AN INVESIGATION INTO THE REHABILITATION OF PATIENTS FOLLOWING PRIMARY TOTAL HIP REPLACEMENT DUE TO OSTEOARTHRITIS

By

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ABSTRACT

This thesis investigates the effectiveness of occupational therapy interventions for patients undergoing primary total hip replacement for osteoarthritis using two research methodologies.

A systematic review and meta-analysis assessed the effectiveness of occupational therapy interventions delivered either pre-admission, during hospital stay, or post-discharge. Findings indicated the interventions reduced anxiety, improved pre-surgery and long-term function, and reduced length of stay. Small sample sizes, high levels of clinical and statistical heterogeneity and lack of specific occupational therapy studies reduced the strength of findings. The PROOF-THR feasibility study (ISRCTN38381590) recruited 44 participants to investigate recruitment and randomisation processes, acceptance of group allocation, fidelity of the intervention, and appropriateness of outcome measures and data collection methods. The intervention group received a bespoke pre-surgery home visit by an occupational therapist; the control group received treatment as usual. The intervention was delivered successfully with no withdrawals or crossovers, and reasonable retention rates indicating a definitive trial could be conducted following the feasibility methodology, although methods to improve follow-up data collection should be implemented.

This thesis concluded that higher quality occupational therapy specific research is needed to establish the efficacy and effectiveness of occupational therapy practices. A complex rehabilitation intervention can be successfully investigated by following established procedures.

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Jepson, P., Sands, G., Beswick, A.D., Davis, E.T., Blom, A.W., Sackley, C.M. (2015). A feasibility randomised controlled trial of pre-operative occupational therapy to optimise recovery for patients undergoing primary total hip replacement for

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Smith, T.O., **Jepson, P**., Beswick, A., Sands, G., Drummond. A., Davis, E.T., Sackley, C.M. (2013) Assistive devices, hip precautions, environmental modifications and training to prevent dislocation and improve function after hip arthroplasty **(Review**).

LIST OF ABBREVIATIONS

ADL	Activities of daily living
AIMS	Arthritis Impact Measurement Score
ACR	American College of Rheumatology
ARUK	Arthritis Research United Kingdom
BAO	British Orthopaedic Association
BMI	Body mass index
CCT	Controlled clinical trials
CI	Confidence intervals
COT	College of Occupational Therapists
CONSORT	Consolidated Standards of Reporting Trials
CRSI	Client Service Receipt Inventory
DH	Department of Health
EULAR	European League Against Rheumatism
ES	Effect size
ESR	Erythrocyte sedimentation rate
F/U	Follow-up
FSI	Functional status index
GNP	Gross national product
GRADE	Grading of Recommendations Assessment, Development and Evaluation
HRQoL	Health related quality of life
ICF	International Classification of Function, Disability and Health
i-CSP	interactive Chartered Society of Physiotherapy website

ISRCTN	International Standard Randomised Controlled Trial Number
JSN	Joint space narrowing
LOS	Length of Stay (in hospital)
MD	Mean difference
MJS	Minimal joint space
MRC	Medical Research Council
NAO	National Audit Office
n	Number of subjects in study
NEADL	Nottingham extended activities of daily living questionnaire
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
HADS	Hospital anxiety and depression scale
NIHR	National Institute for Health Research
NJR	National joint registry
NSAIDs	Non-Steroidal Anti-inflammatory Drugs
OA	Osteoarthritis
OARSI	Osteoarthritis Research Society International
OHS	Oxford hip score
OR	Odds ratio
OT	Occupational therapist
OTs	Occupational therapists
P	Probability
PEP-R	Patient Experience Partnership in Research

PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PT	Physiotherapist/Physical therapist
PPIs	Proton pump inhibitors
PROM	Patient reported outcome measure
QALY	Quality-adjusted life years
RA	Rheumatoid arthritis
RCT	Randomised controlled trial
ROM	Range of movement
SMD	Standard mean difference
SD	Standard deviation
SF-12	Short form – 12 question version
SF-36	Short form – 36 question version
SIP-68	Sickness impact profile (68 question version)
SOP	Standard operating procedure
STAI	State Trait Anxiety Inventory
THR	Total hip replacement
TKR	Total knee replacement
UK	United Kingdom
UKCRN	United Kingdom Clinical Research Network
VAS	Visual analogue scale
WHO	World Health Organisation
WOMAC	Western Ontario and McMasters University arthritis Index
WFTO	World federation of occupational therapists

1 INTRODUCTION

1.1 Chapter overview

This chapter will first provide a working definition of osteoarthritis (OA). Although it is beyond the scope of this thesis for a full discussion on the complex pathophysiology of OA, an overview of the disease is then provided. The clinical significance of this disease is illustrated by explaining its prevalence and the associated health care costs. The implications of the method of diagnosis are discussed and how this affects estimates of prevalence. Factors likely to affect the prevalence such as the ageing population are also discussed. Within the sections on prevalence, diagnosis and costs, information on OA in general is provided first followed by information specific to hip OA.

Due to OA being one of the most common disability causing diseases (Zhang et al, 2007), a plethora of different treatments exist; thus a comparative overview of non-surgical management is presented. As the focus of this thesis concerns the rehabilitation of people following total hip replacement, more detailed aspects of OA specifically relating to the hip joint are presented and then information on the surgical option of the total hip replacement is explained in more detail.

The last section of the introduction summarises the current state of knowledge regarding general rehabilitation of patients following THR for OA in the UK. Finally, rehabilitation therapies provided by occupational therapists will be discussed, as OT interventions are investigated in both the subsequent systematic review and clinical trial.

1.2 What is osteoarthritis

OA is an inflammatory disease that affects joints and the surrounding musculoskeletal tissue. Although multiple different types of inflammatory arthritic conditions exist, OA accounts for approximately 95% of all these (NHS, 2014). OA is a disease that affects animals as well as humans with evidence of its existence dating back 100 -130 million years in fossil remains (Dequeker and Luyten, 2008; Rothschild et al, 2012).

The disease name 'osteoarthritis' comes from prefix terms 'osteo' and 'Arthro' pertains to bone and joint respectively, and are both derived from ancient Greek. The suffix 'itis' is derived from New Latin and is used as a suffix for any disease that is characterised by inflammation. The name therefore suggests a disease that affects the bones and joints of the body that is characterised by inflammatory signs. However, although the term OA is widely used, it can be considered to be somewhat problematic as it inherently suggests that it is predominantly an inflammatory condition which does not correspond to the pathology of the disease; alternative names for the disease have therefore been proposed such as osteoarthrosis or degenerative joint disease (Dequeker and Luyten, 2008).

Additionally, as OA is responsible for the fourth most common cause of years lost to disability worldwide (WHO, 20002), any discussion relating to the disease needs to take in to account the effect it may have on the individual suffering with this disease

1.2.1 Definition of osteoarthritis

Many previous definitions of OA exist (Felson and Zhang, 1998) which have generally been criticised for being either too simplistic or focusing primarily on the pathophysiology of the disease (Hunter and Felson, 2006; Dequeker and Luyten, 2008; Brandt et al., 2008). The definition below by Lane et al, (2011) was formulated in response to a call for a working definition by the United States Food and Drugs Administration (FDA) to reflect the heterogeneity of the disease and thus improve the appropriateness of research outcomes measured in clinical trials (Lane et al, 2011). This definition takes in to account the complexity of the structures that may be affected, the underlying pathophysiology, the symptoms experienced and the causative factors:

> "*Osteoarthritis is usually a progressive disease of synovial joints that represents failed repair of joint damage that results from stresses that may be initiated by an abnormality in any of the synovial joint tissues, including articular cartilage, subchondral bone, ligaments, menisci (when present), periarticular muscles, peripheral nerves, or synovium. This ultimately results in the breakdown of cartilage and bone, leading to symptoms of pain, stiffness and functional disability. Abnormal intra-articular stress and failure of repair may arise as a result of biomechanical, biochemical and/or genetic factors. This process may be localized to a single joint, a few joints, or generalized, and the factors that initiate OA likely vary depending on the joint site"* (P 479).

1.2.2 Pathophysiology of osteoarthritis

It is beyond the scope of this thesis to provide a comprehensive and detailed discussion on the pathophysiology and pathogenesis of OA; however, an overview of the pathophysiology is provided below.

OA is characterised by a failure of the repair process of joint cartilage due to biomechanical and biochemical changes to the joint cartilage and synovium, with associated changes in the subchondral bone of eburnation (change in subchondral bone in which it is converted into a dense substance with a smooth surface like ivory), osteophyte (bony spurs that grow around the joint margins) and enthesophyte (bony spur growing into a tendon or ligament where it attaches to the bone) formation (Ashkavand et al, 2013; Bijlsma et al, 20011; Felson et al, 2000; Rogers et al, 1997). The destruction of the cartilage, joint space loss and the formation of the bony osteophytes are such characteristic pathophysiological processes associated with OA, that presence of these changes is required by the American College of Rheumatology for a diagnosis of OA to be made (Felson & Neogi, 2004).

The progressive degradation of the articular cartilage and the resultant changes to the underlying bone form the basis of the widely accepted Osteoarthritis Research Society International (OARSI) grading system (Pritzker et al, 2006); this system is presented in Table 1 below. Grades 1 - 4 of this grading classification relate to cartilage changes alone; the last two grades 5 - 6, relate to destructive changes to underlying bone. This OARSI grading system reflects the long held consensus that the first signs of OA changes are the biochemical changes to the cartilage (Madry et al, 2012). However, Felson & Neogi (2004)

argue that the bony changes can occur first in some people without any cartilage destruction. Furthermore, due to the variety of presentations of the pathophysiological changes associated with OA, and the different risk factors and pathophysiological changes attributed to different joints, Felson et al (2000) question whether OA is a single distinct disease, or several disorders with a final common pathway.

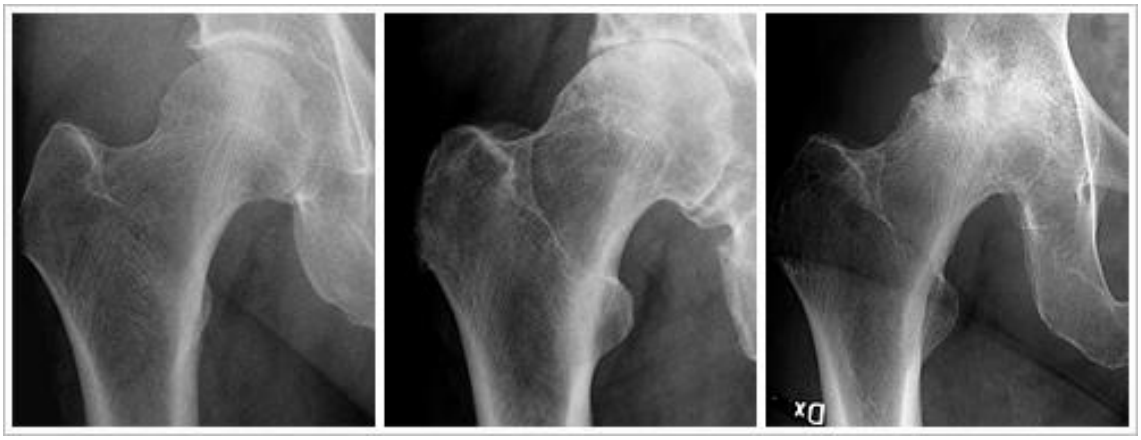
Table 1 OARSI osteoarthritis pathology assessment and grading system

OARSI grade	Description	Associated criteria
0	No arthritis	Cartilage surface intact; matrix normal; cells intact and appropriate orientation.
1	Surface intact	Matrix: superficial zone intact, oedema and/or superficial fibrillation (abrasion), focal superficial matrix condensation Cells: death, proliferation (clusters), hypertrophy, superficial zone Reaction must be more than superficial fibrillation only
2	Surface discontinuity	As above, plus Matrix: discontinuity at superficial zone (deep fibrillation) Cells: death, proliferation (clusters), hypertrophy
3	Vertical fissures	As above, plus Matrix: vertical fissures into mid zone, branched fissures Cells: death, regeneration (clusters), hypertrophy, cartilage domains adjacent to fissures
4	Erosion	Cartilage matrix loss: delamination of superficial layer, mid layer cyst formation Matrix: loss of superficial layer and mid zone (excavation)
5	Denudation	Surface: sclerotic bone or reparative tissue including fibrocartilage within denuded surface. Microfracture with repair limited to bone surface
6	Deformation	Bone remodelling (more than osteophyte formation only). Includes: microfracture with fibrocartilaginous and osseous repair extending above the previous surface

OARSI: osteoarthritis research society international

Figure 1 illustrates X-ray images of the area around the hip bone and the pelvis. The three images show different stages of osteoarthritis, from healthy hip joint (left) to fully developed osteoarthritis (right).

Figure 1 Radiographic images of osteoarthritis progression at the hip joint



1a) Normal healthy hip	1b) Mid stage osteoarthritis	1c) advanced osteoarthritis

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Figure 1a shows a radiographic image of a normal healthy hip joint. In figure 1b, the characteristic decreased joint space between the femoral head and the acetabulum is seen along with sclerosis. Figure 1c shows the complete loss of joint space, osteophyte formation at the rim of the acetabulum, increased sclerosis and flattening of the femoral head.

Alongside the bone and cartilage changes, OA is also characterised by inflammatory joint swelling and effusion due to thickening of the synovium and inflammation (Berenbaum, 2013). Additionally, Joint capsule tightening (Bijl et al, 1998), and muscle atrophy as a result of both pain inhibition and muscle wasting occurs as a result of progressive inactivity (Wieland et al, 2005). An additional specific feature of advanced hip OA (OARSI grade 3+) is a flattening of the femoral head (Harrison et al, 1953). As a consequence of the capsular

tightening of the hip, the load bearing is concentrated on a small section of the femoral head; this then leads to micro-fracture under the load and collapse of the trabecular structure. Once the femoral head starts to flatten, this further limits the movement available at the joint surfaces, and thus an increased rate of micro-fracturing and further flattening (Harrison et al, 1953).

This variety of physiological changes affecting various biological systems highlights the complex pathophysiology of OA.

1.3 Causes of osteoarthritis

The causes of OA are referred to as being 'primary' or 'idiopathic' when there is no known extrinsic cause. The term 'secondary' OA is used when the onset of OA occurs at a younger age than normally anticipated as a consequence of a known risk factor such as biomechanical abnormality, disease or trauma to the joint (Cooper et al, 2013). A synopsis of the seven main risk factors associated with OA and, where applicable, with specific relation to hip OA, is presented below.

Age

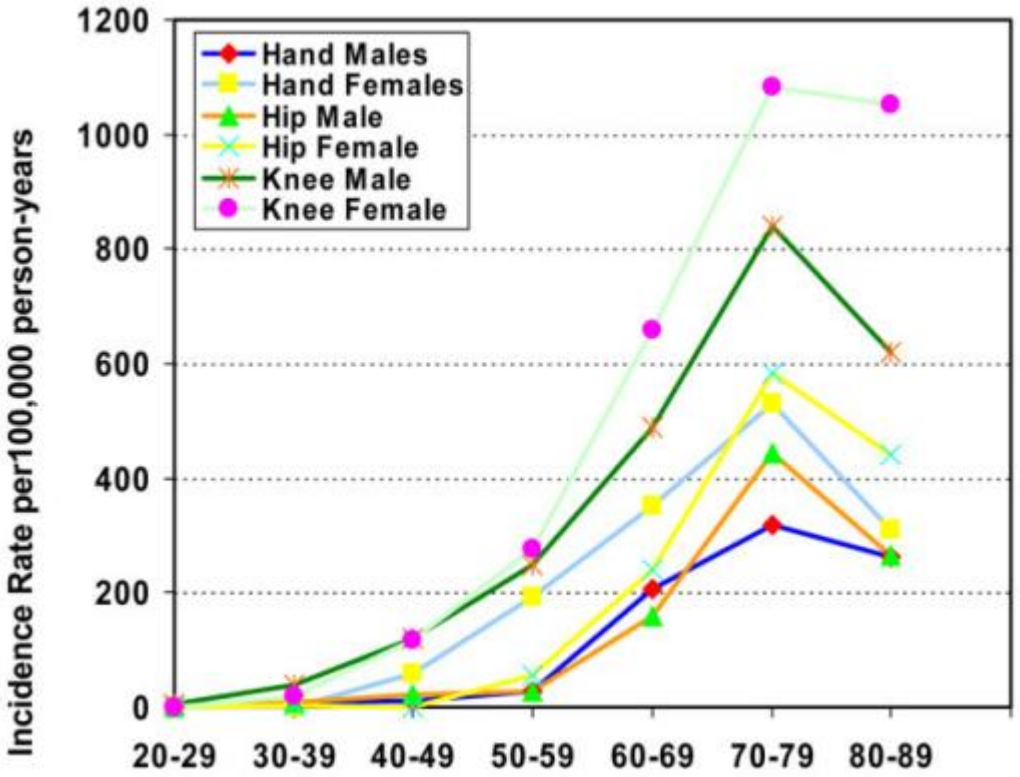
Age is the strongest risk factor for the development of OA with the prevalence and incidence considerably increasing with age (Cooper et al, 2013). As the likelihood of an individual getting OA increases with age without any known secondary factors, age is generally seen as the main primary cause of OA (Ashkavand et al, 2013). Figure 2 shows the relationship between age and OA at various joints reported by Oliveria et al (1995). For the production of

this age related data Oliveria et al (1995) re-assessed approximately 130,000 initial health records of patients attending a general community hospital between 1988 and 1991 for evidence of the first radiographic diagnosis of OA of x-rays taken for any purpose. Although the hospital provided a range of services (mental health, respiratory care, radiotherapy, ophthalmology, medicine etc.), the x-rays would only have been taken based on clinical need, so they may not be representative of the general population.

Gender

The incidence of OA in women increases at menopause suggesting a possible hormonal cause (Cooper et al, 2003). A subsequent meta-analysis by Srikanth et al (2005), which contained 34 studies, also found a greater incidence of OA in women; however, no association to hormonal levels could be identified. In this review by Srikanth et al (2005), men had an overall RR of 0.93 C.I. 0.80-1.08 compared to women of developing OA in any body region. The risk ratio analysis by joint region was lower in men than women for the knee (0.55 C.I. 0.32-0.94) and hip (0.64 C.I. 0.48-0.86). The results also revealed the severity of knee OA was significantly worse in women than men (SMD 0.20 C.I. 0.11-0.82, $p<0.001$) but not in the hip (SMD 0.20 C.I. -0.07 - 0.10, $p=0.65$). However, women appear to have a higher prevalence of OA at all ages so the effect of hormone levels seems unlikely.

Figure 2 incidence of OA by joint



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Ethnicity and genetics

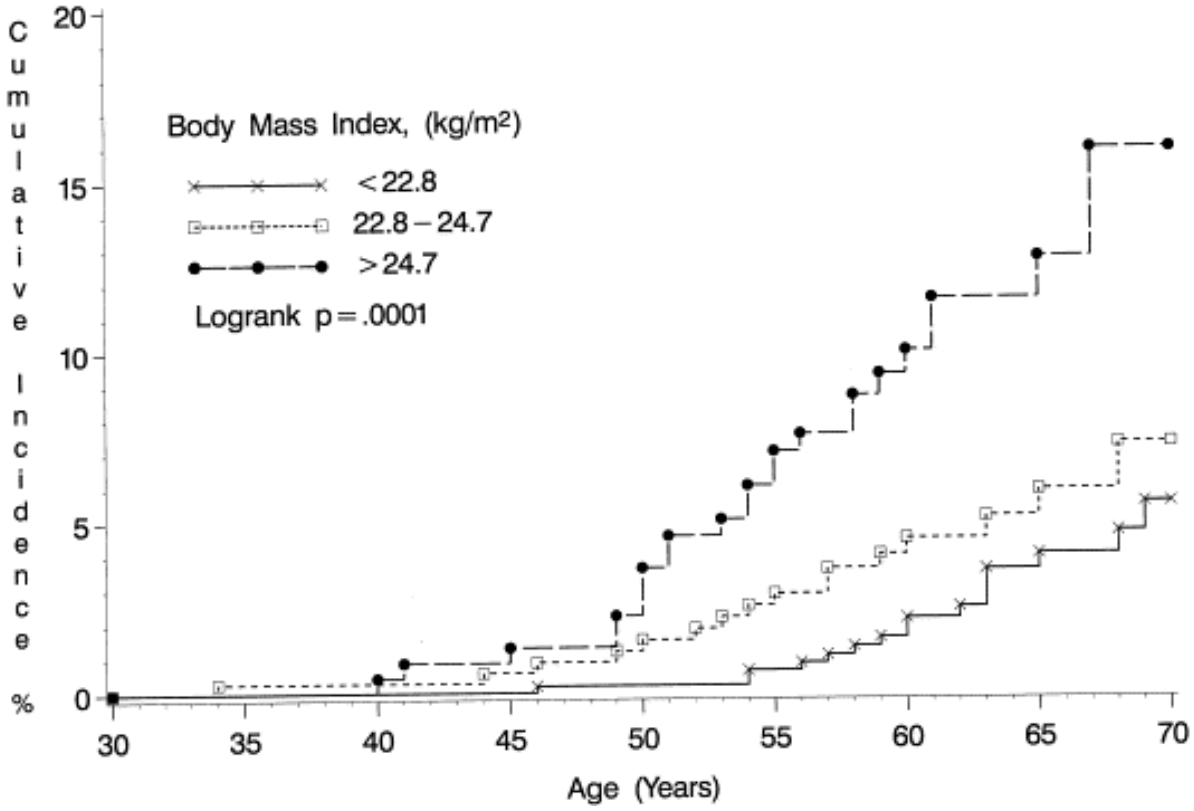
Although the prevalence of OA varies between different ethnic groups, no one ethnic group has systematically less prevalent OA; in some joints the prevalence compared to another group is lower, but in other joints higher usually as a result of cultural norms such and practices such as squatting or prolonged kneeling (Cooper et al; 2003). However, the systematic review by Srikanth et al (2005), found OA in any joint to be lower in people of Caucasian origin compared to non-Caucasians (RR 0.84: C.I. 0.72 – 0.99). Ashkavand et al, (2013) report that between 39% and 65% of OA in the general population can be attributed to genetic factors.

Obesity

Obesity has long been considered as one of the most important risk factors for the development of OA (Cooper et al, 2003). The link to knee OA is well established, mainly due the additional weight transferred through the joint (Toivanen et al, 2010). Yet despite the hip joints also bearing greater stress with increased body mass index (BMI), the relationship between hip OA and BMI is not certain. Lievense et al (2002) conducted a systematic review of five longitudinal and seven cross-sectional studies and reported moderate evidence of a positive association (OR ≥ 1.25) between increased BMI and the risk of developing hip OA compared to healthy weight individuals. Holliday et al (2011) in a case-control study also found a positive association (OR≥1.65, 95% CI 1.46-1.87). However, several other studies show no association between increased BMI and hip OA. Gelber et al (1999) in an observational study assessed BMI in 1,271 male medical students who trained between 1948 and 1964 (aged 20-29). The participants were then followed up by questionnaire at 5 year periods until 1995, for a median of 36 years. A total of 1185 people completed the study. The self-reported BMI of the participants was then averaged of the study period. Figure 3 shows those in the higher BMI category (>24.7) had a threefold risk of developing knee OA compared to those in the lowest BMI group (<22.7). However, this study found no relationship between the incidences of hip OA and BMI over the study period. Although this study had good retention and was able to follow up for 36 years, the participants were all doctors and therefore the results may not be transferrable to the general population. Additionally, all the participants were male, so the data may not be generalisable to women. A general population epidemiological study was conducted in Norway by Grotle et al (2008)

but this only had a 10 year follow-up. An initial 2891 agreed to join the study, of which 1854 (64%) responded to the follow-up survey 10 years later. The results show a high BMI (>30) was significantly associated with knee OA (OR 2.81 C.I. 1.32-5.96), hand OA (OR 2.59 C.I. 1.08–6.19) but not for hip OA (OR 1.11 C.I. 0.41–2.97).

Figure 3 Cumulative incidence of knee osteoarthritis by body mass index



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Bone density

The evidence on the relationship between bone density and OA is not well understood. Although it has long been known that people who suffer with osteoporosis have a considerably lower incidence of OA, and increased bone density is risk factor for the

development of both hip and knee OA, (Foss and Byers, 1972), the physiological reason for this is not yet fully understood (Tarantino et al, 2014). This is an area where more research is needed.

Joint injury, abnormality and altered joint biomechanics

Injury is one of the strongest risk factors for development of OA to any joint (Cooper et al, 2003). Development disorders of the hip which alter the normal biomechanics such as Legg-Calvé-Perthes disease (Ganz et al, 2008), developmental dysplasia (Hadley et al, 1990), and actual or sub-clinical slipped capital femoral epiphysis (Goodman et al, 1986) are clinically recognised causes of secondary OA. Froberg et al (2011) contacted 167 adults at a mean follow-up period of 47 (range 37-58) since they were conservatively treated for Legg-Calvé-Perthes disease (LCPD) and compared them to an age and gender matched control. The percentage of the LCPD having THR (13%) or OA (7%) was greater than the control; THR (0%) and OA (1%). Femoroalacetabular impingement has also been suggested as a cause of secondary OA (Beck et al, 2004; Imam and Khanduja, 2011). Ganz et al (2008) suggest that plain radiographs were unable to detect minor developmental deformities, and if they were detected, they were generally overlooked, thus their link to OA went unrecognised until imaging techniques improved. With the causal link to minor biomechanical abnormalities now established, many researchers now believe that most hip OA should be classified as secondary (Harris, 1986; Solomon, 1976).

Occupation or hobbies

The repetitive loading of any joint as a consequence of hobbies, sports or occupations increases the risk of developing OA (Cooper et al, 2003). However, the link between sporting activity and OA is still not well understood (Buckwater, 2003) though excessive loading in activities such elite long distance running puts participants at a high risk of developing knee and/or hip OA, yet regular recreational activity does not (Buckwater and Lane, 1997).

1.4 Prevalence and future predictions of hip osteoarthritis

This section will provide details of how estimates of the prevalence of OA are dependent on the method of diagnosis and predicted rise of prevalence due to an aging population.

1.4.1 The problem of diagnosis

Although there are many types of arthritic diseases; OA is by far the most common form of arthritic joint disease responsible for reduced functional independence and disablement in older adults (Zhang et al, 2007). Arden & Nevitt (2006) also suggest it is the most common joint disorder in the world, the most frequent cause of pain, loss of function and disability in adults, and second most common cause of health related lost days at work. However, understanding of the actual prevalence of OA is problematic due to variations in diagnostic criteria; these can be based on radiological changes alone, by signs and symptoms alone, by a combination of both or by self-reporting (Croft et al, 1990; Pereira et al, 2011; Zhang et al, 2007). A systematic review has examined the effect of OA definition on prevalence and incidence of hip OA (Pereira et al, 2011). This review contained 27 studies on the prevalence

of hip OA published up to 2010. Of these 27 included studies 19 used radiological diagnosis alone, with a mean prevalence of 9.75%; 4 studies used self-reported measures with mean prevalence of 6.85%; and 4 studies used symptomatic reporting (combination of radiographic and clinical findings) resulting in a mean prevalence of 3.73%. This review reveals both that radiological diagnosis alone is by far the most common method used in prevalence studies, and that different prevalence rates are found depending on the diagnostic criteria employed. Additionally, the proportion of the population not seeking treatment for OA is also unknown. Kellgren and Lawrence (1952) studied coal miners and dock workers routinely screened for occupational health purposes; of those who showed definitive radiological signs on x-ray of OA in the knee, only 24% had ever previously reported any symptoms of the disease. This was the first study to highlight that radiological changes may occur without symptoms or prior to the development of symptoms. It is now quite widely accepted that there is only a weak association between the clinical signs and symptoms of OA and radiographic findings (Bedson and Croft, 2008; Kinds et al, 2011).

1.4.2 Radiological diagnosis

Although hip OA can be diagnosed by magnetic resonance imaging (MRI), (Waldschmidt et al, 1999) or by computerised tomography (CT) (Turmezei et al, 2014) they are not widely employed. The radiological plain X-ray is still the main imaging method employed clinically (Braun & Gold, 2011) due to it being widely available, cheap and providing instant results that can be quickly interpreted (Kinds et al, 2011). Due to the combination of its clinical effectiveness and almost ubiquitous use, in 1961 the World Health Organisation (WHO)

designated radiological diagnosis as the gold-standard method of determining the presence of OA (Hart & Spector, 1995).

The occupational cohort studies reported by Kellgren and Lawrence (1952) were the first large scale epidemiological studies of OA and from this work they defined a grading scale of OA which now carries their name; The Kellgren-Lawrence scale (see Figure 4). This is now the most widely used scale both clinically and in epidemiological studies (Felson et al, 2011). Despite is wide usage, this scale is criticised for two main reasons. First it was originally based on the presence of osteophytes which are not always be present, and second, the minor radiological differences between grade 0 or 1 is subject to subjective interpretation (Reijman et al, 2004; Felson et al, 2011; Terjesen & Gunderson, 2012). Felson et al (2011) also suggests this difficulty in assigning radiographs to either grade 0 (no arthritis) or grade 1 (arthritis) may be responsible for the wide variations in prevalence of OA in different epidemiological studies.

Initially the Kellgren-Lawrence scale was developed specifically for knee OA. However, following the 1961 decision by the WHO in designating radiological diagnosis of OA as the gold-standard, the Kellgren-Lawrence scale became the accepted diagnostic scale for the presence and/or severity of OA for most synovial joints (Hart & Spector, 1995). However, since its initial acceptance, modifications of the Kellgren-Lawrence scale and new joint specific scales have been developed (Arden & Nevitt, 2006). Croft et al (1990) developed the first variation of the Kellgren-Lawrence scale specifically for the hip and named this the Croft scale (see Figure 5). Croft et al (1990) also found that joint space narrowing alone was a valid

and reliable indicator of low grade hip OA and Croft el al (1994) proposed a new grading system based on this alone (see Figure 6)

Figure 4 The Kellgren-Lawrence radiographic grading scale

OA Grade	Radiographic Criteria
Grade 0	No osteoarthritis
Grade 1	Doubtful narrowing of joint space and possible osteophytic lipping.
Grade 2	Minimal definite osteophytes, definite minimal/little narrowing of joint space.
Grade 3	Moderate multiple osteophytes, definite narrowing of joints space narrowing of at least 50%, some sclerosis and possible deformity of bone contour.
Grade 4	Large osteophytes, severe loss of joint space, severe sclerosis and definite deformity of bone contour.

Figure 5 The 'Croft Grade' modification of the Kellgren-Lawrence system

OA Grade	Radiographic Criteria
Grade 0	No change
Grade 1	Definite osteophytes only
Grade 2	Joint space narrowing only (defined as an minimal joint space of 2.5 mm)
Grade 3	Presence of two of the following: joint space narrowing, osteophytosis, subchondral sclerosis (of >5 mm), cyst formation
Grade 4	Presence of three of the following: joint space narrowing osteophytosis, subchondral sclerosis (of >5 mm), cyst formation
Grade 5	Same as grade 4, but with deformity of the femoral head or total hip replacement due to OA (verified by record view)

Figure 6 The Croft minimal joint space grading system

OA Grade	Radiographic Criteria
Grade 0	Minimum joint space > 2.5mm
Grade 1	Minimum joint space of > 1.5 mm ≤ 2.5mm
Grade 2	Minimum joint space ≤ 1.5mm

Reijman et al (2004a) conducted a study of the validity, reliability, and applicability of these three radiographic definitions of hip OA from 148 x-rays. The K-statistic was used to determine inter-rater reliability. The highest K statistic 0.68 (0.44 – 0.92) was for the Kellgren-Lawrence (at ≥ grade 2), followed by then the minimum joint space (≤ 2.5mm) at 0.62 (0.43 – 0.81), followed by the Croft grade (≥ grade 3) at 0.51 (0.35 – 0.67). They reported that the Kellgren and Lawrence grade and the minimum joint space had a higher positive correlation with the clinical symptoms of pain and disability reported by the participants than the Croft grading system. Although other radiological grading systems do exist for hip OA, these three measures are the most widely employed both clinically and in epidemiological studies (Reijman et al, 2004b). However, this study by Reijman et al, (2004b) reveals issues that make relying on radiological diagnosis alone problematic. Inter-rater reliability of the interpretation of radiological findings is poor, even at the higher grades where the clinical signs are more definitive and even less reliable at the lower grades where changes are more subtle. Additionally, there is no correlation with the symptoms. Consequently, in epidemiological studies where determining the presence or absence of OA

is critical, radiographic evidence alone cannot give accurate predictions of societal symptomatic burden.

1.4.3 Symptomatic diagnosis

An algorithm for the symptomatic diagnosis of hip OA without use of radiographs was developed in 1991 by The American College of Rheumatology (ACR) (Altman et al, 1991). This classification required:

- the patient to complain of hip pain, have active internal rotation of <15°, and erythrocyte sedimentation rate (ESR) of ≤45 mm/hour, or if ESR is unavailable,
- the patient to complain of hip pain, have active internal rotation of <15° and active hip flexion ≤115°, or
- the patient to complain of hip pain, have active internal rotation of <15° and active hip flexion ≤115°, and pain on internal rotation, and morning stiffness, and >50 years of age.

They found this classification based on symptom reporting to have a sensitivity of 86% and a specificity of 75%.

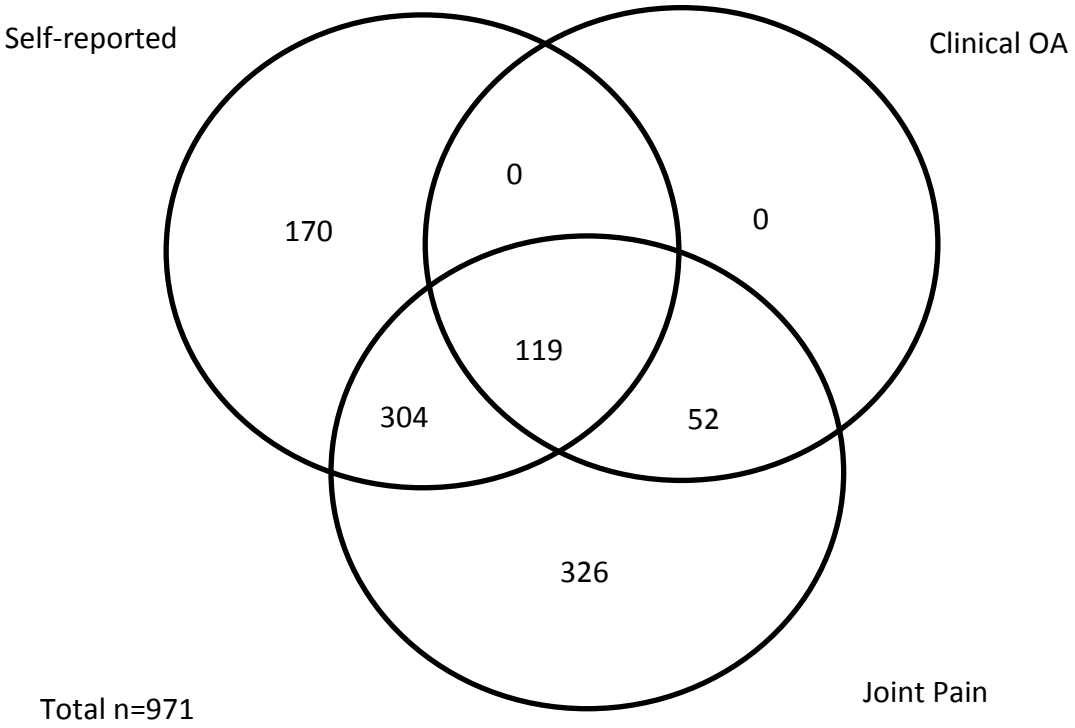
When ESR and radiographs are available, the ACR recommended the clinical diagnosis of OA as: hip pain, and presence of osteophytes (femoral or acetabular) on radiograph or ESR ≤20mm/hour, and axial joint space narrowing on radiograph. This combined approach of including patient reported symptoms, radiographs and laboratory tests yielded a sensitivity of 91% and a specificity of 89% compared to using the clinical criteria alone.

An analysis of general practitioner consultations using the Consultations in Primary Care Archive (CiPCA) database has recently been undertaken by Arthritis Research UK (2013) in collaboration with the Arthritis Primary Care Centre at Keele University, UK. Extrapolation for this data set estimated 2.12 million people having symptomatic hip OA and revealed the hip was only second to the knee as the most common joint for which people sought treatment.

1.4.4 Diagnosis by self-reporting

Edwards et al (2014) conducted a European study in six countries by randomly contacting individuals between the ages of 65-85 until they had recruited 2,294 participants and assessed the relationship between self-reporting of hip, knee, or hand OA. Participants were simply asked “do you have OA”. If they said yes, they were then asked to tick all the relevant areas on a body chart, which had the 10 most common sites of OA identified, at which joints their OA was sited. Participants were then classified as self-reporting of hip, knee or hand OA if they indicated one of these sites. All participants were then assessed for OA at the hip, knee and hand using the ARC clinical diagnosis criteria without radiographs (Altman et al, 1991). This European study revealed self-reported rates of OA were much higher than clinical OA: individuals with clinically diagnosed hip OA (n=171) were highly likely to self-report OA (n=119, 70%) but of those who self-reported OA (n=593), only a fifth (n=119, 20%) had a clinical diagnosis (see Figure 7).

Figure 7 Diagram of the overlap between definitions of self-reported and clinical hip OA



1.5 Disease progression

Despite being such a common disease, the natural progression and prognosis for OA is poorly understood (Spector et al, 1992) though disease progression is usually slow, occurring over years or decades (Lohmander, 2000). Due to the time taken for disease progression, long term longitudinal studies are difficult to conduct and expensive (Wolfe and Lane, 2002). Wolf and Lane (2002) also highlight that old radiographs, other than those used in clinical trials, are now routinely sold due the high value of the silver in the films. As a consequence, retrospective studies are also difficult due to this. However, the studies which have been conducted are reviewed below. The current gold standard for measuring disease progression

of hip (Altman et al, 2004) and knee (Ornetti et al, 2009) OA is the rate or percentage of joint space narrowing (JSN).

Dieppe et al (1997) conducted a 3 year longitudinal study of OA disease progression of 500 patients attending a rheumatology clinic. At the 3 year conclusion to the study, 415 participants were asked how they thought their OA had progressed; 243 (58.3%) reported an overall worsening of their OA, 87 (21.0%) with no change, and 85 (20.5%) reported an overall improvement. However, there was no significant change ($p=0.82$) in VAS pain score but there was a significant deterioration in function ($p<0.001$) measured using the Steinbrocker score (Steinbrocker et al, 1949). Radiographs at the start and conclusion of the study were only available for 145 participants with knee OA. Changes in joint space narrowing of >2mm were used as the minimal significant change, and this was only recorded in 30% of the knee radiographs at 3 years follow-up. The participants in this study had a mean age of 65.6 (24-88) at the start of the study and had 'relatively severe OA' (Grade of OA not defined) as they were already attending a rheumatology clinic.

Spector et al (1992) also conducted a longitudinal study on the progression on knee OA with fewer participants than the Dieppe et al (1997) but with a longer time frame. Participants (n=167) originally enrolled on two different clinical trials conducted in 1975 and 1976 were contacted 11 years latter to obtain consent for new radiographs. A total of 63 subjects (126 knees) were paired with radiographs taken for the initial studies and re-analysed using the same protocol. With the minimal significant change set a one grade change in the Kellgren-Lawrence scale, after 11 years 51 knees (40%) were assed as having no grade change, 12

(10%) had improved by at least one grade, and 63 (50%) had deteriorated by at least one grade. When the minimal significant change was increased to 2 grades in the Kellgren-Lawrence scale, 95 (75%) were assed as having no change, no knees improved, and only 19 (30%) had deteriorated. The mean age of the participants at follow-up was 69 (52-87) and all the subjects were again already attending a rheumatology clinic when they were recruited to the original clinical trials.

Dougados et al (1996) conducted a longitudinal study on participants with hip OA. The participants had to fulfil the American College of Rheumatology (ARC) criteria for the diagnosis of hip OA and be between the ages of 50-75. Information is not provided on where the participants were recruited and whether they were seeking treatment. However, in order to fulfil the ARC criteria, the patient pain had to be poorly controlled and impact on their daily function. The mean age of the patients at baseline was 63 (S.D. 7.0). Of the initial 508 patients recruited, 476 underwent radiological evaluation 1 year later. Using change in joint space as the indicator of progression, after 1 year, only 102 (22%) showed any disease progression. Further analysis on the correlation between age at onset of OA and the risk of progression, revealed progression in 15% of patients aged <55 and 55-60, 20% for those aged 60-65, 27% for those aged 65-70, and 33% for those aged >70 at time of disease onset. Although this study only followed up at participants at 1 year, the results indicated that the older someone is when the disease first becomes symptomatic, the quicker the disease progresses.

All three of these previously reported studies on disease progression either recruited participants that were already in attendance at rheumatology clinics (Dieppe et al, 1997; Spector et al, 1992) or those whose pain was not adequately managed by pharmacological or conservative interventions (Dougados et al, 1996). These therefore only provide information in to rate of progression of the disease in its advanced symptomatic phase where people's function is already compromised.

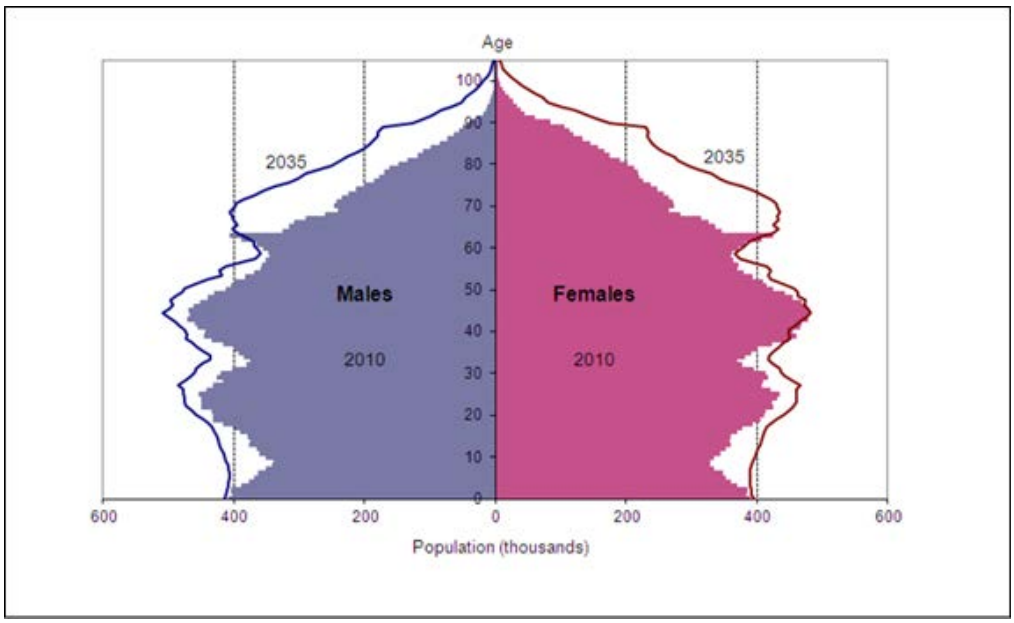
Wolfe and Lane (2002) conducted a much larger longitudinal study following some participants for up to 23 years. Initially recruitment started in 1976 of patients attending a specialist arthritis care centre in the USA for knee OA. The study then expanded in 1996 to recruit participants for 3 years from the community (n=657) with symptomatic knee OA who had not yet sought treatment. In total 2,400 participants were recruited of which 1,507 had paired 'before and after' radiographs at the end of the study. The mean age of the participants at time of recruitment was 63.4 (S.D. 11.8). The community participants were given three follow up radiographs between 1985 and 1999; those attending the arthritic care centre received additional radiographs as part of their routine care. Kaplan-Meier survival analyses to obtain rates and prediction of progression to 'joint failure'. Joint failure was defined as a Kellgren-Lawrence joint space narrowing (JSN) score of 3 which is highly significant in the USA as this is the grade at which a patient should be offered a joint replacement. Of the 1,507 participants with paired radiographs, 1,232 had grades 0-2 when first assessed. The results present the 75th and 50th survival time (to JSN score of 3). For those with an initial grade = 0, the 75th and 50th survival times are 11.27 and 17.84 years, for those with grade = 1 at onset, 7.41 and 12.03 years, and for those with grade = 2, 4.49

and 7.44 years. A Cox regression revealed the rate of progression is greatest in those with established radiographic changes. This suggests the once the disease has progressed from grade 0 to grade 2 or more, the rate of disease progression then accelerates.

1.5.1 Age and the increased prevalence of hip OA

The Office of National Statistics estimates that the number of people over state pension age will increase by 28% in the UK; from 12.2 million in 2010 to 15.6 million in 2035 (see Figure 8).

Figure 8 Actual 2010, and projected 2035 age structure in the United Kingdom (ONS, 2011)



Due to OA being a disease that primarily affects older people; as people live longer and the proportion of the population over 60 increases, more people will be living with OA (Cross et al, 2010; Pereira et al, 2011). Murphy et al (2010) analysed longitudinal data (n=3068) from a population based study in North Carolina, USA and estimated the lifetime risk of developing hip OA by age of 85 is 25.3% (95% CI; 21.3-29.3%).

1.6 Current concepts of conservative management

Recent guidelines have been released involving non-pharmacological conservative management of osteoarthritis by four authorities and influential organisations: The Osteoarthritis Research Society International (OARSI) (Zhang et al, 2010); The American College of Rheumatology (ACR) (Hochberg et al, 2012); The European League Against Rheumatism (EULAR) (Fernandes et al, 2013); and The National Institute for Health and Care Excellence (NICE, 2014).

The ACR grading (Hochberg et al, 2012) of recommendation used four categories (Strong, Conditionally, No recommendation, and Strong recommendation not to use) based on the strength of evidence supporting the modality coupled with the extent to which the benefits were considered to outweigh any possible harm. 'Strongly recommend' required high quality evidence of any benefits to greatly outweighing any potential harm. Most informed patients would choose this management and clinicians should offer this treatment. 'Conditionally recommend' inferred the absence of high quality evidence and/or small difference between benefit. This can be offered if the patient prefers these options to the strongly recommended ones. 'No recommendation' was made when there were no RCTs and no

evidence of benefit. ‘Strong recommendation not to use’ was made when there were no RCT’s and/or in opinion of the expert panel potential harm may outweigh any benefits. A different approach is taken in the EULAR guideline (Fernandes et al, 2013) which is based on providing the user with the grade of evidence supporting each conservative intervention but no specific recommendation for its implementation is made. The level of research evidence graded in to four categories. Grade 1 evidence is subdivided in to level 1a (meta-analysis of RCTs) and level 1b (at least one RCT). Grade 2 is also subdivided in to 2a (at least one controlled clinical trial) or 2b (at least one quasi-experimental study). The lower level categories are Grade 3 (observational studies) and Grade 4 (expert opinion or experience of respected authorities). The OARSI recommendations (Zhang et al, 2010) were based on synthesis of evidence from published systematic reviews (64), RCTs (266) and economic evaluations (21) up to January 2009; a dichotomous approach to ‘recommend’ or ‘not recommend’ is used. The NICE guidelines (NICE, 2014), which specifically relate to the UK, use a best available evidence approach to provide a strength of recommendation to health care providers; wording denoting certainty with which the recommendation is made such as ‘offer’ or ‘consider’. Three interventions are considered as core treatments (education, activity & exercise, weight loss) which should be offered to all people with clinical osteoarthritis. The ACR, OARSI and EULAR guidelines provide recommendations for hip OA separately which are those presented in Table 2 below. The NICE guidelines do not differentiate their recommendations by affected joint, though mention is made if the evidence does relate to a specific joint only.

Table 2 shows that all four guidance documents agree that education and self-management and exercise are considered as the main conservative treatments that should be offered. The evidence for other management options is less clear and dependent upon the review strategy used by the various guideline production teams. For example, the OARSI (2010) recommend the use of acupuncture but not electrotherapy, whereas in contrast, NICE (2014) recommend acupuncture should not be offered but state transcutaneous electrical nerve stimulation electrotherapy should be considered, yet neither of these conservative interventions are addressed by the ARC (2012) or EULAR (2013) guidelines.

Table 2 Summary of the recommendation for the management of hip osteoarthritis

	OARSI (2010)	ACR (2012)	EULAR (2013)	NICE (2014)
Education and self-management	Recommended Education, self-management and provision of information on OA is a core recommendation	Conditionally	Level 1b	Offer (core treatment) Accurate verbal and written information and education on OA. This should be part of an overall management plan, not a single event.
Thermotherapy (Heat or Cold)	Not addressed	Conditionally	Not addressed	Consider Local heat and cold as adjunct to core treatment
Exercise	Recommended Exercise regime that included strengthening and aerobic exercises. Land based class based exercises are more cost-effective than home based or aquatic based exercises.	Strong Cardiovascular and/or resistance exercises and/or aquatic exercises. No recommandation Balance exercices, tai chi	Level 1a People with hip OA should be taught a regular individualised exercise regime that included strengthening exercises for both legs. This should include range of movement/stretching exercises.	Offer (core treatment) Recommended irrespective of age, comorbidity, pain or level of disability. Exercise **should** include local muscle strengthening and general aerobic fitness. Delivery should be based on individual circumstances.
Manual Therapy	Not addressed	Conditionally In combination with supervised exercise. No recommendation manual therapy alone	Not addressed	Consider Manipulation and stretching as adjunct to core treatment, particularly for hip OA.
Electrotherapy	Not recommended	Not addressed	Not addressed	Consider Transcutaneous electrical nerve stimulation (TENS) as adjunct to core treatment

Acupuncture	Recommended	Not addressed	Not addressed	Do not offer
Assistive devices	Not addressed	Conditionally Walking aids as needed	Level 1b Walking aids and assistive technology (hand rails, walk-in showers, increase height chairs) as part of an intervention package. Level 3 If provided not part of an intervention package.	Offer Advice on appropriate footwear with shock absorbing properties. Consider Assistive devices/walking aids
Weight Loss (if overweight)	Not recommended Good evidence exists for weight reduction for people with knee OA, no evidence is available to support this intervention for people with hip OA	Strong	Level 1b	Offer (core treatment)
Orthotics	Not addressed	Not addressed	Level 1b foot orthotics	Consider
Psychosocial interventions	Not addressed	Conditionally	Level 3 Counselling on change of work task, altering work hours, use of assistive technologies at work, workplace modification, commuting.	Not addressed

OA; osteoarthritis

1.7 The total hip replacement

The NICE (2014), OARSI (2010) and the ARC(2012) guidelines for the care and management of OA recommend that conservative treatment should be offered first, but the decision for people to be considered for THR is not based on the extent of the pathophysiological progression of the disease, but on patient symptoms alone. Consideration for a THR should be given once people have ongoing pain, joint stiffness, reduced function and poor quality of life that are not managed by conservative means. The THR is probably one of the most successful orthopaedic surgical procedures and has been described as one of the greatest successes of medical care (Bunker et al, 1994). At one year post surgery, several studies have shown that quality of life indices for people with a THR are similar to age matched people without hip OA (Zhang et al, 2008). It is generally accepted that primary THR is a cost-effective treatment (NAO, 2003) and the cost for quality-adjusted life years (QALYs) compares favourably with other health interventions (Holzwarth & Cotogno, 2012).

Although the THR is considered a clinical and cost effective intervention, all health systems constantly strive to increase quality and reduce costs. Joint registries were initially set up to enable this (Holzwarth & Cotogno, 2012) by providing continuous feedback. The Scandinavian counties were the first to adopt national registers, soon followed by most other European countries (Holzwarth & Cotogno, 2012). The National Joint Registry (NJR) of England and Wales started a systematic approach to recording all joint replacement procedures performed in 2004. Table 3 shows the steady year on year increase in the number of THR procedures performed in England & Wales. The compliance rate is calculated

by the NJR from data provided to UK Department of Health by joint prostheses manufacturers on implants sold in England & Wales compared to the number of operative procedures reported. The number of primary THR procedures (excluding hip resurfacing) is then multiplied by the compliance rate to estimate the total number of primary THR procedures; these data are presented in Figure 9.

Table 3 Estimates of primary THR procedures for England & Wales by the NJR 2004-13

NJR Report	Compliance %	Primary THR	Number of resurfacing procedures	Primary THR Excluding Resurfacing	Estimate of total THR activity
2004	0.43	32,221	-	32,221	50,458
2005	0.69	56,454	1694	54,760	71,955
2006	0.82	60,027	6003	54,024	63,965
2007	0.81	67,380	6064	61,316	73,211
2008	0.95	70,636	5651	64,985	68,039
2009	0.92	71,000	4260	66,740	72,346
2010	1.00	73,155	2195	70,960	70,960
2011	1.00	75,916	1518	74,398	74,398
2012	0.90	79,792	798	78,994	86,657
2013	0.91	80,194	802	79,392	86,537

Figure 9 Estimates of primary THR surgery rates in England & Wales using NJR data

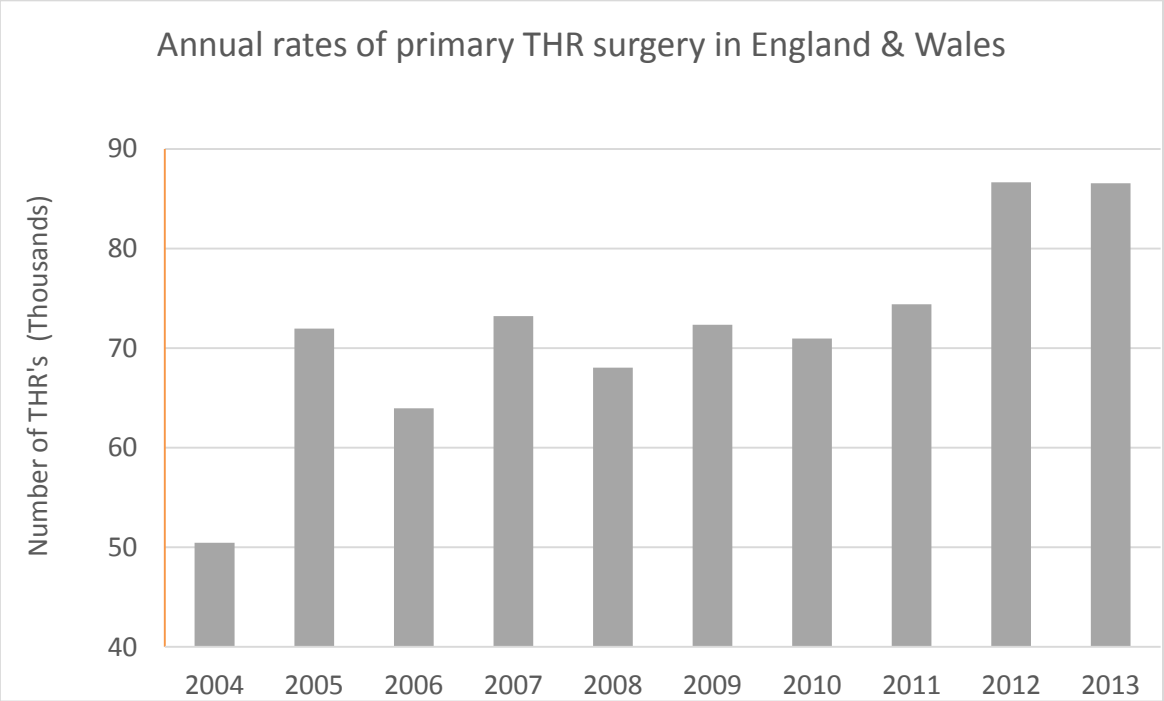
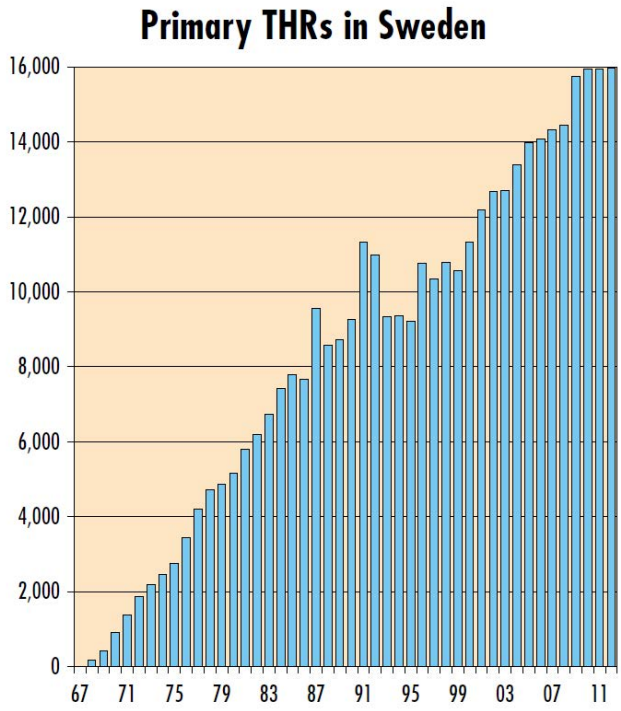


Table 3 shows a drop in compliance for 2012 (90%) and 2013 (91%) compared to the 100% for 2010 and 2011. Consequently, these compliance figures are expected to be revised upwards in subsequent NJR reports due to the long time delay in reporting the use of the registered prosthesis.

The Swedish Hip Arthroplasty Registry was the first national database to be set up and has records going back to 1967 making it the longest national record. As reporting is mandatory for all state funded hospitals, and all private hospitals are included in the data collection, it also makes it one of the most complete national records of hip replacement activity. The annual number of hip replacements performed in Sweden is shown in Figure 10 below (Swedish Hip Arthroplasty Registry, 2012).

Figure 10 Swedish hip arthroplasty data from 1967 to 2012



The number of primary total hip arthroplasties performed in Sweden from 1967 (6 operations) to 2012 (15 978 operations).

Reproduced with permission of the Swedish arthroplasty registry

1.8 Overview of current UK rehabilitation practice

1.8.1 Rehabilitation providers

Rehabilitation in health care settings usually refers to the processes and interactions which aid the physical or mental recovery after injury or disease and also to the management of long-term conditions. Medline and the US National Library of Medicine state rehabilitation is regaining strength, relearning skills or finding new ways of doing things. The Charted Society of Physiotherapy (CSP, 2015) defines rehabilitation as:

> "*Rehabilitation aims to optimise patient function and well-being, to help integrate that patient back into their chosen lifestyle activities whether at home, work or leisure. Rehabilitation should focus on changes to functional disability and lifestyle restrictions based on the patient's own goals for functional improvement*"

Khan et al (2009) in a review of multidisciplinary rehabilitation following hip or knee replacement state that the three main aims of rehabilitation are to prevent problems such as deep vein thrombosis or dislocation, to regain lost strength due to long term deconditioning, and to regain independence and participation in society. They also suggest that for most people without any comorbidities, rehabilitation by a single health professional may be sufficient, but those with more comorbidities may require several professionals such as doctors, nurses, physiotherapists and occupational therapists (OT).

