum	.32	.30
	Maximum	.87	.73

1. *A higher score for each summary measure indicates better health related quality of life*
2. *For the PCS and MCS a normal score is a mean of 50.*
3. *The SF-6D scores range from 0.3 to 1.0 (good health).*

Table 25 Comparison of WOMAC & SF-36 scores for participating and withdrawn patients

Independent Samples Test

		t-test for Equality of Means					
						95% Confidence Interval of the Difference	
		t	df	Sig. (2-tailed)	Mean Difference	Lower	Upper
Pre-operative SF-36 PHYSICAL FUNCTIONING (0-100	Equal variance not assumed	.108	59.131	.914	.4	-6.6	7.3
Pre-operative SF-36 ROLE-PHYSICAL (0-1	Equal variance not assumed	-1.858	48.926	.069	-11.3	-23.6	.9
Pre-operative SF-36 P. INDEX (0-100)	Equal variance not assumed	-.676	52.660	.502	-2.5	-9.8	4.9
Pre-operative SF-36 GENERAL HEALTH	Equal variance not assumed	2.140	56.018	.037	9.2	.6	17.7
Pre-operative SF-36 ENERGY/VITALITY	Equal variance not assumed	2.974	53.968	.004	11.0	3.6	18.4
Pre-operative SF-36 SOCIAL FUNCTIONIN	Equal variance not assumed	.771	53.062	.444	4.9	-7.8	17.6
Pre-operative SF-36 ROLE-EMOTIONAL	Equal variance not assumed	-.059	57.515	.953	-.5	-18.5	17.4
Pre-operative SF-36 MENTAL HEALTH IND	Equal variance not assumed	1.971	49.421	.054	8.2	-.2	16.6
Pre-operative SF-36 PHYSICAL COMPONE	Equal variance not assumed	.924	49.224	.360	5.9	-7.0	18.9
Pre-operative SF-36 MENTAL COMPONEN	Equal variance not assumed	1.720	49.112	.092	12.8	-2.2	27.7
Pre-operative SF-6D preference-based	Equal variance not assumed	1.168	44.929	.249	.024	-.018	.066
Pre-operative WOMAC Pain Dimension	Equal variance not assumed	1.701	57.809	.094	1.0	-.2	2.3
Pre-operative WOMAC Stiffness Dimension	Equal variance not assumed	1.665	68.139	.101	.4	-.1	.9
Pre-operative WOMAC Physical Function	Equal variance not assumed	.384	54.019	.702	.9	-3.6	5.4

6.3 Baseline comparisons of participants

6.3.1 Demographic and Primary Outcome data

One patient died post-operatively. The two treatment groups did not differ significantly with respect to age, gender, previous history of knee surgery and important co-morbidity (Table 26) and baseline WOMAC and SF-36 scores (Table 27). Patients in the home care group had a significantly longer mean preoperative waiting time, 30.7 weeks, compared with 25.5 weeks for the hospital treatment group (p=0.036) (Table 28). However, this difference of 5.2 weeks was not felt to be clinically significant.

Table 26 Baseline comparison of patient characteristics by treatment group

Characteristic	Hospital group	Home group
Mean age at total knee replacement in years (SD)	70.6 (8.2)	70.0 (7.2)
	numbers (n) (%)	numbers (n) (%)
Women	30 (52.6)	36 (63.2)
Heart Problems	10 (18.9)	8 (16)
Chest problems	7 (12.7)	6 (11.5)
Stroke / Transient Ischaemic attack	1 (1.80)	0
Diabetes	6 (11.1)	6 (11.5)
Raised Blood pressure	21 (37.5)	23 (46.3)
Previous knee/hip surgery	33 (57.9)	30 (53.6)
Previous TKR other knee	14 (26.4)	9 (15.8)
Lives alone	*12 (21.1)*	*17 (29.8)*

NB: Some patients did not answer all questions; therefore, total number in hospital group varies between 53-57 and between 50-57 in home group.

Table 27 Baseline comparison of WOMAC and SF36 scores by treatment group

Health status measure	Hospital group n=57	Home group n=57
WOMAC dimension*	Mean (SD)	Mean (SD)
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)

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

◊ SF36 dimension scores range from 0-100, a higher score for each summary measure indicates better health related quality of life. The SF-6D scores range from 0.3 to 1.0 (good health).

Table 28 Preoperative waiting time (weeks) for TKR by group

Group	Mean (SD)	Median	Range	*P* value, mean difference (95% CI) *t-test (2-tailed)*
Hospital n=55	25.5 (12.9)	25.1	2.0 - 45.3	0.036, 5.2 (0.4 to 10.1)
Home n=56	30.7 (13.1)	31.9	7.1 - 64.7	

6.4 Primary outcome measures

The postoperative WOMAC and SF36 questionnaire response rate was 98% (114/116). One patient died postoperatively. Both groups made significant improvements postoperatively on all dimensions of WOMAC, i.e. they reported less pain, less stiffness and improved physical function as measured by WOMAC (Table 29).

Analysis of the SF-36 dimensions, by group, demonstrated highly significant (p=<0.001) improvement in energy, bodily pain, physical function, role physical and a significant improvement in social functioning (p=0.002) for the home group. The hospital group showed significant improvement in bodily pain (p=<0.001), physical function (p=0.001) and role physical (p=0.0046). Theses changes pre- and post-operatively by group are summarised in Tables 30 and 31.

Table 29 Pre and postoperative WOMAC scores

WOMAC Dimension	Pre-op (n=57)	Post-op (n=57)	P-value (95% CI) t-test (2-tailed)
Hospital group	Mean score (SD)	Mean score (SD)	
Pain (0-20)	12.0 (3.1)	6.9 (4.3)	0.000 (3.91 to 6.31)
Stiffness (0-8)	5.2 (1.4)	3.6 (2.1)	0.000 (1.05 to 2.25)
Physical function (0-68)	40.6 (11.2)*	26.0 (15.0)*	0.000 (10.99 to 18.17)
Home group			
Pain (0-20)	12.4 (3.4)	6.8 (3.7)	0.000 (4.45 to 6.81)
Stiffness (0-8)	5.4 (1.4)	3.5 (1.4)	0.000 (1.38 to 2.47)
Physical function (0-68)	40.0 (11.0)*	24.9 (13.4) *	0.000 (11.43 to 18.75)

**n=55*

Table 30 Pre- and postoperative SF36 Scores for home and hospital groups

	Pre-op *(n=57)* **Mean score (SD)**	**Post-op** *(n=57)* **Mean score (SD)**	**P-value (95% CI)** *t-test (2-tailed)*
Home Group SF-36 Dimension			
General Health	57.0 (21.4)	61.0 (23.4)	0.113 (-8.93 to 0.97)
Mental Health	69.3 (18.9)	68.0 (20.4)	0.576 (-3.41 to 6.08)
Energy	42.1 (18.4)	50.7 (19.5)	0.000 (-12.53 to -4.66)
Bodily Pain	29.2 (17.5)	46.6 (20.6)	0.000 (-23.48 to -11.22)
Physical Function	21.8 (17.5)	41.6 (22.2)	0.000 (-25.18 to -14.33)
Role Emotional	43.9 (44.2)	48.0 (46.7)	0.503 (-16.27 to 8.08)
Role Physical	10.1 (23.6)	27.6 (37.1)	0.000 (-26.84 to -8.25)
Social Functioning	52.6 (28.6)	64.1 (26.6)	0.002 (-18.41 to -4.59)
Hospital group SF-36 Dimension			
General Health	56.9 (20.3)	61.0 (22.9)	0.100 (-8.87 to 0.80)
Mental Health	70.4 (15.7)	71.2 (20.0)	0.711 (-5.37 to 3.69)
Energy	44.2 (18.3)	48.2 (23.7)	0.179 (-9.76 to 1.87)
Bodily Pain	27.7 (15.6)	48.5 (26.8)	0.000 (-27.73 to -13.99)
Physical Function	27.0 (17.8)	43.3 (27.6)	0.000 (-23.11 to -9.38)
Role Emotional	39.8 (45.6)	45.6 (44.8)	0.322 (-17.56 to 5.87)
Role Physical	12.3 (26.4)	23.2 (36.2)	0.046 (-21.75 to -0.18)
Social Functioning	59.3 (29.2)	60.8 (33.1)	0.708 (-9.85 to 6.73)

Table 31 **Pre- and postoperative SF-36 summary measures by group**

	Pre-op *(n=57)* **Mean score (SD)**	**Post-op** *(n=57)* **Mean score (SD)**	**P-value (95% CI)** *t-test (2-tailed)*
HOME GROUP SF-36 Summary measure			
Mental component scale (MCS)	2.36 (33.16)	14.3 (37.9)	0.003 (-19.58 to -4.25)
Physical component scale (PCS)	-36.81 (28.07)	-11.5 (36.1)	0.000 (-32.35 to -18.19)
SF-6D: preference-based measure of health	0.52 (0.09)*	0.57 (0.9)*	0.000 (-0.08 to -0.03)
HOSPITAL GROUP SF-36 Summary measure			
Mental component scale (MCS)	5.06 (33.20)	13.1 (43.3)	0.102 (-17.83 to 1.66)
Physical component scale (PCS)	-32.49 (29.40)	-12.4 (45.2)	0.000 (-30.47 to -9.71)
SF-6D: preference-based measure of health	0.51 (0.10)*	0.56(0.12)*	0.003 (-0.08 to -0.02)

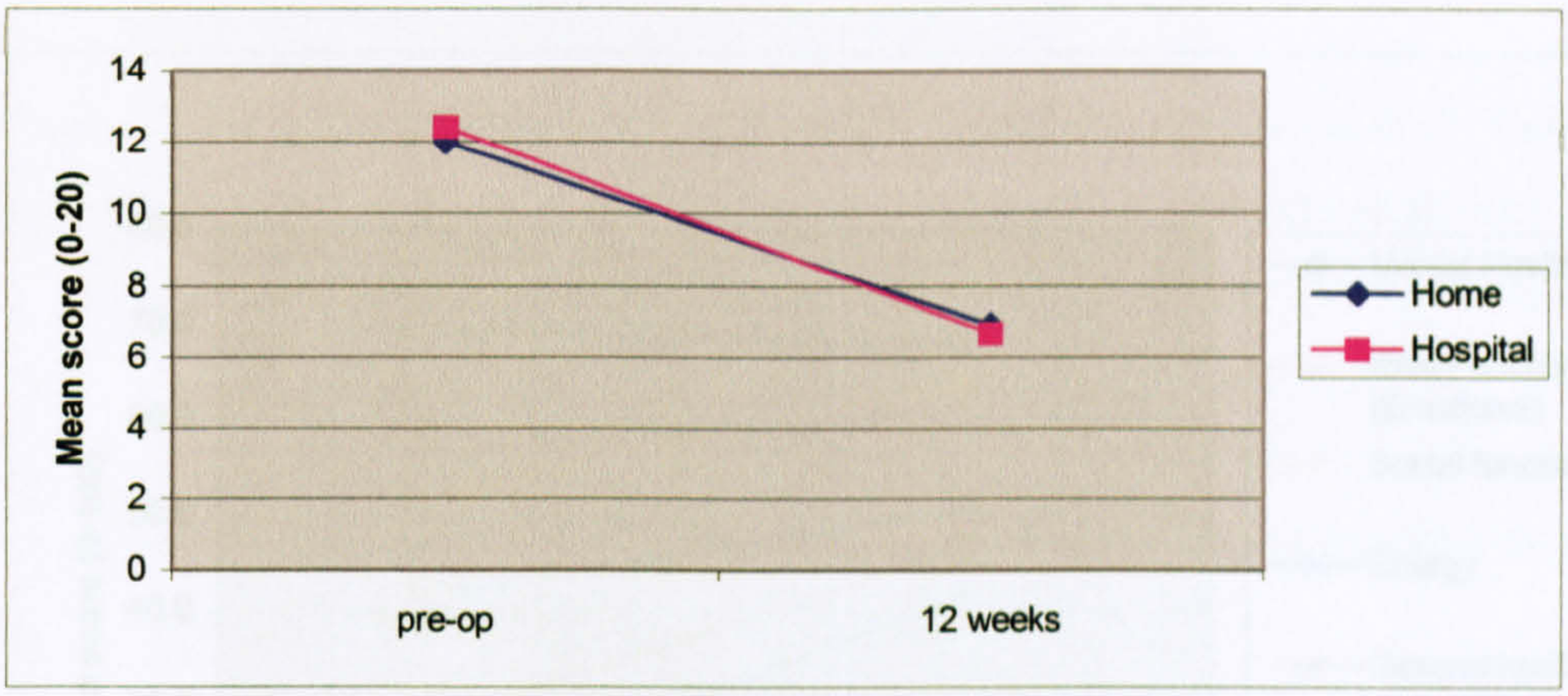
**n=56*, there are 2 decimal places for summary measure pre-op but 1 for post-op

6.4.1 WOMAC and SF-35 scores; comparison of scores by intervention group pre- and postoperatively

Figures 6-8 allow direct comparison between the two groups as regards their changes on the WOMAC pain, stiffness and physical functioning dimensions.

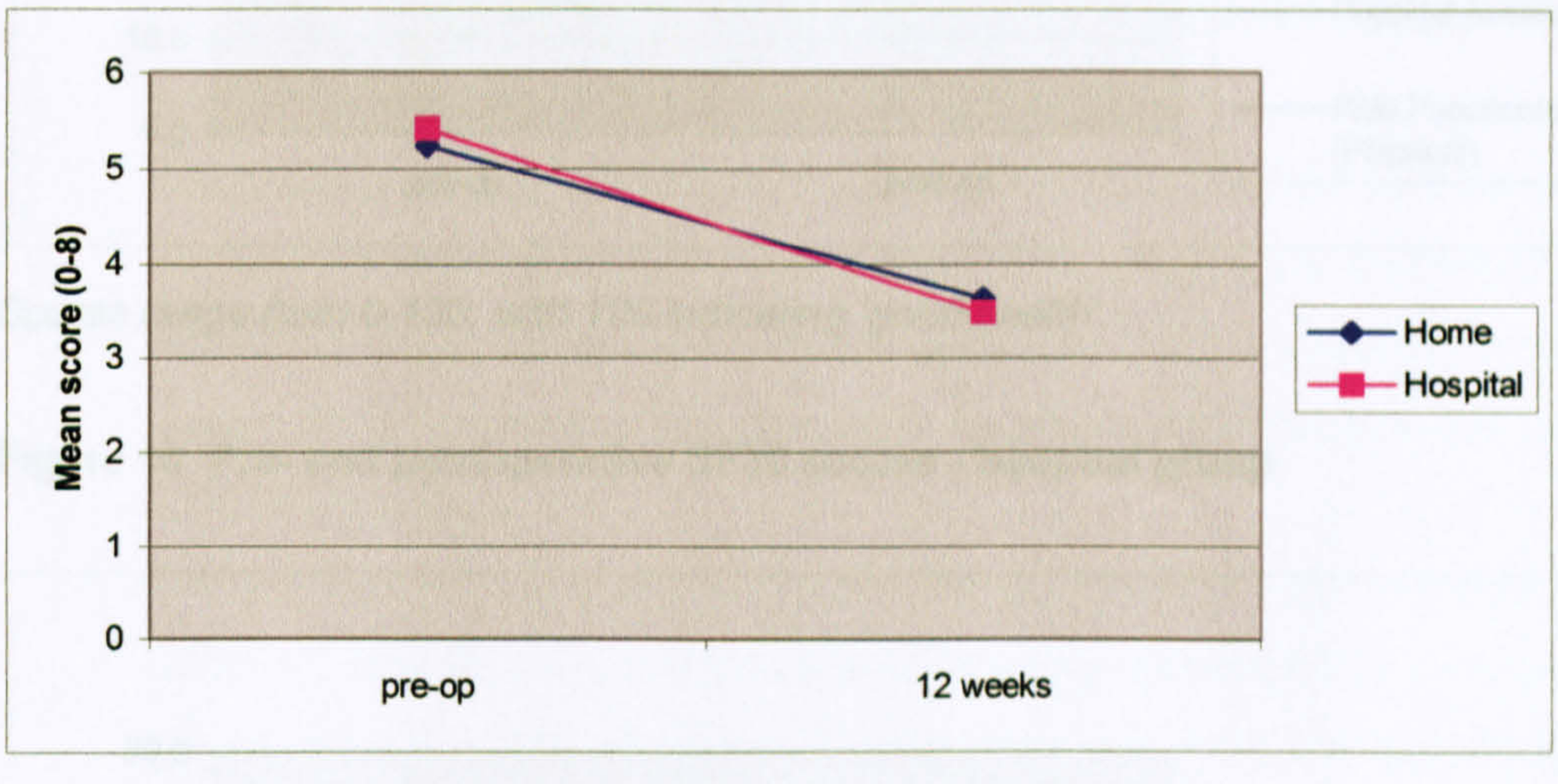
Figures 9 and 10 show the changes in SF-36 dimensions for the two groups.

Figure 6 Pre- and postoperative WOMAC pain scores for hospital and home groups



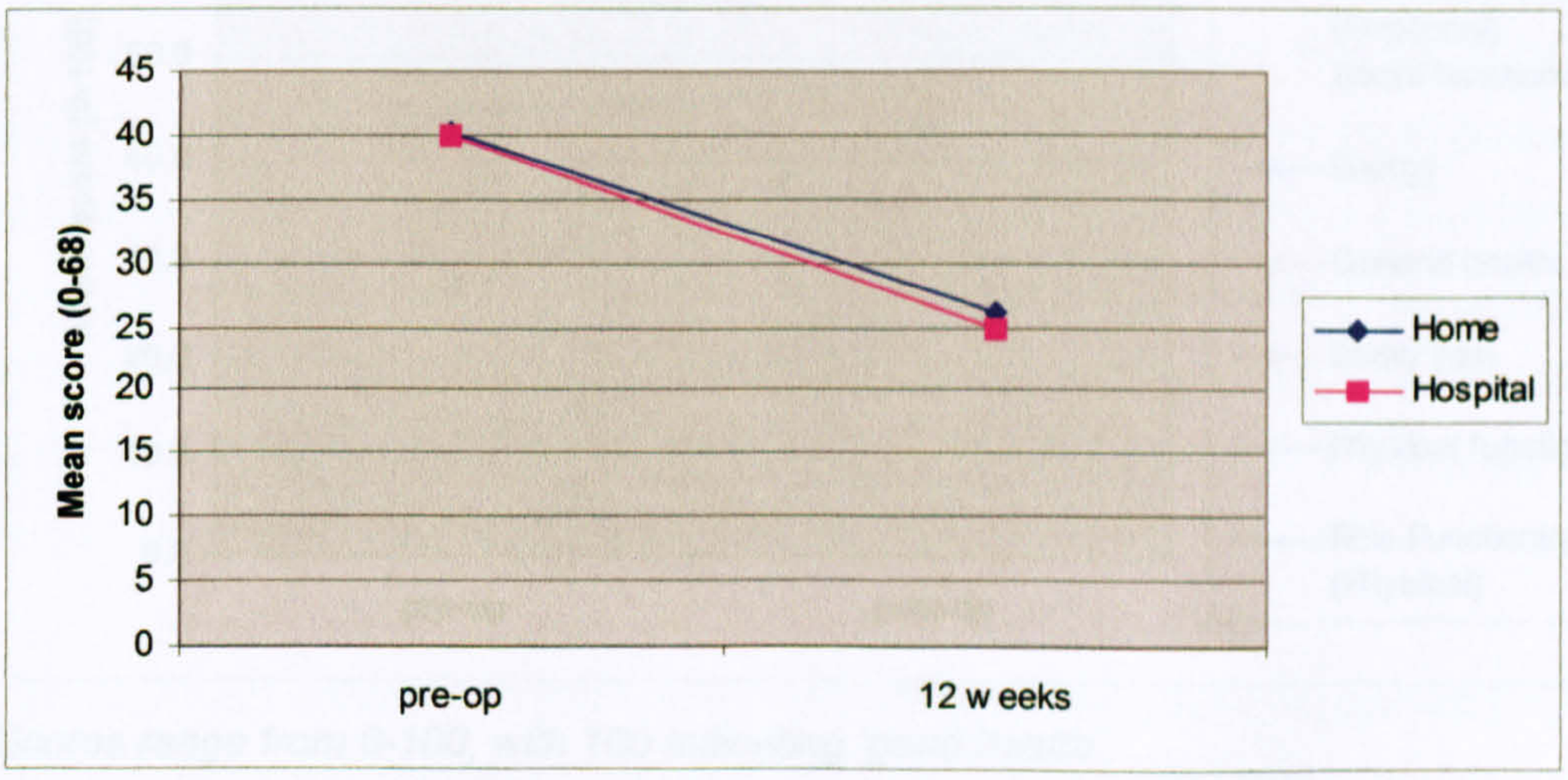
Scores range from 0–20; the higher the score, the greater the pain

Figure 7 Pre- and postoperative WOMAC stiffness scores for home and hospital groups



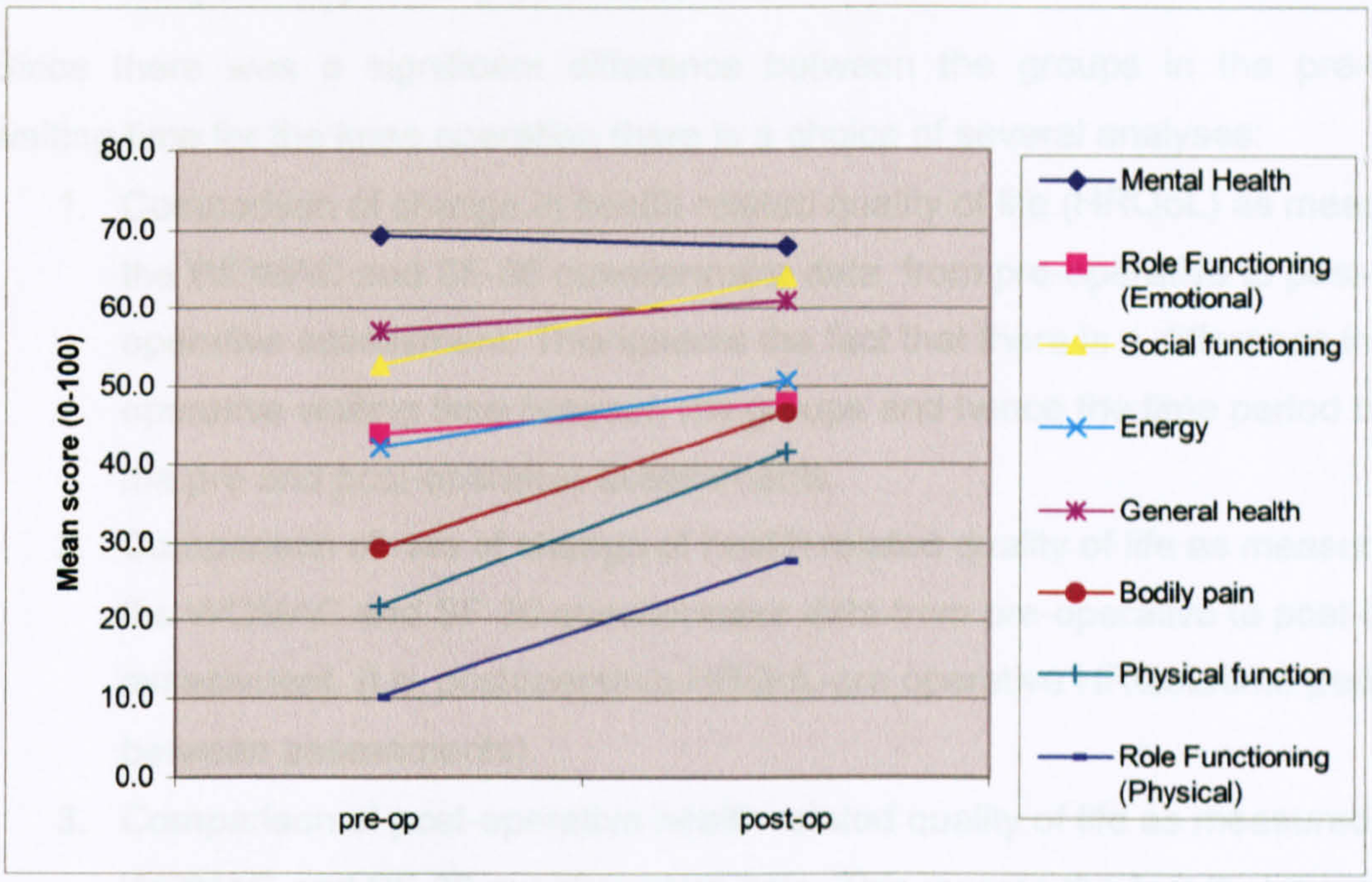
Scores range from 0–8; the higher the score, the greater the stiffness

Figure 8 Pre- and postoperative WOMAC physical function scores for home and hospital groups



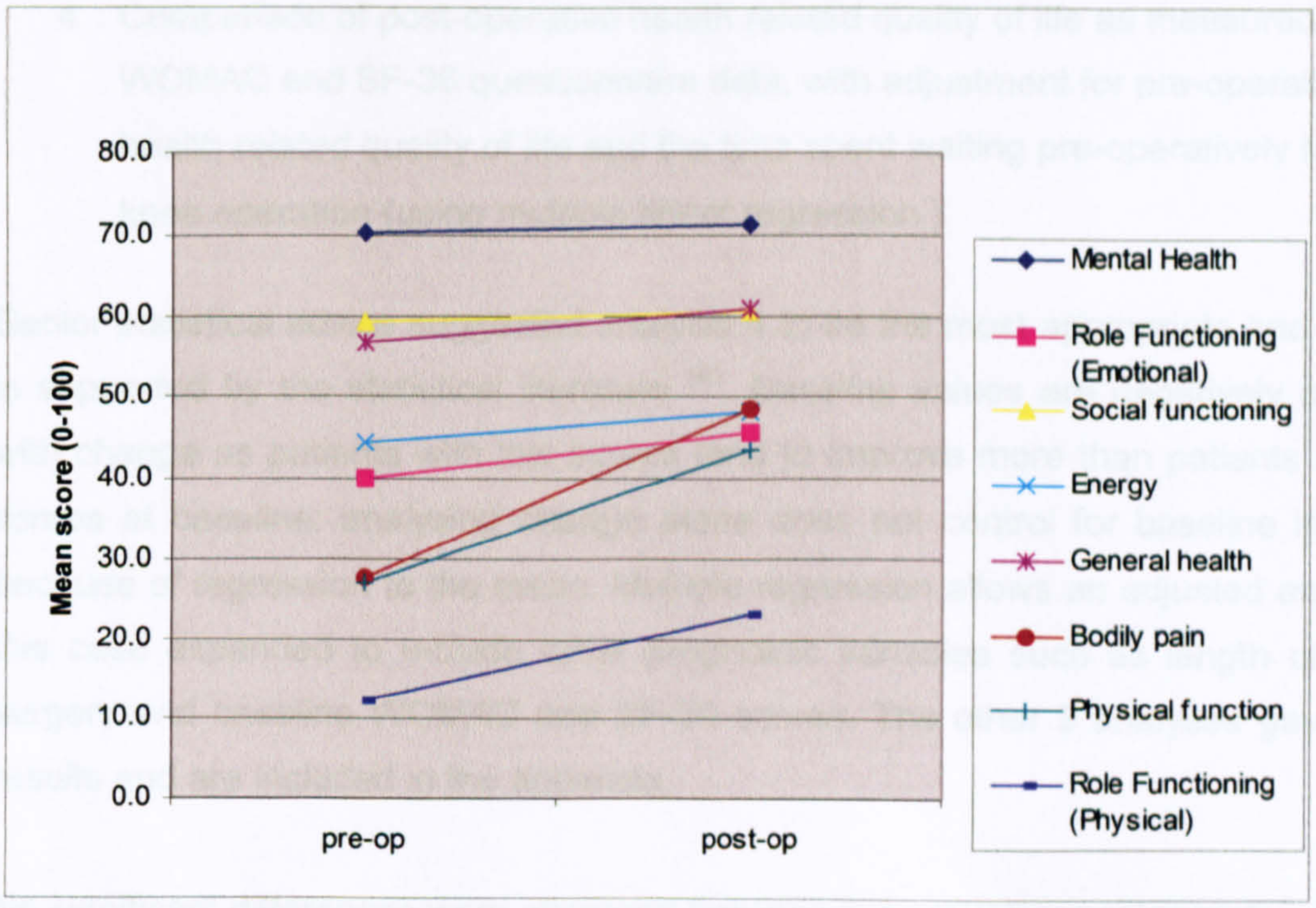
Scores range from 0–68; the higher the score, the poorer the level of functioning

Figure 9 Pre- and postoperative SF36 scores - home group



Scores range from 0-100, with 100 indicating 'good health'.

