An Investigation on Physical Activity Engagement in People Before and After Total Hip Replacement

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Presentations and Publications Arising from the Thesis

Publications

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Presentations

7th July 2016, European College of Sport Science, Oral Presentation: What is the effect on independent recovery of using pedometers as a tool to prescribe exercise following total hip replacement?

16th April 2016, Physiotherapy Research Society Annual Conference, Oral Presentation: Is there a difference in total physical activity levels before and after elective unilateral total hip replacement? A systematic review and meta-analysis.

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Abstract

Background: Total hip replacement (THR), is one of the most common elective surgical operations performed in the United Kingdom. There is however little evidence examining physical activity in this population or interventions to increase it.

Study 1: A systematic review examined physical activity change in the THR population pre- compared to up to one year post-THR. Studies were eligible for inclusion if they presented a pre-operative and post-operative measure of physical activity. A total of 17 studies were included. The quality of the included studies was rated as low to moderate. There was no significant difference in pre- versus post-operative physical activity ($p>0.05$). The lack of significant physical activity difference should be considered in the light of the poor to moderate methodological quality.

Study 2: No previous studies have assessed change in physical activity pre- compared to more than one year post-THR. A secondary data set analysis was undertaken to assess this, and examine if having a THR significantly predicted physical activity. This showed a significant decrease in physical activity pre- compared to post-THR ($p<0.05$) nor was having a THR a significant predictor of physical activity ($p>0.05$).

Study 3: A feasibility randomised control trial was undertaken to examine the feasibility of a pedometer-prescribed walking intervention post-THR. The primary outcome measure was the Oxford Hip Score. Secondary measures were physical activity and quality of life. There was no significant between group differences for any measure ($p>0.05$). The intervention was poorly adhered to. There is a need to better understand the barriers to physical activity intervention adherence in this population.

Conclusions: These studies have contributed new knowledge to the field. The lack of improvement in physical activity pre- compared to post-THR and the results of the feasibility RCT highlighted the need to better understand barriers to physical activity in this population.

Table of Contents

Figures and Tables Legends

Figures Legends

Table Legends

Abbreviations

12 mwt: 12-minute walk test

6 mwt: Six-minute walk test

ANCOVA: Analysis of co-variance

ANOVA: Analysis of variance

CI: Confidence Interval

CPEX: Cardiopulmonary exercise test

IQR: Inter-quartile range

m: Metres

MD: Mean difference

$ml.min^{-1}.kg^{-1}$: millilitre per minute per kilo

NJR: National Joint Registry

NNUH: Norfolk and Norwich University Hospital

OHS: Oxford hip score

PASE: Physical activity score for the elderly

RCT: Randomised control trial

SF-12: 12-Item short form health survey

SF-36: 36-Item short form health survey

SD: Standard deviation

SMD: Standardised mean difference

THR: Total hip replacement

TKR: Total knee replacement

VAS: Visual analogue scale

Chapter 1 Introduction

1.1 Background

Total hip replacement (THR) is one of the most commonly performed orthopaedic operations in the United Kingdom (UK)(NJR, 2015). A total of 83,125 THR were performed in England, Wales and Northern Ireland in 2014 (NJR, 2015). The indications for THR include: osteoarthritis, rheumatoid arthritis, genetically inherited conditions, cancer and hip fractures (NJR, 2015). The most common indication for surgery is osteoarthritis (93%). Total hip replacement is the complete removal of the femoral head and neck, along with the acetabulum and any other bone the surgeon views as appropriate to remove. This is followed by fixation of at least an artificial femoral head and acetabulum into the remaining femur and pelvis. The majority of patients presenting for THR have mild disease that is not incapacitating according to the American Society of Anesthesiologists (ASA) classification system (NJR, 2015). The median age at primary operation 69 (IQR 61 – 76) (NJR, 2015), with the average patient is classed as overweight based on the BMI classification (BMI, 28.68 $kg.m^{-2}$)(NJR, 2014).

There are currently a number of published systematic reviews in the area of THR and physical activity and/or exercise. The most recent, undertaken by the author and presented in greater detail in Chapter 3, (Withers, Lister, Sackley, Clark, & Smith, 2016) showed that there was no change in physical activity undertaken when comparing pre-THR to up to one year following the operation. These findings were echoed by the findings of Arnold, Walters, and Ferrar (2016) who also showed in a systematic review of 135 THR patients, no significant change at six months post-operatively (Standardised mean difference (SMD: -0.2 to 1.8) and physical activity levels that were considerably lower than controls at one year post-operatively (SMDs -0.25 to -0.77). This is in line with the findings from Minns-Lowe, Davies, Sackley and Barker's (2015) systematic review of 11 trials

(n=576 participants), which examined exercise prescription following post-THR that was led by a physiotherapist. They concluded that there was insufficient evidence to establish the effectiveness of physiotherapy exercise following primary THR. The review was limited to patients who underwent THR due to osteoarthritis. However, osteoarthritis is by far the most common reason to require a THR being the principle indication for 93% of THR performed in 2013 (NJR, 2015). An earlier systematic review of 18 studies, concluded that increasing physical activity before THR reduces hip pain post-operatively (SMD = 0.45, 95% confidence interval 0.15-0.75) (Gill & McBurney, 2013). A large number of studies included in the review analysed THR and total knee replacements collectively (Arnold et al., 2016; Barbay, 2009; Gill & McBurney, 2013). This therefore potentially confused the conclusions in relationship to the benefits of physical activity in THR specifically. The final systematic review in this area, consisting of 11 studies, (Di Monaco & Castiglioni, 2013) concluded that in the early post-operative period, favourable outcomes were seen for those who received cycle ergometery and maximal strength training, though inconclusive results were reported for aquatic exercises. However, there is insufficient evidence to build an 'ideal' exercise programme following THR.

In general, previous research has investigated the effect and impact of a physical activity intervention on patient-reported outcome measures or quality of life measures, as discussed above. However currently no studies examine a novel post-operative home-based intervention to increase physical activity. This is a worthwhile undertaking to ensure that the post-operative recovery of THR is determined. This would therefore have positive implications not only on the individual patient's recovery and health, but also would have wider social and economic implications given that improved physical activity could reduce hospital readmission and primary care health burden (Chawla, Bulathsinghala, Tejada, Wakefield, & ZuWallack, 2014; Stewart, Marley, & Horowitz, 1999) .

1.2 Study Objectives

The objective of the studies that are contained within this thesis were two-fold; firstly to determine what happens to physical activity profiles before and after a THR. This was performed through a systematic review and data analyses which subsequently informed a feasibility randomised control trial (RCT) where a novel pedometer-prescribed walking intervention was administered to assess a new potential method of increasing physical activity, the second objective, following THR. These will be summarised below.

For this thesis, physical activity is defined using the definition of the Chief Medical Officers. That being that physical activity is a generic term for any activity that involves movement which results in an increase in heart rate and calorific expenditure (Department of Health, 2011). Physical activity can be divided into three sub-categories;

1. Everyday activity, for example active travel and occupational activity.
2. Active recreation, for example recreational walking, active play and dance.
3. Sport, this includes any sport competitive or non-competitive (Department of Health, 2011).

1.2.1 *Systematic Review: Physical activity pre- and post-total hip replacement*

The objective of this systematic review was to assess whether physical activity changes pre- compared to up to one year post-THR. Published and unpublished databases (AMED, CINHAL, EMBASE, MEDLINE, Central (Cochrane), OPENSIGLE, ClinicalTrials.gov and UK Clinical Trials Gateway) were searched systematically and data was extracted from papers that fulfilled the eligibility criteria. The eligibility criteria for the study were that studies measured physical activity both pre- and post-THR. Where appropriate, the data were synthesised in a meta-analysis. The Critical Appraisal Skills Programme (CASP) case-control and cohort study checklists were used to assess the quality of evidence. The search was undertaken on 13th July 2016. In total, 6024 citations

were identified; 17 studies met the eligibility criteria. Nine studies were included in a meta-analysis. The quality of the evidence was graded low to moderate. There was no statistically significant difference in physical activity pre- to post-THR when assessed using: movement-related activity (mean difference (MD): -0.08; 95% confidence interval (CI):- 1.60 to 1.44; I^2=0%; n=77), percentage of 24 hours spent walking (MD: -0.21; 95% CI: -1.36 to 0.93; I^2=12%; n=65), six minute walk test (MD: -60.85; 95% CI: -122.41 to 0.72; I^2=84%; n=113) and the cardiopulmonary exercise test (MD: -0.24; 95% CI: -1.36 to 0.87; I^2=0%; n=76). This systematic review concluded that there was no difference between physical activity pre- compared to and up to one year post-THR. However, the low methodological quality of the included papers may have introduced bias. Further research is recommended, to better understand the changes in physical activity between pre- and post-THR.

1.2.2 Secondary Dataset Analysis

Following the findings of the systematic review, which demonstrated no significant change in physical activity up to one year following THR, an analysis of a prospectively-collected, community-based dataset, the European Prospective Investigation into Cancer and Nutrition (EPIC) dataset, was undertaken. The EPIC dataset is a cancer cohort dataset based in Norfolk. Two hundred and twenty six participants in the dataset received a THR. These were each matched with two control participants (n=452). The controls were matched to the cases by age (±3 years), sex and date of baseline health check (±3 months). The measures were taken pre-THR (January 1998-January 2001) and after (September 2006 – September 2007). There was a significant difference between case and controls for weight (t_{420}=-4.2, p<0.001, equal variance not assumed p=0.024) and BMI (t_{395}=-4.0, p<0.001, equal variance not assumed p=0.006). For participants following THR, a small but significant decrease in the number of flights of stair per week climbed was seen, walking to work or for pleasure, duration of total recreational activities and diastolic blood pressure. This dataset analysis suggested that over a longer time period than the

systematic review, people post-THR may become significantly less active following surgery, though this may be due to ageing.

1.2.3 Feasibility Randomised Controlled Trial: The use of pedometers as an intervention to influence physical activity following THR.

The objective of this study was to examine the feasibility of undertaking a pedometer-based exercise programme in the THR population with the aim of increasing physical activity levels. The study was a two-arm randomised control trial; the control arm containing 17 participants. The experimental arm contained 18 participants. The control group received normal rehabilitation and recovery care. The intervention group received normal rehabilitation and recovery care and a pedometer-based exercise programme from discharge to 24 weeks following THR. Patients on the waiting list for elective primary unilateral THR were recruited. The primary outcome measure was the Oxford Hip Score (OHS). Secondary outcome measures were hip dislocation, quality of life measured by self-completed questionnaire and physical activity level determined through accelerometry and a physical activity questionnaire. The measures were taken pre-operatively and at 4, 12 and 24 weeks post-operatively. The study had no adverse events that occurred during the study were attributed to the study processes. Recruitment was a challenge and did not follow the projected recruitment rate. Data collection, particularly in respect to accelerometry data, was a significant problem. Fidelity to the targeted step programme and use of the pedometer was a reported study design limitation. Accordingly, the study concluded that whilst a RCT was feasible to investigate the effectiveness of a pedometer-prescribed walking intervention, further consideration should be made on recruitment strategies, intervention adherence and data collection processes.

1.3 Thesis Outline

This thesis is divided into four sections and eight chapters as follows:

Section One: Introduction

The aim of this section is to broadly discuss the scope and purpose of the thesis and the key principles within it.

Section Two: Current literature and dataset analysis

This section reviews the current literature, which is subsequently split into chapters two, three and four. Chapter two gives background to both THR and physical activity, the third chapter is a systematic review examining the current physical activity levels in the THR population, an updated version of a systematic review that has been previously published (Withers et al., 2016). The fourth chapter is an analysis of the EPIC dataset.

Section Three: Feasibility RCT

This section contains the methods, results and discussion of the feasibility RCT.

Section Four: Clinical and Research Implications and Conclusions

This section discusses the clinical and research implications of the entire thesis.

1.4 Summary

This chapter has offered both a summary and introduction to the work contained within this thesis, the main theme of which is physical activity within the THR population. This was examined by undertaking a systematic review, dataset analysis and a feasibility randomised control trial. The aim of this thesis is to add to the understanding of physical

activity habits within the THR population and examine a novel intervention that may improve them.

Chapter 2 Total Hip Replacement and Physical Activity

2.1 Introduction

The previous chapter introduced the objectives of this thesis. This chapter presents both the demographic, surgical and outcome information for total hip replacement (THR), in addition to the definitions of barriers and facilitators of physical activity.

2.2 Indications and Contraindications for Total Hip Replacement

There are a number of indications and contraindications for THR. The most common indication for THR is osteoarthritis in 93% of cases, and the sole reason in 89% of cases (NJR, 2015). Other common indications are presented in Table 2.1.

Table 2.1: Common indications for THR (NJR, 2015).

Common indication for THR
Osteoarthritis
Inflammatory arthroplasty
Congenital Dislocation
Dysplasia of the Hip
Avascular Necrosis
Trauma
Failed Hemi-athroplasty
Previous hip surgery
Previous arthrodesis
Previous infection

As with all surgery, there are also a number of contraindications. These are listed in Table 2.2.

2.3 Operation

The earliest recorded THR, using ivory, was performed in Germany in 1891 (Knight, Aujla, & Biswas, 2011). The first 'modern style' THR was performed by George McKee in 1953,

though the first THR that is identical, in principal, to the ones used today was designed and developed in the early 1960s by a team lead by Sir John Charnley (Knight et al., 2011). A THR is the complete removal of the femoral head and neck and the acetabulum, with any other bony spurs the surgeon views as appropriate to remove. This is followed by fixation of at least an artificial femoral head and acetabulum into the remaining femur and pelvis. This should not be confused with femoral resection which is the complete or partial removal of the femur and is different to the THR as it additionally involves removal of part or all of the shaft of the femur. THR should also not be confused with a hemi-arthroplasty which is removal of the head of the femur only. Neither hemi-arthroplasty nor femoral resection will be discussed in this thesis.

Table 2.2: Contraindications for THR, modified from Crawford and Murray (1997).

Absolute and relative contraindications for surgery
Significant medical disease where risk of surgery outweighs the expected benefit
Psychiatric disease
Dementia
Systemic infections
Poor vascular supply locally
Poor local soft tissue cover
Local ulcers
Neuropathic disease of the hip

There is, however, much debate in respect to what is the ideal surgical approach for a THR: lateral, posterior or anterolateral (Jameson *et al*., 2014; Jolles & Bogoch, 2006). Theoretically, a lateral approach should be of the greatest benefit to the patient, as the risk of dislocation is lowered due to the incision not being in line with the most common direction of dislocation, posteriorly (NJR, 2015). However, the research shows that this approach does not affect outcome (Jameson et al., 2014; Jolles & Bogoch, 2006). When comparing the posterior to the lateral approach, Jolles and Bogoch's (2006) Cochrane Review showed that there was no significant difference in dislocation rate (Relative Risk (RR): 0.35; 95% CI; 0.04-3.2), presentation of post-operative Trendelenburg gait (RR: 0.5,

95% CI; 0.2-1.3) and risk of nerve paralysis or injury (RR: 0.2, 95% CI; 0.03-0.8). Only the average range of internal rotation was significantly higher when using a posterior approach (weighted mean difference: 16 degrees, 95% CI: 8 to 23). The data presented in this review was generally of poor quality. An analysis of English and Welsh primary THR outcomes by Jameson et al. (2014) showed similar results with no significant difference between approach for all cause revision risk (cemented p=0.73, un-cemented p=0.30) and revision for dislocation (cemented p=0.18, un-cemented p=0.70) using data from 37,593 procedures. An additional analysis of 3881 cases did however show that the posterior approach resulted in greater improvement in function (OHS: 20.8 versus 18.9, p<0.001) (Jameson et al., 2014). These two key papers show that although outcome is not affected by approach, a posterior approach resulted in greater movement following surgery. Additionally, NJR (2015) showed that a posterior approach has the additional benefit of reducing 90 day post-operative mortality risk (p<0.05).

An alternative to the lateral or posterior approach is the anterolateral approach. This has the benefit of theoretically not disturbing any posterior hip tissues (Palan, Beard, Murray, & Nolan, 2009). Palan et al. (2009) reported that using the anterolateral approach resulted in an improved OHS at three months (25.7±8.0 vs 24.4±7.4, p=0.013) and one year (20.7±8.7 vs 19.2±7.7, p=0.011) post-THR, but no significant difference at three (20.3±9.2 vs 20.2±9.0, p=0.89) or five years (19.9±8.9 vs 20.2±9.0, p=0.71). This suggests that from a patient-reported outcome perspective, the anterolateral approach is less beneficial in the short term. However, from a surgical perspective the anterolateral approach has no benefit (p>0.05) over the posterior in respect to dislocation over any femoral head size (Palan et al., 2009).

Another point of debate within the THR literature is the optimal size of the femoral head. Femoral head size is a compromise between increasing size to enhance stability, against increasing resultant volumetric wear that occurs as a consequence with the increase in head size (Cross, Nam, & Mayman, 2012). It is also suggested that below a given

threshold, the exact size of which is not clear, the probability of dislocation is increased (Cross et al., 2012). However a recent multiple register analysis showed that head size does not affect mortality following surgery (Allepuz et al., 2014). However this finding should be taken with caution as the heterogeneity of the data is likely to be considerable as different registers record results in different ways. Conversely, Jameson et al. (2014) showed, using data from 251,719 THR that there was a significant reduction in dislocations when a larger femoral head (≥36mm) was used, though there was no difference in 18 month revision rate. Therefore apart from dislocation rate, the evidence strongly supports the assumption that femoral head size does not affect outcome following surgery.

Revision surgery occurs following a major post-THR complication. The revision rate at one year is 0.8% (0.7 to 0.8), five years is 2.6% (2.6 to 2.7) and 10 years is 5.6 % (5.5 to 5.8) (NJR, 2015). The most serious post-THR complication is death. The 30-day all-cause mortality rate is 0.2% (0.2 to 0.2), one year is 1.5% (1.5 to 1.5), five years is 9.4% (9.3 to 9.5) and 10 years is 24.1% (23.9 to 24.3).

A number of factors have been associated with outcome following THR. Wagner, Kamath, Fruth, Harmsen, and Berry (2016) demonstrated in a 17,774 patient cohort that the risk of implant revision or removal was significantly lower in patients with a BMI of 25-29.99 $kg.m^{-2}$ (Hazard Ratio (HR): 0.9 95% CI: 0.8-0.99, p=0.03) and significantly higher in patients with a BMI of ≥40 $kg.m^{-2}$ (HR: 1.3 95% CI: 1.04-1.7, p=0.02) compared to patients with a 'healthy' BMI of 18-24.99 $kg.m^{-2}$. There is no clear evidence to explain why a slightly elevated BMI significantly lowers this association. Early dislocation risk, by six months, and periprosthetic infection risk both increase from a healthy BMI upwards (NJR, 2015). Early dislocation risk is significantaly greater for patients with a BMI of 35-39.99 $kg.m^{-2}$ (HR: 1.5 95% CI: 1.03-2.2 p=0.04) and ≥40 $kg.m^{-2}$ (HR: 1.6 95% CI: 1.02-2.6 p=0.04), compared to patients with a 'healthy' BMI (Wagner et al., 2016). Infection risk is significantly greater for patients with a BMI between 30-34.99 $kg.m^{-2}$ (HR: 1.6 95% CI: 1.2-

2.2 p=0.001), 35-39.99 kg.m^{-2} (HR: 1.9 95% CI: 1.3-2.8 p=0.001) and ≥40 kg.m^{-2} (HR: 4.1 95% CI: 2.8-5.9 p<0.05) compared to patients with a 'healthy' BMI (Wagner et al., 2016).

Current tobacco use is also associated with poorer outcomes following THR. An analysis of 7926 patients showed that the hazard ratios for deep infection and implant revision is 2.4 (95% CI: 1.2 to 4.7; p=0.01) and 1.8 (95% CI: 1.0 to 3.1; p=0.01; (Singh et al., 2015). Cherian et al. (2015) systematic review, which included 209 studies demonstrated that being male (OR: 1.4; 95% CI; 1.2-1.6, p=0.001) and having a higher activity level (University of California, Los Angles activity score ≥8 points; OR: 4.2, 9% CI; 1.2-1.6, p=0.001) were associated with aseptic loosening. However obesity (OR: 1.0; 95% CI;0.7-1.4, p=1.0 and tobacco use (OR: 2.0, OR; 0.4-9.0, p=0.4) did not significantly increase the risk of asceptic lossening. These results should however be treated with caution, due to the large range in the confident intervals, which suggests considerable inter-participant variability.

2.4 Population Characteristics

From 1st April 2003 to 31st December 2014, 708,311 primary THR were undertaken by 3056 consultants in 463 units in England, Wales and Northern Ireland (NJR, 2015). Of these patients, 40% were male with a median age at operation of 69 years (interquartile range (IQR): 61-76). Un-cemented THR were more common that cemented, 39% and 36% respectively; 17% were hybrid, meaning a cemented acetabular fixation with an uncemented femoral prosthesis fixation.

A total of 2,288,579 primary THRs were performed in the United States of America (USA) between 1990 to 2004. Of these, 955,381 (42%) patients were male. The majority of these patients (58%) were in the 65 to 79 age bracket. Osteoarthritis was the most common indication for THR (Liu, Della Valle, Besculides, Gaber, & Memtsoudis, 2009). The Australian joint registry also offers a similar profile recording a total of 296,550 THRs

performed from 1999 to 2013. Of these, 53.5% (158,542) were female, minimum age 11 years, maximum 102 years, the mean age was 67.0 years (standard deviation: 11.9 years) (*Demographics of Hip Arthroplasty Supplementary Report*, 2014). As the data above shows, the demographics are very similar across these three western joint registries.

Among 835 patients who have undergone THR, Dowsey, Nikpour, & Choong (2014) demonstrated that the pre- and post-operative changes in the Harris Hip Pain score is not affected by socio-economic status (SES) (Low SES: 34.3±10.3 versus High SES: 34.2±10.9, p=0.89), nor is the Harris Hip Score for function (Low SES: 17.2±11.3 versus High SES: 17.1±10.8, p=0.94) (Dowsey, Nikpour, & Choong, 2014). However, Clement, Muzammil, MacDonald, Howie, and Biant (2011) analysis of data from 1312 patients who underwent THR, showed deprivation was associated with an increased risk of dislocation (Odd Ratio (OR): 5.3, p<0.001) and 90 day mortality (OR: 3.2, p=0.02). A systematic review by Tilbury et al. (2013), which included 3872 patients, showed the range of patients returning to work ranged from 25% to 95% at one to 12 months. However, as noted by Kuijer, De Beer, Houdijk, and Frings-Dresen (2009), there is sparse information available in regards to the beneficial and limiting factors affecting return to work.

2.5 Rehabilitation and Recovery Following Total Hip Replacement

In this section the evidence for rehabilitation following THR will be discussed and current best practice highlighted.

2.5.1 In-Hospital Rehabilitation and Recovery

There is emerging evidence in regards to hospital rehabilitation and recovery. Siggeirsdottir et al. (2005) showed, in a 50 patient cohort, that early mobilisation and

discharge, through pre-operative education of post-operative rehabilitation methods, with home rehabilitation was better than in-hospital mobilisation alone with significantly reduced mean hospital stay (6.4 days compared to 10 days, $p<0.001$). However the same study showed that early mobilisation and discharge resulted in a significantly lower Oxford Hip Score (OHS) at two (19±6.3 compared to 24±9, $p=0.03$) four (15±4.2 compared to 22±8.7, $p=0.007$) and six months (14±4.3 compared to 21±7.2, $p=0.001$). It has been previously suggested that a conservative estimate of the minimum significant clinical difference in the OHS being five points (Murray et al., 2007).

Two trials have examined the prescription of bed exercises as an intervention following THR. Smith, Mann, Clark, and Donell (2008) reported in their randomised control trial (n=30, both groups) that bed exercise for the first six weeks following THR did not improve Short Form-12 (SF-12) ($p=0.26$), duration of hospital admission ($p=0.52$) or the Iowa level of assistance scale score ($p=0.05$) compared to not prescribing these exercises. The one year follow-up study reported the same findings with no significant difference ($p>0.05$) in the Iowa level of assistance scale and the SF-12 health survey (Smith, Mann, Clark, & Donell, 2009). These findings reflect those of Jesudason and Stiller (2002) randomised control trial (n=21, both groups). Which reported that there was no significant difference in flexion ($p=0.11$), abduction ($p=0.94$) and the Iowa level of assistance scale score ($p=0.07$) at seven to eight days post-operatively when comparing those who were provided with bed exercises compared to no bed exercises. Therefore, it can be reasonably assumed that there is no benefit to bed exercises following THR.

2.5.2 Early and Post-Discharge Rehabilitation and Recovery

It has been shown that rehabilitation and mobilisation are key to improving outcome following THR (Iyengar, Nadkarni, Ivanovic, & Mahale, 2007; Smith, McCabe, Lister, Christie, & Cross, 2012). A paper on the Norwich Enhanced Recovery Programme

(NERP), showed that early mobilisation, within the first four hours, post-THR or knee replacement, improved functional outcome and reduced length of stay (median length of stay = 3 days) (Smith, McCabe, et al., 2012). Iyengar et al. (2007) showed that enhanced recovery at home and early discharge is also economically beneficial, saving £192,750 in 220 THR patients, a mean of £876.14 per patient compared to conventional rehabilitation pathways. Schneider et al. (2009) reported that early discharge at three, four and five days respectively can be predicted by the 3 meter get-up-and-go test (p=0.005, 0.001, 0.004, respectively). The full data are presented in Table 2.3. Therefore, there is a strong mandate to encourage early rehabilitation post-THR.

Table 2.3: Predicting variable for discharge following THR at Days 3, 4 and 5 post-operatively, modified from Schneider et al. (2009).

Day 3	Day 4	Day 5
PCA (post-op morphine use) (p=0.019)	Age <75 (p=0.037)	Age <75 (p=0.008)
	General health (SF-36) (p=0.005)	Lives alone (p=0.014)
		Walking distance (>1 mile)(p=0.021)
		Bodily pain (SF-36) (p=0.008)
		Mental health (p=0.048)

PCA – patient controlled analgesia

An additional method of improving outcome post-THR is by telephoning participants post-discharge as a reminder for their rehabilitation. Li et al. (2014) randomised control trial (n=249) showed that there was a significant difference in the Harris Hip Score between conventional rehabilitation and those who received a telephone consultation in addition to conventional rehabilitation post-surgery (72.5 ± 20.2 vs 86.38 ± 14.9, p=0.003).

Minns-Lowe, Davies, Sackley, and Barker (2015) narrative analysis systematic review of 11 trials on the effectiveness of land-based physiotherapy exercises concluded that there was insufficient evidence to determinethe effectiveness of these exercises. They also concluded that there was ‘suggestive’ evidence that there may be benefits in terms of

function, walking and muscle strengthening with physiotherapy. However high quality adequately powered trials with long term follow-up are required.

2.5.3 Post-Operation Guidelines

There are currently no guidelines pertaining to the rehabilitation of patients post-THR. However the College of Occupational Therapists (2012) suggest that functional independence should be maximised through early resumptions of activities of daily living. Anxiety should be reduced by exploring potential anxieties during the pre-operation assessment. It is not clear what the recommended way of delivering these are, but the common route of pre-operative education has been shown to have little effect on post-operative anxiety. McDonald, Page, Beringer, Wasiak, and Sprowson (2014) systematic review which included 1463 participants who received pre-operative education prior to THR and total knee replacement showed that pre-operative education lowered anxiety by 2.3 points on the Spielberger Stat-Trait Anxiety Index (lower score equate to less anxiety), post- compared to pre-operatively (MD:-2.3, 95%CI -5.7 to 1.1, I^2=22%). In spite of this, the burden on friends and family members looking after patients following THR following discharge should also be considered. In a small study of 23 carers following THR, Chow (2001) found that 91% of carers were very, moderately or quite stressed before the THR. This reduced by 23% post-operatively (p<0.06, Wilcoxon test, z=1.9, this is a no significant difference).

To summarise, it has been shown that the key to rehabilitation following THR is early mobilisation and activity, something which the guidelines discussed above focus on.

2.6 Post-Operative Outcomes

The outcomes following THR are largely favourable. A number of different measures have been used to assess outcome following surgery. Based on UK data from the NJR (2015),

the 90-day mortality is greater in males than females and increases with age, 70 to 74 year old males 0.48% (0.42% to 0.54%; n=49,056) compared to females 0.30% (0.27% to 0.34%; n=78,160). Overall, the cumulative percentage of death has been reported as 0.49% (0.47% to 0.50%; n=704,274)(NJR, 2015). There was a significant decrease in the percentage of mortality from 0.56% in 2003 to 0.29% in 2011 (p<0.05). This decrease has been associated with several modifiable clinical factors, such as an increased adoption of posterior surgical approach, mechanical thromboprophylaxis, chemical thromboprophylaxis and spinal anaesthetic (Hunt et al., 2013). As recommended by Hunt et al. (2013), if these four clinical management strategies were widely adopted, it is likely that death rates would decrease further. Berstock, Beswick, Lenguerrand, Whitehouse, and Blom (2014) systematic review of 32 studies including 1,129,330 patients presented similar results when assessing 30 and 90-day mortality. They reported 30-day mortality at 0.30% (95% CI: 0.22 to 0.38) and 90-day mortality at 0.65% (95% CI: 0.50 to 0.81). The significant risk factors for mortality were reported as increasing age, male and increasing number of co-morbid conditions, in particular, cardiovascular disease (Berstock et al., 2014). This has overtaken pulmonary emboli as the leading cause of death following THR (Berstock et al., 2014).

The mean improvement in OHS following THR has been reported as 26.5 (standard deviation: 9.5) at three months and 22.4 (standard deviation: 9.2) at 12 months, compared with 45.3 (standard deviation: 7.3) pre-operatively (The Royal College of Surgeons of England and the British Orthopaedic Association, 2000). Patients treated by a surgeon performing more than 100 total and revision THRs each year had a significantly better OHS (p<0.05) compared to a surgeon performing fewer than 20 up to five years post-operatively (Field, Cronin, & Singh, 2005). Field et al. (2005) examined a subset of patients that were operated on by the primary author. They showed the mean OHS was significantly better in patients who were operated on privately compared to the NHS (p<0.05). This finding should, however, be treated with caution as the data is presented from one surgeon.