In the UK, the main profession providing rehabilitation after THR is OT (Drummond et al, 2012) though this is not the same in other countries. Although the world federation of occupational therapists (WFOT, 2015) list 59 full member counties and 18 associate member counties in their organisation, professional boundaries of practice vary between and within countries depending on the regulatory framework for that profession. It is not unusual for specialist rehabilitation nurses or physiotherapists to perform the same interventions with regards to rehabilitation following THR as would be performed by an OT within the UK. Increasingly within the NHS many aspects of routine pre-admission therapy services and rehabilitation interventions are administered by generic rehabilitation assistants who deliver a range of cross discipline interventions. As a consequence, it is important to differentiate the therapy intervention from the profession of the person delivering it in order to allow research to be inclusive of international differences in health care delivery.

1.8.2 Rehabilitation practice in the United Kingdom

This section will provide a general overview of rehabilitation of patients undergoing THR. A more detailed discussion of OT practice is contained within chapter 2.

Although he built on previous work by other orthopaedic surgeons around the world, the English surgeon Sir John Charnley is credited with development of the first effective THR procedure in the 1950's. His pioneering work included not only the design and manufacturing of the prosthesis, but also the development of the cement fixation method and the first effective clean air operating theatres required to reduce the risk of infection (Reynolds & Tansey, 2006). In this history of development of the THR, Reynolds & Tansey (2006) do not provide details of the rehabilitation provided; however, they do state that *"The patient remained in bed for ten or 12 days, until the wound was healed, and stayed in hospital for maybe three or four weeks (p 11)".* Despite the very limited information available on rehabilitation procedures in this period (Khan et al, 2009), the importance placed on rehabilitation can be evidenced by a correspondence to the British Medical Journal in 1954 by Sir John Charnley, commenting on a previous article discussing surgical procedures for treating OA hips.

> "*In the future surgery of the hip joint the quality of the surgery will be inversely proportional to size of the physiotherapy department…..with the new look surgery* [referring to a THR] *the physiotherapist of the future will still be at the right hand of the surgeon but she will get her results merely by assisting the patient to take the first steps and, which is even more important, by dispelling the fears and uncertainties which beset the patient during the many hours when the surgeon is absent."* (p 1564)

As the volume of surgical procedures increased and the quality of surgical procedures improved, the length of stay (LOS) in hospital following surgery reduced. In the 1990's the American Academy of Orthopaedic Surgeons were recommending a typical LOS should be about 12-14 days for uncomplicated patients (AAOS, 1991). This initial reduction in LOS was mainly driven by the need to reduce hospital acquired functional decline which is a recognised problem with prolonged stay for people over 65 years of age (Hoogerduijn et al, 2005; Roos et al, 2003). However, in the UK hospitalisation of 10 days or more post THR was still routine practice in the UK prior to 2000 (The National Audit Office, 2003). Since 2000, primarily as a consequence of economic pressures (Cookson & Laudicella, 2011), the LOS has been further reduced to the now typical stay of only 3-4 days.

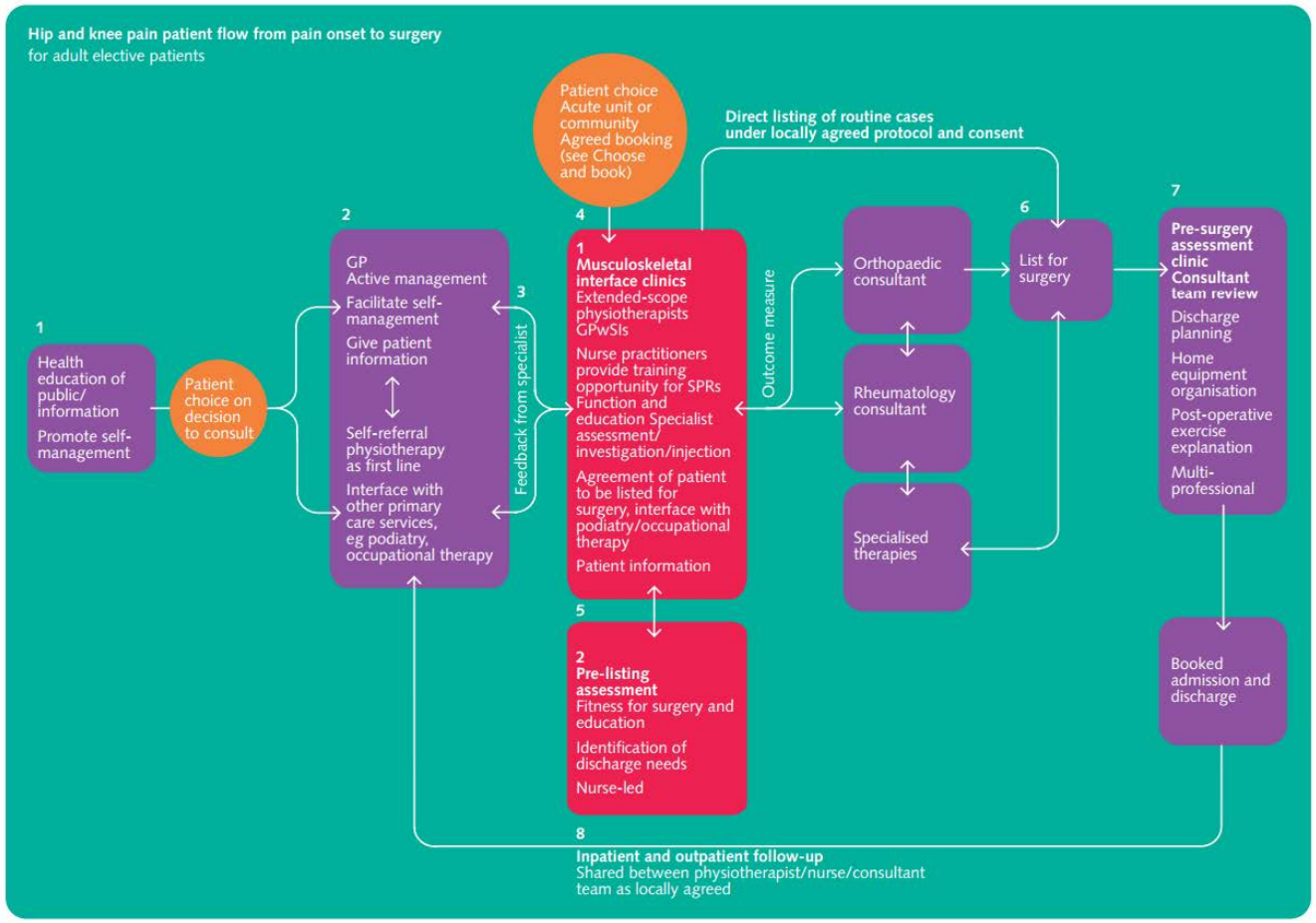
The Musculoskeletal Service Framework (Department of Health, 2006) recommends that patients with hip or knee pain should have access to multi-professional rehabilitation services prior to, and after discharge from hospital, following elective joint replacement procedures (see Figure 11) which is endorsed by the British Association of Orthopaedics (BOA) guide to good practice (2006). Despite these recommendations that patients should receive rehabilitation, no national guidelines exist as to the nature or amount of rehabilitation that should be offered (Westby et al, 2006; COT; 2012). Westby et al (2008) suggest that as a consequence of the absence of clinical guidelines and lack of high quality evidence, most rehabilitation programmes that do exist follow clinical experience, surgeon preference or anecdotal reports. Additionally, since the development of the first THR the 'traditional' rehabilitation for patients undergoing elective THR has occurred in the post-surgery hospitalisation recovery stage. Now that uncomplicated patients are routinely

discharged after 3-4 days, very little time exists for rehabilitation to occur in the acute care setting. (Westby et al, 2006).

To gain an understanding of current UK national practice, a Chartered Society of Physiotherapy (i-CSP) internet survey question was posted in October 2010 requesting information on current pre- and post-operative practice for lower limb joint replacement (Appendix I). Although a small sample (n=6), the results showed the variability in current UK practice with some NHS trusts providing pre-operative advice packages in accordance with the BAO and DH guidance on good practice, whereas others provided none whatsoever. Discussion with clinicians reinforced this variable picture. This variability in practice shown by this small i-CSP survey was reinforced in a subsequent observational study by Artz et al (2012). This observational study of rehabilitation practice in 24 high volume NHS orthopaedic centres in England and Wales revealed that no routine rehabilitation is offered following discharge to patients undergoing THR.

Due to national variability in practice and the identified lack of high quality research specific to rehabilitation, the optimum amount of rehabilitation needed to enable the recipient to fulfil their maximum quality of life is unknown. Correspondently, the minimum amount of rehabilitation required to reduce of the adverse consequences of dislocation is also unknown.

Figure 11 Flow chart adult elective patients with hip or knee pain



1.8.3 Current occupational therapy practice in the UK

Although UK practice is variable, occupational therapists are the main health professionals associated with providing rehabilitation services to patients undergoing THR. A recent survey of OT practice in the UK (Drummond et al, 2012) found that OTs who work in an orthopaedic setting spent approximately 40% of their working time treating people who have had a THR. Dislocation is the second most common complication (other than aseptic loosening) following THR with incidence reported as ranging between 0.5% - 10%. (Blom et al, 2008). Therefore, a substantial component of this practice was providing assistive devices and advice in order to prevent dislocation of the new prosthetic hip. The incidence of dislocation is particularly high in the first few months following surgery with a smaller risk persisting throughout life (Lübbeke et al, 2009). Consequently, in the first few vulnerable months following surgery, patients are routinely advised to restrict the range of motion of the prosthetic hip (Restrepo et al, 2011). Advice usually includes avoiding hip flexion of more than 90°, internal and external rotation more than 20°, adduction past the midline and specifically the combined movement of flexion/adduction which occurs during sitting cross legged (Peak et al, 2005, Lübbeke et al, 2009). The time period these movement restrictions are in place varies due to surgical approach and style of prosthesis fixation, but is usually between 6-12 weeks (NHS Choices, 2014). The 6 week minimum is to allow tissue healing of the joint capsule, ligaments and muscles which normally stabilise the hip that have to be cut during surgery. If more extensive tissue is cut using a different surgical approach, or an uncemented prosthesis fixation method is used then the time frame for all the tissues to heal can take up to 12 weeks. There is also some element of 'surgeon preference' that

dictates these time frames (Westby et al, 2006). Adherence with these movement restrictions has negative consequences on many normal functional activities of daily living (ADL). As a result, OTs (or OT assistants) routinely provide adaptive equipment and functional aids to patients, along with comprehensive education in their usage, to help with ADLs and prevent dislocation of the new prosthesis during the critical first few months. Due to the age of the cohort undergoing THR, many patients have a range of other physical and psychological co-morbidities which further complicates their functional capabilities. As a consequence, OTs will provide specific assistive devices tailored to the individual's needs and educate them in their usage.

When OTs perform home visits, the home environment is assessed for safety, with trip hazards being one of the fundamental aspects of this assessment. The NICE (2004) falls prevention guidelines recommend that a multifactorial risk assessment should be routinely performed on all people considered at risk of falling, with a home safety assessment being one of the recommended elements. This guideline also suggests altered gait, balance and mobility, and muscle weakness are potential causes of falls which are all typically found in people with OA hip.

Despite the variety of practice previously discussed, the majority of patients in the UK are still provided with assistive devices just before they are ready for discharge (McMurray et al, 2000). However, as a result of economic pressures to reduce length of stay (LOS) in hospital, the time to discharge has decreased: The National Audit Office (NAO 2003) report found average LOS had reduced from 11 days in 1999 to 8 days in 2002. An audit of NHS records from 2001 to 2007 by Cookson and Laudicella (2011) showed a year on year reduction in

average LOS following THR from 10.86 days in 2001 to 7.14 days in 2007. The NHS choices website (2014) suggests current anticipated in-patient LOS is between 3-5 days; with patients eligible for rapid discharge schemes returning home 1-3 days following surgery. As a consequence, time for in-patient rehabilitation, education and counselling has decreased. This ever decreasing in-patient rehabilitation period has resulted in patients having to learn about precautions and adaptive equipment within one to two days following surgery when anxiety and stress levels are still high (Butler *et al*, 1996; Crowe and Henderson, 2003; Spalding 2003) and cognitive ability may be impaired. Moller et al (1998), in a study of the effects of anaesthetic gases in older (>60 years) patients (n=1218) undergoing cardiac surgery, found significant ($p<0.0001$) cognitive dysfunction was still present in 25.8% (CI 23.1-28.5%) at 1 week post-surgery, and was still significant ($p>0.0037$) in 9.9% (CI 8.1-12.05) at three months after surgery compared to age matched controls. Additionally, the analgesia used may also still be affecting cognitive function and the processing of information (William-Russo et al, 1992). Therefore, pre-admission services are now increasingly important to aid post-discharge planning (Westby *et al*, 2009) and improving the patient experience (Spalding 2003). An important corollary of this reduced length of stay is the time available for recuperation, in-patient rehabilitation, education and discharge procedures (Westby et al 2009). Although some variation in practice does occur, it is usual practice in the UK for occupational therapists to provide assistive devices, together with education of its use, in this short post-surgery/pre-discharge period. Pre-surgery home based provision has been identified as desirable by patients and possibly assist functional rehabilitation (Orpen & Harris, 2011).

1.9 The patient experience of the THR

A search was conducted for qualitative articles regarding patient's experiences of undergoing a THR which resulted in 12 articles. Studies that interviewed patient prior to undergoing THR revealed that people expected the hip replacement to relive the pain and enable them to return back to higher levels of function, especially re-engagement with societal participation (Fielden et al, 2003; Grant et al, 2009; Manusco et al, 1997). The studies that interviewed participants after their THR revealed the participants were generally satisfied with their lives. However, they also expressed that they had to modify their pre-operative expectations in terms of returning to higher levels of function and/or the rate of recovery (Fielden et al, 2003; Grant et al, 2009; Gustafsson et al, 2009; Manusco et al, 1997). In the Gustafsson et al (2009) study, participants spoke of a 'naïve understanding' pre-operatively that could unexpectedly lead to negative outcomes of bitterness and despair if their recovery did not progress as expected. Concerns about coping post-operatively were expressed in three studies (Heine et al, 2004; Hunt et al, 2009; Soever et al, 1010). Lack of access to post-operative rehabilitation was identified in two studies (Hunt et al, 2009; Soever et al, 1010) as a source of concern; participants thought they may not be able to return back to their desired levels of function without this. The importance of pre-operative education was identified in five studies (Fielden et al, 2003; Heine et al, 2004; Orpen and Harris, 2010; Spalding, 2003; Soever et al, 2010) in terms of reducing pre-operative anxiety, but also informing them of what to expect after discharge. In the study by Orpen and Harris (2010) participants also expressed the desire for the adaptive equipment to be delivers pre-

operatively due it being of assistance while living with OA prior to surgery. Also, it would give them confidence to use it post-surgery.

1.10 Economic cost of general osteoarthritis in the United Kingdom

Despite its prevalence, there is very little published information relating to the economic costs of OA to the UK economy (Chen et al., 2012). Instead, the majority of health economic research on the cost of musculoskeletal disorders has focused on the cost to the individual (March and Bachmeier, 1997). Additionally, gaining a realistic economic cost of OA is compounded as it is primarily a disease affecting older persons who are also likely to have other comorbidities attracting health care and societal costs. However, using a variety of published data, March and Bachmeier (1997) estimated the cost of OA in various developed countries as generally being between 1% - 2.5% of the gross national product (GNP), with the estimate for the UK being 1.1% (£4 billion in 1986). With the present GNP of the UK economy being estimated at approximately 2.5 trillion US$ (World Bank, 2014), this estimate of 1.1% of the UK GNP would now equate to ~£17 Billion. A more recent study by Oxford Economics (2010) (commissioned for the Arthritis Research Council (ARC)) attempted to estimate the full economic cost of arthritis to the UK economy. A prevalence of 6.65m people with OA (see Figure 12) was assumed. The results of this analysis only presented separately values specific to OA for the estimates of '*value of healthy life lost*' and the '*direct health costs'*; all other costs were combined estimates for OA and rheumatoid Arthritis (RA). However, as OA accounts for approximately 95% of all possible types of arthritic disease

(NHS, 2014), these figures would not be greatly reduced if economic data for OA could be isolated. Chen et al (2012) provide a breakdown of the component parts (drug costs, iatrogenic drug costs, arthroscopy, and joint replacement) used to estimate their direct 2010 health cost for the UK (see Figure 13). From this, it can be seen that the most significant direct cost is associated with joint replacement which accounts for £852m (85%) on the total direct costs of £1007.7m. However, this analysis has not taken in to account the cost of cortioco-steroid injections which are widely used for pain relief (Hirsch et al, 2013) and conservative treatments provided before joint replacement surgery is considered. With the increasing age demographic in many developed countries, all these components of the full economic costs of OA will increase.

Figure 12 Full economic cost of arthritis in the UK (Oxford Economics, 2010)

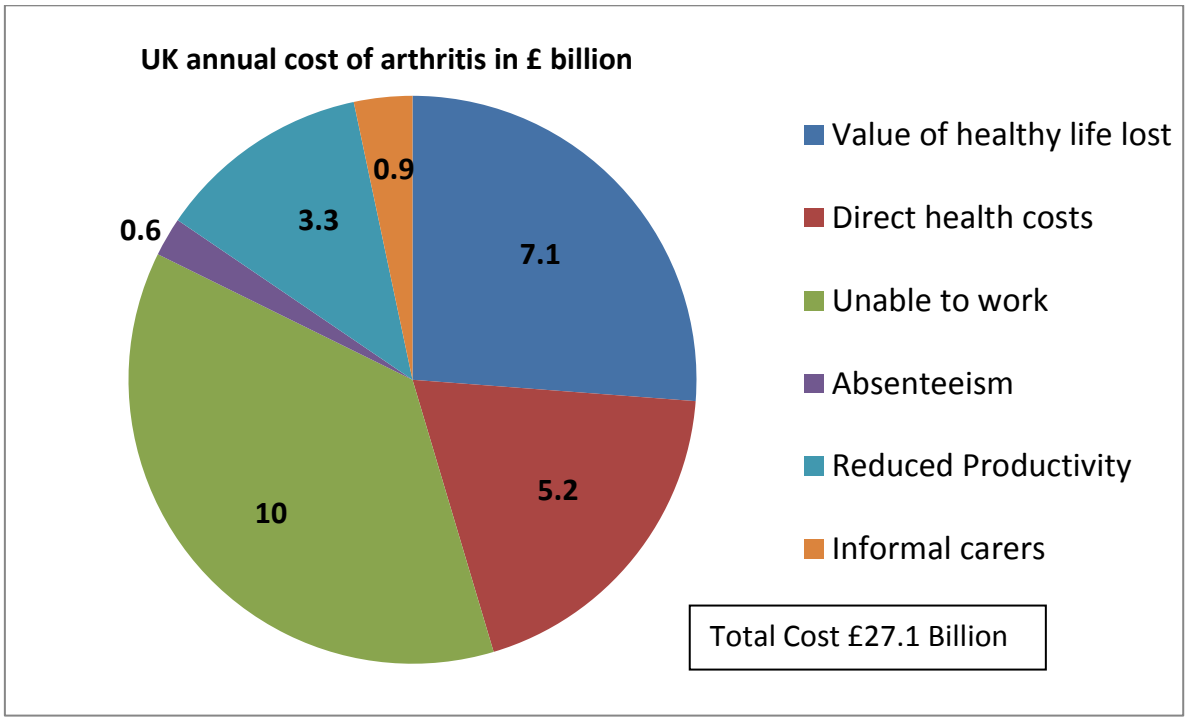
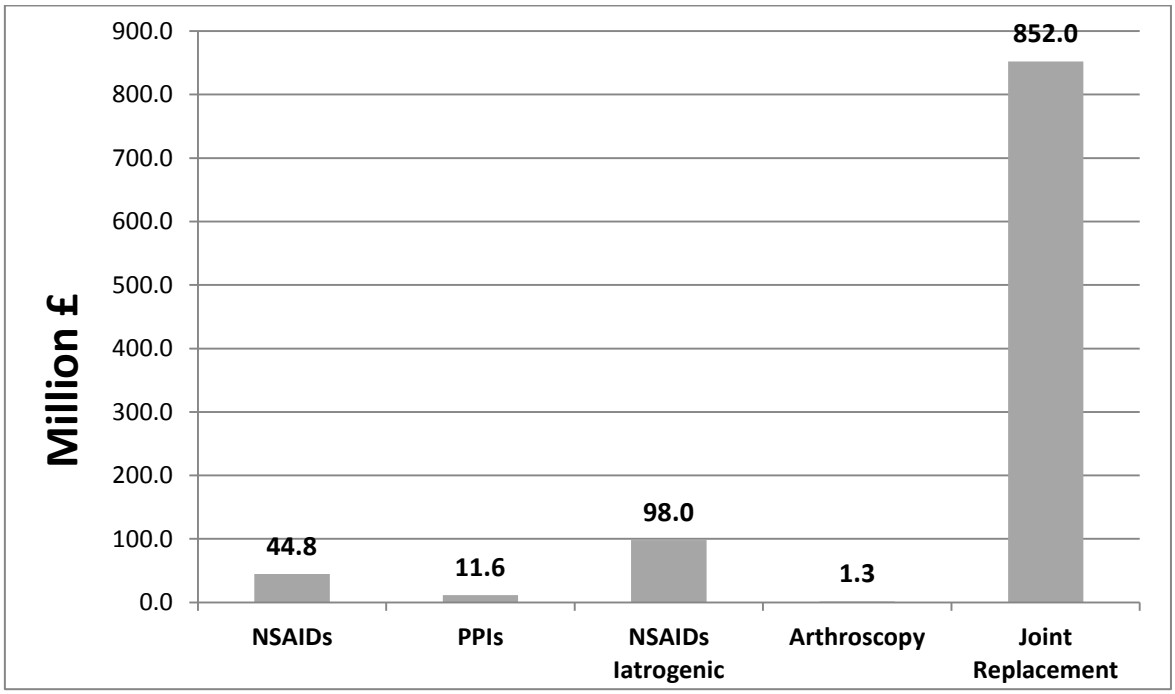


Figure 13 Direct costs of treating OA (from Chen et al, 2012)



NSAIDs, Non-Steroidal Anti-inflammatory Drugs; PPIs, Proton Pump Inhibitors

1.11 Economic cost of hip osteoarthritis

1.11.1.1 *Direct costs*

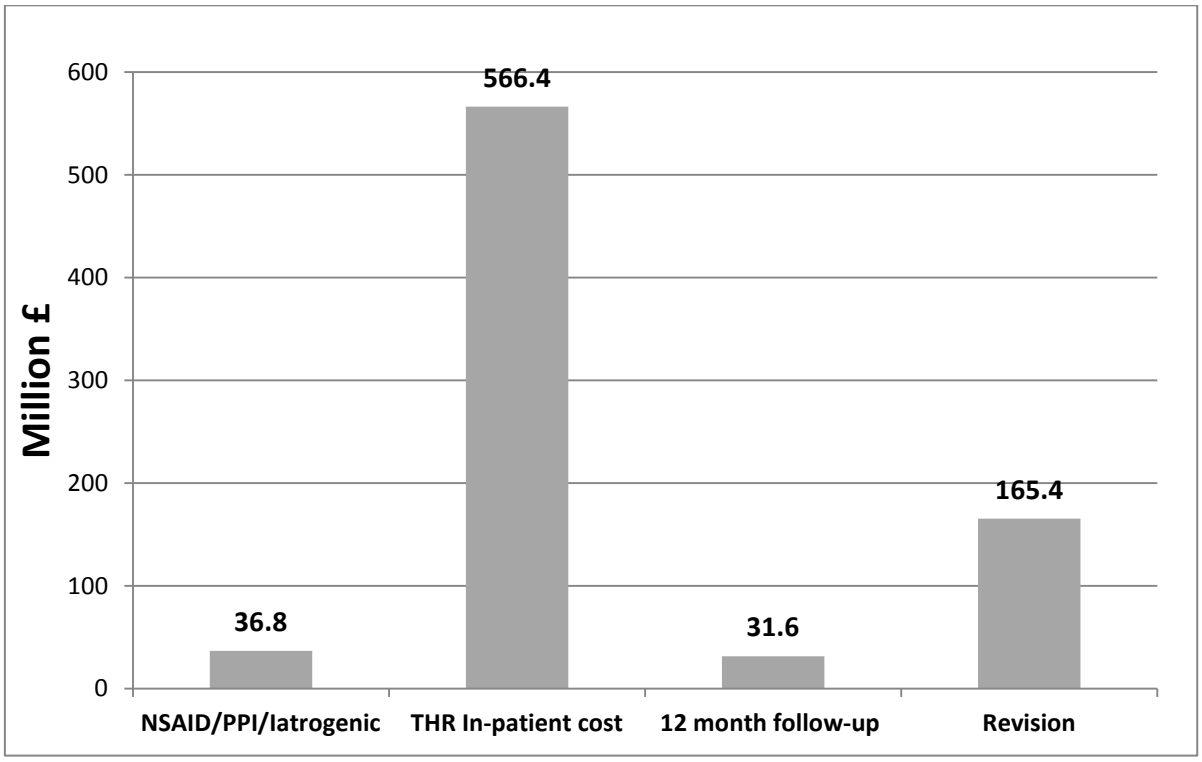
The GP consultation study by Arthritis Research UK (2013) estimated there were 2.12 million people in the UK with hip OA, and hip OA accounted for 24% of all GP consultations concerning pain of OA origin. Figure 14 illustrates a breakdown of the estimated direct costs. If an assumption is made that 24% of all pain relieving medication for OA is therefore related to the treatment of hip OA, using the figures provided by Chen et al (2012) it can be estimated that this then accounts for £36.8 million (at 2010 prices). The NICE technology appraisal for THR (2014) calculated the average cost (2012 prices) of prosthesis (£2517), sum cost of performing the surgery (£2805) and the average in-patient stay following surgery (£1678) as costing the NHS £7,063 per person. In 2013 there were 80,194 THR procedures recorded (NJR, 2014); the direct cost of performing this number of hip joint replacements can be calculated as costing £566.4 million. The (2014) NICE technology appraisal also calculates the average 12 month follow–up cost for outpatient appointments, primary and community care costs as being £394 per person. This adds another £31.6 million to the direct costs.

In their economic analysis, Chen et al (2012) did not include revision surgery. However, as >90% of all primary THR is performed due to OA, the cost of revision should realistically be included. Revision surgery is more complex and the average age of the patient is older (70.7 years) for revision surgery compared to primary surgery (68.8 years) so the cost per procedure is higher (NJR, 2014). NICE (2014) calculate the total cost of revision at £16,571

plus an additional £394 per person for average postoperative complications cost. This equates to £16,965 per procedure. In 2013 there were 9,751 revision procedures (NJR, 2014) giving an additional overall cost of £165.4 million.

This analysis is probably an underestimate of the true direct cost as it does not include patients who need longer episodes of hospital care nor the cost of steroid injections which are recommended by the American College of Rheumatology (Hochberg et al, 2012) for the management of hip OA.

Figure 14 Estimate of direct costs for hip osteoarthritis



Note: these cost estimates are based on 2010 prices. Where data was not available for 2010, inflation factors were used to calculate 2010 prices from most recent available data.

1.11.1.2 *Indirect costs*

There is not enough information to make any form of estimate of the proportion of the overall indirect costs as reported by Chen et al (2012) or by Oxford Economics (2010) that can be attributed specifically to hip OA. However, either hip or knee OA, when analysed together, are the principal causes of mobility related disability in an elder population (Felson et al, 2000) and form the two most common large joints affected (ARUK, 2013). It is therefore reasonable to assume that the contribution of hip OA to the overall indirect cost is at least proportional to its reported 24% representation of all OA (ARUK, 2013).

1.12 Summary of current evidence regarding occupational therapy practice for patients undergoing THR

This section will present a summary of current evidence from systematic reviews focused on THR rehabilitation.

1.12.1 Rehabilitation for patients undergoing THR

1.12.1.1 *Pre-operative interventions*

Fortin et al conducted a two centre observational study of 379 participants undergoing elective THR or TKR due to OA (Fortin et al (1999). This study found that functional activity at both 3 and 6 after surgery was positively correlated with pre-operative functional status. Since this initial observational study, several other studies have been conducted to see if pre-operative exercises aimed at improving pre-surgery function can affect post-surgical outcomes. A systematic review of physiotherapy interventions prior to patients undergoing their THR or TKR was conducted by Ackerman and Bennet (2004). This review only contained two studies relating to THR patients, of which both are contained in the more recent review and meta-analysis by Gill & McBurney (2014). This review by Gill & McBurney (2014) contained at total of 18 studies of which six related to patients undergoing THR. This review found a significant improvement, with a medium size effect, in favour of the pre-operative exercises for both pain (SMD 0.45; C.I. 0.15 – 0.75, p=0.0004) and function (SMD 0.46; C.I. 0.20 - 0.72, p=0.006) measured prior to admission. The heterogeneity I^2 statistic was zero for both of the meta-analyses indicating confidence in interpreting these findings. This review

searched 4 electronic databases (CINAHL, MEDLINE, Embase, and Cochrane Library) and had good methodology and discussion, though the results lacked clear reporting of the study characteristics (size, follow-up periods, and specific content of the interventions). However, the authors do state that several of the included studies did not provide specific details of the exercise based interventions. As a consequence, they were also unable to make any specific recommendation as to the type, intensity or duration of pre-operative the exercise programs.

McDonald et al (2014) conducted a review of pre-operative education which contained 18 studies (1463 participants), thirteen of which involved people undergoing a THR. The main outcomes of this review were preoperative anxiety, though some complex interventions were included that also measured long term outcomes of pain and function. All of these studies are contained in the systematic review reported in chapter 2 of this thesis so the will discussed later.

1.12.1.2 *Post-operative interventions*

Three systematic reviews have been conducted on the effect of post-operative exercise (Di Monaco et al, 2009; Di Monaco and Castiglioni, 2013; Minns-Lowe et al, 2009).

The Minns-Lowe et al (2009) review searched 8 electronic databases plus hand searched three journals and conference proceedings up to April 2007 resulting in it containing 8 studies. Only two of the studies enclosed had data presented suitable for meta-analysis. The outcomes were self-reported function, walking (speed or timed distance), hip range of motion, muscle strength, and quality of life. The review was of high quality with all elements

of the PRISMA (Moher et al, 2009) checklist clearly reported. Minns-Lowe et al (2009) concluded that due to the diversity of outcomes used, and the poor quality of the included clinical trials, that it was not possible to establish the effectiveness of post discharge exercises. In contrast, the review by Di Monaco et al (2009), published in the same year and contained nine studies, concluded that 'convincing evidence' for the effectiveness of partial weight bearing treadmill training, resistance training of the quadriceps muscle on the operated side, and use of an arm ergometer when included in general exercise programmes. However, this review is of much lower quality than the one by Minns-Lowe et al (2009). The search strategy only involved electronic searching of MEDLINE, only one person assessed eligibility criteria, and only the final PEDro score was presented for the quality appraisal, and no study selection diagram is presented. Additionally, the method of evidence synthesis used to arrive at the conclusions of the effectiveness of the interventions is not reported, nor does any actual method of synthesis appear to be employed. The finding of this review must therefore be considered with caution and more emphasis placed on the findings of the Minns-Lowe et al (2009) review.

Di Monaco and Castiglioni (2013) updated the Di Monaco et al (2009) review and this was conducted and reported to a higher quality (Moher et al, 2009) though it still lacked some important aspects of quality (Moher et al, 2009). The search was widened to include 4 electronic databases (MEDLINE, PEDro, Cochrane library, Cinahl) and included 8 RCTs published after January 2008 to December 2012. Two reviewers assessed inclusion eligibility, a flow diagram is presented, but again, only the final PEDro scores are presented. Again, a narrative review was undertaken but no apparent method of synthesising the information

was employed. The review concludes that robust evidence is available for ergometer cycling and resistance training in the early stages of rehab, and weight bearing exercises in the later stages. However, although this review is of higher quality than the one it updated, caution still has to be applied in interpreting these findings. Together, these three systematic reviews suggest there is insufficient evidence to determine the effectiveness of post-surgery exercise for patients who have had a THR.

Khan et al (2008) conducted a high quality systematic review on post-operative multidisciplinary programmes for THR and TKR patients which included 5 studies. No meta-analysis was undertaken, thus a strength of evidence method (Tugwell et al, 2004) was used to synthesise the findings. A level of evidence approach was taken form conclusions. This review concluded that there was silver level evidence that early multidisciplinary rehabilitation can improve function in THR patients at six months following surgery. It also concluded that there was a lack of evidence regarding rehabilitation, and the evidence that was available, was of a low to moderate quality.

1.12.1.3 *Combined preoperative and post-operative interventions*

Skoffer et al (2014) conducted a systematic review with a wider search of 9 electronic databases (PubMed, Embase, Cochrane Library, Web of Knowledge, PEDro, Cinahl, SveMed+, SPORTDiscus and Bibliotek.dk) to investigate the effectiveness of progressive resistance training (PRT) programs conducted both pre-surgery, and continued post-surgery, on strength and function before and after TKR or THR. This review contained 4 RCT's with 136 participants undergoing THR, though the authors report that the quality of reporting in the

included studies made meta-analysis unfeasible, so a strength of evidence synthesis approach was taken. The results in this review were poorly reported; the flow diagram reports 14 studies were included but only 7 are contained in the outcome of the review and only percentages changes were presented, not the original data. Also, although the authors discuss risk of bias, the bias associated with each study is not presented. Although the review suggests a weak-to-moderate beneficial effect of PRT in strength and functional capacity was found, the actual evidence synthesis methodology used is not reported. These results should therefore be treated with caution.

1.12.2 Occupational therapy and rehabilitation following THR

The UK College of Occupational Therapists recently recognised the lack of practice guidelines and released the first clinical guidelines for occupational therapists working with patients undergoing elective THR (COT, 2012). An overview of systematic reviews of the efficacy of OT in different conditions found none relating to rehabilitation following THR (Steultjens et al, 2005). The most recent published systematic review (Hand et al, 2011) relating to OT is specific to community based OT interventions for chronic conditions and the search strategy did not include articles relating to OT for THR surgery. However, a previous systematic review by Steultjens et al (2004) concluded that strong evidence exists for the efficacy of OT practice of provision and advice in use of assistive devices as part of a home hazards assessment to maintain functional ability in elderly community dwelling adults. The provision of assistive devices is a key aspect of OT involvement in THR rehabilitation, yet none of the included studies specifically included this. Despite the endorsements by NICE (NICE 2003) and the British Orthopaedic Association (BOA, 2006) for OT interventions of

people undergoing THR, the evidence base required to underpin effective rehabilitation programs has not been established; this has resulted in existing protocols being based either on 'clinical experience, surgeon preference or anecdotal reports' (Westby et al, 2006). This review will help to address the limited review based evidence that currently exists for a condition that has high prevalence (Drummond et al, 2012), wide variation in current clinical practice (Khan et al, 2012) and substantial economic implications (Chen et al, 2012). The completed review will strengthen the evidence base, help clinicians determine optimum rehabilitation strategies and enable patients to make informed choices about their rehabilitation following a THR.

1.13 Rationale for study

The evidence surrounding pre-operative education involving OTs, coupled with the pressure to reduce length of stay suggested it may be more effective to provide ADL adaptive equipment, and education in their use, pre-surgically in the familiarity of patients' own homes. This would alleviate the need for this to happen in the immediate aftermath of major surgery and had the potential to improve patients' worries and anxieties about returning home. Organisation of patients for discharge can be a complex scenario with many professions involved. Anecdotal reports from practicing OTs suggested that the delay in the supply of OT assistive devices can contribute to delayed discharge, especially if discharge is due at a weekend; McMurray et al (2000) found only 5% trusts surveyed provided any OT or assistant cover at weekends. Supply of assistive devices, together with education in their use

in the patient's own home prior to surgery may also streamline discharge and improve patient outcomes.

1.14 Chapter summary

This chapter has introduced the basic pathology of OA and the debate that still exists regarding risk factors for developing hip OA. It reveals that defining the epidemiology of hip OA is highly dependent on the diagnostic method used and that more research is needed into quantifying risk factors. A summary was presented showing the variation in recommendations for conservative therapies by stakeholder organisations. More detailed summary information was provided on the economic cost of OA and specifically hip OA when there was enough information to provide this detail. The chapter then discussed the rehabilitation of THR and the role within this usually provided by occupational therapists. A brief summary was then provided on previous research in to OT rehabilitation interventions which revealed more research is needed in to the effectiveness of OT intervention in relation to patients undergoing THR due to OA.

2 SYSTEMATIC REVIEW

2.1 Chapter overview

This chapter presents a systematic review and meta-analysis that was undertaken regarding the efficacy and effectiveness of occupational therapy interventions in relation to patients undergoing primary THR due to osteoarthritis. The conduct of this review was done in accordance with the guidance provided by the Cochrane handbook (Higgins & Green, 2011) and is reported following the PRISMA guidelines (Moher et al, 2009). Following the meta-analysis, a GRADE approach (GRADE working group, 2004) has been taken to synthesise the findings. The review was undertaken in order to inform the clinical trial reported in chapter 3 of this thesis. Additionally, a version of this review (without the studies by Peak, 2005; Ververeli, 2009 and Wong, 1990) also forms part of the final report submitted in November 2014 to the NIHR for the project "Improving patients' experience and outcome of total joint replacement" grant number RP-PG-0407-10070.

2.1.1 Aims

The aims of this review are to evaluate the efficacy and effectiveness of all pre- and post-operative OT interventions for patients undergoing elective primary or revision THR using patient centred outcomes.

2.2 Methods

2.2.1.1 *Search strategy*

Electronic databases were used to perform a standardised search in order to identify relevant published studies. Search dates were set to start in all electronic searches from 1st January 1980; studies published prior to this were excluded on the basis that the low quality reporting of older studies and their lack of relevance to current clinical practices (Cochrane, 1999). The first electronic search was undertaken in December 2011 then repeated again prior to the final write up of this review in July 2013. The electronic databases searched are as follows:

- Cochrane Register of Controlled Clinical Trials (CENTRAL) via the Cochrane library,
- MEDLINE via Ovid, EMBASE via Ovid,
- CINAHL plus (Cumulative Index to Nursing and Allied Health Literature) via EBSCO,
- AMED (Allied and Complementary Medicine Database) via EBSCO,
- PEDro (Physiotherapy Evidence database) http://www.pedro.org.au/,
- ERIC (Education Resources Information Centre) via ProQuest,
- CIRRIE (Centre for International Rehabilitation Research Information & Exchange) via http://cirrie.buffalo.edu/database/,
- OTDbase via http://www.otdbase.org/,
- Web of Science via http://apps.webofknowledge.com/

The electronic search strategy developed for MEDLINE is available in Appendix 2. Search terms for the other databases were developed to match this.

In addition to the standard electronic databases, other electronic platforms were searched to identify unpublished articles. On-going trials were searched through national registers and their respective web sites; Controlled Clinical Trials (www.controlled-trials.com) and the National Institute of Health Trial Registry (http://clinicaltrials.gov) and the International Clinical Trial Registry Platform of the World Health Organisation http://apps.who.int/trialsearch/); grey literature was searched using the OpenGrey database (http://www.opengrey.eu/).

Citation checks of the included articles were performed using the Web of Science citation search facility. National and international experts in OT orthopaedic research were contacted for knowledge of on-going studies, published data not available electronically, or unpublished work.

2.2.2 Inclusion and exclusion criteria

2.2.2.1 *Types of studies*

Randomised controlled trials (RCTs) are considered as the 'gold standard' of clinical research (Moher, 2010). Due to this, many literature reviews limit the inclusion criteria to RCT's only. However, due to the anticipated limited quantity of evidence available if the search was restricted to RCTs alone, the search was expanded to include controlled clinical trials (CCTs). To be included, CCTs had to have a concurrent comparator. Clinical trials without a

concurrent comparator or trials comparing OT provision of services against other professions delivering the same services were excluded because outcomes could be affected by other differences in care provided (anaesthetic, operative procedures, antibiotics etc.)

2.2.2.2 *Types of participants*

The search strategy focused on comparative trials of patients undergoing primary or revision THR surgery for osteoarthritis. Excluding studies that have included a minority of participants who have received a THR for reasons other than OA could limit the available information to be included in this review; whereas including studies where the majority of participants received THR for conditions other than OA (e.g. rheumatoid arthritis, trauma) would bias the results. Therefore, studies were included providing that 50% or more of participants received THR surgery due to osteoarthritis. All types of prosthesis, fixation methods and surgical approaches were considered for inclusion. Studies relating to participants receiving hemi-arthroplasties or resurfacing procedures were excluded.

2.2.2.3 *Types of interventions*

For the purpose of this review, OT was defined as a rehabilitation programme that addresses all, some, or one of the following interventions:

- Assessment, facilitation, practice and/or re-assessment of function. This included self-care activities of daily living tasks (ADL's) to foster independence and skills in these activities.

- Training of societal participation or extended activities of daily living (EADL) skills aimed at improving social reintegration. This included specific training to facilitate activities beyond personal or self-care ADL's. This therefore included activities such as gardening, shopping, return to work, sport and social pursuits.
- Hip precautions: this was defined as any form of counselling, advice on ADL's, practise with participants, or the provision of, or education in their use of assistive devices (raised toilet seats, furniture raises, dressing aids, perching stools, long handled reachers and commodes) used to avoid the specific movements thought to be associated with increased risk of hip dislocation (flexion, adduction, external rotation).
- Education sessions designed to inform patients of their expected pathway from the operative procedure to recovery at home, to reduce anxiety, or preparation for discharge. This may therefore include education on activity pacing and avoidance of specific joint positions associated with joint dislocation (hip flexion beyond 90°, adduction beyond the mid-line and to avoid internal and external rotation beyond 20° from neutral (Lucas 2008).
- Environmental adaptations such as removal of trip hazards, layout of furniture to improve access around the home, layout of specific rooms such as bathrooms, the kitchen and bedroom, and installation of hand rails or grab rails.

These interventions applied pre- or post-operatively, in a health care setting or in any community setting, or provided by therapy assistants under the supervision of qualified OT staff were also accepted. In several countries, the specific profession of OT does not exist,

though other health professionals such as nurses or physiotherapists carry out interventions equivalent with OT practice. Therefore, interventions provided by health care staff other than designated occupational therapists, which are commensurate with UK OT practice were accepted. Professor Avril Drummond (AD), a specialist in OT research at the University of Nottingham, assessed any studies of this nature to ensure the intervention met accepted OT practice.

In the clinical environment, rehabilitation is generally multidisciplinary; consequently, many clinical trials on rehabilitation are pragmatic in nature and do not isolate individual practices. In order to maximise the number of included studies, OT interventions provided as part of a multidisciplinary package were included if the nature of the OT intervention was adequately described and formed a substantial element of the overall rehabilitation, or the outcome could be assessed independently.

These OT based interventions were compared to routine care, no OT, or alternative/novel OT approaches.

2.2.2.4 *Types of outcome measures*

The World Health Organisation has developed an International Classification of Function, Disability and Health (ICF) (WHO, 2001). This original ICF classification of 'function' contained various levels of human activity from basic movements to full societal activity. Jette et al (2003) initially proposed that this classification of function should be divided into two distinct categories of 'activities' and 'participation' which is now widely used. OT involvement in elective THR primarily addresses the impact of disease according to this ICF

classification at the levels of 'activity limitation' and 'restriction in participation'. For this review, the primary outcomes were selected to concur with this stratification of function as identified below.

2.2.2.5 *Primary outcomes*

Function

For this review 'function' was defined as the basic activities which everyone undertakes to maintain a personal level of care (e.g. feeding, toileting, washing, bathing, transfer in/out bed/chair, mobilising). This addresses the ICF 'activity' classification in which activity is defined as the execution of a task or action by an individual (WHO, 2001).

Societal participation

For this review, societal participation relates to the ability of an individual to carry out their life habits in their environment such as home, work place, local neighbourhood, and wider social circles (INDCP, 2014). This incorporates the higher functional skills required to live independently and manage a dwelling (e.g. preparing own meals, doing housework, managing own money, shopping). This outcome also includes activities sometimes termed as societal reintegration or discretionary activities, which involve higher function activities such as driving, using local services, return to work or sport, using public transport, socialising with friends, attending social or cultural events. This addresses the ICF 'restriction' classification.

Health related quality of life

Health related quality of life (HRQoL) is an important concept to both clinicians and policy makers (Guyatt, 1993) with outcomes often used to measure the effectiveness or cost-effectiveness of therapeutic interventions. The underlying principle of HRQoL is how the individual rates the quality of their life. A THR is a major surgical procedure specifically designed to both reduce pain and improve HRQoL. Additionally, an underlying principle of OT practice is to improve overall quality of life, hence the inclusion of this outcome.

Anxiety

Despite the common nature of the THR, it is still a major life decision for an individual to choose to have a THR which evokes feelings of fear and anxiety as well as hope for the future (Gustafsson, 2010). One of the main aims of pre-operative education is to reduce the anxiety associated with major surgery and the preparedness for return home afterwards. (McDonald et al, 2004).

Pain

Only data collected by previously validated outcomes for pain were accepted for inclusion in the review. These could be discrete measures of pain including the visual analogue scale, or with tools such the McGill Pain Questionnaire (Melzack, 1971). Subsections of other validated measures, which have a domain of pain, were also accepted if the validation extended to subsection analysis.

Dislocation

The frequency of total hip replacement dislocation are reported as the number of incidences where a participant required a manipulation under anaesthetic to reduce a dislocated hip prosthesis, or the requirement of a revision procedure due to recurrent hip dislocation.

Length of Stay

Length of stay (LOS) following surgical procedure. Time spent in any form of sub-acute rehabilitation facility following discharge from the acute hospital where the THR surgery occurred is not included in the analysis.

2.2.2.6 *Selection of studies*

All levels of study selection were performed by two independent reviewers (PJ & NB). If necessary, authors were contacted for further information to determine if the study met the inclusion criteria or for additional information not reported in the published articles. Professor AD was consulted in cases of uncertainty regarding the OT involvement in the study or equivalent practice by other health care professionals. If a consensus could not be achieved by the two primary reviewers about suitability for inclusion, this was resolved by consultation with an independent third person with expertise in systematic reviewing (AB). The reviewers were not masked to the name(s) of the author(s) or publication source at any level of the review.

2.2.3 Assessment of risk of bias

Many clinical trials, including randomised controlled trials regarded as the highest standard of clinical trial, are often poorly conducted and/or inadequately reported. When conducting a systematic review it is important to consider the risk of bias otherwise incorrect conclusion may be reached, i.e. 'garbage in: garbage out' (Hróbjartsson, 2013). Many methods are available to assess the risk of bias of clinical trials though no consensus exists as to which is the best approach (Jüni, 2001). The Cochrane risk of bias tool (Higgins, 2011) was used to assess the quality of the included studies. As recommended by Cochrane, the assessment of bias was conducted by two independent authors using a standard format. Each bias domain was determined as being subject to either a low, high, or unclear risk of bias. Authors were contacted for additional information to clarify allocation of the correct bias and information from previous Cochrane reviews was used in cases of bias allocation uncertainty.

Blinding is considered one of the most important sources of bias in clinical trials (Karanicolas, 2010). In rehabilitation trials, it is not usually possible for the participants or the study personnel to remain blinded from the intervention: hence, the 'blinding of participants and personnel' domain was not used for assessment of bias in this review. Blinding of the outcome assessor is practicable, and is considered highly important when using subjective outcomes (Boutron, 2006) hence the risk of bias for blinding was based entirely on the reported status of the outcome assessor.

If the overall loss to follow up was less than 20% (Altman, 2000), the domain addressing the analysis of incomplete outcome data was automatically assigned a low risk of bias. If loss to

follow up was greater than 20%, the risk of bias assessment was judged high if a per-protocol analysis was performed (Higgs & Green, 2011). If an intention to treat analysis was performed (participants being analysed in the group to which they were originally allocated) a low risk of bias was attributed. If the method of analysis could not be determined, a judgement of an unclear risk of bias was allocated. If the two independent reviewers were unable to reach consensual agreement about bias allocation, this was resolved by discussion with an independent third person Andrew Beswick (AB); an expert in systematic reviewing.

2.3 Quality of studies

A GRADE approach (GRADE working group, 2004) was used to rate the quality of evidence in this review. Using this approach, all the RCT's are initially ranked as providing a high quality level of evidence and the CCT's ranked as providing low quality evidence. Review authors are then required to make an overall judgement on whether the quality of evidence for an outcome warrants adjustment on the basis of the outcome of the risk of bias assessment. As RCTs are initially ranked as high quality, any adjustment can only be a downgrade; on rare occasions observational studies may be upgraded. To maintain the objectivity of this review, a methodology was pre-defined before undertaking the risk of bias assessments for this grade adjustment. The mean time since the studies included in this review were conducted is 11.5 years ago (mode 11, range 6-24). Although the first CONSORT guidelines were introduced in 1996, a large proportion of potentially well conducted studies were still poorly reported in the subsequent years (Altman et al, 2001) which is the time period commensurate with the majority of the studies in this review. Consequently, the GRADE

methodology presented in section 12.2 of Cochrane (Higgins & Green, 2011) was slightly adapted as presented (see Figure 15). This adjusted approach allows slightly more potential sources of bias in the non-critical domains (loss to follow-up, selective outcome reporting and other sources of bias) to be tolerated than in the Cochrane guidance.

Figure 15 Adjusted GRADE approach to downgrading the level of evidence following the risk of bias assessment.

Randomised controlled trials	
High quality	No high risk of bias, or one domain identified high risk of bias other than randomisation, allocation concealment or blinding.
Moderate quality	Any two domains identified as high risk of bias, or one domain if this includes randomisation, allocation concealment or blinding.
Low quality	Three, or more, domains identified as high risk of bias, or if any two out of the three domains of the randomisation, allocation concealment or blinding identified as high risk of bias.
Clinical controlled trials [(1)]	
Low quality	One or less domains, identified as high risk of bias, unless the one domain is blinding.
Very low quality	The domain of blinding identified as high risk of bias, or any other two domains.

Note (1): In the risk of bias analysis, the CCT's were automatically allocated a high risk of bias for randomisation and allocation concealment. Therefore, these domains were not used to grade the quality of the studies.

2.4 Meta-analysis

Data for the meta-analysis was extracted in to data extraction tables and was checked by a second person prior to meta-analysis (Appendix 3). In studies in which confidence intervals were not presented, the effect size was calculated using the formula advocated by the Centre for Evidence Based Medicine (CEBM calculator, 2013). Once all the data had been extracted from the included studies, and checked for errors, data pertaining to the pre-determined outcomes were tabulated in an Excel spreadsheet in preparation for the meta-analyses using RevMan 5.2, the Cochrane Information Management System. Due to the wide variety of outcomes and interventions acceptable for this review, some a priori meta-analysis guidelines were adopted. This is considered good practice (Higgs & Green, 2011) as it limits the extent of possible sub-group analyses and prevents spurious findings from multiple analyses.

Outcome measures

If studies measured the same outcome using different instruments, in such circumstances, the following hierarchy was adopted: patient reported outcome (single outcome) > patient reported outcome (domain of multi-outcome instrument)>researcher measured>surgeon measured.

Timing of interventions effects

Rehabilitation interventions are provided to either improve the overall health status of patients prior to admission; at the point they are discharged from the care setting back in to

the community, and to improve their long term health status. The effects of the interventions provided were therefore measured at three time points:

1. Pre-surgery: This time point was set to measure the effect of any pre-admission intervention.
2. At point of discharge: This time point was set to measure the effect of any intervention delivered pre-admission or during admission.
3. Long-term follow up (>3 months): this time point measured the long-term effect of all intervention delivered prior to admission, during hospitalisation, or post discharge.

Heterogeneity

Assuming that clinical diversity (also termed clinical heterogeneity) has been accounted for by selecting appropriate studies to combine for meta-analysis, the observed effects between groups may be more different than one would expect from chance alone; this is referred to as statistical heterogeneity (Higgins & Green, 2011). The Cochrane handbook (Higgins & Green, 2011) indicates the following guide to interpreting statistical heterogeneity which is termed the 'I^2' statistic.

- 0% - 40% may not be important
- 30% - 60% may represent moderate heterogeneity
- 50% - 90% may represent substantial heterogeneity
- 75% - 100% considerable heterogeneity

The I^2 statistic also gives guidance on the most appropriate modelling method for meta-analysis. If the I^2 statistic is <60% this indicates only a moderate level of heterogeneity may be present and indicates that a fixed effect meta-analysis model could be appropriate. Above this figure, significant heterogeneity may be present, indicating a random effects model is more appropriate. However, this figure can only be used for guidance as studies with small sample sizes can appear to give a low I^2 statistic, whereas there may well be quite large heterogeneity. Higgins and Thompson (2002) suggest some element of heterogeneity is always likely to be present in clinical studies so the choice of analytical method used for meta-analysis may be irrelevant. Given the Cochrane guidance (Higgins & Green, 2011) recommends considering caution if you have small data sets, the inherent diversity in the timings and nature of the interventions and comparator groups, random effects modelling was chosen for all meta-analyses.

Analysis method: Standardized mean differences were used for all meta-analyses that included outcomes measured by different instruments. When the same instrument was employed in all studies to measure the outcome, mean differences were used. If actual baseline and follow-up data are not presented in the studies, Higgins & Green (2011) suggest it is appropriate to include change from baseline scores in meta-analyses as there is no statistical reason why they should not be combined and the inclusion of more data increases the strength of the findings; hence, any data reported in such a way has been included.

Variance: Different formulae exist to transform standard error to standard deviation. Where studies reported variance in terms of standard error, the RevMan 5.2 'calculator' function was used to convert to an equivalent standard deviation. Where studies provided no

statistical measure of variance other than a mean and range, the range data was used to calculate the SD using the formulae of range/4 for studies with ≥ 15 participants in each group, or range/6 for studies with > 70 participants in each group as advocated by Hazo et al (2005).

Dichotomous outcomes: Odds ratio modelling was used for the meta-analysis of dichotomous outcomes.

2.4.1.1 *Presentation of results of the meta-analyses*

The directionality convention was employed, to assist with clarity for the reader, such that all outcome data is presented with a larger numbers representing worse patient outcomes and a smaller numbers representing better patient outcomes. Where outcome scales included in the meta-analyses varied from this convention with lower scores indicating worse outcomes, their directionality was altered using negative values.

2.4.2 Final quality of evidence: study quality adjustment following meta-analysis

Although meta-analysis is an effective way of synthesising health related evidence, the approach does not accommodate for the quality of the included trials. This method of data synthesis is therefore only acceptable as the sole method of synthesising information when all the included studies are of high methodological quality and the heterogeneity between studies is not high. However, for many aspects of health research, there is limited research and often the studies are of mixed methodological quality, as is the situation in this review.

Several methods of synthesising information have been proposed (Slavin, 1995; Van Tulder et al, 2003; Treadwell et al, 2012). The GRADE working group (2008) developed the strength of evidence approach that allows for aspects of study quality adjusted for bias to be combined with results of the meta-analysis to produce a more comprehensive evaluation of a body of evidence (Owens et al, 2010). A summary of this strength of evidence approach is shown in Figure 16. The full version of this table and the definition of all the terms are presented in Appendix 4. In the GRADE approach all RCTs are initially assumed to be high quality evidence and observational studies low quality; the approach then allows for RCTs and observational studies to be graded by the reviewers on the bias assessment and the findings of the meta-analyses. Inconsistency relates to the degree to which reported effect sizes from included studies appear to have the same direction of effect. Indirectness relates to whether the evidence links the interventions directly to health outcomes. For a comparison of two treatments, directness implies that head-to-head trials measure the most important health or ultimate outcomes. Imprecision is the degree of certainty surrounding an effect estimate with respect to a given outcome (i.e., for each outcome separately). As a meta-analysis was performed, this will be the confidence interval around the summary effect size.

Figure 16 Summary of the (2008) grading recommendations development and evaluation (GRADE) approach to combing quality of evidence with meta-analyses results.

<table>
<tr><th>Study design</th><th>Quality of evidence</th><th>Lower if:</th><th>Higher if:</th></tr>
<tr><td rowspan="4">Randomised trials →

Observational studies→</td><td>High</td><td rowspan="4">Risk of bias
-1 Serious
-2 Very serious

Inconsistency
-1 Serious
-2 Very serious

Indirectness
-1 Serious
-2 Very serious

Imprecision
-1 Serious
-2 Very serious

Publication bias
-1 Likely
-2 Very likely</td><td rowspan="4">Effect size
+1 large
+2 Very large

Dose response
+1 Evidence of a gradient

All plausible confounding
+1 would reduce a demonstrated effect, or

+1 would suggest a spurious effect when results show no effect</td></tr>
<tr><td>Moderate</td></tr>
<tr><td>Low</td></tr>
<tr><td>Very low</td></tr>
</table>

2.5 Results

2.5.1 Results of search

The searches identified 4878 articles, of which 13 duplicates were removed, 4593 were excluded by title alone, and 240 after abstract reading. Twenty nine articles were reviewed in full. Fifteen articles met the eligibility criteria for inclusion in this review (see Figure 17). Twelve of these were randomised controlled trials (Butler, 1996; Crowe, 2003; Ferrara, 2006; Gocen, 2004; McGregor, 2004; Munin, 1998; Peak, 2005; Sandell, 2008; Siggeirsdottir, 2005; Ververeli, 2009; Weaver, 2003; Wong, 1990) and three were controlled clinical trials with a

comparator group (Rivard, 2003; Rosendal, 2000; Tappen, 2002). All eligible articles were written in English; four were conducted in Canada (Butler, 1996; Crowe, 2003; Rivard, 2003; Wong, 1990), five in the USA (Munin, 1998; Peak, 2005; Tappen, 2003; Ververeli, 2009; Weaver, 2003), two in the UK (McGregor, 2004; Sandell, 2008), one in Iceland (Siggeirsdottir, 2005), one in the Netherlands (Rosendal, 2000), one in Turkey (Gocen, 2004) and one in Italy (Ferrara, 2008). The reasons for exclusion of the articles after obtaining the full text are outlined in Table 4.

2.5.2 Risk of bias assessment

The risks of bias assessments of the included studies are reported in Table 5 to Table 19 below in study alphabetical order. A summary of the bias associated with all included studies is shown in Figure 18.