Figure 10 Pre- and postoperative SF36 scores - hospital group



Scores range from 0-100, with 100 indicating 'good health'.

6.5 Analysis of primary outcome data

Since there was a significant difference between the groups in the pre-operative waiting time for the knee operation there is a choice of several analyses:

1. Comparison of change in health related quality of life (HRQoL) as measured by the WOMAC and SF-36 questionnaire data from pre-operative to post-operative assessment. This ignores the fact that there is a difference in the pre-operative waiting time between the groups and hence the time period between the pre and post-operative assessments.
2. Comparison of rate of change of health related quality of life as measured by the WOMAC and SF-36 questionnaire data from pre-operative to post-operative assessment. (I.e. postoperative HRQoL-pre operative HRQoL/time period between assessments).
3. Comparison of post-operative health related quality of life as measured by the WOMAC and SF-36 questionnaire data. This ignores the fact that there is a difference in the timing of the assessments and the pre-operative health related quality of life. (Although pre-operative health related quality of life was the same for both Groups).
4. Comparison of post-operative health related quality of life as measured by the WOMAC and SF-36 questionnaire data, with adjustment for pre-operative health related quality of life and the time spent waiting pre-operatively for the knee operation (using multiple linear regression.)

Senior statistical advice suggested analysis 4 to be the most appropriate and this view is supported by the statistical literature [101]. Baseline values are negatively correlated with change as patients with low scores tend to improve more than patients with high scores at baseline; analysing change alone does not control for baseline imbalance because of regression to the mean. Multiple regression allows an adjusted analysis, in this case expanded to include other prognostic variables such as length of wait for surgery and baseline WOMAC and SF-36 scores. The other 3 analyses gave similar results and are included in the appendix.

No significant differences were observed between the groups in postoperative WOMAC and SF36 mean scores (Table 32). The regression coefficient for study group represents the effect on postoperative WOMAC and SF36 scores of moving from Group 1(usual care) to Group 2 (intervention) after adjusting for preoperative WOMAC

and SF36 scores and preoperative waiting time. Data for 111 participants were used for this latter analysis since trial entry data for three participants were unavailable.

Table 32 Mean scores and results of multiple linear regression analysis of postoperative WOMAC and SF-36 by treatment group

Health status measure	Hospital group mean score (SD)	Home group mean score (SD)	*N*	Regression Coefficient[a] (95% CI)	*P* value	R^2
WOMAC[b]:						
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
Physical Function	26.4 (14.9)	24.9 (13.4)	108	-1.0 (-5.9 to 3.8)	0.677	0.24
SF-36[c]:						
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

a. The regression coefficient for study group represents the effect on post-operative health related quality of life of moving from Group 1 (Hospital) to Group 2 (Home) after adjusting for preoperative HRQoL and preoperative waiting time

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

c. SF36: scores for dimensions range from 0-100; a higher score indicates better health related quality of lifeThe SF-6D scores range from 0.3 to 1.0 (good health)

6.6 In summary

As demonstrated in Figures 6-10 and Table 32, no significant differences were observed between the two groups in postoperative mean scores on any dimension of the WOMAC or SF-36 including the primary outcome measure, the WOMAC pain dimension (p = 0.53; mean difference -0.5; 95% CI = -2.0 to 1.0), even after adjustment for preoperative health related quality of life and preoperative waiting time

6.7 Physiotherapy outcomes

Physiotherapy data were missing for 9/114 patients due to missing hospital notes, despite repeated hospital data collection visits, and non-returned questionnaires (1 patient died and 5 participants from the hospital group had no physiotherapy). Physiotherapy outcome data were therefore complete for 105/114 participants within the intention to treat analysis. The home physiotherapy group had more treatment sessions than the hospital group: a mean of 8.4 sessions (including a mean of 2.8 preoperative sessions) compared with a mean of 3.5 sessions; four home group patients also had hospital outpatient sessions which increased that group's total mean number of treatment sessions to 8.7, the difference between them and the hospital group being statistically significant (p=0.001, 95% CI = -6.3, -4.1). The comparison of physiotherapy resource use for the two treatment groups is described in the economic analysis. The mean wait to first postoperative physiotherapy appointment after hospital discharge was significantly longer (p=0.001) for the hospital outpatient physiotherapy group (mean 18.6 days) compared with the home physiotherapy group (mean 3 days); see Table 33.

Physiotherapy treatment outcomes, by group, are summarised in Table 34. Forty-four patients (79%) from the home care group completed the standard pre- and postoperative home physiotherapy rehabilitation programme. Four patients had NHS funded total knee replacement at a local private hospital (waiting list initiative) and two of these patients opted to have NHS funded private outpatient physiotherapy, having already had preoperative home physiotherapy. Two patients mistakenly attended knee classes postoperatively but then reverted to their community input. Two patients were referred directly to hydrotherapy from the hospital ward. Five patients were referred on to hydrotherapy following their community input. The majority of the hospital outpatient physiotherapy group had 'knee class' rehabilitation sessions only (64%); five patients had no postoperative physiotherapy; six had only private outpatient sessions; and four patients were referred on to hydrotherapy after having had knee classes.

In addition to the study participants, 19 patients from the home group who withdrew or were withdrawn received some preoperative home physiotherapy sessions. One of these was known to have cancelled their operation because of improvement in their knee.

Table 33 Time to first post-operative physiotherapy appointment after hospital discharge

Treatment group	Mean days to 1st post-op appt (range)	SD	Standard Error of the Mean	P-value, mean difference (95% CI) *t-test (2-tailed)*
Hospital care n=52	18.62 (2-97)	16.72	2.32	p= <0.001 15.5 (10.82- 20.17)
Home care n=51	3.12 (1-10)	1.90	0.27	

Table 34 Physiotherapy treatment outcomes

Treatment outcome	Home care group *n= 56* No *(%)*	Hospital care group *n=53* No *(%)*
Completed treatment protocol	44 *(78.6)*	34 (64.1%)
NHS funded private TKR + private postoperative physiotherapy	2 *(3.6)*	6 *(11.3)*
Referred directly to hydrotherapy from the ward	2 *(3.6)*	0
Knee classes (by mistake) + community physiotherapy	2 *(3.6)*	-
Had community (non-research) physio post-op	-	4 *(7.5)*
Transferred to outpatients physiotherapy post-op as withdrew	1 *(1.8)*	0
Referred on to hydrotherapy	5 *(8.9)*	4 *(7.5)*
No postoperative physiotherapy	0	5 *(9.4)*

6.8 Economic evaluation

The aim of the economic evaluation was to compare costs and outcomes at 12 weeks post-TKR for the two treatment groups. Given that health outcomes (WOMAC and SF36) were similar for both groups at 12 weeks post TKR, the economic analysis was limited to a comparison of costs between the control and intervention groups (cost-minimisation analysis). The primary analysis compared the aggregate mean NHS cost per patient in each group at 12 weeks post TKR. Final results were subjected to sensitivity analysis of the key assumptions about unit costs and observed variance in resource use. P-values are from the two-independent-samples t-test, a significance level of p=0.005 was used.

Study subjects were included in the economic analysis if they had had a total knee replacement (TKR) operation and if the date of their entry into the trial was known: n=56 and n=55 in the intervention and control groups respectively. These were the same groups that were chosen for analysis of change, and rate of change, of health related quality of life (WOMAC and SF-36) in the post-operative period. Missing values for pre or post-operative NHS resource use were imputed using the average for all study subjects whenever possible.

Of the remaining patients in the intervention group 13 who were on the waiting list received pre-operative physiotherapy but did not go on to have a TKR operation. Similarly, 23 patients in the control group who were on the waiting list for a TKR did not have an operation but they did *not* receive pre-operative therapy as part of this trial. In the analysis presented here the resource-use and costs associated with cancelled operations were not included. If future evidence indicated that pre-operative physiotherapy alone improved a patient's condition so that an operation was avoided then those cost savings would need to be taken into account. The results of the primary analysis are described in detail in the following sections.

6.8.1 Community physiotherapy costs

Community physiotherapy resource use and costs were analysed at 12 weeks post-operatively to coincide with the measurement of health outcomes. The estimated cost per minute of community physiotherapists' time for home visits was £0.64. The estimated cost of training was £0.35 per home visit. Home group patients had an average of 2.8 physiotherapy visits prior to TKR (Table 35). The average length of a visit was 36 minutes (Table 36) and the average cost of one preoperative visit was £23.6, with a median of £22.6 (quartiles = £19.4 - £29.0). The average cost per patient for their preoperative visits was £65.60. The total cost of pre-operative physiotherapy for the 56 intervention group patients was £3675. The physiotherapists made 156 visits altogether to the patients preoperatively; the total cost of these visits for the 56 home group patients was £3675.

In the 12 weeks after the TKR operation, patients had an average of 5.6 home visits by a community physiotherapist; the average length of these visits was 35 minutes (Table 36). The average cost per patient for their postoperative visits was £125.5. The total cost of postoperative home physiotherapy for the 56 patients was £7028 (315 visits). The total average cost per patient for their home physiotherapy was £191.1. In addition, four home group patients had hospital input, which brought the total average cost to £197.9.

Table 35 Resource use per pre-operative community physiotherapy visit

n = 156	Mean (SD)	Median (quartiles)
Length of visit (minutes)	36 (15)	35 (30-45)
Number of visits	2.8 (1)	3 (2-3)

Table 36 Resource use per post-operative community physiotherapy visit

n = 315	Mean (SD)	Median (quartiles)
Length of visit (minutes)	35 (11)	30 (30-45)
No. of visits	6 (3)	5 (4-7)

6.8.2 Hospital physiotherapy

Hospital physiotherapy resource use and costs were analysed at 12 weeks post-operatively to coincide with measurement of health outcomes and are summarised in Table 37. Table 38 shows NHS costs for the post-operative period of 12 weeks as well as for the pre-operative period. Four home group patients, out of the 56 who were included in this analysis, received hospital physiotherapy, by mistake, in the form of knee classes or one-to-one sessions. However, no usual care group patients received community physiotherapy.

Patients in the usual care group attended 2.3 knee classes on average in the post-operative period. The mean cost of this service, per patient was £36.0 (SD=£42.0). Two patients from the intervention group attended knee classes at hospital. The mean cost of using this service was £0.8 per patient in this group (SD=£4.6). Two patients from the intervention group attended one-to-one sessions with a hospital physiotherapist compared to 10 from the usual care group. The mean costs per patient, for this service, were £4.40 (SD=£23.7) and £19.20 (SD=£43.8) for the intervention and usual care groups, respectively. The overall mean cost of physiotherapy services for the usual care group was £61.50.

Thus physiotherapy services for the intervention group were significantly more costly than for the usual care group: £197.9 compared to £61.5 (mean difference = -£136.5, P=0.001).

6.8.3 Hydrotherapy

The number of hydrotherapy referrals was measured, however data regarding the number of sessions attended was not available. It was assumed that patients usually attended six times (local NHS trust data) and therefore a typical total hydrotherapy cost was £85.98. Mean costs for the home and hospital group were £1.5 and £6.3 respectively. This was based on one patient from the home group and four from the hospital group being referred to hydrotherapy. As can be seen from Table 35, five home group patients were actually referred but incomplete hydrotherapy referral data was available to the health economist.

6.8.4 GP consultation costs

The mean number of GP consultations was very similar for both groups both pre- (in the 12 months prior to surgery) and postoperatively (Table 39). Preoperatively, patients had approximately 7 consultations; the mean cost of these was £130 for the home group and £128.5 for the hospital group. In the three months following TKR, the mean number of

consultations was 2.6 and 2.8 for the home and hospital groups respectively; the corresponding mean costs per patient being £48.9 and £53.9.

6.8.5 In-patient costs

The mean length of hospital stay for the home group was 9.2 days compared to 9.6 days for the hospital group (Table 38). Although not statistically significant, the difference between the groups of 0.4 days resulted in a lower mean cost for the home group of £4993 (SD=£906) compared to £5089 (SD=£785) for the hospital group (Table 39).

6.8.6 NHS transport costs

About half of the hospital group patients used NHS (ambulance or medicar) transport to attend hospital physiotherapy. The mean cost per patient for the hospital group for ambulance and car services combined was £38.7 (Table 39). Five patients from the home group used NHS transport to attend hospital physiotherapy. The mean cost difference per patient between the two groups was £31.6 and was statistically significant (p=0.002).

6.8.7 Total NHS costs

The mean NHS preoperative total cost per patient for the home group was £195.6 compared with £128.5 (Table 39) for the hospital group; the difference between the two, £67.1, being statistically significant (p=0.001). This difference is mostly accounted for by the costs of the preoperative community physiotherapy services received by the home group. The mean NHS postoperative total cost per patient for the home group was £5181 compared with £5243 for the hospital group; the difference between the two, £62, was not statistically significant. When preoperative and postoperative NHS costs were combined, the mean total NHS cost per patient in the home group was £5376 compared to £5372 for the hospital group. The difference of £4.7 was not statistically significant.

Table 37 Quantity of NHS resources consumed by patients

NHS Resource	Home group *n=56* Mean (SD)	Home group *n=56* Median (quartiles)	Hospital group *n=55* Mean (SD)	Hospital group *n=55* Median (quartiles)	Mean Diff (95% CI)	*P* value
Preoperative						
Community physio visits	2.8 (1.0)	3.0 (2.0-3.0)				
GP consultations	6.8 (4.4)	6.0 (3.0-9.0)	6.8 (4.6)	6.0 (3.0-10.0)	-0.08 (-1.8 to 1.6)	0.929
Postoperative						
Length of hosp stay (days)	9.2 (3.4)	8.0 (7.0-10.0)	9.6 (3.0)	9.0 (7.0-11.0)	0.4 (-0.8 to 1.6)	0.550
GP consultations	2.6 (2.0)	2.0 (1.0-3.0)	2.8 (2.1)	3.0 (1.0-4.0)	0.3 (-0.5 to 1.0)	0.504
Hosp physiotherapy:						
Knee classes	0.1 (0.3)*	0.0 (0.0-0.0)	2.3 (2.7)	2.0 (0.0-3.0)	2.3 (1.6 to 3.0)	0.001
One to one sessions	0.3 (1.4)*	0.0 (0.0-0.0)	1.2 (2.7)	0.0 (0.0-0.0)	0.9 (0.1 to 1.7)	0.029
Hydrotherapy referrals	0.0 (0.1)*	0.0 (0.0-0.0)	0.1 (0.3)	0.0 (0.0-0.0)	0.1 (-0.0 to 0.1)	0.166
Community physio sessions	5.6 (2.8)	5.0 (4.0-7.0)				
Ambulance journeys	0.1 (0.5)*	0.0 (0.0-0.0)	1.3 (3.3)	0.0 (0.0-1.0)	1.2 (0.3 to 2.0)	0.010
Medicar journeys	0.3 (1.5)*	0.0 (0.0-0.0)	1.0 (1.8)	0.0 (0.0-1.0)	0.6 (-0.0 to 1.2)	0.066

1. **Some home group patients had hospital physiotherapy as well as community physiotherapy*
2. *P-values are from a 2 independent sample t-test.*

Table 38 NHS costs per patient by treatment group**

NHS Resource	Cost (£)					P value*
	Home group *n=56*		Hospital group *n=55*			
	Mean (SD)	Median (quartiles)	Mean (SD)	Median (quartiles)	Mean diff (95% CI)	
Preoperative						
Community physio. visits	65.6 (15.0)	67.9 (55.9-74.2)				
GP consultations	130.0 (83.1)	114.0 (62.0-171.0)	128.5(87.3)	114.0 (57.0-190.0)	-1.4 (-33.5 to 30.6)	0.929
Total pre-op costs	**195.6 (81.5)**	**183.4 (143.9-239.6)**	**128.5(87.3)**	**114.0 (57.0-190.0)**	**-67.1 (-98.8 to -35.3)**	**0.001**
Postoperative						
Inpatient stay (inc TKR)	4993 (906)	4678 (4415-5204)	5089 (785)	4941 (4415-5467)	97 (-222 to 416)	0.550
GP consultations	48.9 (37.5)	38.0 (19.0-57.0)	53.9 (41.5)	57.0 (57.0-76.0)	5.0 (-9.8 to 19.9)	0.504
Hospital physio.						
Knee classes	0.8 (4.6)	0.0 (0.0-0.0)	36.0 (42.0)	31.0 (0.0-46.4)	35.2 (24.0 to 46.3)	0.001
One to one	4.4 (23.7)	0.0 (0.0-0.0)	19.2 (43.8)	0.0 (0.0-0.0)	14.8 (1.6 to 28.0)	0.029
Hydrotherapy	1.5 (11.5)	0.0 (0.0-0.0)	6.3 (22.5)	0.0 (0.0-0.0)	4.7 (-2.0 to 11.4)	0.166
Community physio. visits	125.5 (67.9)	114.9 (87.8-164.0)				
Total post-op physio costs	*132.3 (60.7)*	*117.9 (90.8-164.0)*	*61.5 (57.1)*	*46.4 (31.0- 82.7)*	*-70.8 (-93.0 to -48.6)*	*0.001*
Ambulance journeys	1.9 (8.9)	0.0 (0.0-0.0)	23.0 (59.2)	18.0 (0.0-18.0)	21.0 (5.2 to 36.9)	0.010
Medicar journeys	5.2 (27.9)	0.0 (0.0-0.0)	15.7 (32.0)	0.0 (0.0-18.0)	10.6 (-0.7 to 21.9)	0.066
Total NHS transport costs	*7.1 (28.9)*	*0.0 (0.0-0.0)*	*38.7 (67.4)*	*18.0 (0.0-54.1)*	*31.6 (12.2 to 51.1)*	*0.002*
Total post-op costs	**5181 (919)**	**4953 (4630-5363)**	**5243 (796)**	**5172 (4593-5696)**	**62 (-262 to 386)**	**0.703**
Total costs	**5376 (916)**	**5143 (4800-5584)**	**5372 (832)**	**5241 (4754-5924)**	**-4.7 (-334 to 324)**	**0.978**

*two-independent samples t-test. **costs estimated at 2001 / 2002 prices

6.8.8 Prescriptions

Although it was not possible to cost prescriptions, the number issued by GPs within each category (analgesics + non-steroidal anti-inflammatory drugs (NSAIDS), anti-depressants and night sedation) were measured (Table 40). For all categories, there was no statistically significant difference between the two groups in the mean number of prescriptions issued in the pre- or postoperative period.

6.8.9 Patient Costs

Patient costs comprised private transport and other out of pocket expenses (Table 40). The mean cost per patient of private transport was £13.8 (SD=£22.5) for the hospital group compared with £2.3 (SD=£7.9) for the home group. One patient in the home group reported spending £5 for an ice pack. No other out-of-pocket expenditures were reported.

Table 39 Number of prescriptions used per patient pre- and postoperatively by treatment group

PRESCRIPTION CATEGORY	Home group *n=56* Mean (SD)	Hospital group *n=55* Mean (SD)	Mean Diff (95% C.I.)	*P* value*
Preoperative (12 months)				
Analgesics +NSAIDS	7.7 (6.7)	5.9 (4.7)	-1.8 (-4.0 to 0.4)	0.099
Antidepressants	0.8 (2.6)	0.9 (3.1)	0.1 (-0.9 to 1.2)	0.820
Night sedation	0.3 (1.2)	0.2 (1.1)	-0.1 (-0.5 to 0.3)	0.685
Postoperative (3 months)				
Analgesics +NSAIDS	2.3 (1.8)	2.1 (2.1)	-0.2 (-0.9 to 0.5)	0.598
Antidepressants	0.3 (0.8)	0.3 (1.1)	0.1 (-0.3 to 0.4)	0.748
Night sedation	0.2 (0.7)	0.1 (0.5)	-0.1 (-0.3 to 0.2)	0.650

** P-values are from a two independent sample t-test.*

Table 40 Private transport costs per patient (£)

Costs of Resources	Intervention (n=56)		Control (n=55)			
	Mean (SD)	Median (quartiles)	Mean (SD)	Median (quartiles)	*P* value*	Mean Diff (95% C.I.)
Private transport costs	2.3 (7.9)	0.0 (0.0-0.0)	13.8 (22.5)	8.4 (0.0,13.2)	0.000	11.5 (5.2,17.8)

**P-values are from the two-independent-samples t-test*

6.9 Sensitivity analysis

The mean total costs of pre and postoperative NHS services were similar for both treatment groups but community physiotherapy was significantly more costly than hospital physiotherapy in this study. There appeared to be three ways of reducing community physiotherapy costs: a) shorter visiting times in the patients' homes; b) a reduction in the number of visits made to each patient; or c) provision of knee classes in community clinics instead of one-to-one home visiting. Options a and c were unlikely to be feasible: physiotherapists currently spend as much time as is necessary in a patient's home and it is thought that patient care would suffer if length of visits were shortened (option a) and option c might be of limited value practically since patients would still need to be transported to community clinics. However, option b would be acceptable to the community physiotherapists.

The protocol for physiotherapy treatment for the intervention group made assumptions about the average number of contacts that TKR patients might have in a hospital setting, based on the hospital physiotherapists' feedback. However, the mean number of knee classes and one-to-one sessions for patients treated at hospital was 3.5 in total compared to 8.4 (pre- and postoperative) home visits in the community. Therefore, the sensitivity analysis measured the impact on physiotherapy costs of reducing community visits by one third: a reduction in the mean number of preoperative visits from three to two and a reduction in the mean number of postoperative visits from six to four. The mean cost per patient in the preoperative period for physiotherapy services would decrease from £65.6 (Table 39) to £44.0 (Table 41), a reduction of £21.6. The mean cost per patient in the postoperative period for physiotherapy services would decrease from £132.3 to £90.8, a reduction of £41.5, resulting in the difference between the groups being reduced to £29.4 (Table 41) instead of £70.8 (Table 38). The total mean cost difference per patient between the two groups for physiotherapy services overall would reduce to £76.50 (Table 41). However, this would still be significantly more costly ($p = 0.001$).

Table 41 Sensitivity analysis: Revised costs per patient when mean number of home visits reduced by a third

NHS Resources	Home n=56 Mean (£) (SD)	Home n=56 Median (£) (quartiles)	Hospital *n=55* Mean *(£)* (SD)	Hospital *n=55* Median *(£)* (quartiles)	*P* value*	Mean Diff. (95% CI)
Preoperative physiotherapy	44.0 (10.0)	45.5 (37.4,49.7)				
Postoperative physiotherapy costs (inc. hosp physio)	90.8 (41.0)	81.5 (60.9,115.0)	61.5 (57.1)	46.4 (31.0, 82.7)	0.001	-29.4 (-48.1 to -10.7)
Total physiotherapy costs	135 (43.5)	129 (104.8, 158.1)	61.5 (57.1)	46.4 (31.0, 82.7)	0.001	-76.5 (-95.1 to -57.8)

** P-values are from a 2 independent sample t-test.*

6.10 Summary of economic evaluation

The mean total costs of pre and postoperative NHS services were almost identical for both treatment groups: £5376 and £5372 for the home and hospital groups respectively (mean difference = -£4.7). However, physiotherapy services for the home group were significantly more costly than for the hospital group: £197.9 compared to £61.5 (mean difference = -£136.5, P=0.001). Reducing home visits by a third would still result in a significantly more expensive service. There was no evidence that the home group patients consumed more or fewer NHS services in terms of length of hospital stay, general practitioner contacts and medical prescriptions. The similar total mean NHS costs for the two groups were the consequence of a non-significant difference in the hospital length of stay in the community treatment group, which reduced that group's overall costs.