Implant failure is a rare occurrence following THR (NJR, 2015). Nonetheless some patients are at increased risk. Johnsen et al. (2006), using data from 36,984 Danish THR procedures, showed that being male and with a high Charlson Comorbidity Index were strong predictors of failure regardless of follow-up period. Age and primary presentation for THR were also time dependant predictors of failure in this series (Johnsen et al. (2006). The first 30-days following THR and age of ≥80 years, sequel of trauma, avascular necrosis or paediatric conditions were also associated with an increased risk of failure. However, from six month to 8.6 years following surgery, being aged under 60 years was the only independent predictor of failure (Johnsen et al. (2006).

2.7 Summary of THR Operation

THR is one of the most common elective orthopaedic operations. There is a general agreement in respect to the indications for surgery. With respect to rehabilitation following THR, there is agreement that early mobilisation post-surgery is important, although agreement in respect to how this should be achieved is not as clear (College of Occupational Therapists, 2012; Westby, Brittain, & Backman, 2014).

2.8 Definitions for Physical Activity

Physical activity is defined by the Chief Medical Officers as a generic term for any activity that involves movement which results in an increase in heart rate and calorific expenditure (Department of Health, 2011). Physical activity can be divided into three sub-categories:

1. Everyday activity, for example active travel and occupational activity.
2. Active recreation, for example recreational walking, active play and dance.
3. Sport, this includes any sport competitive or non-competitive (Department of Health, 2011).

The above definition of physical activity is the definition that will be adopted in this thesis.

Older adults (>65 years) account for the majority of the patients that are represented in this thesis. In this age group, it is recommended that physical activity should be undertaken to maintain good physical and cognitive function (Department of Health, 2011). A more detailed description of this is provided in Table 2.4. In general, in the older population aged >65 years, there is at least initially a moderate increase in physical activity before a decline in levels of physical activity in later life. However, less than 50% of the population still reach the recommended levels (Caspersen, Pereira, & Curran, 2000).

Table 2.4: Physical Activity guidelines for older adults (Department of Health, 2011).

Physical activity guidelines for older adults
1. Older adults who participate in any amount of physical activity gain some health benefits, including maintenance of good physical and cognitive function. Some physical activity is better than none, and more physical activity provides greater health benefit.
2. Older adults should aim to be active daily. Over a week, activity should add up to at least 150 minutes (2½ hours) of moderate intensity activity in bouts of 10 minutes or more – one way to approach this is to do 30 minutes on at least 5 days a week.
3. For those who are already regularly active at moderate intensity, comparable benefits can be achieved through 75 minutes of vigorous intensity activity spread across the week or a combination of moderate and vigorous activity.
4. Older adults should also undertake physical activity to improve muscle strength on at least two days a week.
5. Older adults at risk of falls should incorporate physical activity to improve balance and co-ordination on at least two days a week.
6. All older adults should minimise the amount of time spent being sedentary (sitting) for extended periods.

2.9 Health and Societal Benefits of Physical Activity

There is a considerable body of evidence supporting the notion that participation in physical activity can have a positive impact on modifying disease risk (Department of Health, 2011). Physical activity has benefits not only on an individual but also at a society and global level (Department of Health, 2011). Physical inactivity is estimated as being the principal cause for approximately 21% to 25% of breast and colon cancer burden, 27% for diabetes and 30% for ischaemic heart disease (World Health Organization, 2009). In addition, non-communicable diseases now account for nearly half of the overall global burden of disease (Mathers, Fat, & Boerma, 2008). It was estimated in 2004 that for every 10 deaths, six can be attributed to non-communicable conditions (Mathers, Fat, & Boerma, 2008). These findings were further supported by a recent systematic review (Kyu et al., 2016) of the physical activity and the risks of breast cancer, colon cancer, diabetes, ischemic heart disease and ischemic stroke.

Evidence indicates that participation in higher levels of physical activity can be associated with a reduced mortality and morbidity risk (Kyu et al., 2016). For example, for those with a diagnosis of diabetes, individuals with a physical activity level of 600 MET minutes a week demonstrated a two percent lower risk of diabetes compared to those who did not participate in physical activity. However, when physical activity participation was increased from 600 to 3600 MET minutes/week, this risk further reduced by an additional 19% (Kyu et al., 2016).

Participation in physical activity also has economic benefits for society as a whole. The most recent economic analysis of the effect of physical inactivity on the National Health Service (NHS) (Scarborough et al., 2011) illustrated that the cost of physical inactivity to the NHS has been estimated to be £0.9 billion, with obesity associated with £5.1 billion. Therefore promotion and increasing physical activity engagement across society has a significant beneficial impact.

Although it is widely agreed that regular physical activity does not impact on the pathological process of osteoarthritis progression, regular physical activity still improves function and decreases pain (Bennell & Hinman, 2011). Fransen, McConnell, and Bell (2002) in a systematic review which included 549 participants from a total of nine RCTs, indicated that exercise reduced pain (standardised mean difference (SMD) -0.38, 95% CI -0.55 to -0.20) and improved physical function (SMD -0.38, 95% CI: -0.54 to -0.05) immediately after treatment for patient with osteoarthritis of the hip. Additionally, on a 0 to 100 pain scale, exercise reduced pain by eight points (95% CI; 4 to 11; number needed to treat for an additional beneficial outcome 6).

It is also important to consider the external factors that can additionally affect levels of physical activity. Van Cauwenberg et al. (2011) in their narrative systematic review proposed that walkability, perceived access to walking and cycling facilities or safety did not significantly predict physical activity levels in the over 55 age group, however access to shops and services did.

2.10 Barriers and Enablers to Physical Activity Participation

There is a small body of literature which has examined the reasons (barriers and facilitators) for physical activity engagement in people following THR. Smith, Latham, Maskrey, and Blyth (2015) meta-ethnography of 13 papers that were judged to be of moderate to poor quality, summarised that the main barriers to physical activity in the THR population are: a lack of information on recovery, expected capability and fear of 'damaging' the recovery process or implant. There was also suggestive evidence that patients use a 'substitution of reasons' for not engaging in physical activity. For example, a patient may pre-THR use waiting for a THR as an "excuse" for a sedentary lifestyle but may change this reason to their age or comorbidity following the THR. These findings could be considered as perceived barriers to physical activity, therefore, through education and intervention it may be possible to reverse these. There was a clear need for

further research to be undertaken to better understand how these barriers may be overcome.

Gustafsson, Ponzer, Heikkilä, and Ekman (2007) identified a number of barriers to physical activity. They reported that people post-THR may only wish to return to their pre-pathology activity level, which for many is normally sedentary. Some of the barriers to physical activity engagement were regarded as 'perceived' and others were 'real'. For example, a small number of medical conditions were suggested as being physically limiting to allow safe physical activity participation (Brill, 2012). Harding *et al.* (2014) suggested that there were three themes in relation to a lack of physical activity within the THR population; (1) physical activity is for enjoying living, (2) new limitations on physical activity present post-THR these can included age and other co-morbidities, (3) the belief that it is simply nice to know you can be physically active but no urge to actually be active.

2.11 Psychological Models and Behaviour Change for Physical Activity

The aim of this section is to provide a brief discussion of the common models of behaviour change that are applicable to physical activity. Williamson et al. (2015) systematic review of 11 randomised controlled trials with a total study population of 2741, investigated behaviour change and physical activity interventions in lower-limb osteoarthritis. They showed that there was a small but significant improvement in self-reported physical activity at six to 12 months with the introduction of such interventions (SMD; 0.53, 95% CI: 0.41 to 0.65, p<0.00001). However these results should be interpreted with caution due to the high statistical heterogeneity (I^2=66%).

It has been recommended that a key method to induce behaviour change is to target self-efficacy, ensuring that goals that are set are achievable and measureable. How to achieve this, is a challenging question (Williams & French, 2011). It may be argued that eliciting physical activity behavioural change in people post-THR is more of a challenge

than the non-THR population, as a proportion of the pre-surgery information is about reducing or limiting physical activity. Pre-operative education is variable from hospital to hospital and there are no guidelines or similar that specifically suggest what exactly should be covered and how. However, in general, patients are encouraged to restrict their activity for the first three to six months post-operatively (Charnley, 1970). Therefore, it could be suggested that this maybe unintentionally discouraging physical inactivity.

There is no unified theory on how behaviour change is elicited. Instead there are a number of key individual theories. (Antonovsky (1979), 1987); Bassuk (1978)) suggested that to help protect against vulnerability and disease, individuals develop coping strategies, some of which may be damaging to health. For example, a sedentary lifestyle, and subsequent behaviour change to a more active lifestyle can only occur if individuals are willing to change this behaviour. Bourdiou (1977) offered a more simplistic approach simply noting that many behaviours people engage in are long-term habits and are therefore very difficult to change. (Giddens (1979), 1984); Giddens and Dallmayr (1982)) suggested that society was a product of human interaction and the social structure. Therefore to change an individual's behaviour requires them to change their perception of what societal belief is. Alternatively, the theory of planned behaviour (Ajzen, 1991) suggests that intention is the main determinant of action and is predicted by attitude, subjective norms and perceived behaviour control. Therefore the individual's perception of how well they can control their actions and consciously elicit behaviour change is key in deciding if they can succeed.

To aid this, the UK's National Institute for Health and Care Excellence (NICE) (2014) have provided guidelines on how healthcare behaviour change should be elicited. These are summarised in Table 2.5. NICE (2014) also identified a number of current gaps in the research that they recommend should be addressed to further improve understanding in this area. These were:

1. The reporting of delivered interventions need to be clear and in more detail.

2. Research should take in social and cultural contexts when devising an intervention.

3. Allow for adequate time for the intervention to take place and collect baseline data.

4. Cost effectiveness should also be considered.

Table 2.5: NICE guidelines for changing behaviour to improve health (NICE, 2014).

NICE guidelines for changing behaviour to improve health
Base interventions on a proper assessment of the target group, where they are located and the behaviour which is to be changed; careful planning is the cornerstone of success
Work with other organisations and the community itself to decide on and develop initiatives
Build on the skills and knowledge that already exists in the community, for example, by encouraging networks of people who can support each other
Take account and resolve problems that prevent people changing their behaviour
Base all interventions on evidence that works
Train staff to help people change their behaviour
Evaluate all interventions

Therefore, based on the above guidelines, interventions in the THR population should identify the behaviour that is in need of changing (physical activity) and develop the intervention with patient involvement whilst ensuring that the individual/s that deliver the intervention are appropriately trained.

2.12 Summary

This chapter has highlighted the reasons for surgical and rehabilitation implications associated to THR. In addition, it has provided a summary around the definition of physical activity and its importance in this population. The chapter has identified the potential barriers and facilitators to physical activity engagement, and the principles behind common behaviour change approaches which may be important psychological principles behind why people may (or may not) find it difficult to be more active after a THR.

The next chapter is a systematic review which will quantify current physical activity levels within the THR population pre-operatively and up to one year post-operatively, to understand, based on the current evidence-base, how active people really are following a THR.

Chapter 3 Systematic Review of the Literature

3.1 Introduction

The purpose of this chapter is to determine the current knowledge regarding physical activity levels in people pre- and up to one year post-total hip replacement (THR).

3.2 Background

Physical inactivity is a leading cause of mortality, and a significant challenge faced by the National Health Service (NHS) (Department of Health, 2011). Total hip replacement is a common elective operation (NHS Choices, 2014). A total of 620,300 THR were undertaken in England, Wales and Northern Ireland from April 2003 to December 2013 (NJR, 2015). Osteoarthritis is the most common indication (93%), with 60% of patients being women. The median age of 69 years of people undergoing primary THR, and there is a trend away from cemented THR with 60.4% of THR being cemented in 2003 and 21.8% in 2014. (NJR, 2014).

There are currently a number of published systematic reviews on THR and exercise. Most recently, Arnold et al. (2016) showed no significant difference in outcomes (p>0.05) between pre- compared to six-month post-THR (Standardised Mean Difference (SMD): -0.20 to 1.80). However, the picture at one-year is less clear given that the data is only derived from one study (Fujita, Makimoto, Tanaka, Mawatari, & Hotokebuchi, 2013). At this time-point there was a significant improvement up to one year post-THR compared to pre-THR in the number of steps (4,632 ± 2,246 vs 6,163 ± 2,410 steps, p<0.001), light physical activity (107 ± 49 vs 125 ± 42 minutes per day, p=0.005) and moderate physical activity (16 ± 18 vs 46 ± 50 minutes per day, p<0.001). Minns-Lowe et al. (2015) systematic review of physiotherapist-led exercise post-THR concluded that there was insufficient evidence to establish the effectiveness of physiotherapy-led exercise following

primary THR. A later systematic review concluded that increasing the amount of exercise undertaken pre-THR can reduce post-operative hip pain (n=117 standardised mean difference = 0.45, 95% confidence interval 0.15-0.75)(S. D. Gill & McBurney, 2013). However a large number of studies included in this review analysed THR and Total Knee Replacement (TKR) together (Barbay, 2009; S. D. Gill & McBurney, 2013), therefore potentially confusing the picture in relationship to the benefits of physical activity in THR alone. Although there are similarities between factors that predict post-surgery outcome, such as age and walking distance over one mile between THR and TKR, there are also factors that only predict THR, such as: the 3 meter timed get-up-and-go test, home situation, body pain (Short Form (SF)-36) and mental health (SF-36). A fourth review by Di Monaco and Castiglioni (2013) concluded that there was insufficient evidence to develop a research-based post-THR exercise programme.

Whilst this provides an illustration of exercise and THR, there is currently no systematic review which has examined the change (if any) in physical activity, measured either objectively or subjectively, pre- compared to post-THR. Given this, the purpose of this systematic review was to examine whether physical activity changes pre- compared to up to one year post-THR. The specific questions were:

1. Is there a significant difference in physical activity pre- versus post-THR operation?

2. Is the level of physical activity undertaken following THR associated with improved quality of life?

3.3 Methods

This systematic review was registered on the International Prospective Register of Systematic Reviews (PROSPERO) (registration number: 42014013227). The registration details are presented in Appendix 1 and protocol in Appendix 2.

3.3.1 Data Sources and Searches

The electronic databases: AMED, CINHAL, EMBASE, MEDLINE, Central (Cochrane), OPENSIGLE, ClinicalTrials.gov and UK Clinical Trials Gateway were searched up to and including the 13th July 2016. This was an updated search from the one contained within the published version of this systematic review (Withers et al., 2016). The justification for using these database is presented in Table 3.1. The search strategy for each database is shown in Table 3.2. No date restrictions were applied. Whilst it was considered that although rehabilitation practice has changed since the inception of the THR in the 1960s, all papers were initially considered but a sub-analysis could be undertaken to examine the differences upon which age of publication may have on outcome. Only papers written in English were included, as no resources were available to translate papers that were written in languages other than English. The reference list of *'Occupational therapy for adults undergoing total hip replacement: Practice guideline'* (College of Occupational Therapists, 2012) was also scanned for potential studies, as it is the principal guidelines in relation to THR rehabilitation. In addition the reference lists of all included papers were scanned for any additional potentially eligible studies, to reduce the risk of research being missed.

3.3.2 Study Selection

For a study to be eligible for inclusion:

- participants must be at least 18 years old, to ensure the effects of skeletal maturation did not affect the outcomes

- participants underwent an elective unilateral THR and no other procedure, to ensure that studies only examined the effects of THR and no other procedures

- at least one measure of physical activity was taken pre-THR and post-THR to ensure a cross-operative change can be examined

- participants are not given any medication in addition to their normal care, to ensure that potential additional pharmacological effect did not affect the outcome of the result.

Table 3.1: Databases used and justification for adoption

Database	Reason for using database
AMED	Database of allied and complementary medicine
MEDLINE	Database of published biomedical research
EMBASE	Database of published biomedical research
CENTRAL	Cochrane central register of controlled trials
CINHAL	Database of nursing and allied health journals
OpenSIGLE	Database of grey literature
ClinicalTrials.gov	Registry for privately and publically funded clinical studies of human participants around the world
UK Clinical Trials Gateway	Database of clinical research trials currently running in the United Kingdom

3.3.3 Primary Outcomes Measure

The primary outcome measure for this systematic review was change in physical activity. Physical activity being defined for any activity that involves movement which results in an increase in heart rate and calorific expenditure (Department of Health, 2011), a definition of physical activity is discussed in greater detail in Section 1.2 Study Objectives. This

would enable an appreciation of levels of physical activity before and after surgery, thereby answering the research question.

Table 3.2: Summary of the search strategy adopted for this systematic review.

Database	Search Terms	Search filters applied
AMED	"Hip"(whole document) and "arthroplasty" or "replacement" or "arthroplast*" (whole document) and "exercise" or "sport" or "physical activity" or "physical therap*" or walking" (whole document)	
CINHAL	"Hip"(whole document) and "arthroplasty" or "replacement" or "arthroplast*" (whole document) and "exercise" or "sport" or "physical activity" or "physical therap*" or walking" (whole document)	Exclude MEDLINE records Human Age group 19 years and older English language
EMBASE	"Hip"(whole document) and "arthroplasty" or "replacement" or "arthroplast*" (whole document) and "exercise" or "sport" or "physical activity" or "physical therap*" or walking" (whole document)	Human English Language Exclude MEDLINE
MEDLINE	"Hip"(whole document) and "arthroplasty" or "replacement" or "arthroplast*" (whole document) and "exercise" or "sport" or "physical activity" or "physical therap*" or walking" (whole document)	English Language Humans
Central (Cochrane)	"Hip"(whole document) and "arthroplasty" or "replacement" or "arthroplast*" (whole document) and "exercise" or "sport" or "physical activity" or "physical therap*" or walking" (whole document)	
OPENSIGLE	"Hip"(whole document) and "arthroplasty" or "replacement" or "arthroplast*" (whole document) and "exercise" or "sport" or "physical activity" or "physical therap*" or walking" (whole document)	
ClinicalTrials.gov	"Hip"(whole document) and "arthroplasty" or "replacement" or "arthroplast*" (whole document) and "exercise" or "sport" or "physical activity" or "physical therap*" or walking" (whole document)	18 and over
UK Clinical Trials Gateway	"Hip"(whole document) and "arthroplasty" or "replacement" or "arthroplast*" (whole document) and "exercise" or "sport" or "physical activity" or "physical therap*" or walking" (whole document)	

Measures that are considered suitable to measure the change in physical activity were: questionnaires that assessed physical activity, laboratory and/or field-based tests. A non-exhaustive list of example measurement methods are shown in Table 3.3. this also included a brief description of the psychometric properties for each measure. Measures of strength or power such as dynamometry were not considered a measure of physical activity. These measure muscular power rather than physical activity. Similarly biomechanical measures such as walking speed and peak impact force were not considered measures of physical activity, but rather measures of physiological efficiency. All other measures of physical activity were included in this study to ensure that the maximum amount of data could be synthesised, answering the research question.

Table 3.3: Examples of measures that can be used to measure physical activity.

Measure	**Psychometric property of measure in THR population**
Questionnaire	
Physical Activity Scale for the Elderly (PASE) (Washburn, Smith, Jette, & Janney, 1993)	Can be administered by researcher of self-administered. Reliability mail r=0.84 and telephone r=0.68 (Washburn et al., 1993)
International Physical Activity Questionnaire (IPAQ) (Booth et al., 2003)	IPAQ produces repeatable test-retest reliability spearman's rho (ρ) clustered around 0.8. Criterion validity compared against accelerometers showed fair to moderate agreement (pooled ρ=3 95% CI: 0.26-0.39) (Booth et al., 2003)
Lab-based test	
Cardiopulmonary exercise test (CPEX)	Gold standard for measurement of exercise capacity (Eston & Reilly, 2013)
Sub-maximal exercise test	Multiple different types with varying validity and reliability
Field-based test	
6 minute walk	No data about measure in THR population
12 minute walk	No data about measure in THR population
Accelerometer	No data about measure in THR population

3.3.4 Secondary Outcomes Measures

The secondary outcomes measures were: health related equality of life and hip dislocation.

3.3.4a Quality of Life

Quality of life was used as an outcome measure as it has been shown that increased physical activity has been highly correlated to quality of life in other conditions and this may be considered an important potential benefit of an increase in physical activity following THR (Mereles et al., 2006; Tsai et al., 2004). Anticipated quality of life measures are presented in Table 3.4. All forms of administration of the measures were acceptable (i.e. self-administered; with or without a researcher present, over the telephone or by post).

Table 3.4: Example quality of life questionnaires.

Quality of life questionnaires
SF-36 (RAND Health)
SF-12 (RAND Health)
EQ-5D (EuroQolGroup, 1990)

3.3.4b Hip Dislocation

Hip dislocation was also a secondary outcome variable as there have been previous concerns that an increase in physical activity may result in an increased dislocation risk (Meira & Zeni, 2014). Hip dislocation was measured by number of participants that reported dislocation regardless of mechanism.

3.3.5 Data Extraction

In line with the Cochrane Collaboration's guidelines (Higgins & Green, 2008), study titles were initially screened for eligibility by the primary reviewer (TW). If unclear, article abstracts were read in detail. If still unclear, the full-text was read. If it was still unclear

whether the paper fulfilled the inclusion criteria, the corresponding authors were contacted for further detail and finally if still unclear a member of the team (TS) reviewed.

Data from all eligible papers was extracted using a data extraction table. All physical activity, quality of life, dislocation and demographic data were extracted from the eligible papers. In the event of missing data, the corresponding authors were emailed and asked for clarification. The primary reviewer (TW) screened, identified studies and extracted data. A second reviewer (SL) reviewed and agreed or disagreed with the primary reviewer's decisions. This was done to reduce the effects of reviewer bias (Higgins & Green, 2008). When required, a third reviewer (TS) adjudicated any disagreements.

3.3.6 Critical Appraisal

A critical appraisal of studies was undertaken to ensure that the relative quality of each study contributing to the analysis. All included studies were appraised using the CASP Cohort Study Checklist ("CASP Cohort Study Checklist," 2013). This is a 12 item appraisal tool which has been previously used in musculoskeletal research ("CASP Cohort Study Checklist," 2013). An additional question (*6c. Was the characteristics of excluded participants examined?*) was added to the appraisal tool by the review team, as it was considered specifically important to this review. This was justified as it has previously been shown in different populations that there is a tendency for more active older adults to agree to take part in exercise and/or physical activity studies (Martinson et al., 2010). Therefore, this could potentially bias the data if it was unknown what the characteristics of those excluded from the study were.

3.3.7 Data Synthesis and Analysis

Data extraction tables were reviewed to determine the study-based or clinical heterogeneity. This indicated whether there was low heterogeneity between the studies in respect to participant characteristics, study design exposure and assessment methods. Accordingly a meta-analysis was deemed appropriate. A narrative analysis review of the evidence was undertaken when there was moderate to high evidence of between-study or clinical heterogeneity.

After the data from all included papers had been collected, an assessment of heterogeneity was undertaken using the I^2 test where appropriate, the data was synthesised and a single or multiple meta-analysis was undertaken. Heterogeneity examines the null hypothesis that all studies are evaluating the same effect (Higgins, Thompson, Deeks, & Altman, 2003). The Cochrane Collaboration recommend interpretation of I^2 should be used and interpreted as shown in Table 3.5 (Higgins & Green, 2008).

Table 3.5: Cochrane suggested interpretation of I^2 values (Higgins & Green, 2008).

I^2 range	Interpretation
0% to 40%	Might not be important.
30% to 60%	May represent moderate heterogeneity.
50% to 90%	May represent substantial heterogeneity.
75% to 100%	Considerable heterogeneity.

If there was insufficient data for individual measure analysis, the measure was converted into the standardised mean differences using the equation below. Through this, the standardised mean difference is the difference in mean outcome between groups, divided by the standard deviation of outcome among participants.

$$Standerdised\ Mean\ Difference = \frac{Difference\ in\ mean\ outcome\ between\ groups}{Standard\ deviation\ of\ outcome\ among\ participants}$$

All meta-analyses were presented as mean differences with 95% confidence intervals, as the data presented was continuous. Each analysis was represented graphically using a forest plot.

A sub-group analysis of the six minute walk test was undertaken, with the result of removing one paper; Oosting (2012), it was the only paper where an age restriction was enforced for participants over 65 years old.

Analysis was undertaken using Review Manager 5.3 software (Review Manager (RevMan) [Computer Program]). Version 5.3. Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2014).

3.4 Results

3.4.1 Search Results

A summary of the search results is presented in Figure ***3.1***. A total of 6024 citations were identified after duplicates were removed. A breakdown of the results by database are presented in Table 3.6. Seventeen of these were eligible and included. Nine papers provided sufficient data which were subsequently used in the meta-analysis. Eight papers (Arborelius, 1976; Arbuthnot, Mc Nicholas, Dashti, & Hadden, 2007; Chatterji, 2004; Delasotta et al., 2012; Harding, Holland, Delany & Hinman, 2007; Macnicol, McHardy & Chalmers, 1980; Smith 2016; Smith et al., 2016) were not included in the meta-analysis as the data was not presented in a way to facilitate pooled analysis. However, they were included in the narrative analysis.

3.4.2 Quality Assessment

A summary of the study appraisal results are presented in Table **3.7**. Overall the evidence-base was rated as poor to moderate in quality. Recurrent strengths included all studies clearly addressing a focused research question. All studies, with the exception of four, also recruited participants in a clearly defined way (Arborelius, 1976; Macnicol, McHardy, & Chalmers, 1980; Pugh, 1973; Ries et al., 1997). Three studies did not clearly state how they recruited the study cohort (Arborelius, 1976; Macnicol et al., 1980; Pugh, 1973). The outcome and exposure was accurately measured in all studies

Table 3.6: Search strategy results presented by search database.

Database	**Citations identified**
AMED	246
CINHAL	2988
EMBASE	2070
MEDLINE	1779
Central (Cochrane)	270
OPENSIGLE	0
ClinicalTrials.gov	174
UK Clinical Trials Gateway	40
Total	7567
Total with duplicates removed	6024

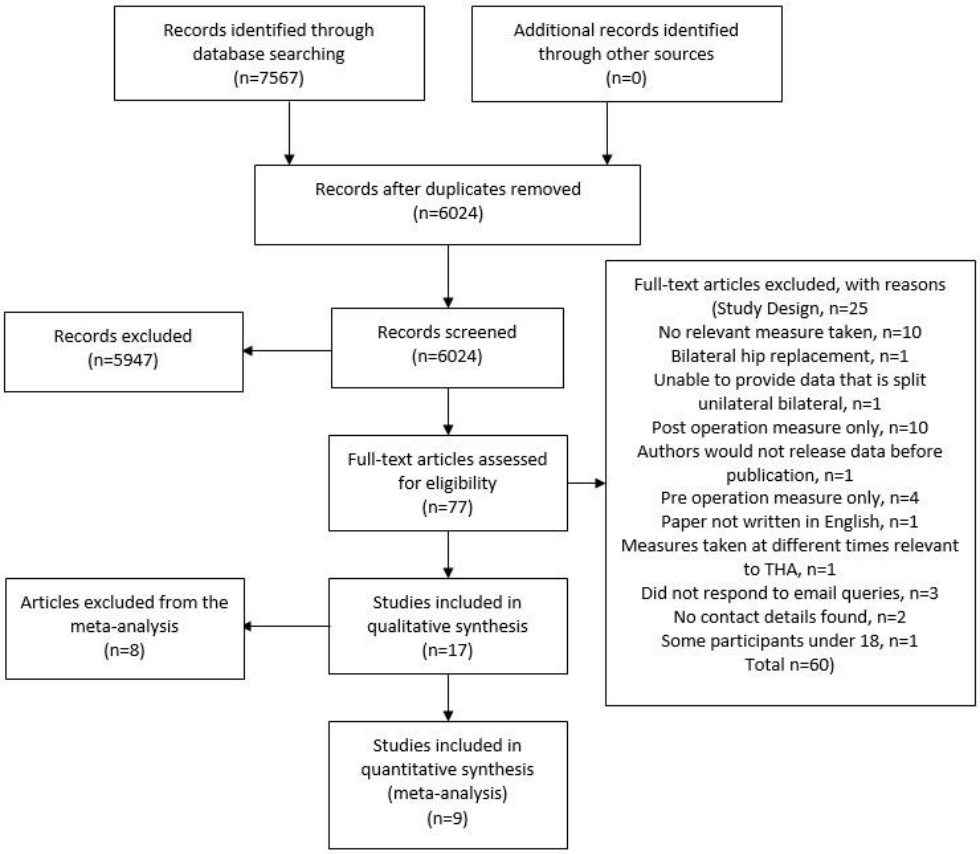

Figure 3.1: Summary of search results.

were applicable. Subjects were followed up appropriately in nine studies, one study did not (Arborelius, 1976) and it was not possible to ascertain this in one (Lin, Thomas, Spiezia, Loppini, & Maffulli, 2013). However, no studies considered potential confounding factors in the design and analysis of the study. Nevertheless the results were broadly speaking applicable to the THR population.

3.4.3 Characteristics of Included Studies

A summary of the demographic data for all included papers is presented in **Error! eference source not found.**. In total 483 participants were included Arbuthnot, McNicholas, Dashti, and Hadden (2007) did not clearly state the number of participants in their study. Cohort sample size ranged from one (Pugh, 1973) to 88 participants (Heiberg, 2013). Three studies (Arbuthnot et al., 2007; Delasotta et al., 2012; Pugh, 1973) did not clearly state the ratio of males to females in the remaining studies. Two hundred and

eighty-seven participants (68%) were female, two studies had an exclusively female cohort (Lin *et al.*, 2013; Macnicol *et al.*, 1980), Horstmann *et al.* (2012) had the lowest proportion of females (51%). Of the included papers, all but one (Oosting, 2012) were observational, longitudinal studies. Age was not presented in three papers but the remaining studies Delasotta *et al.* (2012) had the lowest age, 43.2 years (standard deviation: 5.5). There was an age restriction of those younger than 50 years old. The oldest cohort was 75.0 years (standard deviation: 6.3) in Oosting (2012).