Figure 17: PRISMA Systematic review flow diagram (Moher et al, 2009)

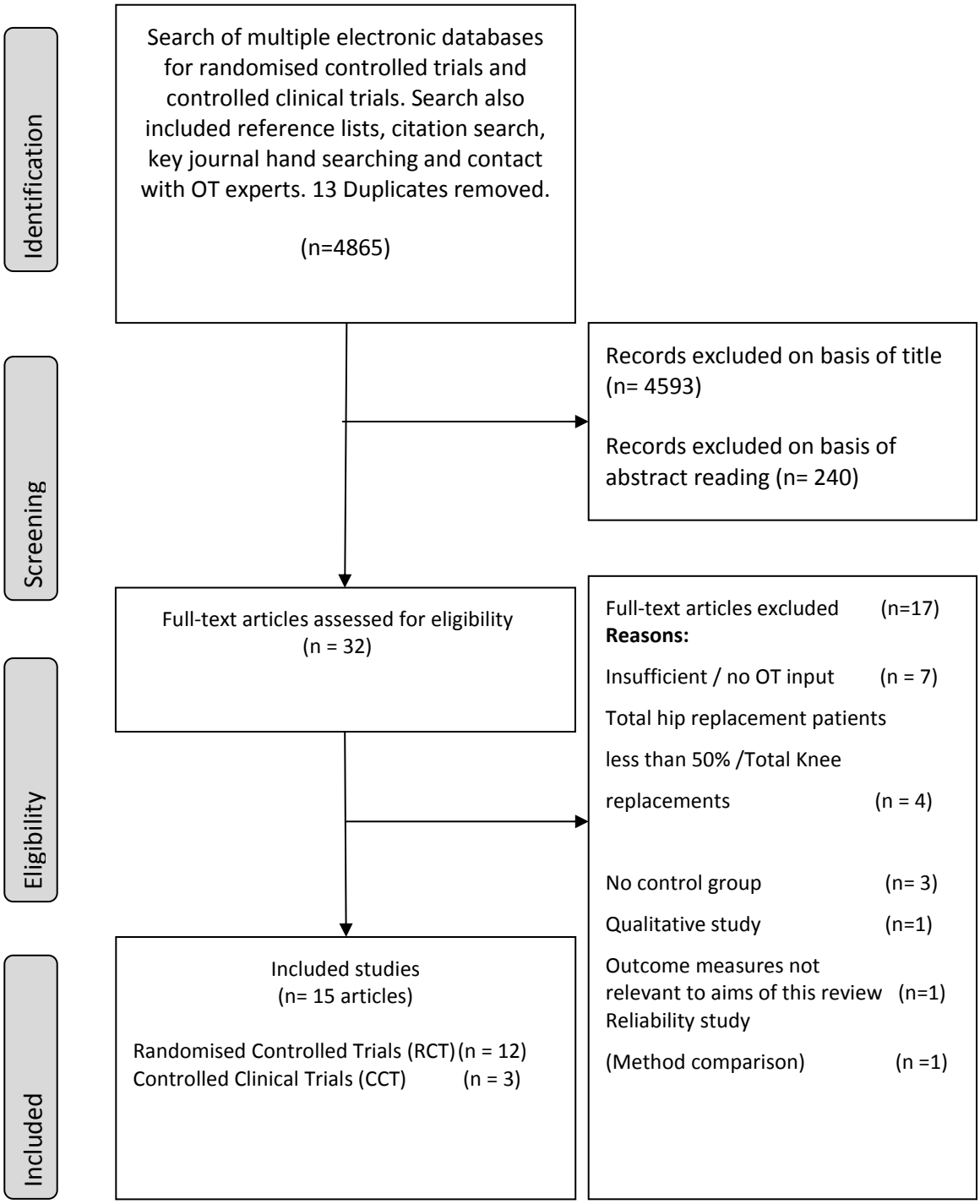


Table 4: Reason for exclusion following screening of full article

Study	Reason for exclusion
Hoffmann (2008)	A method comparison reliability study
Kiefer (2006)	Population = TKR, no control group
Larsen (2008)	Quasi-experimental study analysing coordination and organization of care
Mahomed (2008)	Population = TKR
Moffet (2004)	no OT component identified. Population=TKR, intervention=PT exercices.
Moller (1992)	No OT component identified, Feasibility study of hospital versus home care,
Novalis (2000)	Descriptive study, no intervention or control group
Petersen (2006)	No OT component identified
Petersen (2008)	No OT component identified
Spalding (2003)	Qualitative study
Stevens (2004)	No OT content identified
Trahey (1991)	Outcomes measures do not measure activity or participation. Study designed to measure patients' ability to follow instructions e.g. compliance with hip precautions and attention to safety issued during activities.
Woo (2000)	Observational study with cross-sectional analysis, no before-after intervention comparisons
Mancuso (2008)	Intervention has no OT input, outcome measures not validated and measures expectation, which is not a review outcome.
Daltroy (1998)	Minority THR patients and intervention focus is on psychological profiling in to "deniers" and "copers"
Rodenas-Martinez (2008)	Population = TKR
Bai (2009)	Intervention is predominantly exercise based with insufficient OT content.

Abbreviations: OT, Occupational therapist; PT, Physiotherapist; TKR, total knee replacement
Note: all studies are denoted only by the first author for clarity

2.5.2.1 *Risk of bias tables of included studies*

Table 5 Butler (1996)

Pre-hospital education: effectiveness with total hip replacement surgery patients (Butler, 1996)		
Domain	Judgement	Description
Adequate sequence generation (selection bias)	UNCLEAR Uncertain risk of bias	*"A patient guide booklet was randomly added to half the pre-admission packages mailed out to THR patients"* (p 192) Insufficient information about sequence generation method to permit judgement.
Allocation Concealment (selection bias)	UNCLEAR Uncertain risk of bias	Author additional information: allocation concealed by an admission clerk
Blinding Participants Personnel Outcome assessors (Performance bias)	UNCLEAR Uncertain risk of bias	**Participants:** At the time of booklet mail-out, *"Patients were not informed of the study at this point, and there was no indication that the booklet would be evaluated"* (p 192) **Assessor:** All patients were told about the purpose of the study on the day of admission (except 6 patients who were approached the following day). Content of information given to participants at this time is not clear. **Outcome assessors**: no information provided.
Incomplete outcome data (attrition bias)	Low risk of bias	Consent obtained after randomisation. STAI at admission: 8/80 missing (10%) STAI at discharge: 3/80 missing (3.75%) LOS: 12/80 missing (15%) Data not separated by group assignment. Reasons for missing data not provided. Method of analysis not mentioned though it appears all participants were analysed according to group allocation.
Selective outcome reporting (reporting bias)	UNCLEAR Uncertain risk of bias	No study protocol available which is not unusual for studies of this age.
Other bias	Low risk of bias	43/123 participants were excluded after randomisation as they had previously undergone at least 1 THR. Since prior exposure to THR education and experience with a THR could be expected to weaken the hypothesized influence of the booklet, this was not considered a risk of bias. Patients in the intervention and control groups were not treated differently during their hospital stay. During their care, patients in both groups received education that paralleled the contents of the booklet, so that by the time of discharge, all patients had been exposed to the same information.

Table 6 Crowe (2003)

Pre-arthroplasty rehabilitation is effective in reducing hospital stay (Crowe, 2003)		
Domain	Judgement	Description
Adequate sequence generation (selection bias)	Low risk of bias	*"Subjects were allocated to one of the two groups by means of a random number table"* (p 90)
Allocation Concealment (selection bias)	Low risk of bias	*"using a system of sealed envelopes"* (p 90)
Blinding Participants Personnel Outcome assessors (Performance bias)	Low risk of bias	**Participants:** blinding of participants is unclear, however the review authors judge that the outcomes (meeting discharge criteria) are not likely to be influenced by lack of blinding the participants to group assignment. **Personnel:** Insufficient information to permit judgement of 'yes' or 'no' **Outcome assessors:** "Outcomes (meeting discharge criteria) were measured in hospital by an investigator who was blinded to group allocation" (p 90)
Incomplete outcome data (attrition bias)	Low risk of bias	From author correspondence: Days to meet discharge criteria: Usual care:7/68 missing, Rehab: 6/65 missing LOS: Usual care:1/68 missing, Rehab: 1/65 missing Discharge destination: Usual care:0/68 missing, Rehab: 4/65 missing Reasons for missing data not given.
Selective outcome reporting (reporting bias)	UNCLEAR Uncertain risk of bias	No study protocol available which is not unusual for studies of this age.
Other bias (attention bias)	High risk of bias	At baseline, the control group were significantly more disabled and significantly more anxious. The intervention group received more attention than the controls, which may have introduced attention bias.

Table 7 Ferrara (2008)

Effect of pre-operative physiotherapy in patients with end-stage osteoarthritis undergoing hip arthroplasty (Ferrara, 2008)		
Domain	Judgement	Description
Adequate sequence generation (selection bias)	Low risk of bias	The patients were randomised using a table of random numbers.
Allocation Concealment (selection bias)	UNCLEAR Uncertain risk of bias	Even numbers were allocated to the control group and odd numbers to the intervention group Insufficient information on the allocation concealment process to permit judgement of 'yes' or 'no'
Blinding Participants Personnel Outcome assessors (Performance bias)	Low risk of bias	**Participants:** unable to be blinded **Study personnel:** Physiotherapists providing pre-surgery intervention cannot be blinded. Physiotherapist delivering post-operative rehabilitation was not blinded. This could have led to treatment bias with more rehabilitation/attention given to the control group. **Outcome assessors:** Two research assistants and two physicians who were blinded to the group allocation administered outcome assessment.
Incomplete outcome data (attrition bias)	Low risk of bias	Intervention group: all patients entering study are analysed in T1 (up to 15 days post-surgery) and T4 (3 months post-surgery). Control group: all patients analysed at T1 (up to 15 days post-surgery); at T4 (3 months post-surgery) 2 from 12 (16.66%) patients lost to follow-up. Method of analysis not mentioned but participants analysed in allocated group Loss to follow-up is low enough not to significantly affect analysis.
Selective outcome reporting (reporting bias)	High risk of bias	Only significant data (VAS pain, Hip external rotation) is presented at T3 (4 week follow up) in form of poorly annotated figure with no actual raw data presented. No study protocol available which is not unusual for studies of this age
Other bias (selection bias)	High risk of bias	Patients with end stage hip osteoarthritis did not participate due to difficulties with access and ability to carry out exercises. This can lead to sampling bias as only more able participants took part in the intervention group. Patients with mini mental state examination score of ≤ 23 were excluded which can also lead to sampling bias and population not representative.

Table 8 Gocen (2004)

The effect of preoperative physiotherapy and education on the outcome of total hip replacement: a prospective randomized controlled trial (Gocen, 2004)		
Domain	Judgement	Description
Adequate sequence generation (selection bias)	Low risk of bias	Patients randomly divided in to two groups by using a table of random numbers of a computer programme (Excel 2000).
Allocation Concealment (selection bias)	UNCLEAR Uncertain risk of bias	Even numbers were allocated to the control group and odd numbers to the intervention group Insufficient information on the allocation concealment process to permit judgement of 'yes' or 'no'.
Blinding Participants Personnel Outcome assessors (Performance bias)	Low risk of bias	**Participants:** not possible **Study personnel:** pre-operatively the physiotherapy providing the intervention could not be blinded. The physiotherapist providing post-operative rehabilitation was blinded. It is not reported if other hospital staff were blinded to group allocation. **Outcome assessor:** a staff physiotherapist who was blinded to the study performed all measurements. Results assessed in a blinded fashion.
Incomplete outcome data (attrition bias)	Low risk of bias	All control patients followed up at all measurement stages throughout the study. One patient dropped out of the intervention group following the 8-week assessment. All other 29 followed up to the end of the study. No study protocol available which is not unusual for studies of this age.
Selective outcome reporting (reporting bias)	UNCLEAR Uncertain risk of bias	Absolute pain and hip abduction data is not presented on change score from pre-operative assessment to discharge. Pain is not recorded at 3 month and 1-year follow-up. The authors report patients were assessed at 1 year which was the last follow-up period in the flow diagram. However, no data is presented for this measurement stage and Harris Hip Score data for a 2-year follow-up period.

Other bias (attention bias, selection bias, recording bias)	High risk of bias	Baseline characteristics only recorded for patients in the intervention group. Patients in intervention group received a lot more attention; therefore, attention bias is possible. Patients in intervention group were significantly younger than those in the control (*p*=0.01, (I) 46.95, SD±11.48; (C) 55.50 SD±14.44) The average age of patients in both arms of this study is not representative of the typical population who undergo THR due to osteoarthritis. Only one physiotherapist was recording the first day of activities. It is therefore possible for recoding bias to occur as transfer activates may have begun when the physiotherapist was not working.

Table 9 McGregor (2004)

Does preoperative hip rehabilitation advice improve recovery and patient satisfaction (McGregor, 2004)		
Domain	Judgement	Description
Adequate sequence generation (selection bias)	UNCLEAR Uncertain risk of bias	*"At preadmission, patients were allocated randomly into either group A or group B"* (p 465) *"patients were randomized by age and not functional status"* (p 465) Author correspondence: Random blocks
Allocation Concealment (selection bias)	Low risk of bias	No information provided Author correspondence: Concealed envelopes
Blinding Participants Personnel Outcome assessors (Performance bias)	UNCLEAR Uncertain risk of bias	**Participants:** Not possible **Personnel:** Insufficient information is provided as to the blinding status. This is considered low risk of bias. **Outcome assessors:** Insufficient information is provided as to the blinding status to permit judgement of 'yes' or 'no'.
Incomplete outcome data (attrition bias)	Low risk of bias	Numbers of participants analysed for each outcome are not presented in published article. Maximum number of observations taken from final report, provided by the author: Pre-admission: Group A=16/16, Group B=20/20 Admission: Group A=14/16, Group B=20/20 Discharge: Group A=14/16, Group B=20/20 *"The data generated were analysed using an unbalanced analysis of variance"* (p 466) Author correspondence: An unbalanced ANOVA was required as occasionally review assessments were missed for varying reasons. Reasons not given.
Selective outcome reporting (reporting bias)	UNCLEAR Uncertain risk of bias	Protocol for study is not available which is not unusual for studies of this age. Incomplete reporting of psychological measures. Satisfaction and EQ-5D presented as graphs with no raw data available. Discussion is in text that all unreported data was not significant.
Other bias (selection bias, attention bias)	UNCLEAR Uncertain risk of bias	Large differences between groups at baseline. The intervention group were younger, had a shorter duration of symptoms and spent less time on the hospital waiting lists then the control group. Intervention group received more attention than the controls, which may have introduced attention bias.

Table 10 Munin (1998)

Early Inpatient Rehabilitation After Elective Hip and Knee Arthroplasty (Munin, 1998)		
Domain	Judgement	Description
Adequate sequence generation (selection bias)	Low risk of bias	Random listing of 100 numbers, using zero to equal day 3 group and 1 to equal day 7 group, was generated in blocks of 10.
Allocation Concealment (selection bias)	Low risk of bias	Generated random numbers were stored in locked cabinet and administered by blind executor.
Blinding Participants Personnel Outcome assessors (Performance bias)	UNCLEAR Uncertain risk of bias	**Participants:** No information provided **Personnel**: discharge from rehabilitation unit determined by interdisciplinary team of clinicians, some of whom were not blinded to randomization. However, standardized, objective criteria used for discharge. **Outcome assessors**: insufficient information to permit judgement.
Incomplete outcome data (attrition bias)	Low risk of bias	Of 86 randomised, 71 completed rehab (15 (17%) lost to follow-up). FIM Days 1-5: study group = 14/14, control group = 11/12 Days 6-10: study group = 14/14, control group = 11/12 Loss to follow-up balanced between groups
Selective outcome reporting (reporting bias)	UNCLEAR Uncertain risk of bias	Study protocol is not available which is not unusual for studies of this age.
Other bias (attention bias)	UNCLEAR Uncertain risk of bias	Clients in the intervention group received more rehabilitation than the controls, which may have introduced attention bias.

Table 11 Peak (2005)

The role of patient restrictions in reducing the prevalence of early dislocation following total hip arthroplasty: a randomized, prospective study (2005).		
Domain	Judgement	Description
Adequate sequence generation (selection bias)	Low risk of bias	Participants were randomised using a random number table (p 249)
Allocation Concealment (selection bias)	Low risk of bias	Randomisation performed pre-operatively. Sealed-envelope opened at the end of surgery by the study coordinator. Designation of the patient "*double-blinded until completion of wound closure to avoid patient selection bias or alteration in surgical technique*" (p 249)
Blinding Participants Personnel Outcome assessors (Performance bias)	High risk of bias	**Participants*:*** unable to be blinded **Personnel*:*** unable to be blinded **Outcome assessors:** Participants self-completed questionnaires at 6 weeks and 6 month from home and posted them back to the research team. "*The accuracy of the patient reported information was by discussion with family members and health care personnel"* (p 249) No mentioning of assessor blinding and discussion of accuracy suggests blinding cannot be assured.
Incomplete outcome data (attrition bias)	Low risk	All participants who were randomised were accounted for in the follow-up data
Selective outcome reporting (reporting bias)	UNCLEAR Uncertain risk of bias	Study protocol is not available which is not unusual for studies of this age.
Other bias (selection bias)	UNCLEAR Uncertain risk of bias	*"..the number of patients who required a rehabilitation stay was significantly higher in the restricted group than in the unrestricted group (125 hips compared with 100 hips; p < 0.002)"* (p 251). This could indicate the restricted group were more functionally disabled as they would not stay in hospital any longer than required or there was delay in discharge.

Table 12 Rivard (2003)

The efficacy of pre-operative home visits for total hip replacement clients (Rivard, 2003)		
Domain	Judgement	Description
Adequate sequence generation (selection bias)	High risk of bias	*"The distribution of clients to one or the other hospital depended on the retrospective surgeons' admitting privileges"* (p 229)
Allocation Concealment (selection bias)	High risk of bias	*"The clients were assigned to a cohort based on the location of their surgery"* (p 230)
Blinding Participants Personnel Outcome assessors (Performance bias)	Low risk of bias	**Participants:** length of stay is unlikely to be influenced by lack of blinding the participants. **Personnel:** prospective chart review with intervention based on hospital location. The review authors judge that the primary outcome (length of stay) may be influenced by lack of blinding of hospital staff. **Outcome assessors:** not blinded but unlikely to affect the outcome.
Incomplete outcome data (attrition bias)	Low risk of bias	The authors state that all 268 clients who consented to participate were included in the analysis. However, numbers of participants not reported in the results tables.
Selective outcome reporting (reporting bias)	UNCLEAR Uncertain risk of bias	The study protocol is not available but this is not unusual for studies of this age
Other bias (deviation from protocol)	High risk of bias	Outcomes (LOS and Discharge destination) influenced by hospital (and therefore group) e.g. bed pressures. *"Some clients in the study reported anecdotally that they could have been discharged directly home if they had been able to remain in the acute facility one or two days more. However bed pressures were as such that they were discharged to the sub-acute facility, and once there, remained for an additional 5 days"* (p 231)

Table 13 Rosendal (2000)

Can shared care deliver better outcomes for patients undergoing total hip replacement (Rosendal, 2000)		
Domain	Judgement	Description
Adequate sequence generation (selection bias)	High risk of bias	No randomisation. *"The assignment to either one of the two settings is dependent on the place of residence of patients"* (p 3) *"Randomisation of patients in order to eliminate selection bias within one setting was not possible."* (p 7)
Allocation Concealment (selection bias)	High risk of bias	Investigators enrolling participants could foresee assignments and thus introduce a selection bias. Control group and intervention group were based at two different hospitals so researchers would be aware of allocation
Blinding Participants Personnel Outcome assessors (Performance bias)	UNCLEAR Uncertain risk of bias	**Participants:** they were blind to intervention *"They did not know whether their setting was considered as the experimental or the control setting in this study"* (p 2) **Personnel:** Insufficient information to permit judgement of 'yes' or 'no' **Outcome assessors**: Insufficient information to permit judgement of 'yes' or 'no'
Incomplete outcome data (attrition bias)	Low risk of bias	No missing outcome data All patients reported to be involved in study are accounted for in outcome measures post intervention and at 6 month follow-up
Selective outcome reporting (reporting bias)	UNCLEAR Uncertain risk of bias	The study protocol is not available but this is not unusual for studies of this age.
Other bias	UNCLEAR Uncertain risk of bias	Insufficient information to assess if other risks of bias exist.

Table 14 Sandell (2008)

A multidisciplinary assessment and intervention for patients awaiting total hip replacement to improve quality of life (Sandell, 2008)		
Domain	Judgement	Description
Adequate sequence generation (selection bias)	Low risk of bias	Randomisation performed using a computer generated randomisation table.
Allocation Concealment (selection bias)	Low risk of bias	Participants given a study number after they had agreed to join the trial. The number corresponded to a numbered sealed envelope containing the group allocation.
Blinding Participants Personnel Outcome assessors (Performance bias)	UNCLEAR Uncertain risk of bias	**Participants:** unable to be blinded **Personnel:** unable to be blinded **Outcome assessors:** Insufficient information provided as to the blinding status to permit judgement of 'yes' or 'no'.
Incomplete outcome data (attrition bias)	High risk of bias	Eighty-nine patients entered the study but only sixty-six completed (26% loss to follow-up). Not all reason for loss accounted for. No intention to treat analysis.
Selective outcome reporting (reporting bias)	UNCLEAR Uncertain risk of bias	The study protocol is not available but this is not unusual for studies of this age.
Other bias (attention bias, researcher bias)	High risk of bias	Patients in intervention group received a lot more attention than those in the control, which can introduce attention bias. Only one author attributed to study and no acknowledgements. Whole study appears to be performed by one researcher who inputted outcome measure data and performed analysis of results.

Table 15 Siggeirsdottir (2005)

Short hospital stay augmented with education and home based rehabilitation improves function and quality of life after hip replacement (Siggeirsdottir, 2005)		
Domain	Judgement	Description
Adequate sequence generation (selection bias)	UNCLEAR Uncertain risk of bias	Participates were randomised in to one of the two groups by opening a sealed envelope containing a note indicating which group the patient was to be allocated. Insufficient information about sequence generation method to permit judgement.
Allocation Concealment (selection bias)	Low risk of bias	Sealed envelopes used
Blinding Participants Personnel Outcome assessors (Performance bias)	UNCLEAR Uncertain risk of bias	**Participants:** Participants could not be blinded to the intervention as it required home visits to take place. Review authors judgement is that the outcome is not likely to influenced by this lack of blinding as they would be unaware of what was the normal care provided **Personnel:** OT & PT staff had to administer the intervention. Insufficient information to permit judgement of 'yes' or 'no' as to if they were aware of the participants involvement in the study **Outcome assessors**: Insufficient information to permit judgement of 'yes' or 'no'
Incomplete outcome data (attrition bias)	Low risk of bias	Only 1 participant outcome data missing at the 4 month follow up. Otherwise, all patients reported to be involved in study are accounted for in outcome measures at all other measurement intervals. The missing outcome data not enough to have a clinically relevant impact on observed size effect.
Selective outcome reporting (reporting bias)	UNCERTAIN Unclear risk of bias	The study protocol is not available which is not unusual for studies of this age.
Other bias (deviation from protocol)	High risk of bias	Changes were required to the study after the original protocol had been accepted as the university hospital had a major reorganisation affected the study resulting in uneven contribution to the study from the two hospital sites originally identified. This is a major deviation from original protocol

Table 16 Tappen (2003)

Effect of a video intervention on functional recovery following hip replacement and hip fracture repair (Tappen, 2003)		
Domain	Judgement	Description
Adequate sequence generation (selection bias)	High risk of bias	Randomization to intervention or control groups was not possible because of institutional constraints and concerns about contamination of control subjects potentially viewing the videotaping of treatment subjects during therapy sessions.
Allocation Concealment (selection bias)	High risk of bias	Data collected on all comparison subjects before the tapings to prevent contamination of the intervention group. Investigators enrolling participants could foresee assignments and thus introduce a selection bias.
Blinding Participants Personnel Outcome assessors (Performance bias)	UNCLEAR Uncertain risk of bias	**Participants:** insufficient information to permit judgement. However, participants likely to be aware. This is considered low risk of bias **Personnel:** unlikely as videos made during physiotherapy sessions. This is considered low risk of bias **Outcome assessors**: insufficient information to permit judgement.
Incomplete outcome data (attrition bias)	UNCLEAR Uncertain risk of bias	Attrition after admission to study was 39/121 (32%) due to unavailability for follow-up (26), discharge before testing or taping (10), illness/ death (3). Insufficient information to identify if there is any missing data from outcome measures. Method of analysis not mentioned though it appears all participants were analysed according to group allocation.
Selective outcome reporting (reporting bias)	UNCLEAR Uncertain risk of bias	Study protocol is not available which is not unusual for studies of this age.
Other bias	Low risk of bias	The intervention group was significantly older and had more chronic illnesses than the control group; however, this is accounted for in the analysis.

Table 17 Ververeli (2009)

Evaluation of reducing postoperative hip precautions in total hip replacement: a randomized prospective study (2009)		
Domain	Judgement	Description
Adequate sequence generation (selection bias)	Low risk of bias	*"Group assignment were generated by the research coordinator using a random number table"* (p 2)
Allocation Concealment (selection bias)	Low risk of bias	Sealed envelopes used
Blinding Participants Personnel Outcome assessors (Performance bias)	High risk of bias	**Participants:** unable to be blinded **Personnel:** unable to be blinded **Outcome assessors:** Insufficient information provided as to the blinding status to permit judgement. Method by which follow-up data is recorded is very poorly documented and open to bias.
Incomplete outcome data (attrition bias)	Low risk of bias	All participants randomised in to the study are shown in the results table. Reporting of data is generally poor.
Selective outcome reporting (reporting bias)	High risk of bias	Very limited data provided on Harris Hip Score, Short-Form 12 (mental & physical) or patient satisfaction. Not all data for all time points of collection was presented in results that were reported in abstract. Also in the abstract it is mentioned that follow up data is collected *at "4 weeks, 1 month, 3 month and 1 year".* (p 1)
Other bias	UNCLEAR Uncertain risk of bias	Insufficient information to assess if other risks of bias exist. Study poorly reported.

Table 18 Weaver (2003)

Comparison of two home care protocols for total joint replacement (Weaver, 2003)		
Domain	Judgement	Description
Adequate sequence generation (selection bias)	Low risk of bias	*"Consenting TJR patients were stratified by type of procedure (Unilateral TKR, bilateral TKR or THR) and randomly assigned within each stratum…"* (p 524)
Allocation Concealment (selection bias)	UNCLEAR Uncertain risk of bias	The comment "*To preserve integrity of the intervention and prevent contamination between treatment and control conditions, only staff from the city-wise agency were trained in the treatment protocol"* (p 524) suggests allocation concealment was considered. However, Insufficient information on the sequence generation process is provided to permit judgement of 'yes' or 'no'
Blinding Participants Personnel Outcome assessors (Performance bias)	UNCLEAR Uncertain risk of bias	**Participants**: blinding to intervention is not possible as a home visit before surgery in the intervention group had to be pre-arranged with the participant. This should not be considered as source of bias **Personnel:** Initial home visit by nurse who could not be blinded to this as it was not customary practice. Insufficient information is provided as to the blinding status of the PTs & OTs providing the treatment in control & intervention group. **Outcome assessor** insufficient information is provided as to the blinding status the personnel administering the outcome measurements. In summary, the lack of information for all personnel associated with this study signifies an uncertain risk of bias.
Incomplete outcome data (attrition bias)	Low risk of bias	Intervention Control @ baseline n = 69 n = 67 @ 1 month FU n = 65 n = 65 @ 6 month FU n = 61 n = 62 Loss of 2 participants from the intervention group and 1 from the control group due to mortality. Other losses not explained other than *"No significant differences were seen in rates of attrition by group, and overall attrition was low; 91% completed 6 month post-test"*(p 526) The missing outcome data not enough to have a clinically relevant impact on observed size effect.
Selective outcome reporting (reporting bias)	UNCLEAR Uncertain risk of bias	The study protocol is not available which is not unusual for studies of this age.

Other bias (selection bias)	UNCLEAR Uncertain risk of bias	*"Main reason for ineligibility for inclusion in the study was lack of Medicare coverage"* (p 525); 46% of excluded participants were due to this. Most participants were living with person capable of assisting with care (86% and 90%). This sample groups are not fully representative of society limiting the applicability of its findings. This is not explored by the author.

Table 19 Wong (1990)

Effects of an experimental program in post-hospital adjustment of early discharged patients (Wong, 1990)		
Domain	Judgement	Description
Adequate sequence generation (selection bias)	UNCLEAR Uncertain risk of bias	*"A list of patients scheduled for a total hip replacement operation between 1 February 1986 and 31 December 1987, was secured from five orthopaedic surgeons. The patients were then randomly assigned to one of three groups"* (p 10). No information provided on the sequence generation
Allocation Concealment (selection bias)	UNCLEAR Uncertain risk of bias	*"The impartial observers (no's 2 and 3) knew neither the specific objectives of the study nor whether a patient being observed was in the experimental or control group, although they occasionally deduced some patients"* (p 13). This statement indicates there was an attempt to maintain allocation concealment though there is insufficient information to confirm.
Blinding Participants Personnel Outcome assessors (Performance bias)	Low risk of bias	**Participants:** unable to be blinded **Personnel:** unable to be blinded **Outcome assessors:** impartial observers used (p 13)
Incomplete outcome data (attrition bias)	UNCLEAR Uncertain risk of bias	It is not possible to work out if all participants were accounted for as only summary statistics are presented in the article. Unable to contact author for confirmation.
Selective outcome reporting (reporting bias)	UNCLEAR Uncertain risk of bias	No study protocol available which is usual for studies of this age. No data presented other than *p*-values.
Other bias (attention bias, performance bias)	High risk of bias	Participants in the early discharge group received more attention and reinforcement of the intervention. *"During these visits, the research assistant reinforced patient learning initiated at hospital, assessed these patients' performance of home exercises, and reminded them to carry out exercises regularly. Her visits to these patients one week after discharge seemed critical, as many of them raised numerous questions concerning after-care. The control patients received some information on home exercises, but their learning was neither reinforced nor monitored."* (p 16)

Figure 18: Summary risk of bias chart (Higgins, 2011)

	Adequate sequence generation	Allocation Concealment	Blinding [1]	Incomplete outcome data addressed at follow-up	Free from selective outcome reporting	Free from other bias	GRADE adjusted quality of evidence
Butler (1996)							High
Crowe (2003)							High
Ferrara (2008)							Moderate
Gocen (2004)							High
McGregor (2004)							High
Munin (1998)							High
Peak (2005)							Moderate
Rivard (2003)[2]							Low
Rosendal (2000) [2]							Low
Sandell (2008)							Moderate
Siggeirsdottir (2005)							Moderate
Tappen (2003) [2]							Low
Ververeli (2009)							Low
Weaver (2003)							High
Wong (1990)							Moderate

	Low risk of bias
	Uncertain risk of bias
	High risk of bias

Note [1]: The bias associated with blinding has been determined by the status of outcome assessor only.

Note [2]: These are controlled clinical trials. For the risk of bias assessment they have been allocated a high risk of bias in the domains of 'adequate sequence generation' and 'allocation concealment'.

The analysis of the included trials shows that only four of the trials were free from at least one source of bias (Butler, 1996; McGregor, 2004; Munin 1998; Weaver, 2003). Of these four, only the trial by Munin (1998) had three criteria assessed as being a low risk of bias; the other studies having only two criteria assessed as low. Despite contact with authors (Munin 1998, McGregor, 2004, Siggeirsdottir, 2005), many risk categories were still unclear, making the overall classification of the quality of the studies uncertain. Additionally, as none of these studies had prior protocols published, establishing the risk of bias for selective outcome reporting was hard to establish such that an uncertain risk of bias was allocated. Only the study by Crowe (2003) had four or more criteria assessed as being of low risk. In four studies (Butler, 1996; Peak, 2005, Ververeli, 2009, Weaver, 2003), the outcome assessors were not blinded which is considered as a potential source of bias. In the studies by Butler (1996) and Weaver (2003), the outcomes were assessed by patient completed questionnaires, so both were allocated an uncertain risk of bias. However, in the other two studies (Peak, 2005, Ververeli, 2009) some of the outcomes were assessed by members of the research team who were aware of group allocation, so these have been graded as containing a high risk of bias.

Overall, six of the 12 RCT's were graded as high quality studies (Butler, 1996; Crowe, 2003; Gocen, 2004; McGregor, 2004; Munin 1998; Weaver, 2003); five moderate quality studies (Ferrara, 2008; Peak, 2005; Sandell, 2008; Siggeirsdottir, 2005; Wong, 1990) and one a low quality study (Ververeli, 2009). All three CCT's were graded as low quality (Rivard, 2003; Rosendal, 2000; Tappen, 2003).

2.5.3 Description of studies

The characteristics of the included studies are shown in Table 20 and the nature and timing of the intervention is shown in Table 21.

2.5.3.1 *Participants*

These trials contained 1,509 participants in total, of which 1396 (92.5%) underwent a THR. The number of participants in each trial was small with a median value of 86 (range 23 to 303) and the mean age of the participants in each trial was similar with a range of mean ages from 51.2 to 74.0 (weighted mean 66.2, SD±6.1). Three trials (McGregor, 2004; Tappen, 2003; Peak, 2005) did not report gender; 424 (28%) of all participants did not have gender reported. In the trials that reported gender, 700 (64.5%) of the participants were female and 385 (35.5%) male. This gender difference was most extreme in the study by Weaver (2003) which had 126 (86.3%) females as compared to only 20 (13.7%) males. Only Gocen (2004) contained more male 38 (64%) than female 21 (36%) participants.

The majority of participants underwent joint replacement surgery due to osteoarthritis with the exception of Tappen (2003) where 50% of the participants underwent hip fracture repair (precise surgical procedure not reported). All participants in Gocen (2004) received a THR, with 29 (49%) being due to primary osteoarthritis and 30 (51%) due to secondary osteoarthritis; 13 (22%) as a result of development dysplasia, 10 (17%) due to idiopathic avascular necrosis of the hip, and 7 (12%) as a result of hip fracture. Eight of the trials specifically excluded participants undergoing revision surgery (Butler, 1996; Crowe, 2003; Ferrara, 2006; McGregor 2004; Peak, 2005; Rivard, 2003, Ververeli, 2009). In five trials, the

inclusion or exclusion of revision surgery is not explicitly reported (Gocen, 2004; Sandell, 2008; Tappen, 2003; Weaver, 2003; Wong, 1990). Participants undergoing hip revision surgery were included in two studies, and both studies contained similar percentages. Munin (1998), contained n=4 (28.8%) participants undergoing revision surgery in the intervention group, and n=5 (41.5%) in the control; Rosendal (2000), contained n=19 (44%) in the intervention group and n=15 (25%) in the control.

Only two trials included all participants due to undergo surgery as a consequence of hip OA, with no other exclusion criteria, which makes these truly representative of the actual population receiving total hip replacements (Sandell, 2008; Weaver, 2003). Eight studies excluded patients with cognitive impairment; Tappen (2003) excluded participants with a Mini Mental Exam score <20 and Ferrara (2008) with a score ≤23. McGregor (2004) excluded patients who were 'mentally confused' (method of evaluation not reported). Patients with Alzheimer's or dementia were excluded by Peak (2005), Rosendal (2003), Siggeirsdottir (2005) Ververeli (2009) and Wong (1990). Wong (2009) also excluded patients with "*manifest abnormality of mental state*" *(p 10)*, though the method of evaluation is not reported. The Peak (2005) study included Alzheimer's disease as an exclusion criterion, though the authors state no patients were excluded due to this. As this study had the second lowest average age (58.3) of all the included studies, this may explain why no one was excluded as the prevalence of all-cause dementia is less than 1% for people under 60 (Alzheimer's Society, 2014). However, as the average age of all patients in the Peak (2005) study is 7.9 years younger than the overall average age of all patients included in this review (66.2), and 9.3 years younger than average for the concurrent time frame of this study in

England and Wales (NJR, 2005), this may suggest there was a potential element of recruitment bias. Ververeli (2009) also excluded participants who were either under 21, weighed greater than 275 pounds and those unable to ambulate greater than 30 feet without an assistive device.

Four studies excluded patients who were not fluent in reading/writing the native language (Butler, 1996; McGregor, 2004; Rosendal, 2003; Tappen, 2003). Five studies excluded participants with co-morbidities; Gocen (2004) excluded participants with any chronic disease, McGregor (2004)excluded cardiovascular, respiratory and neuromuscular diseases, Ferrara (2008) Parkinson's disease and sensitive neuropathy, Peak (2005) "*neuromuscular compromise p.248)*" such as hyper flexibility syndrome or Parkinson's Disease, and Wong (2009) "*severe diseases such as peripheral vascular disease or RA of the lower extremities*" and "*apparent visual and/or auditory impairment (p.10)*". In contrast, the inclusion criteria for the Munin (1998) trial were participants who were identified as at risk for delayed discharge and therefore would require in-patient rehabilitation (≥70 and living alone, ≥70 with 2 co-morbidities, or any age with 3 co-morbidities). Crowe (2003) only included patients who were not coping well because of their joint dysfunction, and had limited social support and/or co-morbid medical conditions. Patients with good social support networks or who could cope well alone with activities of daily living were specifically excluded.

Of the included trials, twelve trials had interventions directed solely at patients undergoing THR (Butler, 1996; Ferrara, 2006; Gocen, 2004; McGregor, 2004; Munin, 1998; Peak (2005); Rivard, 2003; Rosendal, 2000; Sandell, 2008; Siggeirsdottir, 2005; Ververeli, 2009; Wong,

1990); , two directed at THR or TKR patients (Rivard, 2003; Weaver, 2003), and one for THR or hip fracture repair (Tappen, 2003).

2.5.3.2 *Interventions*

An inherent characteristic of complex interventions is that they exhibit a wide variation in content. Even though the specific content is different they can be classified by the time point(s) the interventions were delivered in the trials. Eight studies compared a pre-admission intervention with the usual care (Butler, 1996; Crowe, 2003; Ferrara, 2006; Gocen (2004) McGregor, 2004; Rivard, 2003; Rosendal, 2000; Sandell, 2008). Two of these studies (Rosendal, 2000; Weaver, 2003) evaluated home based interventions against the usual care situation where the similar rehabilitation services were provided post operatively. Two studies (Rivard, 2003; Siggeirsdottir, 2005) evaluated interventions that contained both pre and post-surgery components. Three studies compared an alternative post-surgery intervention with the usual post-surgery care (Munin, 1998; Tappen, 2003; Wong 1990). The Wong (1990) study had two experimental groups; one group received the enhanced post-surgery education package and home care experimental intervention alongside the normal in-patient care and usual LOS, the other experimental group only received the intervention package but were discharged earlier than usual. Two studies compared the usual care against removal of most post-surgery restrictions with no provision of the adaptive devices usually provided by OTs to reduce the risk of dislocation (Peak, 2005; Ververeli, 2009).

Table 20 Characteristics of included studies

Study	Study design Start date	Participants	Intervention	Outcomes	Notes
Butler (1996)	Quasi-RCT September 1993	I: 32 (18 female, 14 male, mean age 63.86) 100% THR C: 48 (22 female, 26 male, mean age 61.83) 100% THR F/U Day of Discharge	I: Pre-admission education booklet C: Usual care – same information as in pre-admission booklet given following admission	State-Trait Anxiety Inventory, patient satisfaction questionnaire, exercise log and details of home adaptations, LOS	Country: Canada
Crowe(1) (2003)	RCT Not stated	I: 65 (51 female, 14 male, mean age 66.9) THR 55%; TKR 45% C: 68 (55 female,13 male, mean age 70.7) THR 43%; TKR 57% F/U Day of admission	I: Usual care plus pre admission bespoke rehabilitation package including education, advice, home adaptations, provision of adaptive devices, social work and counselling input as required. C: Usual care –single 7 hour pre-operative clinic visit approximately 2 weeks pre-surgery.	State-Trait Anxiety Inventory, time to meet discharge criteria, LOS	Country: Canada
Ferrara(1) (2006)	RCT January 2006	I: 11 (7 female, 4 male, mean age 63.82) 100% THR C: 12 (7 female, 5 male, mean age 63.08) 100% THR F/U Day before surgery, 15 days, 4 weeks, 3 months	I: 5 day pre-admission intervention package 1 month before admission consisting of exercise, postural advice, advice on movement restrictions and prevention of prosthesis dislocation, use of devices (crutches, elevated toilet sets, bed raises, dressing/undressing adaptive devices), washing and bathing(2). C: No pre-admission intervention.	WOMAC, SF-36, VAS (pain), Barthel, hip strength and range of movement.	Country: Italy
Gocen(2) (2004)	RCT Not stated	I: 30 (13 female, 16 male, mean age 46.93) 100% THR C: 30 (8 female, 22 male, mean age 55.5±14.44) 100% THR. F/U Day of discharge, 3 months, two years	I: Pre-operative exercises plus OT based education class (movement restriction, use of adaptive devices, lifting and carrying, washing and dressing. C: Usual care: no pre-operative intervention	Harris Hip Score, VAS (pain) Days to achieve functional milestones (Walking, stairs, bed transfer, toilet transfer, chair transfer	Country: Turkey Demographic data taken on day of discharge, not baseline, 1 participant withdrew before baseline taken

Table 20 Characteristics of included studies (continued)

Study	Study design Start date	Participants	Intervention	Outcomes	Notes
McGregor (2004)	RCT Not stated	I: 19 (mean age 70.8) 100% THR C: 20 (mean age 72.8) 100% THR Gender not reported F/U Day of admission, discharge, 3 months	I: Pre-admission hip class plus education booklet C: Usual care – not stated	WOMAC, Harris Hip Score, Barthel ADL, Positive-affect Negative-affect scale, Helplessness subscale of Rheumatology attitudes index, Cantril life satisfaction ladder, VAS (pain, fatigue and function), EQ-5D	Country: UK
Munin (1998)	RCT August 1993	I: 14 (12 female, 2 male, mean age 75.7) 100% THR C: 12 (10 female, 2 male, mean age 74) 100% THR F/U 4 months	I: phased post-operative rehabilitation starting day 3 post surgery. C: Usual care – rehabilitation starting day 7 post surgery	Functional status Index, RAND-36, LOS, Complications	Country: USA Mixed study of THR/TKR with data presented separately. Participants high risk for delayed discharge home
Peak (2005)	RCT March – December 2002	I: 151 C: 152 126 female, 139 male, mean age 58.3 100% THR F/U 6 weeks, 6 months	I: Reduced restrictions with advice to only limit flexion to <90°, internal and external rotation to <45% and no adduction for first 6 weeks. No other precautions required. C: Usual care - Precautions as for intervention group plus use of abduction pillows in bed, elevated toilet seats and elevated chairs in the hospital, in the rehabilitation facility, and at home; and were prevented from sleeping on the side, from driving, and from being a passenger in an automobile for first 6 weeks.	Dislocation, limp, LOS, Cost. Patient compliance, satisfaction and time to return to activities of daily living measured using 'standardised questionnaire'.	Country: USA

Table 20 Characteristics of included studies (continued)

Study	Study design Start date	Participants	Intervention	Outcomes	Notes
Rivard (2003)	CCT January 1996	I:102 (62 female, 40 male, mean age 66.97) 100% THR C:104 (61 female, 43 male, mean age 67.4) 100% THR F/U Day of discharge	I: Pre-admission home visit by OT: education, advice, home assessment and adaptations, discharge preparations made. C: Usual care – hospital based OT assessment in a group setting. Therapists relied on client/family reports detailing their home environment to inform discharge planning.	LOS	Country: Canada Convenience sampling from two hospitals. Both hospital adopted the same in-hospital care map
Rosendal (2000)	CCT December 1996	I:56 (45 female, 16 male, mean age 69.8) 100% THR C:59 (49 female, 10 male, mean age 67.2) 100% THR F/U 6 months	I: Pre-admission home visit by home care coordinator (3): education, advice, home assessment. Home adaptations and discharge care preparations prior to discharge. C: Usual care – any required home adaptations and discharge care during hospitalisation or after discharge.	Sickness Impact profile-68, Hip rating-questionnaire, Patient satisfaction questionnaire	Country : Netherlands Convenience sampling from two hospitals with comparable social and cultural circumstances. Primary and revision surgery patients included
Sandell (2008)	RCT Not stated	I: 43 (23 female, 10 male mean age 70.33) 100% THR C: 46 (18 female, 12 male, mean age 65.8) 100% THR FU day of admission	I: Preadmission multidisciplinary intervention by physiotherapist (exercises and gait improvement), nurse (additional advice). Pre-operative OT home assessment of functional constraints and provision of adaptive devices. C: No additional pre-operative treatment by OT or PT and standard advice from nurse	Arthritis Impact Measure Score 2, Nottingham Health Profile.	Country: UK. Convenience sampling from patients on waiting list for THR surgery. Only 33 intervention and 30 control at FU analysis.

Table 20 Characteristics of included studies (continued)

Study	Study design Start date	Participants	Intervention	Outcomes	Notes
Siggeirsdottir (2005)	RCT December 1997	I: 27 (14 female, 13 male, mean age 69) 100% THR C:23 (12 female, 11 male, mean age 66) 100% THR F/U 2, 4, 6 months	I: Pre-admission training and education programme. Post discharge home PT/OT/nurse input as required C: Usual care – not specified	Oxford Hip Score, Nottingham Health Profile, Harris Hip Score, Meurle d'Abuigne and Postel score	Country: Iceland Included THR for RA, hip fracture, femoral head collapse or Perthes disease. 90% of patients in intervention and 91% in control had THR due to OA. Major protocol deviation occurred during study due to hospital reorganisation.
Tappen(1) (2002)	CCT Not stated	I: 39 (mean age 75.28) C: 43 (mean age 69.61) 51.2% Hip fracture repair, 48.8% THR. Both groups equal proportion. Gender balance not reported. F/U Day of discharge, 1 week, 3 months	I: Post surgery psycho-educational video (Rehabilitation exercises, home safety and adaptations, use of assistive equipment, how to perform basic and extended ADL's whilst movement restrictions apply, energy conservation, medical, psychological and nutritional advice) C: Usual care – Not specified	Self-as-carer inventory (perceived self-care) Functional Independence Measure, Jalowiec coping scale, 6-min walk, Functional life scale, Physical activity scale for the elderly	Country: USA 50% THR, 50% Hip fracture repair (method not stated). Unable to separate data
Ververeli (2009)	RCT 2004 -2008	I: 38 (16 female, mean age 60.8; 22 male, mean age 58.8 100% THR C: 43 (16 female, mean age 59.8; 27 male, mean age 57.4) 100% THR F/U 4 weeks, 1 month,[sic] 3 months, 1 year	I: Advice on reduced hip precautions and outpatient physical therapy on discharge. C: Usual care – Standard hip precautions advice. Physical therapy 3x week at home for 1 month after discharge and as an outpatient after 1 month.	Short Form -12, Harris Hip Score, days to walk with cane, without cane and days to driving, Dislocation	Country: USA

Table 20 Characteristics of included studies (continued)

Study	Study design Start date	Participants	Intervention	Outcomes	Notes
Weaver(1) (2003)	RCT Not stated	I:69 (59 female, 10 male) 49% THR/51%TKR C:67 (67 female, male 10) 51% THR/49% TKR Overall, mean age 72 years. F/U 1 and 6 months	I: Pre-admission home visit (4) (education, advice, exercises, home assessment and adaptations, provision of assistive devices) C: Usual care – home care protocol comprising 2 post-op nurse visits and 1-3 PT visits per week in weeks 1-9 (THR) or 3-5 PT visits per week in weeks 1-9 (THR)	Barthel self-care Index, WOMAC, SF-36, Ware satisfaction with care scales, Adverse outcomes	Country: USA Mixed THR/TKR study with
Wong (1990)	RCT February 1986 to December 1987	IA: 50 (26 female, 24 male, mean age 63.37) 100% THR 1B: 48 (35 female, 13 male, mean age 71.7) 100% THR C: 48 (29 female, 19 male, mean age 64.8) 100% THR F/U 2 weeks, 6 months	IA: Early Discharge & enhanced recovery (Videotape, pamphlet, advice) IB: Conventional discharge & enhanced recovery (as 1A) C: Usual care: Conventional discharge and traditional rehabilitation program	Objective Functional Capability Index; Subjective Functional Capability Index; Subjective Psychosocial Capability Index; Knowledge Test Post Hip Arthroplasty Complications; Perceived Preparedness For Discharge Scale; the Patient Compliant Scale (Behaviour Index and the Exercise compliance subsets). LOS	Country: Canada 90% of participants had THR due to OA, 5% for RA and 5% due to traumatic hip fracture.

Abbreviations: ADL, activities of daily living; C, control; CCT, controlled clinical trial; F/U follow up; I, intervention; LOS, length of hospital stay; min, minute; OT, occupational therapist, PT, physiotherapist, RCT, randomised controlled trial; THR, total hip replacement; TKR, total knee replacement; VAS visual analogue scale; WOMAC The Western Ontario and McMaster Universities Arthritis Index.

Notes: [(1)] Included by consensus decision. [(2)] Although intervention is delivered by physiotherapist, substantial element of the intervention package was equivalent to recognised OT practice. [(3)] The service provided by the home care coordinator is equivalent to social services occupational therapist. [(4)]Although the intervention was delivered by a physiotherapist and a specialist nurse, a substantial element of the intervention package was equivalent to recognised OT practice. Inclusion of both of these studies was confirmed with Professor Avril Drummond, a professor of occupational therapy at Nottingham University who acted as OT expert for this review.

Table 21 Intervention characteristics of included studies

Study	Timing	Location	Content	Number/duration of contacts	Delivered by	Notes
Butler (1996)	(I): Prior to admission; (6 weeks) (C): None	(I): Home (C): None	(I): An 18 page booklet posted to participants. Content of book included: anatomy; exercises to practice prior to admission; precautions to follow post THR; preparing for discharge (rearranging furniture, meal preparation, community service contact information) (C): None	(I): No therapy contact (C): None	(I): Multidisciplinary: prepared by nurse, OT, PT, discharge planning and social work (C): None	Participants who were unable to read English to grade 6 were excluded
Crowe (2003)	(I): Prior to admission(1) and post discharge(2) (C): 2 weeks prior to surgery	(I): Hospital, outpatient clinics, rehabilitation hospital or home as required (C): Hospital	(I): Bespoke package of individualised education, provision of adaptive devices and training of their use, provision of non-standard adaptive devises as required, home adaptation advice, advice on ADL and hip precautions, information booklet, physical conditioning programme, Home visits by range of health professionals as required (post-surgery) (C): Standard care: pre-surgery medical checks, brief education class about hospital stay and immediate post-operative phase, and hip precautions	(I): 47% received one PT or OT session, 30% attended outpatient PT or OT, 6% home care PT or OT, 9% attended day hospital, 6% multidisciplinary home care. Number and duration of contacts not reported. (C): One standard seven hour class	(I): Multidisciplinary: OT, PT, social work (C): Nurse	Both groups received the same preoperative clinic medical checks In intervention group, home visits were available to those that required them post discharge
Ferrara (2006)	(I): Prior to admission (1 month) (C): None	(I): Hospital (C): None	(I): Individualised flexibility, strengthening, and cardiovascular exercise program, postural advice, advice on hip precautions post THR, practice in use of adaptive devices, advice on ADL post-surgery (C): None	(I): 20 sessions of 60-minute duration. Each session 40 minutes group work and 20 minutes individually with therapist. (C): None	(I): PT only(3) (C): None	

Table 21: Intervention characteristics of included studies (continued)

Study	Timing	Location	Content	Number/duration of contacts	Delivered by	Notes
Gocen (2004)	(I): Prior to admission (8 weeks) (C): None	(I): Not reported (C): None	(I): Flexibility & strengthening home exercise program, postural advice, advice on hip precautions post THR, practice in use of adaptive devices, advice on ADL post-surgery (C): None	(I): Home exercises evaluated by PT at 2-week intervals. (C): None	(I): PT only(3) (C): None	Location of PT evaluation and delivery of other elements of intervention are not documented
McGregor (2004)	(I): Prior to admission (2 to 4 weeks) (C): None	(I): Hospital (C): None	(I): An advice booklet containing information on exercises, hip precautions, ADL post THR, the hospital stay and rehabilitation. Content of book reinforced during an education class which also contained advice on home adaptations and using walking aids (C): None	(I): A one off class, duration not reported (C): None	(I): PT only(3) (C): None	Author provided copy of the advice booklet. This was requested to establish if level of OT content sufficient to be included in this review
Munin (1998)	(I): Post surgery (C): Post surgery	(I): Hospital (C): Hospital	(I): Therapy commenced in the in-patient rehabilitation unit 3 days following surgery (C): Therapy commenced in the in-patient rehabilitation unit 7 days following surgery	(I): Two 60-minute OT and PT sessions daily starting day 3 post-op (C): Two 60-minute OT and PT sessions daily starting day 7 post-op	(I): Multidisciplinary; PT and OT, recreational therapist and clinical psychologist (C): Multidisciplinary; PT and OT, recreational therapist and clinical psychologist	Both groups received same ward based rehabilitation of two 30-minute PT session starting on day 2 and one 30-minute OT session starting day 3 (plus one 30-minute PT session if hospital stay included a Saturday.

Table 21: Intervention characteristics of included studies (continued)

Study	Timing	Location	Content	Number/duration of contacts	Delivered by	Notes
Peak (2005)	(I): Immediately prior to admission and during hospital stay (C): Immediately prior to admission and during hospital stay	(I): Hospital (C): Hospital	I: Reduced restrictions with advice to only limit flexion to <90°, internal and external rotation to <45% and no adduction for first 6 weeks. No other precautions required. C: Usual care - Precautions as for intervention group plus use of abduction pillows in bed, elevated toilet seats and elevated chairs in the hospital, in the rehabilitation facility, and at home; and were prevented from sleeping on the side, from driving, and from being a passenger in an automobile for first 6 weeks.	(I): Number and duration of contacts not documented (C): Number and duration of contacts not documented	(I): Nurse & PT[(3)] (C): Nurse & PT[(3)]	
Rivard (2003)	(I): Prior to admission (2 weeks) and post discharge(2) (C): Prior to admission. (1-2 weeks)	(I): Home (C): Hospital	(I): Prior to admission: usual care content delivered one-to-one. Additionally, a bespoke therapy package provided which included individual exercise program, receipt of adaptive devices and in-situ training in their use, comprehensive home assessment for non-standard adaptive devices or home alteration planning, transfer practice, advice on ADL and hip precautions. Information sent to hospital on participants' mobility status, home environment, support networks, psycho-social-mental state and health concerns. Post discharge: Home visit by same OT who conducted pre-surgery home visit. Further therapy home visits available if required. (C): Education, functional assessment, assessing adaptive and home adaptation requirements	(I): Prior to admission: 1 home visit, duration not reported. Post discharge: home visits available for 'a few weeks'(2) (C): one contact only, duration not reported.	(I): prior to admission: OT Post discharge: OT and/or PT (C): None	

Table 21: Intervention characteristics of included studies (continued)

Study	Timing	Location	Content	Number/duration of contacts	Delivered by	Notes
Rosendal (2000)	(I): Prior to admission (2 weeks) (C): Post discharge	(I): Home (C): Hospital/ post discharge	(I): Advice, assessment for adaptive devices and home adaptations, assessment of support requirements. Home adjustment completed and support services organised before patient discharge. Patient visited while in hospital to ensure process is working. (C): Adaptive devices given post-surgery before discharge. Home adaptation requirements assessed and carried out while in hospital or after discharge	(I): Number of contacts and duration not reported (C): Number of contacts and duration not reported	(I): Home care coordinator[3] (C): Not reported	
Sandell (2008)	(I): Prior to admission(1) (C): None	(I): Hospital & Home (C): None	(I): Education, individualised exercise program, training in use of mobility aids, home assessment, advice on hip precautions post THR, practice in use of adaptive devices, advice on ADL post-surgery, advice on pain management (C): None	(I): One home visit by OT, duration not reported. Number of contacts and duration of hospital based part of intervention not reported (C): None	(I): Multidisciplinary; OT, PT, orthopaedic specialist nurse and pain specialist nurse (C): None	Overall OT contacts: (I) 3, (C) 4.4 (duration of each contact not reported)
Siggeirsdottir (2005)	(I): Prior to admission (1 month) and post discharge (up to 2 weeks) (C): None	(I): Hospital (pre-op) & Home (post-op) (C): None	(I): Prior to admission: Education on post-op rehabilitation, practice of post-op exercises, practice use of adaptive devices, illustrated brochure on ADL and hip precautions. Post discharge: Therapist accompanied patient home if required, home therapy visits (C): None	(I): One pre-op education class, duration not reported. Post-op 2-9 (median 4) home visits, duration of visits not reported. (C): None	(I): OT and PT (C): None	Author provided copy of the illustrated booklet. This was requested to establish if level of OT content sufficient to be included in this review

Table 21: Intervention characteristics of included studies (continued)

Study	Timing	Location	Content	Number/duration of contacts	Delivered by	Notes
Tappen (1) (2002)	(I): Post surgery (C): Post surgery	(I): Hospital (C): Hospital	(I): Usual care plus reinforcement by watching video; additional motivational video made of progress in rehabilitation. Participants given both videos to take home. (C): usual care: rehabilitation exercises, use of ambulatory aids, ADL training, practice use of adaptive devices, discussion of home circumstances and planning for home adaptations, counselling	(I): Number of contacts and duration of intervention not reported (C): Number of contacts and duration not reported	(I): Nurse & PT(3) (C): Nurse & PT(3)	
Ververeli (2009)	(I): Post surgery & up to 3 months post-discharge (C): Post surgery & up to 3 months post-discharge	(I): Hospital/ Post discharge (C): Hospital/ Post discharge	I: Reduced restrictions; only instructed to not cross legs at thighs. Able to begin outpatient physical therapy on discharge. C: Avoid hip flexion >90°, riding in a car, crossing legs; to use elevated toilet seat, sit on elevated chair, to sleep flat on back with abduction pillow for 4 weeks. Physical therapy at home for 1 month after discharge and as an outpatient after 1 month. To avoid flexion >90° and adduction >5° for a further 2 months.	(I): Advice only during hospital stay. (C): Advice in hospital and PT 3 times per week for 4 weeks. Duration not reported.	(I): Not documented but advice is commensurate with standard OT practice (C): PT[(3)]	

Table 21: Intervention characteristics of included studies (continued)

Study	Timing	Location	Content	Number/duration of contacts	Delivered by	Notes
Weaver(1) (2003)	(I): Prior to admission (10 days) and post discharge (up to 4 weeks) (C): Post discharge (up to 9 weeks)	(I): Home (C): Home	(I): Home visit prior to surgery with reduced visits post-surgery. Content of pre admission home visit: health checks, home assessment for adaptive devices and home adjustments, advice on ADL and hip precautions, post discharge home exercises practiced, (C): 'Customary home care program' content of which is not reported	(I): Prior to admission: One home visit Post discharge: up to 7 home visit (THR), 11(TKR). Duration of visits not reported. (C): Prior to admission: None Post discharge: two nurse visits and 11-47 therapy visits. Duration of visits not reported.	(I): Nurse and PT(3) (C): Nurse and PT(3)	Not clear if nurse and PT conduct home visits together or independently. Number of visits assumes they are done independently.
Wong (1990)	(IA): Post-surgery & post discharge (1B): Post-surgery & post discharge (C): Post-surgery	(IA): Hospital & home (1B): Hospital & home (C): Hospital	(IA): Early Discharge & enhanced recovery (Videotape, pamphlet, advice) [(4)]. Home visits to reinforce education and exercises at each follow-up time point. (IB): Conventional discharge & enhanced recovery (as 1A) [(4)] (C): Usual care: Conventional discharge and traditional rehabilitation program [(4)] and 'yoked-placebo home visit' [(5)]	(IA): Duration and number of visits not documented (1B):): Duration and number of visits not documented (C): Not documented	(IA): Multidisciplinary; OT, PT, Nurse. (1B): Multidisciplinary; OT, PT, Nurse (C): Multidisciplinary; OT, PT, Nurse	Two experimental groups. Nature of the usual care program is not presented in the written article.