6.11 Patient satisfaction

6.11.1 Patient satisfaction quantitative data analysis

114 patient satisfaction questionnaires were returned, 57 from group 1 and 57 from group 2. Satisfaction with physiotherapy for TKR was high (86%) in both treatment groups Table 42). When asked about where individual patients would prefer to have physiotherapy for TKR, 64.9% of the home group would chose home physiotherapy again, compared with 47.4% of the hospital group who would chose to have their hospital treatment again. However, there was no significant difference between the two treatment groups for preferred site of treatment (Table 43) ($p = 0.13$, $\chi^2 = 4.084$, df = 2).

Table 42 Patient response re helpfulness of physiotherapy

Helpfulness of physio	Control group - n (%)	Intervention group - n (%)
Helpful	49 (86.0)	49 (86.0)
Unhelpful	1 (1.7)	0
Neither helpful nor unhelpful	5 (8.8)	2 (3.5)
Both helpful and unhelpful	1 (1.7)	1 (1.7)
Not answered	1 (1.7)	5 (8.8)
Total	57 (99.9)	57 (100)

Table 43 Preferred site of future physiotherapy

Site for physiotherapy	Hospital care group - n *(%)*	Home care group - n *(%)*
Community	13 *(22.8)*	37 *(64.9)*
Hospital	27 *(47.4)*	10 *(17.5)*
No preference	15 *(26.3)*	8 *(14.0)*
Not answered	2 *(3.5)*	2 *(3.5)*
Total	57 *(100)*	57 *(99.9)*

6.11.2 Patient views: qualitative data

Transcriptions of free text patient responses were independently coded and analysed by the principal investigator and a second researcher using Atlas-ti software. Themes were identified using an iterative process whereby constant comparisons were made between developing concepts and the raw data, including a search for contrasting observations. An academic partner undertook independent analysis and verification of the identification of emergent themes to minimise bias. A response framework was constructed to compare the frequency of participant responses, by theme. The response themes and frequencies are presented below.

Table 44 summarises patient feedback to the question:

'What was the most helpful aspect of physiotherapy care you received?

Responses indicated positive response from both groups. Many more home care patients mentioned attributes of the physiotherapists as being helpful (7% as opposed to 19%) and more home care patients reported the helpfulness of being given support/ reassurance/ confidence/ help/ encouragement (10.5% as opposed to 26%).

Table 44 Helpful aspects of physiotherapy treatment

Response	Usual Care group No *(%)*	Intervention Group No *(%)*
Was useful/ helpful/ good/ 1st class / (very positive response)	7	10
Attributes of physios: kind/caring/patient/efficient etc	4 *(7)*	11 *(19)*
Gave support/ reassurance/ confidence/ help/ encouragement	6 *(10.5)*	15 *(26)*
Explanation (including about exercises)	6	6
Info/ advice (including re aids /exercise/ advice cards)	4	2
Knowing how to help self	1	
Knew could contact physio		1
Continuity of care	1	1
Pre-op		9
Soon after op	1(?as in-patient)	2
Muscle strengthening	4	6
Maintain muscle function		1
Pain relief	6	3
Pain relief – not knee	1	
Specifics: acupuncture	1	
exercises	7	3
Home exercises/ ex. sheets	1	1
Advice re home exercises	2	
hydro	4	
massage	1	
No travelling		6
In own home		9
Elaborations of being in own home		6 (includes some of above)
Help with walking/moving about	2	
Eased/ loosened/ improved knee	6	11
(Non-specific) improvement/ easier	2	
Walking /movement/ getting around better	5	1
Back to nearly normal /recover function	1	1
Good progress / recovery		2
Complete success	1	

Table 45 summarises participant responses to the question;

'What was unhelpful about the physiotherapy care you received?'

The majority in both groups (54% of group 1; 63% of group 2) did not respond.

Of the rest approximately 50% in each group reported 'nothing' unhelpful.

Responses indicated very few unhelpful aspects to either mode of delivery.

More hospital patients reported 'not enough' and 'delay in starting'; but only small numbers.

Table 45 Unhelpful aspects of physiotherapy treatment

Response	Usual care group n=	Intervention Group n=
No response	31	36
'nothing'	11	13
'No improvement'	1	
Repeat of positive		1
In-patient problems	3	1
Poor liaison re physio	1	
Delay in start	3	1
Not enough	3	
Not long enough	1	3
Not frequent enough	1	
Limited time	1	
Need check visit after one month		1
'just being told what to do'	1	
Wrong physio, hydro better		1
Felt isolated		1

Table 46 summarises patient responses to the question;

'How could your physiotherapy care have been improved?'

Just under half (24 (42%) in each group) did not respond. More respondents in the home group suggested 'none' and more repeated their satisfaction with the service they had received than in the hospital group (although fairly small numbers). However, 12 of the home group said their service 'could not improve', compared with 3 in the hospital group. More respondents in the hospital group suggested 'more' sessions and five suggested being seen sooner.

The appendix includes the complete framework for coded responses by group to the 'Patient Views' questionnaire.

Table 46 Suggested improvements to physiotherapy care

Responses	Usual care group n=	Intervention Group n=
No response	24	24
'none'	3	7
'Could not improve'	3	12
Repeat satisfaction	6	9
Don't know		1
In patient physio	1	
Post-op discharge	1	
Hosp – physio liaison		1
Pre-op chat / what to expect	2	
parking	1	
Seen sooner	5	
Less emphasis on getting 90 degrees (knee)	1	
More frequent	1	1
More sessions	7 (+1 re private)	
Longer duration		2
Hydro / more hydro	2	
Address home function	1	
More flexible working times	1	
Follow-up session	1	1
Final session in hosp		1 (not same person as above)
Advice re swelling		1

6.11.3 Patient comments

Although patient satisfaction was high in both treatment groups, analysis of free text responses illustrated differences in patient views about physiotherapy treatment. Although few people made negative comments, more of the hospital group mentioned the wait for physiotherapy after hospital discharge and not receiving enough physiotherapy:

> *'...not receiving any after the operation for 18 days. By then the knee was not flexible'* Hospital Group UPN10

> *"I would have liked a chat with them (physiotherapists) before the operation. I had no idea what to expect. I was discharged from hospital 20th December and didn't see anyone until Jan 24th"* Hospital Group UPN6

Several patients (mostly in the hospital group, two home care patients), commented that they would have preferred more frequent physiotherapy sessions with follow up continuing for longer:

> *'I was restricted to two sessions only. More sessions would have helped'* Hospital Group UPN32

A lack of pre-operative information was commented on in the hospital group.

> *' Maybe it would be helpful to give advice of some form of general exercises that could help build up physical all-round strength, that was neglected through not being active for a long time before the operation on the knee'*, Hospital group UPN13

During the treatment and follow up stages of the trial, waiting list initiative monies were used to invite four patients to have their knee joint replaced in a private hospital. For one patient lack of organisation caused difficulties with physiotherapy aftercare as a result of transfer to private care.

'On discharge from private hospital, I was told I needed 3 sessions per week. When it was discovered that I could not pay for my own transport, my sessions were severely reduced. My situation, living alone with 21 steps to climb to my flat was not addressed' Hospital group UPN23

Hydrotherapy is an important service for patients who do not achieve sufficient range of movement in their new knee joint and participants from both treatment groups could be directly referred for this additional treatment if necessary:

'Treatment is better in hospital. At hydrotherapy you get longer. It seems easier to have therapy under water' Home Care group UP9

More of the home physiotherapy patients commented positively on the support they received; personal attributes of their physiotherapist; the preoperative care; not having to travel; and their treatment being at home:

"Before surgery it built up my leg muscles and I was able to walk better". Home Care group UPN7

"When I came out of hospital my leg was very swollen and inflamed. My physiotherapist came very quickly and was most reassuring. I had therapy as I needed it. I couldn't imagine having to get to hospital. The home therapy was excellent". Home Care group UPN103

More of the control group mentioned the benefits of exercises; specific treatment modalities; pain relief; and advice given:

"It provided a guide to the type of exercise needed to give pain relief" Hospital Group UPN32

More of the home care group stated that their physiotherapy care could not have been improved upon, some of them being able to contrast it with previous physiotherapy:

"It couldn't (be improved). .....It was nice to know someone was there to be asked questions of and urge you to keep going. I have had physiotherapy in hospital before but this was definitely better" Home Care group UPN67

6.12 Summary Results

- The WOMAC and SF36 response rate was 98% (114/116)
- No significant differences were observed between the two treatment groups in mean scores, even after adjusting for preoperative HRQoL and preoperative waiting time.
- 28.1% of participants withdrew from the study, 15% due to TKR cancellation.
- Study withdrawal did not vary by treatment group, or WOMAC dimension scores. However, withdrawn patients had significantly poorer scores on the General Health (p=0.04), Energy (p=0.004) and Mental Health (p=0.05) dimensions of the SF-36 and were also significantly more likely to report heart problems (p=0.02) and stroke/TIA (p=0.01).
- The mean wait to first postoperative physiotherapy appointment after hospital discharge was significantly longer (p<0.001) for the hospital group compared to the home group.
- The home group had a greater mean number of physiotherapy sessions than the hospital group (8.4 versus 3.6).
- Home physiotherapy for TKR was significantly more expensive than hospital outpatient physiotherapy, although there was no significant difference in the total NHS costs per patient between groups.
- TKR patients were equally satisfied (86%) with physiotherapy at home or in hospital.

6.13 Conclusions

Home physiotherapy rehabilitation is acceptable to patients and is as effective as hospital outpatient physiotherapy for unilateral TKR. There is no statistical evidence from this study to suggest that individual pre- and post-operative home assessment and treatment by a community physiotherapist improves outcome after unilateral total knee replacement compared to usual post-operative hospital out-patient physiotherapy rehabilitation based in a hospital outpatient setting.

7 DISCUSSION

The first part of the discussion examines each of the research questions with reference to the results of the study and the literature review. Secondly, the quality of the study is evaluated. Finally the implications of the study are presented in terms of future research questions and NHS policy.

7.1 Research Question 1

Does pre- and post-operative home assessment and treatment by a community physiotherapist improve patient outcome after unilateral TKR for people with knee OA, compared to usual post-operative hospital out-patient physiotherapy care alone?

7.1.1 Primary Outcomes

TKR significantly improved health related quality of life in both physiotherapy rehabilitation groups. There was no difference in patient perceived health outcomes between the two treatment groups, as measured by the WOMAC and SF-36 questionnaires; community physiotherapists provided as effective physiotherapy care at home for TKR as usual hospital outpatient care. A randomised controlled trial by Kramer et al (2003) used WOMAC as a secondary outcome measure to compare home-based rehabilitation following TKR to clinic-based rehabilitation. This study demonstrated that TKR patients who completed a post-operative home exercise program, with follow up by periodic phone calls from a physiotherapist had similar outcomes to patients who completed regular outpatient clinic sessions in addition to the home exercises. The authors concluded that this post-operative home exercise programme was as effective as clinic-based physiotherapy rehabilitation for TKR[102]. A study by Mahmood et al (2000) investigated determinants of rehabilitation setting (home based versus inpatient) after total joint replacement, and its influence on early functional outcomes at an average of 8 months post-total joint replacement. A retrospective sample of both hip and knee replacement patients were asked to complete WOMAC and SF-36 questionnaires. The study suggested no difference in outcomes between the 36% of respondents who had home-based physiotherapy rehabilitation and those who had in-patient physiotherapy. This study's conclusion that home based rehabilitation was as effective for large joint replacement as inpatient rehabilitation is less credible since the study was poorer quality overall than the Kramer study; there was retrospective data collection, participants could show a preference for either rehabilitation treatment (therefore treatments weren't randomly allocated) and the inclusion criteria included both knee and hip replacements [103].Our study also

supports the findings of previous smaller studies, using a variety of patient outcome measures, in that there was no additional benefit of preoperative physiotherapy on postoperative outcomes for TKR[36;36],[33;37].

The study's power was reduced by a higher than anticipated trial withdrawal rate, but this was largely unavoidable. The observed differences in patient-perceived health outcome measures were small, and, although low power can explain the lack of significance, it cannot explain the size of the observed effect. Overall, it is unlikely that the study failed to detect any important differences. In 2001 McConnell et al presented a systematic review of the utility and measurement properties of the WOMAC index [48]. The authors abstracted effect size data from a total of 25 studies which satisfied their criteria for inclusion, of which most were drug or arthroplasty studies, reflecting bias in the evidence base already described by Tallon 2000[31] and Chard (2000)[42]. McConnell's systematic review confirmed the large effect sizes associated with TKR alone on which the original sample size calculation was estimated in 1999. The effect sizes for drug interventions varied from small to large and there was even greater variation in the range reported for the 'miscellaneous category' which comprised just one physiotherapy study (for OA knee), one exercise study and four acupuncture studies.

The WOMAC and SF-36 may have been too insensitive to detect change or distinguish differences in outcomes between the two physiotherapy treatment groups. However, previous studies had suggested that the WOMAC is the 'instrument of choice' for evaluating the outcome of new health technologies, including physiotherapy interventions, for OA knee[1;33;46;48;83;104-108]. However even instruments such as WOMAC, developed following an extensive qualitative interview phase, may not provide an unbiased patient perceived health outcome measure. Campbell and Dieppe (2003) describe a mismatch between patients' expression of pain and disability during qualitative interviews with a researcher in their own homes and their WOMAC responses a short time before the interview. Individuals had tended to minimise their symptoms when asked closed WOMAC questions by the clinician in an outpatient setting, rather than the usual self-administration of the instrument [45]. Our study achieved a 96% response rate for the self-administered WOMAC and SF-36 postal questionnaires, with excellent completion rates. The clinicians were not directly involved in administering the questionnaire, although a consent process which usually involved a home visit and explanation of the questionnaire data collection by a practice nurse may have contributed to the exceptional response rate.

7.1.2 Physiotherapy outcomes and adherence to the treatment protocol

The community physiotherapists saw knee replacement patients significantly more quickly postoperatively than their hospital counterparts and provided a functional home assessment and continuity of care throughout a care pathway lasting 12 to 15 months. Prompt community postoperative treatment could reflect the enthusiasm associated with a new service, although this access measure was unchanged over the 30 months of the study. Hospital physiotherapy provided the potential benefits of access to gym equipment and group work, however, patients required NHS or private transport (accompanied by a carer) to attend appointments.

The NHS funding for the intervention 'home care' group was ring-fenced and four community physiotherapists delivered a consistent intervention adhering closely to the number of sessions specified in the protocol. However, it was not possible to ensure that the control group ('usual' hospital care) received the amount of physiotherapy initially defined by the senior orthopaedic physiotherapist as usual practice. In addition, the use of waiting list initiative funding, part way through the study, to transfer small numbers of patients to private care added another dimension to the comparisons between groups. The home physiotherapy group had more treatment sessions overall despite the design of the intervention to match the maximum sessions expected for hospital outpatient physiotherapy with agreed common discharge criteria. Patient outcomes within the hospital physiotherapy treatment group however, were not adversely affected by a smaller number of physiotherapy contacts overall. Our study suggests that less intensive physiotherapy rehabilitation after TKR does not adversely affect patient perceived health outcomes. The randomised controlled trial by Kramer et al (2003) substituted physiotherapist telephone calls for follow up visits for TKR patients following a standardised postoperative home exercise programme and these patients had similar outcomes to the second treatment group who followed the home exercise programme in addition to outpatient clinic rehabilitation sessions [102].

The percentage of participants completing the home physiotherapy intervention per treatment protocol (73.6%) compares favourably with another study; O'Reilly et al (1998) et al reported 70% adherence to 75% of an exercise programme for OA knee [27]. No other OA knee or TKR physiotherapy intervention studies reported adherence to treatment protocol. The hospital group showed greater variation in treatment received (59% adherence to protocol), with some participants reporting that they had no physiotherapy at all after hospital discharge. An estimate of treatment protocol deviation should have been made during the pre-protocol phase and the target sample size increased.

The physiotherapists in both community and hospital outpatients recorded objective clinical outcomes such as degree of knee flexion initially and at discharge from physiotherapy treatment. These data were not analysed as patient perceived health outcome measures were chosen as the primary outcome measures. Studies of physiotherapy interventions have, in the past, tended to prioritise professional 'objective' assessments of clinical outcomes [34;36;37]. However clinician assessment may introduce observer bias and provide an additional research burden on NHS staff if carried out by physiotherapists treating patients Furthermore, Turner (1999) has expressed concerns about the consistency and quality of recording of routine clinical data in an audit of physiotherapy notes of TKR and low back pain patients conducted across three UK sites [35].The resources were not available to employ independent physiotherapists to carry out 'objective' clinical secondary outcome assessments from this study and there was also a concern that this would be an additional respondent burden for participants. Health care research is usually concerned with addressing outcomes based on the assessment of health, illness and benefits of health interventions from a patient perspective, thus, there has been a move away from clinician derived and observed outcome measures in recent years.

This was a pragmatic randomised controlled trial, measuring effectiveness in routine clinical practice rather than efficacy, the benefit a treatment produces under ideal conditions [52]. This comparison of two complex physiotherapy interventions illustrates that whilst adherence to the trial protocol for the home rehabilitation group was maintained, '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.

7.2 Research Question 2

Is pre and post -operative physiotherapy at home more cost-effective than usual hospital outpatient post-operative physiotherapy for OA patients having unilateral total knee replacement?

7.2.1 Economic evaluation

The results of the economic evaluation suggest that the total mean costs to the NHS, per patient, were very similar for the intervention and control groups for similar health outcomes. However the intervention group physiotherapy treatment cost significantly more per patient. The latter was due to several factors: the intervention group had a higher total number of consultations (including pre-operative physiotherapy) and home physiotherapy was delivered on a one-to-one basis by a senior physiotherapist, whereas in hospital the patient: physiotherapist ratio was lower and the hospital group physiotherapy intervention was delivered by a team which included senior physiotherapists, junior physiotherapists and technical assistants.

Part of the cost difference for physiotherapy services is offset by the costs of NHS transport within the hospital physiotherapy treatment group. About half of the control group attended hospital in NHS provided transport and the mean cost difference between the two groups for this resource was £32 (p=0.002). Furthermore, many control group patients travelled to hospital with the help of carers; the mean cost difference between the two groups for private transport was estimated at £12 (p=0.001).

Analysis of prescribing data was limited to a description of the type and number of prescriptions administered by the practice. It was not possible to provide accurate cost data of drugs actually used by the participants as this data collection would need to have been supplemented by a further self-assessment by patients of drugs used. This patient data was not collected in the pre- and post-operative questionnaires, as this would have increased participant time burden and may have reduced the quality of primary outcome data collected and the questionnaire response rate.

The incremental costs of introducing a pre- and post-operative home physiotherapy service for TKR patients would be likely to comprise the additional costs of community physiotherapy over usual hospital care; reallocation of resources from the local NHS transport budget would be unlikely. The sensitivity analysis explored the impact on physiotherapy costs of reducing the total number of community physiotherapy visits. These changes would reduce the mean costs per patient but costs would still be higher than with usual hospital care. There is little evidence to suggest that very different conclusions

regarding an economic evaluation would result from studies undertaken elsewhere. If health care commissioners planned to introduce this type of community based programme at the lowest possible cost then site (home or clinic) of treatment and number of treatments would come under most scrutiny because they have the biggest impact on costs. A home physiotherapy team could introduce a skill mix to include supervising senior physiotherapists supervising more junior physiotherapists and technical assistants which would reduce the costs of delivering a home physiotherapy intervention. However this skill mix within the hospital team was facilitated by delivering physiotherapy rehabilitation treatment in groups providing a level of senior supervision to less skilled health professionals which would be difficult to replicate in one-to-one treatments in individual patients homes. The study by Kramer et al (2003) lacked an economic evaluation but did demonstrate the potential of telephone follow up by physiotherapists substituting for home visits without adversely affecting patient outcomes [102].

7.3 Research Question 3

Does pre and post -operative physiotherapy at home increase patient satisfaction after TKR compared to usual hospital outpatient post-operative physiotherapy?

7.3.1 Patient satisfaction and patient views

The study provides new information about NHS patient experiences of physiotherapy care for TKR and the acceptability of home physiotherapy care from a patient perspective. The high satisfaction rates within both treatment groups reflect the tendency of NHS patients, to be highly satisfied with health care services in most published literature Typically, at least 80% of respondents in NHS patient surveys express satisfaction to any given question and older adults are less likely than younger respondents to be critical about their care[89;94].The patient satisfaction tool used in this study was not a validated, established patient satisfaction measure and the minimal piloting of this instrument before use is a methodological weakness of the study. However, resources were not available for more extensive development of this tool and the primary aim was to allow participants to give free text responses about their views of physiotherapy services for TKR. In this study, even highly satisfied patients made constructive negative comments about certain aspects of their care[91]. The involvement of service providers and patients in the development of a short service specific questionnaire and the high survey response rate demonstrate an acceptable methodology which can be used to incorporate patient feedback about quality and process of care in the evaluation of other care pathways[92;94]

Home physiotherapy patients appeared to be more positive overall because they had more physiotherapy contacts, with a single physiotherapist, suggesting greater continuity of care. The tendencies of home care patients to cite functional outcomes as helpful may reflect the holistic focus of a care process, which includes individual home assessment rather than outpatient knee classes. Previous studies have focused on institutional or hospital outreach provision of rehabilitation care. Patient feedback in this study demonstrates the acceptability to patients of physiotherapy at home pre- and post-operatively for TKR. Access to hospital-based hydrotherapy is an important additional therapy for a minority of TKR patients.

7.4 Results summary

- There was no difference in patient perceived health outcomes between the hospital and home physiotherapy rehabilitation groups. This suggests that community physiotherapists can provide as effective physiotherapy care at home for TKR as the usual hospital outpatient care. There was no additional benefit of preoperative or individual rather than group physiotherapy on postoperative outcomes for TKR.
- The community physiotherapists provided a functional home assessment and continuity of treatment throughout a care pathway lasting 12 to 15 months and saw knee replacement patients significantly more quickly postoperatively than their hospital counterparts.
- The hospital physiotherapy group had less than half the number of postoperative physiotherapy sessions than originally intended. This less intensive outpatient postoperative physiotherapy rehabilitation programme did not adversely effect patient perceived outcomes at three months within the hospital group.
- Participants were highly satisfied (>80%) with the physiotherapy treatment received and there was no significant difference in patient satisfaction rates, nor in preferred site of physiotherapy between the two treatment groups. Home physiotherapy patients appeared to be more positive overall in the qualitative analysis of free text feedback comments.
- The economic evaluation suggests that the total mean costs to the NHS, per patient, were very similar for the home and hospital physiotherapy groups for similar health outcomes. This was largely due to a non-significant longer hospital stay (0.4 days) and, unsurprisingly, significantly greater use of NHS patient transport services within the hospital physiotherapy group.
- The home group physiotherapy treatment cost significantly more per patient due to a higher total number of consultations (including preoperative physiotherapy) and the delivery of home physiotherapy on a one-to-one basis, whereas in hospital the patient : physiotherapist ratio was lower.

7.5 The quality of the study

The literature review illustrated variable quality in the evidence base of physiotherapy interventions for knee osteoarthritis. Overall the studies assessing rehabilitation interventions in the care pathway for TKR were of poor quality and did not fulfil CONSORT standards for the reporting of randomised controlled trials [43],[44]. The CONSORT summary attached as an appendix summarises the standards achieved by this study, using the CONSORT quality criteria. Specifically the adherence to the study protocol, clear inclusion criteria, high participation and questionnaire response rates, large sample size, defined primary and secondary outcome measures, participant follow up data and detailed description of the complex physiotherapy rehabilitation programmes distinguish this study from those previously undertaken.

7.6 Study bias, setting and generalisability of results

Selection bias was minimised by the use of computer-derived block randomisation (with pre-prepared sealed opaque envelopes), independent of the research team and clinicians caring for participants. There was potential for other study bias since it was not possible to conceal allocation of treatment from the patients and physiotherapists. However this bias was minimised by specifying and monitoring treatment policies outwith the intervention for the study groups, blind primary outcome assessment and follow up of all patients randomised. In a pragmatic trial it is accepted that clinician and patient biases are a usual response to treatments and that it is usually not possible to conceal complex treatment allocation from patients using placebos. The treatment response in a pragmatic trial is the difference between two treatments and includes both treatment and placebo effects, which reflects the likely clinical response in practice [52].

Withdrawal rates were equal in both groups and baseline assessment of participants demonstrated that the groups were well matched for potential confounding variables [43],[44]. The study had a very high questionnaire response rate and a detailed description of the characteristics of withdrawn patients, reasons for study withdrawal and adherence to the treatment protocol in both groups is summarised by the CONSORT flow diagram in the results section. In a pragmatic trial participants may not necessarily complete the trial in the treatment group to which they are allocated. Participants are therefore always analysed according to their original treatment group allocation (intention to treat analysis), even if they withdraw from the study or change treatment [52].

Setting the study in a single orthopaedic centre in a large urban area influences the generalisablity of the results. Participants were recruited from eleven consultants working in a large university teaching hospital orthopaedic unit with a high annual arthroplasty rate

(approximately 450 per year including bilateral TKR's and TKR's for trauma and inflammatory arthritis). Thus, there is likely to be clustering of specialist skills and differences between this large surgical team and the characteristics of orthopaedic surgeons working in a smaller team in a district general hospital, for example. Sheffield also has a School of Physiotherapy within Sheffield Hallam University, which might positively influence the skills and willingness of physiotherapists in community and hospital teams to collaborate in the design and implementation of a complex physiotherapy intervention.

Ideally randomised controlled trials of new health technologies should be multi-centred to ensure the results are widely generalisable to other NHS settings and to minimise the bias introduced by clustering of health professional and patient characteristics. Multi-centre randomised controlled trials are expensive and require sophisticated participant tracking systems, monitoring procedures and teamwork across centres which was not possible within the resources available for this study. 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 [14].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 and that the results are generalisable.