3.4.4 Assessment of Physical Activity

A number of different measures were used to evaluate physical activity levels. These included: cardiopulmonary exercise testing (CPEX) used in three studies (Horstmann, 2012; Pugh, 1973; Ries et al., 1997). This is an incremental exercise test to volitional exhaustion. Accelerometers were used in three studies (De Groot, Bussmann, Stam, &

Table 3.7: Summary table presenting the critical appraisal results for all included studies

Criteria	Arborelius (1976)	Arbuthnot et al. (2007)	Chatterji (2004)	De Groot et al. (2008)	Delasotta et al. (2012)	Harding et al. (2014)	Heiberg (2013)	Holstege et al. (2011)	Horstmann (2012)	Lin et al. (2013)	Macnicol et al. (1980)	Oosting (2012)	Pugh (1973)	Ries et al. (1997)	Smith et al. (2016)	Smith et al. (2016)	Vissers et al. (2011)
Did the study address a clearly focused issue?	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Was the cohort recruited in an acceptable way?	NC	✓	✓	✓	✓	✓	✓	✓	✓	✓	NC	✓	NC	✓	✓	✓	✓
Was the exposure accurately measured to minimise bias?	✓	✓	NA	✓	✓	✓	NA	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Was the outcome accurately measured to minimise bias?	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Have the authors identified all important confounding factors?	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×
Have they taken account of the confounding factors in the design and/or analysis?	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×	×
Was the follow up of subjects complete enough?	×	NA	NA	✓	NA	✓	✓	✓	✓	NC	✓	✓	NA	✓	✓	✓	✓
Was the follow up of subjects long enough?	✓	✓	NA	✓	✓	✓	✓	×	✓	✓	✓	×	✓	✓	✓	✓	✓

✓=yes, ×=no, NC=not clear, NA = not applicable.

Verhaar,2008; Lin, Thomas, Spiezia, Loppini, & Maffulli, 2013; Vissers, Bussmann, De Groot, Verhaar, & Reijman, 2011) and the six-minute walk test was also used in three studies (Heiberg, 2013; Holstege, Lindeboom, & Lucas, 2011; Oosting, 2012). A more detailed summary of measures used is presented in Table 3.9.

Table 3.8*3.4.5 Clinical Findings – Primary Outcomes*

Accelerometer: percentage of 24 hours spent walking

Percentage of 24-hours spent walking were analysed from two studies through accelerometry (de Groot *et al.*, 2008; Vissers *et al.*, 2011). On pooled analysis between pre- and post-THR at six months follow-up the mean difference (MD) was -0.21 %24 hours (95% CI: -1/36 to 0.93). There was no statistically significant difference (p=0.72, I^2=12%; n=65;
Figure ***3.2***).

Accelerometer: movement related activity

Three studies provided data on movement-related physical activity, as measured with accelerometery pre- and post-THR (de Groot *et al.*, 2008; Lin *et al.*, 2013; Vissers *et al.*, 2011). The MD was -0.08 %24 hours (95% CI: -1.60 to 1.44). There was no significant difference at the six month follow-up (p=0.92; I^2=0%; n=77;
Figure ***3.2***).

CPEX testing

Three papers undertook CPEX testing (Horstmann, 2012; Pugh, 1973; Ries et al., 1997). One study evaluated this using a cycle ergometer (Ries et al., 1997) and two studies used a treadmill (Horstmann, 2012; Pugh, 1973). All three studies were combined for the meta-analysis. The mean difference was -0.24 $ml.min^{-1}.kg^{-1}$ (95% CI: -1.36 to 0.87). There was no statistically significant difference at a mean nine month follow-up (p=0.67; I^2=0%; n=76; Figure ***3.2***).

Six-minute walk test

Three studies assessed the six-minute walk test (Heiberg, 2013; Holstege et al., 2011; Oosting, 2012). The mean difference was -60.85 m (95% CI: -122.41 to 0.72). There was no significant difference at a mean of 23 weeks (p=0.05; I^2=84%; n=113; Figure 3.3).

A sub-analysis of this meta-analysis was undertaken to exclude data from Oosting (2012). This was justified as it was the only study with an age restriction (greater than 65 years old). The mean difference was -89.09 m (95% CI: -136.40 to -49.79). This resulted in an increase in six minute walk test distance from 60.9 metres to 89.1 metres. There was a significant difference between pre- and post-THR post-operatively (p=0.0002; I^2=68%; n=101; Figure 3.4) up to one year.

Table 3.8: A summary of physical activity measures used within the included papers and associated results.

Authors	Physical Activity Measure	Physical Activity level pre-operation	Physical Activity level post-operation
Arborelius (1976)	VO2 whilst walking as fast as possible	VO2 832 ±219 ml/min VO2 19.5 ±6.5 ml/m WS 46.2 ± 14.6 m/min	VO2 839 ±264 ml/min VO2 18.1 ± 5.3 ml/m WS 48.4 ± 14.4 m/min
Arbuthnot et al. (2007)	Change in golf performance questionnaire	Reported as a change see post	54% improved 42% no change 4% detrition
Chatterji et al., (2004)	Change in recreational and sporting activity	Reported as a change see post.	2 sports significantly increased (p<0.05) participation levels post-surgery walking and aqua aerobics, 3 decreased (p>0.05) golf, tennis jogging.
de Groot et al., (2008)	Accelerometer	Movement related activity (%24 hours) 8.7, 4.0 Walking (%24 hours) 6.3, 3.0 Upright (%24 hours) 20.7, 5.9	Three month Movement related activity (%24 hours) 9.1, 3.9 Walking (%24 hours) 6.8, 3.0 Upright (%24 hours) 20.5, 6.4 Six month Walking (%24 hours) 6.9, 2.8 Upright (%24 hours) 21.4, 6.3
Delasotta et al., (2012)	Physical activity questionnaire	See post-operation	33% increase in recommended 83.3% decrease in occasionally recommended 450% decrease in discouraged
Harding et al., (2014)	Accelerometer	Median IQR time engaged in sedentary activity%	Median IQR time engaged in sedentary activity% 86 (10)

		84 (9.8)	
Heiberg et al., (2013)	6 minute walk test (mwt) Stair climbing test	6mwt (m) 401 (377-425)	3 month 6mwt (m) 437 (416-458) 12 month 6mwt (m) 512 (490-534)
Holstege et al., (2011)	6 minute walk	317.9, 112.3m	6 weeks (n=39) 313.8, 89.6m 12 weeks (n=37) 380.4, 99.0m
Horstmann et al. (2012)	Standardised incremental stress test	VO2max (ml/min/kg): 16.0 (15.0;17.0)	6 months post VO2max (ml/min/kg): 16.0 (15.0;17.0)
Lin et al., (2013)	Accelerometer	1 month pre THR Daily activity time% 55.6, 13.5	6 month post THR Daily activity time 57.2, 12.8
Macnicol et al., (1980)	12 min walk test	12 mwt max 2.52, 0.14 SEM kph mean 112.8, 3.0 SEM bpm	12 mwt 6 months mean 121.9, 4.4 SEM 4.4 bpm 3 months mean 121.9, 4.9 SEM bpm
Oosting et al., (2012) Pugh (1973)	6 min walk CPEX treadmill	340, 78 speed 5km/h VO2peak 1.2 L/min	6 weeks 339, 69 3 month post speed 7 kmh VO2peak1.9 L/min 9 month post 8 km/h VO2peak 2.4 L/min
Ries et al., (1997)	CPEX	PeakVO2ml.kg.min-1:14.7, 3.7 VO2atATml.kg-1:10.4,	6 month post PeakVO2ml.kg.min-1:15.2, 4.2 VO2atATml.kg-1:10.1, 2.6

		2.5	12 month post PeakVO2ml.kg.min-1:15.4, 3.3 VO2atATml.kg-1:9.6, 1.9 24 month post PeakVO2ml.kg.min-1:16.1, 2.9 VO2atATml.kg-1:9.9, 1.8
Vissers et al., (2011)	Accelerometer	Movement related activity (%24 hours) 14.1 (11.8,16.5) Walking (%24 hours) 10.3 (8.5, 12.1)	6 month post Movement related activity (%24 hours) 12.9 (10.8,15.0) Walking (%24 hours) 9.5 (8.1, 10.9)

6 mwt: six minute walk test; AT: Anaerobic Threshold; CPEX: cardiopulmonary exercise test; IQR: inter quartile range; THR: Total Hip Replacement

Narrative Analysis

Eight studies were not included in the meta-analysis, but were analysed narratively. Arborelius (1976) recorded no change in measured physical activity by asking participants to walk as fast as possible and measuring $\Delta\dot{V}O_2$. Arbuthnot et al. (2007) measured change in golf performance by questionnaire and noted that 54% of participants did improve their performance post-surgery. In this context, change in golf performance was considered a measure of physical activity as walking the course of using a golf buggy was considered in the measure. Chatterji (2004) reported a significant increase in reported walking (p<0.0001) and aqua aerobics (p=0.002) post-surgery but a significant decrease in golf (p=0.005), tennis (p=0.01) and jogging (p=0.01). Delasotta et al. (2012) showed that there was a 33% increase in recommended activities, whereas Harding et al. (2014) showed a small increase in time spent in sedentary activities, median 84% to 86% and Macnicol (1980) showed an increase in mean heart rate 112.8 beats per minute (standard error of the mean: 3.0) to 121.9 beats per minute (standard error of the mean: 4.4) at six-months for the 12 minute walk.

(Smith (2016); Smith et al. (2016)) are both secondary dataset analyses of the Osteoartritus Initiative (OAI) and European Prospective Investiation into Cancer and Nutrition (EPIC). Smith et al. (2016) reported that there was a significant decrease in the number of flights of stairs climbed per week (p=0.001), walking for work or for pleasure (p=0.004) and no significant difference in duration of total recreational activities (p=0.21). Smith (2016) showed a significant decrease at 12 months compared to pre-THR (p<0.001). They concluded that this difference was not clinicaly significant.

Table 3.9: Table summarising the quality of life measurements and findings.

Paper	Quality of life measure	Quality of life pre-operation	Quality of life post operation
de Groot *et al*. (2008)	SF-36	Median and range 33 (0-88)	3 month post: 60 (25-100) 6 month post: 70 (20-100)
Harding *et al.* (2014)	SF-12 mental component summary	37 ± 18	6 month post-operatively: 50, 16
Holstege (2011)	SF-36	50.5 ± 6.7	6 week: 55.6, 8.5 12 week: 57.8, 10.6

SF 36: Short form 36 health survey, SF-12 Short form 12 health survey

3.4.6 Clinical Findings- Secondary Outcomes

No included studies reported data on the frequency of hip dislocation in relation to physical activity data. Only three papers measured quality of life, Table 3.9. The SF-36 or 12 was used in all of them. Only two studies reported a significant improvement in quality of life from pre- to post-THR (de Groot *et al.*, 2008; Harding *et al.*, 2014). Holstege *et al.* (2011) reporting no significant change ($p>0.05$) at six and 12 week post-operatively 34.7 ± 13.8 to 21.6 ± 13.3 and 14.7 ± 9.6 respectively using the SF-36 mental health. However de Groot *et al.* (2008) showed a significant increase ($p<0.001$) in quality of life using the SF-36, 33 (0-80) pre-operatively to 60 (25-100) at three-months and 70 (20-100) at six-months respectively. Harding *et al.* (2014) reported a significant increase ($p=0.001$) in quality of life

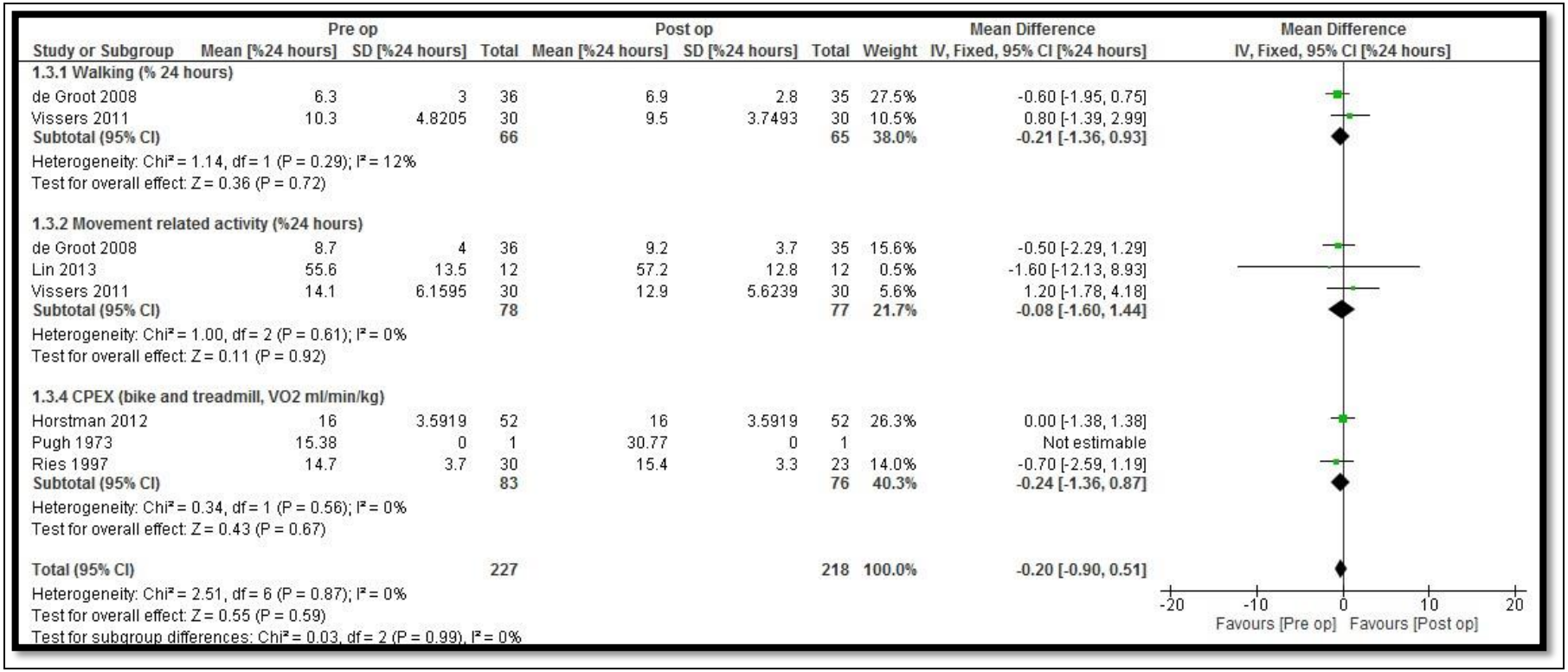

Figure 3.2: Forest-plot to illustrate the meta-analysis findings from the fixed-effect analyses.

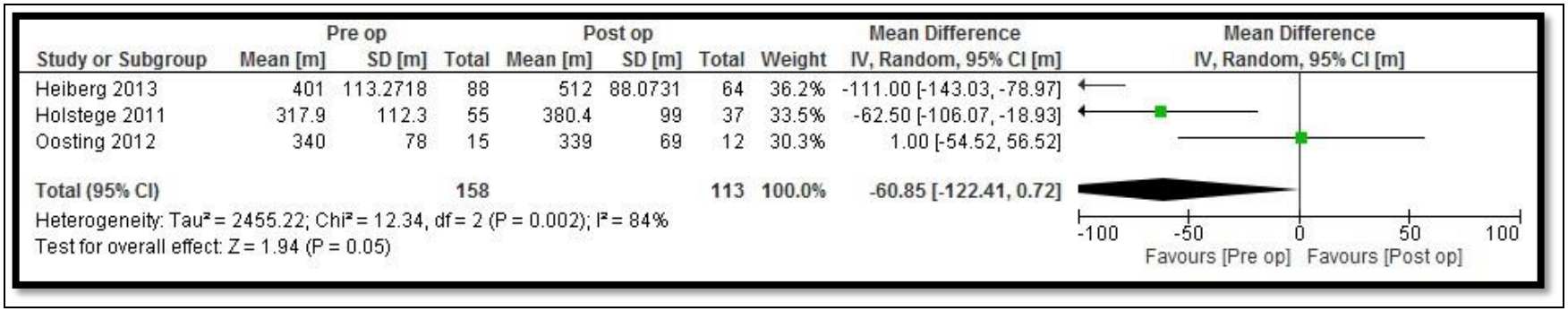

Figure 3.3: Forest-plot to illustrate the random effects meta-analysis six minute walk.

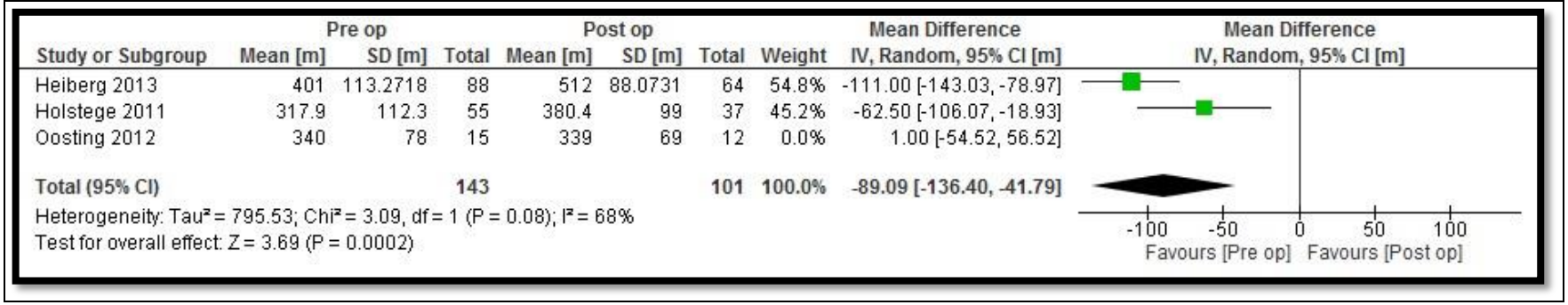

Figure 3.4: Forest-plot to illustrate the random effects meta-analysis six minute walk, removing Oosting et al. (2012).

using the SF-12 mental component summary, 33 (standard deviation: 18) pre-operatively to 50 (standard deviation: 16) at six-months respectively.

3.5 Discussion

The data from this systematic review concludes that there appears to be no significant change in physical activity between pre- and up to one year post-THR. This has been determined through accelerometery, physical activity testing and cardiopulmonary exercise testing. Initially, this may be thought of as somewhat surprising given that the clinical justification for a THR is often to reduce pain thereby increasing function and physical activity (Morrey, 1993).

The methodological quality of the research included within this review was generally low to moderate. Only one study (Holstege et al., 2011) examined the characteristics of the excluded participants, therefore providing limited information to ascertain if the data were representative of the THR population or whether there was a risk of selection bias. Additionally, no authors attempted to identify confounding factors which may have influenced the level of physical activity that participants undertook. Therefore, it was not possible to appreciate whether cohort characteristics such as pre-existing musculoskeletal pain, medical morbidities, age or gender impacted on the results. As has been previously reported, musculoskeletal pain, medical morbidities, increased age of participant and being female is associated with a decrease in physical activity (Leeuw et al., 2007; Sarkisian, Prohaska, Wong, Hirsch, & Mangione, 2005; Troiano et al., 2008). It is therefore important to consider the methodological quality of the papers when drawing conclusions from this review. As such the conclusion of this review should be considered in light of not knowing if the characteristics of the participants truly reflects the typical individual who undergoes a THR.

Whilst the six-minute walk test did not reach a statistically significant difference, the difference itself may be regarded as clinically significant with a mean difference of 60.9 metres (95% CI: -122.4 to 0.7). Previous research in chronic lung disease suggests that the clinically significant difference is 54 metres (95% CI: 37 to 71)(Redelmeier, Bayoumi, Goldstein, & Guyatt, 1997). Therefore the 60.9 metre improvement in patients following THR, reported in this analysis could potentially represent a clinically relevant difference. There is no specific data on clinically important difference for the THR population. It is hypothesised that the clinically significant difference for people undergoing THR is likely to be different to that of lung disease, as lung disease aetiology results in a physiological limited exercise capacity, whereas the THR aetiology results in a biomechanically limited exercise capacity.

When the Oosting *et al.* (2012) study was removed from the analysis (Figure 4), being the only study which exclusively recruited patients over 65 year olds, there was an increase in the distance walked between pre- and post-THR from 60.9 m to 89.1m. This suggested that age may be a modifier of the six-minute walk test result following THR. This finding should, however, be considered with considerable caution as it is based on removing one study of 15 participants (Oosting, 2012). However this should be balanced with the weight of evidence reporting that the older the participant, the less physical activity they are likely to undertake (Troiano et al., 2008). Therefore, on the balance of all the evidence, it is suggested that there may be an age-related decline in six minute walk distance resulting in a small pre- compared to post-THR change.

However both pre- and post-operatively, the mean six minute walk test was noticeably less than the population mean. Heiberg (2013) was the only paper that showed the greatest distance pre- and post-operatively (401 metres (standard deviation: 113 metres) and 512 metres (standard deviation: 88 metres) respectively). The reference values for 55 – 75 years old, is 659±62 metre (Camarri, Eastwood, Cecins, Thompson, & Jenkins,

2006). This noticeable difference is suggestive that it is not purely the reason for the THR that may result in the decrease in six minute walk distance compared to the mean for the age group. There is therefore a need to better understand the other factors that may contribute to a decrease in physical activity in this population.

The previous methods of measurement discussed above could be referred to as 'non-laboratory' or 'free-living' based. In other words they are measurements that have been undertaken in the natural environment and therefore not under controlled 'experimental' conditions (Eston & Reilly, 2013). The CPEX is a 'lab-based' measure. The CPEX however is not a measure of physical activity but a measure of exercise capacity. This has therefore been included in this systematic review as an indirect, surrogate measure of physical activity (Eston & Reilly, 2013). This systematic review reported that there is no significant change in CPEX output between pre- and post-THR. This therefore suggests that physiological capacity of the patient does not change pre- compared to post-THR. Considering that the other evidence presented in this systematic review suggests that there is no increase in physical activity, the lack of change in physiological capacity is not surprising as there is no clear mechanism for this to happen.

This study provides important information for healthcare professionals with regard to physical activity post-THR. Based on limited but available evidence, this systematic review reports that there is no change in physical activity following unilateral primary THR. Interview based research suggests that when people prior to THR are asked what their activity aspirations are post-operatively, the most common goal is to return to the level of physical activity that they were undertaking before their hip disease or condition impacted on their lifestyle (Harding *et al.*, 2014). However, the results of this meta-analysis suggest that whilst this may be an aspiration, it does not consistently occur post-THR (Harding *et al.*, 2014). Based on this, further study is warranted to facilitate an increase in physical activity in this population.

There is no clear explanation as to why studies do not agree in respect to quality of life. This may be attributed to the post-operative measures that are taken. Harding *et al.* (2014) collected post-operative measures at six months, de Groot *et al.* (2008) at three and six month, both of which demonstrated a significant difference, compared to Holstege *et al.* (2011) at six and 12 weeks which did not. Therefore, given this uncertainty, more research is needed to better understand the change in quality of life pre- compared to post-THR.

It was not possible to comment on the other secondary outcome, hip dislocation, as there were no data presented on this parameter. This may be because other research groups do not consider it an important measure to consider. Alternatively they may consider that the current evidence is sufficiently strong to support the idea that increasing physical activity does not increase dislocation rate. Smith, Davies, Ingham, and Mann (2012) showing in a review of 100 THR that bed transfers (16%), twisting or turning in bed (13%) and toilet or chair transfers with no twists (13%) were the most common reasons for hip dislocation following surgery. This therefore supports the notion that more conventional physical activity pursuits such as active living, active transport and sports and exercise are less frequently associated with dislocation compared to these more mundane activities of daily living.

As the benefits of regular physical activity are well-documented and widely reported (Health & Services, 1996), this systematic review suggests that a greater effort or that new methods need to be developed to engage people following THR in becoming more physically active. Identifying barriers to physical activity engagement, and strategies to address these are therefore important research priorities, in order to improve the overall health and wellbeing of this population. There is a need to both explore novel interventions to increase physical activity and to undertake exploratory analyses to better understand the characteristics on which to predict physical activity pre- compared to post-THR.

3.6 Conclusion

There appears to be no statistically significant change in physical activity between pre- and post-THR during the first post-operative year. However the low to moderate methodological quality of the included studies should be considered when drawing such conclusions. Further research is warranted to better understand the changes in physical activity between pre- and up to one year post-THR, how patients can be supported to be more physically active and which factors could influence these outcomes.

3.7 Summary

This chapter has presented evidence from a systematic review to illustrate that physical activity does not change pre- compared to up to one year post-THR. This finding suggests that there is a need to better understand the characteristics that predict and can influence physical activity change pre- post-THR in a sample that has more preferential external validity than this systematic review. Therefore the next chapter, a nested case-control study, will examine physical activity in a THR sample with stronger external validity using a UK, community-based cohort.

Chapter 4 Secondary data set analysis

4.1 Introduction

The previous chapter reported that there was no evidence of a significant change in physical activity pre- compared to up to one year post-total hip replacement (THR). However the systematic review was unable to consider in detail how demographic factors may have influenced post-THR physical activity. The systematic review was also unable to determine how physical activity may change during a longer post-operative period than a year. Considering that 'full' recovery from such an operation may take up to 12 months (NIH, 2013), there is a need to determine how physical activity behaves at a longer post-operative time period than a year to provide participants sufficient time to have achieved physical activity change post-operatively. Finally, the current evidence-base was graded as low to moderate. Accordingly, the conclusions drawn from this systematic review were drawn with caution.

Currently, all published data around this question are from clinical trials. These study designs have restrictive inclusion criteria and examine a tightly controlled sub-section of the THR population (Hegedus & Moody, 2010). Accordingly, the representation of participants and the external validity of this evidence-base could be questioned (Arnold et al., 2016; Minns-Lowe et al., 2015). The lack of comparison to comparable individuals who do not have the disease in question (i.e. THR) also means that it is not possible to compare the THR population to what you would expect in the wider age demographic.

Taking these points into consideration, there was a need to undertake research using a more heterogeneous dataset, such as a population cohort study. This would allow an assessment as to whether the trial data is generalisable to a more 'real world' scenario. Therefore, the aim of this chapter was to present an analysis of the physical activity data

of participants within the European Prospective Investigation into Cancer and Nutrition (EPIC) cohort who underwent a THR. The primary hypothesis for the study was that there is no significant change in physical activity pre- compared to post-THR. The secondary hypothesis was that having a THR is a significant predictor of physical activity.

4.2 Methods

4.2.1 Design

A nested case control cohort study was undertaken using the data from the EPIC study. A nested case control was used as only a subset of the original cohort was analysed (Sedgwick, 2014), those being people who had a THR and the associated matched controls. Ideally a case control study would be preferential over a nested case control study as such a study would be designed specifically for the group being examined. However, this was not possible in this instance as there were no appropriate datasets known to the researcher which exclusively examined patients before and after THR compared to controls. Furthermore, due to the costs and time constraints of this PhD programme, it was not possible to design and collect data to construct an inception database. Therefore a more 'convenient' nested case control study design was used as it was possible to use a sub-set of the EPIC dataset to answer the research questions.

4.2.2 EPIC

The EPIC cohort study is an ongoing, large multi-centre international cohort study. This analysis investigated the subsection of participants who lived in Norfolk. The EPIC study is a longitudinal study investigating the potential associations between diet, lifestyle factors and cancer. It was designed to increase the understanding on the demographic and lifestyle factors that 'best' predict cancer risk and prevalence. The EPIC Norfolk

cohort consists of 30,441 participants that represented 5.8% of the overall study population. The Norfolk-based population were exclusively used to ensure that the potentially confounding factors of societal and cultural variables, and wealth and living in a rural or urban area were kept to a minimum (Chen, Liu, & Wang, 2014; Talaei et al., 2013). Appendix 3 contains information on how arthroplasty participants and matched controls were selected from the complete EPIC dataset.

4.2.3 Recruitment and Eligibility

The inclusion criteria for the EPIC study were:

- People aged between 40 and 79 years
- Registered at one of the participating general practices that participated
- Absence of a history of diabetes, cerebrovascular or cardiovascular disease

For this study, only participants who had undergone a THR between the EPIC second and third health checks were eligible. If the participant reported having undergone a THR during this interval, this was verified in the patient's general practitioner medical notes (n=226). Participants who had undergone a total knee replacement (TKR) were excluded. This was to ensure that any differences could be fully attributed to the THR, as there are differences in outcomes in TKR compared to THR (Jansson & Granath, 2011). The data from the first health check was not used as physical activity data was not collected in this data collection wave.

4.2.4 Matched Cases and Controls

For either case or controls to be eligible they were required to have data on physical activity at both health checks. THR was undertaken after the second health check but no

less than six months prior to the third health check. This was justified as three to six months is considered to be the minimum time period required to fully recover from a THR (NIH, 2013). Therefore, the findings of this study would not be dependent on the stage of recovery participants were following THR surgery.

The THR cases were matched at a ratio of 1:2 to controls. This ratio was appropriate in this analysis to increase statistical power (Hennessy, Bilker, Berlin, & Strom, 1999). The control number was not increased to beyond two as the greatest effect is seen increasing the controls from one to two, whereas the effect becomes negligible when the number of controls increases beyond four or five (Hennessy et al., 1999).

The control participants were within three years of age compared to the cases and of the same gender. This was to negate the potential co-founders of age and gender which have been reported to be associated with changes in physical activity (Caspersen et al., 2000). It has been reported that males undertake more physical activity than females, and that in addition inactivity increases with age. The only exception to this is regular vigorous physical activity increases from 45 to 64 years to the over 75 year old age group (Caspersen et al., 2000). Additionally, environmental factors that encourage physical activity differ between men and women. Sallis, King, Sirard, and Albright (2007) reported that living within a community where there were no unattended dogs and low crime rates encouraged physical activity participation for females and males reporting that seeing other people being physically active was a key factor to encourage increased physical activity participation.

Control participant's health checks were within three months of the case's health checks, to ensure that seasonal changes in physical activity or general health did not affect the case-control comparison (Matthews et al., 2001).

4.2.5 Data Collection

Health Check 2 took place between January 1998 to January 2001. Health Check 3 was performed between September 2006 to September 2007. Participants attended one of the data collection centres in Norfolk where demographic and anthrometric measurements were collected by a research nurse. These measures included: age, sex, height, weight, blood pressure and medical history.

Physical activity data on occupational, recreational and household physical activity were collected using in-person interviews or by completing a standardised physical activity questionnaire, the EPIC Physical Activity Questionnaire (Appendix 4)(Wareham et al., 2002). The validity and reliability of the questionnaire has not been tested in the THR population specifically. In the general population the questionnaire is reliable and well validated, Wareham et al. (2002) reported that the repeatability was high (weighted kappa = 0.6, $p<0.0001$) and both strong association with objectaivaly measured metabolic rate ($p=0.003$) and cardiorespiratory fitness ($p=0.001$). These results were used to calculate the level of physical activity participants undertook (Cust et al., 2008). This composite measure incorporated a number of measures of physical activity including: number of flights of stairs climbed per week, walking to work or for pleasure, duration of total recreational activities and physical activity energy expenditure.