Abbreviations: ADL, activities of daily living; C, control; I, intervention; OT, occupational therapist, Pre-op, preoperatively, Post-op, Postoperatively, PT, physiotherapist, THR, total hip replacement; TKR, total knee replacement.

Notes: [(1)] Time before admission is not reported. [(2)]Time post discharge when therapy occurred is not reported. [(3)] Although an OT does not deliver intervention, the intervention is recognised as standard OT practice. OT expert Professor Avril Drummond consulted before inclusion. [(4)] Duration of the traditional length of stay and the enhanced shortened length of stay is not reported. (5) During the 'yoked-placebo home visit' the researcher carried out health checks unrelated to the intervention. However, contamination did occur as the researcher answered questions related to the intervention if asked by the participant (p 12-13).

2.5.4 Meta-analyses

Table 22 presents all statistical data, including assessment time points and statistical tests employed for all the review outcomes.

Table 22: Description of results of included studies

Butler (1996)	
Author	**Description**
Assessment points	Baseline: Day of admission. Follow-up: 1 day before discharge.
Statistical tests	No power calculation Baseline demographics: *t*-test (mean age); X^2 (gender) Analyses of results: MANCOVA (with gender used as covariate).
Summary of results (significant outcomes)	**In favour of the intervention** STAI: on admission (*p*=0.007*)* (I) 27.93±25.24, (C) 42.65±29.06, at discharge (*p*=0.007*)* (I) 21.57±18.44, (C) 31.15±22.93 Self-reported practicing pre-hospital preparatory exercises: Deep breathing and coughing (*p*<0.001) (I) 55% (C) 7%; Log rolling (*p*<0.001) (I) 39% (C) 6%; Leg exercises (*p*<0.001) (I) 65% (C) 11%. Physiotherapy: attendances (*p*=0.006) (I) 7.29±2.79, (C) 9.42±4.34; time units of contact (*p*=0.001) (I) 32.74±14.55 (C) 45.63±21.46 Occupational therapy: attendances (*p*=0.045) (I) 2.21±1.35 (C) 3.07±1.99; direct time units of contact (*p*=0.033) (I) 11.11±6.51, (C) 15.15±8.52; indirect time units of contact (*p*=0.042) (I) 4.35±1.87 (C) 5.78±3.28
Summary of results (non-significant outcomes)	LOS (days): 10.28±4.74 (I), (C) 10.38±5.53
Author's conclusions	The booklet group has less anxiety than the no-booklet group at admission and at discharge [which] clearly supports the advantage of pre-hospital education in this population. There were no significant differences for LOS between booklet and no-booklet groups.

Abbreviations: STAI, State-Trait Anxiety Inventory; LOS, length of stay

Crowe (2003)	
Author	**Description**
Assessment points	Baseline data: 1 to 24 weeks prior to admission (mode = 6 weeks). Follow-up: day of admission.
Statistical tests	No power calculation Baseline demographics: paired *t*-test (Intervention group were significantly more disabled (*p=0.009*) measured using the OHS, and more anxious measured by the STAI *p*<0.000. X^2 for gender, arthroplasty procedure, preoperative diagnosis, comorbidities, living arrangements and marital status) Analysis of results: Unpaired t-test (days to meet discharge criteria, LOS), X^2 (discharge destination)
Summary of results (significant outcomes)	**In favour of intervention** STAI: Patients less anxious (*p*<0.000) on admission (I) 39.7 ±4.8 (C) 44.4 ±7.6 Time to meet discharge criteria: (*p=0.021*) (I) 5.39 ±3.8, (C) 7.98 ±7.7 LOS: (*p=0.032*) (I) 6.55 ±4.2, (C) 10.50 ±14.2 <u>Other measures</u> Function (independently get out of bed): (*p*=0.05), (I) 4.71±3.4 (C) 5.87±3.2 Discharge planning (equipment): (p<0.000), (I) 1.95±5.6, (C) 6.06±4.0. Discharge planning (meals): (p<0.000) (I) 1.37±1.3, (C) 5.80±4.5. Discharge planning (all criteria met): (*p*=0.021) (I) 5.39±3.8 (C) 7.98±7.7 Post-operative complications: (*p*=0.007) (I) 7 (C) 22
Summary of results (non-significant outcomes)	Function (Joint flexion) : (*p*=0.08) (I) 5.12±5.4, (C) 6.54±3.5 Function (days to walk 30m): (*p*=0.23) (I) 5.27±5.9 (C) 6.75±7.5. Function (climb stairs) : (*p*=0.61) (I) 5.83±6.6, (C) 6.38±3.4 Discharge home with no aftercare required (p=0.498) (I) 3.0 (C) 0.0
Author's conclusions	The individually tailored preoperative rehabilitation was effective in reducing the mean number of days to reach discharge criteria and the actual length of stay.

Abbreviations: OHS, Oxford hip score; STAI, State-Trait Anxiety Inventory; LOS, length of stay

Ferrara (2008)	
Author	**Description**
Assessment points	Baseline: One month before surgery. Follow-up: Up to 15 days, 4 weeks, and 3 months
Statistical tests	No power calculation Baseline demographics: Mean and SD values given. No statistical analysis Analysis of Results: comparison between groups using Mann-Whitney U-test; within group comparison using Wilcoxian test.
Summary of results (significant outcomes)	**In favour of the intervention** VAS (pain) at 4 weeks (*P*=0.04) (I) 5.5±2.2 (C) 7.3±2.0; and at 3 months (*P*=0.03) (I) 0.03±0.48 (C) 1.27±1.00, SF-36- physical composite score at 4 weeks (*P*=0.048) (I) 34.4±4.05 (C) 27.3±10.3. <u>Other measures:</u> ROM external rotation at 4 weeks (*P*=0.03) (I) 22.27°±7.86° (C) 14.58°±7.82°; and at 3 months (*P*=0.02) (I) 33.5°±4.11° (C) 33.64°±4.52°
Summary of results (non-significant outcomes)	WOMAC (pain): at 4 weeks (I) 8.0±3.8 (C) 11.0±3.6; at 3 months (I) 1.70±2.35 (C) 2.20±1.75 WOMAC (function): at 4 weeks (I) 33.7±13.8 (C) 43.5±9.5; at 3 months (I) 18.30±12.36 (C) 28.5±10.01 WOMAC (stiffness): at 4 weeks (I) 4.82±1.88 (C) 4.58±1.62; at 3 months (I) 1.00±1.33 (C) 1.3±1.56 Harris Hip Score: at 4 weeks (I) 43.6±15.7 (C) 34.9±15.5; at 3 months (I) 69.47±7.49 (C) 65.2±15.4 Barthel: at 4 weeks (I) 84.5±6.7 (C) 75.0±16.2, at 3 months (I) 95.00±4.08 (C) 91.82±2.52 SF-36 physical composite score: at 3 months (I) 46.60±8.95 (C) 52.09±8.11 SF-36 mental composite score: at 4 weeks (I) 51.1±11.2 (C) 40.9±11.6; at 3 months (I) 53.10±6.65 (C) 51.36±9.03 <u>Other measures</u> ROM (abduction): at 4 weeks (I) 31.81˚±10.55˚ (C) 32.08˚±11.95˚; at 3 months (I) 43.00˚±6.32˚ (C) 39.09˚±4.36˚ Quadriceps strength (Oxford Scale): at 4 weeks (I) 4.50±0.59 (C) 4.25±0.45; at 3 months (I) 5.0±0.0 (C) 5.0±0.0 Hip abductor strength (Oxford scale): at 4 weeks (I) 4.68±0.46 (C) 3.90±0.46; at 3 months (I) 5.0±0.0 (C) 5.0±0.0
Author's conclusions	Pre-operative physiotherapy does not significantly reduce the overall post-surgery disability. It can improve hip rotation and reduce pain in the short term, three months after surgery.

Abbreviations: VAS, Visual analogue scale; SF-36, short form-36; WOMAC, Western Ontario and McMaster Universities Arthritis Index; ROM, range of movement.

Gocen (2004)	
Author	**Description**
Assessment points	Baseline: eight weeks before surgery (study group only), immediately before surgery (control). Follow-up: at discharge, 3 months, two years.
Statistical tests	No power calculation Baseline demographics: paired and independent samples *t*-test where appropriate. Analysis of results: paired and independent samples *t*-test where appropriate.
Summary of results (significant outcomes)	**In favour of intervention** Days to activity: climbing stairs (I) 6.17±1.69 (C) 7.37±1.02; bed transfer (I) 2.93±0.59 (C) 3.33±0.71; toilet transfer (I) 4.24±0.51 (C) 5.07±1.28; chair transfer (I) 4.24±0.74 (C) 5.60±1.45
Summary of results (non-significant outcomes)	Harris Hip Score: at discharge (I) 64.46±6.92 (C) 59.36±6.82 at 3 months (I) 85.30±11.78 (C) 78.70±9.41, at 2 years (I) 97.14±4.32 (C) 95.66±6.08 LOS: author states no significant difference between groups but actual data not presented. VAS (pain): author states no significant difference between groups at discharge. Only change data presented. Effect size (mean ±SE): In favour of control (not significant) VAS pain at rest: at discharge change score (I) 0.28±0.59 (C) 0.04±0.93; ES -0.15±0.26 VAS pain at activity: at discharge change score (I) 1.24±1.60 (C) 1.30±1.73; ES -0.04±0.26 <u>Other measures</u> Hip abduction: at discharge change score (I) 17.2˚±12.6˚ (C) 17.3˚±13.8; ES -0.01±0.26
Author's conclusions	The results reveal no major benefit from routine pre-operative physiotherapy and education programme.

Abbreviations: LOS, length of stay; VAS, Visual analogue scale.

McGregor (2004)	
Author	**Description**
Assessment points	Baseline: 2-4 weeks prior to admission. Follow-up: day of admission, day of discharge, and 3 months.
Statistical tests	No power calculations Baseline demographics: not reported Analysis of results: unbalanced analysis of variance with restricted maximum likelihood. The model contained the fixed effect for study groups and random effect for subjects. The baseline preadmission assessment was included in the model as a covariate.
Summary of results (significant outcomes)	**In favour of intervention** Cantril Life Satisfaction Ladder: on discharge (p<0.01) (I) 98±4, (C) 84±30; at 3 month follow-up; (p<0.01) (I) 98±4 (C) 80±30 [(1)].
Summary of results (non-significant outcomes)	Barthel: admission (I) 19.2±1.3 (C) 19.0±1.3; discharge (I) 19.8±0.4 (C) 18.7±1.4; at 3 months (I) 19.9±0.3 (C) 19.6±0.7 Harris Hip Score: admission (I) 45.4±11.5 (C) 43.2±16.2; discharge (I) 62.6±7.9 (C) 53.8±12.0; at 3 months (I) 74.2±11.7 (C) 68.8±16.2 WOMAC (Pain): admission (I) 10.2±2.3 (C) 10.3±4.1; discharge (I) 3.2±2.7 (C) 4.5±3.0; at 3 months (I) 2.7±2.1 (C) 0.05±04.4 WOMAC (stiffness): admission (I) 4.3±1.3 (C) 4.1±1.7; discharge (I) 1.6±1.8 (C) 2.0±1.5; at 3 months (I) 1.1±1.1 (C) 1.6±1.7 WOMAC (function): admission (I) 35.8±12.0 (C) 41.0±10.0 at discharge (I) 25.7±8.3 (C) 28.3±12.1; at 3 months (I) 15.9±10.3 (C) 18.4±13.8 VAS Pain: admission (I) 7.8±1.5 (C) 7.6±2.0; discharge (I) 2.8±1.7 (C) 3.7±2.1; at 3 months (I) 2.1±2.6 (C) 3.1±2.9 Positive Affect Negative Affect Scale: no comparative data reported Helplessness subscale of the Rheumatology Attitudes Index: no comparative data reported Fatigue: no comparative data reported EQ-5D: admission (I) 69.0±6.0 (C) 59.0±17.25; discharge (I) 77.5±2.5 (C) 77.0±11.75; at 3 months (I) 77.25±13.0 (C) 74.5±20.5 (from scaled up graph) LOS was reduced by 3 days (I) 15; (C) 18. However, no statistical tests were done on the data to show if this is significant. Cost analysis: Cost of care of patients (I) £2,842 (C) 3,429 Occupational therapy costs: control group cost on average £11 more per patient. Actual costs per group not reported.
Author's conclusions	The study showed that the inclusion of a preoperative advice class and booklet improves patient expectations and satisfaction levels. Patients in both groups had equal improvements in pain, function, mood and life satisfaction.

Abbreviations: WOMAC, Western Ontario and McMaster Universities Arthritis Index; VAS, visual analogue scale; LOS, length of stay.

Munin (1998)	
Author	**Description**
Assessment points	Baseline: 4 weeks prior to surgery. Follow-up: 4 months.
Statistical tests	Power calculation: a sample size of 40 patients per group was determined to have adequate statistical power (β=0.8) to detect major effect sizes (SD=0.8) for LOS Baseline demographics: analysis of variance and X^2 showed no significant variance all characteristics for THR patients. Analyses of results: A MANOVA was used to analyse the RAND-36 and the functional state index change scores. A repeated measure MANOVA was used for the functional independence measures that were divided into 3 periods. X^2 analyses were used to analyse dichotomous or ordinal measures. A Bonferroni correction was applied to post hoc analyses when primary analyses were significant.
Summary of results (significant outcomes)	**Effect Size (ES): In favour of intervention (Effect size ±SE)**
Large effect size ≥0.8	LOS: (I) 12.2±2.8, (C) 14.8±2.2; ES -0.99±0.42 FIM PT (Transfer days 6-10): (I) 4.59±0.97 (C) 4.16±0.43; ES 0.58±0.40 FIM PT (Distance walked days 1-5): (I) 12.95±9.39 (C) 5.11±3.84; ES 1.03±0.42 FIM PT (Distance walked days 6-10): (I) 31.79±15.14 (C) 17.7±8.76; ES 1.08±0.42 FIM PT (Ambulation days 1-5): (I) 1.54±0.53 (C) 1.17±0.35; ES 0.97±0.41 FIM PT (Ambulation days 6-10): (I) 3.46±1.58 (C) 1.81±0.81; ES 1.24±0.43 FIM PT (stairs days 6-10): (I) 2.11±1.34 (C) 1.17±0.33; ES 0.90±0.41
Medium effect size ≥0.5	FIM PT (Stairs days 1-5): (I) 1.07±0.17 (C) 1.0±0.0; ES 0.54±0.40 FIM OT (bathing days 6-10): (I) 4.64±0.84 (C) 4.05±0.96; ES 0.64±0.40 FIM OT (lower extremity dressing days 6-10): (I) 4.54±0.81 (C) 4.02±1.12; ES 0.52±0.40
Small effect size ≥0.2	FIM PT (stairs days ≥11): (I) 2.83±1.85 (C) 2.22±1.33; ES 0.36±0.40 FIM OT (bathing days ≥11): (I) 5.4±0.47 (C) 5.26±0.55; ES 0.27±0.40 FSI (difficulty): (I) 8.73±6.98 (C) 6.92±10.52; SE 0.20±0.39 RAND-36 (bodily pain): (I) 39.22±22.26 (C) 29.79±24.04; ES 0.40±0.40 Total cost ($):(I) 28,256±3,545 (C) 29,437±4,352; ES -0.29±0.40
	Effect Size: In favour of control (effect size ±SE)
Large effect size ≥0.8	FIM PT (Transfer day's≥11): (I) 5.12±0.77 (C) 5.72±0.29; ES -0.97±0.42
Medium effect size ≥0.5	FIM OT (tub or shower transfer days >11): (I) 4.54±1.46 (C) 5.15±0.75; ES -0.50±0.40
Small effect size ≥0.2	FIM PT (Distance walked days ≥11): (I) 39.14±12.73 (C) 43.13±8.57; ES -0.35±0.40 FIM OT (toilet transfer days ≥11): (I) 5.34±0.54 (C) 5.52±0.42; ES -0.20±0.39 RAND-36 (physical functioning): (I) 14.06±27.7 (C) 19.58±16.3; ES -0.23±0.39 FSI (assistance): (I) 4.75±13.48 (C) 2.13±9.68; ES -0.21±0.39

Summary of results (non-significant)	**No significant effect size (effect size ±SE)** FIM PT (Transfer days 1-5): (I) 3.2±1.25 (C) 3.33±0.87; E.S.-0.12±0.39 FIM PT (Ambulation days≥11): (I) 4.87±1.51 (C) 4.65±1.32; E.S. 0.15±0.39 FIM OT (lower extremity dressing days ≥11): (I) 5.21±0.64 (C) 5.22±0.7; ES -0.01±0.39 FIM OT (Tub or shower transfer days 6-10): (I) 3.15±1.64 (C) 3.42±1.59; ES 0.16±0.39 FIM OT (toilet transfer days 6-10): (I) 4.63±0.87 (C) 4.5±0.67; ES 0.16±0.39 FSI (pain): (I) 8.07±9.51 (C) 9.25±12.17; SE -0.10±0.39 RAND-36 (emotional role functioning): (I) 2.08±35.42 (C) 5.56±69.39; SE -0.06±0.39 RAND-36 (role functioning, physical): (I) 20.31±38.96 (C) 25±33.71; SE -0.12±0.39 RAND-36 (emotional wellbeing): (I) 3.75±10.38 (C) 5±10.39; SE -0.12±0.39
Author's conclusions	This study supports acute in-patient rehabilitation services beginning on postoperative day three for high risk patients unable to make home transition after total joint replacement.

Abbreviations: LOS, length of stay; FIM PT, Physiotherapy functional independence measure; FIM OT, Occupational Therapy functional independence measure; FSI, functional status index

Peak (2005)	
Author	**Description**
Assessment points	Baseline: Prior to surgery (actual time not stated) Follow-up: Patients were followed up for a minimum of six months. Satisfaction questionnaire completed at six weeks and six months.
Statistical tests	Power calculation: $\alpha = 0.05$, $\beta = 0.08$; historic dislocation rate set at 1%. This indicated 130 patients in each group were needed to prevent a type-II error. Baseline characteristics: No difference between groups (p=0.34). Statistical method used not reported. Analysis of results: X^2 test with a continuity correction for discrete variables. A one-tailed student t-test used for continuous variables with significance set at (α)<0.05
Summary of results (significant outcomes)	**In favour of Intervention** Time to side sleeping (weeks, range): (I) 3.2 (0 - 12), (C) 5.8 (0 – 36), (p<0.001) Time to ride as passenger in car (weeks, range): (I) 1.5 (0.3 - 20.0), (C) 1.9 (0 – 6.1), (p=0.026) Time to drive car (weeks, range): (I) 4.9 (0.5 – 16.0), (C) 6.8 (1.0 – 19.9), (p<0.001) Return to work within 6 weeks (%, range)): (I) 50.0% (49 – 98) (C) 18.8% (16 – 85), (p<0.001) Time to return to work (weeks, range):(I) 6.5 (0.7 – 20.0), (C) 9.5 (1.0 – 32.0) (p<0.001) Ability to perform full ADL at 6 months as a percentile of pre-operative function (%, range): (I) 106.4% (25 -350), (C) 96.5 (25 – 200), (p=0.015) Satisfaction with rate of recovery: (I) 89.4%, (C) 74.3%, (p<0.001) <u>Other measures</u> Number of patients requiring additional hospital rehabilitation stay: (I) 125, (C) 100 (p<0.002) in favour of control. Compliance with restrictions: (I) 90.0%, (C) 95.7% (p=0.001) in favour of control
Summary of results (non-significant outcomes)	Limp: at 6 months: (I) 15%, (C) 12.5%, (p=0.80) Dislocation: (c) 1, (I) 0 (note; this occurred during transfer from operating table to bed, so occurred before the intervention period) LOS (days, range): (I) 3.5 (2 – 8), (C) 3.5 (2 – 5), (p=0.88)
Author's conclusions	The imposition of restrictions, other than the limitation of extreme motion, did not influence the prevalence of early dislocation of the hip.

Abbreviations: ADL, activities of daily living; LOS, length of stay.

Rivard (2003)	
Author	**Description**
Assessment points	Baseline: Prior to admission, at approximately 10 days after being placed on waiting list for hip replacement. Time to surgery not stated. Follow-up: Discharge date
Statistical tests	No power calculation. Baseline demographics: X^2 test for gender and living arrangements. There was no significant difference between groups for age, co-morbidities and WOMAC sores (pain, stiffness, function) – statistical test used not reported Analysis of results: X^2 test for discharge destination (home or sub-acute rehabilitation facility). Analysis method for LOS is not stated[(1)]
Summary of results (significant outcomes)	None
Summary of results (non-significant outcomes)	Discharge destination: no significant difference (*p*=0.74) (I) 64.7% home, 35.5% sub-acute (C) 62.5% home, 37.5% sub-acute. LOS: no significant difference (*p*=0.97) between LOS at acute facility (I) 6.89±1.98 (C) 6.90±1.97; or at sub-acute facility (*P*=0.73) (I) 9.06±3.82 (C) 9.37±4.01
Author's conclusions	The provision of a pre-operative home visit appears to have no distinguishable impact on whether clients are discharged directly home or to a sub-acute rehabilitation facility, nor in their overall (acute plus sub-acute) length of stay.

Abbreviations: WOMAC, Western Ontario and McMaster Universities Arthritis Index; LOS, length of stay.

Rosendal (2000)	
Author	**Description**
Assessment points	Baseline: 2 weeks before surgery. Follow-up: at 6 months.
Statistical tests	No power calculation. Baseline demographics: X^2 test (gender, primary or revision surgery, and living alone) and unpaired *T*- test (age, days waiting to admission) showed no significant differences between the two groups. Analysis of results: The Mann-Whitney U test, Fisher exact test, X^2 test, *T*- test
Summary of results (significant outcomes)	**In favour of the control** SIP-68: mobility subscale (*p*=0.02) (I) -0.18±2.58 (C) -0.76±1.99; SIP-68 overall score (*p*=0.02) (I) -1.92±7.46 (C) -5.11±6.19. Percentage of patients needing home adjustments six months after THR (*p*=0.02) (I) 62% (C) 41% (CI: 0.04, 0.40). Type of homecare delivered a one month post-surgery: - dressing & washing: (p<0.00) (I) 93% (C) 42% - nursing (wound): (p<0.00) (I) 60% (C) 16%
Summary of results (non-significant outcomes)	SIP-68: somatic autonomy (I) 0.18±1.38 (C) -0.03±1.22; SIP-68: motor control (I) -1.26±3.32 (C) -2.21±2.43; SIP-68 psychological autonomy and communication (I) -0.07±1.17 (C) -0.11±0.65, SIP-68: social behaviour (I) -0.70±2.84 (C) -1.38±2.77 SIP-68: emotional stability (I) -0.12±0.61 (C) -0.38±0.97 HRQ: overall impact: (I) 7.9±6.11 (C) 7.8±6.50 HRQ pain: (I) 7.8±6.22 (C) 9.2±5.86, HRQ walking: (I) 3.0±5.50 (C) 3.8±4.86 HRQ function: (I) 1.2±3.36 (C) 2.1±2.46, HRQ total: (I) 18.9±15.64 (C)24.3±14.86 Patients needing home adjustments: one month after THR (I) 75% (C) 39% (CI: -0.08, 2.5), Patients still requiring home care at one month post THR (I) 54% (C) 32% (CI: 0.04, 0.39), Patients still requiring home care at six months post THR (I) 20% (C) 11% (CI: -0.13, 0.15). Time needed for homecare to start: Same day: (I) 37% (C) 5% (CI: 0.11, 0.51); next day: (I) 43% (C) 32% (CI: -0.16, 0.39); a few days: (I) 13% (C) 32% (CI:-0.42, 0.06); a week: (I) 3% (C) 5% (CI: -0.44, 0.02); more than a week: (I) 3% (C) 5% (CI:- 0.14, 0.10) Type of homecare delivered one month post-surgery: household (I) 70% (C)74% Frequency of home care visits one month after THR: -twice a day (I) 33% (C) 5% (CI:0.88, 0.45) -once a day (I) 40% (C) 21% (CI:- 0.14, 0.10) -few times per week (I) 17% (C) 16% (CI:- 0.20, 0.22) -once a week (I) 10% (C) 53% (CI:- 0.67, -0.18) -other (I) 0% (C) 5% LOS: (I) 12.8±7.4 (C) 13.2±3.5. Self-rated satisfaction: no significant difference between groups reported but; actual data not provided.
Author's conclusions	This particular form of shared care is not cost effective. Heath status results at six months favour the control.

Abbreviations: SIP-68, sickness impact profile (68 question version); HRQ, hip rating questionnaire; LOS, length of stay.

Sandell (2008)	
Author	**Description**
Assessment points	Baseline: Before surgery (Note: author states all potential participants who were invited on to the study has a waiting time to surgery of greater than 6 months. However time to surgery is not stated). Follow-up: day of admission
Statistical tests	Power calculation: power set at 90%, NNT calculated at 30 in each group. Baseline characteristics: two sample *t*-test Analysis of results: two sample *t*-test
Summary of results (significant outcomes) Medium effect size ≥0.5 Small effect size ≥0.2 Medium effect size ≥0.5 Small effect size ≥0.2	**Effect Size (ES): In favour of intervention (effect size ±SE)** AIMS hand and finger function (I) 0.45±1.63 (C) -0.35±1.05; SE 0.57±0.26 Nottingham Health Profile social (I) 4.61±14.33 (C) -3.73±14.37; SE 0.57±0.26 AIMS arm function (I) -0.08±1.11 (C) 0.68±1.67; SE 0.42±0.26 AIMS satisfaction with health (I) -0.04±1.32 (C) -0.38±1.54; SE 0.23±0.25 **Effect Size: In favour of control (effect size ±SE)** AIMS arthritis pain (I) -0.09±1.61 (C) 0.74±1.69; ES -0.50±0.26 AIMS mobility (I) -0.35±1.71 (C) 0.31±1.74; ES -0.38±0.25 AIMS walking and bending (I) -0.14±2.09 (C) 0.75±1.50; SE-0.49±0.26 AIMS social activity (I) -0.71±2.01 (C) 0.08±1.37; SE -0.45±0.26 AIMS support from family (I) -0.03±2.00 (C) 0.52±2.53; SE -0.24±0.25 AIMS work (I) -0.37±1.71 (C) 0.44±1.62; SE -0.48±0.26 AIMS arthritis impact (I) 0.00±2.25 (C) 0.58±1.82;SE -0.28±0.25 Nottingham Health Profile energy (I) -9.48±35.59 (C) 6.67±34.66; SE -0.45±0.26 Nottingham Health Profile pain (I) -1.46±22.58 (C) 4.93±22.77; SE- 0.28±0.25 Nottingham Health Profile sleep (I) -5.70±24.54 (C) 5.98±27.02; SE -0.45±0.26
Summary of results (non-significant outcomes)	**No significant effect size (effect size ±SE)** AIMS self-care tasks (I) -0.25±1.79 (C) -0.14±1.95; SE 0.05±0.25 AIMS household tasks (I) -0.23±1.50 (C) -0.13±1.99; SE-0.06±0.25 AIMS levels of tension (I) 0.09±1.65 (C) 0.00±1.55; SE 0.06±0.25 AIMS mood (I) -0.12±1.48 (C) 0.08±1.23; SE -0.14±0.25 AIMS current and future health (I) -0.61±2.34 (C) -0.44±2.44; SE -0.07±0.25 Nottingham Health Profile physical (I) -0.47±12.47 (C) 1.44±23.13; SE -0.10±0.25 Nottingham Health Profile emotional (I) 1.90±13.67 (C) 2.65±18.25; SE -0.05±0.25
Author's conclusions	The study did not show any definitive conclusions that the intervention was beneficial

Abbreviations: AIMS, Arthritis Impact Measurement Score

Siggeirsdottir (2005)	
Author	**Description**
Assessment points	Baseline: 1 day preoperatively. Follow-up: 2, 4 and 6 months.
Statistical tests	No power calculation Baseline demographics: no analysis reported. Analysis of results: Freidman test used to compare measurements over time within each group. Wilcoxon matched-pairs test was used compare measurements within a group at two different times. Mann-Whitney U test used to compare groups at each time point. X^2 test used to compare proportions.
Summary of results (significant outcomes)	**In favour of control.** LOS: (p<0.001) (I) 6.4±2.4, (C) 10.0±3.5 OHS: overall score (pain and function) (p=0.03) at 2 months; (I) 19±6.3 (C) 24.0±9.0; at 4 months (p=0.007) (I) 15.0±4.2 (C) 22.0±8.7; at 6 months (p=0.001) (I) 14.0±4.3 (C) 21.0±7.2 Nottingham Health Profile (no data in article. Only p values given. Author contacted but not able to supply – presume only significant results presented) At 2 months pain (p=0.02) At 4 months emotional reaction (p=0.02), social isolation (p=0.01) At 6 months pain (p=0.02), social isolation (p=0.03), lack of energy (p=0.007) and physical mobility (p=0.003).
Summary of results (non-significant outcomes)	Meurle d'Abuigne and Postel score (no data in article. Author contacted but not able to supply. Only p values given). (p=0.05) Harris Hip Score at 2 months (I) median 76 IQR 56-93 (C) median 71 IQR 31-83 Post-operative complications (I) 5 (C) 11 (p=0.3)
Author's conclusions	Function, pain and quality of life can be improved by pre-operative education with home-based rehabilitation and nursing after discharge.

Abbreviations: LOS, length of stay; OHS, Oxford hip score

Tappen (2002)	
Author	**Description**
Assessment points	Baseline: on admission. Follow-up: at discharge, 1 week and 3 months.
Statistical tests	Power calculation indicated that a minimum of sample size of 30 per group was needed to obtain desired power of 80% or greater. Baseline characteristics: X^2 test showed the intervention group to be significantly older (*p*=<0.05) (I) 75.28±9.48 (C) 69.61±12.65. No other significant difference was found between type of surgery (THR or fracture repair), number of chronic illnesses or medical conditions, age, gender of home arrangements (alone or with someone) Analysis of results: MANCOVAs with repeated measures as the between subject variable.
Summary of results (significant outcomes)	**In favour of intervention** 6-minute walking test: Distance walked (feet) one week post discharge (*p*=0.045) (I) 128.23±229.59 (C) 26.79±70.40. Time walked (seconds) was significant at baseline (*p*=0.006) (I) 99.82±200.17 (C) 0.12±55.81; at discharge (p=0.014) (I) 124.44±191.48 (C) 49.91±125.35; at one week follow-up (*p*<0.000) (I) 271.47±248.58 (C) 60.81±133.34; and at the final 3 month follow-up (*p*=0.027) (I) 314.79±139.59 (C) 204.77±179.70
Summary of results (non-significant outcomes)	6-minute walking test: Distance walked (feet) at baseline (I) 13.85±46.35 (C) 8.56±55.88, 6-minute walking test: Distance walked (feet) at discharge (I) 17.18±34.37 (C) 20.30±70.05, 6-minute walking test: Distance walked (feet) three months post discharge (I) 231.74±169.47 (C) 162.14±249.17. ADL Coping: at baseline (I) 115.03±11.76 (C) 116.49±11.18, at discharge (I) 115.69±11.35 (C) 115.00±11.77, at 1 week (I) 116.74±9.84 (C) 113.54±11.30, at 3 months (I) 117.54±8.01 (C) 114.91±11.76 ADL Self-care: at baseline: (I) 198.47±33.52 (C) 97.51±26.98, at discharge (I) 201.67±36.00 (C) 202.86±26.33, at 1 week (I) 207.74±32.35 (C) 206.79±25.83, at 3 months (I) 203.33±30.10 (C) 216.09±23.87. ADL Functional ability: at baseline (I) 91.33±14.24 (C) 97.61±13.92, at discharge (I) 102.72±11.37 (C) 108.95±9.62, at 1 week (I) 106.80±12.95 (C) 111.26±13.55, at 3 months (I) 119.51±8.36 (C) 121.35±6.51. ADL Independent: at baseline: (I) 142.97±28.78 (C) 142.68±27.05, at 1 week (I) 101.38±21.23 (C) 112.44±24.95, at 3 months (I) 129.97±23.44 (C) 137.42±27.12. ADL Physical activity: at baseline: (I) 67.23±67.53 (C) 73.21±100.92, at 1 week (I) 13.99±20.49 (C) 28.13±50.34, at 3 months (I) 48.05±47.62 (C) 54.51±69.51.
Author's conclusions	Use of video in rehabilitation only has benefits in improving physical functioning.

Abbreviations: ADL, Activities of daily living

Ververeli (2009)	
Author	**Description**
Assessment points	Baseline: before surgery (time not stated) Follow-up: 1 month, 3 months and 1 year
Statistical tests	Power calculation: $\alpha = 0.05$, $\beta = 0.08$; dislocation risk set at 0.33%. This indicated 53 patients in each group were needed to detect a 3% difference in dislocation prevalence. Baseline demographics: no significant differences between the two groups in terms of age (*p*=0.51), or BMI (*p*=0.32). Statistical method not reported. Analysis of results: The Mann-Whitney U test, Fisher exact test, X^2 test, *T*- test
Summary of results (significant outcomes)	**In favour of intervention** Time to ambulate only with a cane (days, ±SD): (I) 12.6±5.5, (C) 16.4±9.5 (Difference in means (±95% CI) 3.82±3.49 Time to ambulate without a cane (days, ±SD): (I) 22.6±11.7, (C) 39.0±15.4 (Difference in means (±95% CI) 12.40±6.12 Time to walk without limp (days, ±SD): (I) 49.9±20.9, (C) 67.3±27.2 (Difference in means (±95% CI) 17.33±10.82 Time to drive car (Days, ±SD): (I) 22.9±11.7, (C) 30.1±8.0 (Difference in means (±95% CI) 7.27±4.40
Summary of results (non-significant outcomes)	No dislocations occurred. Harris Hip Score: at 3 months ES = 0.41, (p=0.07) SF-12 (Physical component) at 4 weeks: ES = 0.38, (p=0.09) All other Harris Hip Scores and SF-12 scores were not significant at all other time measures. (no actual data is provided)
Author's conclusions	Hip restrictions provide no additional benefit and limit patients return to activities. A faster return to activities of daily living following elective THRs is possible without restrictions. It is not possible to conclude if restrictions are a necessary prevent dislocation.

Abbreviations: BMI, body mass index; SF-12, short form (12 questions)

Weaver (2003)	
Author	**Description**
Assessment points	Baseline: before surgery. Follow-up: 1 and 6 months.
Statistical tests	No power calculation Baseline characteristics: *p* values reported but statistical method not reported. Analysis of results: analysis of covariance.
Summary of results (significant outcomes)	**In favour of intervention** Reduction in number of days on home care program : (p=0.035) (I) 29.2 (C) 40.6 Home care reimbursement costs (p<0.001) (I) $1488 (C) $2163. No SD provided.
Summary of results (non-significant outcomes)	**Outcome data presented as mean ±SE** Barthel: at 1 month (*p*=0.940) (I) 96.7±0.07 (C) 96.6±0.7, at 6 months *p*=0.121 (I) 98.9±1.3 (C) 96.1±1.2 SF-36 (general health): 1 month (*p*=0.361) (I) 77.1±2.1 (C) 74.4±2.1, 6 months(*p*=0.984) (I) 78.9±2.5 (C) 78.9±2.4, SF-36 (physical function) 1 month (*p*=0.526) (I) 39.3±2.9 (C) 42.0±2.9 6 months (*p*=0.512) (I) 63.4±3.5 (C) 66.6±3.5 SF-36 (Physical role) 1 month (*p*=0.720) (I) 31.1±5.0 (C) 33.6±4.9 6 months (*p*=0.824) (I) 75.4±4.9 (C) 77.9±4.9 SF-36 (Emotional role) 1 month (*p*=0.423) (I) 91.5±2.7 (C) 94.6±2.7 6 months (*p*=0.431) (I) 95.0±2.6 (C) 92.0±2.6 SF-36 (social function) 1 month (*p*=0.863) (I) 76.2±3.3 (C) 77.1±3.3 6 months (*p*=0.969) (I) 91.6±2.2 (C) 91.7±2.2 SF-36 (bodily pain) 1 month (*p*=0.4.3) (I) 67.1±3.1 (C) 63.4±3.1 6 months (*p*=0.642) (I) 73.4±3.1 (C) 75.4±3.0 SF-36 (vitality) 1 month (*p*=0.482) (I) 54.9±2.8 (C) 52.2±2.7 6 months (*p*=0.280) (I) 56.3±2.7 (C) 60.4±2.6 SF-36 (mental health) 1 month (*p*=0.857) (I) 81.8±1.6 (C) 81.4±1.6 6 months (*p*=0.759) (I) 83.4±1.9 (C) 82.6±1.9. Satisfaction with care (overall): 1 month (*p*=0.987) (I) 4.3±0.1 (C) 4.3±0.1, 6 month (*p*=0.676) (I) 4.3±0.1 (C) 4.3±0.0 WOMAC (pain) 1 month (*p*=0.661) (I) 4.4±0.1 (C) 4.4±0.1, 6 month (*p*=0.925) (I) 4.6±0.1 (C) 4.6±0.0, WOMAC (stiffness) 1 month (*p*=0.125) (I) 3.8±0.1 (C) 4.0±0.1, 6 month (*p*=0.775) (I) 4.1±0.1 (C) 4.2±0.0, WOMAC (function) 1 month (*p*=0.453) (I) 4.2±0.1 (C) 4.1±0.1, 6 month (*p*=0.657) (I) 4.5±0.1 (C) 4.5±0.0 Adverse events: (I) 1 (C) 4 Total reimbursement costs: (I) $24,663 (C) $24,295
Author's conclusions	The addition of the preoperative home visit improved patient satisfaction. Reductions in home care visits can be made without compromising outcomes for patients undergoing THR or TKR.

Abbreviations: SF-36, short form (36 questions); WOMAC, Western Ontario and McMaster Universities Arthritis Index.

Wong (1990)	
Author	**Description**
Assessment points	Baseline: before surgery Follow-up: Two weeks & 6 months
Statistical tests	No power calculation Baseline characteristics: No statistical difference (p <0.05), statistical method not reported. Analysis of results: Mann-Whitney for all analyses.(p 13)[(1)]
Summary of results (significant outcomes)	**In favour of intervention** At 2 weeks Perceived Preparedness for Discharge Scale: both experimental groups (p<0.01) Exercise Compliance Score: both experimental groups (p<0.05) Compliant Behaviour Index for experimental group II only (p<0.05)
Summary of results (non-significant outcomes)	At 2 weeks Experimental group I Compliant Behaviour Index (p = 0.38) At 6 months Experimental group I Objective Functional Capability Index (Muscle strength) (p = 0.69) Objective Functional Capability Index (Mobility Index) (p = 0.70) Objective Functional Capability Index (Walking Ability) (p = 0.55) Objective Functional Capability Index (Stair management) (p = 0.46) Subjective Functional Capability Index (p = 0.34) Subjective Psychosocial Capability Index (p = 0.67) Experimental group II Objective Functional Capability Index (Muscle strength) (p = 0.17) Objective Functional Capability Index (Mobility Index) (p = 0.87) Objective Functional Capability Index (Walking Ability) (p = 0.71) Objective Functional Capability Index (Stair management) (p = 0.50) Subjective Functional Capability Index (p = 0.57) Subjective Psychosocial Capability Index (p = 0.40)
Author's conclusions	The findings suggest that a programme of after-care that combines educational and follow-up home-visit strategies for the early discharged patients provides outcomes that are comparable to the traditional discharge planning for the conventionally discharged patients.
Notes	Experimental group I: Early discharge + educational intervention Experimental group II: Conventional discharge + educational intervention **Note [(1)]:** In table 2 & 3 (p 15) for Objective Functional Capability Index (Mobility Index) a 't' appears in the test column which would normally indicate a t-test. However, the text and the table suggest the Mann Whitney was used throughout.

Note: In all data extraction tables the effect sizes were designated as "small, d = .2," "medium, d = .5," "large, d = .8", based on the classification suggested by Cohen, J (1998)

2.5.4.1 *Presentation of meta-analysis results*

A table of the meta-analysis results is presented in Table 23. The significant findings ($p \leq 0.05$) are shown in bold and the directions of the findings are shown in the final column with the text stating as to whether they favour the intervention or the control.

Table 21 and section 2.5.3.2 show the diversity of the types and timings of the interventions delivered in the included studies. Therefore, the results of the meta-analysis for each outcome shown in Table 24 to Table 32 have been divided in to three sections based on time points of outcome measurement:

Pre-surgery: all studies provide a pre-admission/pre-surgery element to the intervention, and the outcome of the intervention has been assessed at a time point prior to the date of surgery.

Discharge: all studies provide a pre-discharge intervention, and/or pre-admission/pre-surgery intervention, and the outcome of the intervention has been assessed at the point of discharge.

Long term: all studies provide a post discharge intervention, and/or a pre-discharge intervention, and/or pre-admission/pre-surgery intervention, and the outcome of the intervention has been assessed at a time point post discharge. When studies have measured at more than one follow up time point post discharge, the longest follow-up period results are used. Four studies (McGregor, 2004; Tappen, 2003; Ferrara, 2008; Gocen, 2004) reported long-term outcomes at 3 months post discharge; three other studies (Siggeirsdottir, 2005; Weaver, 2003; Rosendal, 2000) used six months; and one study

(Munin, 1998) used 4 months. Ververeli (2009) did not use a fixed time point, but measured days to achieve long-term functional milestones.

Studies reporting outcomes at more than one time point of measurement are presented in each section. Following the convention outlined previously, studies appearing to the left/negative number side of the line are in favour of the intervention and those appearing on the right/positive number side of the line represent studies where the outcome favours the control.

The study by Wong et al (2009) is not included in the meta-analysis as no descriptive data is presented in the study. Attempts were made to contact the authors to obtain the original data but this was not successful. Therefore, a narrative synthesis of the Wong et al (2009) study findings is incorporated with the description of the results of the meta-analysis findings for all the relative outcomes.

Table 23 Summary of meta-analysis results

Outcome measure	Number of studies	Total number participants	Pooled estimate (SMD)	95% confidence intervals		Probability (*p*)	Heterogeneity (I^2)	Findings in favour of
Function – patient reported outcomes								
-Pre-surgery	4	173	0.38	-0.68	-0.07	**0.02**	1%	Intervention
-Discharge	1	39	-0.24	-0.87	0.39	0.45	NA	
-Long-term	5	299	-0.46	-0.87	-0.05	**0.03**	64%	Intervention
Function – all reported outcomes								
-Pre-surgery	5	232	-0.39	-0.65	-0.13	**0.003**	0%	Intervention
-Discharge	3	180	-0.12	-0.95	0.17	0.78	86%	
-Long-term	10	896	-0.21	-0.52	0.10	0.18	78%	
Pain – VAS based analysis								
-Pre-surgery	3	125	-0.37	-0.86	0.13	0.15	44%	
-Discharge	2	98	-0.20	-0.61	0.20	0.33	4%	
-Long-term	5	332	-0.20	-0.55	0.15	0.27	52%	
Pain – WOMAC based analysis								
-Pre-surgery	3	125	-0.41	-0.78	-0.03	**0.03**	5%	Intervention
-Discharge	2	98	-0.18	-0.59	0.23	0.38	0%	
-Long-term	5	332	-0.04	-0.35	0.26	0.78	39%	
Health related quality of life								
-Pre-surgery	3	125	-0.41	-1.16	0.34	0.29	74%	
-Discharge	2	121	0.00	-0.35	0.36	0.99	0%	
-Long-term	5	291	0.25	0.20	0.48	**0.03**	0%	Control
Societal participation								
-Pre-surgery	1	63	0.57	0.07	1.08	**0.03**	NA	Control
-Discharge	1	82	0.47	0.03	0.91	**0.04**	NA	Control
-Long-term	3	541	-0.07	-0.79	0.64	0.84	94%	

Table 23: Summary of meta-analysis results (continued)

Outcome measure	Number of studies	Total number participants	Pooled estimate (MD)	95% confidence intervals	Probability (*p*)	Heterogeneity (I^2)	Findings in favour of
Anxiety							
-Pre-surgery	2	135	-7.97	-15.55 -0.40	**0.04**	45%	Intervention
-Discharge	1	70	-9.58	-19.28 0.12	0.05[(1)]	NA	Intervention
Length of Stay	8	994	-0.12	-1.77 2.01	**0.03**	76%	Intervention
Outcome measure	Number of studies	Total number participants	Pooled estimate (Odds Ratio)	95% confidence intervals	Probability (*p*)	Heterogeneity (I^2)	Findings in favour of
Dislocation	4	553	0.37	0.09 1.48	0.16	0%	

Abbreviations: SMD, standard mean difference; MD, mean difference.

Note [(1)]: Anxiety at discharge probability is only borderline significant as 95% confidence intervals cross the line of no effect

2.5.4.2 *Description of results of meta-analysis*

2.5.4.2.1 Function

Measures reported

A total of 896 participants were included in the meta-analysis of function. Six studies containing 362 participants (see Figure 19) reported function using patient reported outcome measures (PROMs). Ferrara (2006), McGregor (2004) and Weaver (2003) reported results using the function domain of WOMAC, Siggeirsdottir (2005) using the function domain of the Oxford hip score, Rosendal (2000) using the functional domain of the hip rating questionnaire and Sandell (2008) using the physical domain of the Nottingham health profile. Sandell (2008) also reported function as a domain of the arthritis impact measure score; although this is a disease specific measure which would normally be preferential to use over a general measure, it contains domains specific to upper limb function, which are not directly relevant to this review, and could therefore bias the findings. Therefore, the results from the Nottingham health profile were used in preference. Siggeirsdottir (2005) also used the Meurle D'Abuigne & Postel score but these results were not presented in the published article, nor could the author provide them upon request. Two other studies measured function using observational tools of physical function or achievement of milestone tasks completed by researchers. Munin (1998) used the functional status index and Tappen (2002) a functional index measure.

A further four studies containing 534 participants reported function using methods other than PROM. Gocen (2004) employed the Harris hip score and Rosendal (2000) used the hip

rating questionnaire, both of which have a combination of questions and physical measures of hip strength and range of movement that require assessment by a researcher. Munin (1998) used the Functional Status Index which requires scoring of functional ability by the assessor, and Ververeli (2009) used days to achieve functional milestones. The results of these additional studies are included in Figure 20.

Wong (1990) recorded long term function using the Objective Functional Capacity Index and the Subjective Functional Capacity Index. As no data on variance about the mean is presented in the article, this study could not be used in the meta-analysis. At the six month follow up, Wong (1990) reports there was no statistically significant difference between those randomised to the enhanced post-operative education and rehabilitation programme at early discharge or conventional discharge compared to the conventional discharge and traditional rehabilitation programme ($P > 0.33$).

Pre-surgery

Figure 19 and Figure 20 show that the PROMs and all functional outcome analyses have similar results and show a significant improvement between groups in favour of the intervention. Four studies (Ferrara, 2006; McGregor, 2004; Siggeirsdottir, 2005; Sandell, 2008) reported interventions that were delivered partially or in-full, and their effects assessed at a time point prior to surgery using PROMs. For this analysis, the standard mean difference (SMD) between the groups was -0.38 (CI -0.68, -0.07: p=0.02). Addition of the (Gocen, 2004) study to the all functional outcomes meta-analysis results in only small changes; SMD -0.39 (-0.65, -0.13: p=0.003). A total of 232 participants were included in all

measures of function at the pre-surgery time point. The I^2 Statistic is only 1% for the PROM analysis and 0% for all indicating heterogeneity in these findings is of no concern.

Discharge

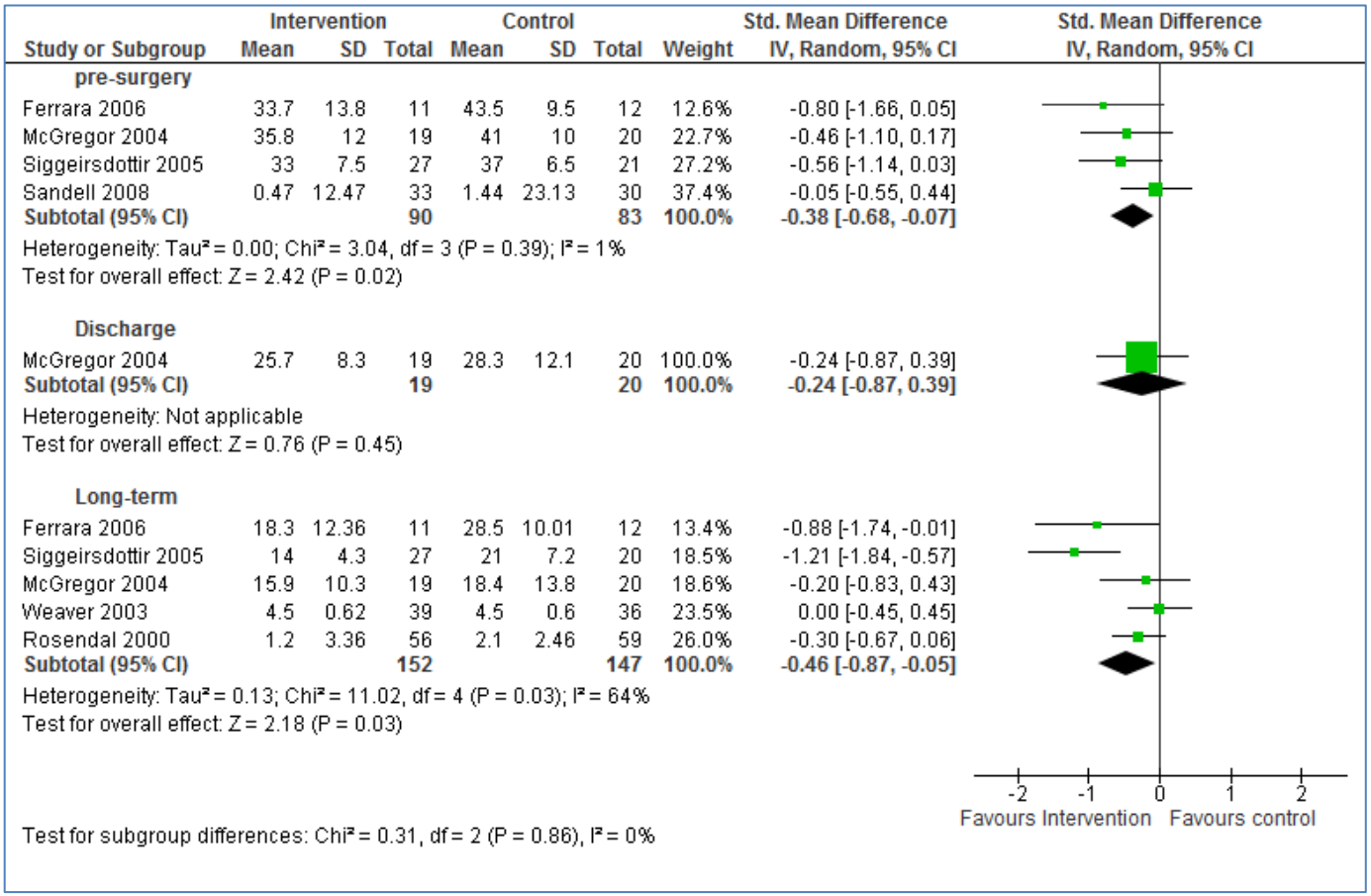
Three studies containing 180 participants measured function by all measures at the point of discharge. Only one study (McGregor, 2004) reported function using PROMs, and two studies (Gocen, 2004; Tappen, 2002) using other outcomes. Both sets of analyses are not significant with a SMD of -0.24 (-0.78, 0.39: *p*=0.45) for the PROM analysis, and a SMD of -0.12 (-0.95, 0.17: *p*=0.78) for all reported functional outcomes. As only one study was included in the patient reported analysis, and three when using all functional measures, these results should be treated with caution. The I^2 statistic for the studies using all functional measures is 86% Indicating considerable heterogeneity may be present. However, the results are not significant.

Long-term

Ten studies containing 896 participants measured long term function by all measures. Five studies containing 299 participants (Ferrara, 2006; Siggeirsdottir, 2005, McGregor, 2004; Weaver, 2003, Rosendal, 2000) report long-term functional effects of the intervention using PROMs. A further five studies containing 667 participants (Gocen, 2004; Munin, 1998; Peak, 2005; Tappen, 2002; Ververeli, 2009) using other measures. Both meta-analyses favour the intervention, but only the analysis using PROMs only were statistically significant. The SMD was -0.46, (-0.87, -0.05; *p*=0.03) for PROMs only, and 0.21(-0.52, 0.10; *p*=0.18) for all outcomes.

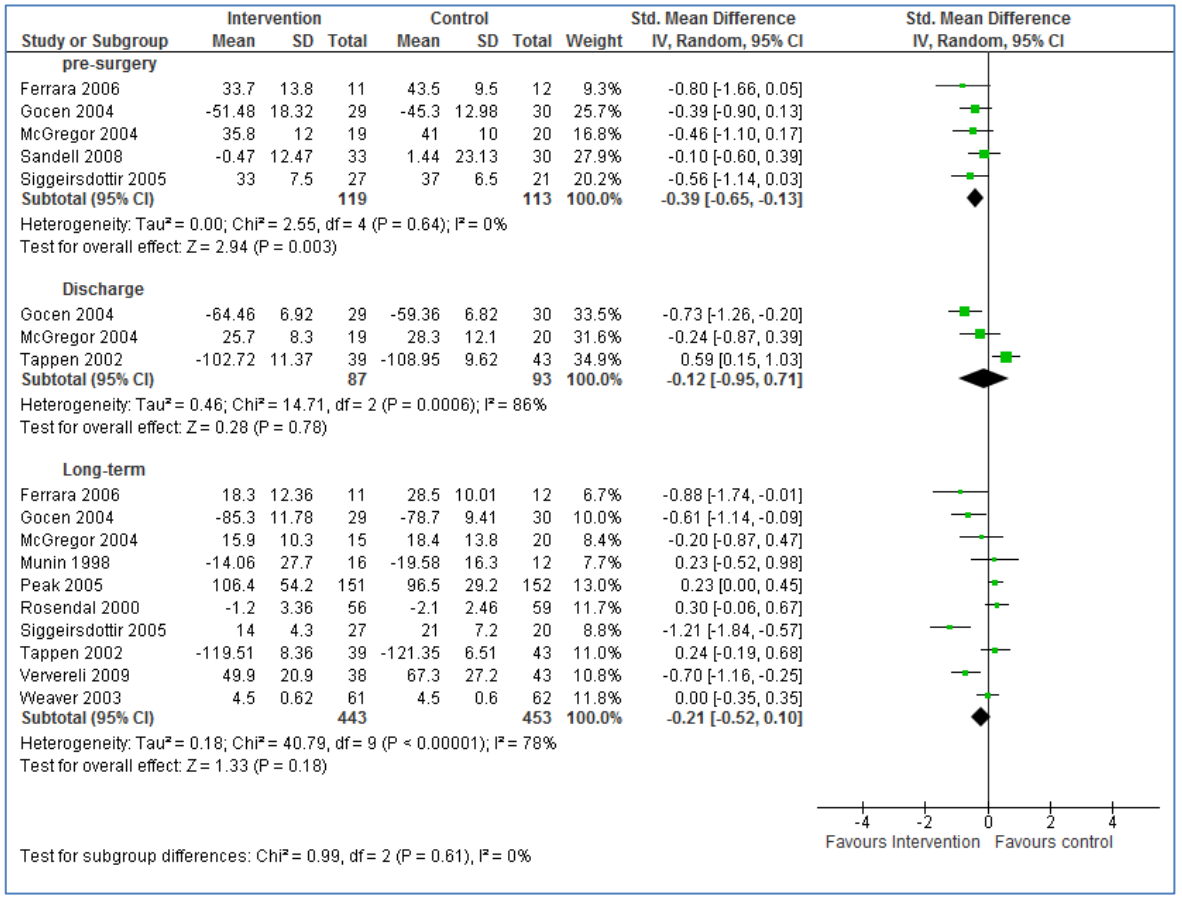
The I^2 statistic for long–term effect on functional outcomes using PROMs only was 64% indicating substantial heterogeneity may be present, so caution should be applied in interpreting these findings.

Figure 19 Function: Patient reported outcomes



WOMAC (Function): Ferrara (2006), McGregor (2004), Weaver (2003); **Oxford Hip Score (function):** Siggeirsdottir (2005); **Nottingham Health Profile (Physical):** Sandell (2008); **Hip Rating Questionnaire (function):** Rosendal (2000)

Figure 20 Function: All outcome measures



WOMAC (function): Ferrara (2006), McGregor (2004), Weaver (2003**); Harris Hip Score:** Gocen (2004); **Functional status index:** Munin (1998); **Nottingham health profile (physical):** Sandell (2008); **Oxford hip score (function):** Siggeirsdottir (2005); **Functional index measure (functional ability):** Tappen (2002); **Hip Rating Questionnaire (function):** Rosendal (2000) ; **Ability to perform ADL's at 6 months post discharge:** Peak (2005) ; **Days to walk without limp:** Ververeli (2009)

2.5.4.2.2 Pain

Measures reported

Seven studies containing 489 participants reported pain; Ferrara (2006), Gocen (2004), McGregor (2004) used the visual analogue scale, Munin (1998) used the bodily pain domain of the RAND-36, Rosendal (2000) used the pain domain of the hip rating questionnaire, Sandell (2008) used the pain domain of the arthritis impact measure score and Weaver (2003) used the pain domain of the WOMAC. Two of these studies, Ferrara (2006) and McGregor (2004), as well as reporting pain using the visual analogue scale (VAS), also reported pain by means of the WOMAC pain domain. As both of these are patient self-reported measures, and the studies report findings at all three time-points used in the meta-analysis, a sensitivity analysis was undertaken. The analyses were run using all studies, but for those studies which reported pain using both measures, one analysis used the VAS data and another used the WOMAC data. Figure 21 (VAS data) presents the results of the meta-analysis for pain using the VAS results Figure 22 (WOMAC data) using results from the pain domain of WOMAC.