7.7 Questionnaire response rate and missing data

The survey questionnaire response rate of 98% is exceptionally high for health services research and this study did not encounter difficulties reported by Mallinson in the postal administration of the SF-36 to an elderly population [109]. The high postal questionnaire response rate was achieved by incorporating several important features into the study design and project management consistently identified as important by a review of the methodological literature[52;62;66-69;110], namely;

- Researcher training in research ethics, consent and tracking and follow up of RCT participants
- Pre-protocol consumer and professional participation in the piloting stage and modification of the design of all written information for patients (letter, consent and information documents) and the design of the questionnaires.
- Assessment of time to complete the survey instruments to minimise respondent research burden

- The invitation to participate was addressed personally to the respondent, signed by their consultant orthopaedic surgeon and referred to the NHS grant sponsoring the research.
- All correspondence included a stamped addressed envelope.
- Respondents were offered a home visit and or telephone call for further discussion of the study if they wished
- A practice nurse followed up non-respondents with a postal reminder and or a telephone call.
- Postal questionnaires and community physiotherapy data sheets were checked for completion on receipt
- Regular research team meetings and summarising of participant tracking data to monitor recruitment, follow up, change in physiotherapy treatment, study withdrawal and critical incidents.

Data were collected from a wide variety of primary and secondary care sources in addition to the patient survey. This enabled an extremely comprehensive evaluation of the intervention but in retrospect may have contributed to missing data such as date of trial entry (for three participants), essential to compare health related quality of life and for the economic evaluation. Missing data are inevitable in any complex study, despite steps described above to minimise this. The acute trust had an unusual hospital physiotherapy notes filing system (based on date of completion of treatment). Notes could only be retrieved a single senior administrator or the senior physiotherapy manager and it was extremely time consuming. Some hospital physiotherapy notes were never located and we were unable to verify patient reported hospital physiotherapy resource use for these participants. The hospital physiotherapy data collection might have been improved by piloting this data collection during the study pre-protocol phase, rather than relying on a (different) senior hospital physiotherapy manager's assessment of ease of data collection and availability of administrative support to retrieve notes for the researcher.

7.8 Study Withdrawal rate

The much higher than anticipated withdrawal rate of 28.1% reduced the study's power. The recruitment sample size of 160 was considered at the outset to be sufficiently high enough to follow up a minimum of 130 participants to the study end point at 12 weeks post-TKR. A dropout rate of a maximum of 18% seemed a reasonable estimate based on Prescott at al's systematic review (1999) of factors that the limit the progress of randomised controlled trials [62]. A review of over 500 randomised controlled trials demonstrated a 'loss to follow up' rate after randomisation of between 10% and 20%. Most studies reported a loss to follow up rate of around 15%.

Furthermore, an assumption was made at the outset that since OA knee patients and clinicians expect a favourable outcome of major prosthetic surgery to last a minimum of 10 years, that participants listed for TKR would be assessed as still likely to benefit from the procedure after a 14 month wait. However, 15% of patients had their knee replacement cancelled, either by the hospital or patient, two patients died whilst on the waiting list and a further patient died post-operatively. Assumptions were made about cancellation rates based on discussions with the orthopaedic department, but a formal audit of cancellation rates was not possible prior to the study using the routine hospital data available at that time. A longer pilot phase monitoring cancellation rates directly prior to recruitment might have improved this

In this study, a significantly higher incidence of important co-morbidity and poorer health related quality of life status within the 'withdrawn' group is worthy of further investigation. If this pre-operative cancellation rate reflects the experience of other orthopaedic provider units, a review of the selection criteria for knee replacement might enable more effective TKR waiting list management. This randomised controlled trial was too small for further sub-group analysis of patient perceived health outcomes by co-morbidity at 12 weeks post-TKR. Hawker et al (1998), in the largest USA community based follow up study to date, used WOMAC and SF-36 to assess patient perceived health outcome two to seven years post-TKR [13]. This survey demonstrated that predictors of better physical function after TKR were an absence of problems with the contra-lateral knee, primary knee replacement (rather than revision), and a lower body-mass index. Age did not have a negative impact on patient-relevant outcomes (pain and physical function) and co-morbidity data were not reported apart from a comment about the 'number' of co-morbidities at baseline.

7.9 Summary: limitations of the 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 physiotherapy rehabilitation outcomes between the two groups, however these outcome measures are the most commonly used to evaluate interventions for OA knee. The study's power was reduced by a higher than anticipated trial withdrawal rate, which was largely unavoidable due to a cancellation rate for TKR of around 15% preoperatively. Study withdrawal was associated with a higher level of important co-morbidity. The observed differences in health related quality of life were small, and, although low power can explain the lack of significance, it cannot explain the size of the

observed effect. Overall, it is unlikely that the study failed to detect any important differences.

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 primary outcome measure and withdrawal rates were equal in both groups. This was a single site study, however, the high patient participation rate and recruitment of the majority of the consultants, suggests that home physiotherapy for TKR is generalisable to other NHS sites.

7.10 Future research questions

There is a lack of evidence-based indications for TKR[111]. Less patients report improvement after TKR than following total hip replacement (THR). Further research is needed to improve patient selection and the timing of surgery and identify the most appropriate physiotherapy rehabilitation treatment for TKR [9]. This study demonstrated the effectiveness of home physiotherapy for TKR, but this was more intensive and expensive than usual care. The preoperative cancellation rate for TKR was high and supports the need for clearer selection criteria with greater consideration of co-morbidity and willingness to undergo surgery[29;30].

Specific research questions identified by the study are:

- What is the ideal intensity and frequency of physiotherapy rehabilitation for TKR?
- Would a less intensive individualised physiotherapy intervention at home deliver expected patient group outcomes and individual rehabilitation goals?
- An increasing numbers of knee replacements will be performed at independent treatment centres, usually distant from the patient's home. Could the model of home physiotherapy described be adapted for more distant non-NHS centres, providing a primary care rehabilitation link within the alternative TKR care pathway?
- Does the pre-operative cancellation rate of 15% recorded in this study reflect the experiences of other orthopaedic arthroplasty centres? A significantly higher incidence of important co-morbidity and poorer health related quality of life status within the 'withdrawn' group is worthy of further investigation and could inform selection criteria for knee replacement.

7.11 Conclusion: Implications for NHS Policy

The 'NHS Plan' promotes enhanced access; patient centred care pathways and increased flexibility in NHS waiting list management [15]. Primary Care Trusts may now commission surgical procedures from either local NHS or private providers such as the new regional 'Independent Treatment Centres' (ITCs); so called 'plurality' of NHS-funded provision. Hip and knee arthroplasty will constitute the majority of procedures undertaken in regional ITCs, to enhance patient choice about the timing and location of surgery and to reduce NHS waiting times to less than 6 months [19]. This may fragment the TKR care pathway from the patient's perspective and if surgery is distant from a patient's home, locally based physiotherapy rehabilitation will be necessary. This study demonstrates that community physiotherapists can provide continuity of care in patients' own homes before and after TKR, regardless of the site of surgery, whilst maintaining current standards of hospital-based physiotherapy. However, the introduction of pre and postoperative home physiotherapy rehabilitation for TKR is likely to be more expensive than usual hospital postoperative physiotherapy treatment in knee classes and would therefore require appropriate resources.

The Audit Commission report ' Trends in Rehabilitation Policy' (1998) describes how service users for other types of rehabilitation often feel that services such as physiotherapy are discontinued too soon and that rehabilitation is incomplete[21]. The pressure on primary care and acute trusts to reduce waiting lists may increase patient throughput for TKR without increasing physiotherapy resources within the care pathway. Patients in the usual care group mentioned more frequently that physiotherapy was insufficient or that more treatment would have been helpful. However, despite the usual care group receiving considerably less physiotherapy overall there was no significant difference in outcomes, compared to the home care group. A critical incident reported within this study illustrates how an existing NHS care pathway may be disrupted by the omission of 'function' and social care needs assessment from a private hospital team focus. This was an exceptional occurrence; the other NHS funded private TKR patients reported satisfaction with private physiotherapy care.

New diagnostic and treatment roles for extended scope physiotherapists are also promoted within the NHS Plan [15]. Physiotherapists working in primary and secondary care orthopaedic screening clinics can reduce orthopaedic surgeon outpatient workload by assessing and treating a wide range of orthopaedic problems referred by GPs [23],[24]. This is a recent service innovation and has not yet been widely adopted throughout the UK as a model for the assessment and management of primary care musculoskeletal problems.

The benefits and costs of such extended roles need to be set in the wider context of the primary care pathway for musculoskeletal problems, such as OA knee, currently dominated by pharmacological interventions. A population study by Jinks et al (2004) of around 9000 people over 50 years found that 1in 4 people aged 50 yrs or over had chronic knee pain and over half of these had severe pain or disability [5]. An editorial by Dieppe (1998) describes the domination of rheumatology research in the Cochrane database by pharmacological interventions and emphasises that the main concerns of patients presenting with musculoskeletal problems to doctors are pain and disability and associated depression. Patients wish to have advice about self help and interventions that are free of side effects, including access to effective physical therapies. [32].

Over the last decade there has been a paradigm shift in the way that back pain is managed in the community following nationally agreed guidelines emphasising early activity and the advantage of physical therapies and self management plans for patients to reduce chronicity. The community management of knee pain could be improved and more evidence based [2].The EULAR recommendations (2003) combine an evidence based approach and expert opinion across a wide range of treatments to inform clinical guidelines on OA knee, incorporating non-pharmacological treatments first. These recommendations emphasise a holistic approach to management; treatment choices are based on knee osteoarthritis risk factors (obesity, physical activity), general risk factors (co-morbidity, polypharmacy), level of pain and disability, signs of inflammation and structural damage [3].

There is potential for physiotherapists to become lead health professionals in the primary care pathway for OA knee, providing assessment and treatment (including exercise), advice on self help to maintain and increase activity, non-pharmacological strategies to deal with pain and orthopaedic screening and pre- and post-operative rehabilitation for TKR within the primary health care team.

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9 APPENDIX

9.1 Ethics approval reference and letter

NORTHERN GENERAL
HOSPITAL N.H.S. TRUST

Herries Road,
Sheffield S5 7AU

Telephone
(0114) 243 4343

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NORTH SHEFFIELD RESEARCH ETHICS COMMITTEE

Chairman: Dr S R Brennan
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Admin Sec: Sue Rose
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Fax: (0114) 271 4771

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Sue.Rose@dial.pipex.com

CMHN/SR/21/6/99
Mitchell/NS99 6 517
(Please quote reference on all correspondence)

2 September 1999

Ms A Haywood
Research Assistant
Institute of General Practice
Community Sciences Centre
Northern General Hospital

Dear Ms Haywood

Re **A randomised controlled trial to compare patient outcomes and a cost - consequences analysis of pre and post-operative community based physiotherapy and usual hospital-based post-operative physiotherapy for patients having total knee replacements as a primary procedure**
NS99 6 517

Thank you for your letter of the 2 August 1999 and enclosed modified patient information sheet.

This is satisfactory and I can now confirm that the above study has full approval on behalf of the North Sheffield Research Ethics Committee.

Yours sincerely

SRosa

pp C M H N Newman
Senior Lecturer in Cardiology/Honorary Consultant Physician

cc Dr C Mitchell
Woodhouse Medical Centre
7 Skelton Way
Woodhouse
SHEFFIELD
S13 7LY

9.2 Patient Information Sheets

The Sheffield Project to evaluate Physiotherapy Care for patients having Knee Replacements at the Northern General Hospital

PATIENT INFORMATION SHEET

A 3 year prospective National Health Service study of Quality of Life of People who are listed for surgery for knee replacement at the Northern General Hospital, which compares the physiotherapy care received by patients, alongside an economic evaluation of this care.

"What is the purpose of this study?"

You are being invited to participate in a study, which compares current usual hospital based post-operative physiotherapy care for patients having knee replacements with community physiotherapy care before and after surgery. The study is important because it will provide information about how to develop physiotherapy services in the National Health Service for knee replacement patients. The Northern General Orthopaedic and Physiotherapy departments will also have a detailed report of the results of knee replacement for the patients who participate in the study.

"What is involved if I agree to take part?"

There are to be two groups of patients, (A and B), and if you decide to participate, you would be placed in one of the groups. The group you are allocated to is to be selected by a computer, using a method similar to that of tossing a coin. You would therefore have a 50/50 chance of being selected for either group. Group A will receive usual hospital post-operative physiotherapy, and participate in a patient postal survey both before, and after surgery. Patients in Group B will also participate in the postal survey, in addition to receiving community based physiotherapy care, both before and after surgery, in their own homes.

"What is the treatment?"

Patients in Group A will receive no changes to their method of treatment. They will receive the usual post-operative physiotherapy, involving intensive rehabilitation as an outpatient at the hospital after joint replacement. Patients in Group B will receive a new type of rehabilitation for knee replacement patients. This provides current treatment, and offers physiotherapy in the patient's own home in the community, both before, (up to four visits), and after their knee replacement. The number of visits would be according to usual hospital practice and the patient's own needs. This service is to be provided by a small specialist team of community physiotherapists working for the project in collaboration with their hospital colleagues.

This would be as an alternative to the usual physiotherapy care offered to knee replacement patients, which involves hospital outpatient physiotherapy after the knee replacement, but not before surgery as well. Group B patients would not have to make any extra visits to hospital, and provided they, their specialist, and their physiotherapist were happy with their progress, would only have to go to the hospital to attend orthopaedic clinic appointments and on admission. Those consenting patients, who are allocated to Group B, will be contacted by the research assistant to arrange a visit to their homes, in order to discuss the community physiotherapy treatment with them personally.

"Will the information be confidential?"

Yes. Neither your name nor your address will appear on the questionnaire, and the information it contains will be added together so individual patients cannot be identified.

"What kind of information about patients is needed by the project?"

With your permission, we would also compare the information on the questionnaire with information about your knee problem from your hospital and general practice notes. This anonymous information will be kept strictly confidential, and only be accessed by the research team. This team consists of the Consultant, GP Researcher and Research Assistant.

"May I obtain further information about the project?"

We enclose a letter from your Consultant, Dr Caroline Mitchell, (GP researcher), and the Research Assistant. If you have more questions, please phone Sheffield 2880394. If you would prefer to discuss the project with someone in person, we can arrange to visit you at home.

"What if I do not wish to take part?"

This will in no way affect your treatment.

"What if I change my mind during the study?"

You are free to withdraw from the study at any time without affecting your management. Just phone Sheffield 2880394, or send us a note in the pre-paid return envelope.

"What will happen to the information from the study?"

All information will be strictly confidential. If you would like to read the final report, we can send you a copy when the results are available from April 2002

.

If you would like to participate in this trial, please keep this information sheet for future reference, and fill out, sign and return the enclosed consent form in the pre-paid envelope.

Research Office: Dr. Mitchell & Partners. Woodhouse Medical Centre, 7 Skelton Lane, Woodhouse, Sheffield, S13 7LY.
Telephone: 0114 288 0394

9.3 Patient Consent Form

The Sheffield Project to evaluate Physiotherapy Care for patients having Knee Replacements at the Northern General Hospital

Patient Code: / /

Patient Consent form

To be completed by the patient:

Have you read the information sheet about this study? YES/NO

Have you been given opportunity to ask questions about this study? YES/NO

Have you received answers to any further questions you may have had? YES/NO

Have you received enough information about this study? YES/NO

Do you understand that you are free to withdraw from this study?

- At any time
- Without giving a reason for withdrawing
- Without affecting your future medical care YES/NO

Can we compare information about your knee problem with Information from your medical records? YES/NO

Do you agree to take part in this study? YES/NO

Signed: .....

Name (Block Letters): .....

Witnessed: .....

Name (Block Letters): .....
A witness can be a member of your family or anyone who knows you well.

Date:

9.4 Standardised letters (patient, consultant, general practitioner)

The Sheffield Project to evaluate Physiotherapy Care for patients having Knee Replacements at the Northern General Hospital

Research Office: Dr. Mitchell & Partners. Woodhouse Medical Centre,

7 Skelton Lane, Woodhouse, Sheffield. S13 7LY

Telephone 0114 288 0394

Dear

We would once again like to thank you for agreeing to participate in this research project.

Would you please fill out the enclosed questionnaire booklet, before returning it to us in the pre-paid envelope.

The Community Physiotherapist will shortly be contacting you with regard to beginning your pre-operative programme of physiotherapy care.

We hope all your questions about the project have been answered today, but should you have any further questions, please telephone the Research Office on Sheffield 288 0394.

Yours sincerely,

Research Assistant
Sheffield Knee Project

The Sheffield Project to evaluate Physiotherapy Care for patients having Knee Replacements at the Northern General Hospital

Research Office: Dr. Mitchell & Partners. Woodhouse Medical Centre,

7 Skelton Lane, Woodhouse, Sheffield. S13 7LY

Telephone 0114 288 0394

Dear

A short while ago you agreed to participate in a study which is comparing usual hospital based post-operative rehabilitation following knee replacement surgery with community physiotherapy before and after surgery.

You have been placed in Group A, and will therefore receive no changes to your method of treatment, but will participate in a postal survey both before and after your knee replacement.

I am enclosing a questionnaire booklet for you to fill out and return to me in the pre-paid envelope. I will send you a further copy of this questionnaire approximately three months after you have had your operation.

If you require any further information, or require a home visit to enable you to discuss the project in greater detail, please contact the Research Office on **Sheffield 288 0394**. Once again, I would like to thank you for agreeing to participate in this research.

Yours sincerely,

Research Assistant

NORTHERN GENERAL
HOSPITAL N.H.S. TRUST

ORTHOPAEDIC
DEPARTMENT

Dear

I am pleased to be working with my colleagues in General Practice and Physiotherapy, on a National Health Service funded study of quality of life and physiotherapy care for Sheffield patients who are having knee replacements for osteoarthritis. I am writing to patients who are awaiting knee replacement, to ask for their help in this study. This study is important because the information provided will help us to plan future physiotherapy care, and also allow us to get direct feedback from patients about the results of their knee replacement.

We are going to compare the usual, proven and effective form of outpatient physiotherapy following knee replacement, (Group A), with rehabilitation which takes place in the patient's home in the community, (Group B). There are no known disadvantages of community physiotherapy, but since this kind of care has never been fully investigated before, we have no other studies to compare it to.

For the purpose of the study, both groups would be asked to participate in a short postal questionnaire survey about arthritis and their health in general. This survey would also enquire about their experience of physiotherapy care both before and after surgery. Questionnaires would take no longer than 15 minutes to complete, and patients would not have to make any extra visits to hospital.

If you are interested in the project, please refer to the enclosed information sheet, which explains the study in more detail. We would like you to feel free to discuss the matter with friends or relatives, and if you have any questions, contact the research team on **Sheffield 2880394. If you agree to participate in the project, please fill out and sign the enclosed patient consent form, and return it to us in the pre-paid envelope. We will then contact you with further information about the project.**

Your agreement to participate in the research will not affect in any way, your treatment by the hospital. You can also withdraw at any time without giving a reason. Your name and address will not appear on the questionnaires, and all information collected in the study will be strictly confidential.

Thank you very much for your help

Yours sincerely

.... (Orthopaedic Surgeon)

..... Dr. C. Mitchell, (GP Researcher)

..... (Research Assistant)

The Sheffield Project to evaluate Physiotherapy Care for patients having Knee Replacements at the Northern General Hospital

Research Office: Dr. Mitchell & Partners. Woodhouse Medical Centre, 7 Skelton Lane, Woodhouse, Sheffield. S13 7LY

Telephone 0114 288 0394

THE SHEFFIELD PROJECT TO EVALUATE PHYSIOTHERAPY CARE FOR PATIENTS HAVING KNEE REPLACEMENTS AT THE NORTHERN GENERAL HOSPITAL

Research Office: Dr. Mitchell & Partners. Woodhouse Medical Centre,

7 Skelton Lane, Woodhouse, Sheffield. S13 7LY

Telephone 0114 288 0394
e-mail: c.mitchell@sheffield.ac.uk

Dear Dr.

I am writing to inform you that your patient
who is currently on the Northern General Hospital waiting list for total knee replacement surgery, has agreed to participate in a research project which has been funded by a National Health Service Primary Care Research and Development grant. The project is comparing physiotherapy care in the patients own home to usual hospital based outpatient care. Patients who are eligible to be approached for this randomised controlled trial have been identified from the hospital waiting list and invited to participate.

Your patient has been randomised to the **intervention** group of the study, who will receive community-based physiotherapy from the research project physiotherapy team at Community Health Sheffield, before and after their knee replacement. This is in contrast to the control group who will receive the usual hospital outpatient physiotherapy following their knee replacement. Both groups will also participate in a postal survey before and after surgery. The survey will comprise of the SF 36 and Womac Osteoarthritis Index (which assesses knee pain and disability), a short demographic data collection sheet and a post-operative evaluation of their physiotherapy care.

With your permission, your patient has also consented to allow us access to limited practice-based primary and secondary care data relevant to their knee problem and post-operative rehabilitation. This data comprises surgery and orthopaedic outpatient attendances, co-existing health problems, prescribing and post-operative complications. Our research nurse will contact the practice before this data collection, which she can do personally if this is acceptable. We will send you a copy of the patients consent form at this time. There will be a standard data access fee payable to each practice to minimise any inconvenience to yourself and your staff.

I am enclosing a brief summary of the project. Should you require a copy of the full trial protocol, I would be happy to forward one to you. If you would like to discuss this further, please do not hesitate to contact me.

Yours sincerely,

Caroline Mitchell.

Dr. Caroline Mitchell.
GP Researcher - Sheffield Knee Project
General Practitioner / Clinical Lecturer, Institute of General Practice and Primary Care,
Sheffield University

The Sheffield Project to evaluate Physiotherapy Care for patients having Knee Replacements at the Northern General Hospital.

Research Office: Dr. Mitchell & Partners. Woodhouse Medical Centre,
7 Skelton Lane, Woodhouse, Sheffield. S13 7LY.
Telephone 0114 288 0394.

Dear

Some time ago you kindly agreed to participate in a National Health Service research project which uses a questionnaire survey to compare physiotherapy care in hospital and community settings for people having knee replacements.

At three months after surgery we need to repeat this survey to find out about your progress since your knee replacement. In addition to the questionnaire, which is similar to the one you filled in last time, there is a second short two-part questionnaire, which asks questions about your experience of physiotherapy care and also about travel for any physiotherapy care. This will provide us with important information to help plan physiotherapy care for knee replacement patients in the future.

This is a three-year project and at the end of this time there will be a final report. If you would like a copy of this report, please tick the box at the end of the questionnaire.

Many thanks for your help with this research; If you have any concerns or questions you would like to discuss further, please contact us at the research office, telephone number above.

Yours sincerely,

Teena Binns (Research Nurse).

Caroline Mitchell

Dr. Caroline Mitchell (GP Researcher).

9.5 Home physiotherapy patient advice sheets

COMMUNITY PHYSIOTHERAPY TREATMENT PROTOCOL

PREOPERATIVE

1. Introduction to the research programme
2. Assessment
    - general health, medication, patient's expectations and goals
    - of the knee: stiffness, pain, giving way
    - mobility
    - activities of daily living
    - home environment
3. Information for patients about total knee replacement
4. Joint agreement of a pre-operative treatment programme to assist muscle strengthening, joint mobility, patient mobility and independence.
5. Further visits as necessary to assess progress and reinforce the treatment programme (maximum 3).

POSTOPERATIVE

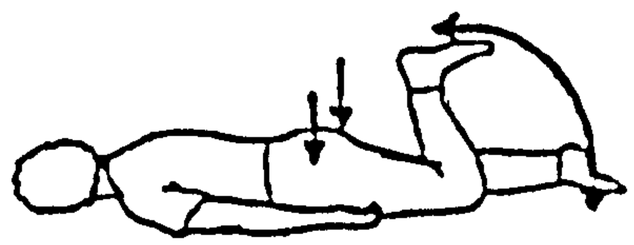
1. See as soon as possible after hospital discharge (1 week maximum)
2. Ensure information available from hospital inpatient physiotherapist regarding the weight-bearing programme to be followed and the degree of knee flexion obtained in hospital.
3. Treatment is aimed towards:
    - Increasing knee range of movement
    - Increasing muscle strength of quadriceps and hamstrings
    - Reducing pain
    - Reducing swelling
    - Re-education of gait
    - Progressing weight bearing in line with consultant guidelines
    - Progressing activities of daily living
    - Progressing mobility, independence and socialising.
    -

Sheffield Knee Project.

Advanced Knee Exercises.

Lying down with your hips straight and knees together.

Bend your knee as far as possible keeping hip straight and ankle flexed. Hold approx.....secs. You can do the exercise with a ....kg weight or a rubber exercise band around your ankle.

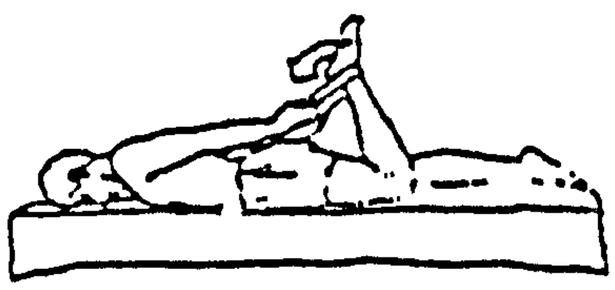


Repeat ..... times.

.....

Lying down with a band around your ankle.

Tighten your stomach muscles to keep your lower back straight. Bend your knee and pull the band with both hands until you feel tightness on the front of your thigh. Hold approx. 20 secs. – relax.