4.2.6 Statistical Analysis

Initially, descriptive statistical analyses were undertaken to determine the mean, standard deviation and frequencies of variables including: gender, age, weight, BMI, diastolic and systolic blood pressure, in addition to the physical activity measures between time-points. The statistical differences of the demographic and physical activity characteristics was determined using dependant t-tests to assess for any differences between the THR group

at Health Check Two and Three. The dependant t-test was used as the measures are continuous variables. The dependant t-test assumes the variance of the two samples are the same. This was confirmed using Levene's Test for Equality of Variance. If equal variance was not assumed, the degrees of freedom of the test would have been adjusted using the Welch-Satterthwaite method.

A forced entry regression model was used to compute a prediction model for change in physical activity between Health Check Two and Three. Forced entry regression modelling was used so that a model with multiple predictors could be computed to ascertain the change in physical activity (Field, 2013). 'Forced' entry was used to ensure that all variables were considered in the model. Significance was set at (p<0.05).

Pre- versus post-THR differences were repeated using only data for participants who had their health checks between six months and two-years inclusively post-THR and six months to one year inclusively post-THR to assess if time since operation influenced physical activity levels. The original analysis plan used only a six month to one year inclusively cut-off post-operatively. However this resulted in only 12 participants being included in the analysis. Therefore an additional sub-analysis of six months to two years was added as this resulted in a substantial increase in the number of included participants (n=65). This sub-analysis was undertaken to analyse how time since surgery may influence outcome post-surgery (Milanović et al., 2013). This was done by comparing the results of the main analysis and the two sub-analyses discussed above.

The complete *a priori* statistical analysis plan for this study is presented in Table *4.1*.

Table 4.1: Statistical analysis plan.

Comparison	Test
Pre-, post-THR differences	T-test to compare difference in the THR group pre- compared to post-surgery
Pre-, post-THR differences sub-analysis	T-test to compare pre- post-THR differences between case and control who had their health check at six to 12 months post-operatively and six to 24 months post-operatively.
Prediction modelling	Forced entry regression model was used to compute a prediction model for any physical activity parameter that were shown to be significantly different in the first analysis.
Graphical analysis	Scatter graphs and correlations of physical activity measures pre- compared to post-THR.

All analyses were undertaken using SPSS (IBM SPSS Statistics Version 22.0, New York, United States of America).

4.3 Results

4.3.1 Demographic Characteristics

A total of 226 cases and 452 controls were included in the analysis. The demographic characteristics of the cases and controls are presented in Table *4.2*. All participant characteristics were broadly similar as would be expected within this population (NJR, 2015). There were more females (59.7%) than males. The mean age of 66 years (standard deviation: 7.0) was broadly similar compared to the average age of operation for THR patients within the UK being 69 years (NJR, 2015).

Table 4.2: Demographic characteristics of case and controls. Presented as mean ± standard deviation, male/female is presented as a count.

	THR (n=226)	Controls (n=452)
Male/Female	91/135	182/270
Age	66±7.0	66±7.0
Weight	77±13	73±12
BMI	28±4.4	27±3.8
Diastolic (n=224, THR group)	84±11	82±11
Systolic (n=224, THR group)	139±18	137±18

The mean level of physical activity at Health Check Two and Three for all four parameters are shown in Table 4.3. The cases and the controls showed similar levels of physical activity both at the second and third health check.

Table 4.3: Mean physical activity for THR and control group at the second and third health check. Presented as mean ± standard deviation.

	Health Check Two		Health Check Three	
	THR	Control	THR	Control
Flights of stairs climbed per week	35.0±35.6 (n=226)	34.1±38.5 (n=452)	28.8±34.9 (n=225)	32.9±39.5 (n=343)
Walking to work or for pleasure (hrs.week^{-1})	2.4±3.5 (n=95)	2.3±3.1 (n=178)	0.35±1.2 (n=36)	0.48±1.2 (n=71)
Duration of total recreational activities (hrs.week^{-1})	8.4±6.9 (n=225)	8.9±7.9 (n=451)	7.2±7.2 (n=219)	9.2±9.7 (n=335)
Physical activity energy expenditure at home, after scaling (MET-hrs.week^{-1})	46.5±29.7 (n=226)	45.3±30.3 (n=452)	47.2±33.4 (n=225)	49.4±31.5 (n=343)

4.3.2 Difference in Cases to Controls at Health Check Three

When comparing the cases and controls at Health Check Three there was a significant change in duration of total recreational activities (equal variance assumed, F=2.8, p=0.093, MD: -2.0±0.76 hrs.week^{-1}, t_{552}=2.6, p=0.01). There was a no significant difference for flights of stairs climbed per week (equal variance not assumed, F=5.9, p=0.015, MD: -4.1±3.2 hrs.week^{-1}, $t_{518.9}$=1.3, p=0.19), walking to work or for pleasure (equal variance assumed, F=1.0, p=0.309, MD: -0.14±0.24 hrs.week^{-1}, t_{105}=0.56, p=0.58)

and physical activity energy expenditure (equal variance assumed, F=0.41, p=0.52, MD: -2.3±2.8 Met-hrs.week^{-1}, t_{566}=0.82, p=0.41).

4.3.3 Predictors of Physical Activity

The predictors for physical activity measures are shown in Table 4.4. For difference in stair climbed per week the significant predictors were: heart attack (ß=-0.45, p=0.004) and stroke (ß=-0.67, p<0.001). Being in the THR or the control group did not significantly predict change (ß=0.54, p=0.73).

The significant predictors for change in duration of recreational activities were weight (ß=-0.76, p=0.034), BMI (ß=2.12, p=0.001), percentage body fat (ß=-1.33, p=0.008) and impedance (ß=1.27, p=0.001). Being in the THR or the control group did not significantly predict change (ß==0.11, p=0.61).

No variable significantly predicted change in physical activity energy expenditure. This included being in the THR or the control group difference in stairs climbed per week (ß=0.54, p=0.73), difference in duration recreational activities (ß=0.11, p=0.61) and difference in physical activity energy expenditure (ß=0.14, p=0.96).

4.3.4 Pre- versus Post-THR

When Health Check Two (pre-THR) data were compared to Health Check Three (post-THR), there was a small but significant decrease in the number of flights of stairs climbed per week (MD: -6.4±28.4, t_{224}=3.4, p=0.001) and walking to work or for pleasure (MD: -1.3±2.3 hrs.week^{-1}, t_{30}=3.1, p=0.004). There was no significant difference in physical activity energy expenditure (MD: 0.8±32.6 Met-hrs.week^{-1}, t_{224}=-0.37, p=0.71) and duration of total recreational activities (MD: -1.1±7.2 hrs.week^{-1}, t_{217}=2.3, p=0.21).

The pre- and post- measure of physical activity correlated on three out of four occasions. Flight of stairs climbed pre-THR was significantly correlated with the number of flights of stairs climbed post-THR (r=0.68, p<0.001, Figure *4.1*). There was a no statistically significant difference in pre-THR compared to post-THR for duration of total recreational activities (r=0.47, p<0.001, Figure *4.2*), physical activity energy expenditure (r=0.47, p<0.001,

Figure ***4.3***) and walking to work or for pleasure (r=0.23, p=0.21,

Figure ***4.4***).

Table 4.4: Results from the regression model of significantly different physical activity measures.

Constant	Beta	*P-Value*
Difference in stairs climbed per week		
THR/Control	0.54	0.73
Asthma	-16.8	0.092
Arthritis	4.94	0.53
Diabetes	-14.59	0.49
Heart attack	-0.45	0.004
Stroke	-0.67	<0.001
Systolic blood pressure	0.19	0.67
Diastolic blood pressure	-0.28	0.64
BMI	4.44	0.20
Weight	-0.10	0.87
Percentage body fat	-1.44	0.075
Impedance	9.15	0.74
Bone mineral density	9.15	0.74
Difference in duration recreational activities (hrs.week^{-1})		
THR/Control	0.11	0.61
Asthma	-1.03	0.76
Arthritis	1.90	0.42
Diabetes	0.97	0.88
Heart attack	0.11	0.99
Stroke	4.19	0.42
Systolic blood pressure	0.30	0.053
Diastolic blood pressure	0.11	0.99
BMI	2.12	0.001
Weight	-0.76	0.034
Percentage body fat	-1.33	0.008
Impedance	1.27	0.001
Bone mineral density	-0.64	0.94
Difference in Physical Activity Energy Expenditure (Met-hrs.week^{-1})		

THR/Control	0.14	0.96
Asthma	-16.41	0.42
Arthritis	6.13	0.71
Diabetes	50.15	0.26
Heart attack	-21.84	0.63
Stroke	24.72	0.48
Systolic blood pressure	-0.92	0.32
Diastolic blood pressure	1.43	0.25
BMI	2.42	0.73
Weight	0.31	0.80
Percentage body fat	2.42	0.73
Impedance	0.25	0.15
Bone mineral density	-47.98	0.40

For the control group, when comparing the data from Health Check Two and Three, there was a small but significant decrease in walking to work or for pleasure (mean difference (MD): -2.01±2.08, t_{62}=7.68, p<0.001). There was a no significant difference for flight of stairs climbed (MD: -2.29±29.02, t_{342}=1.46, p=0.14), duration of total recreational activities (MD: -0.28±9.48, t_{333}=0.54, p=0.59) and total physical activity energy expenditure (MD: -2.72±30.40, t_{342}=-1.66, p=0.099).

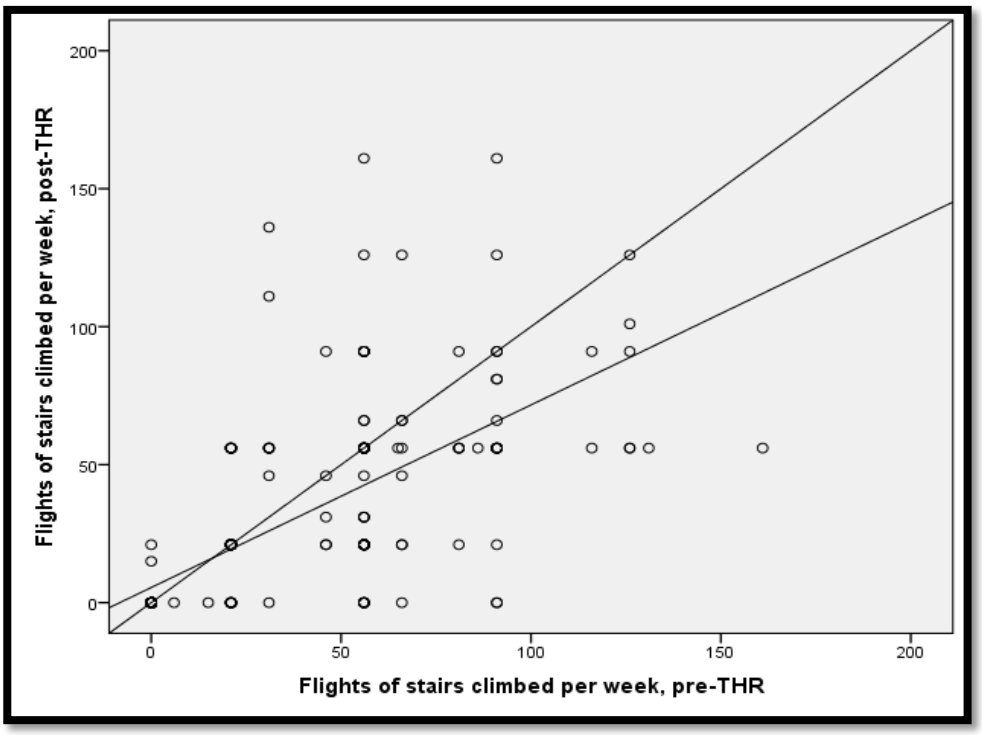

Figure 4.1: A scatter graph to show flights of stairs climbed pre-THR compare to post-THR.

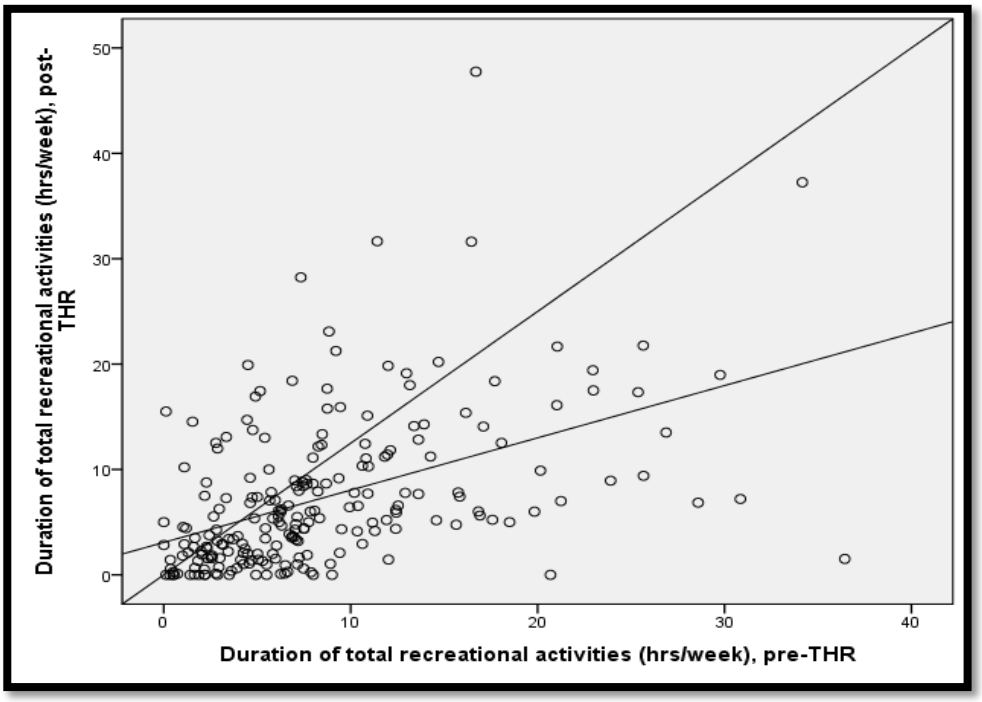

Figure 4.2: A scatter graph to show duration of total recreational activities pre- compared to post-THR.

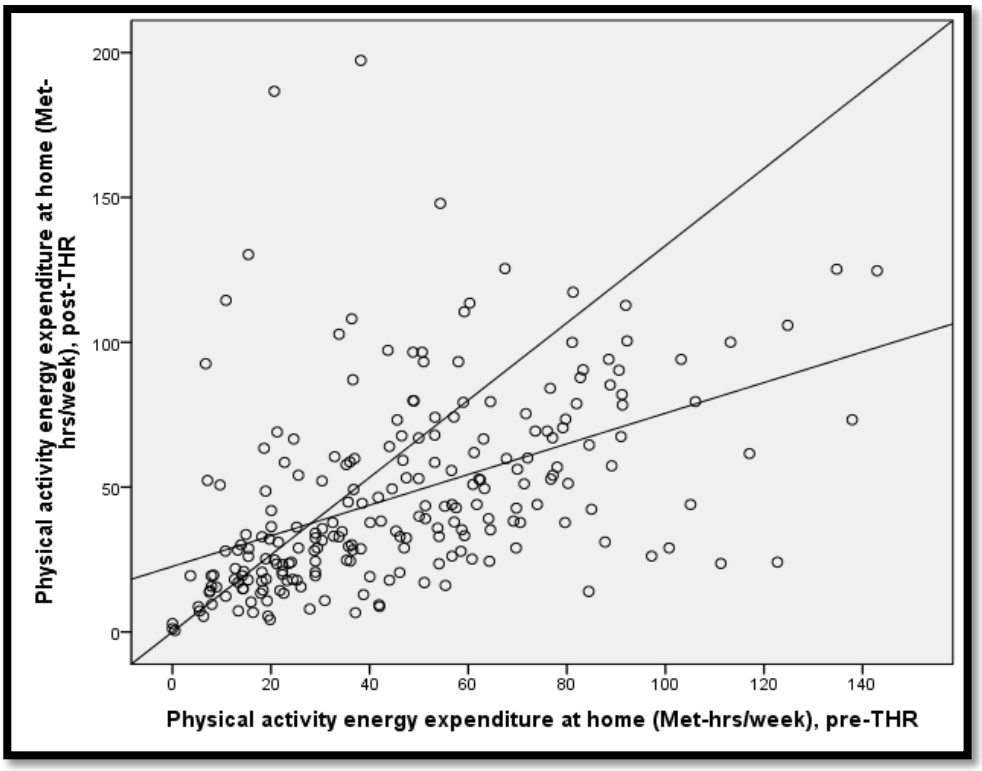

Figure 4.3: A scatter graph to show physical activity energy expenditure at home pre- compared to post-THR.

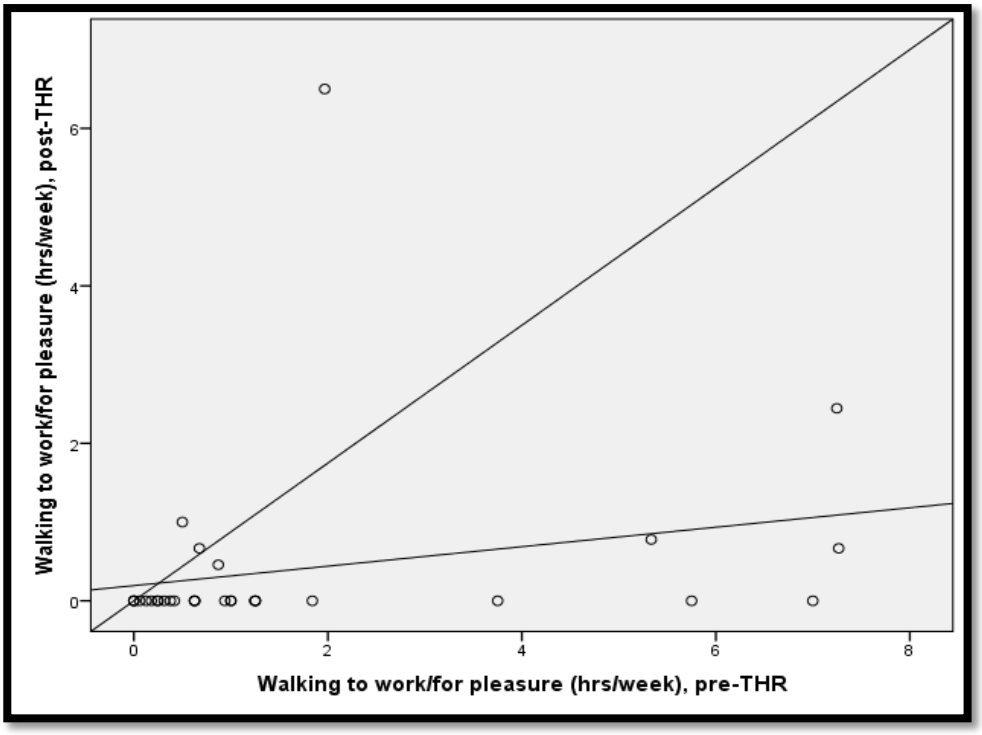

Figure 4.4: A scatter graph to walking to work or for pleasure pre- compared to post-THR.

For participants who had their THR between six months and one year before Health Check Three, there was a no significant difference in flights of stairs climbed per week (MD: 3.8±16.3, t_{11}=-0.80, p=0.44), duration of total recreational activities (MD: -3.4±7.4 hrs.week^{-1}, t_{10}=1.5, p=0.16) and physical activity energy expenditure (MD: 2.2±28.8 Met-hrs.week^{-1}, t_{11}=-0.26, p=0.80). It was not possible to analyse walking for work or for pleasure as only one participant had a complete set of data for this parameter.

4.3.5 Physical Activity Sub-Group Analyses

The sub-analysis of participants who had their THR between six months and two years before Health Check 2 demonstrated a small but significant decrease in the number of flights of stairs climbed (MD: -8.6 ± 26.9 hrs.week^{-1}, t_{64}=2.6, p=0.013). There was a no significant difference in walking for work or for pleasure (MD: 0.78±2.5 hrs.week^{-1}, t_{64}=2.6, p=0.58), duration of total recreational activities (MD: -2.1±8.5 hrs.week^{-1}, t_{60}=1.9, p=0.63)

and physical activity energy expenditure (MD: 1.3±30.8 Met- hrs.week^{-1}, t_{64}=-0.34, p=0.73).

4.4 Discussion

The aim of this study was to analyse physical activity data in people who underwent a THR compared to matched controls from the EPIC-Norfolk study. This was used to assess pre- post-THR change and to compute any potential predictor of physical activity change. The findings indicate that there was a significant decrease in physical activity in two of the four physical activity parameters following THR, those being the number of flights of stairs climbed per week and walking to work or for pleasure. However having a THR is not a significant predictor to physical activity change. Therefore these findings support the notion from previous research that physical activity does not increase post-operatively (Arnold et al., 2016; Di Monaco & Castiglioni, 2013; Withers et al., 2016).

The differences in study outcome between this analysis and previously published findings may be in part due to this being the first nested case control study to analyse pre- compared to post-THR physical activity change. Accordingly, methodological comparison cannot be easily made. The interpretation of these results should therefore be considered in light of the different strengths and weaknesses of this methodological approach compared to that of previous studies which have used more restrictive inclusion criteria and smaller sample sizes (Arnold et al., 2016; Withers et al., 2016).

4.4.2 Study Design

Previous studies have used a number of longitudinal study designs. These could be debated as having either stronger or weaker external validity compared to this study (Arnold et al., 2016). The external validity is a key consideration when considering if the

findings of a study are applicable to the whole of the studied population (Rothwell, 2005). It may be proposed that the nested study design used in this study provides greater external validity than conventional longitudinal cohort studies. As in longitudinal studies, participants have a fully expressed condition such as associated joint pain. Whereas in nested case control studies participants do not. Therefore this is a more realistic representation of participants in the broader demographic. Additionally it is important to consider the differences in participant characteristics being that of the study population and the general population. Although there are no studies that specifically examine the THR population, there is evidence which can be drawn from other clinical specialities. For instance, Aberle et al. (2010) reported from their study of participants attending a lung screening programme, that this cohort were better educated, younger and less likely to be smokers compared to the general population. A study of study attrition characteristics associated in a study assessing spermicide effectiveness, concluded that key characteristics of study attrition were age, marital status and study recruitment at a high versus low recruiting unit (Raymond et al., 2004). Similar findings have been reported by Gades et al. (2006) & Kaiser, Affuso, Desmond, and Allison (2014).

Although there are many strengths of nested case control studies compared to more restrictive study designs, there are also weaknesses in respect to external validity. Principally participants were not asked when they were listed for a THR but instead asked if they had undergone a THR since the previous health check. Accordingly participants in the control group may have been waiting for a THR at either the second or the third health check. This may have therefore not have been representative of a 'true' control group. Nonetheless, the longitudinal, community-based methods meant that on balance, it was suggested that there was strong external validity, particularly due to the nature of the inclusion criteria, the multiple measures of physical activity and the large sample size. Though this study has strong external validity, the purely Norfolk recruited cohort should be considered when applying these results to other populations. Therefore to do this it is

importance to consider the differences and similarities between the Norfolk population and the population which these findings are being applied to.

A number of potential biases may have influenced the finding of this study. These include:

- Selection bias. This is where a study sample has not been selected that truly represents the study population (Coggon, Barker, & Rose, 2009). The bias exists as it relies on participants agreeing to participate in the study. Hegedus and Moody (2010) outlined sub-categories of selection bias in intervention and diagnostic accuracy studies. A number of these are applicable to case-control studies which will be discussed below.

- Authorisation bias. This may have occurred if the release of patient data was not approved by the participant's general practitioner or the participant's treating hospital. It would be unethical to report this for this study (Hegedus & Moody, 2010).

- Berkson's bias. This is when a participant with more than one condition is more likely to be offered an operation therefore leaving in the control group participants who are eligible for an operation but have not been offered it yet due to patients with more severe symptoms taking priority (Hegedus & Moody, 2010). This may have occurred in this study potentially participants that may be potentially eligible to have a THR but as of yet, not offered this procedure.

- Exclusion bias. This may have occurred as the excluded participants may have influenced the results of the study as they may have presented with different characteristics and therefore responses to participants who were included in the study (Hegedus & Moody, 2010).

- Overmatching bias. This may have occurred when the matching criteria for the controls was too specific (Hegedus & Moody, 2010). It is however suggested that this is not the case in this study as the matching criteria for age, sex and date of health check, were criteria that can also influence THR outcomes post-THR. This is also the case for post-hoc analysis bias as there was an *a priori* hypothesis.

- Volunteer bias. This is likely to have occurred in this study. This is where the participants who agree to take part in the study are not representative of the study population as a whole (Hegedus & Moody, 2010). It is not possible to measure volunteer bias beyond comparing study demographic to that of what you would expect in the general population. However this should still be considered when interpreting the results of this analysis.

- Unacceptable disease bias. This should also be considered where participants under-report diseases that they consider socially unacceptable to discuss. These diseases in turn may influence the outcome of the study (Hegedus & Moody, 2010).

- Additionally bias. This can occur if the sample is not sufficiently large enough. However it is suggested with a case-control sample size such as 226 in this case there is a low risk of this occurring. As a small sample reduces the likelihood that a statistically significant result represents a true effect and committing a type II statistical error (Button et al., 2013)

- Recall bias. This is a weakness of nested case-control studies, as the predominately recall based physical activity markers rely on participants remembering what they did (Sedgwick, 2014). As reported by Baranowski (1988)

physical activity recall is a highly complex process. Errors in recall are likely. This therefore should be taken into consideration when considering the implications of the results. However it is suggested that this influence is minimal. Additionally Taylor et al. (1984) study of 12 participants showed that although subjects reported longer durations at higher intensities activities, there was no significance difference between reported and self-reported (p>0.05). It is therefore suggested that recall bias may have had less of an effect on this study because it has been previously shown that activity recall. Additionally it is suggested that the potential effect that recall bias has on the results will be further mitigated by the error being constant across case and control groups.

- Social desirability bias. This may affect outcomes where participants provided answers to questions that they perceive to be more socially desirable than what occurred. Adams et al. (2005) showed in a study of 81 female participants, that social desirability over-reporting physical activity when compared to an activity monitor which resulted in an over reported of physical activity by 0.65 kcal.kg.day^{-1} (Confidence interval (CI): 0.06-1.25 kcal.kg.day^{-1}). They also reported an over-estimated duration of activity by 4.15-11.30 minutes.day^{-1}. Therefore it is suggested that reporting physical activity is likely to be an over-estimation although there is no evidence to suggest that there is variation in the over-estimation.

It is important to consider how the biases mentioned above may influence the outcome of this study. It is proposed that the above biases may suggest that participants have undertaken more physical activity than they actually did and compared to that of the whole population. It is also suggested that study participants will be more active and have less co-morbidities compared to that of the whole THR population. It is also important to consider how the time since data collection may have affected the outcome of the study; data collection commenced in 1998 and ended in 2007. It is suggested that in the case of

this study the time since data collection will have little effect on the relationships reported as there have been no large changes in post-operative rehabilitation programme or participant characteristics within the subsequent years.

4.4.3 Research Implications

Due to this study being a nested case-control study, the results can only make inferences or associations and not causation (Sedgwick, 2014). This is because not all of the variables are the same across both the THR and control group, and it is not possible to control all of the variables that may influence physical activity. Therefore although it can be hypothesised that THR may be the process that causes the significant change in physical activity (or not) as the regression analysis suggests, this should be considered with a reasonable degree of caution. A sufficiently powered longitudinal study with a single intervention where all relevant variables are appropriately controlled would be needed to ascertain causality.

Additionally it should be noted that accurate assessment of external validity is a complex challenge, especially as it relies on experience rather than statistical expertise (Rothwell, 2005). Therefore the author proposes that the external validity for this study is strong due to the broad exclusion and inclusion criteria, particularly as the age restrictions that were applied are relevant to the THR population. A weakness of the study however in respect to external validity is that all of the study participants were from Norfolk so the findings should be generalised to other settings with caution. For example compared to the rest of the United Kingdom, the East of England have lower crime rates and a higher average salary (Corke & Wood, 2009). Both factors may influence physical activity behaviour (Adams et al., 2005; Bauman et al., 2012).

It may be suggested that the significant decrease in physical activity demonstrated in this study is due to age-related decline in physical activity (Milanović et al., 2013). This research suggests that this may be the case as only one measure of physical activity was significantly different pre- compared to post-THR if the operation was within two years of the final health check and none if the restriction was reduced to one year. This finding is expected in the male and elderly population, rather than in females. Milanović et al. (2013) showed that physical activity decreased significantly (p<0.05) from 60 to 69 years to 70 to 80 years for men measured using the eight-foot up and go, arm curl and two-minute step test. However only the eight-foot up and go and arm curl were significantly decreased for ladies (Milanović et al., 2013). Additionally there was only a significant decrease in one parameter, walking for work or pleasure, in the control group from the second to the third health check. Therefore this finding potentially suggests that THR may increase the rate at which physical activity decreases with age.

The regression model of physical activity change did not predict whether having a THR or not was a significant variable (p>0.05). However BMI was a significant predictor (p<0.05) for difference in duration of physical activities. Body mass index has also been reported to increase following THR (Jain, Roach, & Travlos, 2003). Therefore, although having a THR does not directly influence physical activity it is suggested that it does indirectly influence physical activity due to its association with BMI. This supports the argument that physical activity should be encouraged in people following THR.

4.4.4 Clinical Implications

The key clinical conclusion from this study was that physical activity does not increase following THR. However before applying these finding to the general clinical population it is important to consider a number of factors. Firstly, the EPIC study was designed for a cancer cohort. Therefore the appropriate exclusion criteria were applied for this purpose,

for example excluding individuals who had a history of cancer. The validity for this study was not as optimal, as potential participants with a history of cancer were excluded. As the prevalence of Cancer is 168.8 per 100,000 (NIH, 2013), it would be suggested that this weakness is only minimal. Also considering that normally if a patient has cancer and is listed for a THR the operation would be delayed until the cancer is treated. Secondly, there was a paucity of information in respect to participant's operations, operative complications and indication for surgery. Consequently, the clinical application of these finding was potentially more challenging. As it is not clear what subgroups of the THR population these results can therefore be applied to.