Pre-surgery

Three studies containing 121 participants (Ferrara, 2006; McGregor, 2004; Sandell, 2008) reported the effect of interventions intended to reduce pre-surgical perception of pain. When using the WOMAC pain scores for Ferrara (2006) and McGregor (2004), there is an overall significant decrease in pain in favour of the interventions. The SMD between the groups was -0.41 (-0.78, -0.03: p=0.03). The results of the pre-surgery analysis using the VAS

results also tend to favour the intervention but are not significant; the SMD between groups was -0.37 (-0.86, 0.13; *p*=0.15). The heterogeneity associated with the significant finding for reduction of pre-surgery pain using the WOMAC based analysis had an I^2 of 5% indicating heterogeneity may be of little concern, and therefore findings can be treated with confidence. The I^2 value for the non-significant VAS based analysis was 44% in indicating moderate heterogeneity may be present.

Discharge

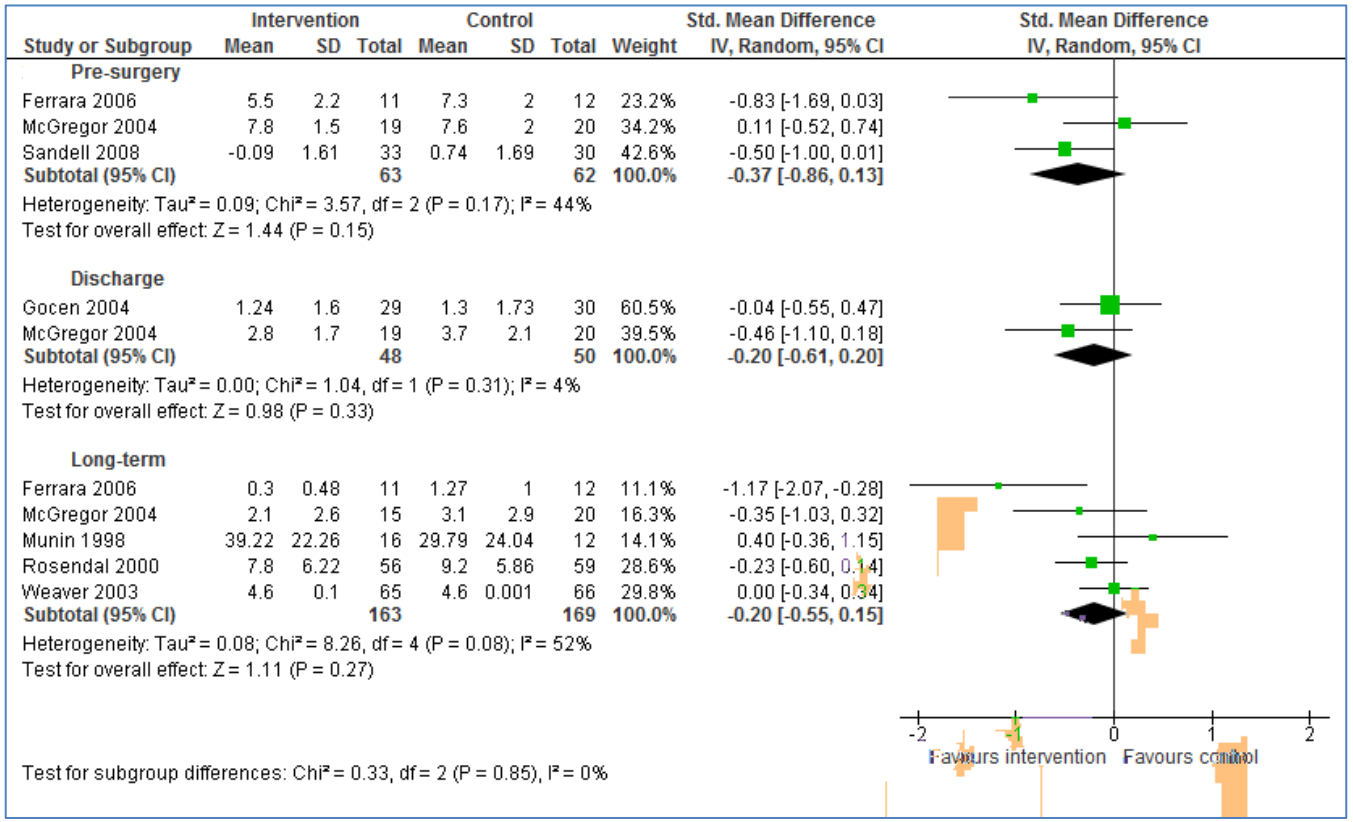
Only two studies containing 94 participants (Gocen, 2004; McGregor, 2004) reported levels of pain at point of discharge. Both the VAS and WOMAC based analyses show that the OT interventions have no significant impact on pain. At discharge, the SMD between groups for the VAS based analysis was –0.20 (-0.61, 0.02; *p*=0.33) and -0.18 (-0.59, 0.23: *p*=0.38) for the WOMAC pain domain analysis. The I^2 statistic was only 4% for the VAS based analysis and 0% for the WOMAC indicating the heterogeneity was low in both analyses. However, as only two studies were included, caution must be used interpreting the results of this discharge time point analysis, as the findings may not be representative.

Long-term

Five studies containing 332 participants (Ferrara, 2006; McGregor; Munin, 1998; Rosendal, 2000; Weaver, 2003) report long-term levels of pain. For the both the VAS and WOMAC based analyses, the results tend to favour the interventions but are not significant; the SMD between groups was –0.20 (-0.55, 0.15: *p*=0.27) for the VAS based, and -0.04 (-0.35, 0.26: *p*=0.78) for the WOMAC based. The I^2 statistic is 52% for the VAS analysis and 39%

suggesting only moderate heterogeneity is present so these results can be treated with confidence.

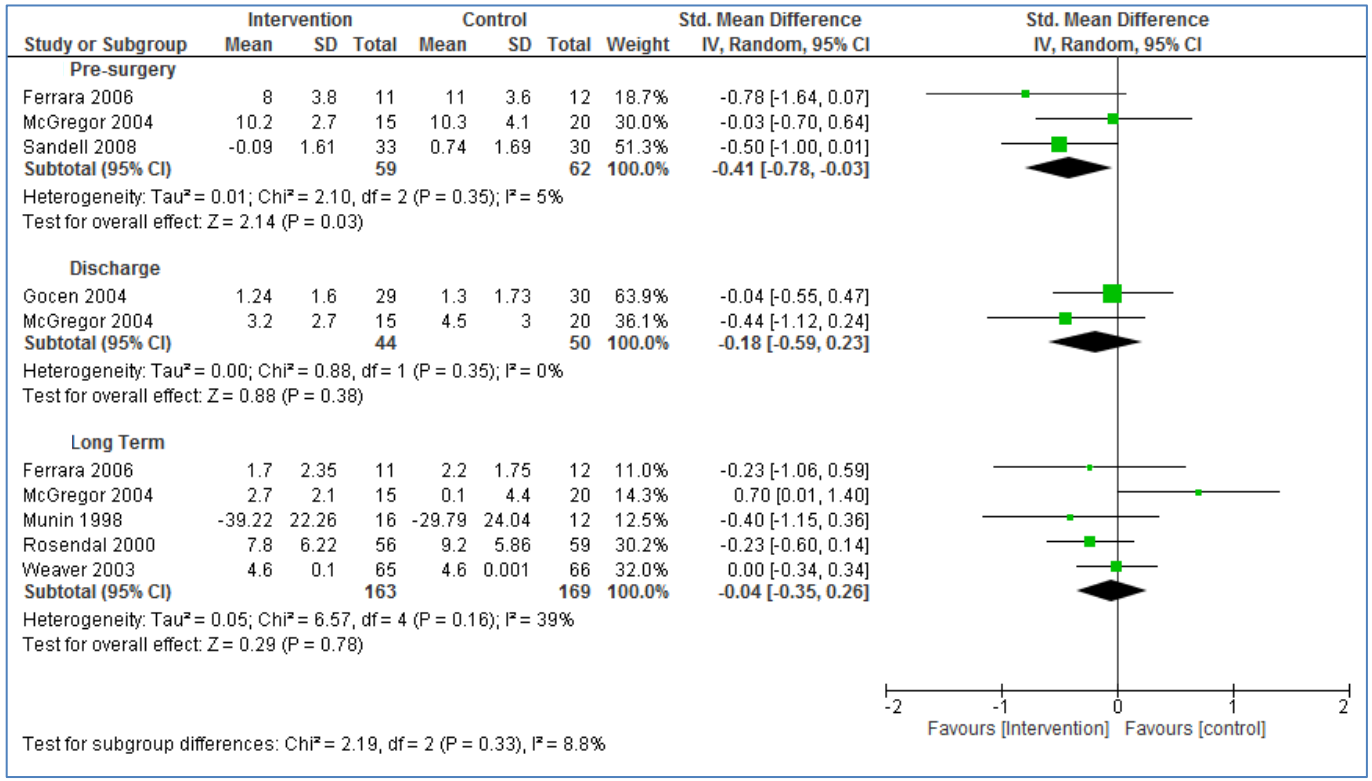
Figure 21–Pain (VAS based analyses)



Visual Analogue Scale: Ferrara (2006), Gocen (2004) [(1)], McGregor (2004) ; **RAND-36 (bodily pain):** Munin (1998) ; **Hip Rating Questionnaire (pain):** Rosendal (2000) Arthritis impact measure score (pain): Sandell (2008); WOMAC (pain): Weaver (2003)

Note [(1)]: Gocen (2004) VAS (on activity)

Figure 22–Pain (WOMAC based analysis)



Visual Analogue Scale: Gocen (2004) [(1)]; **RAND-36 (bodily pain):** Munin (1998); **Hip Rating Questionnaire (pain):** Rosendal (2000); **Arthritis impact measure score (pain):** Sandell (2008); WOMAC (pain): Weaver (2003), McGregor (2004), Ferrara (2006),

Note (1): Gocen (2004) VAS (on activity)

2.5.4.2.3 Health related quality of life

Measures reported

Six studies containing 380 participants (Ferrara, 2006; McGregor; Munin, 1998; Sandell, 2008; Tappen, 2002; Weaver, 2003) reported quality of life findings; each study using different methods or measures (see Figure 23). Ferrara (2006) and Weaver (2003) both employed the SF-36, the former aggregating the physical domains and presenting the physical composite score whilst Weaver (2003) presented all component scores; the physical role results being used in the meta-analysis. McGregor (2004) used the EQ-5D, though results were only presented in graphical form requiring the data to read from the graph (author contacted for original data but was not able to provide). Munin (1998) presented results to evaluate health related quality of life by way of the 'role functioning physical' domain of the RAND-36, Sandell (2008) the 'satisfaction with life' domain of the arthritis impact measure score and Tappen (2002) the Jalowiec coping scale.

Pre-surgery

Three studies containing 125 participants (Ferrara, 2006; McGregor, 2004; Sandell, 2008) reported the findings of interventions at the pre-surgery point of measurement. The results were not significant; the SMD between groups -0.41 (-1.16, 0.34; p=0.29). The I^2 statistic of 74% indicating substantial to considerable heterogeneity may be present; and as only three studies were included, caution must be used when interpreting the findings.

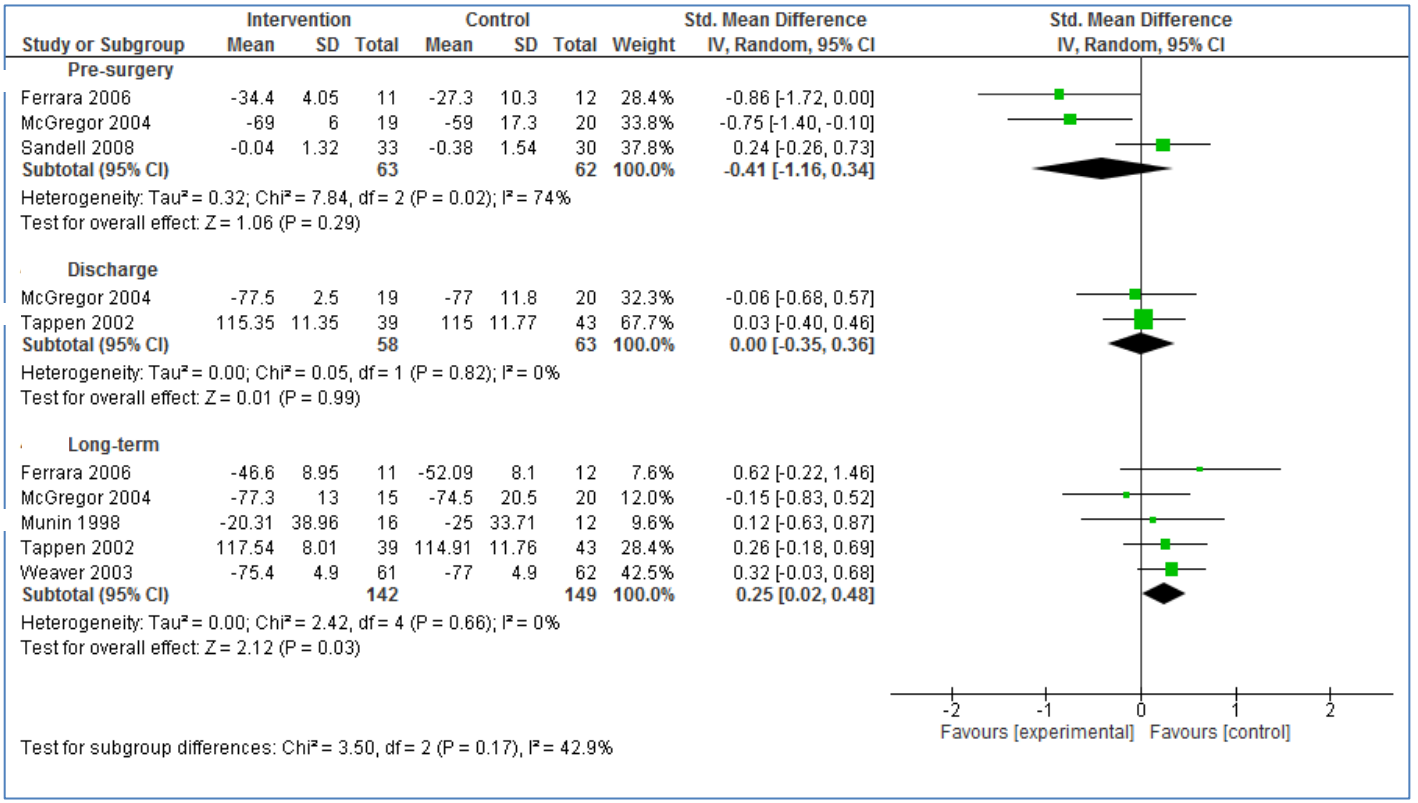
Discharge

Two studies containing 121 participants (McGregor, 2004; Tappen, 2002) reported results of interventions at the point of discharge. These show no effect on health related quality of life; the SMD between groups was 0.00 (-0.35, 0.36; p=0.99). The I^2 statistic is 0%, indicating no heterogeneity. However, as only two studies were included, caution must be used interpreting the results of this discharge time point analysis, as the findings may not be representative.

Long-term

Five studies containing 291 participants (Ferrara, 2006; McGregor; Munin, 1998; Tappen, 2002; Weaver, 2003) reported long-term results for heath related quality of life. Only the McGregor (2004) study showed a weak trend in favouring the intervention; all the others showed a trend towards favouring the control, though none were individually significant. However, the overall meta-analysis is significant favouring the control; the SMD between groups was 0.25 (0.20, 0.48; p=0.03). The I^2 statistic for the long-term analysis is 0% suggesting heterogeneity is not important; therefore these findings can be treated with confidence.

Figure 23 –Health related quality of life



SF-36 (physical composite score): Ferrara (2006); **EQ-5D:** McGregor (2004) (Data Scaled from graph – original data not available); **RAND-36:** (Role functioning physical): Munin (1998); **Arthritis impact measure score (satisfaction with life):** Sandell (2008); **Jalowiec coping scale:** Tappen (2002); **SF-36 (physical role):** Weaver (2003)

2.5.4.2.4 Social Participation

Measures reported

Five studies containing 686 participants (Sandell, 2008; Tappen, 2002, Peak, 2005; Rosendal, 2000; Weaver, 2003) measured social participation using different PROMs (Figure 24). Peak (2005) used return to work, Rosendal (2000) presented results using the SIP-68, Sandell (2008) the 'satisfaction with health' domain of the Arthritis Impact Measure Score, Tappen (2002) the functional life scale and Weaver (2003) the 'social function' domain of the SF-36.

Pre-surgery

Only Sandell (2008) reported societal participation at the pre-surgery time point with an SMD of 0.57 (0.07, 1.08: p=0.03) significantly in favour of the control group.

Discharge

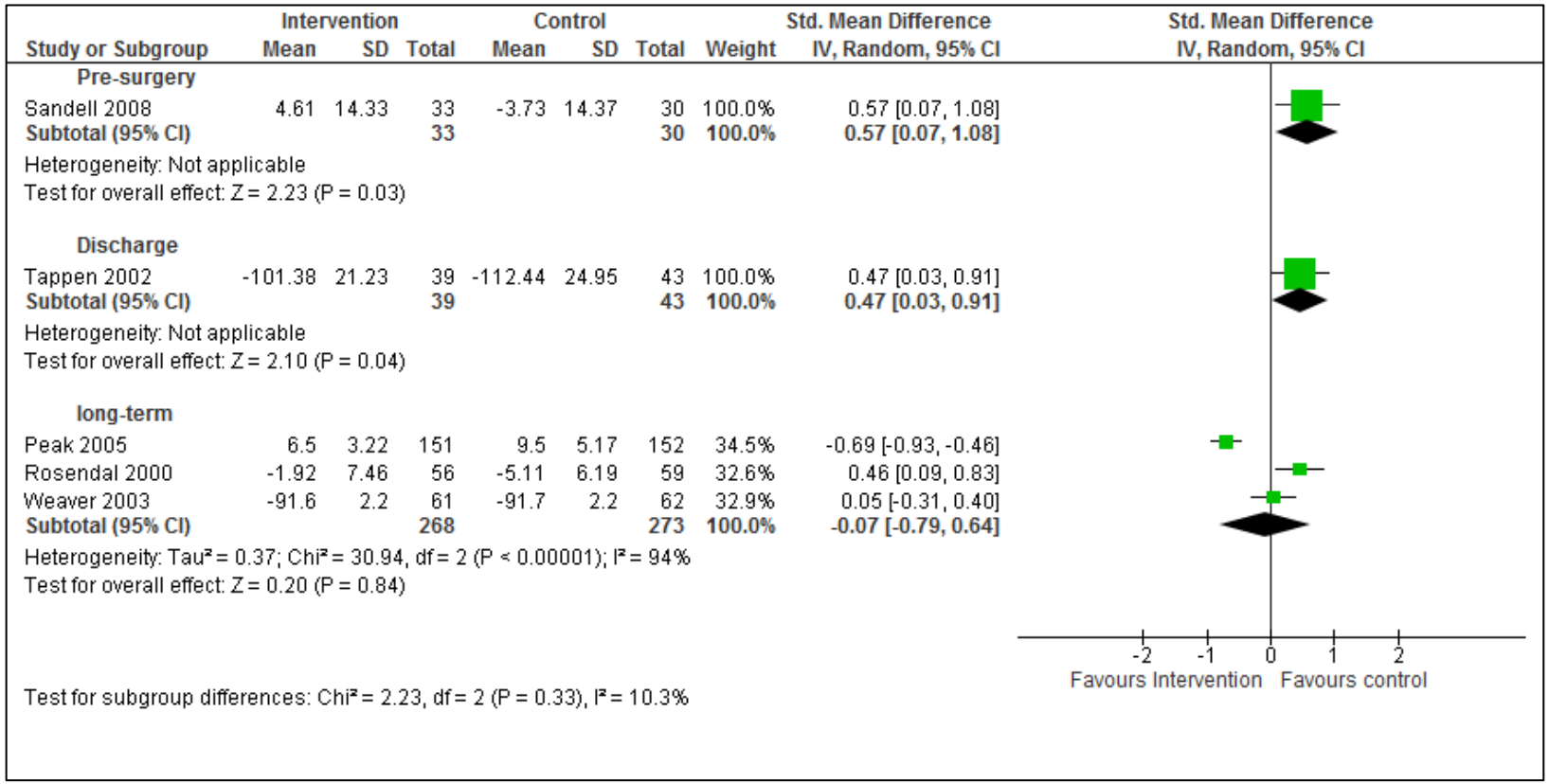
Similarly, only one study (Tappen, 2002) reported results at the point of discharge, with findings also significantly in favour of the control: the SMD was 0.47 (0.03, 0.91: p=0.04).

As both of these analyses, measured pre-surgery and at point of discharge, have only one study, the results of this analysis may not be representative of the general population and must be interpreted with caution.

Long-term

Three studies containing 541 participants (Peak, 2005; Rosendal, 2000; Weaver, 2003) reported long-term results for societal participation with an SMD between groups of -0.07 (-0.79, 0.64; p=0.84). The I^2 statistic for the long term societal participation was exceptionally high at 94% indicating considerable heterogeneity is present. Such a high level of heterogeneity means this finding must be treated with great caution. This level of heterogeneity also suggests that these studies may not be suitable for meta-analysis (Higgins and Green, 2011).

Figure 24 – Social participation



SIP-68: Rosendal (2000); **Arthritis impact measure score (satisfaction with health):** Sandell (2008); **Functional life scale:** Tappen (2002) **SF-36 (social function)**; Weaver (2003); **Return to work:** Peak (2005)

2.5.4.2.5 Anxiety

Measures reported

Two studies containing 135 participants, Butler (1996) and Crowe (2003), measured anxiety (Figure 25). As both studies used the same outcome measurement instrument; the state-trait anxiety inventory mean difference (MD) modelling was used in the meta-analysis.

Pre-surgery

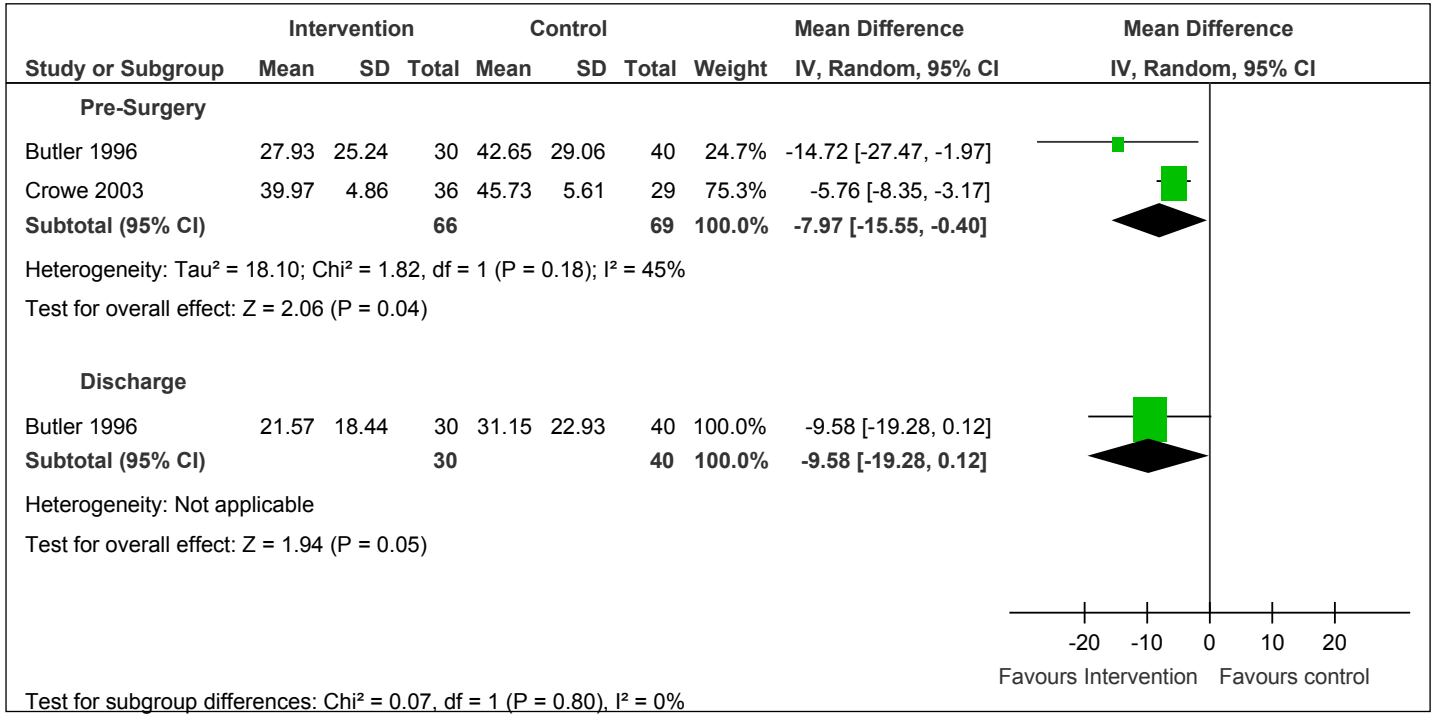
Both studies reported significant pre-surgery results from pre-admission interventions. The MD between the groups was -7.97 (-15.55, -0.40: p=0.04) in favour of the interventions. The I^2 statistic was 45% indicating only moderate heterogeneity may be present.

Discharge

Only Butler (1996) measured anxiety levels at discharge; the findings were borderline significant in favour of the intervention with a MD of -9.58 (-19.28, 0.12: p=0.05) between groups. Although, the probability was calculated at 0.05 it is borderline significant (the accepted level of significance is <0.05), and the 95% confidence intervals cross the line of no effect.

As only two studies were involved in the pre-surgery analysis and one study at discharge, both with small participant populations, the results of this analysis may not be representative of the wider population undergoing THR due to OA and therefore must be interpreted with caution.

Figure 25 Anxiety



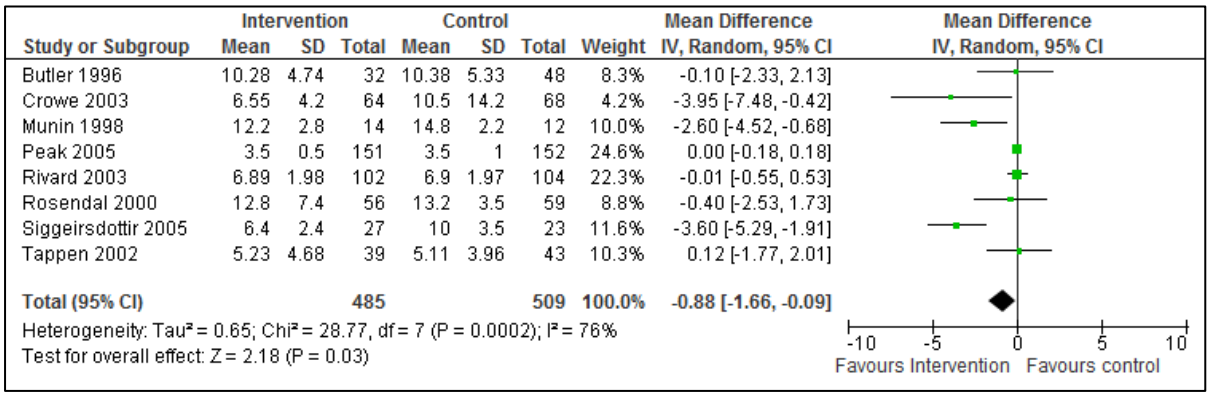
State-Trait anxiety inventory: Butler (1996), Crowe (2003)

2.5.4.2.6 Length of stay

Nine studies containing 994 participants reported the length of hospital stay (Butler, 1996; Crowe, 2003; Munin, 1998; Peak, 2005; Rivard, 2003; Rosendal, 2000; Siggeirsdottir, 2005; Tappen, 2002; Wong, 1990) and mean difference modelling was employed (Figure 26). Three studies (Crowe, 2003; Munin, 1998; Siggeirsdottir, 2005) reported the intervention had a statistically significant effect on reducing the hospital length of stay. The other five included studies showed almost no effect. The overall result of the meta-analysis shows a statistically significant effect in favour of OT interventions reducing hospital length of stay; MD between groups was -0.88 (-1.66, -0.09: p=0.03). However, the I^2 statistic was 76% indicating substantial to considerable heterogeneity may be present. This suggests the results should be treated with a degree of caution.

The Wong (2009) study provided no data on variance about the mean, so could not be included in the meta-analysis. There was no significant statistical difference in length of stay in those allocated to the enhanced post-operative education and rehabilitation programme (mean: 13.85 days) compared to the conventional discharge and rehabilitation regime (mean: 12.75).

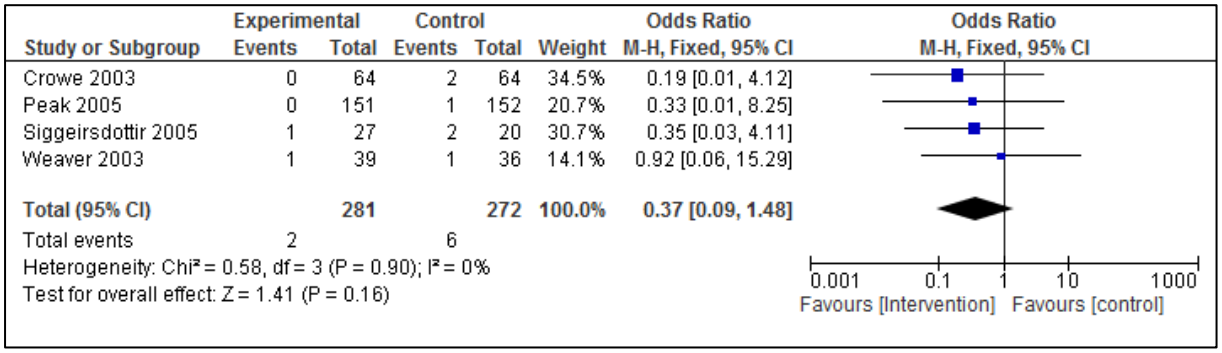
Figure 26 Length of Stay (days)



2.5.4.2.7 Dislocation

Four studies containing 553 participants (see Figure 27) report the number of dislocations; Crowe (2003), Peak (2005), Siggeirsdottir (2005) and Weaver (2003). As dislocation is a dichotomous outcome an odds-ratio modelling was used as the meta-analysis method. Although the overall number of dislocations reported were lower in the OT intervention groups (n=2) compared with the number in the control groups (n=6), the results of the meta-analysis O.R. 0.37 (0.09, 1.48; *p*=0.16) favour the intervention, but are not significant.

Figure 27 Prosthesis dislocation



2.5.5 Synthesis of meta-analysis results with quality of studies

The combination of the meta-analysis results with the bias adjusted quality of the studies for the various outcomes and time-points are shown in Table 24 to Table 32 below. Non-significant outcomes have been graded as providing '*no evidence of effect*' due to the few studies with small sample sizes for each outcome. However, the results of the GRADE analysis are still reported in parenthesis to illustrate the final quality of the evidence for that outcome.

Table 24 level of evidence analysis for function (PROM only)

Time Point	Study	Study design	GRADE Adjustment due to:						GRADE of Evidence
			Initial quality of evidence	Consistency	Directness	Precision	Plausible confounding	Strength of association	
Pre surgery	Ferrara (2006)	RCT	Moderate	Consistent No adjustment	Direct No adjustment	Precise No adjustment	NA	NA	**Moderate to High**
	McGregor (2004)	RCT	High						
	Siggeirsdottir (2005)	RCT	Moderate						
	Sandell (2008)	RCT	Moderate						
Discharge	McGregor (2004)	RCT	High	Consistency unknown (single study)	Direct	Imprecise -1 grade adjustment	NA	NA	**No Evidence** (Moderate)
Long-term	Ferrara (2006)	RCT	Moderate	Consistent No adjustment	Direct No adjustment	Imprecise -1 grade adjustment	Absent – no adjustment	NA	**Moderate to Very low**
	McGregor (2004)	RCT	High						
	Siggeirsdottir (2005)	RCT	Moderate						
	Weaver (2003)	RCT	High						
	Rosendal (2000)	CCT	Low						

Table 25 level of evidence analysis for function (all outcome measures)

Time Point	Study	Study design	Grade Adjustment due to:						GRADE of Evidence
			Initial quality of evidence	Consistency	Directness	Precision	Plausible confounding	Strength of association	
Pre surgery	Ferrara (2006)	RCT	Moderate	Consistent No adjustment	Direct No adjustment	Precise No adjustment	NA	NA	**Moderate to High**
	Gocen (2004)	RCT	High						
	McGregor (2004)	RCT	High						
	Siggeirsdottir (2005)	RCT	Moderate						
Discharge	Gocen (2004)	RCT	High	Consistent No adjustment	Direct No adjustment	Imprecise -1 grade adjustment	Absent – no adjustment	NA	**No Evidence** (Moderate to Very low)
	McGregor (2004)	RCT	High						
	Tappen (2002)	CCT	Low						
Long-term	Ferrara (2006)	RCT	Moderate	Inconsistent -1 grade adjustment	Direct No adjustment	Imprecise -1 grade adjustment	Absent – no adjustment	NA	**No Evidence** (Low to No evidence)
	Gocen (2004)	RCT	High						
	McGregor (2004)	RCT	High						
	Munin (1998)	RCT	High						
	Peak (2005)	RCT	Moderate						
	Rosendal (2000)	CCT	Low						
	Siggeirsdottir (2005)	RCT	Moderate						
	Tappen (2002)	CCT	Low						
	Ververeli (2009)	RCT	Low						
	Weaver (2003)	RCT	High						

Table 26 Level of evidence analysis for pain (VAS)

Time Point	Study	Study design	Grade Adjustment due to:						GRADE of Evidence
			Initial quality of evidence	Consistency	Directness	Precision	Plausible confounding	Strength of association	
Pre surgery	Ferrara (2006)	RCT	Moderate	Inconsistent No adjustment as inconsistency not serious	Direct No adjustment	Imprecise -1 grade adjustment	NA	NA	**No Evidence** (Moderate to Low)
	McGregor (2004)	RCT	High						
	Sandell (2008)	RCT	Moderate						
Discharge	Gocen (2004)	RCT	High	Inconsistent No adjustment as inconsistency not serious	Direct No adjustment	Imprecise -1 grade adjustment	NA	NA	**No Evidence** (Moderate)
	McGregor (2004)	RCT	High						
Long-term	Ferrara (2006)	RCT	Moderate	Inconsistent -1 adjustment as inconsistency serious	Direct No adjustment	Imprecise -1 grade adjustment	Absent No adjustment	NA	**No Evidence** (Low – No evidence)
	McGregor (2004)	RCT	High						
	Weaver (2003)	RCT	High						
	Munin (1998)	RCT	High						
	Rosendal (2000)	CCT	Low						

Table 27 Level of evidence analysis for pain (WOMAC)

Time Point	Study	Study design	Grade Adjustment due to:						GRADE of Evidence
			Initial quality of evidence	Consistency	Directness	Precision	Plausible confounding	Strength of association	
Pre surgery	Ferrara (2006)	RCT	Moderate	Inconsistent No adjustment as inconsistency not serious	Direct No adjustment	Imprecise -1 grade adjustment	NA	NA	**Moderate to Low**
	McGregor (2004)	RCT	High						
	Sandell (2008)	RCT	Moderate						
Discharge	Gocen (2004)	RCT	Moderate	Inconsistent No adjustment as inconsistency not serious	Direct No adjustment	Imprecise -1 grade adjustment	NA	NA	**No Evidence** (Moderate to Low)
	McGregor (2004)	RCT	High						
Long-term	Ferrara (2006)	RCT	Moderate	Inconsistent -1 adjustment as inconsistency serious	Direct No adjustment	Imprecise -1 grade adjustment	Absent No adjustment	NA	**No Evidence** (Low – No evidence)
	McGregor (2004)	RCT	High						
	Weaver (2003)	RCT	High						
	Munin (1998)	RCT	High						
	Rosendal (2000)	CCT	Low						

Table 28 Level of evidence analysis for HRQoL

Time Point	Study	Study design	Grade adjustment due to:						GRADE of Evidence
			Initial quality of evidence	Consistency	Directness	Precision	Plausible confounding	Strength of association	
Pre surgery	Gocen (2004)	RCT	High	Inconsistent -1 adjustment as inconsistency serious	Direct No adjustment	Imprecise -1 grade adjustment		NA	**No Evidence** (Low- No evidence)
	Ferrara (2006)	RCT	Moderate						
	Sandell (2008)	RCT	Moderate						
Discharge	McGregor (2004)	RCT	High	Consistent No adjustment	Direct No adjustment	Imprecise -2 grade adjustment	Absent No adjustment	NA	**No Evidence** (Low – No evidence)
	Tappen (2002)	CCT	Low						
Long-term	Ferrara (2006)	RCT	Moderate	Inconsistent -1 adjustment as inconsistency serious	Direct No adjustment	Imprecise -2 grade adjustment	Absent No adjustment	NA	**Low to No Evidence** (Control)
	McGregor (2004)	RCT	High						
	Munin (1998)	RCT	High						
	Weaver (2003)	RCT	High						
	Tappen (2002)	CCT	Low						

Table 29 Level of evidence analysis for societal participation

Time Point	Study	Study design	Grade adjustment due to:						GRADE of Evidence
			Initial quality of evidence	Consistency	Directness	Precision	Plausible confounding	Strength of association	
Pre surgery	Sandell (2008)	RCT	Moderate	Consistency unknown (single study)	Direct No adjustment	Precise No adjustment		NA	**Moderate (Control)**
Discharge	Tappen (2002)	CCT	Low	Consistent No adjustment	Direct No adjustment	Precise No adjustment	Absent No adjustment	NA	**Low (Control)**
Long-term	Peak (2005)	RCT	Moderate	Consistent No adjustment	Direct No adjustment	Imprecise -1 adjustment	Absent No adjustment	NA	**No Evidence** (Moderate to Very low)
	Weaver (2003)	RCT	High						
	Rosendal (2000)	CCT	Low						

Table 30 Level of evidence analysis for anxiety

Time Point	Study	Study design	Grade adjustment due to:						GRADE of Evidence
			Initial quality of evidence	Consistency	Directness	Precision	Plausible confounding	Strength of association	
Pre surgery	Butler (1996)	RCT	High	Consistent No adjustment	Direct No adjustment	Imprecise No adjustment	NA	NA	High (Intervention)
	Crowe (2003)	RCT	High						
Discharge	Butler (1996)	RCT	High	Consistency unknown (single study)	Direct No adjustment	Precise No adjustment	NA	NA	No Evidence (High)

Table 31 Level of evidence analysis for length of stay

Study	Study design	Grade adjustment due to:						GRADE of Evidence
		Initial quality of evidence	Consistency	Directness	Precision	Plausible confounding	Strength of association	
Butler (1996)	RCT	High	Inconsistent No adjustment as inconsistency not serious	Direct No adjustment	Imprecise No adjustment	Absent No adjustment	NA	Moderate (Intervention)
Crowe (2003)	RCT	High						
Munin (1998)	RCT	High						
Peak (2005)	RCT	Moderate						
Siggeirsdottir (2005)	RCT	Moderate						
Rivard (2003)	CCT	Low						
Tappen (2002)	CCT	Low						
Rosendal (2000)	CCT	Low						

Table 32 Level of evidence analysis for dislocation

Study	Study design	Grade adjustment due to:						GRADE of Evidence
		Risk of Bias	Consistency	Directness	Precision	Plausible confounding	Strength of association	
Crowe (2003)	RCT	High	Consistent	Direct	Precise	Absent	NA	**No Evidence** (Moderate to High)
Peak (2005)	RCT	Moderate	No adjustment	No adjustment	No adjustment	No adjustment		
Siggeirsdottir (2005)	RCT	Moderate						
Weaver (2003)	RCT	High						

2.5.6 Results of the combined evidence synthesis

2.5.6.1 *In favour of interventions*

The results of this meta-analysis show there is high quality evidence from two studies (n=205) that occupational therapy interventions delivered pre-admission help to reduce pre-surgery anxiety. There is a moderate to high level of evidence from 5 studies (n=232) that occupational therapy interventions delivered pre-admission help to improve pre-surgery function measured either by patient reported outcomes only or by other methods of assessment. There is moderate evidence from 8 studies (n= 994) that occupational therapy interventions delivered prior to admission or during the acute hospital stay significantly reduce the duration of hospital stay. There is moderate to low levels of evidence from 3 studies (n=125) that occupational therapy interventions delivered prior to admission significantly decrease patients' experience of pain when the WOMAC pain score is used to replace the VAS in studies that reported both outcomes. There is moderate to very low evidence from 5 studies (n=229) that occupational therapy interventions delivered either prior to admission, during the acute hospital stay or post discharge significantly improve long term function measured using patient reported outcome measures. However, there was substantial heterogeneity for this outcome which suggests that the interpretation of this finding must be treated with caution.

2.5.6.2 *In favour of control*

There is a moderate level of evidence from one study (n=63) that occupational therapy interventions delivered prior to admission significantly decrease societal participation prior

to admission, and a low level of evidence from 1 study (n=82) that interventions delivered prior to admission reduce societal participation measures at point of discharge. There is also low to no evidence from 5 studies (n=291) that occupational therapy interventions delivered either prior to admission, during the acute hospital stay, or post discharge, significantly decrease long term health related quality of life.

2.5.6.3 *No evidence of effect*

There no evidence to support that occupational therapy interventions assist with function at time of discharge using all measures, or patient reported outcomes only, or in the long term using all reported outcomes. There is also no evidence that occupational therapy interventions reduce patients' perception of pain pre-surgery or in the long term using either the WOMAC pain domain or the VAS pain bias method of measurement; also there is no evidence that interventions reduce pre-surgery pain using the VAS based outcome. There is no evidence that occupational therapy interventions affect heath related quality of life pre-surgery or at discharge, or long term societal participation, or anxiety at discharge, or the rate of prosthesis dislocation.

2.6 Discussion

2.6.1 Strengths and weaknesses of included studies

2.6.1.1 *Study design*

Twelve out of the fifteen included studies were RCTs which are considered the highest standard of clinical trial (Guyatt et al, 2000). All the included studies experienced minimal

loss to follow-up and none were identified as of being at high risk of bias for loss of blinding of the outcome assessor. Additionally, none of the 12 included RCTs were considered to contain a high risk of bias in the categories of randomisation sequence generation and allocation concealment. The majority of the studies were carried out prior to, or soon after release, of the original 2001 CONSORT statement (Moher et al, 2001) for parallel arm RCTs. It is therefore possible that several categories have been associated with an uncertain level of bias due to poor reporting rather than due to poor actual conduct of the trials.

The sample sizes in many studies were very small with a median value of 86 (range 23 to 303). Cohen (1998) indicates that for medium effect size of 0.5 (with p=0.05 and 80% power), a minimum of 50 participants per group is required: only five studies met this sample size minimum value (Crowe, 2003; Rivard, 2003; Peak, 2005; Rosendal, 2000; Weaver, 2003). Additionally, most of the studies measured multiple outcomes with no statistical plan or corrections applied for the effect this has on further reducing the power of the studies to detect a true clinical difference (Revicki et al, 2000). This small sample may lead to an underestimation of the efficacy of OT.

2.6.1.2 *Occupational therapy involvement*

The study data in Table 21 shows only two of the included studies were exclusively evaluating OT practice, and furthermore, the OT intervention in the Rosendal (2003) study was carried out by a home care coordinator. Five studies were mixed therapy interventions with significant OT input from a registered occupational therapist, and seven were mixed therapy interventions where the person carrying out the recognised OT practice was either a

nurse or physiotherapist and not a specialist occupational therapist. The occupation of the person performing the recognised OT practice in Ververeli (2009) is not recorded. Although the inclusion criteria only allowed studies to be included where the mixed therapy interventions contained a significant OT content, this predominance of mixed therapy interventions is the major weakness of this review in evaluating the effectiveness of OT practice. However, this multidimensional therapy input is more representative of clinical practice. Additionally, the inclusion of recognised OT interventions performed by other health care professionals makes the finding of this review more internationally applicable, as in many countries, no occupational therapy profession exists.

2.6.1.3 *Participants*

The characteristics of the study participants in the review are closely representative of the general UK population undergoing THR with the average age of a recipient being 67.2 years, and 60% female (NJR, 2012). This makes the results of this study generalisable.

2.6.1.4 *Multiple outcome measures*

Many different outcomes were measured in the studies and recorded by different measures; a weakness also noted by Khan et al (2008) in their review of multidisciplinary rehabilitation. All the outcomes other than anxiety used multiple measurement instruments measuring the same outcome. Although the use of SMD modelling is designed to accommodate this, the strength of the review would have been improved if the included studies used standardised instruments to measure each outcome. The effect of this variation in outcomes by using different PROMs is illustrated by analysis of the results of the two studies reporting pain by

both the WOMAC and VAS. The McGregor (2004) study shows the use of the WOMAC or VAS produced very similar results at all three time points of measurement. In contrast, the findings of Ferrara (2006) show almost identical levels of pain at the pre-surgery time point; however, at the long term-term time point, the VAS results are strongly in favour of the intervention whereas using the WOMAC data, the findings show almost no effect.

2.6.1.5 *Multiple time point of assessment*

Many of the interventions in the included studies were complex in nature. This can be considered as a strength of the studies as they were representative actual OT clinical practice. However, multiple time points of assessment were used which made the meta-analysis complex. Interventions that were carried out pre-admission sometimes had outcomes measured before admission, on admission or the day before surgery. The post discharge follow-up period in most studies were varied and were mainly very short term. Better consistency in time points of measurement and determination of primary time points would improve the quality of research in to rehabilitation.

2.6.1.6 *Relevance to the NHS*

With regards to UK practice and relevance to the NHS, one of the weaknesses of this review is that only two of the included studies were carried out in the UK; and in both of these, the OT intervention was performed by either a nurse or a physiotherapist. However, in both of these studies, the therapist conducting the intervention did so in consultation with registered occupational therapists to guide their intervention. Additionally as there is such a wide variation in NHS practice (Westby et al, 2006), and all the interventions carried out in

the non-UK studies are accepted practice in the UK, the results of this review are relevant to NHS practice.

The three strongest findings from this review relate to improvements in pre-surgery levels of pain, function and anxiety which may be important (Fortin et al, 1999) to the eventual long term outcome following THR. Fortin et al (1999) conducted an observational study of 379 participants with OA waiting for elective surgery and found that function at six months was better in the participants who had higher levels of preoperative function and lower levels of pain. However, they did find that the improvements were much better for those participants undergoing TKR compared to THR. Fortin et al (1999) also found that this improved pre-operative status had no effect on reducing LOS, complications or re-hospitalisation.

2.6.2 Strengths and weaknesses of the review process

2.6.2.1 *Procedural process of the review*

A major strength of this systematic review is that, at all stages, it has been conducted in accordance with the recommendation of the Cochrane Collaboration (Higgins & Green, 2011). Two people independently screened for duplicate identification, selection or exclusion of articles and conducted the risk of bias assessment. If any differences could not be agreed on, a third independent person was used to adjudicate. A professor of occupational therapy was used to determine whether the content of the interventions was commensurate with OT practice. The main deviation from the standard Cochrane procedure was the inclusion of the three controlled clinical trials, as the Cochrane guidelines now only recommend the inclusion of RCTs. CCTs are more prone to bias and the effect of

confounding variables and their inclusion can be considered to weaken the review. However, this has to be balanced against the wider body of research evidence that can be incorporated to strengthen the findings. The strict quality criteria used to enable the CCTs to be included in the review minimised as much as possible the bias associated with using CCTs. Additionally, in the risk of bias assessment all three included CCTs were automatically allocated a high risk of bias for randomisation and allocation concealment and therefore considered as low quality of evidence for the evidence synthesis. However, although the review has been done following the rigorous Cochrane process, being a novice researcher is a potential weakness of this review.

One of the major difficulties of this review was due to the complex nature and wide variations in the nature of the interventions provided. Previous reviews of interventions for patients undergoing THR have either focused on a particular intervention such as pre-operative education (Mc Donald et al, 2014) or pre-operative exercise regimes (Coudeyre et al, 2007; Di Monaco et al, 2009; Dauty et al, 2007; Kuster, 2002), or mixed interventions delivered at a particular time point (Khan et al, 2008). To overcome the complexity of this review, a priori criteria were defined to classify the outcome time points of measurement as either pre-surgery, during hospital stay, or long-term. However, some of the studies had complex interventions that had components of the interventions delivered in two (pre-surgery & during hospitalisation, or during hospitalisation and post discharge) or all three phases (pre-surgery, during hospitalisation and post discharge) of the patient journey.

Although multiple outcome measures were used, a strength of this review process was that only outcome measures that have been validated were used.

The process of establishing a priori decision algorithms strengthened the systematic process and therefore the quality of the review. However, despite the strict methodological process taken, due to the complexity of the review undertaken, the novice status of the reviewer in synthesising such complex interventions must also be considered a weakness of the review.

2.6.2.2 *Reporting*

A major strength of this review is that it has been reported in accordance with the PRISMA guidelines (Moher et al, 2009) for reporting systematic reviews. A PRISMA checklist is contained in Appendix 5

2.7 Conclusions

2.7.1 Summary of key findings

- There is a high level of evidence that OT interventions help to significantly improve pre-surgery anxiety
- There is a moderate level of evidence that OT interventions help to significantly improve pre-surgery function
- There is a moderate to low levels of evidence that OT significantly helps to reduce pre-surgery levels of pain.
- There is moderate to very low evidence that OT interventions reduce the overall length of acute facility hospital stay and reduces societal participation pre-surgically and at point of discharge.

- There is low to very low levels of evidence that OT interventions assist with improving long-term function.
- There is no evidence that OT interventions assist with function at time of discharge, pain at point of discharge and long term, health related quality of life pre-surgically, at point of discharge or long term, long term societal participation or rates of prosthesis dislocation.
- There was a wide clinical heterogeneity in the types of interventions delivered, the duration and intensity of those interventions and a wide variation in the rehabilitation received by the comparator group receiving usual care. Although the majority of participants were receiving THR due to OA, there were some mixed studies and wide variation in exclusion criteria with regards to levels of cognitive impairment.
- The majority of the studies had small sample sizes, and all outcomes except pain function and LOS, had less than four studies to base the findings upon.

2.7.2 Reduced length of stay

Although this review concludes there is moderate to very low evidence that interventions reduce the overall length of acute hospital stay; the age of the studies do not reflect current clinical practice. The typical length of stay at the time the studies were conducted was approximately 10 days where patients now typically only reside in acute hospital beds for three to four days. Therefore, although these findings are statistically significant, they may no longer be clinically significant.

2.7.3 Implications for practice

This review shows overall that there is a moderate to low level of evidence that occupational therapy practice can improve the patient experience and functional outcomes. Also, as in fifty percent of the included studies, the OT intervention was not carried out by a registered occupational therapist; there is an implication that the OT intervention may be effectively performed by other therapists or nurses. However, no sub group analysis was performed.

2.7.4 Recommendations for further research

The process of undertaking this review has revealed there is a paucity of high quality research in to the effectiveness of OT practice for patients undergoing a total hip replacement. To overcome the heterogeneity of the outcomes measured and the wide variety of outcome assessment instruments used, consensus is required as to which outcomes should be measured and what are the most appropriate assessment instruments to measure OT practice for patients undergoing total hip replacement. To measure the specific efficacy of OT more research is required relating directly to OT interventions. More high quality RCTs are required. None of the studies included in the review measured the cost-effectiveness of the interventions. A further recommendation is that any future research should include cost-effectiveness.

2.8 Chapter summary

Chapter 2 reported a systematic review analysing the effectiveness of a wide range of OT interventions for people undergoing primary THR due to arthritis. The interventions

intended to either improve function, societal participation, and heath related quality of life, or decrease anxiety, pain, length of hospital stay or prosthesis dislocation. The findings of this review cannot be taken as conclusive but there is an indication that OT interventions may help reduce pre-surgery pain, increase function and reduce levels of anxiety both at admission and discharge. Although the meta-analyses revealed some significant findings, the findings relating to OT practice must be considered with caution as only two of the studies assessed unique OT practice. However, as rehabilitation is usually multi-professional, it is safer to assume that this review reveals that multi-professional rehabilitation with a significant OT component may achieve the aforementioned benefits. The need for further research to investigate the efficacy of OT intervention for patient undergoing THR has been revealed.

It also became clear as this review proceeded, that home adaptations and provision of adaptive devices to enable patients to gain independence in activities of daily living was a core intervention for OTs working in this discipline, and therefore any proposed clinical trial of the effectiveness of OT practice, would need to contain these elements in the intervention.

2.8.1 Output from this chapter

A Cochrane protocol for a more focused review, specifically on interventions to prevent dislocation and improve function, has emanated from the work for this review and has been published (Jepson et al, 2013); the completed full review is currently with the Cochrane editorial board.

3 PROOF-THR METHODS

A feasibility randomised controlled trial of pre-operative occupational therapy to optimise recovery for patients undergoing primary total hip replacement for osteoarthritis (PROOF-THR)

3.1 Chapter overview

This chapter presents the randomised controlled feasibility trial of a bespoke pre-surgery domiciliary based occupational therapy intervention compared to usual care to optimise recovery for patients undergoing total hip replacement for osteoarthritis. Justification for the intervention, outcome measures, the methodological approach use, and the associated research governance will be explained. This study was registered on the NIHR controlled clinical trials database with the international trial registration number: ISRCTN38381590. The reporting of this trial will be in accordance with the CONSORT guidelines for parallel RCTs (Schulz et al, 2010). This study has been published (Jepson et al, 2015). The following three chapters (methods, results and conclusions) include sections of text, diagrams and figures from this publication.

3.2 Rationale for study

Total hip replacement is considered one of the greatest successes of medical care (Bunker et al, 1994). However, restoration of mobility and activity can take anything from one to two years, even in the total absence of pain (Vissers et al, 2011; Okoro et al, 2012) and 14-36% of patients may have no functional improvement 12 months after total hip replacement (Judge

et al, 2010). The health benefits of early mobility are evident in many medical conditions (Alder and Malone, 2012) and functional decline in activities of daily living (ADL) due to relatively short periods of reduced activity in the older person is well documented (Rasch et al, 2009; Hoogerduijn et al, 2007). McWilliams (2008) reports that even young healthy individuals confined to bed rest lose approximately 5% of muscle mass per week. The current typical stay for THR patients of three to five days has mitigated against complications and functional decline due to inactivity (Bandholm and Kehlet, 2012). However, with no post discharge rehabilitation normally provided in the UK (Artz et al, 2012) the emphasis is placed on the patient to return to functional activities as soon as possible after discharge home.

There is evidence to suggest that home environment modifications and adaptive devices for older people can slow the rate of functional decline (Mann et al, 1999), decrease difficulty, increase safety of activities of daily living (Peterson et al, 2008) and reduce certain in-home care costs (Mann et al, 1999). Additionally, a Cochrane review reported that home safety assessment and modification interventions were effective in reducing falls, especially when delivered by occupational therapists (Gillespie et al, 2009). Although this demonstrates positive impacts of occupational therapy interventions with older people in general, the systematic review undertaken for this thesis revealed there is no evidence relating to the pre-admission provision of home-based occupational therapy, without subsequent home follow-up, and its effect on long term functional recovery and societal reintegration for patients undergoing total hip replacements. The pre-operative domiciliary provision of assessment, advice, and appropriate adaptive equipment has been previously identified by

patients in a qualitative study as desirable (Orpen and Harris, 2010) and may enhance activity and mobility recovery.

The aim of this study was to assess the feasibility of conducting a large scale randomised controlled trial to investigate the clinical effectiveness and cost effectiveness of a pre-surgery home based occupational therapy intervention versus usual care in accordance with guidelines produced by the Medical Research Council (Craig et al, 2008) for conducting feasibility studies.

3.3 Study design and setting

This feasibility study used a parallel RCT design with randomisation at the level of the individual and located in two acute hospital trusts in the West Midlands which provided elective Orthopaedic services (The Dudley Group of Hospitals NHS Foundation Trust and The Royal Orthopaedic Hospital NHS Trust). The study was located on two sites to enhance the recruitment rate but also to make the results more generalizable (Flynn, 2009).

The proposed main study would take the form of a RCT as this method of investigation reduces confounding variables and thus provides the highest level of evidence available from a clinical trial (Abel and Koch, 1999; CEBM, 2009). The feasibility study therefore took the same design as the proposed study so the process could be replicated and the willingness of participants to be recruited and randomised could be assessed.

3.4 Patient identification & recruitment

All orthopaedic consultants at the recruiting sites gave permission for their patients to be approached for inclusion in the trial. The details of patients who had been listed for THR surgery were screened by research nurses to match the inclusion criteria. Eligible participants were then posted a study invitation pack which contained the patient information leaflet (Appendix 6), a copy of the consent form, with the signature sections removed (Appendix 7), and an 'invitation to join the study' letter which contained information on how to contact the research nurses if they wanted to discuss joining the study or required more information (Appendix 8). Patients who had not made any contact with the research nurses were telephoned at approximately 10-14 days following the posted date of their study pack to remind them about the study. During the telephone call, it was expressly forbidden for the research nurses to try in any way to persuade the patient to join the study. If the patient expressed an interest in joining the study, the research nurse arranged to meet the participant at their pre-assessment clinic; normally scheduled six weeks prior to the planned admission date.

This identification and recruitment procedure above was a change to the original proposed procedure; hence a substantial ethical amendment was required. The original design was for the study invitation pack to be sent to patients prior to attendance at the review clinic along with their clinic appointment letter. Patients who had been accepted for THR surgery would then be approached by research nurses who would discuss recruitment in the study. The ethical approval for the study required the participants to have the minimum of 72 hours to

consider consenting to participate, meaning the research nurses could not consent the participants at this point. Therefore, a member of the research team would visit the potential participant in their home to complete the consent process. However, during a team meeting of the orthopaedic consultants, where the study was explained to them, several of the consultants voiced concern. It was felt that if the patients received the invitation study pack with their appointment letter; this may lead the patients to automatically assume the consultant would offer them a THR and consequently make the review clinic very difficult if for any reason the consultant felt a THR was not appropriate.

3.5 Inclusion/exclusion

The inclusion and exclusion criteria used and the reason for selection are explained in Table 33 below.

Table 33 Inclusion and exclusion criteria

Inclusion Criteria	Rationale
Patients accepted for primary THR surgery	Primary surgery represents approximately 89% of all THR surgery (NJR, 2012). Patients having a primary THR also have high expectations of the quality of life they can expect afterwards. Patients undergoing revision surgery are generally more elderly and the complexity of the surgery does not lead to high functional expectations. As the Royal Orthopaedic Hospital is a regional specialist centre, there is a far higher percentage of revision surgery performed than the national average of 11%. Inclusion of revision surgery patients would therefore reduce the external validity of the findings.