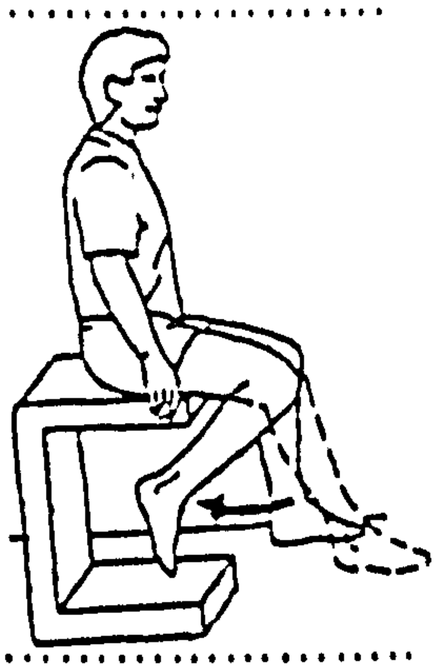
Repeat ..... times.

.....

Sit on a chair.

Bend your knee as much as possible.

Repeat..... times.

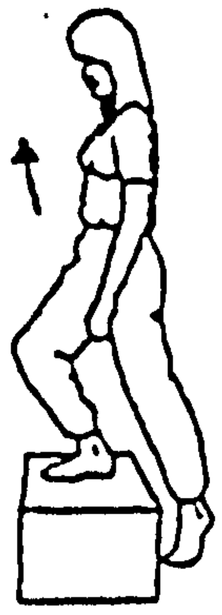


.....

Stand in front of a 20 – 40 cm step.

Step up ..... Times with one leg leading and then repeat with the other leg leading.

Repeat ..... times.

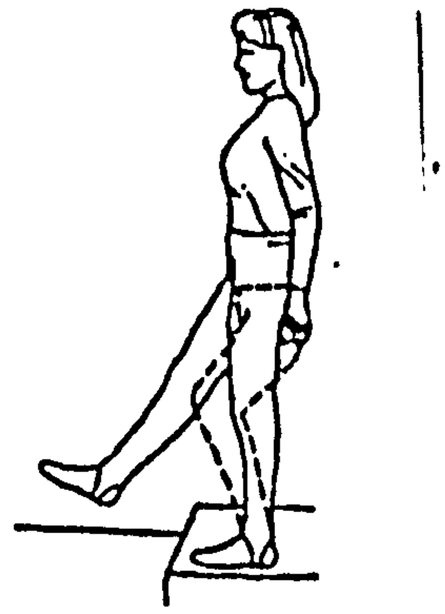


.....

Stand on one leg on a step facing down.

Slowly lower yourself by bending your knee to 30 degrees. Return to starting position.

Repeat ..... times.

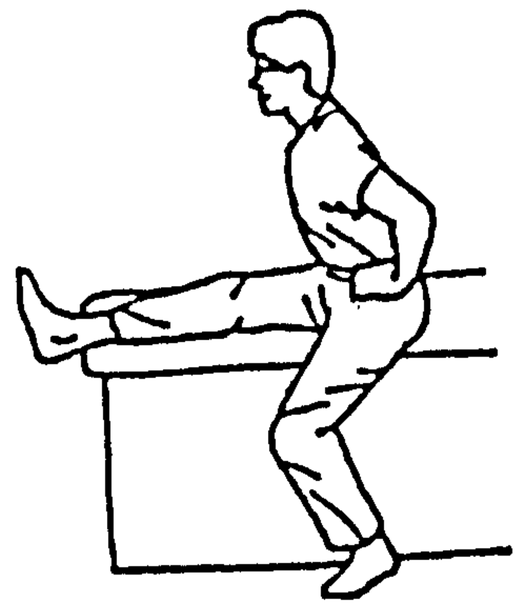


.....

Sit on a table with one leg straight in front of you with the heel over the edge and the other leg on the floor (as shown).

Bend your upper body forwards keeping your back straight. Hold approx. 20 secs.

Repeat ..... times.



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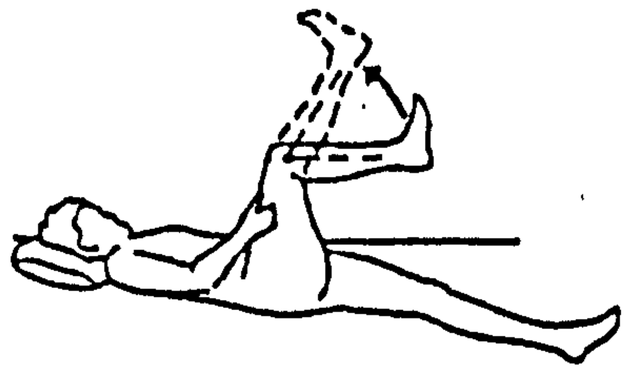
START POSITION : Lie on the back with both legs straight. Bend one hip to 90 degrees and hold the thigh in this position. The knee should be relaxed.
ACTION: Holding the thigh in position, slowly straighten the knee until a stretch is felt at the back of the thigh. Sustain this stretch.



Hold for ..... Secs. Repeat ..... times. L R

.....

Stand. Hold onto a support and bring one leg slightly backwards. Bend your knee and lift your foot off the floor.
Hold .... Secs.

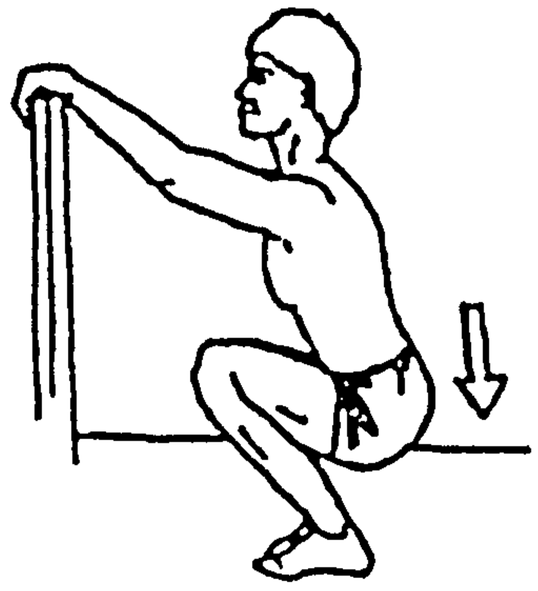
Repeat ..... times.

.....

Stand in front of the sink holding on to the support with both hands.

Slowly crouch keeping your back straight and heels on the floor. Stay down for approx. 20 secs. And feel the stretching in your buttocks and the front of your thighs.

Repeat ..... times.

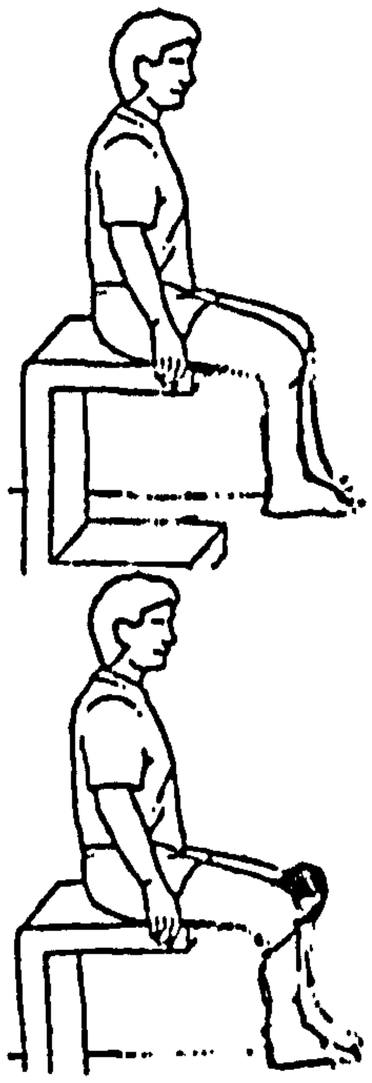


.....

Sit on a dining chair.

Without using your hands stand up from the chair then sit down slowly.

Repeat 10 times.



.....

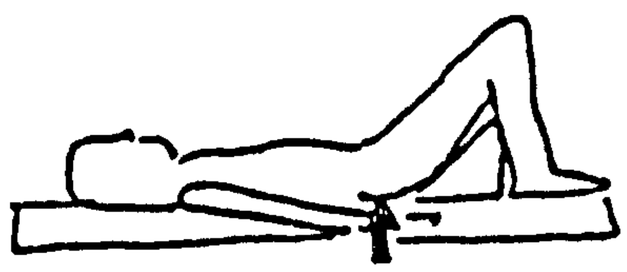
Sitting, holding a soft ball between your knees squeeze hard, then relax.

Repeat 20 times.

.....

Lying on your back, knees bent.

Lift your bottom off the bed as high as you can.
Lower slowly.



Repeat 10 times.

.....

ADVICE SHEET FOR PATIENTS FOLLOWING TOTAL KNEE REPLACEMENTS.

After knee surgery it is important to exercise the muscles around the knee to regain movement and improve stability of the knee.

Try to do your exercises at least 4 times per day, in addition to the sessions with the physiotherapist.

It is best to have regular, frequent short periods of exercise than to tire yourself by continuing too long. (A few of each every hour is best).

Begin by doing each exercise 5 times, increasing to 10 gradually. Continue increasing by 5-10 for the next few weeks.

1. When your scar is well healed and the stitches have been removed Massage over and around the scar with a good skin cream and move the kneecap in all directions. X 3 daily.

2. If your knee feels hot, applying ice may be useful. Your physiotherapist will instruct you in the use of ice if necessary.

If you have been having ice prior to exercise in hospital with no adverse effect, you may continue to use it at home - but with great care because it can cause burns if not used properly.

ALWAYS USE FLAKED ICE - wrap ice cubes in an old tea towel and hammer with a rolling pin until crushed.

Make your ice pack in a damp cloth and leave it on until your skin is pink and slightly numb to touch - usually 10-15 minutes.

If you feel any burning sensation, remove pack immediately, but remember it always feels a bit funny when it first goes on.

Some people find it easier to use something like a packet of frozen peas instead of ice. If you do, it is better to wrap the pack in a damp tea towel.

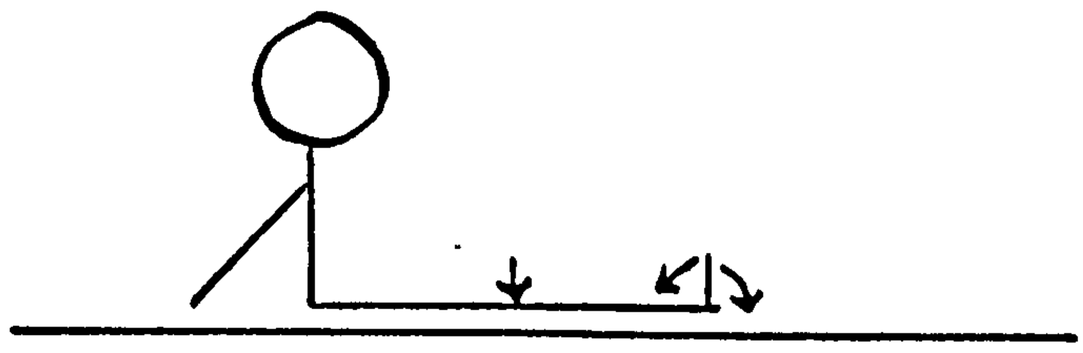
EXERCISES.

SIT ON THE BED.

1.STATIC QUADRICEPS CONTRACTION (SQC).Keeping the leg straight,pull toes up towards you and brace the back of the knee into the bed. This tightens the muscles (Quadriceps) on the front of the thigh.

Hold for up to 10 seconds then relax

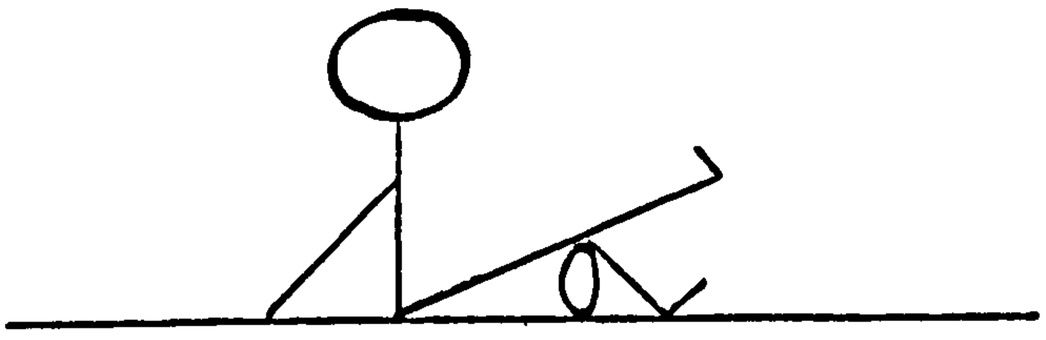
Repeat..... Sets.....



2. Put a small rolled up cushion or towel under your knee. Pull the foot up at the ankle and brace the knee back into the cushion, lifting the heel up from the bed.

Hold for up to 10 seconds and then relax.

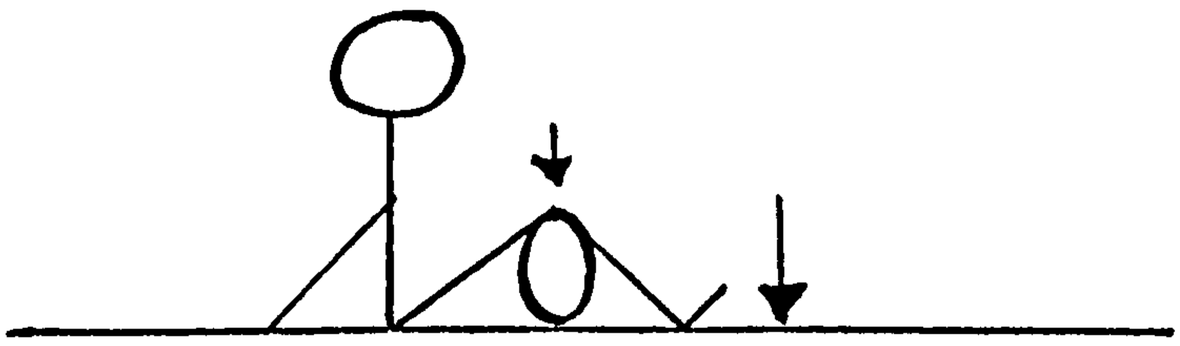
Repeat..... Sets.....



3. Keep the rolled up towel under your knee. Push the heel down into the bed, at the same time push the back of the knee onto the roll. Tighten the muscles on the front and back of the thigh.

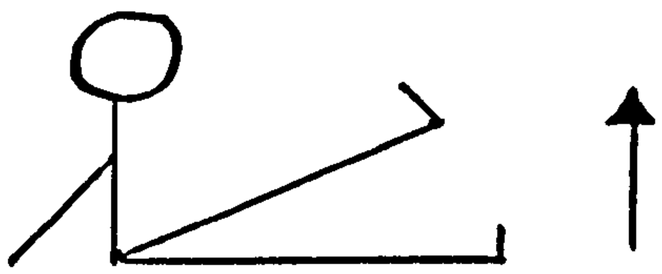
Hold for up to 10 seconds and then relax

Repeat.....Sets.....



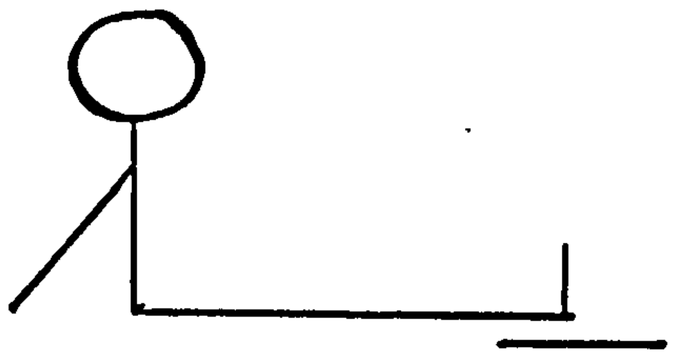
4. Do SQC (as 1) then lift the straight leg up from the bed. Hold for 3 seconds and then lower the leg down keeping the knee straight throughout the whole exercise.

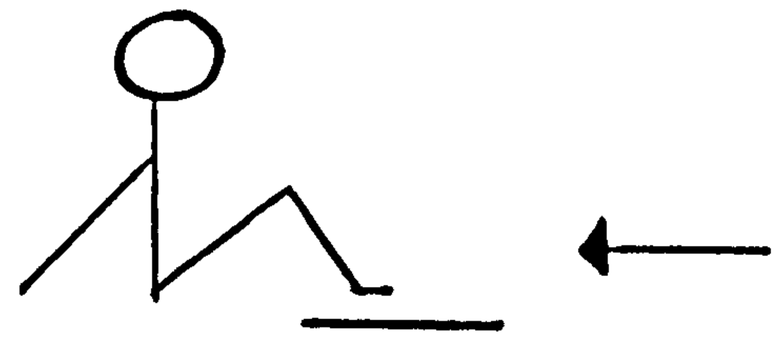
Repeat.....Sets.....



5. Place a tray and soft cloth under your heel. Slide the foot towards you, bending the knee within comfortable limits. Then slide the foot away, straightening the knee as much as possible.

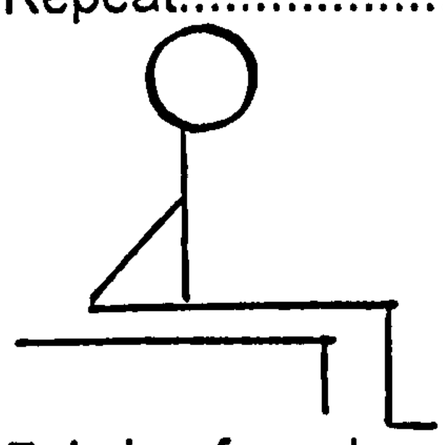
Repeat.....Sets.....

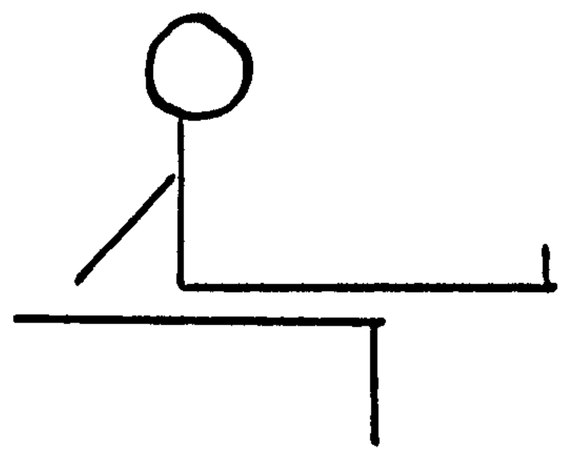




6. Sit over the edge of the bed or on a chair, make sure your feet are not touching the floor. Swing your foot gently up and down, straightening and bending your knee.

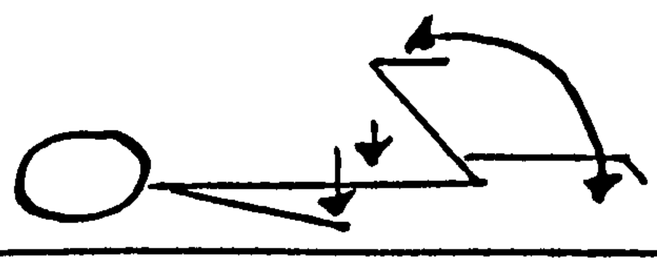
Repeat.....Sets.....





7. Lying face down with your hips straight and knees together. Bend your knee as far as possible keeping hip straight and ankle flexed.

Hold approx..... secs. Repeat, this time resisting with the other leg. Repeat.....times.



9.6 Description of usual hospital inpatient and postoperative outpatient physiotherapy treatment

VISIT TO WARDS AND KNEE GROUP 15TH JUNE, 1999

WARDS

Met with [redacted], Superintendent Physiotherapist.

Before patient is admitted to hospital, (ideally 2 – 4 weeks before their operation but can be longer or shorter), they visit the pre assessment clinic. Their appointment lasts approximately 4 hours.

Patients usually spend 10 14 days in hospital after their operation, and begin physiotherapy the day after surgery.

When the patient is discharged from hospital, the ward physiotherapists have no further contact with them, unless they are re-admitted, (e.g. some may require MUA, (manipulation under anaesthetic). They are therefore unaware of any outcomes. I will keep Linda informed about the progress of the study, by sending updates from meetings etc.

Hydrotherapy – Is given if the patient is not progressing as they should. They can be referred for hydrotherapy whilst still on the ward, or via outpatients, when they come for their physiotherapy.

KNEE GROUP

The knee group is conducted three times per week, (Monday/Tuesday afternoons and Thursday mornings).

There are usually 7-12 patients present at each session.

Patients meet in the physiotherapy gym and follow a circuit programme around the gym. This circuit takes approximately one hour to complete. There are set exercises, but some patients do more than others depending on their level of ability.

Sessions are run by two physiotherapists and one assistant, (or student). In addition to the circuit, patients see the physiotherapist for individual treatment lasting approximately 15 minutes. During this session, the physiotherapist will manipulate the affected knee to improve range of movement, and speak to the patient about how their treatment will progress. They also measure the degree of flexion.

Patients usually visit the gym once or twice a week and visits start on discharge from the wards after their operation, unless there is a waiting list.

Not all patients require outpatient physiotherapy, only those who are not progressing as they should. If patients are still making unsatisfactory progress at the knee group, they may be referred on to hydrotherapy.

Over half the patients, who attend the knee group, come by ambulance.

(Aug.'99 – hospital care. Current post-op physio practice)

KNEE CLASS

1. There should be 2 physiotherapists and 1 assistant to do the knee class. The physiotherapists mainly perform individual treatments and reviews whilst the assistant supervises the exercise circuit.

2. All knee class paperwork can be found in purple file on gym shelf.

3. SET UP THE CIRCUIT - the assistants should be familiar with this if you are not sure.

STATION	EXERCISE
1	WHEELIE CHAIR
2	SIT TO STAND
3	SQUATS
4	CALF RAISES
5	STEP UPS
6	HAMSTRING CURLS
7	KNEE FLEXION
8	SQUEEZING THE BALL
9	BRIDGING
10	PASSING THE BALL

Once the patient has been assessed you can also add on other exercises:

e.g. Static bike
Step machine
Bench slides
Gait & balance work etc

Depending on ROM, WB status, and level of rehab as appropriate.

4. Fetch the knee class patients and their notes from reception.

5. If possible see NP's first (ie as they arrive). When you are very busy, however, it may be necessary to set them off on the circuit under the assistant's supervision and get to them when you are next available. Try to see other patients in the order they arrive.

6. Attendance Sheet

Record all patients attendance's on sheet marked 'knee class' and record date. Fill in patients name and when you want them to attend next; day and date (if Thursday, must specify AM or PM). In transport box indicate ambulance/own. If you feel the patient should be able to make their own way here, but are still receiving transport please discuss cancelling the transport with the patient. In discharge indicate YES/NO for whether they have been discharged or not. Please also record UTA's and DNA's on attendance sheet.

At the end of the class the attendance sheet goes to , in reception so she can re-book the patients for their next session.

7. It is up to the physiotherapist to decide when the patient should attend ie once a week, twice a week, fortnightly as appropriate.

8. After seeing each patient PLEASE write the date you wish to see them next on their appointment card and tell them to show it to Vicky on reception before they leave (or they may end up not being booked in again!).

9. New Patients
Subjective information should be available on the referral sheet or in-patient notes. It is not necessary to fill out a body chart - your assessment can be done in S.O.A.P format as long as it includes all the relevant details, and a detailed plan including anticipated regularity and number of treatments required.

Provide new patients with:

- Education / advice re TKR rehabilitation

- Ice and/or hot cold contrast advice sheet)
- Basic and/or advanced exercise sheets) should be in rack on gym wall
- ARC booklet 'A New Knee Joint')

- Advice re scar massage, muscle massage, patella mobilisations

Once you have finished your assessment, hand the patient over to the assistant to explain and supervise the circuit.

10 Treatment Suggestions

To increase flexion: Flexion mobilisations
PA to proximal tibia at EOR flexion
Quads stretches and STM
Hold relax (can be very effective)
PFJ mobilisations in flexion

To increase extension: Extension mobilisations
AP to proximal tibia at EOR extension
Hams stretches and STM
Hold relax (can be very effective)

General: Rotations to proximal tibia can help with extremely stiff joints
H-wave for pain relief and/or muscle stimulation
? TENS for pain relief
Gait re-education and progression as appropriate
(different consultants prefer protected weight bearing status for different lengths of time. Generally:
Cemented TKR's PWB x 6 weeks
Uncemented TKR's PWB x 12 weeks
Mr X's patients PWB x 12 weeks
If in doubt, ask)

11. At the end of the class take down the signs for the circuit (except after Thursday AM class), and put them back in the purple file.

Take attendance list to Z in reception

That's it!!

GYM/KNEE CLASS

9.7 Baseline patient questionnaires

CONFIDENTIAL

Patient Code: .....

Consultant Code: .....

Group: .....

The Sheffield Project to evaluate Physiotherapy Care for patients having Knee Replacements

at the

Northern General Hospital

Enclosed are some questions asking you what you think and feel about your *OWN* health. To begin, there are a few questions which provide us with background information. Please give an answer to *EVERY* question. This questionnaire should take no longer than 15 minutes to complete.

Your name and address does not appear in the questionnaire. The information you give will not be used in any way that could identify you.

If you have difficulties or concerns please contact: The Research Office: Sheffield 288 0394

CONFIDENTIAL Patient Code: ...../...../....

THIS INFORMATION IS SOLELY FOR OUR RECORDS

TO BE COMPLETED BY THE PATIENT.

1). Name: ..... 2). Date of birth: .....

3). Address:.....
.....
.....
.....

4). Have you had any previous surgery on either your hip or knee joints? (Please delete as appropriate). YES/NO

4a). If 'Yes', please describe .....
.....

5). In addition to your knee problem, do you also suffer from any of the following health problems? (please delete as appropriate).

5a). Heart problems? YES/NO 5b). Chest Problems? YES/NO

5c). Diabetes? YES/NO 5d). Raised blood pressure? YES/NO

5e). Stroke/Transient Ischaemic Attack? YES/NO

5f). Other?, (please indicate) .....

6). Do you live alone? YES/NO

6a). If 'No', who do you live with? .....

6b). Does this person help to care for you? YES/NO

7). If you need help at home, who is your main carer? (e.g. spouse; partner; relative; friend; home help). Please indicate

.....