Thirdly data collection for this study occurred between January 1998 and September 2007, it is therefore important to consider how both in-hospital and post-hospital care may have changed in the preceding years. The only noticeable change that has occurred is an improvement in surgical outcome (NJR, 2015) particularly a decrease in revision rates. It could be suggested that an improvement in surgical outcome would also result in an improvement in post-surgical physical activity. However there is suggestive evidence that pre-operative exercise therapy may benefit post-operative outcome (Valkenet et al., 2011). Valkenet et al. (2011) demonstrated that pre-operative inspiratory muscle training significantly predicted pulmonary complications after cardiac or abdominal surgery (MD: 0.40 95% CI: 0.23 to 0.72, I^2=0%). However there was no significant difference for both pre-operative exercise therapy for both post-operative complications (MD: 0.59 95% CI: 0.25 to 1.41, I^2=0%) and length of hospital stay (MD: -0.09 95% CI: -0.55 to 0.37, I^2=0%) after joint replacement. More research is needed to better understand the potential effect of physical activity on surgical outcome.

Considering the findings, it is suggested that clinicians should consider that there is compelling evidence that physical activity does not improve following THR. Therefore if not already implemented, patients should be encouraged to be more active following THR. This may be achieved by modifying the advice currently being given to patients or sign-

posting patients in the direction of appropriate exercise and/or fitness classes, such as health walks or gym sessions for older people. Additionally, it is also important to consider whether it would be appropriate to target any physical activity interventions to a particular proportion of the population. This could be done by either targeting patients that would partially benefit increasing their physical activity levels or patients that would be particular receptive to undertaking such an intervention. There may be overlap between these two groups.

4.5 Conclusion and Summary

This study has demonstrated that physical activity does not increase following THR. However it is not clear whether this is due to the processes of natural ageing, having a THR or the risk factors associated with THR. Further research is warranted to better understand the demographic characteristics that result in physical activity change pre-compared to post-THR. There is an additional need for a novel intervention to be developed to increase physical activity levels within this population. An intervention that is successful would have a dual benefit: (1) improving the levels of physical activity amongst the THR population and (2) decreasing the volume of inactivity related-illness within the THR population.

Building on the findings of this study and the preceding systematic review chapter, the remainder of this thesis will examine the feasibility testing of a novel intervention to increase physical activity within the THR population.

Chapter 5 Feasibility Randomised Control Trial Methods

5.1 Introduction

The previous chapters have demonstrated the importance of people adopting and maintaining a physically active lifestyle, strategies to promote it and the benefits of THR surgery. The systematic review in Chapter Three reported no significant change in physical activity between pre- compared to post-THR. Chapter Four confirmed that there is no improvement in physical activity pre- compared to post-THR and that certain measures demonstrated a decrease in physical activity. This evidence suggested that interventions are needed to increase physical activity levels in individuals following THR.

This chapter will discuss the methods used in a feasibility randomised control trial (RCT) that aimed to evaluate a pedometer-prescribed walking intervention to increase physical activity following THR.

5.2 Protocol Registration

The study protocol was registered on the ISRCTN registry (ISRCTN16250771). This is an open access randomised control trial registry. Although the registration of this study was not explicitly required by the funders (the University of East Anglia), registration nevertheless had a number of benefits. It decreased the chance of similar research being conducted, assuming that other research groups searched for the registered study. This reduces the risk of duplication of work. It also enables the readers of the research to compare the protocol reported in the research article to the protocol before the research began (Chan, Hróbjartsson, Haahr, Gøtzsche, & Altman, 2004; Mills, Wu, Gagnier, & Devereaux, 2005), thereby increasing the transparency of reporting any protocol deviations which may have occurred during the conduct of the study. It also ensured that

any publications from this research project complied with Guideline 35 of the Declaration of Helsinki, every research study involving human subjects is recommended to register in a publicly accessible database before recruitment of the first subject (World Medical Association, 2013). A number of leading journals in the field of medical research will not publish a clinical trial unless it has been registered before the first participant has been recruited (DeAngelis, Drazen, Frizelle, & et al., 2004). The protocol approved by the ethics committee is presented in Appendix 5 and the ethics approval letter is presented in Appendix 5.

5.3 Research Questions

The research questions for this study are listed below:

1. Is the proposed method of prescribing a pedometer-based walking intervention a feasible intervention for the THR population?

It has been previously shown, in a number of different populations, that prescribing physical activity results in a greater increases than simply informing patients to do more physical activity (Jones & Rose, 2005).

2. Is the provision of a pedometer-prescribed walking programme associated with a change in quality of life?

It has been shown in other populations that increasing physical activity also improves quality of life. It is proposed that this could also occur in the THR population (Belardinelli, Georgiou, Cianci, & Purcaro, 1999; Painter, Carlson, Carey, Paul, & Myll, 2000).

5.4 Patient and Public Involvement Consultation

In line with the Medical Research Council guidelines for complex interventions (Craig et al., 2008), a proposed protocol was discussed with a patient focus group at an early stage for public consultation (11th December 2013). This aimed to seek patient and public opinions. Involving patients and the public in research design ensures that the research is relevant to patients (Thompson, 2007). It may highlight challenges and provide solutions that the investigators may not be aware of or realise (Thompson, 2007).

An early draft of the protocol was presented to the patient and public involvement group. The patient and public involvement group consisted of six members of the public who had a general interest in orthopaedic research, have had or were on the waiting list for a THR, or a close relative or friend who had had a THR. A short summary of the study was presented to the members of the group which was followed by a discussion led by the researcher. The original protocol compared normal care to no hip precautions, with the aim of examining the effect on physical activity levels through the removal of hip precautions. Hip precautions are movement restrictions that are placed on patients and aids to reduce hip movement post-THR.

The focus group's overall opinion of the original research was that it was a worthwhile research project but they felt it may be particularly challenging to recruit participants for this study, as the intervention involves taking something away. The focus group suggested that this research project was 'too soon' and that an initial research investigating interventions to increase physical activity using a method that involves 'giving' the intervention group something, may be preferable. The focus group suggested ways in which, in their opinion, this affect could be mitigated and aired other questions about the research. These are listed below:

- Ensure that the potential health economics benefit of the study was mentioned but it is made clear that this was not the main reason why the study was taking place.

- Will not giving hip precautions result in the patients modifying their behaviour to avoid excessive pain. For example, will this result in patients not going to the toilet as often as perhaps they would regularly?
- Stress the lack of the information with regards to the use of hip precautions and that the point of this study was to clarify their use.
- Consider the burden that this study will put on the close family and friends of the participant and how this can be mitigated.
- How was the study going to control the provision of hip precautions through other means?
- Consider the effect that waiting list time may have on physical activity.
- Would it be appropriate for there to be a 'pilot' study initially to assess the appropriateness of the study?

5.5 Intervention Rationale

Taking into consideration the feedback from the focus group on the originally proposed study, the intervention was revised. A targeted pedometer-prescribed walking intervention was proposed as the physical activity intervention. In this instance the participants in the intervention group would be given a pedometer and a targeted number of steps to achieve. The reason for choosing a pedometer-prescribed walking intervention is discussed in greater detail in Section 5.12.2. The change was therefore as a direct response to the patient and public involvement panel's recommendations, whilst also answering a question which was generated from Chapters Three and Four on physical activity profiles in people following THR.

5.6 Study Design

This study was a two-armed feasibility RCT where participants were randomly allocated to a treatment as usual or an experimental exercise intervention arm. An RCT was chosen over other experimental designs as it is the gold standard design to test interventions (Akobeng, 2005). The reason why an RCT is the gold standard is due to its ability to minimise selection bias to the greater extent than other study designs (Roberts & Torgerson, 1998). This therefore makes it more likely that known and unknown baseline characteristics that may or may not affect the outcome of the trial, such as: sex, age, weight and height are equal between the two study groups (Akobeng, 2005). For this study, patients were individually randomised to study arms as opposed to cluster randomised as the risk of group contamination was considered to be low. This was justifiabile as there was no group care delivered post-THR. It was thought unlikely that participants allocated to different groups would meet during the study. As during the participants hospital stay, study participants were not exclusively treated together, instead they were treated as general orthopaedic patients. No study participant was in the same place at the same time, further reducing contamination risk.

5.7 Inclusion and Exclusion Criteria

The study inclusion and exclusion criteria are presented below. Potential participants were required to meet all of the inclusion criteria.

<u>Inclusion criteria:</u>

- Potential participants were on the waiting list for a primary unilateral, elective, THR Participants had not previously undergone joint replacement.
- Potential participant were 18 years of age or older

- Potential participant were able to walk at least 10 meters pre-operatively.

Unilateral THR were chosen as the outcomes following bilateral surgery differ. Bilateral THRs are less common, representing 0.6% of the total number of THRs recorded (NJR, 2015). Elective patients were only considered, so there was sufficient time to consent participants before surgery. In addition to ensure that the study outcomes were not influenced by the process of skeletal maturation, (Lin, Brown, & Walsh, 1994) participants had to be over the age of 18. Additionally as the physical activity requirements differ for over 18 (150 minutes a week) to under 18 year olds (60 minutes a day) (Department of Health, 2011), we excluded those aged less than 18 years.

This study only assessing change in ambulatory patients. Ten metres was chosen as an arbitrary figure to ensure that participants are able to ambulate more than moving from sitting to sitting somewhere else.

The exclusion criteria are summarised below.

<u>Exclusion criteria:</u>

- Participants unable to give informed consent.
- Participants scheduled for two different procedures combined together in one operation for example THR followed by bunion removal.
- There is a known reason why a participant should not take part in physical activity or exercise.
- Participants who lived in a care home.
- A reason a participant was unable to receive a THR due to a diagnosis of cancer.

Participants who lived in a care home were excluded from the study as it has been previously shown that the significant differences in social environment between living in a care home and other forms of living have an effect on physical activity participation (Saelens, Sallis, Black, & Chen, 2003). In addition, participants who undergo a THR due to cancer were excluded due to the significant differences in the pathophysiology of cancer being different to the vast majority of other conditions where THR is indicated (Kumar & Clark, 2012; NJR, 2014). Furthermore the recommendations on physical activity participation for people diagnosed with cancer differs to that of the majority of people post-THR (Moore, Durstine, & Painter, 2016). Potential participants who had a contraindication to exercise, as defined by the American College of Sports Medicine were excluded from the study (Gibbons et al., 2002). An alternative method would be to use the PAR-Q (Thomas et al., 1992). However as a past medical history would have already been taken to check if the participants fulfilled some of the other inclusion criteria, like this being there first joint replacement, it was decided to use this to check for contraindication of exercise to save the participants the need of filling out an additional form.

5.8 Change from Definitive to Feasibility Randomised Control Study

Initially it was proposed that this trial would be a definitive RCT. Therefore a sample size was initially calculated for this study to ensure that neither too few or too many participants were recruited (Jones, Carley, & Harrison, 2003).

Using the method detailed by Jones et al. (2003) and the data presented by Restrepo, Mortazavi, Brothers, Parvizi, and Rothman (2011) and Talbot, Brown, and Treble (2002) on the Oxford Hip Score (OHS), five point and 10 point difference were computed for difference between the means and standard deviation respectively. This therefore provided a standardised difference of 0.5 if power levels were set at 0.8. This provided a group sample size of 64 and a study sample size of 128. It was assumed that the study may experience a 20% drop-out rate, due to there being relatively little participant

commitment. Vissers et al. (2011) the most recent THR study to use accelerometers reported a 0% drop out rate, therefore the 20% was consider a generous assumption. The aim was therefore to recruit 160 participants.

However, by October 2015, it became clear that the study was poorly recruiting and the feasibility of a pedometer-based walking intervention was questionable despite pre-trial expectations. A study design change was implemented and approval by the awarding ethics committee was obtained for this major amendment (Appendix 7). This change was to introduce a study feedback questionnaire and changed the focus of the trial from a definitive trial to a feasibility study. Also due to the feasibility nature of the trial, the power calculation became obsolete as the focus of the trial changed from testing the effectiveness of an intervention, to one of assessing the feasibility of a study design (Eldridge et al., 2016).

Using a confidence interval based method described by Cocks and Torgerson (2013) which showed using a one sided confidence interval and power of 0.8, the minimal sample size need for such a study should be at least 9% of the sample size needed for a definitive trial. Therefore for this trial, six participants per group (64×0.09) would be the minimum number of participants needed per group. It was felt that recruiting to a trial with a total aim of 12 participants may not fully explore the feasibility of this intervention. Therefore 20% of the overall sample size was adopted which resulted in a target recruitment of 13 participants per group (64×0.2) which considering the proposed dropout rate of 20%, provided an overall recruitment target of 32 participants ($(13 + 13) \times 1.2$).

Finally, following the change in study design, a revised list of study objectives were developed to align to the objectives of a feasibility study. These objectives were:

- To test the recruitment of participants to the study

- To test the acceptability of randomisation for participants onto the study
- To assess the adherence and fidelity of participants to the experimental intervention.
- To explore the acceptability of the outcome measures to study participants
- To determine the level of missing data at each data collection interval, recorded during the six month follow-up interval

5.9 Participant Recruitment

The Norfolk and Norwich University Hospital (NNUH) and Spire Norwich, subsequently referred to as 'Spire,' were approached and agreed to participate in the study. The NNUH and Spire were first approached to take part in the study as previous rehabilitation studies had successfully recruited from the NNUH. Spire was added as a proportion (n=540, 42%) of NNUH patients are transferred to have their operation at Spire, based on 2012 figures.

Participants were recruited from the NNUH and Spire Norwich. All participants recruited to this study had their initial consultation at the NNUH. However a proportion of patients were offered for their care to be provided by the Spire hospital team. The exact rationale and parameters for offering specific patients this choice was not publically available. However these participants appeared to have fewer co-morbidities and the operation was considered a non-complex THR for surgeons.

Initially a letter was sent to all potentially eligible participants. Individuals who were interested in participating in the study were asked to return the second page of an invitation to participate using a provided pre-paid envelope.

At the pre-operation clinic, the eligibility of the participants to participate in the study was verified. If a participant was still eligible and was willing to participate, they were then

asked to sign a consent form. The pre-operation clinic was chosen as the location for consent to occur as it was convenient for the participant, given they were already present in the hospital. The consenting process took under 20 minutes.

5.10 Consent

Participant consent was obtained at the pre-operation clinic where their eligibility to participate in the study was verified and any questions which participants may have had were answered. Consent was obtained pre-operatively so difference in pre/post-operation physical activity could also be noted. Consent was taken at a time during the pre-operation clinic when the patient had opportunity to ask questions. This was either after the pre-operation clinic had finished or at a point during the clinic to avoid the potential for participants having to waiting for extended periods of time.

5.11 Randomisation

Participants were block randomised by the researcher, in blocks of eight after they had been consented using a computer generated eight-point integer random number table. A block size of eight was used as it is a multiple of two, and it is at the upper limit of two, four or eight suggested by Suresh (2011). This was to mitigate the potential problem of block randomisation allowing the researcher to ‘guess’ the allocation of the next participant. Additionally block randomisation was chosen to ensure that the number of participants in each arm was equal (Efird, 2011). Participants with an even random number were allocated to the control group and participants with an odd number were allocated to the exercise prescription group. An example of how the random number table was used is shown in Table 5.1.

Table 5.1: Example of how the random number table was used to randomise participants.

Participant	Random Number	Group Allocation
1	1	Exercise group
2	9	Exercise group
3	8	Control group
4	6	Control group
5	4	Control group
6	3	Exercise group
7	5	Exercise group
8	2	Control group

Randomisation was not stratified by hospital site the patients were recruited from the same demographic pool and followed the same surgical and post-operative recovery programme. Participants were told of which group they were allocated to once consent had been obtained.

5.12 Intervention

As previously noted, this study was a two-armed feasibility RCT. The control arm received treatment as usual, whilst the intervention group received usual care in addition to a pedometer-prescribed walking intervention.

5.12.1 Routine Rehabilitation

Participants in both groups received the standard rehabilitation programme which commenced Day 0 post-operatively with sitting on the edge of the bed, to attempting to stand and walk using an appropriate walking aid. This was then repeated at least once daily for the duration of a participant's hospital stay. The participants were then progressed in walking distance and aid dependency from one frame, to two elbow crutches or two sticks. Step and stair practice was undertaken when appropriate. Progression was determined by the ward physiotherapist, dependent on patient

performance. Patients were encouraged to mobilise throughout the day, either independently or with the assistance of nursing staff. Assistance in standing and mobilisation was provided by the ward physiotherapist and an appropriately qualified assistant if necessary. Before discharge, participants were provided with generic advice to encourage physical activity post-THR but no specific exercises or regimes were provided. Both hospitals used the same post-operative rehabilitation pathway (Smith, McCabe, et al., 2012), that complied with the relevant guidelines (College of Occupational Therapists, 2012).

5.12.2 Control Group

The control group received usual care rehabilitation, as described above, with no additional rehabilitation interventions.

5.12.3 Experimental Pedometer-Prescribed Walking Intervention Group

The experimental group received the usual care as described above in addition to a pedometer-prescribed walking intervention. In this, participants were asked for two days a week to wear a pedometer and to aim to complete given number of target steps. Two days was chosen as there was a wish to ensure that the participants could achieve this number of steps during their recovery. The target number of steps that participants were asked to aim for is presented in Table 5.2. There is no conclusive evidence to support the calculated number of target steps but a focus group of physiotherapists were consulted whilst designing the intervention. They considered that 300 steps was a reasonable number to achieve in the first week. Furthermore 10,000 is generally considered to be the minimum number of steps needed as part of a healthy lifestyle (Tudor-Locke & Bassett Jr, 2004). It has however been suggested that it is not enough steps in an older population (White et al., 2013). Nonetheless a ceiling target of this was deemed appropriate.

If the participant contacted the research team and felt that they were unable to achieve the target number of steps, their target number of steps were reduced by no more than 15%. For the number of steps to be decreased, the participants must have: failed to reach the target number of steps for at least three weeks and wished to change their target to a lower target. Persinger, Foster, Gibson, Fater, and Porcari (2004) noted the importance of setting achievable goal when prescribing exercise. Accordingly participant targets were decreased if they were not achieving them. Goal setting is a recommended method for behaviour change in the healthcare setting (NICE, 2014). However it is acknowledged important that goals are achievable so participants feel that they care achieve these, otherwise they are likely not to attempt to achieve them (Bodenheimer & Handley, 2009).

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Table 5.2: Exercise prescription for participants allocated to the experimental treatment intervention.

Week post-surgery	Target Steps (per day)	Per cent increase compared to previous non-active recovery week
1	300	
2	330	10
3	363	10
4	399	10
5	363	Active recovery
6	459	15
7	528	15
8	607	15
9	698	15
10	607	Active recovery
11	838	20
12	1006	20
13	1207	20
14	1448	20
15	1207	Active recovery
16	1810	25
17	2263	25
18	2828	25
19	3536	25
20	2828	Active recovery
21	4596	30
22	5975	30
23	7768	30
24	10098	30

Participants allocated to the intervention arm were also asked to record how many steps they actually undertook on a given day. Participants were reminded that these were a target number of steps, and it was desirable but not imperative they reached or exceeded them. As the purpose of this intervention was to facilitate increased physical activity and not to achieve a given amount of physiological change. Over-achieving in respect to steps performed was considered acceptable.

When setting pedometer-based walking targets in this and any population, it is also important to consider the validity of the intervention. In this instant, this refers to how well actual number of steps taken correlates with the number of steps taken displayed on the pedometer. It is proposed that the validity of a pedometer in the THR population is poorer than in the general population. This is because it is widely reported that both pre- and post-operative gait in patients following THR is atypical (Bennett, Humphreys, O'Brien, Kelly, Orr, & Beverland, 2008; Foucher, Hurwitz, & Wimmer, 2007; Wall, Ashburn, & Klenerman, 1981). Foucher, Hurwitz, & Wimmer, 2007 showed that post-operative gait adaptation still being present one year post-operatively in clinically well-functioning patients noting that pre- and post-operative range of movement, peak adduction and external rotation were all significantly correlated ($p<0.02$), suggested a potential learned effect. These finding were supported by a later study (Bennet et al., 2008) which showed that even the youngest THR patients do not return to normal gait kinematics up to 10 years post-operatively.

5.12.4 Rationale of the Pedometer-Prescribed Walking Intervention

A pedometer-prescribed walking intervention was chosen as the method to increase physical activity for three reasons:

(1) It is a relatively cheap intervention, approximately £10 per patient, compared to other forms of exercise prescription. Therefore it could be cost-effective or cost-neutral more easily compared to other more expensive interventions such as a supervised gym class.

(2) Pedometer-prescribed interventions have been previously undertaken in other populations (Bravata et al., 2007; Vallance, Courneya, Plotnikoff, Yasui, & Mackey, 2007). Due to the marked demographic differences that are seen in the THR population, it is suggested that it would be inappropriate to assume that such an intervention would also work in the THR population. Mainly due to the barriers to physical activity that have been reported in the THR population (Smith et al., 2015). It is therefore suggested that there is a need to explore this pedometer-prescribed walking intervention in the THR population.

(3) Walking is the most common exercise performed by people aged 65 years and over (Natural England, 2006). Given the average age people undergo primary THR is 69 years (NJR, 2015), a walking-based intervention was deemed appropriate to investigate for this population.

A key component of exercise prescription is periodisation (Garrett & Kirkendall, 2000). This has been commonly used in high performance sport since 1974 (Krüger, 1974). It has been less commonly used in clinical settings (Kell & Asmundson, 2009; McNeely, Peddle, Parliament, & Courneya, 2006). The concept of periodisation is a central concept of training theory and is based on the principals of splitting the training or physical activity intervention into blocks of a smaller time periods to maximise physiological gains of the intervention (Bompa & Haff, 2009). The key benefits of periodisation are reduced risk of overtraining and ensuring optimal physiological gain from the exercise programme (Fry, Morton, & Keast, 1992; Matthew R Rhea & Alderman, 2004). Periodisation has not been previously used in the THR population. The most recent systematic review of the literature on periodisation (Lorenz, Reiman, & Walker, 2010) concluded that there is very little information on periodisation in the rehabilitation literature. Rhea *et al.* (2003) showed in a

study of 68 healthy participants that the effect of repeat linear periodisation, increasing volume and gradual decrease in intensity, showed a greater effect size (0.27), compared to a constant linear progression of both variables (-0.02). The key recommendation from this study was that a training programme with a constantly increasing volume is optimal for improving local muscular endurance. This recommendation is important for the THR population as following the operation, there is a need to improve local muscular endurance of the hip due to both the muscular damage that occurs during the surgery, and the detraining effect of physical inactivity and pre-operative chronic pain (Lobo, Carvalho, & Santos, 2011)

Accordingly, a pedometer-prescribed walking intervention with periodisation was deemed a highly appropriate and novel intervention to test within this clinical setting for people post-THR.

5.13 Outcome Measures

A total of five outcome measures were used in this study, four questionnaires and accelerometry. The questionnaires used are presented in Table 5.3. In addition to this all patients, notes were checked for any major or minor adverse events, which may have occurred during the study.

Table 5.3: Questionnaires to be used in the study

Questionnaire	**Domain**
Oxford Hip Score	Outcome measure following THR.
EQ-5D-5L	Provides a single value for health status.
Global rating of change scale (GRCS)	Patients based opinion in change in health.
Physical Activity Scale for the Elderly (PASE)	Estimate of physical activity for the elderly.

5.13.1 Oxford Hip Score

Background and Development Psychometric Properties

The OHS (Dawson, Fitzpatrick, Carr, & Murray, 1996) is a 12-item questionnaire which provides a single measure of outcome following THR or revision THR revision. It was developed from a cohort of 185 patients who underwent THR or revision THR. The psychometric properties of the OHS are presented in Table 5.4.

Table 5.4: Example of psychometric properties definition modified from Dawson et al. (1996).

Property	**Standard**
Internal consistency	Cronbach alpha = 0.84 and 0.89 pre and post operatively respectively
Test-retest reliability	Coefficient of reliability 7.27.
Construct validity	Correlated moderately with the Charnley score (Charnley, 1972).
Responsiveness/Sensitivity to change	Patients report a very substantial improvement in health status at 6 months. The effect size was also larger than for SF-36 or the Arthritis Impact Measurement Scale.

Each item of the 12 items of the OHS have five possible responses. It is scored out of 60 where each item is scored one to five, one representing the response of least restriction and five the most. The maximum score and least restriction is 48 $(60 - (1 \times 12)$, and the minimum score and most restriction is 0 $(60 - (5 \times 12)$. The following ranges have been applied to provide an indication of severity: 0 to 19 may indicate severe hip arthritis, 20 to 29 may indicate moderate to severe hip arthritis, 30 to 39 may indicate mild to moderate hip arthritis and 40 to 48 may indicate satisfactory joint function (Dawson et al., 1996).

Initially, both the OHS (Dawson et al., 1996) and the Western Ontario and McMaster Universities Index (WOMAC) (Bellamy, 2008) were considered to measure hip health in this study. Though the WOMAC provides more detail than the OHS as it is a multi-

dimensional measure assessing pain, stiffness and function, it was disregarded because it is not a specific outcome questionnaire for the hip but instead has been validated for people with osteoarthritis only (Bellamy, 1988). Additionally the OHS is routinely collected as part of the National Joint Registry (NJR) core outcome measures. The use of questionnaires that are also used in the NJRimproves the external validity of the research and therefore ensures the research can be more widely disseminated.

Summary

To conclude the OHS was a validated outcome measure for the THR population (Dawson et al., 1996), and is also the used by the NJR. Consequently this was the measurement tool used to assess hip health.

5.13.2 Physical Activity Score for the Elderly

Background and development psychometric properties

Physical activity levels were assessed in this study since they are a key component of healthy lifestyle (Department of Health, 2011). A number of questionnaires have been developed to assess this domain. When considering which questionnaire to use to assess physical activity, it was important to consider the parameters that the questionnaire has been validated against. The key parameter to consider when considering the THR population was that this population are predominantly elderly. Therefore physical activity performed is largely at a lower intensity compared to a younger population (Forsen et al., 2010). Finally, since the objective of this study was to test an intervention aimed at increasing physical activity, it was important to assess physical activity as a specific outcome. Thus this would assess whether the desired treatment goal was achieved through this intervention. Therefore for this study, the Physical Activity Score for the

Elderly (PASE) was the physical activity questionnaire used as it is designed for the over 65 year olds (Washburn et al., 1993).

The PASE was developed by analysing the results of 40 previous publications on questionnaire assessment used for physical activity (Washburn et al., 1993). The draft version of the PASE was then pilot tested on a group of 36 elderly people (over 65 years old). It was further developed when participants were asked further about the draft PASE (Washburn et al., 1993). This processes resulted in the final PASE scale used today, with a minimum score of zero and no defined maximum score, due to hours worked paid or voluntary directly contributing to the overall score (Washburn et al., 1993).

The data that the PASE scale was based on was collected in 1980 in Massachusetts. It is one of the few physical activity questionnaires that has considered the effect of population socio-economic status on physical activity using a stratified sampling method (Washburn et al., 1993). Change in PASE score has also significantly correlated to temperature (Matthews et al., 2001). The PASE therefore echoes the seasonal change that is seen in physical activity levels (Matthews et al., 2001).

The PASE scale has been previously used in THR research (Whitney, 2002). However no information has been reported on its psychometric properties for the THR population. Though Washburn et al. (1993) presented evidence to suggest that the PASE is sufficiently validated in an elderly population. It must also however be taken into consideration that this scale has been poorly validity for use with patients with osteoarthritis (Svege, Kolle, & Risberg, 2012). Svege et al. (2012) using the Norwegian version of the PASE scale used in a group of patients with hip osteoarthritis showed moderate test-retest reliability (ICC = 0.61, $p<0.01$). There was however a large standard error of measurement (31). The minimal detectable change was 87 points, and the limits of agreement for the lower score was -65 and upper was 100.

However a significant consideration for this study was that it is highly likely that not all participants were over 65 years old, although the median age of patients who had THR in 2012 was 69 years (IQR 61-76 years) (*National Joint Registry 10th Annual Report 2013*, 2013). Though this may be seen as an experimental risk, physical activity was also evaluated using accelerometry so two measures of physical activity were collected. It was therefore considered important to use an age-relevant questionnaire, especially in the older population, as previous research has shown that non-age specific physical activity questionnaires are less valid in the older population (Shephard, 2003).

Table 5.5: The psychometric properties of the PASE scale modified Washburn et al. (1993)

Property	**Standard**
Internal consistency	Not stated
Test-retest reliability	ICC: 0.75 (95% CI 0.69-0.8)
Construct validity	Grip strength r=0.37 Static balance r=0.33 Leg strength r= 0.25 Resting HR r=-0.13 Age r=-0.34 Perceived health status r=-0.34 Overall sickness impact profile score r=-0.42
Responsiveness/Sensitivity to change	Not stated

Summary

The PASE is a validated questionnaire for an older population, although not validated specifically in the THR population. Multiple measures are being used to measure physical activity and therefore assessing physical activity using an age-related questionnaire was deemed appropriate.

5.13.3 EQ-5D

The EQ-5D is a standardised instrument for use as a measure of health outcome. It is non-disease specific (EuroQolGroup, 1990). The EuroQol group first met in 1987 with the aim of developing a standardised non-disease specific instrument for describing and valuing health-related quality of life (Brooks, 1996). It is therefore a generic instrument that allows comparison across different diseases. It is routinely collected as part of the NJR data (NJR, 2015). The psychometric properties of the EQ-5D are shown in Table *5.6*.

Table 5.6: Psychometric properties of the EQ-5D modified from (Ananth, Jones, King, & Tookman, 2003; Janssen et al., 2012; Pickard, Neary, & Cella, 2007).

Property	**Standard**
Internal consistency	Cronbach alpha 0.68, in Cancer patients
Test-retest reliability	Kappa >0.70, in cancer patients.
Construct validity	Significant (p<0.001) correlation between EQ-5D and WHO-5 (Janssen et al., 2012).
Responsiveness/Sensitivity to change	Not stated

Summary

The EQ-5D was used as a questionnaire for this study as it is part of the NJR's core outcome data collection process and is a validated measure of health-related quality of life. The EQ-5D assessed the overall health of the participants and can be compared to a normative cohort.