No previous lower limb joint replacement surgery	Patients who have had previous joint replacement surgery would be familiar with the hospital procedure and the surgical experience which could impact anxiety levels. Patients would also have preconceptions regarding the rehabilitation service delivery.
No planned additional lower limb joint replacement surgery within 12 months	Patients who already had further planned joint replacement surgery are likely to have severe functional limitations which may not be expected to be addressed / overcome until the subsequent surgery is completed.
Osteoarthritis as the primary indication for surgery	93% of all THR procedures are performed as a consequence of osteoarthritis; the other reasons include rheumatoid arthritis or congenital dysplasia (NJR, 2012). Both of these client groups have different functional requirements to the average THR patient. Patients with RA are usually far more functionally disabled with many lower limb and upper limb joints affected and they require much more intensive OT input. It is usual practice that patients having THR for hip dysplasia are aged 30-40 (NJR, 2012); the patients will therefore have a very different function expectation and demands. As a specialist orthopaedic centre, the ROH has a higher caseload of this specialist surgery compared to the national average which is only about 2% for either condition, inclusion of patients would therefore reduce the external validity of the findings.

Unilateral surgery	Bilateral surgery is not commonly done in the NHS and the short term functional disablement requires extensive OT input.
Sufficient understanding of English to complete questionnaires (or proxy completion by representative who understands English)	Many of the outcome measures used have not been validated in languages other than English.
Exclusion Criteria	
Patients with inflammatory arthritis	As osteoarthritis accounts for 93% of all THR's (NJR, 2012) the medical notes often lack the specific diagnosis of OA. Patients with no specific pathology were therefore initially included. When the research nurses approached the patients for consent, they checked this diagnosis with the patient and excluded if required.
Primary indication for surgery is for pain relief with no functional improvement anticipated	Very occasionally highly disabled people are given a THR purely for pain relief and with no expectation that this will enhance their functional capacity.
Patients unable to provide informed consent	Provision was provided for patients who could not read English or for those lacking mental capacity to be consent by proxy by a relative or carer.

3.6 Withdrawal criteria

Any patient wishing to withdraw from the study had the right to do so at any point and was not required in any way to justify/explain the reason. If patients withdrew consent prior to supply of the OT adaptive devices, they could revert to usual NHS care provided by the individual trusts. If home equipment had already being supplied, the patient would not be required to return equipment and the normal discharge procedures were followed. Data up to the point of withdrawal would be included unless otherwise indicated by the participant.

3.7 Consent

In both recruiting centres, potential participants (and carers/relatives) were met at the pre-assessment clinic by a research nurse and were given a full explanation of the trial. The University of Birmingham Department of Primary Care Clinical Sciences Standard Operating Procedure (SOP) 12-02 'Obtaining Informed Consent (Adults)' was followed. During the consent process all participants and their family and/or other carers were given the opportunity to discuss the study. Following consent, the participants were given a copy of the UKCRN publication, 'Understanding Clinical Trials'. As the consent forms were only available in English, consent by proxy was accepted from a relative that understood English. Arrangements were made for patients who missed the appointment with the research nurse or where asked to join the study at the pre-assessment clinic to be consented at home.

3.8 Baseline assessment & demographics

Baseline assessments were taken by the research nurses at the pre-assessment clinic (or at patient's homes) prior to randomisation as recommended in guidelines for good practice in clinical trials (Altman *et al* 2001). A patient demographics form was also completed (Appendix 9)

3.9 Randomisation & allocation concealment

Participants were randomised between the two groups (50:50) via the University of Birmingham Primary Care Clinical Trials Unit randomisation service using a random assignment computer algorithm using an 8 block size with stratification for recruitment site and age. All trial staff adhered to the University Of Birmingham Department Of Primary Care Clinical Sciences SOP 14-01: 'randomisation and blinding'.

3.10 Blinding in rehabilitation trials

All investigators on the trial were blinded to the randomisation and to any information indicating group assignment. Group allocation was only revealed to the treating therapists. Although lack of blinding is considered one of the most important sources of bias in clinical trials (Day & Altman, 2000), it is not possible in rehabilitation trials to blind the study personnel who are delivering the intervention or the participants themselves. It is therefore important to maintain the assessor and other investigators blind to group allocation in order to remove potential bias (Boutron, 2006). Established procedures to conduct rehabilitation

trials to avoid bias were followed (Siemonsma and Walker, 1997; Minns-Lowe et al, 2011) which included maintaining assessor blinding until the trial was completed, siting research staff in separate offices, maintaining study documents in locked cabinets, using an established clinical trials unit to securely randomise participants, using codes as patient labels on all documents and storing all data in a password protected database.

3.11 Intervention and control

3.11.1 Intervention

Patients randomised to the intervention arm of the study were contacted by the study OT and an appointment was made to visit the participant at home. During the home visit the OT assessed the individual needs of each participant and their individual home circumstances. The required adaptive devices were provided, fitted and their use demonstrated (e.g. toilet seat raises, grab rails, furniture height adjustments, shower chairs). The OT also discussed the patient's expectations; any anxieties the patient (or carer) may have; gave explanations about the surgery, hospital stay and post-operative rehabilitation as an in-patient. In addition, the OT also discussed in depth with the participant how they planned to manage when they returned home and liaised with other professionals as they felt appropriate (e.g. social services).

THR patients have several risk factors associated with falls (NICE 2004) which as well as predisposing the patient to the usual ill-health consequences associated with falling, it is also one of the main reason for prosthesis dislocation. Therefore the OT also performed a

structured home safety assessment based on the Westmead Home Safety Assessment form (Clemson, 1997) and explained how the home layout could be temporarily or permanently adapted to lessen the chance of falling and to prevent accidental dislocation of the hip by the patient having to adopt positions of dislocation risk to carry out normal activities of daily living.

All aspects of the complex intervention provided were standard OT practice in the UK and included all components of the pre and post-operative services provided by the occupational therapists at the recruiting sites. The individualised domically provision of education and adaptive devices, time available for discussion, and the home safety assessment are additional components received compared to participants randomised to usual care.

3.11.2 Control

Patients randomised to this arm of the study received the usual NHS care provided to patients undergoing elective THR in the recruiting NHS trust where they received surgery. In both trusts patients attended a pre-admission clinic at the hospital where they received a 20-30 minute group education session deliver by an OT, physiotherapist or therapy assistant regarding their hospital admission, stay and discharge. Patients at the Royal Orthopaedic Hospital were asked to complete a 'home assessment' form prior to attending the clinic in which they were asked to provide details such as height of bed, chairs, toilets, access and home layout. Based on this form, an OT or OT assistant would order routine assistive devices and then these were delivered to the patient's home by a delivery driver before, or on, the final discharge date. No education in their use at home was provided by the delivery driver.

At the Dudley Group of Hospitals, a similar 'home assessment' form was completed by the patients but the assistive devices were given to the patient (carer or ambulance driver) at time of discharge for the patient to take home with them.

3.12 Outcome measures

3.12.1 Primary Outcomes

The primary outcome of this study was to assess the feasibility of a full scale RCT. Feasibility studies for complex interventions have been advocated since the publication of the Medical Research Council guidelines for the development and evaluation of complex interventions (MRC, 2000). In this document, the MRC provide a four step model for complex interventions (1. Theoretical / pre-clinical 2. Modelling 3. Exploratory trial 4. Definitive RCT) based on the model for clinical drug trials. The feasibility study is the phase three, or exploratory phase, in this model. This guidance was updated in 2008 (MRC, 2008) which provided more guidance on what the outcomes a feasibility study should measure. The primary outcomes listed below for this feasibility are those advocated in this guidance document:

Recruitment procedures and success: Information was collected from screening logs on the number of patients eligible for the study, methods of identification, and recruitment and retention rates of subjects to the trial.

Suitability of outcome measures: Refining the choice of outcome measures to be taken forward to the main trial.

Fidelity of the intervention: This included practicalities of OT compliance to the intervention delivery as designed in the protocol, the quality of the delivery and patient adherence with the intervention. An intervention study log was completed by the OTs; a method that has been used successfully in previous studies (Sackley et al, 2009; Sackley et al, 2012). This log contained the detailed the assessment, treatment, assistive devices provided and advice given to the participants, plus any deviations in protocol. These logs were retained by the NHS Trusts as they were classed as treatment notes containing confidential information. Only deviations from the protocol were reported.

Effect size & Sample size: To provide data on the effect size, and its variance, to allow a more accurate estimate of the sample size required for the main study.

3.12.2 Secondary outcome measures

The second outcome of this feasibility study was to measure the clinical effect size and directionality of the outcome measure questionnaires. The principle outcome addressed was function. The other outcome measures, in addition to function, that were investigated in this study were pain and societal participation. These outcomes were assessed by use of a range of validated patient administered questionnaires that were posted to the study participants at 4, 12 and 26 weeks following surgery. If any hip dislocations occurred, these data were reported as an adverse event.

3.13 Patient reported outcome measures (PROMs)

In clinical trials, choice of the outcome measure to be used is a fundamental aspect of the study design. This section will discuss the rationale for the section of the outcomes measures used in this study.

3.13.1 The importance of PROMs

The preferential use of patient reported outcome measures (PROMs) in all aspects of clinical research, audit and practice was one of the key recommendations of the interim Darzi (2007) report in to the future of the NHS. Nelson et al, (2015) reiterates the importance of using PROMs in research studies as they provide the researcher with information of the effectiveness of interventions from the patient perspective rather than efficacy of interventions from a health provider's perspective. PROMs also enable clinicians to measure the impact of interventions and provide health care commissioners with validated evidence of health from the point of view of the user or patients (Kyte et al, 2015). Additionally, they can also enable service development by providing evidence of the outcomes for the purposes of audit, quality assurance and comparative performance evaluation (Gibbons and Fitzpatrick, 2010). Since the final Darzi (2008) report , many aspects of health care practice in the NHS have been required to provide PROM data annually to the Department of Health; for patients undergoing primary unilateral THR, the reporting of PROM data is a condition of payment under the NHS contract (Gibbons and Fitzpatrick, 2010).

3.13.2 Selection of PROMs

PROMs can be classified into two categories: those which are population or condition specific and those measuring generic health statuses. Condition-specific instruments relate to a particular disease or health condition (e.g. osteoarthritis), a specific patient population (e.g. elderly), or a specific health outcome (e.g. pain, function, ADL). In contrast, generic instruments are designed to be relevant to as wide a range of population as possible (e.g. SF-36, SIP). Gibbons and Fitzpatrick (2010) suggest that generic category can be split in to those that measure health status only (e.g. SF-36) and those that measure health status but can also provide utilities or values to enable cost-utility analyses of interventions (e.g. EQ-5D). A combination of a generic, utility and specific measures are recommended to be used in order to assess all aspects of health relevant to the particular population concerned (Gibbons and Fitzpatrick, 2010). Despite the importance of using PROMs, there is often no consensus as to which instruments should be used (Garratt et al., 2002). Calvert et al (2014) also suggest that the guidance that does exist is often conflicting and hard to find; in a recent systematic review, only 8 out of 54 guidance documents used in the review were available electronically. The health care worker or clinical researcher therefore often has to decide on which are the most appropriate PROMs to use. However, a Health Technology Assessment (HTA) report (Fitzpatrick et al, 1998) provides guidance on all the aspects that should be considered when choosing a PROM in clinical trials and identified 5 intrinsic and 3 extrinsic criteria (Table 34). The intrinsic factors of PROMs are determined by comparative trials and statistical methodology and it is important that only those that have had these criteria evaluated and found to be acceptable are used. The extrinsic criteria are directly related to

the populations in which they are employed and the design of the study in which they are used need to be assessed in pilot or feasibility studies; hence why this is one of the outcomes of this study.

Table 34 criteria that investigators should apply to evaluate candidate patient-based outcome measures for any specific clinical trial (Fitzpatrick et al (1998)

Criteria	Explanation/definition
Intrinsic criteria	
Reliability	This requires that an instrument is reproducible and internally consistent.
Validity	This is involved in judging whether an instrument measures what it purports to measure. This has to consider both construct validity (the ability of the scale to differentiate known groups) and content validity (the extent to which the content of a scale is representative of the conceptual domain it is intended to cover).
Responsiveness	This addresses whether an instrument is sensitive to changes of importance to patients including 'floor' and 'ceiling' effects.
Precision	This is concerned with the number and accuracy of distinctions made by an instrument.
Interpretability	This is how meaningful are the scores from an instrument.
Extrinsic criteria	
Appropriateness	This requires that investigators consider the match of an instrument to the specific purpose and questions of a trial.
Acceptability	This is how acceptable is an instrument for respondents to complete.
Feasibility	This is concerned with the extent of effort, burden and disruption to participants, staff and clinical care arising from use of an instrument.

3.13.3 Selection of PROMs for the PROOF-THR feasibility study

Several factors were taken in to account during the selection of the PROMs for the PROOF-THR feasibility study. As a pre-requisite, any of the PROMs considered for use in the study had to have been previously adjudged to be 'valid & reliable'. The other considerations are detailed below.

3.13.3.1 *Responsiveness to level of function*

Following surgery, patients were followed up for six months. Over this time scale, the functional ability status of the participants was expected to be wide ranging from a relatively low level of function in the first few weeks following surgery, to full societal reintegration at six months. Due to this, several functional PROMs were needed to capture this range of improvement due to anticipated floor and ceiling effects (Fitzpatrick et al, 1998).

3.13.3.2 *Standardisation to overall NIHR programme*

This feasibility study was part of the patient experience section of a large NIHR programme grant incorporating a wide range of clinical studies throughout the pathway of patients undergoing THR due to osteoarthritis. In order to standardise the reporting for the final NIHR report, all participants included in the clinical trials had baseline WOMAC (Bellamy et al 1988) scores assessed as this is a validated disease specific (OA) and joint specific (hip or knee) PROM. Additionally, NHS guidance (Department of Health, 2008) specified that from 2009 the Oxford Hip Score (OHS) should be the joint specific PROM and the EQ-5D (EuroQol

group, 1990) the generic health status PROM routinely collected for all people undergoing THR, these PROM were standardised across all studies.

3.13.3.3 ***Acceptability, appropriateness and patient burden***

Prior to ethics application, all the PROMs proposed to be used in the feasibility study were first discussed at a trial steering group meeting to ensure they conformed to the standardisation requirements as well as assessing them for their likely acceptability, appropriateness and burden. Having being agreed, they were then trialled for approval by patients at Southmead Hospital who formed the 'patient partnership in research' (PEP-R) group. This public involvement group were asked to comment on the acceptability, appropriateness and ease of use of each measure and the overall burden of completion when they were grouped together into one questionnaire pack. All members of this group had previously received joint replacement surgery. They found the entire questionnaire pack took approximately 6-8 minutes to complete which they felt was not an onerous burden. They agreed all the proposed PROMs were appropriate and generally acceptable. With respect to the Nottingham extended activities of daily living questionnaire (NEADL) they reported that two of the questions *'were demeaning'* and would like these removed. This was agreed and a method of imputing the two removed sets of data was developed. As the PEP-R group were generally younger than the anticipated age of trial participants, the questionnaire burden was also trialled on older volunteers who also agreed that completion was not burdensome.

3.14 Patient reported outcome measures used

The justification for the choice of each PROM is provided.

3.14.1 Oxford hip Score (OHS)

The OHS (Dawson *et al*, 1996) is a validated questionnaire (Atchen *et al*, 2010) designed to measure pain and functional outcome from the patient's perspective following THR. It is a self-administered 12 item questionnaire which has two domains of pain and function only. On an updated scoring system (Murray *et al*, 2007), each question scores between 0-4, generating an overall score ranging from 0 (worst health status) to 48 (best health status). It has been extensively used in orthopaedic literature, has been shown to have good specificity and sensitive to change (Murray *et al*, 2007); and despite there being no psychometric properties associated to this questionnaire, it has been shown to correlate well with other instruments that measure patient satisfaction (Wylde *et al*, 2005). The OHS is now widely used in the UK and overseas and is currently the PROM designated by the NHS to be used in studies relating to THR in England.

3.14.2 Western Ontario and McMaster universities arthritis index (WOMAC)

The WOMAC was developed by Bellamy *et al* (1988) as a disease specific measure containing a set of standardized questions for hip or knee arthritis, and has since been used extensively in osteoarthritis or joint replacement research. It contains 24 questions that assess pain (5 questions), joint stiffness (2 questions), and physical and social function (17 questions) of a

person with osteoarthritis in determining the overall level of disability. Each question is scored between 0 (best health status) to 4 (worst health status) giving an overall score range of 0 (best health status) to 96 (worst health status).The overall results presentation will be transformed by multiplying the final score by 100/96 to transform the scale to go from 0-100 which is a commonly accepted method to aid interpretation (Roos *et al*, 1999; Judge *et al*, 2010). As well as an overall WOMAC score, each of the 3 subscales is reported independently.

3.14.3 The Aberdeen impairment, activity limitation and participation restriction (AIP) measure

The AIP measure (Pollard *et al*, 2009) was chosen as it is designed to measure higher levels of function than the OHS or WOMAC. It is a self-administered questionnaire developed to measure health components as identified by the international classification of function, disability and health (WHO, 2001) and specifically relates to osteoarthritis. The measure assesses impairment (9 items), activity limitation (17 items) and participation restriction (9 items). A high score relates to a worse health outcome and a low score, a better health outcome. The 3 sections of this outcome measure are analysed separately as a combined total score of the 3 sections has not yet been validated.

3.14.4 Nottingham extended activities of daily living questionnaire (NEADL)

The NEADL (Nouri & Lincoln, 1987) is a patient reported self-administered questionnaire comprising 22 items grouped into 4 categories: mobility, including public transport, (6 items), kitchen tasks (5 items), domestic tasks (4 items) and leisure activities (6 items). Each item has 4 possible responses: 0 (unable to do), 1 (able with help), 2 (able on own with difficulty) and 3 (easily managed alone). For scoring purposes the scale can be dichotomised into 'not-independent' (0, 1) or 'independent' (2, 3) giving an overall score of 1 (poor activity level) to 22 (good activity level) or can be used as a 0-3 scale giving an overall score of 0 (worst) to 66 (Best). Although this PROM was originally designed and validated for stroke patients, Harwood and Ebrahim (2002) assessed the NEADL for use in patients undergoing THR. They found it valid and reliable in people with osteoarthritis of the hip, though it underestimated the gain after THR compared to other scales. This PROM was chosen as it measures extended levels of activity which are between the low level of function measured by the OHS or WOMAC and the societal reintegration of the AIP measure.

3.14.5 Hospital anxiety and depression scale (HADS)

The HADS (Zigmond and Snaith 1983) is a 14-item questionnaire which scores anxiety and depression on separate seven item subscales scored from 0-21. A higher score represents greater levels of anxiety and depression on each responsive subscale. The overall score is classified in to three categories; Normal (0-7), borderline abnormal (8-10) and abnormal (11-21). Although the name of the scale suggests its application is in the hospital environment,

many studies have shown it is a useful tool in community settings and primary care (Snaith, 2003). Two reviews (Bjelland et al, 2002; Herrmann, 1997) have found the HAD scale to be a valid and reliable instrument for assessing symptom severity of anxiety and depressive disorders in medical and primary care patients. Although the review by Herrmann (1997) is a non-systematic literature synthesis, his review contained over 200 international studies containing approximately 35,000 participants. As well as finding it both valid and reliable in a variety of populations, he also found it to be highly acceptable with 95-100% response rates. Bjelland et al (2002) conducted a higher quality systematic review of 71 studies of validity, reliability or sensitivity. They also found HADS to be valid and reliable in general practice and the general population as well as in psychiatric patients.

3.14.6 Euro-Qol EQ-5D-3L

The Euro-Qol EQ-5D-3L (EQ-5D) is a standardized measure of health status developed by the EuroQol Group in order to provide a simple, generic measure of health for clinical and economic appraisal (EuroQol group, 1990) which is applicable to a wide range of health conditions and treatments. It is also the PROM for general health status designated by the Department of Health to be collected for patients undergoing THR. It provides a simple descriptive profile and a single index value for health status that can be used in the clinical and economic evaluation of health care as well as in population health surveys. The EQ-5D-3L descriptive system comprises the following 5 dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension has 3 levels: no problems, some problems, severe problems. It is self-administered and the respondent indicates their health state in each of the 5 dimensions. This decision results in a 1-digit

number expressing the level selected for that dimension. The digits for 5 dimensions can be combined in a 5-digit number describing the respondent's health state. A utility analysis can then be undertaken using the current UK tariff.

3.14.7 The ICECAP-O

The ICECAP-O (Coast *et al*, 2008) is a measure of capability in older people for use in economic evaluation. Unlike most profile measures used in economic evaluations, the ICECAP-O focuses on wellbeing defined in a broader sense, rather than health. The measure covers attributes of wellbeing that were found to be important to older people in the UK. It comprises five attributes: attachment, security, role, enjoyment and control and was developed using qualitative methods in a best-worst scaling study of older people in England. Each question has four possible answers which correlate with wellbeing in the five attributes. This decision results in a 1-digit number expressing the level selected for that dimension. The digits for 5 dimensions are combined in a 5-digit number describing the respondent's state of wellbeing; a code of 44444 represents full capability and has a tariff of 1, a code of 11111 represents worst capability and has a tariff of 0; all other states have a value between 0-1 which can then be used to signify 1 of 20 other intermediate states which can then be used to perform an economic analysis based on the respondents state of wellbeing (Flynn *et al*, 2008). NICE (2015) accept capability measures as an alternative to the EQ-5D when used for social outcomes or those that measure ADL's. The inclusion of both the EQ-5D and the ICECAP-O was to allow for a comparison of the two measures.

3.14.8 Client services receipt inventory

The Client Service Receipt Inventory (CSRI) allows systematic recording of service use in a manner commensurate with estimating the costs of support packages (Beecham, 2000). A version of the CSRI (Beecham and Knapp, 2001) adapted for this study was used to record the frequency and duration with which participants used education, health and social care services and supports, including their accommodation and personal care/staff arrangements and relevant informal care inputs. It is an established tool for collecting retrospective service use information and has been used for a variety of populations (Busse et al, 2011) and in over 150 health and social care economic evaluations (Patel et al, 2005)

3.14.9 Other data collected at baseline

Other information collected at baseline included participant address, age, GP contact details, and whether the patient lived alone or not.

3.14.10 Adverse events

A system was devised to report any adverse events. During the pre-operative intervention phase of the feasibility study, and adverse event would be reported by the trial OT. Each trial OT was issued with a mobile phone and participants were encouraged to contact the OT should any equipment malfunction occur. Dislocation of the new prosthesis was the adverse event measured after the patient had received surgery. Should any patient in either arm of the trial be re-admitted due to dislocation, the lead research nurse at each recruitment site would report this to the main researcher.

3.15 Assessment time points

Baseline assessments were conducted prior to randomisation as recommended in guidelines for good practice in clinical trials (Altman et al, 2001). This enables identification of whether those recruited have characteristics similar to the general population with hip osteoarthritis undergoing THR. It also enables imbalances at baseline to be identified which would raise concerns about recruitment bias. The patients were followed up for six months following their date of surgery. Questionnaire packs were posted to participants with an enclosed pre-paid envelope for return when completed at 4, 12, and 26 weeks post-surgery; a schedule is shown below (see Table 35).

Telephone calls were made to all non-respondents, at each time point, for a period of two weeks following the due date of the follow-up questionnaire. At the final assessment time point, a deviation from this protocol occurred and the non–responders were telephoned for up to 8 weeks after the 26 week time point. As this method was deviation from protocol, only OHS data only were collected to enable more data for the power calculation for the main trial which would be primarily based on this outcome. Three participants provided this limited additional data.

Table 35 Assessment schedule

Data to be collected	Baseline Assessment Prior to Randomisation and before Surgery	Follow up assessments – from date of surgery		
		4 weeks	12 weeks	26 weeks
Nottingham EADL	✓	✓	✓	✓
Oxford hip score	✓	✓	✓	✓
WOMAC	✓	✓	✓	✓
Aberdeen IAP	✓	✓	✓	✓
HADS	✓	✓	✓	✓
ICE-CAP	✓	✓	✓	✓
EuroQol EQ-5D-3L	✓	✓	✓	✓
Client Services Receipt Inventory				✓

3.16 Blinding

Group allocation was concealed from the independent assessors. However, as it was not possible to mask the treating occupational therapists or participants. Guidelines developed in previous rehabilitation trials (Siemonsma and Walker, 1997; Minns-Lowe et al, 2011) were used to minimise any associated bias. The measures undertaken involved the researcher being located in a different room to the trial OTs, using a clinical trials unit to set a secure database with different levels of password protected access, trial records being kept in locked cabinets, and all office staff knowing procedures to engage in telephone conversation with participants until the main researcher left the office. During surgery and recovery in hospital the trial participants had an identifier on their medical notes for discharge planning purposes so the hospital occupational therapists and discharge planners knew the patients

already had all the required adaptive devices fitted at home. Additional guidelines to improve independent assessment previously developed by the University of Birmingham primary care department through their experience of conducting rehabilitation trials were also followed. This included practical measures such as treating therapists and assessors being located in separate places.

3.17 Data analysis of outcome measure

Prior to the analysis, the guidance documents for each outcome measure were used to identify procedures the authors recommend for integrating any missing data in to the final analysis. The WOMAC guidelines (Bellamy, 2002) suggest that any participant with greater than 3 missing questions should be removed from the analysis. For 3 or less missing questions, the average value should be imputed. The OHS has similar guidance (Murray et al, 2007), though with the exclusion limit set at greater than 2 missing questions. The HADS guidance (GL assessment, 2014) recommends that if one item is missing from the depression or the anxiety scale, then the item score can be inferred by using the mean of the remaining 6 items. If more than one item is missing from either scale, then the scale should not be scored. No published guidelines are available for the NEADL or the Aberdeen IAP measure. The same guidance protocol suggested for the WOMAC was therefore adopted for the Aberdeen IAP measure and the NEADLE on the logic that these contain similar amounts of questions.

Although the NEADL has been validated for use with patients who have received THR surgery (Harwood & Ebrahim, 2002), it was originally developed for stroke victims and thus contains

several items that relate to upper limb function. The version of the NEADL used in the questionnaire pack in this study had two items removed; items *'do you manage to feed yourself'* and *'do you do the washing up'* at the request of the patient and public advisory group as they found these questions demeaning. An approach was developed to normalise the data by inputting into the missing items the values reported from items *'do you manage to make hot snacks'* and *'do you manage to wash small items of clothes'* as these were considered to be equitable functional tasks and would therefore likely to be scored the same. This approach was used in this analysis. The final results can either be analysed dichotomously in to '*unable*' (scores 0 or 1) or '*able*' (scores 2 or 3), or analysed as a 4 point continuous scale of 0-3 giving an overall score range of 0-66.

The WOMAC has been validated for results of the overall score and for the individual subsections (Murray et al, 2007). The data for the subsections pain (0-20), stiffness (0-8) and function (0-68) are presented as the aggregate value of the score for those sections. However, as the total score available is 0-96, it is usual practice to transform the results in to 0-100 scale by multiplying the final score by 96/100. This convention has been adhered to in the presentation of WOMAC results in this study. The three domains Aberdeen IAP measure (Impairment, activity restriction, participation) and the two domains of the HADS (anxiety, depression) measure independent constructs so it is not valid to aggregate the domain scores in these measures.

The HADS has been presented with the mean score for each domain. Additionally, the number of participants with normal (0-7), mild (8-10), moderate (11-15) or severe (16-21) symptoms is presented.

In both the ICECAP-O and EQ-5D-3L, the items 1-3 ticked in each domain have no arithmetical value so no method of imputing missing data is available as the full 5 digit code is required to be used to translate the responses in to a health state. Therefore in the analysis of these data, any responses containing missing data have been removed. The UK data set has been used to translate the responses in to the health states for the ED-5D-3L and the UK index values available from the University of Birmingham have been used for the ICECAP-O.

Only outcome measures data designated in the protocol were collected and all outcome measures collected are reported in the results. All participants remained in their allocated group throughout the trial period.

3.18 Risk assessment

A risk assessment was conducted prior to the start of the trial and it was considered that the trial was low risk. All perceived risks identified were discussed with the 'Patient Experience Partnership in Research' (PEP-R) group, a patient representative, and a member of Arthritis Research UK who formed part of the trial steering group. All the outcome measures used are designed to measure quality of life and are all widely used validated instruments, with the exception of the ICECAP-O which is a recently developed instrument used in economic evaluations. A small risk was identified that some questions in the quality of life questionnaire may cause emotional distress if the participants felt they were not recovering as well as anticipated following surgery. In response to this, each participant was given a contact number of someone not directly involved in the trial to discuss any issues they had.

If the contact person felt they were not able to deal with the issue the participant was asked to contact their GP.

The main risk identified was considered to be the OT being a lone worker in the community and delivering the intervention required them being in the patient's home for longer than would be normal practice. To manage this trial staff adhered to the University Of Birmingham Department Of Primary Care Clinical Sciences SOP 21-01: Community Visits and Lone Worker Policy. In addition, lone working policy specific to the nature of this trial was developed by the candidate (Appendix 10) which included processes to record scheduled visits, confirm arrival and departure times with a named contact person during home visits and use of an anonymous phrase to be used in a telephone call that indicated the therapist is in difficulty and requires the police to be called.

3.19 Statistical procedure

A bespoke password protected database was developed by University Of Birmingham Department Of Primary Care Clinical Sciences Clinical Trials Unit. All data collected was entered in to this database. Data cleaning was used before analysis of the data.

The primary analysis was the response to all the outcome measures at 4, 12 and 26 weeks following surgery in the intervention and control arms of the study. The primary analysis was by intention to treat, whereby patients were analysed according to the intervention to which they were randomised regardless of whether they complied with this treatment. Distribution of the data was analysed for normal distribution, skewness and kurtosis to determine

whether the descriptive data should be presented as mean ± SD, or the median and IQR to be presented. The analysis showed the data was not normally distributed indicating the median and IQR to be reported as the point vale and variance. However, as a grant proposal to the HTA was submitted for funding to expand this feasibility study in to a full RCT, both analysis methods were presented so that comparisons could be made at a later date should the funding bid be successful. However, In accordance with MRC guidelines (Craig et al, 2008) on feasibility studies, no p-values are reported as this guidance document expressly states that comparative statistical analyses should not be performed. However, a power calculation was to be performed to estimate the number of participants that would be required to power a full RCT.

3.20 Data storage

In accordance with MRC guidelines provision was made at the study sites for all data to be stored for at least 20 years after the last patient completed follow-up to allow adequate time for review, reappraisal or further research, and allow any queries or concerns about the data, conduct or conclusions of the study to be resolved. All electronic data files were password protected and paper documentation was securely stored.

3.21 Research governance and ethics

The trial was conducted in accordance with the Medical Research Council Guidelines for Good Clinical Practice (1998). It also conformed to the Mental Capacity Act (2005). All relevant Standard Operating Procedures produced by Birmingham's PC-CRTU were also

adhered to. The trial sponsor was the University of Birmingham. Costs associated with this feasibility study were funded by the National Institute for Health Research (NIHR) project "Improving patients' experience and outcome of total joint replacement" grant number RP-PG-0407-10070. The trial was adopted on to the ISRCTN database (ISRCTN38381590). It was also adopted by both the Primary Care and Musculoskeletal Clinical Local Research Networks which paid for all costs associated with patient recruitment. The candidate had some backfill time paid for by the West Midlands Strategic Health Authority via a nursing, midwifery, and allied health professionals research training award.

3.22 Public and patient involvement

The NIHR actively promotes public involvement in research through INVOLVE, the UK's national body for patient engagement in research. INVOLVE (2015) define involvement when the public are actively involved in research projects or organisations and get involved in activities such as identifying research priorities, commenting on and developing patient information leaflets or other research materials, or as members of a steering group. However, Gooberman-Hill et al (2013) suggest even though the ethical reason for patient involvement is clear, and patient involvement in research is here to stay, there is a need to evaluate the impact of patient involvement as the gains may be diffuse and hard to quantify. The public and patient involvement in this trial was provided by a group of patients willing to take an active part in all aspects of research at The Avon Orthopaedic Musculoskeletal Research Unit in collaboration with North Bristol NHS Trust known as the 'Patient Experience Partnership in Research' (PEP-R) group. The group met regularly provided input in all stages

including design of trial protocol, refinement of outcome measure questionnaires and dissemination of findings. The PEP-R group had 12 members who elected between themselves a patient representative to sit on the trial steering group. Extensive input was also put in to the design of this trial by a representative of the Arthritis Research Campaign who also sat on the steering group. This active participation of the public adhered to the aspirations of INVOLVE.

3.23 Chapter summary

This chapter has explained the methods used for the feasibility trial and has discussed some of the practicalities of how the quality of conducting rehabilitation trials can be maintained. It also explained the governance of the trial and how the requirement to involve the public in clinical research was met.

4 PROOF-THR RESULTS

4.1 Chapter overview

This chapter starts by presenting the CONSORT flow diagram (Schulz et al, 2010) showing the flow of participants through the study. Data related to the specific outcomes for feasibility studies such as recruitment, retention, and acceptability of the intervention and control are presented first. The demographic mix of the participants is also shown. This is then followed by presentation of descriptive results for all the secondary outcomes at baseline and the follow-up time points.

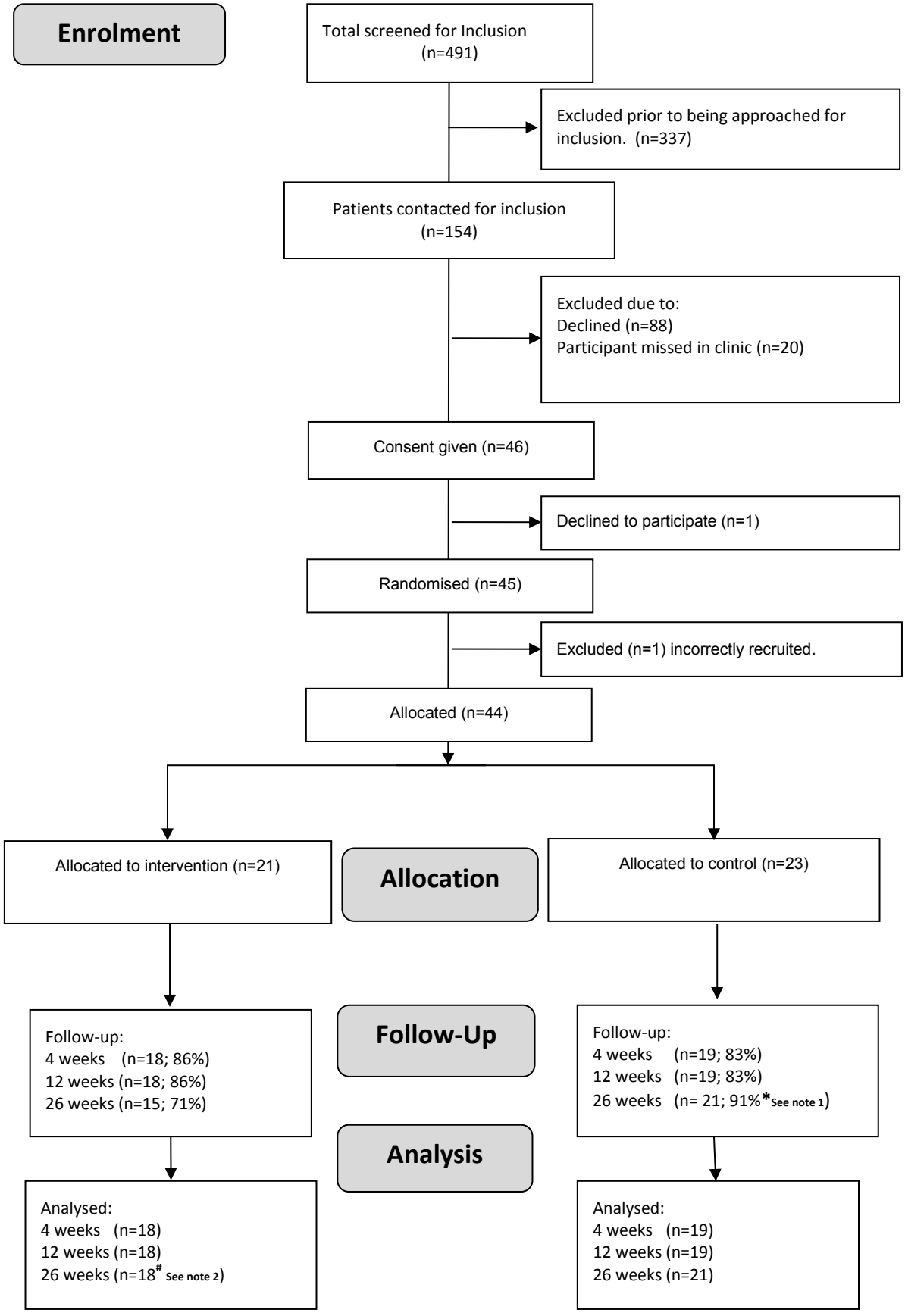
4.2 PROOF-THR descriptive statistics

The study CONSORT flow diagram (Schulz et al, 2010) is presented in Figure 28. In total 491 patients were screened for inclusion, 337 were excluded prior to being approached for inclusion. Of the 172 patients approached, 46 consented to join the study. Following consent, one participant withdrew prior to randomisation; another one participant was withdrawn following randomisation due to incorrect recruitment (previous THR). Neither of these two participants is contained in any of the follow-up statistics. The reasons for these exclusions after the patients were approached are detailed in the CONSORT flow diagram Table 36 presents a full breakdown on the reasons for exclusion prior to approach in clinic.

Three additional limited data sets (OHS only) for participants in the intervention group were collected by telephone in a time period that constituted a deviation from protocol at the final 26 week time point. As these additional data sets are included in the descriptive statistics, they are included in all the CONSORT flow diagram. However, as they were

collected outside of the main study data collection, these 3 participants are not contained in the analysis of retention, missing data and social classification (section 4.6 to 4.8).

Figure 28 CONSORT flow diagram (Schulz et al, 2010)



***Note 1:** Two participants did not receive 12 week follow-up questionnaire but completed 26 week follow-up
#**Note 2**: This includes n=3 participants who completed the OHS by telephone follow-up outside the study period

4.3 Recruitment

Prior to contacting patients for possible inclusion, research nurses screened all patients listed for THR surgery against the inclusion and exclusion criteria at the two recruitment sites. During the conduct of the study, patients had to be excluded for a variety of other reasons prior to initial contact for inclusion. These reasons for exclusion during screening against the inclusion criteria and the other reasons are shown in Table 36 below.

Of the total 491 potential participants listed for surgery, 114 were excluded at the screening process for not meeting the inclusion criteria. This accounts for 23.2% of all exclusions. An additional nine patients were excluded at screening for reasons not originally identified as exclusion criteria. Four patients asked to be taken off the list for surgery, and one patient was incorrectly listed for a THR. Another four patients were excluded as they did not have a Dudley or Birmingham postcode so the required OT adaptive devices could not be provided due to financial reasons.

A further 223 (45.4%) of all the listed patients were ineligible for other reasons not associated with the study exclusion criteria; two main reasons accounted for this. The largest reason eligible patients were excluded (N=109) from the PROOF-THR study was due to two other contemporaneous studies recruiting patients with very similar inclusion criteria. Due to one study nearing completion, and another one being privately funded and therefore being financially rewarding to the Trust, both these studies had priority over this study. The 109 participants allocated to these other studies accounts for 22.2% of all screened participants, and 49% of eligible patients excluded after screening.

Table 36 Reason for exclusion

Reason for exclusion	Number excluded
Listed patients (n=491) excluded at screening due to not meeting inclusion criteria	
Previous lower limb joint replacement	80
Scheduled for other lower limb surgery	4
THR not due to osteoarthritis	16
Does not speak English	3
No functional improvement expected	2
Taken off waiting list for surgery	4
Out of area postcode	4
Incorrectly listed for THR (Should have been total knee replacement)	1
Sub Total excluded at screening	**114**
Eligible patients (n= 337) excluded prior to approach for other reasons	
Eligible for other concurrent clinical trials	109
Insufficient time between pre-operative clinic and surgery to deliver intervention	59
Insufficient time between pre-operative clinic and surgery to deliver intervention following planned appointment being bough forward	22
Temporary closure of recruitment due to unavailability of study occupational therapists	21
Did not receive participant information sheet	4
Patient previously screened	1
Other non-eligible (reasons not documented)	7
Sub Total excluded for other reasons	**223**
Eligible patients (n=154) excluded after contact with research nurse	
Declined to participate	88
Appointment missed in clinic by research nurses	20
Sub Total excluded (Declined/missed)	**108**
Patients consenting to participate	**46**

The second most common reason participants (n=59, 17.5%) could not be approached for recruitment was due to insufficient time between the pre-operative clinics, where patients were recruited, to the scheduled date of surgery. The normal scheduled time interval, at both recruiting sites, between pre-assessment and surgery was 6 weeks. The main phase of recruitment to this trial coincided with one trust undertaking an initiative to boost joint replacement surgery numbers due to being behind their planned schedule for the year. This had the effect of reducing the time between pre-assessment and surgery to as little as 7-10 days. As well as the practical difficulties of scheduling and delivering the intervention within such a short time frame, In order to standardise the delivery of the intervention, the protocol aimed to try to standardise the delivery of the intervention at 3-5 weeks before surgery. Therefore, unless the time between surgery and pre-assessment clinic date was greater than 4 weeks, patients were excluded. Additionally, a further n=22 had their surgery date moved forward after the pre-assessment clinic which was initially within the allotted time frame. These patients therefore also had to be excluded even if they had been sent the patient information pack to inform them of the study. Overall, this shortened time frame between pre-assessment clinic and surgery date resulted in 81 eligible patients having to be excluded. This accounts for 16.5% of all screened participants, and 36.3% of eligible patients excluded.

The other main reason for exclusion of screened patients (n=21) was due to a period where both occupational therapists and other study staff were unavailable at the same time. Due to practical difficulties of administering the intervention which could not be overcome, a temporary four week recruitment closure was required. This accounted for only 4.3% of all listed patients and 9.4% of eligible patients excluded.

Other minor reasons included 4 participants who had been sent the patient information pack stated they had not received it when approached in the pre-assessment clinic. As the ethics for this study required participants to have 72 hours to consider the documentation before consenting, these patients could not be recruited in the pre-assessment clinic. One patient was listed twice for the same surgery and 7 others were excluded by the research nurses with reason for exclusion not-documented.

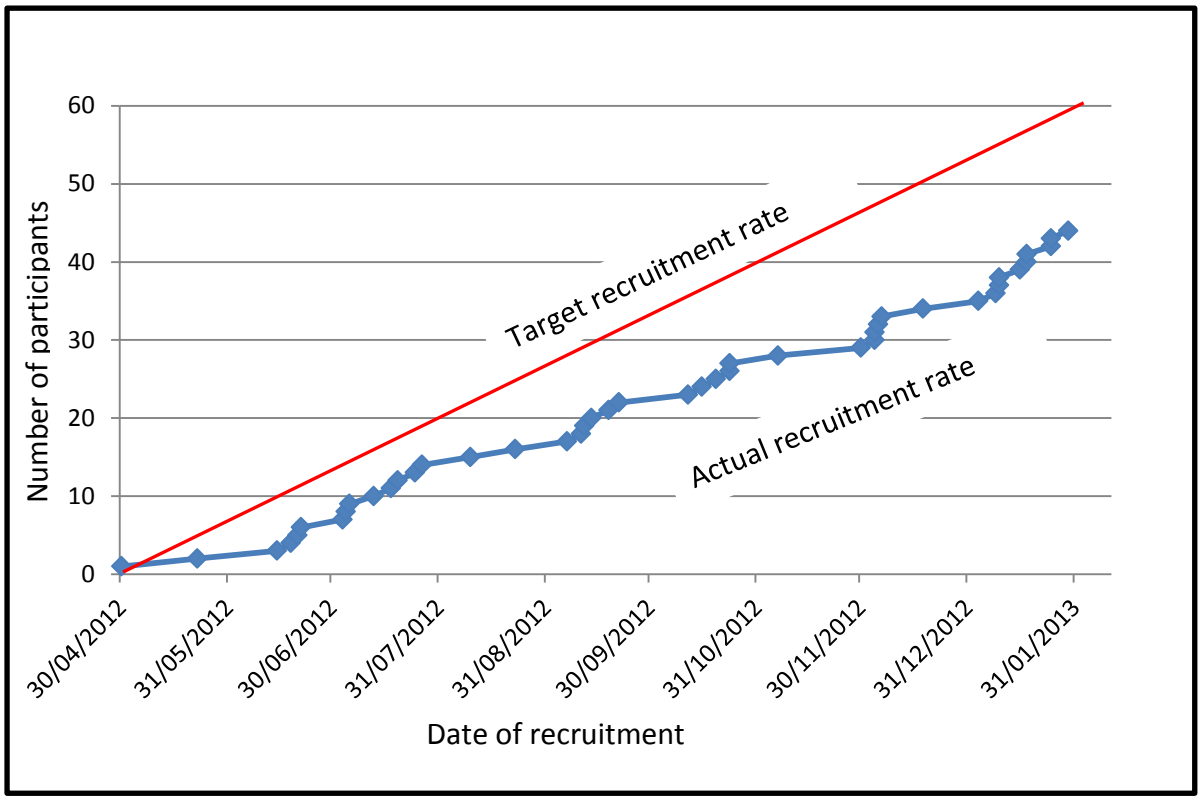
Of the remaining 154 patients, 88 declined to participate, accounting for 17.9% of all screened patients, 26.1% of all eligible patients, and 57.4% of patients approached in clinic. A further 20 patients who had agreed to discuss participation were unable to be recruited due to the research nurses missing the clinic appointment of the patient; this accounted for 4.1% of all screened patients, 5.9% of all eligible patients, and 13.0% of patients approached in clinic.

4.4 Recruitment rate

The recruitment phase of the trial lasted for 9 months with the first participant recruited on the 30/04/2012. The target in this recruitment phase was for 60 participants, which equated to approximately 7 participants per month. The recruitment rate was set at this level as initially the study had only had one occupational therapist working part time on the study. In October 2012 a second part-time occupational therapist was recruited to increase the recruitment rate. However, overall the average recruitment rate achieved was 5 participants per month. Although the recruitment rate increased to the target level with the addition of the second occupational therapist working on the trial, recruitment was terminated at the

intended finish date due to the overall time requirements of the study. The recruitment rate is shown in Figure 29 below.

Figure 29 Recruitment rate



4.5 Fidelity of intervention delivery

A 100% delivery of the intervention was achieved. The occupational therapists allowed 4 hours for each intervention which included travel time to the patient's home and collection of adaptive devices from the store depot. Deviation from this protocol occurred on only 3 occasions. On two occasions it was due to the participant requiring special equipment which the OT had to order then schedule another appointment to deliver to the participant. On one other occasion, the social services store failed to process an equipment order for standard equipment, again requiring the OT to re-order the equipment and make a second

visit. The OT intervention logs only recorded deviations from protocol when more than 4 hours were needed to deliver the intervention; no records were kept of the actual time taken.

The OTs delivering the home based intervention made patient treatment notes in which the type of equipment delivered was recorded. However, as a condition of each site's research and development permission, the OTs were required to gain temporary contracts with each trust and pass these treatment notes to the NHS Trust's OT department as these were considered patient records and thus and to be kept confidential. Despite in section 3 of the consent form, the participants agreed for their medical note to be made available to the research team. The R&D permission at the recruitments sites did not allow this. As a consequence, a record of the adaptive aids delivered is not available. A method to satisfy the recruiting NHS trusts that medical records can be viewed by the research team will need to be developed for the proposed full RCT so a full economic costing can be performed.

4.6 Retention

A total of 46 participants consented to join the study. One participant withdrew from the study before completing the baseline questionnaire, prior to randomisation. One participant completed the baseline questionnaire but was withdrawn following randomisation due to incorrect recruitment, having already received a previous THR. Retention of participants throughout the study is evidenced by the return rates of the 4, 12 and 26 week follow-up questionnaire shown in Table 37 below. Return rates were very similar (82-84%) at all follow-up points. Overall, the loss to follow-up ranges between 16%-18% which is below the 20% indicated by Sackett et al, (1997) as being a significant source of bias. This retention

data is based on the 44 participants correctly recruited and the number of returned questionnaires at the end of the study. All the retention data presented in the results is based on the number of returned questionnaires at the completion of the study. The retention and completion data for the CSRI is discussed separately in section 4.11.

Table 37 Overall retention and loss to follow-up (excluding CSRI)

Time Point	Participants recruited (n)	Data collected		Lost to follow-up (%)
		(n)	%	
Baseline	44	44	100%	0%
4 week	44	37	84%	16%
12 week	44	37	84%	16%
26 week	44	36 [(1)]	82%	18%

Note [(1):] The three additional OHS sets collected at 26 weeks are not included

When retention is analysed by group allocation (see Figure 28), it shows very similar rates at 4 and 12 weeks for both groups, whereas at 26 weeks only 2 participants were lost to follow-up in the control group but 6 were lost to follow-up in the intervention group.

4.7 Missing data

The following Table 38 to Table 42 report the amount of missing data. Table 38 shows the missing baseline data for each outcome measure. The 4, 12 and 26 week missing data is shown in Table 39 to Table 41 respectively. Table 42 presents the total amount of missing data. The WOMAC and NEADL scales appear to have the most missing data.

Table 38 Baseline missing data

Questionnaire (Total no. of questions)	Total questions missing	Max. per participant	Max. per question	No. of participants with 3+ missing
WOMAC (24)	14	8	2	1
OHS (12)	3	1	2	0
Aberdeen I (9)	4	4	2	1
Aberdeen A (17)	9	4	2	1
Aberdeen P (9)	0	0	0	0
NEADL (20)	21	12	2	2
HADS A (7)	2	2	1	0
HADS D (7)	1	1	1	0
EQ-5D-3L (6)	0	0	0	0
ICECAP (5)	0	0	0	0
Total	54			5

Table 39 Four week missing data

Questionnaire (Total no. of questions)	Total questions missing	Max. per participant	Max. per question	No. of participants with 3+ missing
WOMAC (24)	66	7	8	9
OHS (12)	8	3	2	1
Aberdeen I (9)	5	3	2	1
Aberdeen A (17)	26	4	8	5
Aberdeen P (9)	3	1	1	0
NEADL (20)	59	15	8	8
HADS A (7)	2	1	1	0
HADS D (7)	2	1	1	0
EQ-5D-3L (6)	8	5	2	1
ICECAP (5)	6	3	2	1
Total	185			26

Table 40 Twelve week missing data

Questionnaire (Total no. of questions)	Total questions missing	Max. per participant	Max. per question	No. of participants with 3+ missing
WOMAC (24)	30	5	4	5
OHS (12)	2	1	1	0
Aberdeen I (9)	1	1	1	0
Aberdeen A (17)	21	15	4	1
Aberdeen P (9)	0	0	0	0
NEADL (20)	13	2	4	2
HADS A (7)	0	0	0	0
HADS D (7)	0	0	0	0
EQ-5D-3L (6)	0	0	0	0
ICECAP (5)	0	0	0	0
Total	67			8

Table 41 Twenty six week missing data

Questionnaire (Total no. of questions)	Total questions missing	Max. per participant	Max. per question	No. of participants with 3+ missing
WOMAC (24)	12	4	2	2
OHS (12)	1	1	1	0
Aberdeen I (9)	1	1	1	0
Aberdeen A (17)	3	1	1	0
Aberdeen P (9)	1	1	1	0
NEADL (20)	12	4	3	2
HADS A (7)	0	0	0	0
HADS D (7)	0	0	0	0
EQ-5D-3L (6)	4	2	1	0
ICECAP (5)	1	1	1	0
Total	35			4

The total questions missing: The sum total of questions missing for the outcome measure.
Maximum per person: The maximum number of questions missed per outcome measure.
Maximum per question: The maximum number of times the same question was missed.
Number of participants with 3+ missing: The number of participants who omitted to answer more than 3 questions per outcome measure.

The total number of questions requiring response in the questionnaire pack was 116. Table 42 shows the percentage of the total missing questions per follow-up time period. This analysis shows that with the exception of the 4 week time point, the amount of missing data ranges between 0.84%- 1.56%. The higher rate of 4.13% at 4 weeks may be due, partly, to some questions in the WOMAC and NEADL that are at odds with recommended hip precautions e.g. bending or driving a car at four weeks are not advised. Additionally, the independent researcher assigned to telephone participants to complete missing data was unable to establish contact with the majority of participants at the 4 week follow-up point. Despite this, the overall amount of missing data only constituted 1.91% of the total data.

Table 42 Total amount of missing data from respondents

Time point	Number of Participants	Total responses required	Total Missing Questions	Percentage missing
Baseline	44	5104	54	1.06%
4 weeks	37	4292	185	4.31%
12 weeks	37	4292	67	1.56%
26 weeks	36	4176	35	0.84%
Total	154	17864	341	1.91%

4.8 Demographic data

Baseline data (see Table 43) were collected on the following characteristics; age at date of surgery, gender and whether the participant lived alone. The postcode data of the participants was used to identify the socio-demographic of the participants (Figure 30) using the Acorn index of social classification system which informs most other indexes of social deprivation (Acorn, 2014). Analysis of the data in Table 44 shows that 26 (59%) of

participants lived in areas classified from 3H and above with 12 (27%) living in the highest 1.A – 1.C groups classified together as ‘affluent achievers’ (Acorn, 2014). Conversely, only 8 (18%) lived in areas of the lowest socioeconomic classification of 5Q ‘difficult estates’. Further analyses of these data using the spider plot showed that 7 of the 8 participants living in the lowest socioeconomic area were recruited from Dudley Group of Hospital NHS Trust site. The data in Table 44 is presented graphically using a spider plot in Figure 31.

Table 43 Demographic data

	Baseline		4 weeks		12 weeks		26 weeks	
	(I)	(C)	(I)	(C)	(I)	(C)	(I)	(C)
Age at surgery								
<50	1	2	1	1	1	1	1	1
50 – 59	5	2	4	2	4	0	3	2
60 – 69	6	10	6	9	4	9	5	10
70 – 79	6	8	6	6	6	8	5	7
>79	3	1	1	1	3	1	1	1
Mean ±SD	67±11.2	65±10.7	65.9±10.3	66.3±9.2	68.1±11.7	68.3±8.1	66±10.7	66.3±8.9
Living alone								
Yes	1	5	1	4	1	5	1	5
No	17	17	14	14	14	13	11	15
No comment	3	1	3	1	3	1	3	1
Gender								
Female	7(33%)	13(57%)	7(39%)	9(47%)	6(33%)	11(58%)	7(47%)	11(52%)
Male	14(67%)	10(43%)	11(61%)	10(53%)	12(67%)	8(42%)	8(53%)	10(48%)

Figure 30 Social demographic groupings of participants based on the Acorn (2014) classification

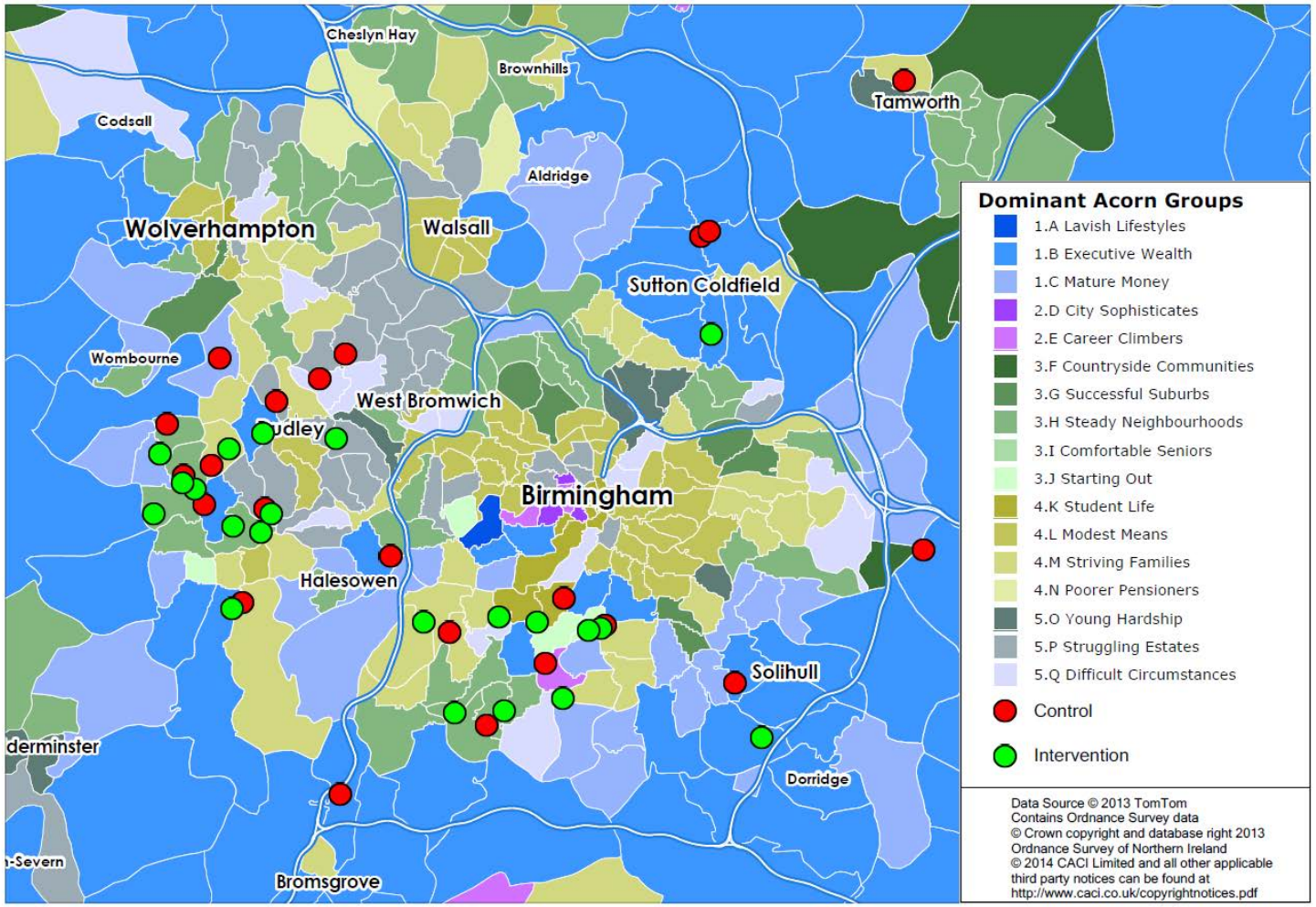
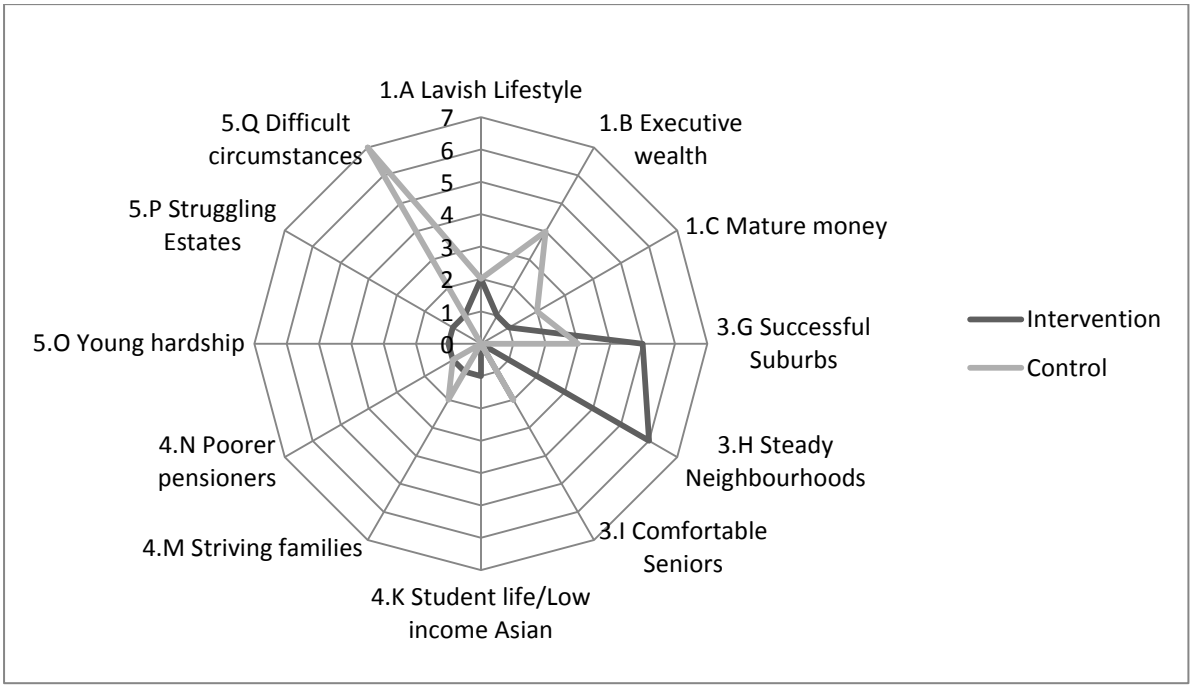


Table 44 Acorn social classification grouping

Social Classification	Intervention	Control
1.A Lavish Lifestyle	2	2
1.B Executive wealth	1	4
1.C Mature money	1	2
3.G Successful Suburbs	5	3
3.H Steady Neighbourhoods	6	0
3.I Comfortable Seniors	0	2
4.K Student life/Low income Asian	1	0
4.M Striving families	1	2
4.N Poorer pensioners	1	1
5.O Young hardship	1	0
5.P Struggling Estates	1	0
5.Q Difficult circumstances	1	7

Figure 31: Spider plot of Acorn social classification



This demographic data (Table 43) show both groups were similar in age with the average age of the participants in the intervention group (67 ±11.2) being only 2 years older on average than the average age of those in the control (65 ±10.7). Gender distribution between the two groups varied with the proportion of females in the control group (57%) being almost twice that of the control (33%). The proportion reporting that they lived alone was much higher in the control group (n=5, 21.5%) than in the intervention group (n=1, 4.8%). The social classification (Table 43) of the participants revealed a far greater proportion of the intervention group (71.4%) classified as belonging to the wealthier sections of society (social classifications 1-3) compared to the control (56.5%) and more participants in the control group (43.5%) living in the economic deprived sections of society (social classifications 4-5) compared to the intervention group (28.6%).