8). Could you please let us have a contact number for this person/organisation?
.....

THANKYOU VERY MUCH

Health Status Questionnaire (SF-36)

Health Status

The following questions ask you about your health, how you feel and how well you are able to do your usual activities.

If you are unsure how to answer a question, please give the best answer you can.

1. In general, would you say your health is:

(Tick One)

Excellent ☐

Very good ☐

Good ☐

Fair ☐

Poor ☐

2. Compared to one year ago, how would you rate your health in general now?

(Tick One)

Much better than one year ago ☐

Somewhat better than one year ago ☐

About the same ☐

Somewhat worse now than one year ago ☐

Much worse now than one year ago ☐

HEALTH AND DAILY ACTIVITIES

3. The following questions are about activities that you might do during a typical day. Does your health limit you in these activities? If so, how much?

(Circle one number on each line)

ACTIVITIES	YES limited a lot	YES limited a little	NO not limited at all
a. Bathing and dressing yourself	1	2	3
b. Walking **100 yards**	1	2	3
c. Walking **half a mile**	1	2	3
d. Walking **more than a mile**	1	2	3
e. Bending, kneeling or stooping	1	2	3
f. Climbing **one** flight of stairs	1	2	3
g. Climbing **several** flights of stairs	1	2	3
h. Lifting or carrying groceries	1	2	3
I. **Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling or playing golf	1	2	3
j. **Vigorous activities**, such as running, lifting heavy objects, participating in strenuous sports	1	2	3

4. During the *past 4 weeks*, have you had any of the following problems with your work or other regular daily activities *as a result of your physical health?*

(Circle one number on each line)

	YES	NO
a. Cut down on the **amount of time** you spent on work or other activities	1	2
b. **Accomplished less** than you would like	1	2
c. Were limited in the **kind** of work or other activities	1	2
d. Had **difficulty** in performing the work or other activities (eg. It took extra effort)	1	2

5. During the *past 4 weeks*, have you had any of the following problems with your work or other regular daily activities *as a result of any emotional problems* (such as feeling depressed or anxious)?

(Circle one number on each line)

	YES	NO
a. Cut down on the **amount of time** you spent on work or other activities	1	2
b. **Accomplished less** than you would like	1	2
c. Didn't do work or other activities as **carefully** as usual	1	2

6. **During the *past 4 weeks*, to what extent have your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours or groups?**

	(Circle one number)
Not at all	1
Slightly	2
Moderately	3
Quite a bit	4
Extremely	5

7. **How much *bodily* pain have you had during the past 4 weeks?**

	(Circle one number)
None	1
Very mild	2
Mild	3
Moderate	4
Severe	5
Very Severe	6

8. **During the *past 4 weeks*, how much did pain interfere with your normal work (including work both outside the home and housework)?**

	(Circle one number)
Not at all	1
A little bit	2
Moderately	3
Quite a bit	4
Extremely	5

YOUR FEELINGS

9. These questions are about how you feel and how things have been with you *during the past 4 weeks*. (For each question, please indicate the *one* answer that comes closest to the way you have been feeling).

(Circle one number on each line)

How much of the time during the past 4 weeks:	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
a. Did you feel full of life?	1	2	3	4	5	6
b. Have you been a very nervous person?	1	2	3	4	5	6
c. Have you felt so down in the dumps that nothing could cheer your up?	1	2	3	4	5	6
d. Have you felt calm and peaceful?	1	2	3	4	5	6
e. Did you have a lot of energy?	1	2	3	4	5	6
f. Have you felt down-hearted and low?	1	2	3	4	5	6
g. Did you feel worn-out?	1	2	3	4	5	6
h. Have you been a happy person?	1	2	3	4	5	6
I. Did you feel tired?	1	2	3	4	5	6
j. Has your health limited your social activities (like visiting friends or close relatives)	1	2	3	4	5	6

HEALTH IN GENERAL

10. Please choose the answer that best describes how *true* or *false* each of the following statements is for you.

(Circle one number on each line)

	Definitely true	Mostly true	Not Sure	Mostly false	Definitely false
a. I seem to get ill more easily than other people	1	2	3	4	5
b. I am as healthy as anybody I know	1	2	3	4	5
c. I expect my health to get worse	1	2	3	4	5
d. My health is excellent	1	2	3	4	5

WOMAC OSTEOARTHRITIS INDEX

A. PAIN

The following questions concern the amount of pain you have experienced due to arthritis in your most affected knee. For each situation please enter the amount of pain experienced in the last 48 hours.

(Please mark your answers with a tick)

How much pain do you have? (Please tick one box for each question)

	None	Mild	Moderate	Severe	Extreme	
1. Walking on a flat surface						PAIN1 ——
2. Going up or down stairs						PAIN2 ——
3. At night while in bed						PAIN3 ——
4. Sitting or lying						PAIN4 ——
5. Standing upright						PAIN5 ——

B. STIFFNESS

The following questions concern the amount of joint <u>stiffness</u> (not pain) you have experienced in the last 48 hours in your most affected knee. Stiffness is a sensation of restriction or slowness in the ease with which you move your joints.

(Please mark your answers with a tick)

(Please tick one box for each question)

	None	Mild	Moderate	Severe	Extreme	
6. How **severe** is your stiffness **after first waking** in the morning?						STIFF6 ——
7. How **severe** is your stiffness after sitting, lying, or resting **later in the day?**						STIFF7 ——

C. PHYSICAL FUNCTION

The following questions concern your physical function. By this we mean your ability to move around and look after yourself. For each of the following activities, please indicate the degree of difficulty you have experienced in the last 48 hours due to arthritis in your affected knee.

(Please mark your answers with a tick)

What degree of difficulty do you have with:

(Please tick one box for each question)

	None	Mild	Moderate	Severe	Extreme	
8. Descending stairs						PFTN8 ____
9. Ascending stairs						PFTN9 ____
10. Rising from sitting						PFTN10 ____
11. Standing						PFTN11 ____
12. Bending to floor						PFTN12 ____
13. Walking on flat						PFTN13 ____
14. Getting in/out of car						PFTN14 ____
15. Going shopping						PFTN15 ____
16. Putting on socks/stockings						PFTN16 ____
17. Rising from the bed						PFTN17 ____
18. Taking off socks/stockings						PFTN18 ____
19. Lying in bed						PFTN19 ____

What degree of difficulty do you have with:

(Please tick one box for each question)

	None	Mild	Moderate	Severe	Extreme	
20. Getting in/out of bath						PFTN20 ____
21. Sitting						PFTN21 ____
22. Getting on/off toilet						PFTN22 ____
23. Heavy domestic duties						PFTN23 ____
24. Light domestic duties						PFTN24 ____

THANK YOU FOR COMPLETING THE QUESTIONNAIRE

9.8 Postoperative patient questionnaires

CONFIDENTIAL

Patient Code: .....

Consultant Code: .....

Group: .....

The Sheffield Project to evaluate Physiotherapy Care for patients having Knee Replacements

at the

Northern General Hospital

Part one of this questionnaire asks you about your transport details and any cost which you might have had in connection with your physiotherapy care.
Part two asks you about your views on your physiotherapy care.
Both these questionnaires should take no longer than 15 minutes to complete.

Your name and address does not appear in the questionnaire. The information you give will not be used in any way that could identify you.

If you have difficulties or concerns please contact: The Research Office: Sheffield 288 0394

SURVEY OF PATIENTS' VIEWS OF PHYSIOTHERAPY CARE

We wish to understand more about how patients having knee replacements feel about the physiotherapy care they have received. Please answer the following questions by ticking the box and feel free to write in the comments sections anything you think might be helpful in planning physiotherapy care for knee replacement patients in the future.

If you are unsure about how to answer a question, please give the best answer you can.

1.	Have you had physiotherapy before you were invited to take part in this research project?	YES 1. ☐	NO 2. ☐
	IF YES PLEASE ANSWER (a), (b) AND (c), IF NO PLEASE GO TO QUESTION 2		
a	Was the physiotherapy for a knee problem?	1. YES ☐	2. NO ☐
b	Have you had knee surgery in the past?	1. YES ☐	2. NO ☐
c	Where did you have the physiotherapy? (please tick a box)	1. Community ☐	
		2. Hospital ☐	
		3. Hospital & Community ☐	
		4. Privately ☐	

2.	Have you had physiotherapy in the 12 months <u>before</u> this most recent knee surgery?	1. YES ☐	2. NO ☐
IF YES PLEASE ANSWER (a), (b) ,(c), d IF NO, GO TO QUESTION 3			
a	Was this physiotherapy provided by the community physiotherapists working with the research project?	1. YES ☐	2. NO ☐
b	Was this physiotherapy provided by the hospital physiotherapists?	1. YES ☐	2. NO ☐
c	Was this physiotherapy provided by the community physiotherapist attached to your GP's surgery?	1. YES ☐	2. NO ☐
d	Did you attend a private physiotherapist?	1. YES ☐	2. NO ☐

3. Did you feel that the physiotherapy you received was – *(please tick a box)*	Helpful? *(go to Q.4)*	1.
	Unhelpful? *(go to Q.5)*	2.
	Neither helpful nor unhelpful?	3.

4. What do you feel was helpful about the physiotherapy care you received?

5. What do you feel was unhelpful about your physiotherapy care?

6. How could your physiotherapy care have been improved?

Where would you prefer to have your physiotherapy care following knee surgery?	1. Community ☐ 2. Hospital ☐ 3. No preference ☐

8. Please write any further comments about the physiotherapy care you have received which you feel would be helpful for us to know:

9. THANK YOU FOR TAKING THE TIME TO COMPLETE THIS QUESTIONNAIRE AND PARTICIPATING IN THIS NHS FUNDED RESEARCH PROJECT. IF YOU WOULD LIKE A COPY OF THE FINAL REPORT WHEN THE PROJECT IS COMPLETED IN 2002, PLEASE TICK THE BOX AND WE WILL SEND YOU A COPY ☐ [1]

[1] POST-OP PT SAT3 2/2000

PATIENT TRANSPORT QUESTIONNAIRE

This questionnaire is to help us find out more about your transport use and any costs you have had in connection with your physiotherapy care

PLEASE TICK OR WRITE IN THE APPROPRIATE BOX- if you are not sure how to respond please answer as best as you can

1) Have you attended outpatient physiotherapy since your knee operation?	(a) YES Go to Q.2	(b) NO Go to Q.8
2) Which outpatient physiotherapy department did you attend?	(a) Northern General Hospital	
	(b) Royal Hallamshire Hospital	
	(a) Other (please name)	
3) How many visits to the hospital for physiotherapy did you make?		
4) How long did the round trip to hospital for physiotherapy treatment take?	(a)Shortest time	
	(b)Longest time	

5) How did you get to your hospital physiotherapy sessions?	(a)Ambulance	
	(b)Own transport	
	(c)Hospital Medicar or taxi	
	(d)Mixture of hospital and own transport	
6) How many trips did you make using each of the following?	(a)Ambulance	
	(b)Own transport	
	(c)Hospital Medicar or taxi	
7) If you attended by your own transport :		
(a) How many miles did you travel to the hospital and back again to your home?	(a)	
(b) Did you pay for parking and if so how much?	(b)YES £ .	NO
(c) If you came in your own transport who brought you?		
8) If you have had community physiotherapy, where have the sessions taken place?	(a) Home	(b) Clinic
9) How many community physiotherapy sessions have you had?	(a) Before your knee replacement	
	(b) After your knee replacement	

10) How long did the community physiotherapy treatment take?	(a) Shortest time	b) Longest time
11) If your community physiotherapy sessions have taken place at a clinic, how many miles did you travel to the clinic and back again to your home?	.	
12) Please describe any other costs you have had in connection with your physiotherapy care?		

THANK YOU·

· patient transport questionaire

· patient transport questionaire

CONFIDENTIAL

Patient Code: .....

Consultant Code: .....

Group: .....

The Sheffield Project to evaluate Physiotherapy Care for patients having Knee Replacements

at the

Northern General Hospital

Enclosed are some questions asking you what you think and feel about your *OWN* health. To begin, there are a few questions which provide us with background information. Please give an answer to *EVERY* question. This questionnaire should take no longer than 15 minutes to complete.

Your name and address does not appear in the questionnaire. The information you give will not be used in any way that could identify you.

If you have difficulties or concerns please contact: The Research Office: Sheffield 288 0394

CODE [ ]

CONFIDENTIAL THIS INFORMATION IS FOR OUR RESEARCH RECORDS ONLY.

1. NAME:	2. DATE OF BIRTH
3. ADDRESS:	

4. In addition to your knee problem, do you also suffer from any of the following health problems? (please tick the box for your answer)		
4(a) Heart problems	YES [ ]	NO [ ]
4(b) Chest problems	YES [ ]	NO [ ]
4(c) Diabetes	YES [ ]	NO [ ]
4(d) Raised Blood Pressure	YES [ ]	NO [ ]
4(e) Stroke / Transient Ischaemic attack (TIA)	YES [ ]	NO [ ]
4(f) Other (please describe)		

5. Since your knee surgery have you had any new significant or serious health problems?	1. YES [ ]	2. NO [ ]
5(a) If yes, please describe		

6. Do you live alone ?	1. YES [ ]	2. NO [ ]
6(a) If not, who do you live with ?		
6(b) Does this person help care for you ?	1. YES [ ]	2. NO [ ]
7. If you need help at home , who is your main carer (e.g. spouse, partner, relative, friend, home help, neighbour, private carer) – please describe		

Health Status Questionnaire (SF-36)

Health Status

The following questions ask you about your health, how you feel and how well you are able to do your usual activities.

If you are unsure how to answer a question, please give the best answer you can.

1. In general, would you say your health is:

(Tick One)

- Excellent ☐
- Very good ☐
- Good ☐
- Fair ☐
- Poor ☐

2. Compared to one year ago, how would you rate your health in general now?

(Tick One)

- Much better than one year ago ☐
- Somewhat better than one year ago ☐
- About the same ☐
- Somewhat worse now than one year ago ☐
- Much worse now than one year ago ☐

HEALTH AND DAILY ACTIVITIES

3. The following questions are about activities that you might do during a typical day. Does your health limit you in these activities? If so, how much?

(Circle one number on each line)

ACTIVITIES	YES limited a lot	YES limited a little	NO not limited at all
a. Bathing and dressing yourself	1	2	3
b. Walking **100 yards**	1	2	3
c. Walking **half a mile**	1	2	3
d. Walking **more than a mile**	1	2	3
e. Bending, kneeling or stooping	1	2	3
f. Climbing **one** flight of stairs	1	2	3
g. Climbing **several** flights of stairs	1	2	3
h. Lifting or carrying groceries	1	2	3
I. **Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling or playing golf	1	2	3
j. **Vigorous activities**, such as running, lifting heavy objects, participating in strenuous sports	1	2	3

4. During the *past 4 weeks*, have you had any of the following problems with your work or other regular daily activities *as a result of your physical health?*

(Circle one number on each line)

	YES	NO
a. Cut down on the **amount of time** you spent on work or other activities	1	2
b. **Accomplished less** than you would like	1	2
c. Were limited in the **kind** of work or other activities	1	2
d. Had **difficulty** in performing the work or other activities (eg. It took extra effort)	1	2

5. During the *past 4 weeks*, have you had any of the following problems with your work or other regular daily activities *as a result of any emotional problems* (such as feeling depressed or anxious)?

(Circle one number on each line)

	YES	NO
a. Cut down on the **amount of time** you spent on work or other activities	1	2
b. **Accomplished less** than you would like	1	2
c. Didn't do work or other activities as **carefully** as usual	1	2

6. **During the *past 4 weeks*, to what extent have your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours or groups?**

	(Circle one number)
Not at all	1
Slightly	2
Moderately	3
Quite a bit	4
Extremely	5

7. **How much *bodily* pain have you had during the past 4 weeks?**

	(Circle one number)
None	1
Very mild	2
Mild	3
Moderate	4
Severe	5
Very Severe	6

8. **During the *past 4 weeks*, how much did pain interfere with your normal work (including work both outside the home and housework)?**

	(Circle one number)
Not at all	1
A little bit	2
Moderately	3
Quite a bit	4
Extremely	5

YOUR FEELINGS

9. These questions are about how you feel and how things have been with you *during the past 4 weeks.* (For each question, please indicate the *one* answer that comes closest to the way you have been feeling).

(Circle one number on each line)

How much of the time during the past 4 weeks:	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
a. Did you feel full of life?	1	2	3	4	5	6
b. Have you been a very nervous person?	1	2	3	4	5	6
c. Have you felt so down in the dumps that nothing could cheer your up?	1	2	3	4	5	6
d. Have you felt calm and peaceful?	1	2	3	4	5	6
e. Did you have a lot of energy?	1	2	3	4	5	6
f. Have you felt down-hearted and low?	1	2	3	4	5	6
g. Did you feel worn-out?	1	2	3	4	5	6
h. Have you been a happy person?	1	2	3	4	5	6
I. Did you feel tired?	1	2	3	4	5	6
j. Has your health limited your social activities (like visiting friends or close relatives)	1	2	3	4	5	6

HEALTH IN GENERAL

10. Please choose the answer that best describes how *true* or *false* each of the following statements is for you.

(Circle one number on each line)

	Definitely true	Mostly true	Not Sure	Mostly false	Definitely false
a. I seem to get ill more easily than other people	1	2	3	4	5
b. I am as healthy as anybody I know	1	2	3	4	5
c. I expect my health to get worse	1	2	3	4	5
d. My health is excellent	1	2	3	4	5

WOMAC OSTEOARTHRITIS INDEX

A. PAIN

The following questions concern the amount of pain you have experienced due to arthritis in your most affected knee. For each situation please enter the amount of pain experienced in the last 48 hours.

(Please mark your answers with a tick)

How much pain do you have? (Please tick one box for each question)

	None	Mild	Moderate	Severe	Extreme	
1. Walking on a flat surface						PAIN1 ——
2. Going up or down stairs						PAIN2 ——
3. At night while in bed						PAIN3 ——
4. Sitting or lying						PAIN4 ——
5. Standing upright						PAIN5 ——

B. STIFFNESS

The following questions concern the amount of joint <u>stiffness</u> (not pain) you have experienced in the last 48 hours in your most affected knee. Stiffness is a sensation of restriction or slowness in the ease with which you move your joints.

(Please mark your answers with a tick)

(Please tick one box for each question)

	None	Mild	Moderate	Severe	Extreme	
6. How **severe** is your stiffness **after first waking** in the morning?						STIFF6 ——
7. How **severe** is your stiffness after sitting, lying, or resting **later in the day?**						STIFF7 ——

C. PHYSICAL FUNCTION

The following questions concern your physical function. By this we mean your ability to move around and look after yourself. For each of the following activities, please indicate the degree of difficulty you have experienced in the last 48 hours due to arthritis in your affected knee.

(Please mark your answers with a tick)

What degree of difficulty do you have with:

(Please tick one box for each question)

	None	Mild	Moderate	Severe	Extreme	
8. Descending stairs						PFTN8 ____
9. Ascending stairs						PFTN9 ____
10. Rising from sitting						PFTN10 ____
11. Standing						PFTN11 ____
12. Bending to floor						PFTN12 ____
13. Walking on flat						PFTN13 ____
14. Getting in/out of car						PFTN14 ____
15. Going shopping						PFTN15 ____
16. Putting on socks/stockings						PFTN16 ____
17. Rising from the bed						PFTN17 ____
18. Taking off socks/stockings						PFTN18 ____
19. Lying in bed						PFTN19 ____

What degree of difficulty do you have with:

(Please tick one box for each question)

	None	Mild	Moderate	Severe	Extreme	
20. Getting in/out of bath						PFTN20 ____
21. Sitting						PFTN21 ____
22. Getting on/off toilet						PFTN22 ____
23. Heavy domestic duties						PFTN23 ____
24. Light domestic duties						PFTN24 ____

THANK YOU FOR COMPLETING THE QUESTIONNAIRE

9.9 Postoperative data collection sheets (hospital, home physiotherapy, general practice)

The Sheffield Project to evaluate Physiotherapy Care for patients having Knee Replacements at the Northern General Hospital

PHYSIOTHERAPY REFERRAL FORM AND RESEARCH DATASHEET

CONFIDENTIAL

Patient's Name: ..... M / F

Patient's Address: Telephone: .....

Postcode: ..... Date of Birth: ..... /...../.....

Consultant: .....

GP: (Name and Address):

Postcode: ..... Telephone: .....

Date of Referral: ..... / ..... / .....

Physiotherapist: Name: ..... Grade: .....

PRE-OPERATIVE PHYSIOTHERAPY SESSIONS

Date of session	Length of session (minutes)	Mileage (miles)[1]	Content of visit[2]

[1] Mileage from previous visit/or base, (if this is your first call of the day), to this patient

[2] Brief description of content of visit

Pre-operative physiotherapy (additional notes):
Telephone Contact:

DATE OF CALL	DURATION OF CALL, (MINS).	CONTENT OF CALL

Any other comments relating to the project therapy, which you think are relevant. Also include patient's contact with therapy services which are unrelated to the project.

Please return forms to: The Research Office, Dr. Mitchell & Partners.
Woodhouse Medical Centre, 7 Skelton Lane, Woodhouse,
Sheffield S13 7LY.
Telephone: 0114 288 0394

POST-OPERATIVE PHYSIOTHERAPY REFERRAL FORM AND RESEARCH DATASHEET

CONFIDENTIAL

Patient's Name: ..... M / F

Patient's Address: Telephone: .....

Postcode: ..... Date of Birth: ..... /...../.....

Consultant: .....

GP: (Name and Address):

Postcode: ..... Telephone: .....

Date of Referral: ..... / ..... / .....

Physiotherapist: Name: ..... Grade: .....

Date of Knee Surgery: ..... /...../..... Date of Discharge: ..... /...../.....

First date seen / First appointment.....

Any post-operative problems ?:

Please return forms to: The Research Office, Dr. Mitchell & Partners.
Woodhouse Medical Centre, 7 Skelton Lane, Woodhouse,
Sheffield S13 7LY
Telephone: 0114 288 0394

Name of patient: Date of birth: ...... /....../......

POST-OPERATIVE PHYSIOTHERAPY SESSIONS

Date of session	Length of session (minutes)	Mileage (miles)	Content of visit

Please return forms to: The Research Office, Dr. Mitchell & Partners. Woodhouse Medical Centre, 7 Skelton Lane, Woodhouse, Sheffield S13 7LY Telephone: 0114 288 0394

Name of Patient: Date of Birth: ..... /...../.....

Post-operative Physiotherapy (additional notes):

Telephone Contact:

DATE OF CALL	DURATION OF CALL, (MINS).	CONTENT OF CALL

Please return forms to: The Research Office, Dr. Mitchell & Partners.
Woodhouse Medical Centre, 7 Skelton Lane, Woodhouse,
Sheffield S13 7LY
Telephone: 0114 288 0394

Name of Patient: Date of Birth: : ..... /...../.....

Post-operative physiotherapy (additional notes):

Completion of programme in primary care. Yes / No.

If 'No' reason for leaving / transfer.

Discharge to further physiotherapy care. Yes / No.

If 'Yes' site of care, hospital, hydrotherapy, community.
(circle as appropriate).

Any other comments relating to the project therapy, which you think are relevant. Also include patient's contact with therapy services which are unrelated to the project and you think are relevant.

Please return forms to: The Research Office, Dr. Mitchell & Partners.
Woodhouse Medical Centre, 7 Skelton Lane, Woodhouse,
Sheffield S13 7LY
Telephone: 0114 288 0394

U/Patient/N [ ] C/Code [ ] Group [ ]

NGH OUTPATIENT ORTHOPAEDIC AND NGH PHYSIOTHERAPY DEPARTMENTS POST-OPERATIVE DATA COLLECTION SHEET

1. NAME		2. DATE OF BIRTH	
3. CONSULTANT			
4. GP practice			
5. Date name placed on waiting list for TKR			
6. Length of wait for surgery (complete weeks)			weeks
7. Date of Admission			
8. Date of knee replacement			
9. Date of hospital discharge			
10. Length of hospital stay (days)			days
11. Re-admission		Yes	No
12. Number of re-admissions			
13. Total Length of Readmission stay (days)			
14. Reason for Readmission/s			
15. First date seen orthopaedic clinic			
16. Number of weeks after TKR of first orthopaedic clinic apptment			weeks
17. Number of orthopaedic outpatient attendances to 12 weeks post-operative			
ORTHOPAEDIC NOTES COLLECTION			
18. Confirm unilateral knee replacement		Yes ☐	No ☐
19. Weight (kg)			Kg
20. Patient co-morbidity (please tick & describe any 'other' below)	a) heart problems	Yes ☐	No ☐
	b) chest problems	Yes ☐	No ☐
	c) diabetes	Yes ☐	No ☐
	d) raised blood pressure	Yes ☐	No ☐
	e) stroke / TIA	Yes ☐	No ☐
	f) other	Yes ☐	No ☐
	g)other knee i)previous TKR	Yes ☐	No ☐
	ii) OA	Yes ☐	No ☐
	iii) other problem	Yes ☐	No ☐
21. Post-operative complications	a) heart problems	Yes ☐	No ☐
	b) chest problems	Yes ☐	No ☐
	c) DVT/Pulmonary embolus	Yes ☐	No ☐
	d) Infection (?site)	Yes ☐	No ☐
	e) stroke / TIA	Yes ☐	No ☐

	f) other	Yes ☐	No ☐
	g) mortality	Yes ☐	No ☐
22. Degrees of knee flexion on discharge		degrees	

PHYSIOTHERAPY OUTPATIENT DATA COLLECTION FORM		
23. Site of physiotherapy sessions	a)Royal Hallamshire hospital ☐	
	b)Northern General hospital ☐	
	c)Research community physiotherapist ☐	
	d)Non-research community physiotherapist ☐	
24. Date of first hospital out-patient physiotherapy appointment		
25. Number of days to first outpatient physiotherapy appointment after knee replacement		
26. Number of knee classes attended	a) sessions	
	b) cost	
27. (a) Number of physiotherapy sessions with a sole therapist	a)	
(b) Grade of hospital physiotherapist	b)	
(c) Cost of physiotherapy care	c)	
28. Discharged from hospital physiotherapy at 3 months	YES ☐	NO ☐
29. Discharge date from hospital physiotherapy		
30. Referral to hydrotherapy	YES ☐	NO ☐
31. Referral to non-research project community physiotherapist	YES ☐	NO ☐

HOSPITAL TRANSPORT BOOKED	
32. Number of Ambulance trips to out-patient physiotherapy	a)
	b) cost
33. Number of Medicar trips to out-patient physiotherapy	a)
	b) cost
34. Number of trips to out-patient physiotherapy without hospital transport	a)
	b) cost

GP DATA COLLECTION FORMS code

CONFIDENTIAL THIS INFORMATION IS FOR OUR RESEARCH RECORDS ONLY.