5.13.4 Global rating of change scale (GRCS)

The global rating of change scale (GRCS) is perhaps the most simplistic objective measure of change in health status that is currently available (Kamper, Maher, & Mackay, 2009). In this measure, a participant simply asked to mark on a scale how a condition or illness has changed over a given time period. An example of a GRCS is shown in Figure 5.1. The psychometric properties of the GRCS are illustrated in

Table ***5.7***.

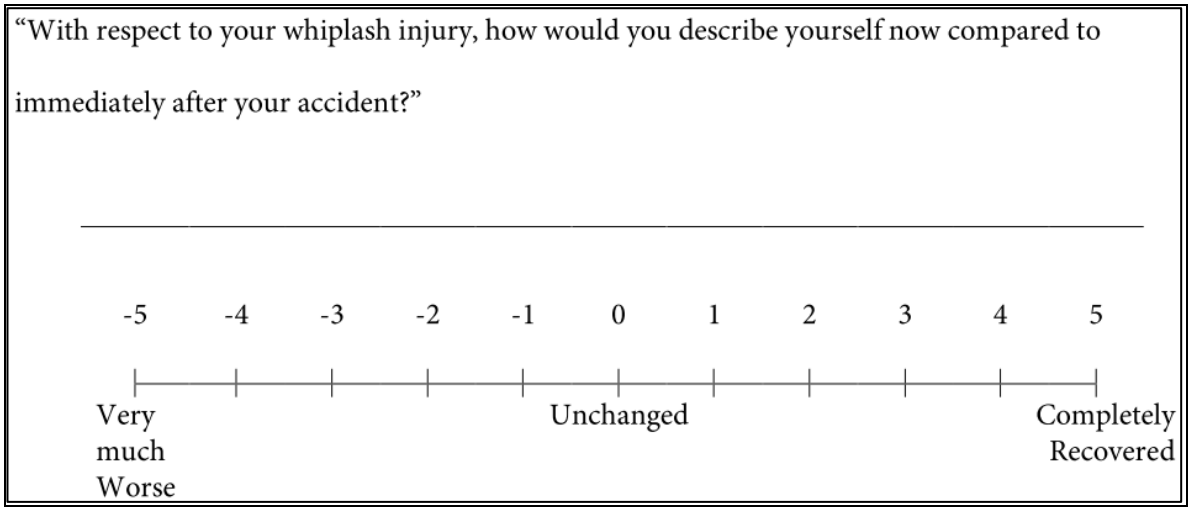

Figure 5.1: Example Global Rating Change Scale, modified from Kamper et al. (2009).

Table 5.7: Psychometric properties of GRCS modified from (Farrar, Young, LaMoreaux, Werth, & Poole, 2001; Fischer et al., 1999; Kamper et al., 2009; Lauridsen, Hartvigsen, Korsholm, Grunnet-Nilsson, & Manniche, 2007)

Property	**Standard**
Internal consistency	Not stated
Test-retest reliability	ICC 0.9 11 point
Construct validity	Significant correlation ($p<0.05$) with change on Roland Morris.
Responsiveness/Sensitivity to change	Standardised response mean 0.2-1.7, 7 and 15 point Standardised response mean 0.5-2.7 (14) 7 point

Question Formation

Kamper et al. (2009) suggested a number of approaches when constructing the question to assess the GRCS to ensure that the intended question is answered. The key guidelines are listed below.

- The condition is mentioned explicitly in the question this is particularly important if the participant being asked has co-morbidities.

- The wording of the question will direct the participant towards the construct that the scale will measure.
- Whatever the construct the question is left open so as to allow the participant to decide what he or she will take into account when considering their response.
- Provide an anchor for the scale so that the current can be compared to a previous time-point.

Despite these guidelines, there remains a number of limitations to the use of the GRCS that are important for researchers to be aware of. The theory of implicit change (Ross, 1989) is important to consider when analysing the GRCS. In short, the theory states that individuals are poor at accurately recalling past health status, but instead retrospectively apply some idea of their change over time. This could lead to an under or over-estimate of the change that has actually occurred. Therefore any change that is reported should not be taken to mean a change in the morphology or pathology of the disease or condition but should instead be taken as a change in the patient's retrospective opinion of how their condition or illness has changed (Kamper et al., 2009).

Considering these guidelines the GRCS question for this study was:

> *With respect to the hip that you had replaced with an artificial one, mark on the scale how you feel that particular hips health status has changed comparing now to immediately before your operation.*

This question adheres to the guidelines established by Kamper et al. (2009) as the condition is mentioned explicitly (THR), the wording directs the participant to the measure (hip health), the question was left open so that the participant can decide if there has been an improvement or deterioration in hip health and a specific time-point has been provided, so that the participant can compare health change between now and immediately before

the operation. The phrase ‘hip health’ was used as the measure of change as it is a vague term, broadly encompassing all the parameters that the participant may think important when assessing overall change in health following THR.

Scale Formation

There are no set guidelines to base the construction of the scale. Scales in previous research have used both negative and positive numbers (Preston & Colman, 2000). It can equally be as valid to use a scale that has purely negative or purely positive numbers nor does the scale need to have numbers on it at all (Preston & Colman, 2000). The number of points on the scale remains unclear. As many as 101 points have been previously used (Jaeschke, Singer, & Guyatt, 1989) and as few as three have been used in previous GRCS (Resnik & Dobrzykowski, 2003).

Preston and Colman (2000) suggested that the optimum number of points to be used on a scale is seven to 11. As they illustrated any less than seven points may led to a tendency for participants to feel that they have had insufficient choice to convey their perceived change. Any more than 11 points, the participants may begin to feel over-whelmed with choice apart from a 101 point scale (Preston & Colman, 2000).

It is proposed for this study that an 11-point scale will be adopted. An 11-point scale was also chosen to minimise the risk of aversion bias. This being the tendency for people selecting scores which are at the extremes of a scale (Streiner & Norman, 2008). Therefore choosing a scale that it was at the higher end of the optimal range was beneficial as it resulted in the greatest possible variation of results (Streiner & Norman, 2008). Taking these points into consideration, the scale that was used for this study’s GRCS is presented as Figure 5.2. The full GRCS used is shown as Figure 5.3.

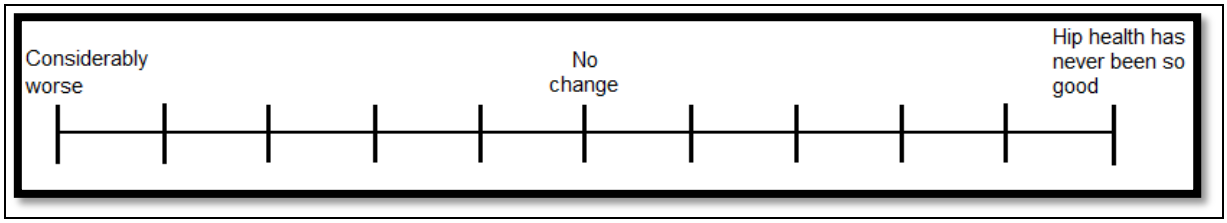

Figure 5.2: *The GRCS scale used in this study.*

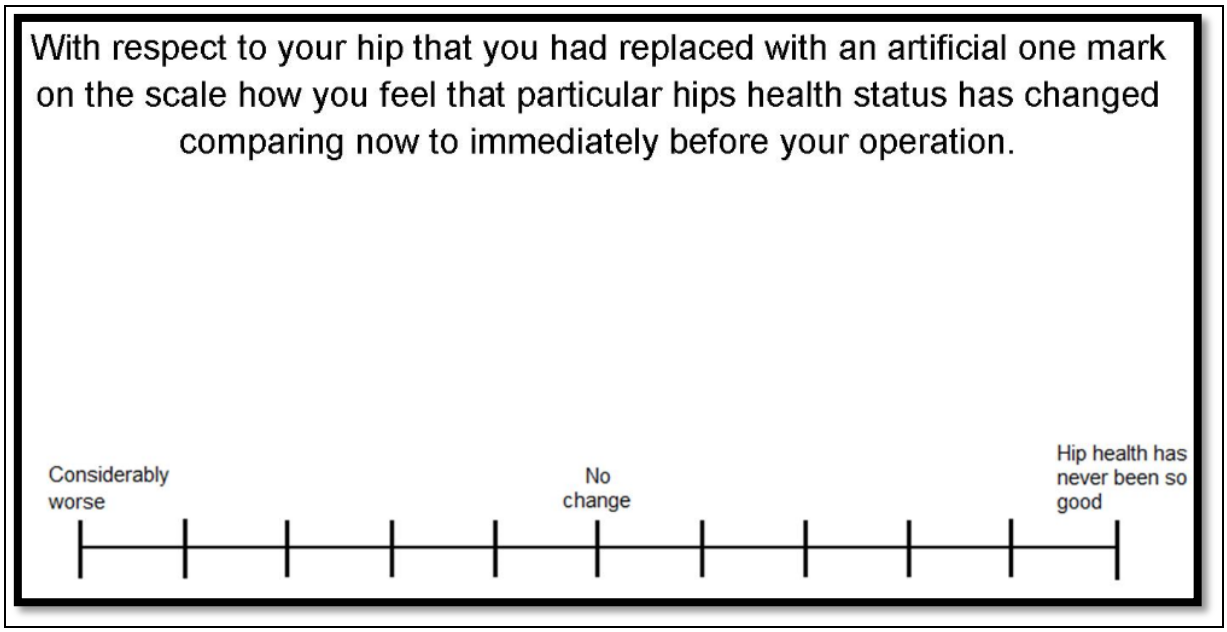

Figure 5.3: *GRCS tool used in the study*

How the GRCS is administered is also as important consideration as a participant answering the GRCS in private is likely to elicit a different response compared to the participant answering it in the present of the research team (Streiner & Norman, 2008). Therefore for this study the participants completed all the questionnaires at home before returning them to the research team. This ensured that the answers to each questionnaire were not influenced by the presence of a researcher.

Summary

The GRCS was used in this study as if offered a simplistic, quick way to assess the participant's opinions of their health change. When reporting any changes that may occur

it was also important to consider the assumptions that the GRCS has based on its construction as itemised above.

5.13.5 Accelerometer

Participants were asked to wear an accelerometer for seven consecutive days. Only one previous study (Groot *et al.*, 2008) used an accelerometer for their participants post-THR. A seven day assessment was chosen to ensure that as much data as possible was collected. In addition to this there are no specific guidelines that dictate how long an accelerometer should be worn for but the general consensus appears to be for approximately seven days (Trost, McIver, & Pate, 2005). Participants were asked to record their activity in an activity log whilst wearing the accelerometer. This allowed any substantial change in physical activity to be quantified, for example if the participant went out for a bike ride. Participants were received a reminder phone call or email if they wished to be reminded about completing the questionnaires and wearing the accelerometer. All questionnaires and the accelerometer were returned to the researcher using a pre-paid recorded delivery envelope that was provided.

The accelerometer used for this study was the Technogym MyWellness Key (TechnoGym, Gambettola, Italy). It was a single axis accelerometer that was clipped to the waist belt. The physical activity data output is reported as *'Moves'* which are strongly correlated to the ActiGraph for free living (r=0.73-0.76 for light to vigorous PA, respectively, p<0.05), though not associated to the Bouchard Activity Record (Bouchard et al., 1983) or the Global Physical Activity Questionnaire (Armstrong & Bull, 2006; Herrmann, Hart, Lee, & Ainsworth, 2011).

This accelerometer assessed two aspects of physical activity: mean MOVES and Activity Levels. Mean MOVES are a measurement of the movement performed and the correlated

metabolic activity level (TechnoGym). Activity level being a standardised measure of metabolic level.

5.13.6 Hip Dislocation

Self-reported hip dislocation of the THR was collected. Hip dislocation was used as a secondary outcome measure as there is evidence to suggest that an increase in physical activity may result in an increase in dislocation risk (Meira & Zeni, 2014). Participants were asked: 'since your hip replacement has your prosthetic hip dislocated?' If participants answered 'yes', they were asked further information about the dislocation. If participants reported a THR dislocation, it was verified by reviewing the hospital records. The expected dislocation rate is one per 1000 patients per years (NJR, 2014). Although this method relied on participants self-reporting hip dislocation, and remembering that it happened, it was assumed that this was an acceptable approach as patents would only need to remember for a maximum of 12 weeks between follow-up intervals and poor reporting would be safe-guarded by the medical note review from NNUH records.

5.14 Data Collection Process

In the pre-operative clinic, after obtaining participants consent, each participant was shown how to wear the accelerometer and provided with an accelerometer, the questionnaires detailed above, an activity log and reminder information about the measures in case they forgot. Demographic and anthropometric measurements were obtained from the participant's pre-operative notes the participants was also be informed about their group allocation.

After the operation, data collected from the participant's surgical records were gathered. These are shown in Table 5.8. The operative data were gathered in case anything that

occurred during the operation resulted in an effect on physical activity following the operation.

Table 5.8: Key measure taken from the participants surgical records.

Measures to be captured	Justification
Patient American Society of Anaesthesiologists (ASA) grade	Subject assessment of patient's overall health, scored 1-6, the lower the score the healthier the patient.
Hospital operation performed at	In case hospital operation is performed in is associated with outcome.
Surgical approach e.g. posterior, lateral	Different approaches cut different muscles that are associated with walking.
Untoward intraoperative event	Can slow down recovery.

Following surgery, participants were sent the same questionnaires (Table 5.3) as pre-surgery in addition to an accelerometer, and the additional questionnaires noted above. The participants were asked to complete the questionnaires and wear the accelerometer on either a Saturday to Friday or Sunday to Saturday at 3-5, 11-13 and 23-25 weeks post-surgery. At these time-points the participants NHS record was checked for additional entries and data gathered accordingly.

5.14.1 End-Points

Data were collected at a primary end-point of 24 weeks post-randomisation. This was to ensure that all the patients would be discharged from the care of the consultant at the final data collection point so that an appreciation of physical activity when a patient was not under the care of a consultant could also be gained.

In addition to pre-operative and week 24 post-operative data collection data was collected at week 4 and 12 post-operatively. It was collected at week 4 post-operatively as it represents the earliest possible time post-operatively that data collection could occur and participants are likely to have covered from the initial surgical trauma (NIH, 2013). Week 12 being chosen as it is midway between the operation and the end point of the study and

because it represents the earliest possible opportunity where the patient is likely to be fully recovered from the THR surgery (NIH, 2013).

5.15 Data Analysis

The data collected were analysed for differences and correlations. Exploratory analyses were also undertaken. Two separate analyses were undertaken. The first was performed with an intention-to-treat analysis principle, where individuals were analysed by the group to-which they were allocated to regardless of treatment received. Through this, it was possible to observe if treatment has an effect on outcome and not just the intervention. Intention-to-treat principles compare the intervention and control group, regardless of whether or not the intervention group completed the targeted walking intervention. This therefore provided a greater degree of externally validity, rather than assessing the fidelity of the analysis. Secondary subgroup analyses were also undertaken. These are detailed below.

<u>Primary Analysis</u>

1. Is the proposed method of prescribing a pedometer-based walking intervention a feasible intervention for the THR population?

<u>Secondary Analysis</u>

2. Is the provision of a pedometer-prescribed walking programme associated with a change in quality of life and physical activity?

   This analysis is split into a number of sub-analyses.

   a. Is there a difference in physical activity between the control and intervention group?

b. Is there a difference in dislocation between the control and intervention group? …

3. Is there a difference in quality of life between the control and intervention group?

The full analysis plan is presented in the protocol contained within Appendix 4.

All analyses were undertaken using the appropriate test. The *p*-value was set at 0.05. All data were presented, if possible, as mean difference 95% confidence interval (CI) and standard deviation.

The validity of using an accelerometer as an alternative to questionnaire-based measurement was also a planned analysis. This would have been considered by assessing the correlation between the accelerometer and questionnaire data. This was not undertaken due to the large amount of missing accelerometer data. This will be discussed in detail in Chapter 7.

Multiple imputation (Rubin, 1977) was not adopted due to the small sample size as part of this feasibility RCT. The drawbacks of multiple imputation were that the smaller the sample the greater the bias introduced in the dataset through imputation (Barnes, Lindborg, & Seaman, 2006). Additionally as this was a feasibility RCT, imputation of the data would have no bearing on the results as we did not aim to assess statistical difference or association but merely feasibility of the study groups.

5.16 Summary

In summary, this chapter has presented the methods for a two-armed feasibility randomised control trial that was used to assess a novel way of increasing physical

activity in the THR population post-surgery. The next chapter will present the results of this study.

Chapter 6 Feasibility Randomised Control Trial Results

6.1 Introduction

This chapter reports the findings of the feasibility randomised control trial (RCT). The data presented in this thesis includes all data that were received from participants on or before 30th September 2016. This permitted time for data analysis before submission of the thesis. Consequently, two datasets were not included in this final analysis. The recruitment period for the trial ran from January 2015 to March 2016.

6.2 Recruitment

A total of 35 participants were recruited. This was less than the planned 160 participants, but three more participants than the revised target of 32. A graph depicting the differences between the originally planned and actual recruitment is presented in Figure 6.1. The reasons behind the low recruitment will be discussed in greater detail in the following chapter.

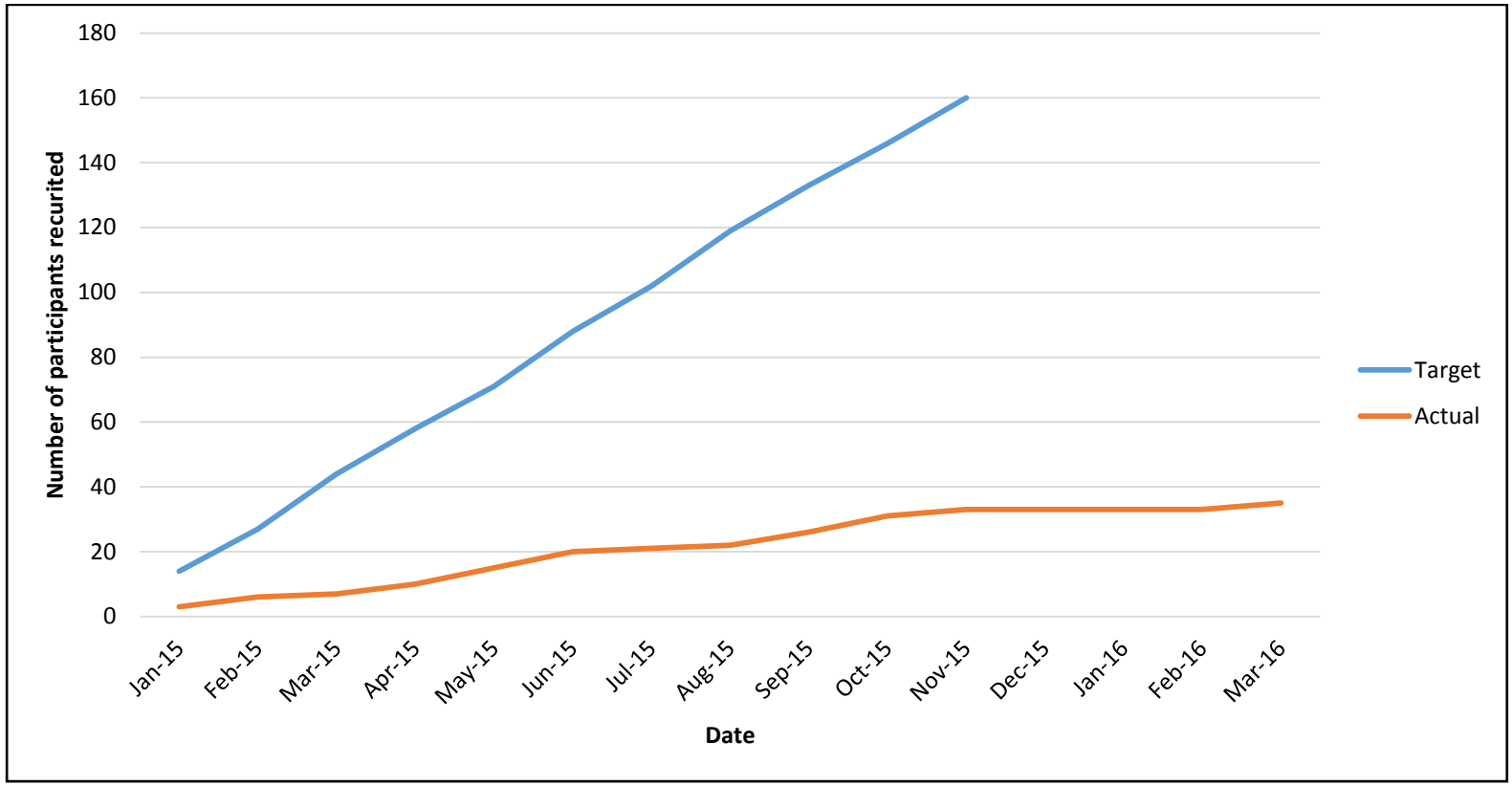

Figure 6.1: A line graph to show the differences in actual and target recruitment.

A summary of study recruitment is presented in Figure *6.2*'s CONSORT flow chart (Consort, 2010). A total of 1242 patients were listed at the recruiting hospitals for a THR during the study period (January 2015 to March 2016). This was an average of 932 per year or 83 per month. A total of 281 invitations were sent to potential participants. The differentiation between patients listed and invitations posted was attributed to:

(1) The hospital secretary who pre-screened the surgical list before letters were sent to potential participants was unable to report how many letters were actually posted. This figure was therefore not included in the 281 invitees.

(2) The initial method used to send out the invitations to participate did not work. The initial method was to send out invitation letters prior to attending the pre-operative clinic. This did not work as a large number of participants either received their letter late, so did not have time to reply, or were phoned up to confirm their appointment as it was booked with too little notice to send out a letter. The revised method of posting letters to potential participants improved this process. The patients that were subsequently missed were only the patients that were transferred to Spire between the list being checked.

The reasons for this large discrepancy will be discussed in greater detail in the following chapter.

From the 281 invitations sent to participants, 88 (31%) of the potential participants replying to register an interest in participating in the study. A total of 53 participants who showed an interest in taking part did not satisfy the eligibility criteria. An additional two participants were excluded after recruitment and randomisation as they became ineligible. In one case this was because their operation was cancelled. In the second case this was

because the operation was changed from a unilateral to a bilateral THR procedure. A complete list of reasons for exclusion is presented in Table 6.1.

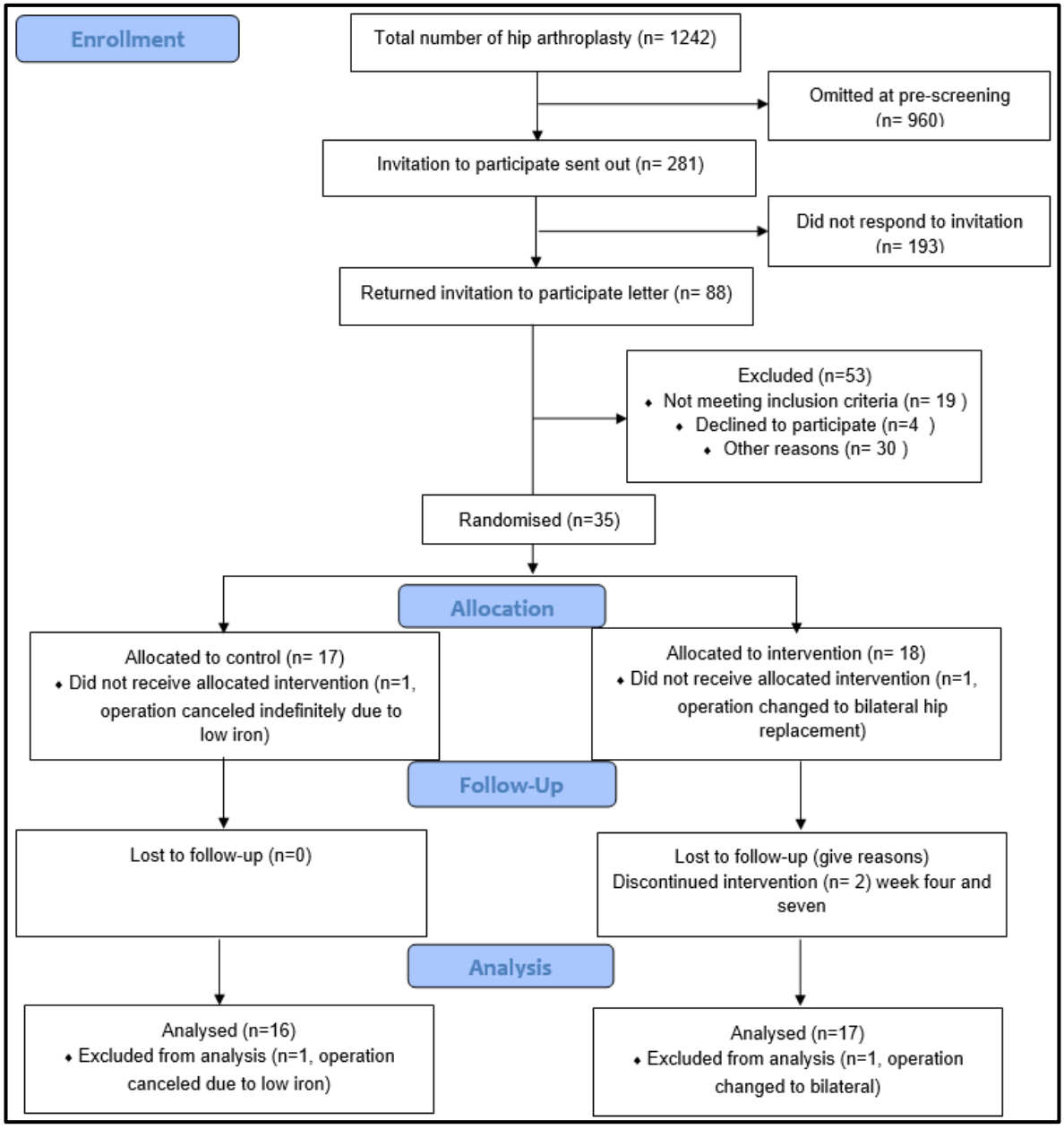

Figure 6.2: A flow chart showing study recruitment.

6.3 Participant Attrition and Missing Data

For the primary outcome measure, the Oxford Hip Score (OHS), there was a total of nine (14%) and 18 (68%) missing data points for the control and intervention groups

respectively. The measure with the most missing data was accelerometry with 47 (73%) and 49 (72%)

Table 6.1: Reasons for potential participant exclusion.

Reason for Exclusion	Frequency
Pre-operative appointment not in study period	6 (11%)
Patient could not be found on system	5 (9%)
Received after pre-operative appointments	11 (20%)
Pre-existing THR	8 (14%)
Did not meet eligibility criteria	19 (34%)
Declined to participate, no reason given	4 (7%)

data points missing for the control and interventions groups respectively. The missing data for each of the outcomes is presented in Table 6.2. The large proportion of missing accelerometry data will be discussed in greater detail in Section 6.6.2.

Table 6.2: Table to illustrate the proportion of missing data. Presented as number of missing data points for measure, with percentage of missing data for measure in brackets.

Outcome measure	Control (%)	Intervention (%)
OHS	9 (14%)	18 (68%)
Moves	47 (73%)	49 (72%)
Activity Level	47 (73%)	49 (72%)
PASE	8 (13%)	21 (31%)
EQ-5D	12 (19%)	21 (31%)
VAS	10 (16%)	20 (29%)
Pre-operative Questionnaire Only		
Global rating of change scale	9 (19%)	19 (37%)

OHS = Oxford Hip Score, PASE = Physical Activity Score for the Elderly, VAS = Visual Analogue Scale

6.4 Cohort Characteristics

A total of 17 participants were included in the analysis of the intervention group, seven were female and eight had a left-sided THR. There was a total of 16 participants in the control group, 12 were female and five had a left-sided THR. A complete description of the cohort characteristics is presented in Table 6.3. Demographic data missing from participant's medical notes during the pre-operative clinic included height and weight for four participants in the control group and two participants in the intervention group. In

addition, data on the American Society of Anesthesiologists (ASA) score was missing for four participants in the intervention group. All participant characteristics were collected from the patient's notes.

Table 6.3: Baseline demographic characteristics, presented as mean ± standard deviation unless stated otherwise

	Control	**Intervention**
Age	71±10	68±11
Weight	73±12	77±12
BMI	27±6	28±6
ASA (Grade: 1/2/3)	8/7/1	2/6/5
Use of assistive walking aid (Yes/No)	7/9	8/9
Gender (M/F)	4/12	10/7
Oxford Hip Score	24±14	23±17
PASE	130±89	77±59
Mean Moves	710±530	181±194
Activity Level	370±272	146±113
EQ-5D	0.48±0.27	0.32±0.25
VAS	60±26	52±22

ASA = American Society of Anesthesiologists; BMI = Body Mass Index; F = Females; M = Males; PASE = Physical Activity Scale for the Elderly; VAS = visual analogue scale

Two participants, both from the intervention group, dropped out during the study. One participant was lost at Week 4 post-operatively because of "family challenges" and one at Week 7 which the participant reported to be due to "being away and a feel that I have missed to much of the study."

6.5 *Primary and Secondary Outcome Measures*

The primary and secondary outcome measures for the studies are presented in Table 6.4.