4.9 Outcome measure analysis

Table 45 shows a summary of the PROMs used identifying the possible range of scores for the overall measure and subscales and the directionality of the results. Following conclusion of the study, at the request of the principle investigator, participants who had not returned the 26 week questionnaire were contacted by telephone and asked for data relating to the Oxford hip score only. Three additional participants in the intervention group provided completed data which is included in the descriptive data below. The descriptive data for all the outcome measures are shown in Table 46 to Table 50 below. Table 46 shows the baseline data for both the control and intervention group and Table 47 to Table 49 show the outcome measure data at 4, 12 and 26 weeks respectively with the group values for each

measure and the between group analysis of the effect size and confidence intervals. Table 50 shows the within group change scores from baseline at each follow-up time point.

Table 45 Summary of Scales

Scale	Scoring system
WOMAC	Three dimensions: Pain (5 Qs), Stiffness (2 Qs), Function (17 Qs). Likert version – summary score for each aspect (max scores 20, 8 and 68). Then converted by 100/98 conversion to 0 (best health) to 100 (worst health) scale.
OHS	New method of scoring adding up all values resulting in a scale of 0 (worst health) - 48 (best health)
Ab-IAP	Impairment, activity limitation and participation scales scoring 1-5; I scale = 9–45, A scale= 17–85, P scale = 9-45. Lower score indicates best health; higher score indicates worse health
NEADL	Contains 22 questions, scoring 0-3 where 0 is dependent and 3 is independent. Should relate to final scores of 0 (worst health) – 66 (best health) using Likert scale or 0-22 if converted into dependant (0, 1) and independent (2, 3). Likert version used as it can detect more subtle changes.
HADS	14 questions: 7 each for anxiety and depression each scored from 0-3 (best to worst). Anxiety and depression are scored separately from 0 (best health) – 21 (worst health).
EQ5D	5 Questions giving an output of collection of numbers e.g. 11111 and 1 which can be converted into a score between -0.594 (Worst health) and 1 (full health). There is also a VAS score 0 (worst health) -100 (full health).
ICECAP	5 Questions giving output of collection of numbers e.g. 11111. This can be converted into a score between 0 (Death) and 1 (full health).

Q, questions; VAS, visual analogue scale

Table 46 Baseline descriptive statistics

Scale	Control					Intervention				
	n	(Mean)	(SD)	Median	IQR	n	(Mean)	(SD)	Median	IQR
WOMAC										
Pain	23	12.76	4.23	12.0	6.00	21	11.35	3.18	11.50	3.25
Stiffness	23	5.24	1.48	5.0	1.25	21	4.50	1.93	4.50	2.25
Function	23	42.69	12.60	41.0	16.25	21	38.39	11.8	38.50	15.22
Total	23	63.22	18.14	59.38	27.34	21	56.50	16.51	56.77	20.28
OHS										
Total	23	17.00	6.28	18.00	8.50	21	18.79	8.38	20.00	14.00
Aberdeen IAP										
Ab I	23	32.04	6.15	31.00	8.50	21	30.58	8.93	30.00	13.37
Ab A	22	52.98	13.82	52.50	16.13	21	48.48	14.46	45.00	21.81
Ab P	23	22.83	6.36	21.00	6.00	21	20.19	8.16	19.00	12.00
NEADL										
Total	22	49.63	10.73	53.00	8.44	20	47.13	15.46	51.50	18.37
HADS										
Anxiety										
Total score	22	6.73	4.61	6.00	4.50	21	6.71	5.33	6.00	6.00
Normal	13					13				
Mild	5					3				
Moderate	3					3				
Severe	1					2				
Depression										
Total score	23	5.64	2.50	5.00	2.50	21	6.48	4.51	6.00	4.00
Normal	18					14				
Mild	3					6				
Moderate	2					0				
Severe	0					1				
EQ-5D-3L										
Descriptive system	23	0.40	0.29	0.59	0.53	21	0.33	0.33	0.20	0.71
VAS	23	65.86	18.07	70.50	23.75	21	67.48	26.41	79.00	35.00
ICECAP-O										
Total	23	0.82	0.11	0.82	0.10	21	0.79	0.26	0.89	0.14

C.I., 95% confidence interval of the between group effect size; IQR, Inter quartile range; n, number of outcome measures analysed; SD, Standard deviation

Table 47 Four week descriptive statistics

Scale	Control					Intervention					Between Group			
	n	Mean	SD	Median	IQR	n	Mean	SD	Median	IQR	Mean Difference	Effect Size	C.I. Lower	C.I. Upper
WOMAC														
Pain	13	4.37	3.98	4.00	1.00	13	5.46	4.59	5.00	6.00	1.09	0.25	-0.53	1.02
Stiffness	13	2.77	1.69	3.00	3.00	13	2.69	1.70	3.00	3.00	-0.08	-0.05	-0.81	0.72
Function	13	24.16	10.91	24.00	14.61	13	22.05	14.61	20.00	13.74	-2.11	-0.16	-0.93	0.61
Overall	13	32.60	15.49	31.25	18.84	13	31.46	21.08	23.96	18.48	-1.14	-0.06	-0.83	0.71
OHS														
Overall	19	27.83	8.62	29.00	9.00	18	28.73	11.99	32.00	16.00	0.90	0.09	-0.56	0.73
Aberdeen IAP														
Ab I	19	18.30	5.85	18.00	7.00	18	19.31	9.06	17.00	6.82	1.01	0.13	-0.51	0.78
Ab A	17	34.36	12.42	29.75	21.50	17	33.84	15.79	29.00	9.00	-0.52	-0.04	-0.71	0.64
Ab P	19	16.70	5.26	17.00	8.50	18	17.76	7.98	15.94	9.50	1.06	0.16	-0.49	0.80
NEADL														
Total	16	46.31	15.12	47.50	28.72	15	43.12	12.83	42.00	20.58	-3.19	-0.23	-0.93	0.49
HADS														
Anxiety														
Total score	19	4.37	3.96	3.00	4.00	18	4.79	4.78	3.50	5.12	0.42	0.10	-0.55	0.74
Normal	16													
Mild	2													
Moderate	1													
Severe	0													
Depression														
Total score	19	3.79	3.14	3.00	3.00	18	5.18	4.40	4.00	3.75	1.39	0.37	-0.29	1.01
Normal	16					14								
Mild	0					2								
Moderate	2					1								
Severe	1					1								
EQ-5D-3L														
Descriptive system	17	0.63	0.29	0.69	0.18	16	0.60	0.27	0.67	0.23	-0.03	-0.11	-0.79	0.58
VAS	19	72.79	17.59	79.00	25.00	17	72.82	21.16	80.00	15.00	0.03	0.00	-0.65	0.66
ICECAP-O														
Total	19	0.85	0.12	0.88	0.12	14	0.80	0.28	0.90	0.16	-0.05	-0.25	-0.93	0.45

C.I., 95% confidence interval of the between group effect size; IQR, Inter quartile range; n, number of outcome measures analysed; SD, Standard deviation

Table 48 Twelve week descriptive statistics

Scale	Control					Intervention					Between Group			
	n	Mean	SD	Median	IQR	n	Mean	SD	Median	IQR	Mean Difference	Effect Size	C.I. Lower	C.I. Upper
WOMAC														
Pain	12	2.92	3.09	2.50	2.75	16	4.44	4.65	3.50	3.5	1.52	0.37	-0.39	1.12
Stiffness	12	2.17	1.95	2.00	0.25	16	2.99	1.90	2.00	2.05	0.82	0.43	-0.34	1.17
Function	12	13.99	10.45	11.50	12.25	16	20.22	14.21	17.55	18.50	6.23	0.49	-0.28	1.23
Overall	12	19.86	15.36	17.71	15.89	16	28.79	20.42	23.44	21.35	8.93	0.48	-0.29	1.23
OHS														
Overall	19	36.42	7.94	37.00	9.50	18	34.68	11.42	36.00	13.75	-1.74	-0.18	-0.82	0.47
Aberdeen IAP														
Ab I	19	15.21	4.66	14.00	5.00	18	17.26	7.90	16.38	6.50	2.05	0.32	-0.34	0.96
Ab A	18	27.06	8.75	24.97	9.19	18	30.78	15.53	27.50	11.42	3.72	0.30	-0.37	0.95
Ab P	19	12.00	3.73	11.00	2.00	18	14.94	8.82	11.50	4.75	2.94	0.44	-0.22	1.08
NEADL														
Total	19	54.02	11.69	54.36	16.00	17	47.94	23.57	59.00	22.00	-6.08	-0.33	-0.98	0.33
HADS														
Anxiety														
Total score	19	2.68	2.65	2.00	3.50	18	3.89	5.19	2.00	4.50	1.21	0.30	-0.36	0.94
Normal	18					15								
Mild	1					1								
Moderate	0					1								
Severe	0					1								
Depression														
Total score	19	1.89	1.73	1.00	1.50	18	3.78	4.47	2.00	5.00	1.89	0.56	-0.11	1.21
Normal	19					16								
Mild	O					0								
Moderate	0					1								
Severe	0					1								
EQ-5D-3L														
Descriptive system	19	0.81	0.17	0.80	0.33	18	0.71	0.33	0.74	0.34	-0.10	-0.38	-1.03	0.27
VAS	19	81.26	16.75	16.75	10.00	18	77.11	20.42	80.00	8.25	-4.15	-0.22	-0.86	0.43
ICECAP-O														
Total	19	0.90	0.10	0.93	0.08	18	0.84	0.10	0.94	0.16	-0.06	-0.60	-1.25	0.07

C.I., 95% confidence interval of the between group effect size; IQR, Inter quartile range; n, number of outcome measures analysed; SD, Standard deviation

Table 49 Twenty six weeks descriptive statistics

Scale	Control					Intervention					Between Group			
	n	Mean	SD	Median	IQR	n	Mean	SD	Median	IQR	Mean Difference	Effect Size	C.I. Lower	C.I. Upper
WOMAC														
Pain	18	2.46	3.61	1.13	2.75	11	1.73	1.68	2.00	3.00	-0.73	-0.24	-0.99	0.52
Stiffness	18	1.67	1.61	2.00	2.00	11	1.18	0.87	1.00	1.50	-0.49	-0.35	-1.10	0.41
Function	18	9.56	11.49	6.00	11.75	11	6.52	6.82	3.00	12.00	-3.04	-0.30	-1.05	0.46
Overall	18	14.25	16.62	9.90	14.84	11	9.54	8.71	6.25	11.46	-4.71	-0.33	-1.08	0.43
OHS [(1)]														
Overall	20	38.88	8.52	41.50	8.75	18	41.17	6.22	42.50	8.50	2.29	0.03	-0.34	0.94
Aberdeen IAP														
Ab I	20	15.38	6.57	13.50	6.00	15	13.67	3.89	14.00	6.50	-1.71	-0.31	-0.97	0.37
Ab A	20	26.70	9.67	25.50	10.00	15	22.79	6.09	21.00	9.50	-3.91	-0.47	-1.14	0.22
Ab P	20	11.45	3.10	10.50	3.25	15	11.33	4.41	9.00	2.50	-0.12	-0.03	-0.70	0.64
NEADL														
Total	19	57.09	17.20	64.00	8.90	15	62.67	6.66	66.00	4.00	5.58	0.41	-0.28	1.08
HADS														
Anxiety														
Total score	20	3.30	3.60	1.50	4.25	15	2.87	3.62	1.00	5.50	-0.43	-0.12	-0.79	0.55
Normal	18					13								
Mild	1					1								
Moderate	1					1								
Severe	0					0								
Depression														
Total score	20	2.05	2.04	2.00	3.00	15	2.67	3.64	2.00	3.50	0.62	0.22	-0.46	0.89
Normal	20					14								
Mild	0					0								
Moderate	0					1								
Severe	0					0								
EQ-5D-3L														
Descriptive system	19	0.86	0.13	0.81	0.25	15	0.86	0.16	0.92	0.27	0.00	0.00	-0.68	0.68
VAS	20	82.11	15.85	87.00	13.50	15	86.47	12.85	90.00	7.50	4.36	0.30	-0.38	0.96
ICECAP-O														
Total	20	0.90	0.11	0.90	0.08	15	0.92	0.15	0.97	0.08	0.02	0.16	-0.52	0.82

C.I., 95% confidence interval of the between group effect size; IQR, Inter quartile range; n, number of outcome measures analysed; SD, Standard deviation

Note [(1)]**:** Oxford hip score at 26 weeks contains data from the additional 3 patients followed up by telephone after completion of study

Analysis showed none of the data sets to be normally distributed. Median and IRQ are therefore the indications of point value and variation for tables 46 to 49

Table 50 Within group analyses (baseline – 4 weeks)

	Change: Baseline to 4 Weeks					
	Control			Intervention		
	Mean Diff	C.I. Low	C.I. Up	Mean Diff	C.I. Low	C.I. Up
WOMAC Pain	8.39	5.47	11.31	5.89	3.18	8.60
WOMC Stiffness	2.47	1.37	3.57	1.81	0.48	3.14
WOMAC Function	18.53	10.05	27.01	16.34	7.05	25.63
WOMAC Overall	30.62	18.45	42.79	25.04	11.84	38.24
OHS	-10.83	-15.48	-6.18	-9.94	-16.58	-3.30
Aberdeen I	13.74	9.97	17.51	11.27	5.42	17.12
Aberdeen A	18.62	10.04	27.20	14.64	4.67	24.61
Aberdeen P	6.13	2.44	9.82	2.43	-2.83	7.69
NEADL	3.32	-5.05	11.69	4.01	-5.91	13.93
HADS (Anxiety)	2.36	-0.35	5.07	1.92	-1.39	5.23
HADS (Depression)	1.85	0.09	3.61	1.30	-1.60	4.20
EQ-5D-3L	-0.23	-0.42	-0.04	-0.27	-0.48	-0.06
EQ-5D-3L (VAS)	-6.93	-18.12	4.26	-5.34	-21.36	10.68
ICECAP-O	-0.03	-0.10	0.04	-0.01	-0.20	0.18

Table 51 Within group analysis (baseline to 12 weeks)

	Change: Baseline to 12 Weeks					
	Control			Intervention		
	Mean Diff	C.I. Low	C.I. Up	Mean Diff	C.I. Low	C.I. Up
WOMAC Pain	9.84	7.02	12.66	6.91	4.30	9.52
WOMC Stiffness	3.07	1.87	4.27	1.51	0.22	2.80
WOMAC Function	28.70	20.06	37.34	18.17	9.49	26.85
WOMAC Overall	43.36	30.85	55.87	27.71	15.39	40.03
OHS	-19.42	-23.85	-14.99	-15.89	-22.33	-9.45
Aberdeen I	16.83	13.37	20.29	13.32	7.81	18.83
Aberdeen A	25.92	18.36	33.48	17.70	7.96	27.44
Aberdeen P	10.83	7.48	14.18	5.25	-0.26	10.76
NEADL	-4.39	-11.39	2.61	-0.81	-13.70	12.08
HADS (Anxiety)	4.05	1.64	6.46	2.82	-0.61	6.25
HADS (Depression)	3.75	2.38	5.12	2.70	-0.22	5.62
EQ-5D-3L	-0.41	-0.56	-0.26	-0.38	-0.59	-0.17
EQ-5D-3L (VAS)	-15.40	-26.36	-4.44	-9.63	-25.15	5.89
ICECAP-O	-0.08	-0.15	-0.01	-0.05	-0.18	0.08

Table 52 Within group analysis (baseline to 26 weeks)

	Change: Baseline to 26 Weeks					
	Control			Intervention		
	Mean Diff	C.I. Low	C.I. Up	Mean Diff	C.I. Low	C.I. Up
WOMAC Pain	10.30	7.77	12.83	9.62	7.51	11.73
WOMC Stiffness	3.57	2.59	4.55	3.32	2.06	4.58
WOMAC Function	33.13	25.41	40.85	31.87	23.96	39.78
WOMAC Overall	48.97	37.83	60.11	46.96	36.02	57.90
OHS [(1)]	-21.88	-26.45	-17.31	-22.38	-27.24	-17.52
Aberdeen I	16.66	12.74	20.58	16.91	11.90	21.92
Aberdeen A	26.28	18.82	33.74	25.69	17.61	33.77
Aberdeen P	11.38	8.22	14.54	8.86	4.14	13.58
NEADL	-7.46	-16.24	1.32	-15.54	-24.20	-6.88
HADS (Anxiety)	3.43	0.85	6.01	3.84	0.61	7.07
HADS (Depression)	3.59	2.17	5.01	3.81	0.94	6.68
EQ-5D-3L	-0.46	-0.61	-0.31	-0.53	-0.72	-0.34
EQ-5D-3L (VAS)	-16.25	-26.79	-5.71	-18.99	-34.01	-3.97
ICECAP-O	-0.08	-0.15	-0.01	-0.13	-0.28	0.02

C.I. Low; lower 95% confidence interval of mean difference, C.I. Up; upper 95% confidence interval of mean difference, Mean Diff; Mean difference

Note [(1)]: OHS analysis contains additional 3 participants contacted after end of study by telephone follow-up

Inspection of the between group effect size (ES), using the parameters defined by Cohen (1998) of ≤0.2 (small ES), ≤0.5 (medium ES) and ≤0.8 (large ES) at all three follow up time points none of the outcomes measures show a large effect size. At 4 weeks the between group ES ranged from 0.07 to 0.34; at 12 weeks between 0.18 to 0.56; and at 26 weeks between 0.00 to 0.47. The within group analysis, using mean differences scores, shows both groups improved at each follow-up time point on all outcomes.

4.10 ICECAP-O & EQ-5D-3L reporting

Table 53 to Table 62 below show the number and percentage of respondents choosing each response category for both the EQ-5D-3L (Table 53 to Table 57) and the ICECAP-O (Table 58 to Table 62).

Table 53 EQ-5D-3L Anxiety & depression

Anxiety & Depression	Intervention			Control		
	1	2	3	1	2	3
Baseline	13 (62%)	8 (38%)	0 (0%)	16 (70%)	7 (30%)	0 (0%)
4 Weeks	10 (63%)	6 (38%)	0 (0%)	14 (82%)	3 (18%)	0 (0%)
12 weeks	13 (72%)	4 (22%)	1 (6%)	18 (95%)	1 (5%)	0 (0%)
26 weeks	11 (73%)	4 (27%)	0 (0%)	16 (84%)	3 (16%)	0 (0%)

The anxiety and depression item of the EQ-5D-3L show that only 1 participant at 12 weeks in the intervention group indicted they were extremely anxious and depressed (3). Between 62%-73% indicated that they had no anxiety or depression (1) in the intervention group, and between 70% - 95% in the control. At both 4 and 26 weeks, the number of participants who indicated the best mental health status was greater in the control than in the intervention group.

Table 54 EQ-5D-3L Pain & discomfort

Pain & Discomfort	Intervention			Control		
	1	2	3	1	2	3
Baseline	0 (0%)	10 (48%)	11 (52%)	0 (0%)	15 (65%)	8 (35%)
4 Weeks	5 (31%)	10 (63%)	1 (6%)	4 (24%)	12 (71%)	1 (6%)
12 weeks	7 (39%)	10 (56%)	1 (6%)	9 (47%)	10 (53%)	0 (0%)
26 weeks	9 (60%)	6 (40%)	0 (0%)	12 (63%)	7 (37%)	0 (0%)

At baseline, more participants in the intervention group (11, 52%) indicated their levels of pain and discomfort to be extreme compared to the control (8, 35%). However, (15, 65%) of participants rated their level of pain and discomfort in the middle category of moderate (2) in the control, compared to (10, 48%) in the intervention group. At all the follow-up points, the results for both groups are very similar.

Table 55 EQ-5D-3L Usual activities

Usual activities	Intervention			Control		
	1	2	3	1	2	3
Baseline	5 (24%)	14 (76%)	2 (10%)	1 (4%)	20 (87%)	2 (9%)
4 Weeks	5 (31%)	7 (44%)	4 (25%)	4 (24%)	9 (53%)	4 (24%)
12 weeks	9 (50%)	7 (39%)	2 (11%)	11 (58%)	8 (42%)	0 (0%)
26 weeks	11 (79%)	3 (21%)	0 (0%)	15 (79%)	4 (21%)	0 (0%)

At baseline five participants (24%) had no problem with their usual activities compared to only (1, 4%) in the control. At all the follow-up points, the results for both groups are very similar.

Table 56 EQ-5D-3L Self care

Self-care	Intervention			Control		
	1	2	3	1	2	3
Baseline	11 (52%)	10 (48%)	0 (0%)	5 (22%)	18 (78%)	0 (0%)
4 Weeks	10 (63%)	6 (37%)	0 (0%)	10 (59%)	7 (41%)	0 (0%)
12 weeks	14 (78%)	3 (17%)	1 (6%)	14 (74%)	5 (26%)	0 (0%)
26 weeks	14 (93%)	1 (7%)	0 (0%)	18 (95%)	1 (5%)	0 (0%)

In the intervention group at baseline (11, 52%) indicated they had no problem with self-care compared to only (5, 22%) in the control; neither group indicated they were unable to wash or dress themselves. Otherwise, at all follow-up time points, the results for both groups are very similar.

Table 57 EQ-5D-3L Mobility

Mobility	Intervention			Control		
	1	2	3	1	2	3
Baseline	0 (0%)	21(100%)	0(0%)	0 (0%)	23(100%)	0 (0%)
4 Weeks	5 (31%)	11 (69%)	0 (0%)	8 (47%)	9 (53%)	0 (0%)
12 weeks	13 (72%)	5 (28%)	0 (0%)	12 (74%)	7 (26%)	0 (0%)
26 weeks	13 (87%)	2 (13%)	0 (0%)	12 (63%)	7 (37%)	0 (0%)

Both groups were identical at baseline in that 100% indicated they had some problems with mobility. At 4 weeks, the difference is small but at 4 weeks (8, 47%) indicated they had no problems with mobility in the control group compared to (5, 31%) in the control. Otherwise, at all follow-up time points, the results for both groups are very similar.

Table 58 ICECAP-O Independence

Independence	Intervention				Control			
	1	2	3	4	1	2	3	4
Baseline	10(48%)	5(24%)	5(24%)	1(5%)	3(13%)	15(65%)	5(22%)	0(0%)
4 Weeks	3 (18%)	10(59%)	3(18%)	1(6%)	4(21%)	13(68%)	2(11%)	0(0%)
12 weeks	9 (50%)	6 (33%)	2(11%)	1(6%)	9(47%)	10(53%)	0 (0%)	0(0%)
26 weeks	11(73%)	3 (20%)	1 (7%)	0(0%)	10(50%)	10(50%)	0 (0%)	0(0%)

At baseline more participants in the intervention group (10, 48%) rated themselves as being completely independent compared to only (3, 13%) in the control. In contrast, (15, 65%) participants in the control group rated themselves as independent in many things compared to (5, 24%) in the intervention. However, the number of participants in the higher affected categories 3 and 4 are otherwise similar. At 12 weeks 100% in the control group rate themselves in the two higher categories (1 & 2) of independence, whereas only 88% do so in the control. At the 4 and 12 week time points, the results for both groups are otherwise very similar.

Table 59 ICECAP-O Enjoyment & pleasure

Enjoyment & Pleasure	Intervention				Control			
	1	2	3	4	1	2	3	4
Baseline	4(19%)	8(38%)	8(38%)	1(5%)	3(13%)	9(39%)	11(48%)	0(0%)
4 Weeks	4(25%)	6(38%)	5(31%)	1(6%)	5(26%)	6(32%)	8(42%)	0(0%)
12 weeks	8(44%)	6(33%)	3(17%)	1(6%)	5(26%)	11(58%)	3(16%)	0(0%)
26 weeks	11(73%)	3(20%)	1 (7%)	0(0%)	7(35%)	12(60%)	1 (5%)	0(0%)

At baseline 4 and 26 week follow-up, both groups rated their enjoyment and pleasure very similarly. At 26 weeks (11, 73%) of participants in the intervention group indicate they can

have all the enjoyment and pleasure they want compared to only (7, 35%) in the control. However, the percentage of participants that rate themselves in the lowest two categories is very similar in the control (5%) and the intervention (7%).

Table 60 ICECAP-O Feeling valued

Feeling valued	Intervention				Control			
	1	2	3	4	1	2	3	4
Baseline	7(33%)	8(38%)	5(24%)	1(5%)	4(17%)	13(57%)	5(22%)	1(4%)
4 Weeks	4(27%)	8(53%)	2(13%)	1(7%)	5(26%)	10(53%)	4(21%)	0(0%)
12 weeks	9(50%)	5(28%)	3(17%)	1(6%)	9(47%)	9 (47%)	1 (5%)	0(0%)
26 weeks	13(87%)	1 (7%)	1 (7%)	0(0%)	7(35%)	12(60%)	1(5%)	0(0%)

At baseline the amount of participants that can do everything (1) or many (2) of the things that make them feel valued is very similar with 71% rating in these two highest categories in the intervention compared with 74% in the control. However, (7 33%) rated themselves in the highest category compared to only (4, 17%) in the control. At 4 weeks, both groups are very similar. At 12 weeks 21% of participants in the intervention group indicate they can only do a few (3) or any (4) of the things that make them valued compared to only 5% in the control. In contrast at 26 weeks (13, 87%) participants in the intervention group are able to do everything they want to be feel valued compared to only (7,35%) in the control. However, the proportions that rate themselves in the lowest categories of feeling valued are very similar in the intervention (7%) and in the control (5%).

Table 61 ICECAP-O Thinking about the future

Thinking about the future	Intervention				Control			
	1	2	3	4	1	2	3	4
Baseline	8(38%)	9(43%)	2(10%)	2(10%)	3(13%)	14(61%)	3(13%)	3(13%)
4 Weeks	8(50%)	5(31%)	2(13%)	1 (6%)	5(26%)	11(58%)	2(11%)	1 (5%)
12 weeks	9(50%)	4(22%)	3(17%)	2(11%)	7(37%)	10(53%)	2(11%)	0 (0%)
26 weeks	8(53%)	6(40%)	1 (7%)	0 (0%)	7(35%)	9 (45%)	3(15%)	1 (5%)

At all 4 time points of measurement, more participants in the intervention group indicated they can think about the future without any concern compared to the control. However the percentage of participants in the intervention group rating their ability to think about the future in the lowest two categories at baseline (20%) and at 4 weeks (19%) is very similar to the control at baseline (26%) and 4 weeks (16%). However, at 12 weeks the percentage in these lowest two categories is higher in the intervention (28%) group compared to the control (11%). In contrast, (8, 53%) of participants can think about the future with no concern compared to only (7, 35%) in the control. Additionally, only 7% of participants in the intervention rated their ability to think about the future in the lowest two categories compared to 20% in the control.

Table 62 ICECAP-O Love & friendship

Love & Friendship	Intervention				Control			
	1	2	3	4	1	2	3	4
Baseline	13(62%)	3(14%)	3(14%)	2(10%)	16(70%)	6(26%)	1(4%)	0(0%)
4 Weeks	10(67%)	2(13%)	2(13%)	1(7%)	7(37%)	11(58%)	1(5%)	0(0%)
12 weeks	13(72%)	3(17%)	1(6%)	1(6%)	13(68%)	5(26%)	1(5%)	0(0%)
26 weeks	12(80%)	2(13%)	0(0%)	1(7%)	14(70%)	5(25%)	1(5%)	0(0%)

Note: In above tables, percentages rounded up to nearest whole number so total may not equal 100%

At baseline only 4% of participants in the control group indicated they can have little or none of the love and friendship that they want compared to 24% in the intervention group. The results are also very similar at 4 weeks with the lowest two categories combined in the control being 5% and 20% in the intervention group, at 12 and 26 weeks the results for these lowest two categories are similar in both groups.

4.11 Client services receipt inventory (CSRI) reporting

The CSRI was only sent out to the participants at the 26 week follow-up time point. Thirty one (70%) of forms were returned; and of those 31 returned, only 15 (48%) were fully completed. Table 63 identifies the sections where data were incomplete on the returned CSRI forms. Approximately twice as many questions in total were missing in the control group compared to the intervention. The two sections of the CSRI form, both within and between groups, which had the highest levels of missing data were those relating to 'medication' and 'Friends/relatives help at home'.

Table 63 Summary of CSRI questionnaire missing responses

	Questions Missing 'n' (%)	
Question	**Control**	**Intervention**
Hospital resource use (A&E, Outpatient appointments, overnight stays)	12 (22.2%)	13 (33.3%)
Service use (e.g. GP, Physiotherapy)	16 (5.5%)	11 (5.3%)
Medication (type and payment)	51 (40.5%)	26 (28.6%)
Personal costs incurred for NHS/social services (e.g. transport, cleaning, child care)	23 (25.5%)	16 (24.6%)
Time off work	4 (4.4%)	1 (1.5%)
Friends/relatives help at home (how many hours of help needed for household tasks)	106 (53.5%)	29 (20.3%)
Friends/relatives time off work (how many hours taken off work to provide help)	1 (5.6%)	1 (7.7%)
Current work situation	3 (2.4%)	0 (05)
Overall total missing questions	**216 (21.8%)**	**97 (13.8%)**

4.12 Chapter summary

This chapter reports the patient retention throughout the study, how the PROOF-THR trial was conducted and the collection of the follow-up data. It revealed that although patient retention was acceptable, there was some loss to follow-up. It also showed that some of the measures used had better completion rate than others, and that the health economic data were subject to low rates of return and high rate of missing questions in the questionnaires that were returned.

5 PROOF-THR DISCUSSION

5.1 Chapter overview

This chapter contains the discussion of the results presented in chapter 4 and compares them to other relevant studies. The feasibility outcomes of recruitment, retention, acceptability and fidelity of the intervention are discussed together with suggestions of how the collection of the follow up data could be improved. Two sets of power calculation are then presented. Following this, the strengths and weaknesses of the study are discussed then followed by conclusions. In accordance with the MRC guideline (Craig et al, 2008) recommendations, no comparative statistical analysis has been undertaken.

5.2 Recruitment

Three main factors affected the recruitment process; other planned surgery, recruitment to other clinical trials, and change of surgery date. From the initial screening 332 (68%) potential participants were identified as meeting inclusion criteria for the trial which represents an acceptable rate of participant identification (Craven et al, 2014). Eighty four (74%) of the screened patients not meeting the inclusion criteria was due to previous or planned additional lower limb joint replacement surgery. Of the 181 participants excluded due to 'other reasons', this was mainly due to 109 (60%) being eligible for the competing trial (adopted prior to this study and therefore prioritised), and to a lesser extent, 58 (32%) having their surgery date brought forward precluding recruitment.

The recruitment rate was 22% of eligible patients which was similar other comparative trials (12%) by Rooks et al, (2006) and (25%) by Weaver et al, (2003) but not as high as some

other studies (42%) by Peak et al (2005) and (77%) by Rivard et al (2003). The high rates achieved by Rivard et al (2003) is potentially due to it being a nested study within a much larger study for which participants had already consented to join, so they are already willing participants. Also this study was comparing hospital based education versus home based OT visits. As this was conducted in Canada participants may long travel distances, they may have been more willing to consent to a home visit to negate the need to travel in to the hospital for their pre-surgery education session. The main factors affecting recruitment identified by Weaver et al (2003) was lack of Medicare coverage (46%) and living out of area (19%). Weaver et al (2003) also report 7% of participants were excluded due to the OT being unable to schedule home visits, which more favourable to the 17.5% in this study. However, this does indicate that in pragmatic health trials, issues such as these are difficult to avoid and may need to be taken in to account during sample size calculation. Rooks et al (2006), which had the lowest level of recruitment (12%), attributed this to only having one recruitment site and the unwillingness of patients to travel to an exercise class. However, no numbers or percentages of participants declining for these identified reasons are presented. In the studies evaluating reduced restrictions following THR, Ververeli et al (2009) only recruited 81 participants over period of 4 years and Peak et al (2005) recruited 42% of eligible participants. However, neither study provides any data on eligibility criteria or recruitment rates.

The patient demographic data revealed that a disproportionate amount of participants from higher socioeconomic populations were recruited to current the study. This is a recognised problem that can affect the generalizability of results from clinical trials (Bartlett et al, 2005; Swanson and Ward, 1995). One of the study occupational therapists also commented that

she felt “the participants were not [socio-economically] representative of the typical patients seen on home visits” (personal comment). In any subsequent full scale clinical trial, consideration of how to improve recruitment from lower socio-economic classes should be given, to make the results more generalisable to the general population. Lower socioeconomic classes often have greater health needs but also poorer access to services (UyBico et al, 2007; Liu et al, 2012).

5.3 Retention

Seven patients (16%) were lost to follow up at both 4 and 12 weeks, which was reduced to 5 (12%) at 26 weeks (Table 42). Although methods to reduce attrition should be considered, loss to follow up was still less than the 20% level at which significant bias can occur (Sackett et al, 1997). This suggests that this trial design could be taken forward into a phase III definitive trial. The rates of follow up were good, however, there was more missing data in some time points (four week) and for some outcome measures (WOMAC, NEADL) indicating that the burden of assessment would need to be considered prior to a main study. Although widely used in other studies (Busse et al, 2011), the health economic data collected using the CSRI form was poorly completed by participants so it would be worth exploring other methods or adaptations for collecting these data. Health economic data can be augmented or estimated from indirect means such as from databases of G.P. records (Roddy et al, 2009) or Hospital Episode Statistics (Health and Social Care Information Services, 2015) and NHS reference costs (Department of Health, 2015).

At 4 and 12 weeks, both the response rate and number of fully completed questionnaires was lower than at the other follow-up time points. Three participants commented on the

returned questionnaires that they had specifically not answered some questions, and left the responses blank, because the questions in the outcome measures conflicted with the routine hip precautions the patients have to comply with after total hip replacements, e.g. not to bend more than 90° for six weeks after surgery or not to drive a car. This may also explain other missing data on the returned questionnaires. At the week 4 and 12 time points, telephone calls were made by the research team if the questionnaire was not returned by the expected date. At the 4 week follow-up, several participants could not be contacted. Abiding by the ethics agreement, the research team were unable to ask people why they were not completing the questionnaire, though some participants voluntarily commented they did not '*feel up to completing it'* as they were more disabled than they had anticipated at this point, or they had made alternative living arrangements and not received the form in the appropriate timeframe for completion. Telephone, text message, or e-mails reminders should be instigated if a main randomised clinical trial is undertaken as these can improve response rates (Nakash et al, 2006). Reducing the patient burden by only having two follow-up time points may also help improve return rates. However, the retention of participants at the end of the study was good, with a follow-up return rate of 88% at 26 weeks which is comparable with the 78% - 92% retention rates in similar clinical trials (Monticone et al, 2014; Vukomanović et al, 2008) using postal PROMs with follow-up periods of 6 months or longer. Other THR rehabilitation studies with much higher follow-up rates (96-100%) are ones in which participants attend follow-up clinics (Barker et al, 2013; Gocen et al, 2004; Gilbey et al (2003); Larsen et al, 2008).

The proportion of fully completed questionnaires (64%) was slightly lower than noted in other trials (Hollis & Campbell, 1997); however, it is not unusual for this type of trial to have

some missing outcome data (Wood et al, 2004). Several participants commented that the questionnaire pack was too long and repetitive. As one of the aims was to compare a number of outcome measures for suitability for a definitive trial, the participant burden of completing the questionnaire was anticipated. However, in any future trial, the questionnaire pack would need to be shorter which should result in higher rates of response (Edwards et al, 2002; Nakash et al, 2006), and less missing data. The scales with the most missing questions across the four time points were the WOMAC and the NEADL scale. The scales with the least amount of missing data were HADS, ICECAP-O, EQ-5D-3L, and OHS. The proportion of missing data in the WOMAC and the NEADL scale, compared to the other scales, suggest that use of these as outcome measures in a future definitive trial requires careful consideration. The PEP-R patient group did not identify any of the PROMs being more difficult to complete than others and the reason for why some of the PROMs had more missing data than others was not followed up by patient interviews. This is therefore an identified weakness which would have to be ameliorated before any definitive trial.

The CSRI health resource use questionnaire had both a poor rate of return (70%), and completion with only 15 (34%) of the 44 participants returning a correctly completed form which is not unusual for health economic information (Marques, 2013). However, the rate of return does compare with other studies; (76%) Patel et al (2005), 66% (Critchley et al, 2007). Patel et al (2005) used the CSRI to collect retrospective health resources usage over a 6 month period and compared its accuracy against GP records and they had a 76% return rate. However, to achieve this return rate, they sent out a second copy after two weeks to non-responders, then after an additional two weeks further non-responders were telephoned and data was collected via a telephone interview. Although they found good

agreement between self-completion via the CSRI to actual GP consultations, the participants in this study were only asked to complete the number and duration of GP visits. In an evaluation of physiotherapy costs associated with treating chronic pain, 66% of participants completed the CSRI at 18 months follow-up but this was not self-reported; the information was collected by telephone interviews (Critchley et al, 2007).

This suggests that for a future definitive trial, methods to improve data capture by the CSRI will need to be implemented. This may include the need for telephone follow-ups to be established, and possibly the form adapted to make it simpler to complete by removing information that can be captured from other sources such as primary care visits and hospitalisation usage. Another method which should be considered is the use of resource use diaries which have been shown to increase the quality of data captured (Marques et al, 2013), or sending more frequent questionnaires to capture data rather than asking people to recollect contact over 6 months. These changes would make it easier for participants to recall the information on social care resource usage provided by friends and relatives.

Due to the lower response rates at 4 and 12 weeks, possibly as a result of some questions contradicting hip precautions, and altered domestic arrangements possibly affecting the 4 week questionnaire response rates, the 26 week time point should be used as the primary time point in any future study.

At 26 weeks, all domains of the WOMAC show a small effect size (E.S. 0.24 to 4.71) in favour of the intervention, whereas the OHS does not (E.S. 0.03). The Aberdeen IAP also shows small effect size (E.S. 3.91) in favour of the intervention at the activity level, as does the EQ-5D-3L VAS pain score (E.S. 3.0) and the HADS (depression) (E.S. 0.22). In contrast, the NEADL

shows a small effect size in favour of the control (E.S. 0.41). All other effect sizes are below the 0.2 threshold. Although the effect sizes are small, the majority of those that are above the 0.02 threshold favour the intervention at 26 weeks, which suggests it may be worth progressing to a full scale trial.

5.4 Power calculation

For sample size calculations based on observed standard deviations from pilot/feasibility studies, the data must be at interval or ratio level (Sim & Lewis, 2011). Cox & Torgerson (2013) suggest that a sample size calculation should only be undertaken from pilot studies where the methodology is a replica of the intended main trial and not conducted from feasibility where the focus is on the development of the intervention and the outcome measures and the main methodology may be subject to change. Both these criteria have been met.

In the feasibility study, the difference between the standard deviation (SD) between groups at baseline and 26 weeks ranged from 2% to 46% SD for all measurement outcomes that have data at a minimum of interval level. From inspection of the data in Table 64, it is reasonable to assume a one third standard deviation difference (Sim & Lewis, 2011) between the two arms (i.e. the potential intervention effect size) is appropriate to use for the sample size calculation. The data in Table 64 shows that with the exception of the Aberdeen (Participation) the observed differences in SD are similar.

Table 64 Sample size calculation per arm of study

Scale (Scale Range)	SD at baseline	1/3 SD	SD at 26 weeks	Difference in SD (%)	Number of participants required per arm of study
WOMAC	14.50	4.83	-3.04	21%	358
OHS	7.30	2.43	3.52	48%	68
Aberdeen (Impairment)	7.40	2.47	-1.71	23%	294
Aberdeen (Activity)	14.20	4.73	-3.91	28%	208
Aberdeen (Participation)	7.30	2.43	-0.12	2%	58093
NEADL	12.50	4.17	5.58	45%	79

Basing the power calculations on the WOMAC data, which has the lowest observed SD difference at 26 weeks (excluding the Aberdeen-Participation), will provide a conservative estimate of the minimum number of patients required to power a main study. With a 1-beta= 80%, alpha=0.05 (two sided) and a 0.33 SD difference between arms, 358 subjects are needed per arm, and a total sample size of 716. However, the feasibility study had an 18% attrition rate from baseline assessment to 26 week measurement. Therefore, based on this observed rate, the number of participants giving consent would need to be increased to 873. Anticipating only 25% of the patients who are approached to join the study, 3358 potential participants would have to be approached. Again, in accordance with the findings of this study, where only 9% of patients initially screened were selected for approach, this would require 9702 eligible patients to be initially screened if the same recruitment procedures were repeated in a full RCT. No other Inflation factors proposed have been used in these calculations (Sim & Lewis, 2011).

However, the WOMAC was one of the outcome measures that suffered from a high rate of missing questions and may therefore be excluded from any future definitive trial. If the Oxford Hip Score was to be used as the main measure of function, it is appropriate to also report a power calculation based on this outcome measure. Using the same calculation criteria 68 participants are needed per arm, or 136 in total. Allowing for the same 18% attrition rate, this would require the number to be increased to 166. With the same 25% consent rate and 9% of screened patients eligible to be approached, 638 patients would have to be approached and 1843 patient's notes screened.

It is important for statistical procedural accuracy that the power calculation should be based on the primary outcome to be used in the proposed future full RCT. The submission to the HTA was based on using the OHS as the primary outcome. This was why additional OHS data only was collected, in method requiring a deviation of protocol, such that the power calculation could be based on more data. All the PROMs used in this feasibility study were acceptable to the patient group involved. However, INVOLVE also encourage that patients views should also be considered in choosing which should be the primary outcome (INVOLVE, 2015).

As previously discussed, the low conversion rate of patients screened to those approached was influenced by the presence of a large competitor study that had been previously adopted by the NIHR so therefore had precedence on access to patients. If no such competing clinical trial was anticipated, the number of patients requiring screening would be greatly reduced.

5.4.1 Recommendation to improve recruitment

With the presence of competing clinical trials being the main reason for patients screened not being eligible for recruitment, it is recommended that the sites chosen for a main RCT should take this into consideration. As the PROOF-THR study was a small feasibility study, if a larger RCT was commissioned, the extra number of patients to be recruited may make it more attractive to the trust. However, due to the impact that a competing trial had, this should still be a major consideration in choosing the recruitment site.

The NJR (2014) report shows that 92.7% of all THR surgery is undertaken by 60% of the surgeons registered to perform THR surgery. Four regions in England were identified (BOA, 2015) in 2015 as having the most active surgeons: Birmingham and the Black Country; Bristol and Avon; London; Surry and Sussex. Artz et al (2012) also identified the 22 highest volume orthopaedic surgery hospitals in England and wales. It is therefore recommended that high volume hospitals should be used.

The power calculation based on the OHS calculation required 1843 patient's notes to be screened is almost equal to the number of hip replacements undertaken, as the screening list contains all the patients listed by surgeons for replacement hip surgery. The 22 high volume NHS orthopaedic hospitals identified by Artz et al (2012) performed 16,309 THRs in 2014 (NJR statistics online, 2015) with an average of 776 (range 274 – 1658) per trust per annum which equates to 64 THRs per site each month. A study with a six month recruitment period would therefore require 14 sites, or 7 sites with a 1 year recruitment period. The five most active trusts in 2014 were the Nuffield Orthopaedic Centre, Oxford (1104), the Robert Jones & Agnes Hunt Hospital, Oswestry (1658), the Royal Devon and Exeter Wonford

Hospital (1004), the Royal Orthopaedic Hospital, Birmingham (1379), and the Elective Orthopaedic Centre, Epsom (1398) which averaged 1,308 THRs per annum. If as many of these hospitals could be included, this would potentially speed up the recruitment rate and thus the time to complete the study.

5.5 Discussion of experimental methodology

5.5.1 Strengths

This study had several strengths. It was conducted following the SOPs of a clinical trials unit which performed the randomisation and maintained the data in a secure bespoke database. All the outcomes used were validated PROMs and their appropriateness, acceptability and burden of completion were trialled on a patient population prior to use in the study. Allocation concealment and outcome assessor blinding was maintained until point of analysis by following established procedures for rehabilitation trials (Siemonsma and Walker, 1997; Minns-Lowe et al, 2011). There were no participant withdrawals after allocation, no crossover from the intervention to control arm and all participants allocated received the occupational therapy intervention. The aim to deliver the occupational therapy intervention between 2 to 4 weeks before surgery was achieved, which demonstrated that the delivery of the intervention in both content and time of delivery is feasible. Despite competition from another large trial recruiting total hip replacement patients at the same recruitment sites, the screening, identification and recruitment procedures were successful and participants were recruited at an acceptable rate. The study had infrastructure support as it was adopted by both the primary care and musculoskeletal clinical research networks and was part of an NIHR programme grant. Throughout the trial, there were no deviations

from protocol and no adverse events were reported by the research nurses. The conduct and reporting of the study have been conducted and reported in accordance with the CONSORT (Schulz et al, 2010) and MRC guidelines for complex interventions (Craig et al, 2008). A CONSORT checklist is provided in Appendix 11.

5.5.2 Weaknesses

The main weaknesses of the trial are the rate of return of questionnaires and the amount of missing data in those returned; this was particularly so for the health resource usage data. This was partially as a consequence of the questionnaire being too long and repetitive, which will be need to be addressed in future.

Another considerable weakness was the lack of economic data collected so the comparative costs of the intervention compared to the routine care cannot be estimated. This is potentially the most important weakness in regards to planning a future trial. Although procedures were established for recording home visits that lasted longer than 2 hours, recording the exact duration of each OT home visit would have been more useful to estimate actual treatment costs. The research OTs kept a record of all the equipment delivered to the intervention group but this was delivered to the Trusts as part of the patient's records which were not available to the researcher; as was the records of equipment delivered to the control group by the Trust's OTs. Robust systems to record this treatment cost data will have to be clearly established if a main study is conducted.

Although patients preferring pre-surgery domiciliary OT was one of the main findings of the recent qualitative study (Orpen & Harris, 2010) and the PROMs used were trialled on a patient population prior to use, determination of the acceptability of the specific

intervention delivered, and the PROMs used, would have been greatly enhanced by the use of qualitative feedback from the participants. The researcher aimed to conduct qualitative interviews at the 4 week follow-up point but this part of the initial protocol was declined by the reviewing ethics panel (on grounds of over-burdening the participants) despite that it is now recommended practice in RCT's (O'Cathain et al, 2014).

The social classification groupings, supplemented by anecdotal comments by the study OTs, indicated the participants in this study did not represent the full diversity of the population having THRs. This is recognised problem in clinical trials due to the over-representation of predominantly white higher socioeconomic classes (Swanson and Ward, 1995). This imbalance in socioeconomic status may also be contained in the patient experience partnership in research group (PEP-R) group which were based in Bristol; the main study site for the NIHR programme grant. Dudley and Birmingham have an overall lower socioeconomically status that the Bristol and Avon area (ONS, 2013). It is therefore recommended that the public involvement in a main trial should be far more representative of the recruiting sites in terms of ethnicity, socioeconomic status, and literacy. If multiple sites are used, the public involvement should represent the populations of each recruiting site.

5.6 Study conclusions

By following established procedures for rehabilitation trials, the study successfully randomised participants, maintained allocation concealment until all participants had been recruited, and outcome assessor blinding was maintained until the follow-up phase

completed therefore confirming that recruitment, randomisation, and delivery of the intervention could be successfully achieved.

The true acceptability of allocation to the intervention or the control group cannot be determined due to the absence of any qualitative interviews. On a basic level, it can be inferred that group allocation was not wholly unacceptable as group allocation was maintained throughout. A recommendation is therefore that qualitative interview must be included in any main is commissioned.

As there were no major protocol deviations and no adverse effects reported, this feasibility study has shown that a pre-surgery home based occupational therapy intervention is safe, feasible to deliver and acceptable to participants.

Participants were recruited over a wide geographical area from two from two sites and the educational component of the intervention was delivered at home. It is therefore highly unlikely that there was any contamination of this element.

Although retention was sufficient to not be a cause of bias, methods to improve retention should be considered. Due to movement restrictions and potential altered domiciliary arrangements on discharge, 26 weeks should be the primary time point of analysis.

It has been demonstrated that a fully powered randomised controlled trial of pre-operative occupational therapy for patients receiving total hip replacement is feasible.

The PROOF-THR feasibility study took a pragmatic approach, which can be considered a strength of the design as it had the advantage of reflecting the variations that actually take place in clinical practice (Roland and Torgersen, 1998). Although both sites provided almost

the same rehabilitation as usual care, information any deviations in the usual care provided was not collected, so it was not possible to determine the exact care received by the control group. From an economic analysis perspective, this may be considered a weakness. Conducting an economic analysis was not an aim of this feasibility study, so no data was collected for by the researcher on the equipment that was provided to both the control and the intervention group. However, it is recommended that this would need to be collected in a future definitive trial so that a full economic analysis can be performed.

5.7 Chapter summary

This chapter revealed that the methods for identification and recruitment of patients were practicable and that patients could be recruited at an acceptable rate. It also revealed randomisation to either the control or intervention group was acceptable to the participants and the intervention could be effectively delivered. A key weakness of the study was revealed to be the return rate and completion rate of the follow-up questionnaires. Reasons for this were discussed and suggestions were presented as to how this could be improved, and what the main time point of analysis should be, if a full scale RCT were to be conducted.

The power calculations showed that if the WOMAC (Bellamy et al, 1998) data was used, this would give a conservative value to the number of patients required at the 26 week point of analysis to power a trial (n=873). However, as the WOMAC was one the questionnaires subject to high non-completion rates, the OHS (Dawson et al, 1996) was suggested as being the main outcome measure to be used. A power calculation based on this only required (n=166) patients to complete the study at 26 weeks which is far more feasible and less costly.

The key finding of this chapter is that this study has shown it is feasible to conduct a full scale RCT using the methodology developed, though robust methods will be needed to collect economic data.

The results of the PROM measures show that the THR is very effective in relieving pain. Analysis of all the functional measures, show that at 4 weeks the deficit from full function is approximately 30%, and at 12 weeks, 20%. Even at 26 weeks, none of the participants, in either group, achieve full functional status with the residual deficit from full function being approximately 10%. Although this shows function improves without any further intervention after the surgical event, the rate of functional improvement, or the overall level of improvement, may be improved with some post-surgery rehabilitation. What would constitute the most effective post-surgery rehabilitation may worthy of further research.

6 THESIS CONCLUSIONS

This section will summarise the main findings and conclusions in the preceding chapters of this thesis.

6.1 Introduction

The introductory chapter revealed a substantial economic cost to the NHS to provide total hip replacements for people with osteoarthritis. This cost is expected to increase annually due to the ageing population demographics and potential increase in some risk factors associated with developing OA. It also revealed with the average typical stay of only 3-4 days for hip replacement surgery, hospital based rehabilitation has decreased and the emphasis has moved to the patient needing to continue their rehabilitation after discharge. A summary of the evidence revealed that there is generally a lack of good quality evidence relating to rehabilitation of patients following THR, and that more, better quality research is needed.

6.2 Systematic review and meta-analysis

The results of the systematic review revealed that although occupational therapists have a substantial role in the rehabilitation of patients; with interventions carried out pre-admission, during hospital stay and after discharge, there is a limited amount of evidence regarding the efficacy or effectiveness of occupational therapy interventions. Of the studies included in the review, only 4 studies were specific to occupational therapy. The other studies were either multidisciplinary or had 'occupational therapy equivalent practice' delivered by nurses or physiotherapists. Most of the studies were over 10 years old and had

small sample sizes limiting their generalizability to modern health care practice. Further high quality research in to the effectiveness of occupational therapy intervention with patients undergoing total hip replacement is recommended.

The meta-analysis revealed significant findings for occupational therapy interventions: there is a moderate level of evidence that interventions help to significantly improve pre-surgery function, pre-surgery anxiety and anxiety at point of discharge; moderate to low levels of evidence that interventions help to reduce pre-surgery levels of pain; moderate to very low evidence that interventions reduce the overall length of acute facility hospital stay and reduce societal participation pre-surgically and at point of discharge; low to very low levels of evidence that interventions assist with improving long-term function. There is insufficient evidence to determine if occupational therapy interventions assist with function at time of discharge, pain at point of discharge and long term, health related quality of life pre-surgically, at point of discharge or long term, long term societal participation or rates of prosthesis dislocation.

This section of the thesis also revealed the need for more standardisation of the outcome measures used. Function was measured in 9 different ways and pain by 4 different PROMs, both by either exclusive measures or as sub-domains of others. Additionally, different follow-up time points were used to assess the effect of interventions. Standardisation of follow-up time points and outcome measures would improve the quality of the synthesis of findings and thus their clinical value and meaning.

There is a need to estimate the cost-effectiveness of OT interventions for patients undergoing THR. The review revealed the real cost to the patients of not providing OT

services could result in increased anxiety, pain and decreased long term function. The cost to the NHS could include increased LOS and dislocation rates. It is therefore important to address if OT is cost-effective or whether other health professionals could deliver the same quality of intervention at reduced cost.

This review identified lack of available data on current OT practice for patients undergoing THR, and especially research conducted in the UK.

6.3 The feasibility study

The feasibility study showed that the identification and recruitment methods were feasible, the recruitment rate was acceptable and the intervention could be delivered and was acceptable to the participants. It also revealed methods to improve the retention of patients and the return of questionnaires need to be considered. Due to problems identified with collection of the 4 week data, 26 weeks should be the primary time point of analysis. Overall, this feasibility study therefore revealed that a full randomised controlled trial following this methodology is practical.

The power calculation showed if a conservative estimate is taken based on the WOMAC data, 716 patients will be required in total (358 each arm) at point of analysis, or 136 in total (each arm 68) will be needed in each arm of the study if an estimate is based on the findings of the Oxford Hip Score.

Future clinical trial may want to consider the most effective time point to deliver rehabilitation. Also, whether combing pre-operative and post-operative rehabilitation may be more effective in returning patients back to function quicker. Additionally, this thesis

revealed different health professionals are routinely involved in rehabilitation of patients undergoing THR. Future studies may want to investigate if routine therapy provision by qualified OTs is required, and may effective services be delivered by therapy assistants. The need for cost effectiveness to be included was revealed as any change to rehabilitation practice will have cost implications. Robust methods for capturing the data required must be considered in the design phase of the study. The results of this study showed none of the participants had full function measure by the PROMs used at 6 months; it is therefore not know if further improvements are achieved. It is therefore important that long term outcomes are measured up to at least one year.

This thesis was originally designed to follow the framework of the MRC guidance for complex interventions and meet the requirements of a PhD. Due to the downscaling to an MPhil; some intended elements of the original investigation were therefore not conducted. This specifically affected collection and analysis of the health economic information. Additionally, the original trial protocol submitted to ethics contained a request to conduct qualitative interviews with the participants at the 4 week follow-up time point which was denied. The glossary of the NIHR Evaluation, Trials and Studies website (2015) provides their definition of the differences between what is a 'feasibility study' and a 'pilot study'. From these definitions, the clinical trial does not quite fulfil all the elements required of a feasibility study mainly as a consequence of the omission of the health economics and qualitative data, and resembles more closely the NIHR definition of a pilot study. However, several studies have shown this is often the case with the only absolute difference being that a feasibility study should not evaluate the treatment effect (Arain et al; 2010; Leon et al, 2011; Whitehead et al 2014).

6.4 Overall thesis

This thesis produced the first comprehensive systematic review and meta-analysis to evaluate the effectiveness of occupational therapy interventions with respect to patients undergoing THR. It therefore successfully contributes to new knowledge in this field. The feasibly study was the first RCT of pre-surgery domiciliary occupational therapy for patients undergoing THR due to osteoarthritis. It has shown a full RCT is feasible using the method developed in this trial. Additionally, as the first trial of its kind, it has also contributed new knowledge in the area of rehabilitation following THR surgery.