1. NAME:	2. DATE OF BIRTH
3. ADDRESS:	

4. Does the patient have any of the following health problems? (please tick the box for your answer)

4(a) Heart problems	YES ☐	NO ☐
4(b) Chest problems	YES ☐	NO ☐
4(c) Diabetes	YES ☐	NO ☐
4(d) Raised Blood Pressure	YES ☐	NO ☐
4(e) Stroke / Transient Ischaemic attack (TIA)	YES ☐	NO ☐
4(f) Other (please describe)	YES ☐	NO ☐

GP CONSULTATION DATA

5. Date entry to trial	6. Date TKR[1] operation	7. Number of months from trial entry to TKR	8. Date of 3 months post TKR

9. Number of GP consultations from 12 months prior to admission for TKR	
10. Number of GP consultations from TKR operation to 3 months (12 weeks) post-operatively	

GENERAL PRACTICE PRESCRIBING DATA

11. List analgesics taken by patient 12 months pre-operatively	11.a. NSAIDS
	11.b. Other
12. Number of pre-operative prescriptions for analgesics for 12 months prior to admission	
13. Name and dose of antidepressants in use pre-hospital admission	

[1] TKR = total knee replacement

14. Number of antidepressant prescriptions pre-hospital admission over 12 months	
15. Name and dose of night sedation	
16. Number of night sedation prescriptions pre-hospital admission over 12 months	
17. List name and dose of analgesics taken by patient **at 3 months** post-operatively	
18. Number of post-operative prescriptions for analgesics[2] over 3 months	
19. List name and dose of antidepressants **at 3 months** post-operatively	
20. Number of antidepressant prescriptions post-hospital admission [3] over 3 months	
21. List name and dose of night sedation prescriptions **at 3 months** post-operatively	
22. Number of night sedation prescriptions post-hospital admission [4] over 3 months	

23. Post-operative complications (please tick)	a) heart problems	YES ☐	NO ☐
	b) chest problems	YES ☐	NO ☐
	c) DVT / Pulmonary Embolus	YES ☐	NO ☐
	d) Infection (?site)	YES ☐	NO ☐
	e) stroke / TIA	YES ☐	NO ☐
	f) other	YES ☐	NO ☐
	g) mortality	YES ☐	NO ☐

[2] analgesics- see explanantory notes
[3] antidepressants- see explanantory notes
[4] night sedation- see explanantory notes

9.10 Consort checklist and summary

PAPER SECTION And topic	Item	CONSORT SUMMARY AND CHECKLIST
TITLE & ABSTRACT	1	**Costs and effectiveness of pre- and postoperative home physiotherapy for total knee replacement: randomised controlled trial.** **Objectives** To assess the effectiveness of pre- and postoperative physiotherapy at home for unilateral total knee replacement (TKR). **Design** Pragmatic randomised controlled trial, with 12 weeks follow-up. **Setting** Participants' homes (4 primary care trust areas), and physiotherapy outpatients in a South Yorkshire teaching hospital trust. **Participants** 160 knee osteoarthritis patients from a NHS waiting list for unilateral TKR, randomly allocated to intervention (home) group (n=80) or control (hospital) group (n=80). **Intervention** Pre- and postoperative home visits for assessment and treatment by a community physiotherapist. **Outcome Measures** Health-related quality of life (HRQoL), measured by the Western Ontario McMaster Osteoarthritis index (WOMAC) and the Short Form 36 health survey (SF-36) at 12 weeks post TKR operation; patient satisfaction; physiotherapy input; NHS resource use. **Results** 28.1% of participants withdrew from the study, 15% due to TKR cancellation. The mean wait to first postoperative physiotherapy appointment after hospital discharge was significantly longer ($p<0.001$) for the hospital group compared to the home group. The WOMAC and SF36 response rate was 98% (114/116); no significant differences were observed between the two treatment groups in mean scores, even after adjusting for preoperative HRQoL and preoperative waiting time. The home group had a greater mean number of physiotherapy sessions than the hospital group (8.4 versus 3.6). Home physiotherapy for TKR was significantly more expensive than hospital outpatient physiotherapy, although there was no significant difference in the total NHS costs per patient between groups. TKR patients were equally satisfied (86%) with physiotherapy at home or in hospital. **Conclusions** Home physiotherapy is acceptable to patients and is as effective as hospital outpatient physiotherapy for unilateral TKR. Additional preoperative home physiotherapy did not improve patient perceived health outcomes. .
INTRODUCTION Background	2	Pre- and post-operative home physiotherapy for TKR has only previously been assessed in very small exploratory trials, which would not fulfil current CONSORT standards for publication. This type of physiotherapy for TKR patients has not previously been assessed in the UK. The research hypotheses are: 1. Pre- and post-operative physiotherapy at home improves patient outcomes following TKR when compared to patient outcomes after usual post-operative physiotherapy in the hospital outpatient clinic after TKR 2. Pre- and post-operative home physiotherapy for unilateral TKR is a cost-effective and acceptable model of physiotherapy for TKR when compared with usual post-operative physiotherapy in the out-patient clinic.
METHODS Participants	3	<u>Eligibility criteria for participants</u>: Patients were included in the study if they: 1) Were on the waiting list for a unilateral total knee replacement (TKR) as a primary procedure, between 1/7/99 and 1/12/2000; 2) had osteoarthritis of the knee 3) were under one of the 9 participating orthopaedic consultants from the Northern General Hospital, Sheffield 4) lived within the Sheffield Health service district boundary. Excluded were patients who 1)were to have revision procedures; knee replacement following severe

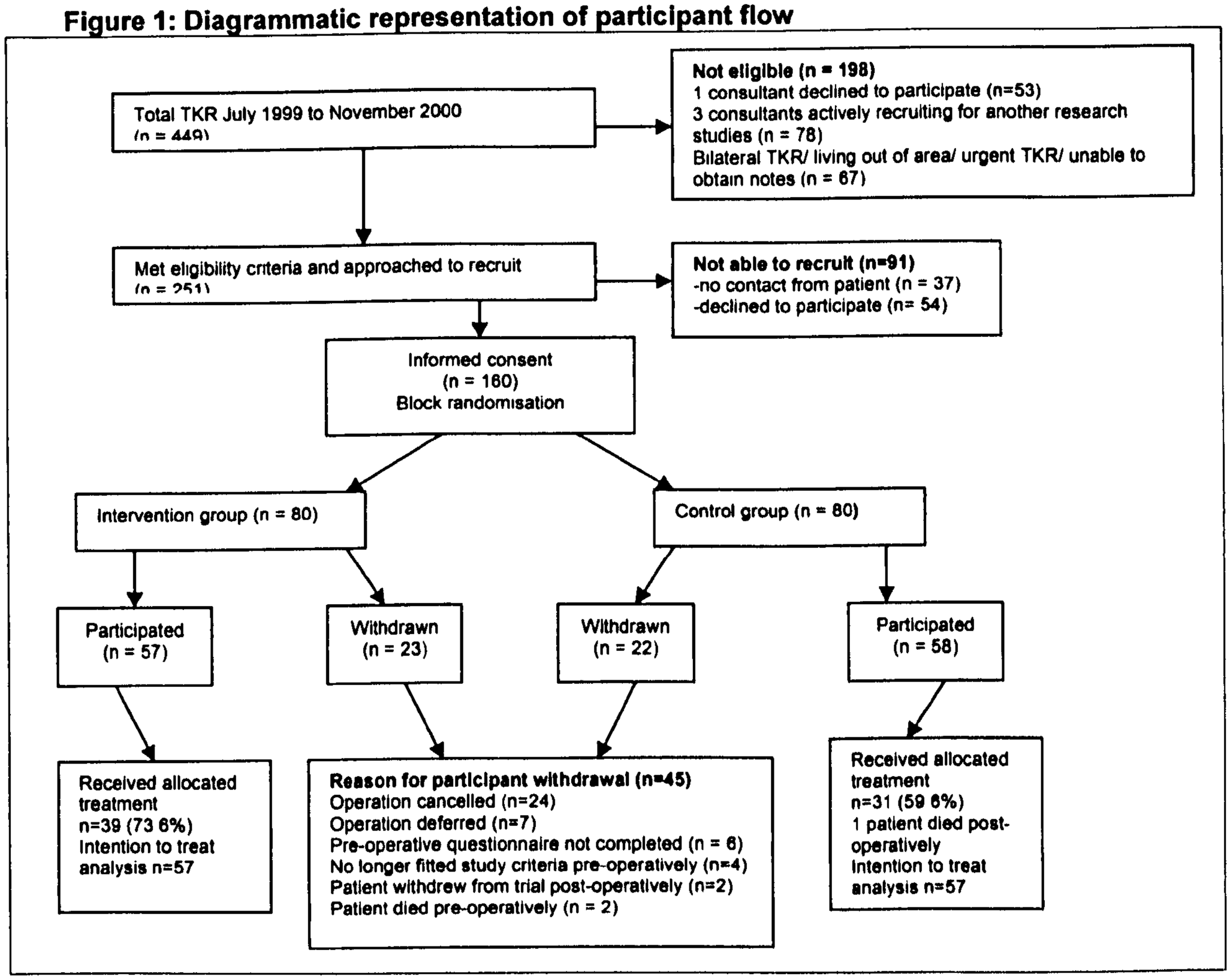
		trauma; or bilateral or unicondylar knee replacements 2) had a contra-lateral knee replacement within the last 12 months 3)developed serious co-morbidity or terminal illness since being placed on the waiting list, which necessitated cancellation or considerable delay in treatment 4)lived outside Sheffield, as the community physiotherapy was a Sheffield based service. Settings and locations where the data were collected. The research team was comprised of a general practitioner lead clinical researcher, research nurse, a research associate, staistician, health economist and a professor of General Practice. The orthopaedic waiting list administrator identified patients from a TKR waiting list, which was updated every 6 weeks. The research nurse consulted orthopaedic notes to check for inclusion /exclusion criteria in order to produce a list of eligible patients. This list was regularly updated. The setting was a single National Health Service provider unit, the Northern General Hospital, Sheffield. The hospital is part of the Sheffield University Hospitals Trust. The orthopaedic unit had 13 consultants regularly performing TKRs at this time. 12 consented to patient recruitment from their waiting lists. However, only 9 consultants were included as 3 were recruiting for other joint arthroplasty studies for the duration of our recruitment phase. The 4 consultants not included in the study did not differ significantly from the other 11 in the number of TKRs performed. The fourth consultant (non-consenting) was atypical in that a different specific model of post-operative physiotherapy care was recommended for his patients
Interventions	4	Precise details of the interventions intended for each group and how and when they were actually administered. Participants were randomised to receive either the usual hospital-based, out-patient physiotherapy post-operatively (control group) or a new, home-based physiotherapy service, pre- and post-operatively (intervention group). The hospital-based physiotherapy took the form of exercises in 'knee classes' in the gymnasium for groups of 10 patients. Individual treatment sessions in the physiotherapy out-patient department were given at the physiotherapists' discretion. The number and frequency of sessions were to be decided by the physiotherapists but at the start of the study, senior physiotherapists defined usual practice as 2-3 sessions per week to a usual total of 9sessions.The knee class protocol stated that 2 physiotherapists and 1 assistant should be present. The classes were to consist of individual treatments supervised by the 2 physiotherapists and an exercise circuit supervised by the assistant. The patients were also to be given advice and written information. Suggested physiotherapy treatments included mobilisations; muscle stretches and proprioceptive neuromuscular facilitation techniques to increase knee flexion and extension. In addition, there might be: electrotherapy for pain relief and/or muscle stimulation; and gait re-education, progressing as appropriate depending on individual consultants' preferences for protected weight bearing status. The new, community-based physiotherapy service was to provide up to 9 sessions from a senior physiotherapist, in the patient's home. Up to 3 sessions were to be given pre-operatively and up to 6 post-operatively to reflect usual hospital practice in terms of total number of physiotherapy sessions per patient. The intervention was designed by a senior community physiotherapist in consultation with a senior orthopaedic physiotherapist, from the Northern General Hospital and the principal investigator. The community physiotherapy protocol stated that pre-operatively the patient would be assessed and treated. The treatment programme would be based on assessment findings. It might include: • treatment for pain relief (e.g. Tens or cold therapy)

		• techniques to improve range of movement at any or all of the lower limb joints • techniques to improve muscle strength at any or all of the lower limb joints • gait re-education • adapting living style or the home environment • advice. Patients would be given written information: 'Diet and Arthritis' and 'A New Knee Joint'. Post-operatively the patient would be assessed and treated. Treatment might include the options above as well as techniques to reduce swelling and techniques to mobilise soft tissue. In summary, the differences between the two groups were that the hospital group did not have access to pre-operative physiotherapy and would not normally have a home-based, functional assessment; the home care group would not have access to gym equipment. However, the physiotherapists in both settings agreed common discharge criteria
Objectives	5	Specific objectives and hypotheses. The hypothesis was that a model of rehabilitation care whereby a community physiotherapist assessed and treated patients having total knee replacement pre-operatively and provided home treatment post-operatively would: 1) improve patient perceived health outcomes 2) be more cost-effective by reducing patient transport costs 3) be more acceptable to patients, compared to the current model of care based on post-operative, outpatient, hospital-based physiotherapy.
Outcomes	6	Clearly defined primary and secondary outcome measures and, when applicable, any methods used to enhance the quality of measurements (*e.g.*, multiple observations, training of assessors). Baseline pre-operative Primary and Secondary outcome data were collected by a questionnaire sent to participants within one week of consent to participation in the study. Non-respondents were followed up with a further questionnaire two weeks later or a phone call from the research nurse. Post-operative questionnaires were sent to participants to be received twelve weeks after the total knee replacement. Again non-respondents were followed up with a further questionnaire 2 weeks later or a phone call from the research nurse. All other secondary outcome data were measured at 12 weeks. The main outcome measures were: • the change in scores between the two treatment groups as measured by standardised questionnaires; the disease specific patient perceived health outcome measure Western Ontario McMaster Osteoarthritis index (WOMAC), supplemented by a generic quality of life measure, the Short Form 36 health survey (SF-36) Secondary outcome measures were: 1. An economic evaluation assessing the average cost per patient of physiotherapy intervention between the two groups (cost consequence analysis). Resource use was compared between the two groups , in order to attribute cost per patient for the two models of physiotherapy care, as measured by data extracted from hospital physiotherapy notes and community physiotherapy responses on self-completion questionnaires: • length of hospital stay • transport costs • attributed costs of physiotherapy sessions 2. the proportion of patients expressing satisfaction with physiotherapy intervention as measured by self-completion questionnaires;

		3. the proportion of patients with post-operative complications and morbidity as measured by data extracted from orthopaedic notes, primary care notes and patient responses on self-completion questionnaires; Data collection forms for secondary outcome measures were developed by the project team.
Sample size	7	How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules. The sample size calculation is based on the expected change in score of the primary outcome measure; WOMAC. A previous study, Brazier et al (1996), demonstrated a Mean Difference of 4 & Standard Deviation of 4.3 in WOMAC scores, when comparing 2 groups of patients (surgical and medical), before and after knee replacement surgery and 2 measures over the same time period for medical out-patient patients. For the purposes of this study, the 'new technology' under evaluation is the physiotherapy component of the knee replacement process for patients. The potential change in WOMAC score associated with an active pre-operative rehabilitation programme, based in the patients own home, before & after knee replacement, compared to usual hospital post-operative care will be smaller than that associated with joint replacement. There are no previous studies conducted to evaluate different models of physiotherapy as part of the pathway of care for knee replacement patients, with large enough numbers or similar patient perceived outcome measures. For this reason the treatment response for different models of physiotherapy was estimated as being a Mean Difference of 1.5. Assuming that a 2-sample t-test with equal numbers in each group is used for analysis then a sample size of 65 in each group is the minimum needed to achieve 80% power. We increased this to 80 in each group to allow for patient withdrawals. The following examples reflect the power and sample size calculations used, with the associated estimates of the difference in scores needed to detect differences in the 2 treatment groups: Mean Difference = 1.5 0.90 Power (1-β), 0.05α; n=86 0.80 Power (1-β), 0.05α; n=65
Randomization -- Sequence generation	8	Method used to generate the random allocation sequence, including details of any restriction (*e.g.*, blocking, stratification). Concealed block randomisation was used. Patients were randomised in blocks of 8 or 10, at the point of consultant allocation to the waiting list, to an intervention or control group according to a list drawn up by the consultant statistician. The randomisation code was developed using a computer random number generator to select random permuted blocks. The block lengths were 8 and 10, varied randomly.
Randomization -- Allocation concealment	9	Method used to implement the random allocation sequence An independent administrator inserted intervention and control cards into 160 sealed envelopes. The randomisation list was then sealed in an envelope, dated and kept securely and separately to the cards. The research assistant did not have access to this randomisation list to 'blind' the allocation process.
Randomization -- Implementation	10	Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups. As patients who consented to participation returned their consent forms to the research office, the sealed envelopes were opened sequentially by the research nurse to allocate them to their treatment group. Thus although the researcher was blinded to the allocation sequence, participants were then made aware of the treatment group to which they were allocated.
Blinding (masking)	11	Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment.

		This is a pragmatic, intention to treat study which compares outcomes for a new model of physiotherapy care. Local ethics committee guidance did not approve a Zelen's Randomised Consent design. Patients and physiotherapists are not blinded to the allocated intervention. The statistician and health economist who undertook the preliminary analysis were blind to group assignment. Survey instruments assess patient perceived health outcome measures. Secondary outcome measure data were collected from a minimum of 2 separate sources by the research nurse.
Statistical methods	12	<u>Statistical methods used to compare groups for primary outcome(s);</u> <u>Methods for additional analyses,</u> An intention to treat analysis was performed whereby the only comparable groups are those that are analysed. The anonymised database of trial outcome data was provided to a statistician and health economist for preliminary analysis. This database comprised WOMAC, SF36 and resource use data from the participant pre- and post-operative surveys. Resource use and other secondary outcome data were provided by data collection sheets completed by the research nurse from hospital physiotherapy, outpatient orthopaedic clinic and primary care records. The intervention group community physiotherapists filled in data collection sheets to describe the intervention content, resource use (number, site and length of patients contacts) and any referral to other forms of rehabilitation care. The health economist, who analysed resource use data, performed an economic evaluation. The lead researcher using content analysis to identify themes undertook qualitative analysis of the Patient Views Questionnaire. Triangulation of data was undertaken by collecting data from multiple sources: orthopaedic notes, General Practice notes, patient questionnaire responses, hospital physiotherapy notes and community physiotherapy notes and questionnaire response
RESULTS Participant flow	13	<u>Flow of participants through each stage</u> Participants were recruited from the waiting lists of 9 out of 13 consultants, who regularly performed TKR. 160/251 (63.7%) of patients fulfilling all eligibility criteria consented to participate in the study. 24/160 (15%) of all participants withdrew from the study when their TKR was cancelled. The overall withdrawal rate from the study was 45/160 (28.1%). There was no evidence that study withdrawal varied by group or WOMAC dimension scores. However, withdrawn patients had significantly poorer scores on the General Health (p=0.037 95% CI 0.6-17.7)), Energy (p=0.004; 95% CI -0.2-16.6) and Mental Health (p =0.054; 95% CI 3.6-=18.4) dimensions of the SF-36 and were also significantly more likely to report heart problems (p =0.012), chest problems (p=0.030) and stroke/TIA (p=0.011)

Figure 1: Diagrammatic representation of participant flow



Recruitment	14	Dates defining the periods of recruitment and follow-up. Recruitment phase: July 1999 to December 2000 Follow up: July 2000 to January 2002
Baseline data	15	Baseline demographic and clinical characteristics of each group. One patient died postoperatively. The two treatment groups did not differ significantly with respect to age, gender, previous history of knee/hip surgery, important co-morbidity and baseline WOMAC and SF-36 scores. Patients in the home care group had a significantly longer mean preoperative waiting time than patients in the hospital group (p=0.036, mean difference 5.2 weeks, 95% CI: 0.4 to 10.1 weeks).
Numbers analyzed	16	Number of participants (denominator) in each group included in each analysis and whether the analysis was by "intention-to-treat" . Intention to treat analysis of primary and secondary outcome follow up data was performed by the statistician and health economist. The same group of participants was analysed for the primary outcome analysis , the economic evaluation and other secondary outcomes. 57/80 group 1 and 57/80 group 2 (see flow diagram- 1 control patient died post-operatively). Qualitative patient satisfaction and feedback data were analysed by the principal investigator, a research associate with independent verification by a third GP academic.
Outcomes and estimation	17	For each primary and secondary outcome, a summary of results for each group, and the estimated effect size and its precision (*e.g.*, 95% confidence interval). The postoperative WOMAC and SF36 questionnaire response rate was 98% (114/116). No significant differences were observed between the groups in postoperative WOMAC and SF36 mean scores. The regression coefficient for study group represents the effect on postoperative WOMAC and SF36 scores of moving from Group 1(usual care) to Group 2

		(intervention) after adjusting for preoperative WOMAC and SF36 scores and preoperative waiting time. Data for 111 participants were used for this latter analysis since trial entry data for three participants were unavailable.Table 2

Table 1: Primary outcome measure WOMAC and secondary outcome measure SF-36

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	0.6 (0.1) *	0.6 (0.1) *	109	0.002 (-0.034 to 0.039)	0.897	0.225
PCS	-12.4 (45.2)	-11.5 (36.1)	111	5.2 (-7.6 to 18.0)	0.422	0.357
MCS	13.1 (43.3)	14.3 (37.9)	111	4.0 (-8.5 to 16.4)	0.528	0.385
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

Ancillary analyses	18	Address multiplicity by reporting any other analyses performed, See flow chart table entry re significant differences between withdrawn and participating patients. Physiotherapy data were missing for 9/114 patients due to missing hospital notes and non-returned questionnaires. The mean wait to first postoperative physiotherapy appointment after hospital discharge was significantly longer ($p<0.01$) for the hospital outpatient physiotherapy group (18.5 days) compared to the home physiotherapy group (3 days). The home physiotherapy group had a mean of 8.4 home treatment sessions (includes a mean of 2.8 preoperative sessions) compared to a mean of 3.6 postoperative hospital treatment sessions. Physiotherapy treatment outcomes, by group, are summarised in Figure 1. Satisfaction with physiotherapy for TKR was high (86%) in both treatment groups. The mean total costs of pre and postoperative NHS services were similar for both treatment groups: £5376 and £5372 for the intervention and control groups respectively (mean difference = -£4.7, p=0.978 95% CI (-334 to324)). 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, p=0.001; 95% CI (-160, -113)). There was no evidence that the intervention group patients consumed more or fewer NHS services during their inpatient episodes or postoperatively through general practitioner service and medical prescriptions.

Adverse events	19	All important adverse events or side effects in each intervention group. No adverse events were reported
DISCUSSION Interpretation	20	Interpretation of the results, Home physiotherapy is acceptable to patients and is as effective as hospital outpatient physiotherapy for unilateral TKR. Additional preoperative home physiotherapy did not improve patient perceived health outcomes.
Generalizability	21	Generalizability (external validity) of the trial findings. This was a single centre study in an orthopaedic unit with a turnover

		of 450 knee replacements per year (this includes arthroplasty for inflammatory and traumatic disorders, bilateral and uni-conylar TKR). However, long term hip and knee arthroplasty outcome data collated across the UK Trent region (97 consultants) demonstrated consistently high patient satisfaction with TKR across the units, regardless of the grade of surgeon. 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. The results are thus generalisable to the UK pathway of care for TKR.

Overall evidence	22	General interpretation of the results in the context of current evidence. **What is already known on this subject** Exercise for OA knee improves patient perceived health outcomes. Previous, very small, studies have suggested preoperative physiotherapy has no impact on clinician observed outcomes and length of hospital stay. The transfer of traditional hospital based services to community settings does not significantly reduce health care costs. There is a dearth of research assessing physiotherapy interventions **What this study adds** Home physiotherapy for total knee replacement is as effective as hospital based care. Preoperative physiotherapy did not improve outcomes nor reduce length of hospital stay in the largest RCT to date. Overall resource use was not reduced by transferring physiotherapy treatments to patients' own homes for this orthopaedic procedure.