Table 6.4: Table illustrating the post-operative measures for the control and intervention groups

Time	Mean ± standard deviation		Mean difference	Confidence interval		p-value
	C	I		Lower	Upper	
OHS						
Week 4	31±8	33±9	-2.20	-8.94	4.54	0.51
Week 12	37±10	43±8	-5.30	12.42	1.99	0.42
Week 24	40±7	41±12	-0.52	-7.56	6.52	0.22
PASE						
Week 4	76±46	78±36	-2.08	35.11	30.95	0.90
Week 12	126±79	128±64	-1.11	62.11	59.89	0.97
Week 24	146±84	138±52	7.43	57.33	72.19	0.79
Mean Moves						
Week 4	227±126	338±138	-111.09	-304.55	82.37	0.22
Week 12	613±308	218±251	394.96	-43.79	833.71	0.071
Week 24	381±142	30±43	351.18	-0.98	701.38	0.050
Activity Levels						
Week 4	113±46	233±143	-119.39	-274.72	35.94	0.21
Week 12	196±66	134±108	61.61	-84.47	207.69	0.35
Week 24	164±109	70±42	93.20	-175.60	362.00	0.35
EQ-5D						
Week 4	0.71±0.15	0.67±0.10	0.04	-0.07	0.15	0.47
Week 12	0.79±0.15	0.83±0.19	-0.04	-0.19	0.11	0.59
Week 24	0.83±0.12	0.84±0.17	-0.02	-0.14	0.10	0.75
VAS						
Week 4	82±11	83±12	-1.54	-10.74	7.66	0.73
Week 12	85±14	84±14	0.41	-11.66	12.48	0.95
Week 24	79±16	88±9	-8.21	-19.86	3.44	0.16
GRCS						
Week 4	0.78±0.14	0.86±0.15	-0.077	-0.20	0.043	0.21
Week 12	0.82±0.14	0.90±0.08	-0.095	-0.19	0.002	0.055
Week 24	0.88±0.08	0.94±0.07	-0.065	-0.14	0.008	0.078

C=control; I=intervention; GRCS = Global Rating Change Scale; OHS = Oxford Hip Scoe; PASE = Physical Activity Scale for the Elderly; VAS = visual analogue scale

6.5.1 *Primary Outcome Measure: Oxford Hip Score*

The following between group differences were observed at each time point for the oxford hip score pre-operative measure (Mean Difference (MD): 1.07, 95%CI: -10.86 to 13.00), Week 4 (MD: -2.20 95% CI: -8.95 to 4.54), Week 12 (MD: -5.30 95% CI: -12.42 to 1.82 and Week 24 (MD: -0.52 95% CI: -8.59 to 7.56) post-operatively.

A summary of the results is presented in

Figure 6.3.

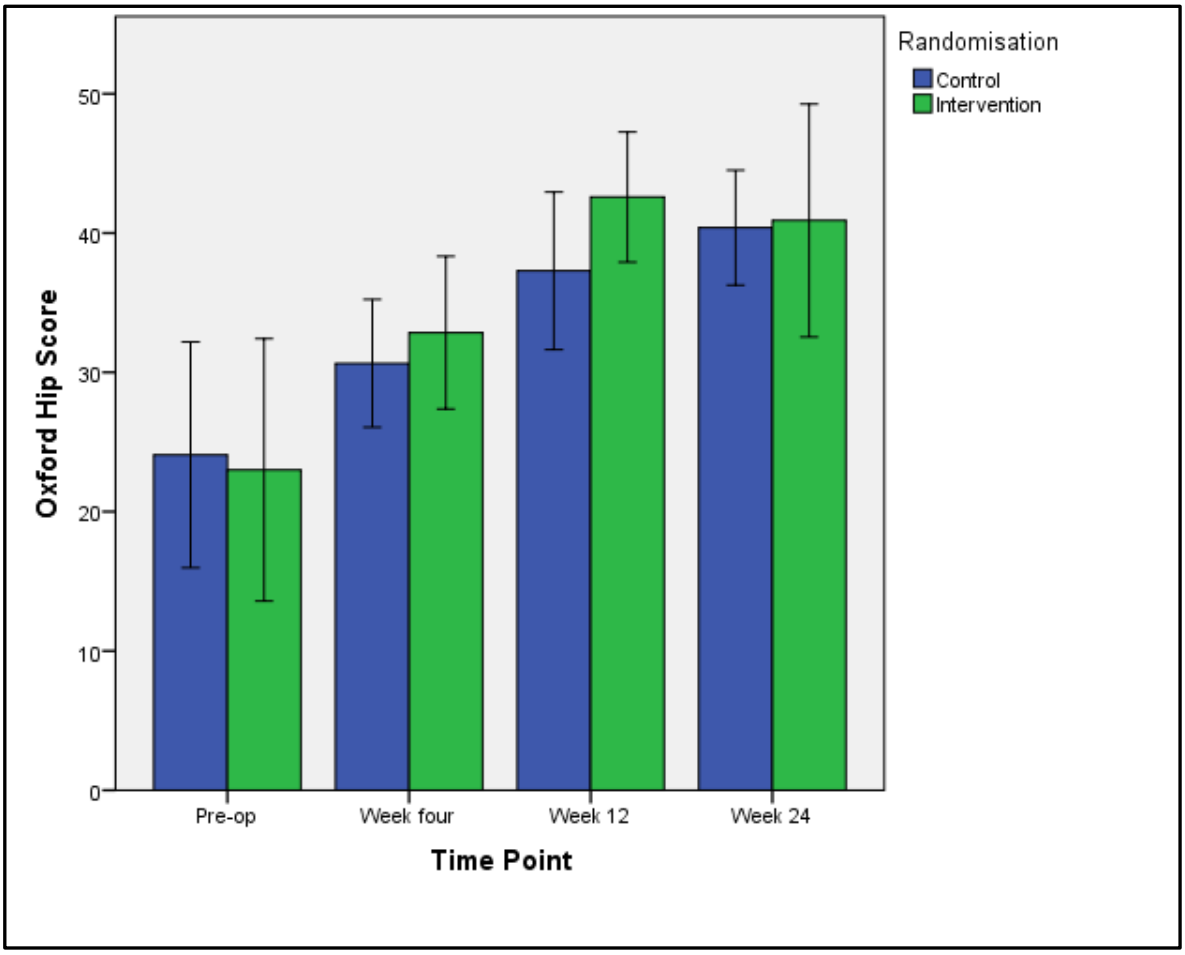

Figure 6.3: A bar chart to illustrate Oxford Hip Score in the intervention and control group across time.

A conservative estimate of the minimal clinically importance difference for the OHS has been reported as five points (Murray *et al.*, 2007). Therefore it is suggested that none of the time point comparisons resulted in a clinical significant difference.

6.5.2 Secondary Outcome Measure: Physical Activity Scale for the Elderly (PASE)

For the PASE the following between groups differences were observed pre-operatively (MD: 52.80 95% CI: -8.47 to 114.07), Week 4 (MD: -2.08 95% CI: -35.12 to 30.95), Week

12 (MD: -1.11 95% CI: -62.11 to 59.89) and Week 24 post-operatively (MD: 7.43 95% CI: -57.33 to 72.19).

The complete total PASE scores are presented in Figure 6.4. The itemised sub-section scores for the PASE is presented in Table 6.5. The maximum score for the leisure time and household activities sub-sections were 502 and 171 respectively. For work activities it was dependent on the hours an individual works as it was calculated using Equation 6.1.

$$Work\ activities = hours\ worked\ per\ week \times \frac{1}{7} \times 21 \qquad \textbf{Equation 6.1}$$

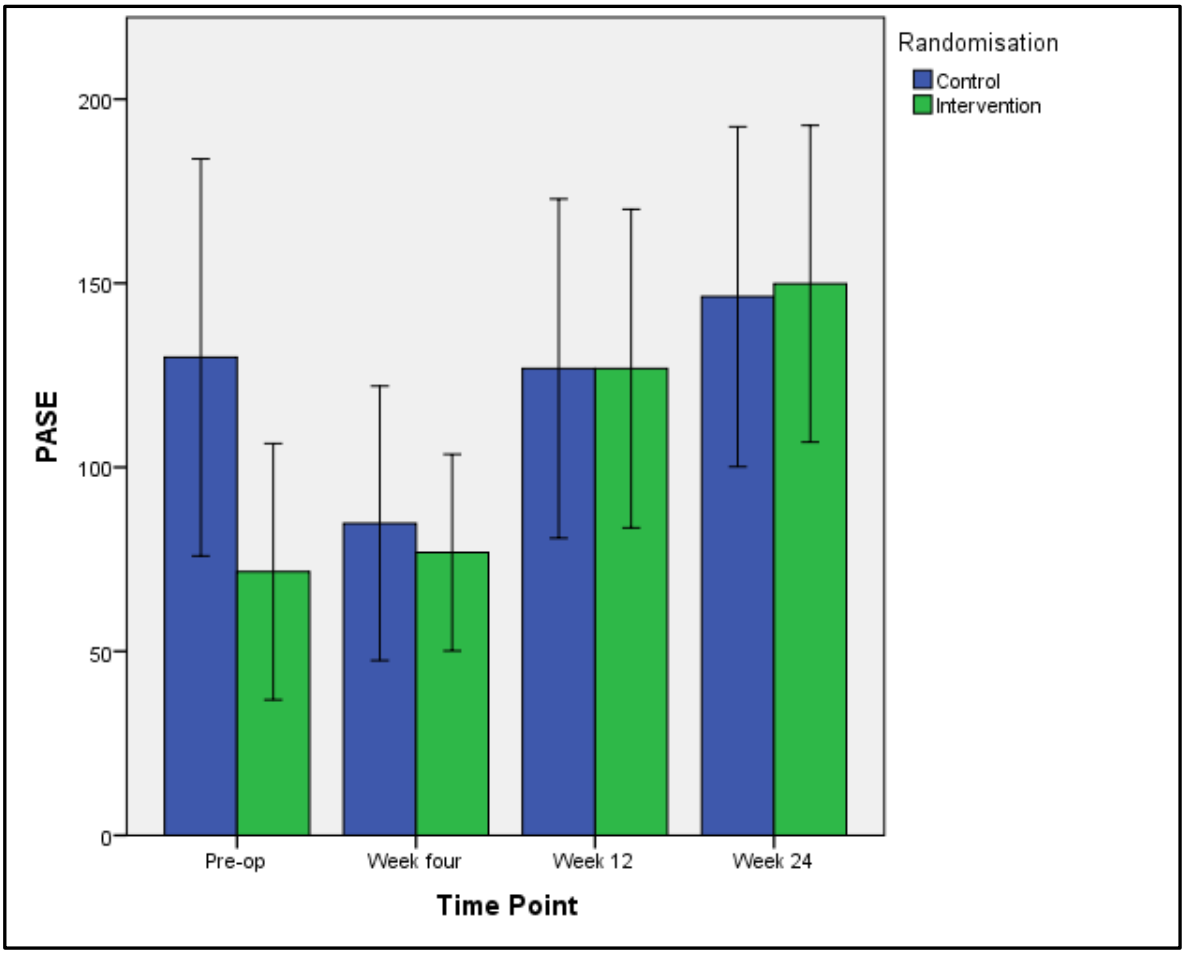

Figure 6.4: A bar chart to illustrate the time-point differences in PASE score for the control and intervention group.

Table 6.5: Table to illustrate the itemised sub-section scores for the control and intervention groups.

Time-Point	Control group			Intervention group		
	Leisure time activities	**Household activities**	**Work activities**	**Leisure time activities**	**Household activities**	**Work activities**
Pre-operatively	45±42	65±40	19±38	15±19	57±48	5±15
Week 4	27±22	48±27	1±4	18±15	59±36	0.46±1.7
Week 12	33±29	80±42	14±39	31±26	88±45	8±35
Week 24	49±40	78±39	19±36	51±35	87±41	0.00±0.00

6.5.3 Accelerometry Data

It should be noted when interpreting the results for accelerometery data that there is a large proportion missing data (47 data-points (73%) and 49 data-points (72%) for the control and intervention group for whole dataset respectively). Therefore this analysis includes the data from eight intervention group participants and seven control group participants. Nonetheless all participants had missing data at, at least one data-point. The number of missing data-points per group is shown in Table 6.6.

Considering the mean Moves initially, the following results were observed pre-operative assessment (MD: 529.00 95% CI: -118.29 to 1176.28), Week 4 (MD: -111.09 95% CI: -304.54 to 82.37), Week 12 post-operatively (MD: 394.96 95% CI: -43.79 to 833.71 and Week 24 post-operatively (MD: 351.18 95% CI: 0.98 to 701.38). The results are presented in figure 6.5.

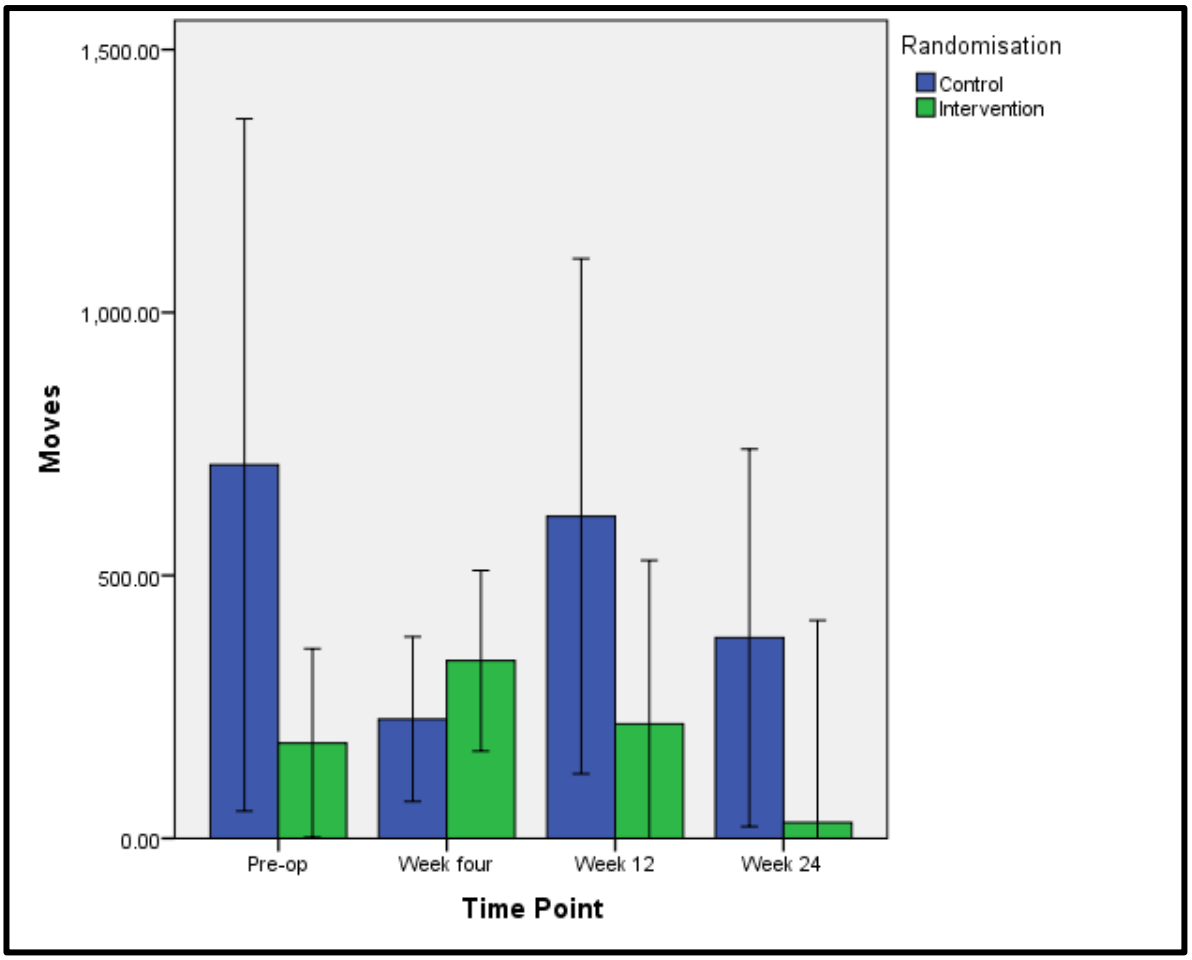

Figure 6.5: A bar chart to illustrated the Mean Moves data per group and at each time point.

For activity level, the following differences between the control and intervention group were observed pre-operatively (MD: 224.31 95% CI: -27.42 to 476.04), Week 4 (MD: -119.39 95%CI: -274.71 to 35.94), Week 12 (MD: 61.61 95% CI: -84.46 to 207.69) and Week 24 post-operatively (MD: 93.20 95% CI: -175.60 to 362.00).

Table 6.6: Table to illustrate the proportion of missing data points for accelerometry data.

Measure	Pre-operative		Week 4		Week 12		Week 24		Mean	
	Intervention	**Control**	**Intervention**	**Control**	**Intervention**	**Control**	**Intervention**	**Control**	**Intervention**	**Control**
Mean Moves	10(60%)	11(69%)	12(71%)	11(69%)	12(71%)	12(75%)	15(88%)	13(81%)	12(73%)	12(74%)
Activity levels	10(60%)	11(69%)	12(71%)	11(69%)	12(71%)	12(75%)	15(88%)	13(81%)	12(73%)	12(74%)

The results are illustrated in

Figure ***6.6***.

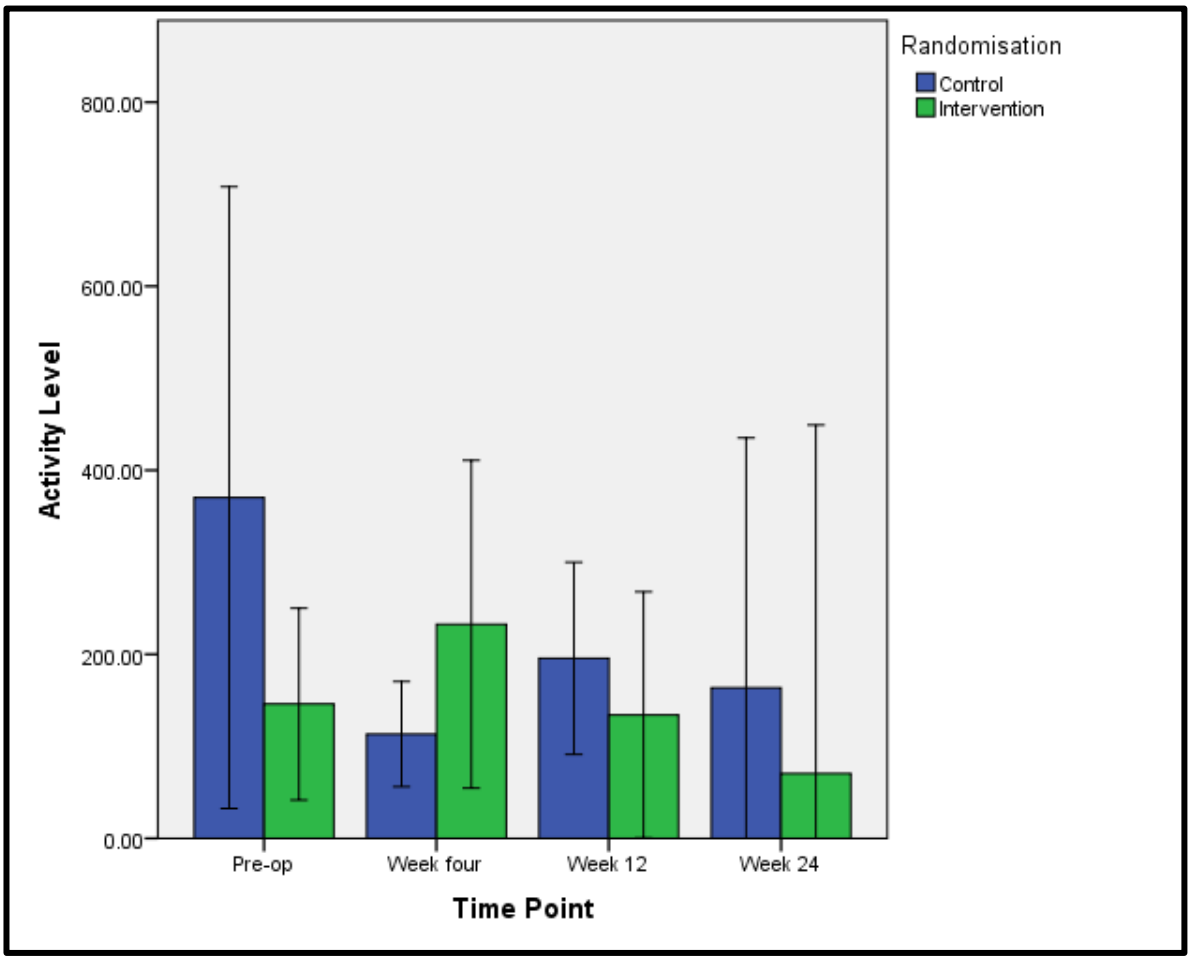

Figure 6.6 A bar chart to illustrate Activity Levels at all time points and between the control and intervention groups.

6.5.4 EQ-5D

For the EQ-5D the following differences between the control and intervention group were observed pre-operatively (MD: 0.16 95% CI: -0.05 to 0.37), Week 4 (MD: 0.04 95% CI: -0.07 to 0.15), Week 12 (MD: -0.04 95% CI: -0.18 to 0.11) and Week 24 post-operatively (MD: -0.02 95% CI: -0.14 to 0.10).

The complete results are illustrated as a bar chart in

Figure 6.7.

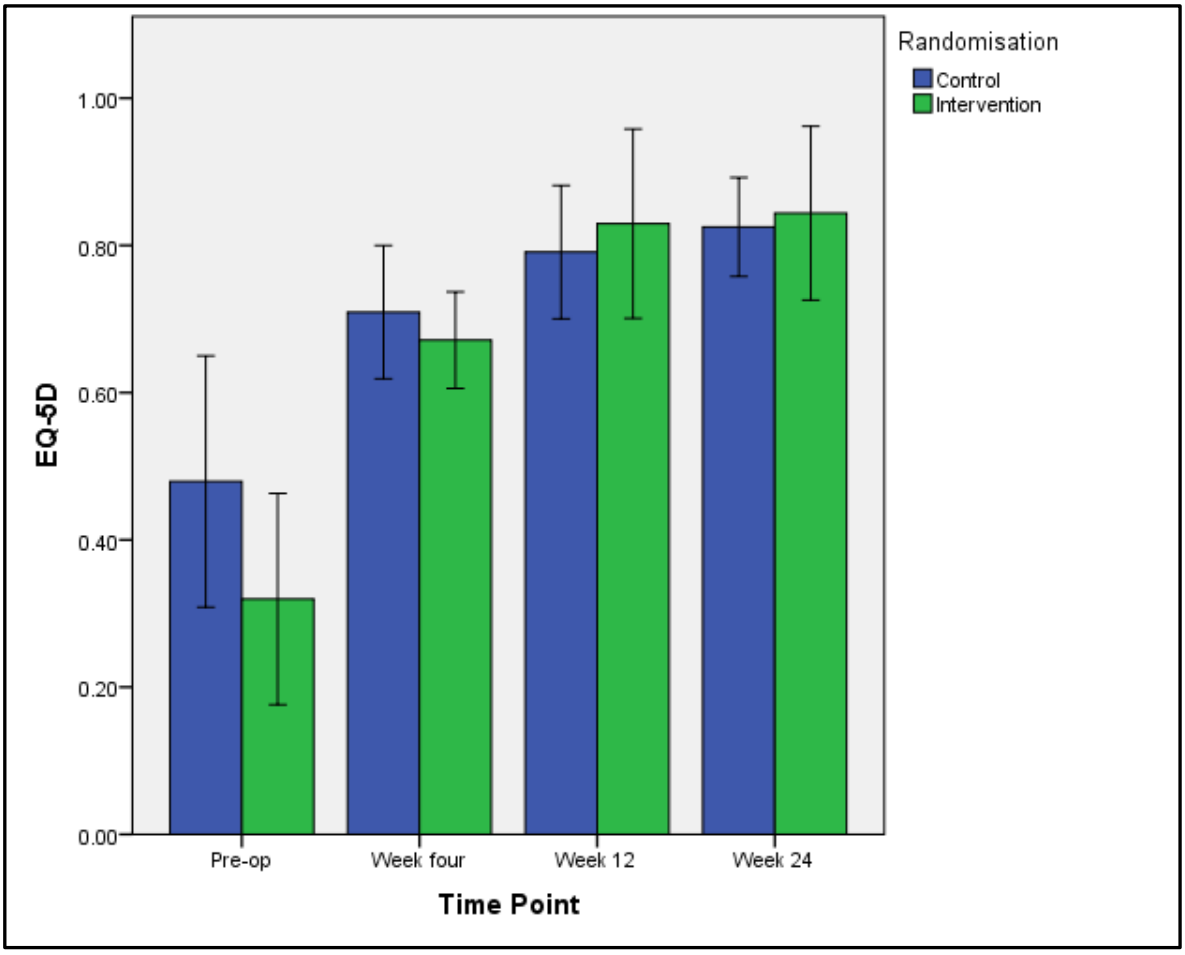

Figure 6.7: A bar chart to illustrate the between-group differences in EQ-5D at each time point.

Considering the visual analogue scale component of the EQ-5D the following between group differences between the control and intervention group were observed pre-operatively (MD: 7.86 95% CI: -11.43 to 27.15), Week 4 (MD: -1.54 95% CI: -10.73 to 7.66), Week 12 (MD: 0.41 95% CI: -11.66 to 12.48) and Week 24 post-operatively (MD: -8.21 95% CI: -19.87 to 3.44). This is displayed in figure 6.8.

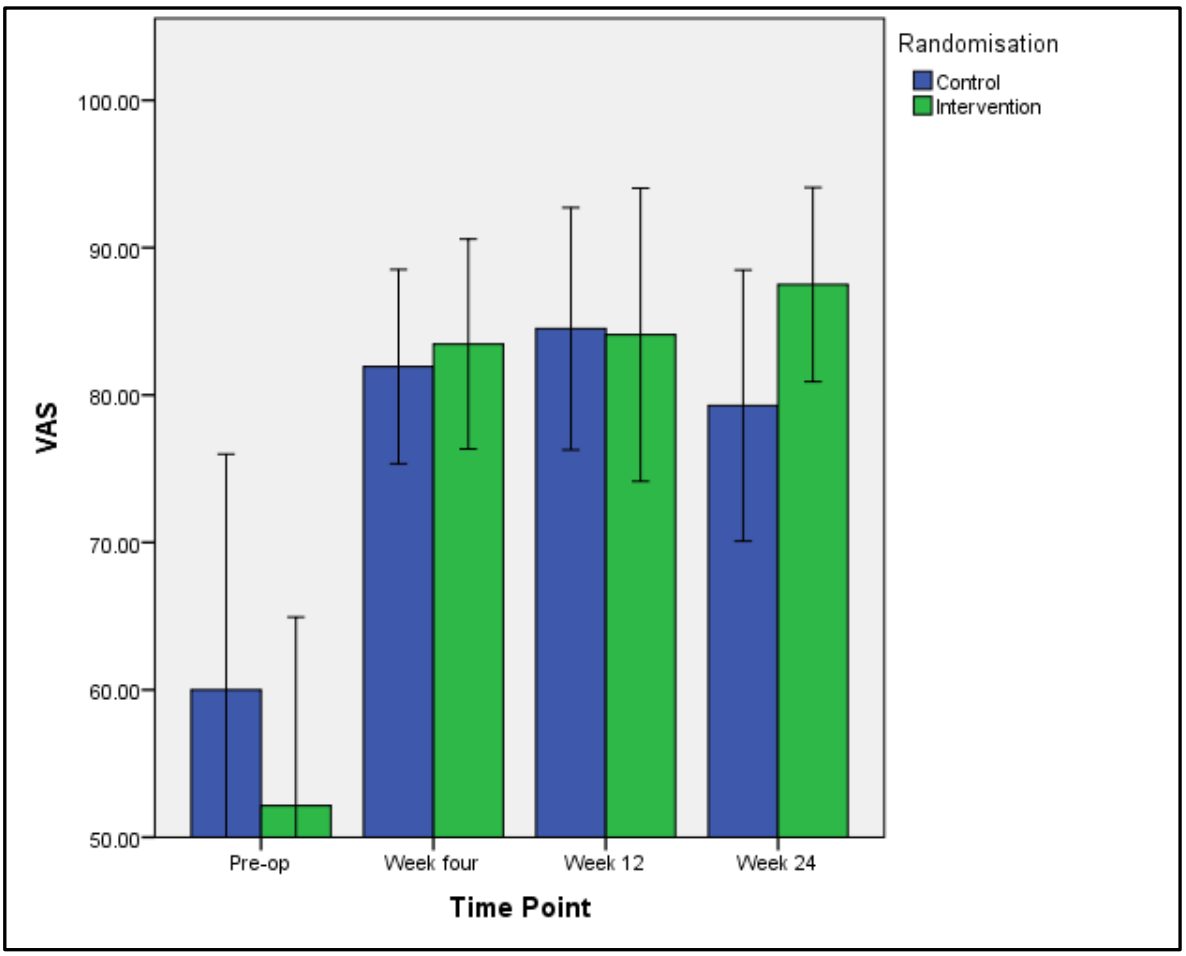

Figure 6.8: A bar chart to show between group differences at each time point.

6.5.5 Global Rating of Change Scale

The following between group differences were observed for the global rating of change scale week 4 (MD: -0.077 95% CI: -0.20 to 0.046), Week 12 (MD: -0.095 95% CI: -0.19 to 0.0022) and Week 24 post-operatively (MD: -0.065 95% CI: -0.14 to 0.0081). The differences are shown in figure 6.9.