This thesis also showed the importance of following the MRC guidance for the development and evaluation of complex intervention. The introductory chapter revealed the gaps in areas of knowledge. The systematic review investigated a clinical question and was conducted following recognised methods to reveal what is known, and what may require further research, with regards to current OT practice for patients undergoing THR. The feasibility clinical trial was based on the findings of the systematic review. This feasibility study identified that a full scale trial is possible using the methodology employed. It also revealed several weaknesses, especially with regards collecting follow up data and specifically health economic data that will need improving if a full scale trial is conducted. Full scale clinical trials are expensive and it is a moral responsibility that health research money is spent effectively and participants aren't recruited to poorly designed trials which may not lead to improved health care. Identifying these weaknesses at this point is therefore important so they can be addressed.

One of the limitations on this thesis is the lack of the patient's voice. Although a summary of qualitative research from patients undergoing THR was included in chapter 1, this does not replace the requirements for gaining the patients perspective on this particular intervention. Any future clinical trial should include a nested qualitative study.

6.5 Clinical messages

- More high quality research is required to investigate the efficacy of occupational therapy practice in the area of rehabilitation of patients undergoing THR de to osteoarthritis.

- Pre-surgery domiciliary occupational therapy assessments and interventions can be effectively delivered and were well received.

- The costs and benefits of this method of service delivery need to be established.

Word Count: 39,445

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8 APPENDICES

Appendix 1	i-CSP survey of current rehabilitation practice
Appendix 2	Medline search strategy for systematic review
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Appendix 4	Grading the strength of evidence U.S. agency for healthcare research and quality guidelines - additional domains
Appendix 5	PROOF-THR Patient Information Leaflet
Appendix 6	PROOF-THR letter Consent form
Appendix 7	PROOF-THR Invitation to join study
Appendix 8	PROOF-THR Patient demographics form
Appendix 9	PROOF-THR Lone worker policy
Appendix 10	Proof-THR questionnaire
Appendix 11	Client services receipt inventory (CSRI)
Appendix 12	Original ethics favourable opinion
Appendix 13	Ethics substantial amendment favourable opinion

Appendix 1 – i-CSP Survey

This small survey provides a brief synopsis of NHS practice regarding pre-operative advice & post-operative rehabilitation. These are replies received from a question posted on the interactive CSP site in October 2010.

	Pre- surgery	Post-surgery	Notes
1	None	Discharged day 3-6 based on range of movement & independently mobile. Given information/exercise booklet. Community/intermediate care if needed	Routine out-patients for TKR but not THR
2	Physiotherapist, Occupational Therapist, Nurse	Home visits 2-3 times week for 3-5 weeks. Then option to refer to specialised TKR or lower limb conditioning class once per week for 6 weeks	Extremely high patient satisfaction scores
3	Pre-admission clinic led by therapists who assess muscle strength, ROM, Quality of Life. questionnaires, use of crutches	Out-patients 2 weeks after discharge for TKR and after 3 weeks for THR for about 4 weeks. Group exercise class plus individual time with therapists.	
4	All patients seen on 1:1 basis. THRs seen by occupational therapist who does home visit to assess equipment needs. TKR's seen by physiotherapist.	No details supplied	currently investigation Pre-op class instead of 1:1
5	Nurse (fitness for Surgery) Individual physiotherapy assessment. Written information booklet (exercise, surgery, home aids & hip precautions)	Discharged day 4.	TKR usually have physiotherapy out-patients, THRs at ward physiotherapist's discretion.
6	Assessed by postal questionnaire	Discharged 3-7 days	No routine follow-up THR or TKR unless problem identified

Appendix 2 – Medline search strategy

First phase search: Study design and participants

1. randomized controlled trial.pt.
2. controlled clinical trial.pt.
3. randomized.ab.
4. placebo.ab.
5. randomly.ab.
6. trial.ab.
7. groups.ab.
8. (animals not (humans and animals)).sh.
9. 1 or 2 or 3 or 4 or 5 or 6 or 7
10. 9 not 8
11. Arthroplasty, Replacement, Knee/ or Arthroplasty, Replacement, Hip/
12. exp Arthroplasty, Replacement, Hip/ or exp Hip Prosthesis/ or hip replacement.mp.
13. 11 or 12
14. exp Arthroplasty, Replacement, Knee/ or exp Knee Prosthesis/ or knee replacement.mp.
15. knee prosthesis.mp. or exp Knee Prosthesis/
16. 14 or 15
17. 16 or 13
18. hip prosthesis.mp. or exp Hip Prosthesis/
19. 18 or 17
20. total hip.tw.
21. total knee.tw.
22. 21 or 20 or 19
23. Orthopedic Procedures/ or orthopaedic surgery.mp.
24. 22 or 23
25. 10 and 24
26. exp preoperative care/
27. preoperative period.mp. or Preoperative Period/
28. pre-surg$.tw.
29. presurg$.tw.
30. before surg$.tw.

31. pre-operat$.tw.

32. preoperat$.tw.

33. 26 or 27 or 28 or 29 or 30 or 31 or 32

34. 25 and 33

Second Phase search: intervention

1. OCCUPATIONAL THERAPY.sh.

2. SELF-HELP DEVICES.sh.

3. SPLINTS.sh.

4. (occupational adj1 therap$).ti,ab.

5. splint$.ti,ab.

6. ((assist$ or help$) adj5 (device$ or technolog$)).ti,ab.

7. ((sel$ or home$) adj5 (care$ or manage$)).ti,ab.

8. ((environment$ or home$ or domestic$ or house$) adj5 (adapt$)).ti,ab.

9. ((daily or domestic$ or house$ or home$) adj5 (activit$ or task$ or skill$ or chore$)).ti,ab.

10. or/1 9

Appendix 3 – Data extraction check table

The data extracted for the meta-analysis was checked for accuracy by an independent person Andrew Beswick. This was the comments made on the initial data extraction.

	Physical function	Pain	Length of stay	HRQoL	Social participation	Anxiety
Butler	X	x	In McDonald 2004 they use n= 30/40 but I haven't changed this	x	X	OK
Crowe	X	x	OK	x	X	OK
Ferrara	OK	OK. VAS used but WOMAC available?	X	SF36PCS Direction changed	X	x
Gocen	OK	OK. Pain at rest	X	x	X	x
McGregor	Intervention N changed to 15 (4 with no data)	Intervention N changed to 15 (4 with no data (author's thesis). "Pain" used but WOMAC was available?	X No variance - we did contact author but not available	Sign changed - was this EUROQOL measured from graph? I can check this	X	x
Munin	SF-36 added to PROM plot. Sign changed (>change is improvement)	Check (>change is improvement)	OK	Direction changed. Rand36 role functioning physical	X	X
Peak	OK	X	OK	X	OK	X
Rivard	X	X	OK	x	X	x

Rosendal	Direction changed. Higher score higher health status. Greater increase in hip rating scale in control group	Direction changed. Higher score *better* pain. Greater increase in control group	OK	x	OK. SIP. "patients in the control group improved more compared to patients in the shared care group"	x
Sandell	NHP – higher better? A negative change is therefore an improvement. Direction changed	Check	X	AIMS Satisfaction with health	NHP social	x
Siggeirsdottir	OK	Could request a pain outcome?	OK	x	X	x
Tappen	Not checked	Not checked	Not checked	Not checked	Not checked	Not checked
Ververeli	OK	X	X	X	X	X
Weaver	SEs changed to SDs	SEs changed to SDs	no variance	Add in an SF36 outcome - I wasn't sure which so I put in Physical role (may need to change)	Direction changed SF36 social function	x
Wong	No extractable data					

X = Outcome not contained in study

Appendix 4 – Grading the strength of evidence U.S. agency for healthcare research and quality guidelines - additional domains (Owens et al, 2010)

Domain	Definition and elements	Score and application
Risk of bias	Risk of bias is the degree to which the included studies for a given outcome or comparison have a high likelihood of adequate protection against bias (i.e., good internal validity), assessed through two main elements: Study design (e.g., RCTs or observational studies) Aggregate quality of the studies under consideration. Information for this determination comes from the rating of quality (good/fair/poor) done for individual studies	Use one of the three levels of aggregate risk of bias: Low risk of bias Medium risk of bias High risk of bias
Consistency	The principal definition of consistency is the degree to which reported effect sizes from included studies appear to have the same direction of effect. This can be assessed through two main elements: Effect sizes have the same sign (that is, are on the same side of ‘‘no effect’’) The range of effect sizes is narrow	Use one of the three levels of consistency: Consistent (i.e., no inconsistency) Inconsistent Unknown or not applicable (e.g., single study) As noted in the text, single-study evidence bases (even mega-trials) cannot be judged with respect to consistency. In that instance, use ‘‘Consistency unknown (single study)’’
Directness	The rating of directness relates to whether the evidence links the interventions directly to health outcomes. For a comparison of two treatments, directness implies that head-to-head trials measure the most important health or ultimate outcomes. Two types of indirectness, which can coexist, may be of concern. Evidence is indirect if: It uses intermediate or surrogate outcomes instead of ultimate health outcomes. In this case, one body of evidence links the intervention to intermediate outcomes and another body of evidence links the intermediate to most important (health or ultimate) outcomes It uses two or more bodies of evidence to compare interventions A and B e.g.,	Score dichotomously as one of two levels directness: Direct Indirect If indirect, specify which of the two types of indirectness accounts for the rating (or both, if that is the case) namely, use of intermediate/surrogate outcomes rather than health outcomes, and use of indirect comparisons. Comment on the potential weaknesses caused by, or inherent in, the indirect analysis. The EPC should note if both direct and indirect evidence was available, particularly when indirect evidence supports a small body of direct evidence.

	studies of A vs. placebo and B vs. placebo, or studies of A vs. C and B vs. C but not A vs. B. Indirectness always implies that more than one body of evidence is required to link interventions to the most important health outcomes. Directness may be contingent on the outcomes of interest. EPC authors are expected to make clear the outcomes involved when assessing this domain.	
Precision	Precision is the degree of certainty surrounding an effect estimate with respect to a given outcome (i.e., for each outcome separately). If a meta-analysis was performed, this will be the confidence interval around the summary effect size.	Score dichotomously as one of two levels of precision: Precise Imprecise A precise estimate is an estimate that would allow a clinically useful conclusion. An imprecise estimate is one for which the confidence interval is wide enough to include clinically distinct conclusions. For example, results may be statistically compatible with both clinically important superiority and inferiority (i.e., the direction of effect is unknown), a circumstance that will preclude a valid conclusion.
Dose-response association	This association, either across or within studies, refers to a pattern of a larger effect with greater exposure (dose, duration, adherence)	This additional domain should be rated if studies in the evidence base have noted levels of exposure. Use one of three levels: Present: dose-response pattern observed Not present: no dose-response pattern observed (dose-response relationship not present) NA (not applicable or not tested)
Plausible confounding that would decrease observed effect	Occasionally, in an observational study, plausible confounding factors would work in the direction opposite to that of the observed effect. Had these confounders not been present, the observed effect would have been even larger than the one observed. In such	This additional domain should be considered if plausible confounding exists that would decrease the observed effect. Use one of two levels: Present: confounding factors that would decrease the

	a case, an EPC may wish to upgrade the level of evidence.	observed effect may be present Absent: confounding factors that would decrease the observed effect are not likely to be present
Strength of association (magnitude of effect)	Strength of association refers to the likelihood that the observed effect is large enough that it cannot have occurred solely as a result of bias from potential confounding factors.	This additional domain should be considered if the effect size is particularly large. Use one of two levels: Strong: large effect size that is unlikely to have occurred in the absence of a true effect of the intervention Weak: small enough effect size that it could have occurred solely as a result of bias from confounding factors
	Publication bias indicates that studies may have been published selectively with the result that the estimated effect of an intervention based on published studies does not reflect the true effect. The finding that only a small proportion of relevant trials (or other studies) has been published or reported in a results database may indicate a higher risk of publication bias, which in turn may undermine the overall robustness of a body of evidence.	Publication bias need not be formally scored. However, it can influence ratings of consistency, precision, magnitude of effect (and, to a lesser degree, risk of bias and directness). If EPCs identify unpublished trials, and if those results differ from those of published studies, they can take these factors into account in their rating for consistency and in calculating a summary confidence interval for an effect. We encourage authors to comment on publication bias when circumstances suggest that relevant empirical findings, particularly negative or no difference findings have not been published or are not otherwise available.

Appendix 5 – PROOF-THR Patient Information sheet

UNIVERSITY OF BIRMINGHAM

PROOF THR

Study Number: UKCRN 11294

Study Title: 'a pilot randomised controlled trial of occupational therapy to optimise recovery of patients undergoing primary total hip replacement for osteoarthritis' PROOF-THR

What is the purpose of the study?
This is a small scale (pilot) study which is going to be used to work out the best method of running a much larger trial in the future. The aim of the overall study is to assess how the adaptive aids (E.g. raised toilet seats; grab rails; shoe horns; sock dressing aid) provided by occupational therapists, that are required for a short period following a Total Hip Replacement, can be best delivered to improve the overall experience of patients. Usually, these adaptive aids are provided after your surgery. Previous studies have found education sessions before patients undergo joint replacement surgery improve patients' satisfaction with the service they have received and reduces overall anxiety levels which can lead to improved rehabilitation afterwards. However, no study in the UK has so far looked at providing adaptive aids before surgery.

Why have I been chosen?
Your consultant has decided that the best treatment now for your hip pain is to have a Total Hip Replacement. You have been asked to take part in this study because the pain in your hip is due to osteoarthritis and you have not had any other joint replacement surgery.

Do I have to take part?
A researcher from the hospital will telephone you to ask if you would like to take part in this study. They will not in any way try to influence you to join the study or not; it is up to you to decide whether or not to take part. If you do decide to take part, a researcher will contact you when you come to the pre-assessment clinic and will ask you to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. This would not affect the standard of care you receive.

What would happen to me if I take part?
Everyone who agrees to take part in the study will be visited by a researcher who will ask you to fill in some questionnaires about your pain, activity levels and satisfaction with life. A

computer will then randomly decide, as if by the toss of a coin, which arm of the study you will be in.

If you are put in the control group, you will be treated just like everyone else having total hip replacement surgery that is not in the study. The occupational therapist will give you the adaptive devices in hospital after you have had your joint replacement.

If you are put in the other group, an occupational therapist will come to visit you at home and will provide you with the same adaptive aids you would receive in the control group. The occupational therapist will explain to you (and your partner/carer if you wish) how to use these adaptive devices and will leave them with you so they are at home when you are discharged from hospital. You will also be able to discuss with the occupational therapist any questions you have about your hospital stay or your rehabilitation afterwards.

What do I have to do afterwards?
If you decide to take part, you will be asked to fill in a further set of the same questionnaires 3 more times: these will be at 4 weeks, 3 months, and finally at 6 months following your surgery.

The researcher would also like to record your mobility activity once you are back home after the surgery. You will also be asked to wear a small digital activity monitor on your unaffected ankle (similar to the size of a wrist watch) or to carry a pedometer (the size of a matchbox) for 8 days which counts the amount of steps you take each day. You will be asked during the consent process to indicate if you are willing to do this and to indicate your wishes on the consent form. It is possible to take part without consenting to this activity measurement.

What are the disadvantages or risks of taking part?
Occupational Therapy is not thought to put individuals at risk. The same adaptive devices that are routinely provided in the NHS will be supplied to everyone in the study. The main disadvantage of taking part is the possibility that the home education service provided by the therapist may have no measurable benefits.

What are the advantages of taking part?
We hope that we can demonstrate that the provision of the required adaptive devices by an occupational therapist prior to surgery will improve the experience of patients having a total hip replacement. We also hope to demonstrate that if patients have a better experience; this may also lead to better functional rehabilitation afterwards. The information we get from this study may help us to determine the most effective way to deliver services in the NHS which will benefit everyone in the future who requires a hip replacement.

What if new information becomes available?
This is the only study of this kind so far in the UK and any new study will add to our knowledge, but other studies may be necessary before practice is changed. If information

becomes available from other work, it will add to our knowledge, but this study will continue as planned.

What happens when the research study stops?
The occupational therapy service provided by this study only affects patients up to the point of discharge. When the participation in the study is over, no further services are provided by the study team. You should contact the usual NHS and/or social services if you have any on-going rehabilitation requirements.

What if something goes wrong?
Occupational therapy is a low risk intervention and it is unlikely that any harm will come from involvement in this study. If for any reason the occupational therapist is unable to provide their service prior to surgery, you will automatically return to usual NHS care.

If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it. Regardless of this, if you wish to complain about any aspect of the way you have been approached or treated during the course of this study, the normal NHS complaints mechanisms is be available to you by contacting PALS on the following numbers (The Royal Orthopaedic Hospital NHS Trust - 0121 685 4128; The Dudley Group of Hospitals NHS Trust - 0800 073 0510).

What if there is a problem?
If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this by contacting [redacted] (Trial Manager) on [redacted]

Will my taking part in this study be kept confidential?
All information which is collected about you during the course of the research will be kept strictly confidential. The questionnaires you fill in will be anonymous. Any information about you that leaves the hospital/surgery will have your name and address removed so that you cannot be recognised from it. Your General Practitioner (GP) would be notified that you are taking part in the study (with your permission). The occupational therapist and nurses that organise your discharge from hospital will need to know if you were in the study. Your contact details would be stored in a locked filing cabinet in a secure, restricted access building in the department of Primary care Clinical Sciences at the University of Birmingham. Information stored electrically would be saved as password protected documents on network restricted computers. Other personal information such as past medical history, medication and any hospital or clinic assessments (if applicable), would have your name and address removed so that you cannot be identified from it – we use a unique code instead. The questionnaires would also be anonymised.
No identifying information would appear in our published results

Who might have access to my personal information?

Named members of the study team would have access to the information that is collected about you during the study including your medical history. By signing a written informed consent form you authorise such access. To monitor the quality and conduct of research, studies might be chosen at random for audit. There is a chance that this study would be subject to review, in which case members of the Independent Review Board / Research Ethics Committee (REC)/ regulatory authorities would be granted direct access to your personal information and medical records for verification of clinical trial procedures and/or data collection. These authorities would treat any information about you as strictly confidential.

What will happen to the results of the study?
The results of this small study may be used to inform a much larger study. The study may also be written up as part of a PhD thesis by the main researcher in the team and may also be published in a scientific journal. No literature, presentation nor publication will identify individuals who participated in the study. (If you would like copies of the publications please inform at the address below).

Who is organising and funding the research?
The study is being funded by the National Institute for Health Research, part of the NHS.

Who has reviewed this study?
NRES West Midlands - Solihull NHS Research Ethics Committee have provided ethical approval for this study

Who do I contact for further information? Please contact or at Primary Care Clinical Sciences, University of Birmingham, Edgbaston, Birmingham, B15 2TT for more information. You will be given a copy of the information sheet and a signed consent form to keep.

Thank you for reading this

Professor Catherine Sackley PhD, MSc, MCSP, FCOT
Professor of Physiotherapy
Chief investigator

Appendix 6 – PROOF-THR Consent form

UNIVERSITY OF BIRMINGHAM

PROOF THR

Study Title: 'A PILOT RANDOMISED CONTROLLED TRIAL OF OCCUPATIONAL THERAPY TO OPTIMISE RECOVERY OF PATIENTS UNDERGOING PRIMARY TOTAL HIP REPLACEMENT FOR OSTEOARTHRITIS' PROOF-THR

Centre ID:

Patient ID:

Patient Initials:

Researcher:

1. I confirm that I have read and understood the information sheet, dated 21/03/2012_version 3.1 for the above study. I have had the opportunity to consider the information, ask questions, and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my medical care or legal rights being affected. ☐
3. I understand that relevant sections of my medical notes and data collected during the study may be looked at by members of the PROOF THR research team, regulatory authorities, or the NHS Trust, where this is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐
4. I agree to my GP being informed of my participation in this study. ☐
5. I agree to take part in the PROOF THR study. ☐
6. I agree to the information gathered in this study being moved from the NHS to the Universities participating in this study (Birmingham, Bristol and East Anglia) ☐
7. I agree that my data gathered in this study may be stored (after it has been anonymised) in a specialist data centre and may be used for future research. ☐

_____	_____	_____
Name of Patient	*Date*	*Signature*
_____	_____	_____
Name of Person taking Consent	*Date*	*Signature*

Appendix 7 – PROOF-THR Invitation to join study letter

STUDY TITLE: 'A PILOT RANDOMISED CONTROLLED TRIAL OF OCCUPATIONAL THERAPY TO OPTIMISE RECOVERY OF PATIENTS UNDERGOING PRIMARY TOTAL HIP REPLACEMENT FOR OSTEOARTHRITIS'.
STUDY NUMBER: UKCRN 11294

Dear Sir/Madam

Information about a research project

You have received this letter because your consultant has put you on the waiting list to receive a total hip replacement and is involved in a research project.

Before you decide if you would like to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the information in the enclosed leaflet carefully and discuss it with friends, relatives and your GP if you wish. Do ask us or the researcher (details below) if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

A researcher will contact you to discuss the study. If you choose to take part, the researcher will contact you again at your pre-assessment clinic appointment and you can formally consent to take part then. A copy of the consent form is also enclosed to ensure you have plenty of time to consider everything before deciding to take part.

As with any research conducted within the NHS you can choose to take part or not and it will not influence any other aspects of your care. You can drop out at any time and all information collected is treated confidentially.

Yours sincerely

Professor Catherine Sackley PhD, MSc, MCSP, FCOT

Contact details:

Primary Care Clinical Sciences
University of Birmingham
Birmingham B15 2TT

Appendix 8 – PROOF-THR patient demographic form

UNIVERSITY OF BIRMINGHAM

PROOF THR

Family Name			
First Name			
Male or Female		Date of Birth	DD/MM/YYYY
Address			
House name/number			
Street name			
Line 1			
Line 2			
Line 3			
Postcode			
Telephone numbers			
Home		Mobile	
GP details			
Name			
Address			
Practice name			
Line 1			
Line 2			
Line 3			
Postcode			
Telephone number			
Hospital site			
Lives alone (yes or no)			

Appendix 9 – PROOF THR Lone worker policy

Emergency phrase: "…….extension 13"

Lone Worker Policy

This study policy is written for any person undertaking lone community visits as part of the PROOF-THR study. This policy has been written to supplement SOP 21-01 (version 3) **'Community Visits'** and SOP 02-05 (version2) **'Risk Assessment'** and should be used in conjunction with this policies.

1. All individuals undertaking lone community visits must provide a mobile telephone number, car registration number and an emergency code word which should be recorded on the **'Community visits log'** QCD 21-02.

2. Any person undertaking the role of 'researcher' or 'Guard' must mutually agree in advance of their visit the designated guard. The guard should make sure they are aware of the duties required of the guard and any subsequent action that may be required. The documentation is available in paper version in a black file labelled ***'PROOF-THR Lone Worker File' in my office*** (room 232) and can also be accessed on-line at T:\Physiotherapy Translational Research Group\PROOF THR\Lone Worker Documentation

3. Before each visit:

3.1 Any researcher undertaking a community visit must complete the named **'Community visits log'** on-line in advance of their visit. The ***patient study ID must be included***. This should

be completed as soon as the visit details have been finalised. The form can be completed electronically and is located at: T:\Physiotherapy Translational Research Group\PROOF THR\OT intervention

3.2 The time entered on the log should be the time the visit is expected to end, NOT the time expected back in to the office. This arrangement accommodates researchers who may be doing multiple visits in one day or returning home after a visit.

3.3 The researcher should organise in advance who will act as the guard and the guard must agree to taking on this role. It must not be assumed that if someone is asked they will perform this duty.

3.4 The 'Guard' must be made aware by e-mail or telephone of every new event entered in to the community visits log. If times of the visit are communicated they MUST be identical to those entered in the community visit log.

3.5 If multiple visits are being undertaken on one day, each visit must be entered as a separate event on the community visit log.

4. On day of Visit

4.1 The lone worker should contact the 'Guard' in advance to let them know the visit is going ahead and make them aware of any circumstances that may vary from the details entered in to the community visits log.

4.2 The guard must confirm that they are still able to fulfil their responsibilities (or have organised another person to take this role).

4.3 When the researcher arrives at the community visit destination, they should telephone the guard to inform that they have arrived.

4.4 At the end of the visit, the researcher must telephone the guard to let them know that the visit has been completed and the researcher has safely left

4.5 A dedicated mobile phone number will be provided for the researcher to call which will be held by the designated guard for the duration of the visit

4.6 If the researcher has not telephoned within 30 minutes of the expected completion time of community visit; the guard must then telephone the researcher. If they obtain no response, they should telephone again in 10 minutes.

4.7 If there is no response from the second phone call, the guard should inform the CI or most senior member of staff available, and seek guidance on what action should be taken.

4.8 IF the emergency code word/phrase is used in any call, the police should be contacted immediately.

4.9 The researcher must inform the guard of any changes to agreed finish time or any other pre-agreed changes which occur while undertaking the community visits.

5. Variations in agreed policy

5.1 This policy must be adhered to by all staff working on the PROOF-THR study

5.2 In areas of poor mobile phone signal the researcher should agree in advance with their guard alternative arrangements. If the patient has a phone, the standard variation of procedure should be that the guard telephones the patient and asks to speak to the researcher at a specific agreed time.

6. Dedicated Mobile Phone

6.1 The mobile phone must remain in the presence of the guard until the communication with the community researcher has been made to establish the visit has concluded safely.

6.2 More than one person can be the guard for a community visit. However, a clear handover of duties and expected call time must be done when the mobile phone is transferred to the new guard. It is preferential that one person is the guard.

6.3 The person holding the mobile phone should indicate this on the white board in the main office (room 248).

7. Personal responsibility

7.1 Everyone is expected to take personal responsibility for their adherence to this policy in accordance with their role as 'community worker' or 'guard'.

7.2 Any variation in practice to this policy MUST adhere to the basic principles of the Guard/researcher duties and MUST be acceptable to both the guard and the community researcher.

7.3 Usually, a community visit should not be carried out if this policy cannot be adhered to.

Appendix 10 – PROOF-THR Questionnaire

A pilot randomised controlled trial of occupational therapy to optimise recovery following total hip replacement for osteoarthritis

Participant Questionnaire Booklet

Participant ID Number:				

	Baseline	4-weeks	12-weeks	26-weeks
Assessment				

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NHS National Institute for Health Research

University of BRISTOL

PART 1A

The following questions concern the amount of pain you have recently experienced in each of your hips. For each question, please tick the amount of **pain** you have experienced during the **PAST 4 WEEKS**. Please (✓) tick **one** column for **each** hip.

A1. How much pain do you have **walking on a flat surface**?

	None	Mild	Moderate	Severe	Extreme
a. Replaced Hip					
b. Other hip					

A2. How much pain do you have **going up or down stairs**?

	None	Mild	Moderate	Severe	Extreme
a. Replaced Hip					
b. Other hip					

A3. How much pain do you have **at night while in bed**?

	None	Mild	Moderate	Severe	Extreme
a. Replaced Hip					
b. Other hip					

A4. How much pain do you have **sitting or lying**?

	None	Mild	Moderate	Severe	Extreme
a. Replaced Hip					
b. Other hip					

A5. How much pain do you have **standing upright**?

	None	Mild	Moderate	Severe	Extreme
a. Replaced Hip					
b. Other hip					

PART 1B

The following questions concern the amount of hip **stiffness** (not pain) you have experienced during the **PAST 4 WEEKS in your replaced hip.** Stiffness is a sensation of restriction or slowness in the ease with which you move your joints. Please tick (✓) one box only.

How much stiffness do you have after…

	9 N one	Mild	Moderate	Severe	Extreme
C18. ..first waking in the morning?					
C19. ..sitting, lying or resting later in the day?					

Section C

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 tick the degree of **difficulty** you have experienced during the **PAST 4 WEEKS due to your replaced hip.** Please tick (✓) one box only.

What degree of difficulty do you have with...

	None	Mild	Moderate	Severe	Extreme
C1. ...descending stairs?					
C2. ...ascending stairs?					
C3. ...rising from sitting?					
C4. ...standing?					
C5. ...bending to floor?					
C6. ...walking on flat?					
C7. ...getting in/out of car?					
C8. ...going shopping?					
C9. ...putting on socks/stockings?					
C10. ...rising from bed?					

	None	Mild	Moderate	Severe	Extreme
C11. ...taking off socks/stockings?					
C12. ...lying in bed?					
C13. ...getting in/out of bath/shower?					
C14. ...sitting?					
C15. ...getting on/off toilet?					
C16. ...heavy household chores?					
C17. ...light household chores?					

PART 2

The following questions ask about any problems you may have been **experiencing with your replaced hip** over the **PAST 4 WEEKS**. Please tick (✓) one box for every question.

During the past **4 weeks**…….

How would you describe the pain you usually had from your hip?

None	Very mild	Mild	Moderate	Severe

Have you had any trouble with washing and drying yourself (all over) because of your hip?

No trouble at all	Very little trouble	Moderate trouble	Extreme difficulty	Impossible to do

Have you had any trouble getting in and out of a car or using public transport because of your hip?

No trouble at all	Very little trouble	Moderate trouble	Extreme difficulty	Impossible to do

Have you been able to put on a pair of socks, stockings or tights?

Yes, easily	With little difficulty	With moderate difficulty	With extreme difficulty	No, impossible

Could you do the household shopping on your own?

Yes, easily	With little difficulty	With moderate difficulty	With extreme difficulty	No, impossible

For how long have you been able to walk before pain from your hip becomes severe? (with or without a stick)

No pain/ More than 30 minutes	16 to 30 minutes	5 to 15 minutes	Around the house only	Not at all – pain severe on walking

Have you been able to climb a flight of stairs?

Yes, easily	With little difficulty	With moderate difficulty	With extreme difficulty	No, impossible

After a meal (sat at a table), how painful has it been for you to stand up from a chair because of your hip?

Not at all painful	Slightly painful	Moderately painful	Very painful	Unbearable

Have you been limping when walking, because of your hip?

Rarely/ never	Sometimes, or just at first	Often, not just at first	Most of the time	All of the time

Have you had any sudden, severe pain – 'shooting', 'stabbing' or 'spasms' – from the affected hip?

No days	Only 1 or 2 days	Some days	Most days	Every day

How much has pain from your hip interfered with your usual work (including housework)?

Not at all	A little bit	Moderately	Greatly	Totally

Have you been troubled by pain from your hip in bed at night?

No nights	Only 1 or 2 nights	Some nights	Most nights	Every night

PART 3

The following questions ask you about the amount of **pain and stiffness** you have experienced due to your hip joint problem. Please enter the amount of pain or stiffness experienced in the **LAST 4 WEEKS**. Please tick (✓) one box for every question and **think about the hip joint that you have had replaced.**

1. How would you describe the pain you usually have from your joint?

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

2. How often have you had severe pain from your arthritis?

Never	Occasionally	Quite often	Most of the time	All of the time
☐	☐	☐	☐	☐

3. Does remaining standing for 30 minutes increase your pain?

Never	Occasionally	Quite often	Most of the time	All of the time
☐	☐	☐	☐	☐

4. How active has your arthritis been?

Not at all	Mildly	Moderately	Severely	Extremely
☐	☐	☐	☐	☐

5. Have you been troubled by pain from your joint in bed at night?

No nights	Occasional nights	Quite often	Most nights	Every night
☐	☐	☐	☐	☐

6. How long has your morning stiffness usually lasted from the time you wake up?

No morning stiffness	Less than 30 minutes	30 minutes to 1 hour	1 to 2 hours	Over 2 hours
☐	☐	☐	☐	☐

7. Have you had any sudden, severe pain - ‘shooting’, ‘stabbing’ or ‘spasms’ - from the affected joint?

Never	Occasionally	Quite often	Most of the time	All of the time
☐	☐	☐	☐	☐

8. Have you felt that your knee or hip might suddenly “give way” or let you down?

Never	Occasionally	Quite often	Most of the time	All of the time
☐	☐	☐	☐	☐

9. How severe is your stiffness after first wakening in the morning?

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

The following questions ask about 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 4 WEEKS**. Please tick (✓) one box for every question and **think about the hip joint that you have had replaced**.

1. Do you need someone to help you when you are walking?

Never	Occasionally	Quite often	Most of the time	All of the time
☐	☐	☐	☐	☐

2. Do you need someone to help you go upstairs?

Never	Occasionally	Quite often	Most of the time	All of the time
☐	☐	☐	☐	☐

3. What degree of difficulty do you have rising from sitting?

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

4. What degree of difficulty do you have bending to the floor?

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

5. What degree of difficulty do you have walking on the flat?

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

6. What degree of difficulty do you have rising from bed?

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

7. What degree of difficulty do you have taking off socks/stockings?

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

8. What degree of difficulty do you have lying in bed?

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

9. What degree of difficulty do you have sitting?

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

10. What degree of difficulty do you have getting on/off toilet?

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

11. What degree of difficulty do you have climbing up and down <u>one</u> flight of stairs?

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

12. What degree of difficulty do you have climbing up and down <u>several</u> flights of stairs?

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

13. What degree of difficulty do you have dressing yourself (except shoes and socks)?

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

14. What degree of difficulty do you have putting on/off shoes?

None	Mild	Moderate	Severe	Extreme

☐ ☐ ☐ ☐ ☐

15. What degree of difficulty do you have washing and drying yourself?

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

16. What degree of difficulty do you have washing your hair?

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

17. What degree of difficulty do you have lifting?

None	Mild	Moderate	Severe	Extreme
☐	☐	☐	☐	☐

The following questions ask about your **social and work life**. For each of the following situations, please indicate how restricted you have been because of your hip in the **LAST 4 WEEKS**. Please tick (✓) one box for every question and **think about the hip joint that you have had replaced.**

1. How does your joint problem restrict you getting on with people (friends and family)?

Not at all	A little	Moderately	Severely	Extremely
☐	☐	☐	☐	☐

2. How does your joint problem restrict you having friends or relatives over to your home?

Not at all	A little	Moderately	Severely	Extremely
☐	☐	☐	☐	☐

3. How does your joint problem restrict you visiting friends or relatives?

Not at all	A little	Moderately	Severely	Extremely

☐ ☐ ☐ ☐ ☐

4. How does your joint problem restrict you telephoning friends or relatives?

Not at all	A little	Moderately	Severely	Extremely
☐	☐	☐	☐	☐

5. How does your joint problem restrict you showing affection?

Not at all	A little	Moderately	Severely	Extremely
☐	☐	☐	☐	☐

6. How does your joint problem restrict you doing your usual social activities?

Not at all	A little	Moderately	Severely	Extremely
☐	☐	☐	☐	☐

7. How does your joint problem restrict your opportunities for leisure activities?

Not at all	A little	Moderately	Severely	Extremely
☐	☐	☐	☐	☐

8. How does your joint problem restrict you affording things you need?

Not at all	A little	Moderately	Severely	Extremely
☐	☐	☐	☐	☐

9. How much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

PART D

The following questions are deigned to assess how well you are now able to perform your usual daily activities. Please think about how you are able to perform these activities **NOW**. Please tick (✓) one box for every question.

10 Do you….	Not at all	With help	On your own with difficulty	On your own easily
Walk around outside?	☐	☐	☐	☐
Climb stairs?	☐	☐	☐	☐
Get in and out of a car?	☐	☐	☐	☐
Walk over uneven ground?	☐	☐	☐	☐
Cross roads?	☐	☐	☐	☐
Travel on public transport?	☐	☐	☐	☐
Manage to make yourself a hot drink?	☐	☐	☐	☐
Take hot drinks from one room to another?	☐	☐	☐	☐
Make yourself a hot snack?	☐	☐	☐	☐

Do You...	Not at all	With Help	On your own with difficulty	On your own easily
Manage your money when you're out	☐	☐	☐	☐
Wash small items of clothing?	☐	☐	☐	☐
Do your own housework?	☐	☐	☐	☐
Do your own shopping?	☐	☐	☐	☐
Do a full clothes wash?	☐	☐	☐	☐
Read newspapers or books?	☐	☐	☐	☐
Use the telephone?	☐	☐	☐	☐
Write letters?	☐	☐	☐	☐
Go out socially?	☐	☐	☐	☐
Manage your own garden?	☐	☐	☐	☐
Drive a car?	☐	☐	☐	☐

SECTION E

The following set of questions ask about your emotions and mood. Please answer them honestly and in a way that describes how you have been feeling over the PAST WEEK.

[A] Do you feel tense or 'wound up'?

- Most of the time ☐
- A lot of the time ☐
- From time to time ☐
- Not at all ☐

[D] Do you still enjoy the things you used to enjoy?

- Definitely as much ☐
- Not quite so much ☐
- Only a little ☐
- Hardly at all ☐

[A] Do you get a sort of frightened feeling as if something awful is about to happen?

- Very definitely and quite badly ☐
- Yes, but not too badly ☐
- A little, but it doesn't worry me ☐
- Not at all ☐

[D] Do you laugh and see the funny side of things?

- As much as I always could ☐
- Not quite so much now ☐
- Definitely not so much now ☐
- Not at all ☐

[A] Do worrying thoughts go through your mind?

- A great deal of the time ☐
- A lot of the time ☐
- From time to time but not too often ☐
- Only occasionally ☐

[D] Do you feel cheerful?

- Not at all ☐
- Not often ☐
- Sometimes ☐
- Most of the time ☐

[A] Can you sit at ease and feel relaxed?

- Definitely ☐
- Usually ☐
- Not often ☐
- Not at all ☐

[D] Do you feel as if you are slowed down?

- Nearly all the time ☐
- Very often ☐
- Sometimes ☐
- Not at all ☐

[A] Do you get a sort of frightened feeling like ‘butterflies’ in the stomach?

- Not at all ☐
- Occasionally ☐
- Quite often ☐
- Very often ☐

[D] Have you lost interest in your appearance?

- Definitely ☐
- You don’t take so much care as you should ☐
- You may not take quite as much care ☐
- I take just as much care as ever ☐

[A] Do you feel restless as if you have to be on the move?

- Very much indeed ☐
- Quite a lot ☐
- Not very much ☐
- Not at all ☐

[D] Do you look forward with enjoyment to things?

- As much as you ever did ☐
- Rather less than you used to ☐
- Definitely less than you used to ☐
- Hardly at all ☐

[A] Do you get sudden feelings of panic?

- Very often indeed ☐
- Quite often ☐
- Not very often ☐
- Not at all ☐

[D] Do you enjoy a good book or radio/ TV programme?

- Often ☐
- Sometimes ☐
- Not often ☐
- Very seldom ☐

PART F

The following questions ask about your health state TODAY. Please tick one box for each question below to indicate which statements best describes your own health state today.

Mobility

I have no problems in walking about ☐

I have some problems in walking about ☐

I am confined to bed ☐

Self-Care

I have no problems with self-care ☐

I have some problems washing or dressing myself ☐

I am unable to wash or dress myself ☐

Usual Activities (*e.g. work, study, housework, family or leisure activities)*

I have no problems with performing my usual activities ☐

I have some problems with performing my usual activities ☐

I am unable to perform my usual activities ☐

Pain/Discomfort

I have no pain or discomfort ☐

I have moderate pain or discomfort ☐

I have extreme pain or discomfort ☐

Anxiety/Depression

I am not anxious or depressed ☐

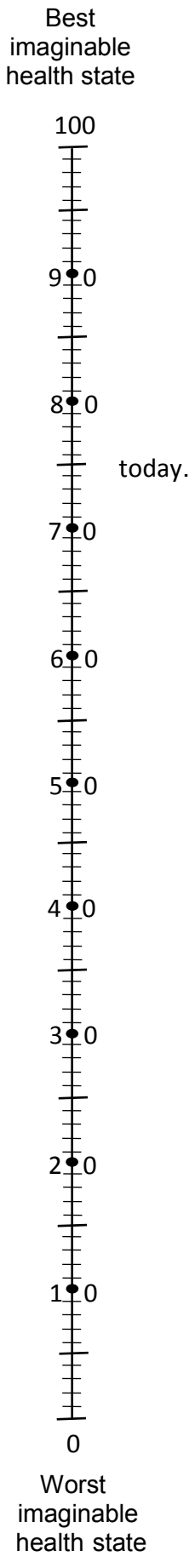
I am moderately anxious or depressed ☐

I am extremely anxious or depressed ☐

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

Your own health state



PART F

The following questions ask about your about QUALITY OF LIFE. By placing a tick (✓) in ONE box in EACH group below, please indicate which statement best describes your quality of life at the moment.

1. Love and Friendship

I can have all of the love and friendship that I want	
I can have a lot of the love and friendship that I want	
I can have a little of the love and friendship that I want	
I cannot have any of the love and friendship that I want	

2. Thinking about the future

I can think about the future without any concern	
I can think about the future with only a little concern	
I can only think about the future with some concern	
I can only think about the future with a lot of concern	

3. Doing things that make you feel valued

I am able to do all of the things that make me feel valued	
I am able to do many of the things that make me feel valued	
I am able to do a few of the things that make me feel valued	
I am unable to do any of the things that make me feel valued	

4. Enjoyment and pleasure

I can have all of the enjoyment and pleasure that I want	
I can have a lot of the enjoyment and pleasure that I want	
I can have a little of the enjoyment and pleasure that I want	
I cannot have any of the enjoyment and pleasure that I want	

5. Independence

I am able to be completely independent	
I am able to be independent in many things	
I am able to be independent in a few things	
I am unable to be at all independent	

THANK YOU FOR COMPLETING THE QUESTIONNAIRE BOOKLET

Please could you check you have completed all the questions and return the booklet.

Appendix 11 Client services receipt inventory

Firstly, please tell us about the health care you have received for your new Total Hip Replacement

1) In the last 6 months, since you were discharged home from you Total Hip Replacement, have you been to hospital because of your Total Hip Replacement?
Note: Do not include physiotherapy or occupational therapy appointments

Please tick 'yes' or 'no' for each line. If you answer 'yes' to any of them, please tell us how many times you used the service.

	No	Yes	
Been to accident and emergency (casualty)	☐	☐	Total number of visits:……. ..
Stayed in hospital overnight	☐	☐	Total number of nights:……
Had a hospital outpatient appointment	☐	☐	Total number of appointments:…..…...

2) **In the last 6 months, have you used any of the services below because of your Total Hip Replacement?**

Please tick 'yes' or 'no' for each line. If you answer 'yes' to any of them, please tell us how many times you used the service, how long your contact with that person lasted (on average if more than once) and when applicable tick if the service was private.

	No	Yes		Number of times	On average, how many minutes did you see/talk to them for?
GP and practice nurse					
Saw GP at the surgery	☐	☐		.....	.....
Saw GP at home	☐	☐		.....	.....
Phoned GP for advice	☐	☐		.....	.....
Saw practice nurse	☐	☐		.....	.....
Phoned practice nurse for advice	☐	☐		.....	.....
Got a repeat prescription (without seeing doctor)	☐	☐		.....	
Social services					
Got meals on wheels	☐	☐		.....	
Home help came around	☐	☐		.....	.....
Saw social worker	☐	☐		.....	.....
Physiotherapist			Private		
Saw at the hospital	☐	☐	☐	.....	.....
Saw at home	☐	☐	☐	.....	.....
Saw at the GP surgery or a clinic	☐	☐	☐	.....	.....

Occupational therapist

Saw at the hospital	☐	☐	☐	.....	.....
Saw at home	☐	☐	☐	.....	.....
Saw at the surgery or a clinic	☐	☐	☐	.....	.....

Other services

Others *(e.g. alternative therapies, voluntary services, orthotics)*	☐	☐	☐	.....	.....

We would now like to know about what your Total Hip Replacement has cost you and others

3) **In the last 6 months, what medicines have you used for your arthritis and how did you pay for them altogether? (Include homeopathic/herbal medicines)**

List all medicines you are taking here because of you hip
(Copy name from the bottle/packet)

Please tick all that apply and fill in any relevant gaps

- ☐ I did not have any medicines
- ☐ I got ……. free prescriptions in the last 6 months
- ☐ I used someone else's medicine
- ☐ I used a pre-payment certificate which cost me £.… for …... months
- ☐ I paid £..... for prescriptions in the last 6 months
- ☐ I paid £.....…..... for non-prescription medicines in the last 6 months

4) **In the last 6 months, have you, your relatives/friends, the NHS or social services paid for any of the following because of your Total Hip Replacement?**

Please tick 'yes' or 'no' for each line and tell us how much it cost

	No	Yes	How much has this cost altogether in the last 6 months?	Who paid for this?
Employing extra help *(e.g. childcare or cleaning)*	☐	☐	.....	.....
Transport to get healthcare *(e.g. to go to your GP surgery or hospital)*	☐	☐	.....	.....

Changes to your home *(e.g. moving bathroom downstairs, stairlift)*	☐ ☐	.....	.....
Special equipment	☐ ☐	.....	.....
Any other costs due to your Total Hip Replacement.....	☐ ☐	.....	.....

.....
.....
.....

5) **<u>In the last 6 months</u>, have you taken any time off work <u>because of your Total Hip Replacement</u>?**
Note: Include any time taken off because you were suffering due to you new THR or using any health services such as those listed in questions 1 & 2.

Yes ☐ ***If yes:*** Please give details below
No ☐
I have not been employed in the last 6 months ☐

Please tell us <u>either</u> the number of days <u>or</u> the number of hours you took off in the last 6 months

	No	Yes	Number of whole working days	Number of hours
Took sick leave from work	☐	☐	.....	.....
Used your paid holiday time from work	☐	☐	.....	.....
Took unpaid leave from work	☐	☐	.....	.....
Just made up the time at work	☐	☐	.....	.....
Other arrangement *(please describe below)*	☐	☐	.....	.....

Have you lost any pay because of this time off work?
Yes ☐ ***If yes:*** How much <u>gross</u> income you have lost in the last 6 months? £.....
No ☐

6) **<u>In the last 6 months</u>, have friends and relatives helped you with tasks at home which you couldn't do <u>because of your new Total Hip Replacement</u>?**

Yes ☐ ***If yes:*** Please tick below the tasks they helped you with and for how many hours per week.
No ☐

Did anyone help you with this task?	No	Yes	Typically, how many hours per week?
Personal care *(e.g. bathing, dressing)*	☐	☐	.....
Care of dependants (e.g. partner or child)	☐	☐	.....
Housework / laundry	☐	☐	.....
Providing transport/taking you out	☐	☐	.....
Preparing meals	☐	☐	.....
Gardening	☐	☐	.....
Shopping	☐	☐	.....

Looking after pets	☐	☐	.....
Generally providing support	☐	☐	.....
Other *(Please describe below)*	☐	☐	.....

7) **<u>In the last 6 months</u>, have friends and relatives stayed off work to help you because of your Total Hip Replacement?**

Yes ☐ ***If yes:*** How many days did they take off work in the last 6 months? ……
No ☐

Now please tell us something about yourself

8) **Which of the following best describes your <u>current</u> situation?**

Please read the whole list first and then write '1' in the box that applies. If other categories apply, write '2', '3' etc. to indicate the order that best describes your situation.

Working full time (30 hours or more per week) ☐
Working part time (less than 30 hours per week) ☐
Unemployed and looking for work ☐
Volunteer ☐
At home and not looking for work ☐
(e.g. looking after home and/or family)
Unable to work ☐ What is the reason for this?

Your THR ☐ *Other illness* ☐ *Other reason* ☐

Made redundant/took early retirement ☐ What is the reason for this?.....
Due to your Hip ☐ *Other illness* ☐ *Other reason* ☐
Retired ☐
Other ☐ *Please describe* .....

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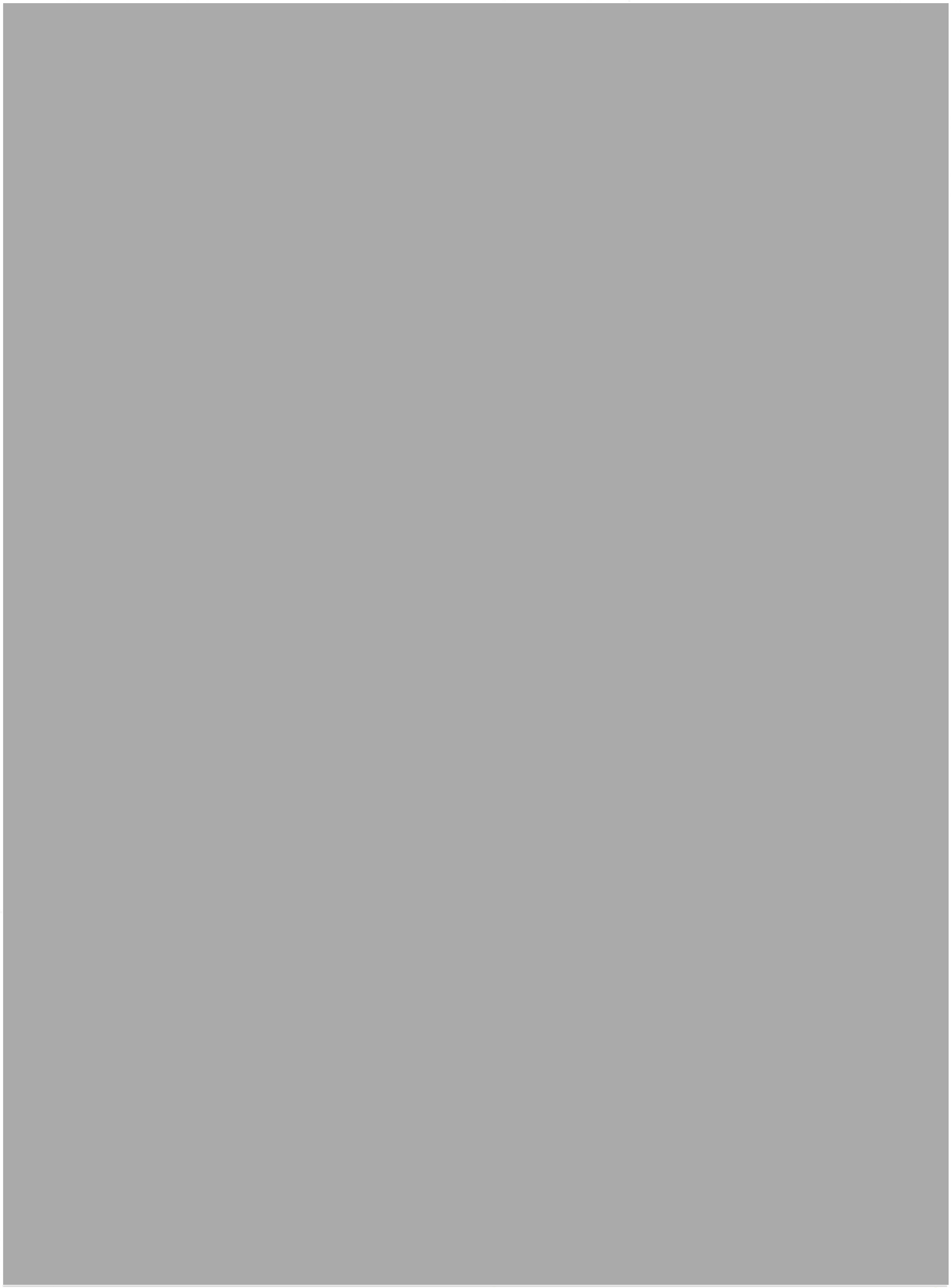
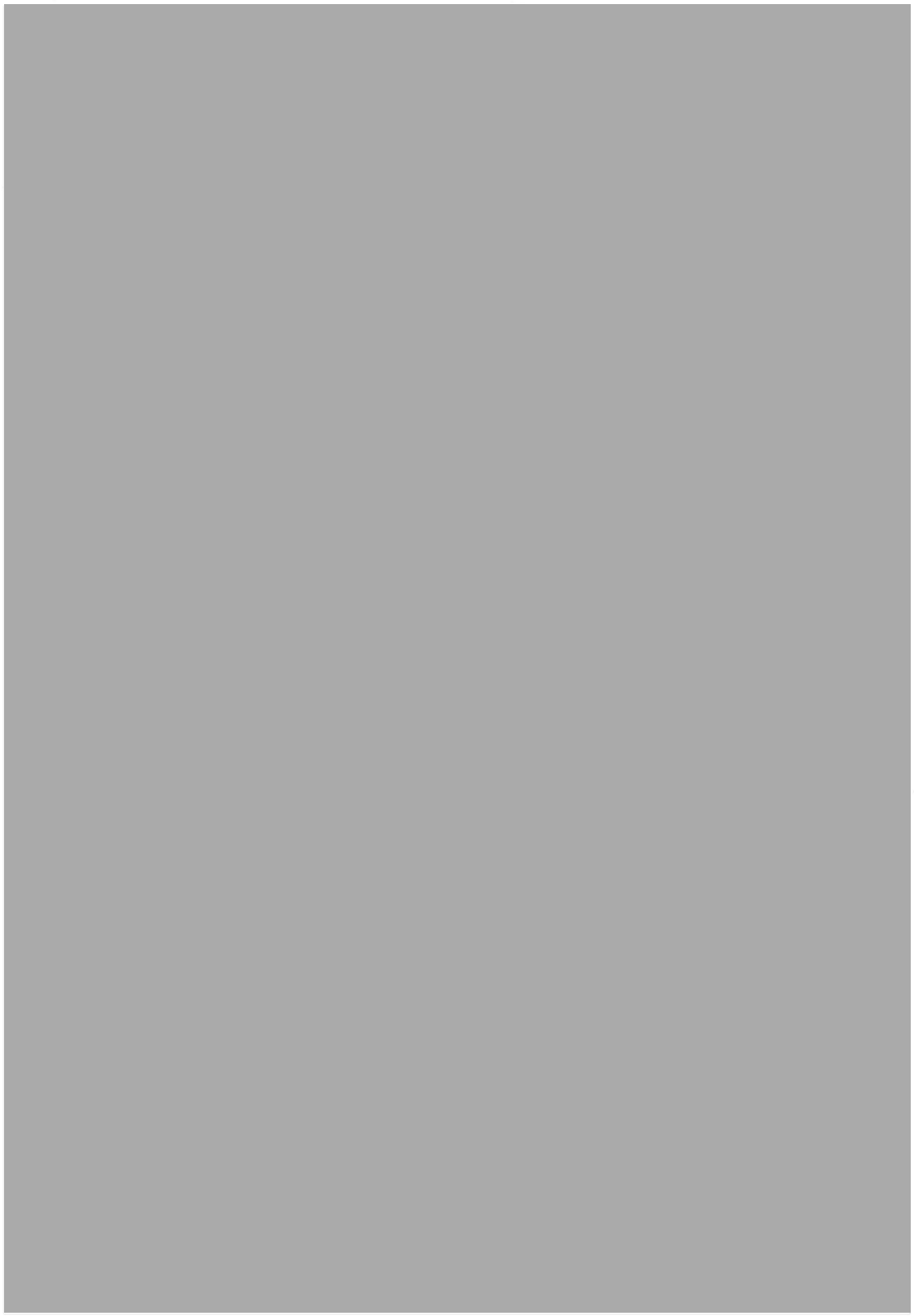
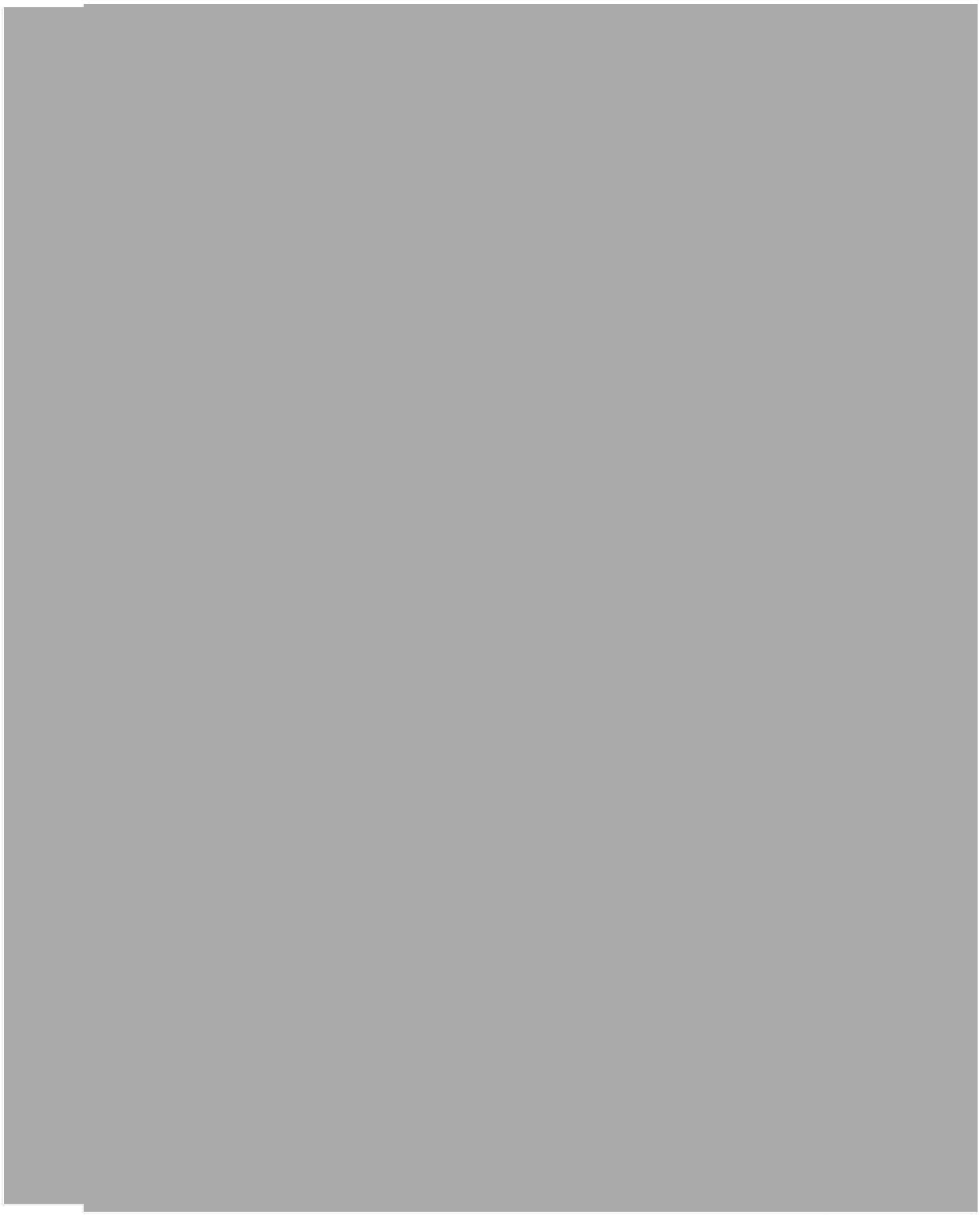
Thank you for completing this questionnaire

Please return it in the stamped addressed envelope provided

Appendix 12 Ethics favourable opinion







Appendix 13 Ethics substantial amendment favourable opinion