9.11 Patient views framework for coded responses by group

Patient Views: Framework for coded responses by group (UPN = Patient identification number)

Response	Question theme															
	Useful aspects				Unhelpful aspects				Improvements				Further comments			
	Hospital Group		Home Group		Hospital		Home		Hospital		Home		Hospital		Home	
	UPN	n	UPN	n	UPN	n	UPN	n	UPN	n	UPN	n	UPN	n	UPN	n
Was useful/ helpful/ good/ 1st class / (very positive response)	107 x2, 1, 95, 134, 153, 57	6	34, 48, 49, 157, 20, 103, 67 x2, 25, 66, 133	10									65, 95, 121, 134, 44, 64	6	101, 34, 66, 92, 18, 53, 60	7
Physio beneficial													142	1	62, 92, 3, 67, 139, 35, 33	7
Repeat of positive							133	1								
Gratitude/ appreciation													64	1	67, 53, 92	3
Satisfied / reiterate satisfaction									52, 57, 64, 74, 108, 113	6	18, 25, 42, 53, 60, 67, 83, 103, 135	9	74, 102, 113	3	3, 78	2
Fulfilled needs													64	1		
Good organisation															18	1
'nothing ' (unhelpful) 'none' (improvements)					13, 26, 44, 57, 64, 74, 75, 82, 88, 121, 134	11	3, 7, 18, 33, 34, 35, 49, 63, 66, 78, 84, 123, 139	13	26, 61, 88	3	34, 48, 49, 123, 133, 139, 159	7				
No improvement					90	1										
'Could not improve'									41, 89, 134	3	3, 7, 29, 33, 35, 42, 51, 66, 67, 84, 92, 103	12				
Couldn't have been better															33, 84, 122	3

Attributes of physios: kind/caring/patient/ efficient etc (Praise for staff)	89 x2, 41, 107, 143	4	24 x2, 25 x4, 48, 49, 53, 97 x2, 122 x3, 123, 63 x2, 92 x2, 133	11									10 x2, 41, 108, 82 x3, 88, 89, 121 x2, 64, 95	9	51 x3, 24 x2, 86, 49, 67, 53	6
Gave support/ reassurance/ confidence/ help/ encouragement	39, 44, 75, 88 x2, 26, 64	6	42, 70 x2, 105 x2, 139, 51 x2, 53, 78, 92, 148, 79, 128, 103, 46, 114, 67	15												
Explanation (including about exercises)	13, 27, 74, 75, 61, 88	6	53, 67, 78, 92, 9, 70	6									121	1		
Info/ advice (including re aids /exercise/ advice cards)	23, 64 x3, 32, 26	4	33, 25	2												
Tailored advice (positive)													82	1		
Knowing how to help self	142	1														
Determination /doing own exercises													41, 99	2	86	1
Knew could contact physio			29	1												
Someone to ask questions															67	1
Continuity of care	64	1	46	1												
One-to-one (positive)													75	1		
Pre-op			7, 9, 18, 31, 35, 46, 70, 73, 115	9											86, 18	2
Need pre-op exercises													13	1		
Pre-op chat / what to expect									6, 44	2						
Need more advice re what to expect - video															70	1
Need talk to someone who'd had TKR – offered to do so to others															67	1
Soon after op (? as in-patient)		1	46, 103	2												
Muscle strengthening	30, 74, 98, 108	4	3, 7, 18, 35, 73, 83	6												
Maintain muscle function			9	1												
Pain relief	32, 82, 102, 116, 127, 142	6	31, 62, 84	3												
Pain relief – not knee	72	1														
Acupuncture	82	1														
Exercises	6, 17, 21, 45, 56, 75, 155	7	29, 46, 73	3												

Home exercises/ex. sheets	27	1	67	1									95	1		
Advice re home exercises	11, 23	2														
Hydro	10, 76, 107, 140	4							21, 76	2			68, 140	2	9x2, 62	2
Wrong physio, hydro better							114	1								
Would have liked hydro															114, 135	2
Need hydro a.s.a.p.													140	1		
Massage	45	1														
Equipment (positive)													75	1		
If tall, hospital equipment															105	1
No travelling			92, 103, 159, 63, 54, 51	6											63 x2, 48	2
In own home			25, 63, 66, 70, 92, 104, 123, 128, 144	9											20, 159	2
Elaborations of being in own home			159, 25 x3, 54, 80, 104, 103,	6												
Address home function									23	1			23	1		
Need advice re getting in bath															135	1
Help with walking/moving about	64, 99	2														
Eased/ loosened/ improved knee	44, 56, 59, 68, 113, 125	6	7x2, 18, 29, 42, 84, 97, 101, 115, 135, 139	10												
(Non-specific) improvement/ easier	120, 121	2														
Walking /movement/ getting around better	56, 59, 65, 68, 108	5	7	1												
Back to nearly normal /recover function	99	1	60	1												
Good progress / recovery			20, 73	2												
Complete success	131	1														
In-patient problems					107 x3	1	70	1								
Better post-op care needed (not physio)													107	1		
In patient physio									10	1						
Post-op discharge									107	1						
Poor liaison re physio					23	1										
Hosp – physio liaison											70	1				
No hospital – home liaison															7	1
Physio liased (positive)													107	1		
Ok with ex sheet given – no physio													32	1		

Delay in start					10, 21, 155	3	70	1								
Seen sooner									6, 10, 11, 50, 140	5						
Not enough					23, 142, 146	3										
More sessions/ more physio									23, 32, 39, 59, 127, 140, 142, 146	8			30, 23	2	78, 118	2
Not long enough					39	1	54, 118, 135	3								
Longer duration											54, 78	2				
Need longer sessions													59, 127	2		
Not frequent enough					59	1										
More frequent									98	1	114	1				
Limited time					127	1										
Need check visit after one month							135	1								
Follow-up session									13	1	135	1				
Final session in hosp											46	1			46	1
'just being told what to do'					52	1										
Felt isolated							46	1								
Don't know											101	1				
Parking									82	1						
Need a nearer hospital													44	1		
Less emphasis on getting 90degrees (knee)									11	1						
More flexible working times									155	1						
Advice re swelling											79	1			79	1
Prefer community															24, 103, 67, 115	4
Both home & hosp good															48	1
Listen to patient													61	1		
Extend the scheme															92	1
Still problems with knee													116, 140	2	31, 94, 135	3

Cp L

9.12 Tables: Analysis of post-operative WOMAC and SF-36

Appendix Results Tables

Analysis of post-operative WOMAC and SF-36

There was a significant difference between the groups in the pre-operative waiting time for the knee operation we have a choice of several analyses.

1. Comparison of change in HRQoL from pre-operative to post-operative assessment. This ignores the fact that there is a difference in the pre-operative waiting time between the groups and hence the time period between the pre and post-operative assessments.
2. Comparison of rate of change of HRQoL from pre-operative to post-operative assessment. (I.e. postoperative HRQoL-pre operative HRQoL/time period between assessments).
3. Comparison of post-operative HRQoL. This ignores the fact that there is a difference in the timing of the assessments and the pre-operative HRQoL. (Although pre-operative HRQoL was the same for both Groups).
4. Comparison of post-operative HRQoL with adjustment for pre-operative HRQoL and the time spent waiting pre-operatively for the knee operation. (This can be done using multiple linear regression.)

Analysis 4 is presented in the results section. The following tables summarise the analyses for tables 1 to 3.

(A) Tables combine analyses 1 & 2:

1. Comparison of absolute change in WOMAC & SF-36 from pre-operative to post-operative assessment. This ignores the fact that there is a difference in the timing of the assessments.
2. Comparison of rate of change of WOMAC & SF-36 from pre-operative to post-operative assessment.

Change in WOMAC & SF-36

The following tables show the pre-operative WOMAC & SF-36, post-operative WOMAC & SF-36, absolute change in WOMAC & SF-36 and the rate of change of WOMAC & SF-36 by group for patients who completed both assessments.
For both groups combined the SF-36 tended to improve post-operatively (compared to the pre-operative level) on all dimensions of the SF-36 except for Mental Health where there was a small observed deterioration. These changes were statistically

significant ($p<0.05$) except for the Mental Health and Role-emotional dimensions of the SF-36. However, these changes in SF-36 did not vary significantly by group (see the analysis below).

For WOMAC a higher score indicates poorer health related quality of life (HRQoL)
A positive change in the WOMAC indicates a health gain

A) WOMAC Pain dimension change by group

Study group	Pre-operative WOMAC Pain Dimension	Post-operative WOMAC Pain Dimension	WOMAC change in Pain	WOMAC rate of change (per week) in Pain
Group 1				
Mean	11.98	6.92	5.06	.28
N	55	55	55	55
StdDev	3.08	4.24	4.30	.28
Group 2				
Mean	12.41	6.70	5.71	.27
N	56	56	56	56
StdDev	3.46	3.70	4.43	.31
Grand Total				
Mean	12.20	6.81	5.39	.27
N	111	111	111	111
StdDev	3.27	3.96	4.36	.30

(A)WOMAC Stiffness dimension change by group

Study group	Pre-operative WOMAC Stiffness Dimension	Post-operative WOMAC Stiffness Dimension	WOMAC change in Stiffness	WOMAC rate of change (per week) in Stiffness
Group 1				
Mean	5.24	3.64	1.60	.08
N	55	55	55	55
StdDev	1.36	2.07	2.14	.22
Group 2				
Mean	5.42	3.49	1.93	.09
N	57	57	57	57
StdDev	1.39	1.40	2.05	.13
Grand Total				
Mean	5.33	3.56	1.77	.09
N	112	112	112	112
StdDev	1.37	1.75	2.09	.18

(A) WOMAC Physical Function dimension change by group

Study group	Pre-operative WOMAC Physical Function	Post-operative WOMAC Physical Function	WOMAC change in Physical Function	WOMAC rate of change (per week) in Physical Function
Group 1				
Mean	40.19	26.14	14.05	.77
N	53	53	53	53
StdDev	11.14	14.85	12.19	.97
Group 2				
Mean	40.03	24.92	15.11	.71
N	55	55	55	55
StdDev	11.11	13.51	13.80	.97
Grand Total				
Mean	40.11	25.51	14.59	.74
N	108	108	108	108
StdDev	11.08	14.13	12.98	.96

For the SF-6D a higher score indicates better health related quality of life (HRQoL)
A positive change in the SF-6D indicates a health gain

SF-6D PREFERENCED BASED INDEX CHANGE BY GROUP

Study group	Pre-operative SF-6D preference-based measure of health	Post-operative SF-6D preference-based measure of health	SF-36 change in SF-6D preference score	SF-36 rate of change (per week) in SF-6D preference score
Group 1				
Mean	.52	.56	.05	.00
N	54	54	54	54
StdDev	.10	.12	.11	.01
Group 2				
Mean	.52	.57	.05	.00
N	55	55	55	55
StdDev	.09	.09	.09	.00
Grand Total				
Mean	.52	.57	.05	.00
N	109	109	109	109
StdDev	.09	.11	.10	.01

SF-36 MENTAL COMPONENTS SUMMARY CHANGE BY GROUP

Study group	Pre-operative SF-36 MENTAL COMPONENT SCALE (MCS)	Post-operative SF-36 MENTAL COMPONENT SCALE (MCS)	SF-36 change in Mental Component Summary	SF-36 rate of change (per week) in Mental Component Summary
Group 1				
Mean	4.8	13.3	8.46	.14
N	55	55	55	55
StdDev	33.7	43.4	36.98	3.57
Group 2				
Mean	2.1	14.6	12.47	.68
N	56	56	56	56
StdDev	33.4	38.2	28.85	1.57
Grand Total				
Mean	3.5	13.9	10.48	.41
N	111	111	111	111
StdDev	33.4	40.7	33.04	2.75

SF-36 PHYSICAL COMPONENTS SUMMARY CHANGE BY GROUP

Study group	Pre-operative SF-36 PHYSICAL COMPONENT SCALE (PCS)	Post-operative SF-36 PHYSICAL COMPONENT SCALE (PCS)	SF-36 change in Physical Component Summary	SF-36 rate of change (per week) in Physical Component Summary
Group 1				
Mean	-32.2	-12.7	19.46	.60
N	55	55	55	55
StdDev	29.9	45.1	38.73	4.12
Group 2				
Mean	-37.2	-11.4	25.77	1.16
N	56	56	56	56
StdDev	28.2	36.5	26.65	1.75
Grand Total				
Mean	-34.7	-12.1	22.64	.88
N	111	111	111	111
StdDev	29.0	40.8	33.19	3.1

SF-36 VITALITY DIMENSION CHANGE BY GROUP

Study group	Pre-operative SF-36 ENERGY/VITALITY (0-100)	Post-operative SF-36 ENERGY/VITALITY (0-100)	SF-36 change in Vitality	SF-36 rate of change (per week) in Vitality
Group 1				
Mean	44.3	48.4	4.09	-.12
N	55	55	55	55
StdDev	18.5	24.1	21.97	3.10
Group 2				
Mean	42.2	50.8	8.57	.36
N	56	56	56	56
StdDev	18.6	19.6	14.98	.64
Grand Total				
Mean	43.2	49.6	6.35	.17
N	111	111	111	111
StdDev	18.5	21.9	18.82	2.23

For the SF-36 dimensions a higher score indicates better HRQoL
A positive change in the SF-36 dimension indicates a health gain

SF-36 GENERAL HEALTH DIMENSION CHANGE BY GROUP

Study group	Pre-operative SF-36 GENERAL HEALTH PERCEPTIONS (0-100)	Post-operative SF-36 GENERAL HEALTH PERCEPTIONS (0-100)	SF-36 change in General Health	SF-36 rate of change (per week) in General Health
Group 1				
Mean	56.7	61.2	4.55	-.03
N	55	55	55	55
StdDev	20.6	23.2	18.35	1.95
Group 2				
Mean	56.8	61.1	4.29	.22
N	56	56	56	56
StdDev	21.6	23.6	18.68	.79
Grand Total				
Mean	56.8	61.2	4.41	.10
N	111	111	111	111
StdDev	21.0	23.3	18.43	1.48

SF-36 MENTAL HEALTH DIMENSION CHANGE BY GROUP

Study group	Pre-operative SF-36 MENTAL HEALTH INDEX (0-100)	Post-operative SF-36 MENTAL HEALTH INDEX (0-100)	SF-36 change in Mental Health	SF-36 rate of change (per week) in Mental Health
Group 1				
Mean	70.5	71.8	1.24	.05
N	55	55	55	55
StdDev	16.0	20.0	17.04	1.33
Group 2				
Mean	69.4	68.0	-1.43	-.06
N	56	56	56	56
StdDev	19.1	20.6	18.04	.71
Grand Total				
Mean	70.0	69.9	-.11	-.01
N	111	111	111	111
StdDev	17.5	20.3	17.52	1.06

SF-36 BODILY PAIN DIMENSION CHANGE BY GROUP

Study group	Pre-operative SF-36 PAIN INDEX (0-100)	Post-operative SF-36 PAIN INDEX (0-100)	SF-36 change in Bodily Pain	SF-36 rate of change (per week) in Bodily Pain
Group 1				
Mean	27.9	48.3	20.40	.85
N	55	55	55	55
StdDev	15.7	26.5	24.82	2.10
Group 2				
Mean	29.4	46.8	17.46	.78
N	56	56	56	56
StdDev	17.7	20.7	23.29	1.39
Grand Total				
Mean	28.6	47.5	18.92	.81
N	111	111	111	111
StdDev	16.7	23.6	24.00	1.77

SF-36 PHYSICAL FUNCTION DIMENSION CHANGE BY GROUP

Study group	Pre-operative SF-36 PHYSICAL FUNCTIONING (0-100)	Post-operative SF-36 PHYSICAL FUNCTIONING (0-100)	SF-36 change in Physical Function	SF-36 rate of change (per week) in Physical Function
Group 1				
Mean	28.0	43.2	15.20	.61
N	55	55	55	55
StdDev	17.4	27.8	25.44	3.24
Group 2				
Mean	21.3	41.3	20.02	.83
N	56	56	56	56
StdDev	17.1	22.2	20.54	1.17
Grand Total				
Mean	24.6	42.2	17.63	.73
N	111	111	111	111
StdDev	17.5	25.1	23.12	2.42

SF-36 ROLE EMOTIONAL DIMENSION CHANGE BY GROUP

Study group	Pre-operative SF-36 ROLE-EMOTIONAL (0-100)	Post-operative SF-36 ROLE-EMOTIONAL (0-100)	SF-36 change in Role Emotional	SF-36 rate of change (per week) in Role Emotional
Group 1				
Mean	39.8	45.6	5.85	.56
N	57	57	57	57
StdDev	45.6	44.8	44.15	2.20
Group 2				
Mean	42.9	48.8	5.95	.72
N	56	56	56	56
StdDev	43.9	46.7	44.09	2.78
Grand Total				
Mean	41.3	47.2	5.90	.64
N	113	113	113	113
StdDev	44.6	45.6	43.92	2.49

SF-36 ROLE PHYSICAL DIMENSION CHANGE BY GROUP

Study group	Pre-operative SF-36 ROLE-PHYSICAL (0-100)	Post-operative SF-36 ROLE-PHYSICAL (0-100)	SF-36 change in Role Physical	SF-36 rate of change (per week in Role Physical
Group 1				
Mean	12.5	21.9	9.37	.51
N	56	56	56	56
StdDev	26.5	35.1	39.19	2.38
Group 2				
Mean	9.8	28.1	18.30	.83
N	56	56	56	56
StdDev	23.7	37.3	34.87	2.27
Grand Total				
Mean	11.2	25.0	13.84	.67
N	112	112	112	112
StdDev	25.1	36.1	37.19	2.32

SF-36 SOCIAL FUNCTION DIMENSION CHANGE BY GROUP

Study group	Pre-operative SF-36 SOCIAL FUNCTIONING (0-100)	Post-operative SF-36 SOCIAL FUNCTIONING (0-100)	SF-36 change in Social Function	SF-36 rate of change (per week) in Social Function
Group 1				
Mean	59.1	61.1	1.98	-.36
N	56	56	56	56
StdDev	29.4	33.4	31.36	3.72
Group 2				
MEAN	**52.6**	**64.1**	**11.51**	**.56**
N	56	56	56	56
StdDev	28.9	26.8	26.29	1.32
Grand Total				
Mean	55.9	62.6	6.75	.10
N	112	112	112	112
StdDev	29.2	30.2	29.20	2.82

(1) COMPARISON OF ABSOLUTE CHANGE IN HRQOL FROM PRE-OPERATIVE TO POST-OPERATIVE ASSESSMENT.

Independent Samples Test

		t-test for Equality of Means						
							95% Confidence Interval of the Difference	
		t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
SF-36 change in Vitali	Equal variance not assumed	-1.326	98.455	.188	-4.6	3.5	-11.6	2.3
SF-36 change in Gene Health	Equal variance not assumed	.015	111.940	.988	.1	3.5	-6.8	6.9
SF-36 change in Ment Component Summary	Equal variance not assumed	-.619	106.107	.537	-3.8	6.2	-16.1	8.4
SF-36 change in Ment Health	Equal variance not assumed	.664	111.750	.508	2.2	3.3	-4.3	8.7
SF-36 change in Bodil Pain	Equal variance not assumed	.763	110.570	.447	3.5	4.6	-5.6	12.6
SF-36 change in Phys Component Summary	Equal variance not assumed	-.827	98.836	.410	-5.2	6.3	-17.6	7.3
SF-36 change in Phys Function	Equal variance not assumed	-.803	106.337	.424	-3.5	4.4	-12.2	5.1
SF-36 change in Role Emotional	Equal variance not assumed	.208	111.833	.836	1.8	8.4	-15.0	18.5
SF-36 change in Role Physical	Equal variance not assumed	-.926	109.608	.357	-6.6	7.1	-20.7	7.5
SF-36 change in SF-6 preference score	Equal variance not assumed	-.194	105.971	.847	-.004	.020	-.043	.035
SF-36 change in Socia Function	Equal variance not assumed	-1.845	108.495	.068	-9.9	5.4	-20.6	.7
WOMAC change in Pa	Equal variance not assumed	-.622	111.951	.535	-.5	.8	-2.2	1.1
WOMAC change in Physical Function	Equal variance not assumed	-.200	108.989	.842	-.5	2.6	-5.6	4.6
WOMAC change in Stiffness	Equal variance not assumed	-.696	111.078	.488	-.3	.4	-1.1	.5

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B) TABLES: ANALYSIS 3: COMPARISON OF POST-OPERATIVE WOMAC & SF-36

This comparison of post-operative WOMAC & SF-36 ignores the fact that there is a difference in the timing of the assessments and the pre-operative WOMAC & SF-36. However, pre-operative WOMAC & SF-36 was the same for both groups. There was no reliable statistical evidence of a difference between the groups in post-operative WOMAC & SF-36.

(B) TABLES: ANALYSIS 3: COMPARISON OF POST-OPERATIVE WOMAC

		Group 1	Group 2
Post-operative WOMAC Pain Dimension	Valid N	N=57	N=57
	Mean	6.9	6.8
	Std Deviation	(4.3)	(3.7)
	Median	7.00	6.00
	Minimum	.0	.0
	Maximum	17.0	15.0
Post-operative WOMAC Physical Function	Valid N	N=57	N=56
	Mean	26.4	24.9
	Std Deviation	(14.9)	(13.4)
	Median	30.00	26.00
	Minimum	2.0	.0
	Maximum	64.0	54.0
Post-operative WOMAC Stiffness Dimension	Valid N	N=57	N=57
	Mean	3.6	3.5
	Std Deviation	(2.1)	(1.4)
	Median	4.00	4.00
	Minimum	.0	.0
	Maximum	8.0	6.0

		Group 1	Group 2
Post-operative SF-36 PHYSICAL COMPONENT SCALE (PCS)	Valid N	N=57	N=57
	Mean	-12.4	-11.5
	Std Deviation	(45.2)	(36.1)
	Median	-5.8	-15.1
	Minimum	-89.3	-74.7
	Maximum	68.3	67.5
Post-operative SF-36 MENTAL COMPONENT SCALE (MCS)	Valid N	N=57	N=57
	Mean	13.1	14.3
	Std Deviation	(43.3)	(37.9)
	Median	16.8	12.3
	Minimum	-66.6	-59.6
	Maximum	84.6	80.2
Post-operative SF-6D preference-based measure of health	Valid N	N=56	N=56
	Mean	.6	.6
	Std Deviation	(.1)	(.1)
	Median	.57	.55
	Minimum	.3	.4
	Maximum	.8	.8

		Group 1	Group 2
Post-operative SF-36 ENERGY/VITALITY (0-100)	Valid N	N=57	N=57
	Mean	48.2	50.7
	Std Deviation	(23.7)	(19.5)
	Median	50.0	50.0
	Minimum	.0	5.0
	Maximum	95.0	95.0
Post-operative SF-36 GENERAL HEALTH PERCEPTIONS (0-100)	Valid N	N=57	N=57
	Mean	61.0	61.0
	Std Deviation	(22.9)	(23.4)
	Median	62.0	62.0
	Minimum	15.0	10.0
	Maximum	100.0	97.0
Post-operative SF-36 MENTAL HEALTH INDEX (0-100)	Valid N	N=57	N=57
	Mean	71.2	68.0
	Std Deviation	(20.0)	(20.4)
	Median	76.0	72.0
	Minimum	24.0	16.0
	Maximum	100.0	100.0
Post-operative SF-36 PAIN INDEX (0-100)	Valid N	N=57	N=57
	Mean	48.5	46.6
	Std Deviation	(26.8)	(20.6)
	Median	44.4	44.4
	Minimum	.0	11.1
	Maximum	100.0	100.0
Post-operative SF-36 PHYSICAL FUNCTIONING (0-100)	Valid N	N=57	N=57
	Mean	43.3	41.6
	Std Deviation	(27.6)	(22.2)
	Median	50.0	40.0
	Minimum	.0	.0
	Maximum	90.0	85.0
Post-operative SF-36 ROLE-EMOTIONAL (0-100)	Valid N	N=57	N=57
	Mean	45.6	48.0
	Std Deviation	(44.8)	(46.7)
	Median	33.3	33.3
	Minimum	.0	.0
	Maximum	100.0	100.0
Post-operative SF-36 ROLE-PHYSICAL (0-100)	Valid N	N=57	N=57
	Mean	23.2	27.6
	Std Deviation	(36.2)	(37.1)
	Median	.0	.0
	Minimum	.0	.0
	Maximum	100.0	100.0
Post-operative SF-36 SOCIAL FUNCTIONING (0-100)	Valid N	N=57	N=57
	Mean	60.8	64.1
	Std Deviation	(33.1)	(26.6)
	Median	66.7	66.7
	Minimum	.0	11.1
	Maximum	100.0	100.0

(B) Comparison of post-operative HRQoL

Independent Samples Test

		t-test for Equality of Means						
							95% Confidence Interval of the Difference	
		t	df	P-value (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
Post-operative SF-36 MENTAL COMPONE SCALE (MCS)	Equal varianc not assumed	-.147	10.078	.883	-1.124	7.6	-16.2	14.0
Post-operative SF-36 PHYSICAL COMPOI SCALE (PCS)	Equal varianc not assumed	-.112	06.818	.911	-.861	7.7	-16.1	14.3
Post-operative SF-6[preference-based	Equal varianc not assumed	-.318	01.512	.751	-.0063	.01991	-.04583	.03315
Post-operative SF-36 ENERGY/VITALITY	Equal varianc not assumed	-.626	07.942	.532	-2.544	4.1	-10.6	5.5
Post-operative SF-36 GENERAL HEALTH	Equal varianc not assumed	.004	11.936	.997	.018	4.3	-8.6	8.6
Post-operative SF-36 MENTAL HEALTH IN	Equal varianc not assumed	.853	11.942	.396	3.228	3.8	-4.3	10.7
Post-operative SF-36 PAIN INDEX (0-100)	Equal varianc not assumed	.435	05.137	.664	1.949	4.5	-6.9	10.8
Post-operative SF-36 PHYSICAL	Equal varianc not assumed	.355	07.032	.723	1.667	4.7	-7.6	11.0
Post-operative SF-36 ROLE-EMOTIONAL	Equal varianc not assumed	-.273	11.807	.786	-2.339	8.6	-19.3	14.7
Post-operative SF-36 ROLE-PHYSICAL (0-	Equal varianc not assumed	-.638	11.939	.525	-4.386	6.9	-18.0	9.2
Pre-operative SF-36 SOCIAL FUNCTIONI	Equal varianc not assumed	1.224	11.952	.223	6.628	5.4	-4.1	17.4
Post-operative SF-36 SOCIAL FUNCTIONI	Equal varianc not assumed	-.589	06.930	.557	-3.314	5.6	-14.5	7.8
Post-operative WOM Pain Dimension	Equal varianc not assumed	.157	09.899	.875	.1184	.8	-1.4	1.6
Post-operative WOM Physical Function	Equal varianc not assumed	.552	10.115	.582	1.4710	2.7	-3.8	6.8
Post-operative WOM Stiffness Dimension	Equal varianc not assumed	.315	97.830	.753	.1053	.3	-.6	.8