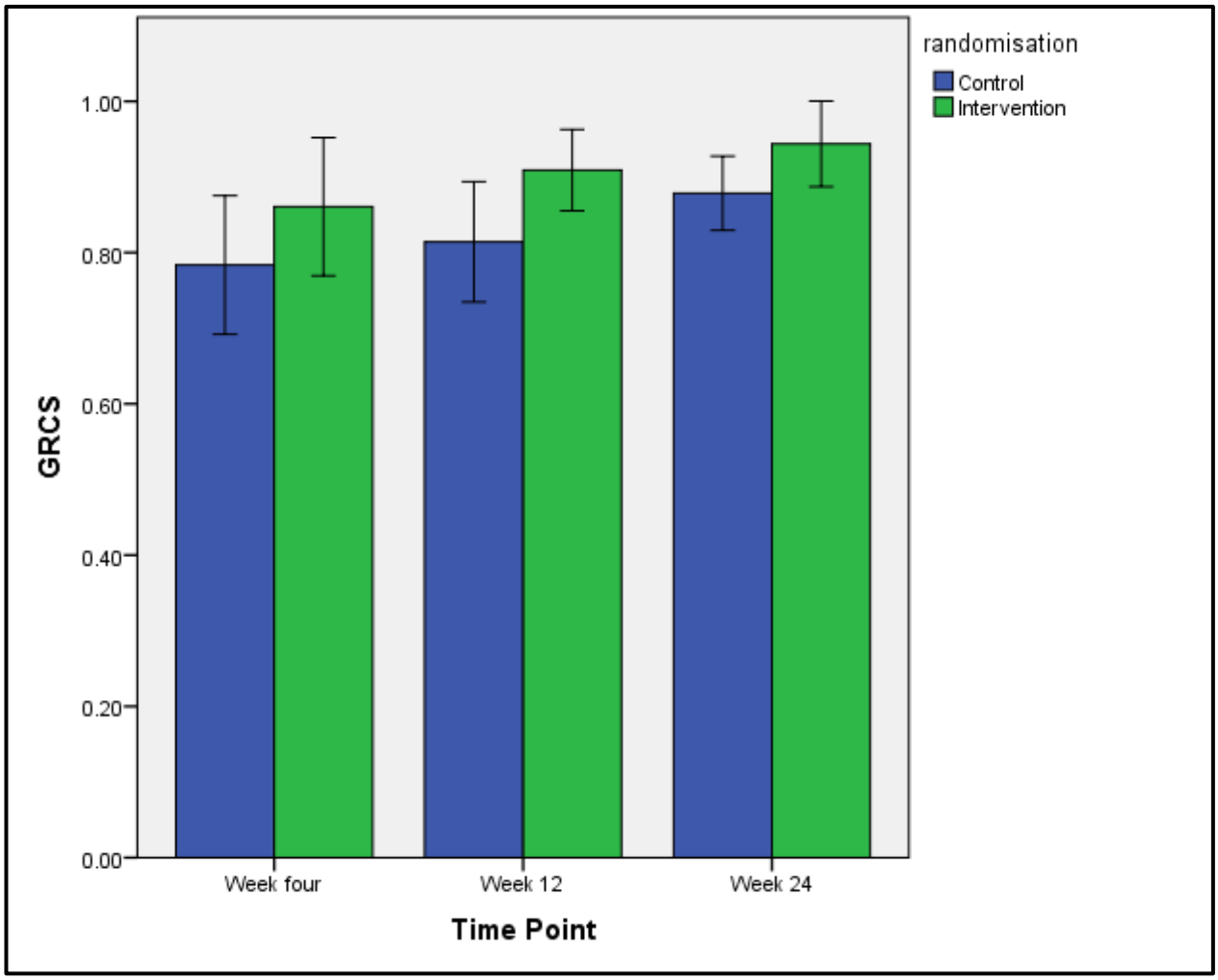

Figure 6.9: A bar chart to illustrate between-group differences at each time point for Global Rating of Change Scale.

6.6 Secondary Outcome Measure: Hip Dislocation and Complications/Additional Treatment

One participant suffered multiple dislocations post-discharge and underwent revision surgery. The clinical team looking after this participant's care were not able to identify the reason behind the multiple dislocations. They did not believe that it was associated with participating in the study, this was recorded as a major adverse event. .

In addition to the one participant who underwent hip revision surgery, seven participants were seen at hospitals as either inpatients or outpatients following their in-patient hospital discharge. None of these consultations were associated with the intervention or study participation. These are summarised in Table 6.7, these were recorded as minor adverse events.

Table 6.7: Post-hospital discharge healthcare consultations.

Control group	Intervention group
Colonoscopy, due to six week change in bowl habits	Dermatology day case, Excision lesion left temple
Audiology outpatients appointment due to recurrent otitis externa	Listed shoulder replacement, due to osteoarthritis of shoulder and gastroscopy
	Diagnosis gynecomastia, same participant had hip revision
	Two lesion in close proximity excised
	Rheumatology outpatient appointment.
	Ophthalmology outpatient appointment.

6.7 Questionnaire Feedback

The results of the study feedback questionnaire are presented below. The closed questions responses are shown in

Table ***6.8***.

Table 6.8: Feedback questionnaire closed results answers.

Question Posed	Yes	No
Concerns about the study?	6%(n=1)	94%(n=16)
Participant inconvenience?	6%(n=1)	94%(n=15)
Friends or family help decide to take part?	6%(n=1)	94%(n=15)
Enough time to complete questionnaire?	100%(n=16)	0% (n=0)
Disappointed not to be given pedometer?	33%(n=2)	67%(n=4)
Enough time to wear pedometer and fill out log?	80%(n=8)	20%(n=2)
If you were not given a pedometer do you think you would be less active?	0% (n=0)	100%(n=3)
Questionnaire easy to answer?	100%(n=15)	0% (n=0)

6.7.1 Questionnaire Feedback (Control Group)

A total of nine participants replied who were allocated to the control group. On reviewing the open questions from the feedback questionnaire, six participants decided to take part in the study to further scientific knowledge, one to get “fit quickly”, one “because I was asked” and one to show appreciation for the care they have received with the THR. One participant responded that they did not have any concern with the study.

Three participants responded to the question about the study being an inconvenience. One participant reporting that it was not an inconvenience. One participant reported that it was an inconvenience but justifiable if it helps other people. One participant reported that they forgot to put ‘the device’ on a couple of times.

No participants answered the questions pertaining to the inconvenience of participating. Four participants responded to the question about being disappointed about not being allocated to the pedometer group. Two participants responded that they were disappointed, one noting that they were not in the pedometer group and the participant reported that were ‘not really’ disappointed. No control group participants answered the question in respect to the ease of completing the questionnaires.

Two participants provided additional comments. One participant noting that the accelerometer was not easily fixed to dresses. The second participant reported that they hoped the study would “prove useful”.

6.7.2 Questionnaire Feedback (Intervention Group)

Eight participants who were allocated to the intervention group replied to the the post-study questionnaire. Of these, six decided to participate in the study to further scientific knowledge, one reported that they participated because the researcher asked if they could take part, and one participant because they wished to be “proactive with recovery post-surgery.” Only one participant responded to concerns about the study. They reported that their orthopaedic consultant had suggested that the study had “very poor data security.”

No participants answered the question regarding the study being an inconvenience to take part in. One participant reported that their wife helped them complete the questionnaire. One participant reported that there was “more than enough time” to complete the questionnaire. No participants answered the question with respect to having enough time to fill out the questionnaire. When the participants were asked if they had enough time to take part in the study five participants responded. One participant reported that they was sufficient time except when they were on holiday and they were late beginning. One participant responded that there was sufficient time “at first, but did not have it late,” whilst one participant replied that it was “because repetitive and non-challenging.” One participant was unclear about the question and one participant replied that they felt “the pedometer didn’t work.”

When intervention participants were asked if they thought that they would be less active if they were not provided with a pedometer, three participants responded. One participant reported that they felt the pedometer “set up a minor competition in oneself,” another noting that the question was irrelevant, and the final participant reported that they thought wearing a pedometer made no difference. Two participants answered the questions about the ease of answering the questionnaires. One participant replied that “classifying activities” may have been useful and the other noting that more information would have been useful to help complete the questionnaire.

When intervention participants were asked to provide any additional comments a total of six responded. One participant reported that they would have like “a little more contact by telephone or email.” Two participants thanked the researcher for the opportunity to take part in the study. One participant reported that the first pedometer they were given was ‘broken’ and that they were unable to wear a dress. Whilst wearing a pedometer, another was concerned about the accuracy of the pedometer compared to “my wife’s fit bit.” One participant documented that their “hip is back to normal.”

6.8 Intervention Adherence

Participants in the intervention group took a significantly greater number of mean steps compared to the mean number of target steps with 4981±1356 and 2169±2545 steps respectively (MD: 2812, 95% CI: 2117 to 3506 steps). The difference is graphically depicted in Figure 6.1. Although adherence to the pedometer based intervention was poor there was an increase in number of steps from Week One (1841 steps) to Week 24 (6106 steps).

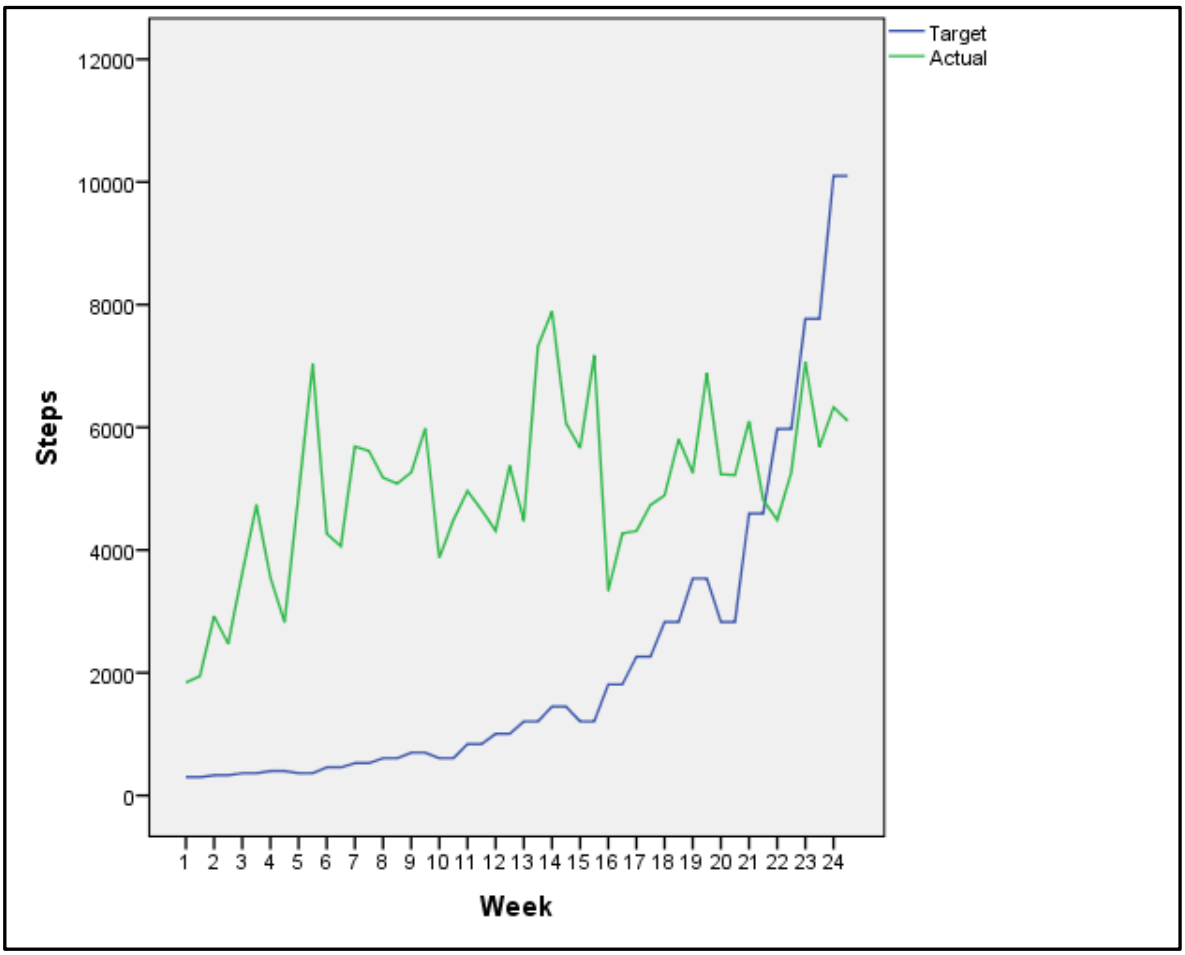

Figure 6.10: Line graph illustrating the target and mean actual number of steps performed by the intervention group.

6.9 Summary

The study design appeared to be feasible although future consideration on study recruitment, intervention adherence and data collection strategies, particularly accelerometry, are required. Nonetheless, the study participants thought it was an appropriate and acceptable intervention.

The next chapter will discuss and draw appropriate conclusions from these results.

Chapter 7 Feasibility Randomised Control Trial Discussion

7.1 Introduction

The results from this feasibility randomised control trial (RCT) suggest that a pedometer-prescribed walking intervention is not at the moment ready to take to a full trial. However, the adherence to this experimental intervention may have affected the outcomes of this study. This chapter will discuss the findings of the feasibility RCT and draw appropriate conclusions.

7.2 Study Design Discussion

The purpose of a feasibility RCT is to test if the proposed method is feasible to address the research questions stated in section 5.3. (Bowen et al., 2009). This should involve considering multiple areas of a trial including study design, recruitment, applicability and identification of outcome measure. Bowen et al. (2009) proposed that there are eight areas which a feasibility RCT should address: acceptability, demand, implementation, practicality, adaptation, integration, expansion and limited-efficacy testing. This section will discuss these eight areas and also the strengths and weaknesses of this study design and how this affects the conclusions drawn from the results.

- Acceptability: How acceptable is a pedometer-prescribed walking intervention.

It is proposed that a pedometer-prescribed intervention for this group of participants is acceptable as the feedback from participants was generally positive and thought to be beneficial. No participant suggested the intervention was not acceptable. The small response size compared to the overall number of participants should however be considered when drawing conclusions. It is however important to note that only a small

number of participants answered the questionnaire. Therefore, although the response was overwhelmingly positive it is suggested that this should be considered with caution as it is unknown why so few participants answered the questionnaire.

- Demand: The estimated use of the intervention in the intervention group.

As this was a home-based intervention, to accurately and directly measure the demand for the intervention was challenging as neither participant recall nor the constant presence of a researcher to assess this were available. Alternatively, an indirect measure or asking the participants directly were two alternatives. For this study it was proposed that participant demand could be indirectly assessed by the number of participants in the intervention group who returned their step log. In all cases, apart from one, this was fully completed. In total five of the 17 (29%) participants in the intervention group returned their step log. This was suggestive that there was poor demand for this intervention.

- Implementation: The likelihood that the pedometer-prescribed walking intervention can be prescribed to the THR population in an uncontrolled study design.

Due to the relative ease of administering the intervention, giving the patient a pedometer and explaining how to use it, is proposed an achievable intervention to implement in an uncontrolled study design. In addition to this, the patient and public involvement group were broadly positive about physical activity interventions in the THR population. They suggest that ‘giving the participant something’ such as a pedometer-prescribed walking programme would be an achievable and implementable intervention.

- Practicality: How the pedometer-prescribed walking intervention could be delivered when resources are restricted.

It is proposed that if resources were restricted, delivery of a pedometer-prescribed walking intervention would be challenging but not impossible. Considering that the intervention is quick to deliver and relatively cheap to deliver, this would be attractive. There is a need for additional research to assess the cost-effectiveness of this intervention within the THR population. Aittasalo, Miilunpalo, Kukkonen-Harjula, and Pasanen (2006) showed that the cost of providing such an intervention in 62 patients was $3427, mean $55.27 per patients, in the primary care population. However if it suggested that this may be an over-estimation in this population, as the cost of the pedometer used in this study was £6.00 ($7.46), it is proposed that the brief time that is needed to explain how to use the pedometer, would not account for the remaining £38.46 ($47.81) per patient.

- Adaptation: The ease of change to the intervention if a new situation arrives.

A pedometer-prescribed walking intervention would be easy to adapt for a different population, as the only modifiable factors are the number of days which the pedometer is worn or the target number of steps. However the validity in a different population should be considered before delivering a pedometer-prescribed walking intervention within it. This was illustrated in a previous systematic review by Bravata et al. (2007). Although there was a significant benefit in providing a pedometer-prescribed intervention (MD: 2491 95% CI: 1098 to 3885, $p<0.001$), there was no clear result in respect to its validity within a given population. To take sedentary individuals as an example, Butler and Dwyer (2004) investigated sedentary adults aged 45 to 65 years and showed no significant difference in step number (MD: 395 95% CI: -118 to 908, $p=0.13$) whereas the Hultquist, Albright, and Thompson (2005) study of sedentary, non-smoking women, aged 33 to 55 years showed a significant difference in step number (MD: 2226 95% CI: 1488 to 2964, $p<0.001$). Considering the very similar inclusion and exclusion criteria for both studies, there was no clear reason for this difference. This is an example of the challenges faced when

assessing the validity of a pedometer-prescribed walking intervention in a given population, and should be considered before adopting it to a different or similar population.

- Integration: The level of system change that would be needed to implement the pedometer-prescribed walking intervention.

It is proposed that for a pedometer-prescribed walking intervention minimal system change would be needed to be sustainable. The two changes that would be needed to integrate a pedometer-prescribed walking intervention into practice would be the purchasing and provision of a pedometer with an appropriate explanation of how to use it. This took 40 minutes in this study in addition to consenting the participant. What is unknown is how, or if, the monitoring of a pedometer-prescribed walking intervention would be undertaken and the affect that this would have on the integration of the programme. This would be in addition to ensuring that an appropriate feedback mechanism is implemented, to ensure any additional appropriate changes were also made.

- Expansion: The potential success of an intervention in a different population.

Pedometer-prescribed walking interventions have previously been shown to be beneficial in other clinical populations (Bravata et al., 2007; L. A. Talbot, Gaines, Huynh, & Metter, 2003). Therefore this intervention is effective in a selected number of other populations. However, the validity of a pedometer-prescribed walking intervention and the evidence to support its use should be considered before using it in a different population, including those following THR.

- Limited-efficacy testing: Feasibility studies are designed to test an intervention in a limited way.

As this study was underpowered due to its small sample size, as would be expected in a feasibility study where the aim is not to detect a statistical difference or association, the weaknesses of underpowered research should be considered when drawing conclusions from the results of this study. Underpowered research reduces the chance of finding a true effect and reduces the chance of detecting a statistically significant difference, but may however identifya clinical meaningful difference (Button et al., 2013).

The following two sub-sections will discuss how recruitment, randomisation, adherence and contamination effected the design of this study in greater detail.

7.2.1 Recruitment

Recruitment challenges are a common difficulty in rehabilitation trials (Beckie et al., 2009; Gandhi, Cooper, & Barker, 2015; Tyson, Thomas, Vail, & Tyrrell, 2015). Gandhi et al. (2015) summarised the difficulties in orthopaedic rehabilitation trials noting that the main difficulty was acknowledgement of the clinical relevance of the research by physiotherapy management staff and physiotherapy management whose sites conducting the trial. A number of papers have explored factors which may address such challenges. Firstly Tyson et al. (2015) suggested the development of a flexible multi-disciplinary team was used to ensure optimum participant recruitment. Beckie et al. (2009) examined the difficulties of recruiting female participants to a cardiac rehabilitation trial. They concluded that recruitment is significantly related to significant patient-orientated biopsychosocial barriers, it is suggested that this is also potentially the case in THR studies. As previous research has shown that a number of barriers exist to physical activity in the THR population for example a fear of dislocation (Smith et al., 2015). To summarise, although

there has been no research that has specifically examined recruitment challenges in the THR population, considering previous research in the field, and the known barriers to physical activity in the THR population, it is reasonable to suggest that recruitment was likely to be challenging in this study.

The recruitment rate in this study was lower than anticipated prior to the study commencing. A number of reasons have been proposed for this. The initial method of recruiting participants was to post a letter to patients with their pre-operative clinic letters. This resulted in an unexpectedly small number of returns (27%). This method of recruitment was chosen as it was used successfully as a method of recruitment in a previous rehabilitation study at the same recruiting hospital (Smith et al., 2008). The hospital staff were also familiar with the methods of recruitment and it ensured that the potential participants were contacted before their pre-operative appointment, to provide sufficient time to consider whether to participate or not. However this strategy was not successful on this occasion. Accordingly in April 2015 an alternative recruitment approach was adopted. Resultantly, the invitation to participate letter was posted when the patient was listed for the THR. This change resulted in an average increase in monthly recruitment from 0.50 patients per week to 0.55 patients per week, an increase of 10%.

The 10% increase in recruitment rate was less than hoped for. However there were a number of factors which contributed to the lower recruitment role which were out of the control of the researcher. The most significant challenge was the bed shortage problems at the participating principal NHS hospital. At the height of the bed shortage, the number of elective THR operations dropped noticeably from a high of 56 per month to 35 per month. This, as would be expected, slowed recruitment. A possible method of increasing the number of recruited participants was to increase the number of recruitment sites. After consideration, it was decided that this would not be done as there remains significant variability in the rehabilitation protocols provided between hospital trusts (Artz et al.,

2013). This was summarised by Artz et al. (2013) in a telephone survey study of 14 high-volume NHS Orthopaedic centres in England and Wales. Even though no centres referred to patients to outpatient physiotherapy routinely, one centre offered telephone conference, one centre offered a drop-in service along with telephone consultation and one centre a review appointment. Post-surgery rehabilitation has been shown to significantly affect post-surgery recovery (Iyengar et al., 2007; Schneider et al., 2009; Smith, McCabe, et al., 2012). Equally this could be used as an argument for using multiple sites as this replicates the differences that occur across healthcare systems.

A major criticism of RCTs is that they lack external validity (Jones, Jones, Mc Cowan, Montgomery, & Fahey, 2009; Rothwell, 2006) due to selecting a specific section of the patient population and delivering an intervention that may not be compatible with normal care for a given healthcare system. For this feasibility RCT, these are not concerns that hold true as the intervention is an addition to normal care, not a change. As orthopaedic rehabilitation research has a developing evidence-base, as only 17 papers were included in the most recent THR rehabilitation systematic review (Withers et al. (2016), it was decided that this would complicate the picture in respect to potential confounding variables. Additionally the more sites a study has, the more expensive the study becomes to run (Kraemer, 2000). It would be financially prohibitive to include additional sites, considering the small budget for this PhD.

As the experimental intervention was a pedometer-prescribed walking intervention, the geography in-which the participant lives and where the research was undertaken should be considered as a further confounder. The area of local green space has been shown to predict the physical activity levels of a population (Lachowycz & Jones, 2014). The findings of this study, based in Norfolk, may not be applicable to patients who live in a more urban area (DEFRA, 2016). This however must be considered with caution as no

work has been reported investigating the benefits (or not) of green space exposure and surgical outcomes.

When considering the time constraints of the PhD research, there was no additional measure that this study could have accounted for to increase participant numbers. However there were two principal strategies that could be actioned to ensure that similar research in the future does not face the same recruitment challenges. Firstly, future studies should either use a multi-centre approach to recruitment and/or secondly the eligibility criteria may be widened to include total knee replacements. Both strategies have positives and negative consequences. Using a multi-centre approach benefits from having access to a greater number of patients to potentially recruit to studies. It is however important to note that patients may not all have the same care as in-hospital post-operative care varies noticeably from hospital to hospital (Artz et al., 2013). This therefore may have an effect on outcome (Artz et al., 2013). To resolve this the whole rehabilitation protocol across all sites would need to be standardised to ensure consistency between the sites for post-operative rehabilitation and recovery. Though not controlling for this may equally be used as an argument for an effective pragmatic trial, as it takes into consideration the external validity differences that occur across hospitals.

An alternative method of improving recruitment would be to widen the inclusion criteria so that more patients were eligible. It was decided against reducing the minimum age of 18 years age as it was perceived that this would have minimal impact since the average age of THR being 69 years. Additionally decreasing the age would have resulted in needing to add an additional recruitment site as the ones used only cared for patients 18 years of age and older and as skeletal maturation may not of been fully achieved this. This may therefore have skewed the outcomes of the study. The inclusion criteria were as relaxed as possible. For example, participants with cardiovascular disease were only excluded if their specific cardiovascular illness suggested that the benefits of exercise were

outweighed by the risk (Gibbons et al., 2002). For example if a potential participant had cardiomyopathy he/she would have been excluded from the study because of the increase risk of exercise induced sudden cardiac death (Gibbons et al., 2002).

The final option would be to either include participants who had a bilateral THR or having an additional operation with their THR. This was not performed as there are some key differences in outcome when comparing unilateral and bilateral THR. Berend et al. (2005) showed that pulmonary complications were significantly greater (1.6% versus 0.7%; $p<0.031$) in the first post-operative year in the bilateral compared to the unilateral THR group. Finally we may have recruited people who had undergone total knee replacement in addition to those who had undergone THR. This has been previously undertaken (Barbay, 2009). However the outcomes from THR and knee replacements are reported to differ (Jansson & Granath, 2011; NJR, 2015). For example Jansson and Granath (2011) reported that although EQ-5D improved from pre-surgery to post in both THR and knee replacement cohort ($p<0.0001$). There was a greater change from baseline in the THR group with 69% (n=254) of THR patients showing a greater than 0.1 increase EQ-5D whereas only 54% (n=196) of people following knee replacement showed the same increase. This difference in outcome between joint replacements would need to be considered if a study including both groups was undertaken.

To ensure that the patient perspective was considered when trying to understand these recruitment challenges, a Week 24 feedback questionnaire was sent out. This feedback provided insights into these design issues. On analysis, patients were broadly positive about the trial, with 100% of participants saying the questionnaires were easy to answer, but no comments were made in respect to the recruitment process for the study. Considering the lack of information in respect to potential reasons for the poor recruitment, there is a need to engage with patient and public involvement groups before undertaking future research to try to better understand the recruitment challenges from a

patient and public perspective. This may mitigate future challenges which have been experienced in this study.

The recruitment challenges that have been discussed in this section are similar to those that have been reported in previous trials (Beckie et al., 2009; Gandhi et al., 2015; Tyson et al., 2015). This feasibility trial provides additional evidence suggesting that recruitment to physical activity interventions in the THR community is a trade-off between a low recruitment rate from one centre or a higher recruitment rate, accepting the challenges that are associated with a multi-centre trial.

7.2.2 Randomisation

The randomisation method used in this study was non-blinded block randomisation. Block randomisation was used to ensure that there was a minimal difference between the control and intervention group (Efird, 2011). This was achieved where the control group included 16 and the intervention group included 17 participants. An equal distribution of participants between control and intervention group was important to ensure that the known and unknown confounding factors that may affect the outcome of the study were equally distributed (Efird, 2011).

The ‘gold standard’ of randomisation is reported as double-blinded randomisation, when both the participant and the experimenter are blinded to group allocation (Misra, 2012). This however was not possible in this study as it was not possible to ensure a viable walking placebo to the control group. Hence un-blinded randomisation was adopted. This study therefore had a naturally high risk of bias, compared to a blinded trial. Though employing a strict protocol, as was done in this case, this was minimised (Higgins & Green, 2008). In addition, the two recruiting hospitals only recruited participants from one

hospital trust. This ensured that care was kept as similar as possible between recruiting hospitals and any undue to differences were therefore be balanced throughout.

To conclude this section, although the gold standard randomisation method was not used, the process adopted was appropriate. The associated biases that resulted from this means that the confounding factors that resulted from this were kept to a minimum.

7.2.3 Adherence and Measurements of Intervention Adherence

There is no recognised method of measuring adherence to a pedometer-prescribed walking intervention. It is however suggested that the adherence to this intervention was poor as the self-reported number of steps undertaken was significantly less than the target number of steps (MD: 2812±2391m). What compounds this uncertainty was that only five of the 17 (29%) participants in the intervention group returned their 'step log'. This therefore questions the feasibility and fidelity of the pedometer-prescribed walking intervention for this population due to the small number of participants who returned the step log, and the significant lack of adherence. Only two of the 10 participants (20%) reported that they did not have enough time to wear the pedometer or complete the step log. Therefore before future research is undertaken, it would be important to understand the barriers to this specific physical activity intervention in this population.

It was not possible to directly measure adherence to this intervention due to its home-based nature. To negate this, a self-reported but directly assessed measure of adherence has to be used. It is proposed that the number of returned fully completed step logs could be used as an indirect measure of adherence. This was 24% (four out of 17). It was not possible however to suggest how accurately this measure of adherence was as no appropriate method of validation has been undertaken. Therefore this should be considered an 'indication' of adherence opposed to a valid measure. An alternative to

using a paper based system to measure adherence would be to use a more advanced device that had an inbuilt method of assessing adherence. However, the financial constraints of the PhD precluded this.

The 24% level of adherence with the intervention group to the intervention was less than what was hoped for. Though the reasons for lack of adherence were not explored, it has been previously shown that non-adherence is multi-faceted, often based on personal reasons for lower adherence. Nonetheless a lack of adherence does not necessarily result in a lack of patient benefit (Jolly et al., 2007). In addition it is also important to note that the reasons for lack of adherence are frequently variable across participants and trials. It is therefore important to identify the reasons for this in THR population for future rehabilitation research (Jolly et al., 2007).

To conclude although the adherence to the intervention was poor, analysis of this intervention in the THR population is beneficial to better inform future studies on physical activity and make the appropriate adjustments to increase the probability of an increased adherence in the future. Considering the poor fidelity and feasibility reported in this study, it was not possible to make firm conclusions on the effectiveness of a pedometer-prescribed walking intervention in the THR population. However before a definitive trial is undertaken, the barriers to physical activity intervention adherence must first be identified and addressed.

7.2.4 Contamination

It could be suggested that typically un-blinded randomised control trials have a high risk of contamination, as the control group could potentially observe and replicate the intervention especially if the intervention was hospital-based. It is proposed that in this study, there was a low risk of contamination as the intervention was only commenced

when the participant was discharged from hospital. For contamination to occur, the control group participants would have needed to acquire a pedometer. This would be relatively easy to do considering that these are freely available to purchase or are on some mobile phones. However, participants would have also needed a copy of the step log, which was not freely available during the study. Therefore control participants could not have easily followed the prescribed-step count protocol.

The accurate measurement of contamination is a challenge. It relies on participants reporting that they are using an experimental intervention when allocated to a control group. Until it is possible to administer a viable placebo for a physical activity intervention, contamination in these studies will always be a potential challenge, it is suggested that a solution in some part may be to use a physical activity intervention that uses equipment but would not provide the 'ingredient' of physical activity. The contamination risk should be considered in all RCT physical activity studies, although due to the location the intervention was administered, it is proposed that contamination was low risk in this study.

7.3 Discussion on Hip Function and Health Measures

In line with previous research (Field, Cronin, & Singh, 2005) the Oxford Hip Score (OHS) significantly improved from pre- compared to post-THR. The OHS is an outcome measure for THR. In addition to this, there was no significant or clinical difference between the groups at any time points based on an OHS. The results of this study are suggestive that the use of a pedometer prescribed walking intervention has no benefit on hip health. A number of points should however be considered before drawing such conclusions. The wide confidence intervals reported for this finding. As the confidence interval is a measure of effect that is to say that the larger the confidence interval the smaller the effect (Higgins & Green, 2008). The width of the confidence interval, to a large extent, is dependent on the size of the sample (Higgins & Green, 2008). However given that this study was under-

powered to detect a difference being a feasibility study. Further larger cohort trials would support or refute this conclusion.

It is also important to consider the weaknesses of the OHS. The most significant weaknesses seen during the development of the OHS was the lack of sampling across the socioeconomic spectrum a key variable when reporting outcome measures (Karpati, Galea, Awerbuch, & Levins, 2002). Though this was a weakness for this questionnaire, it could also be suggested that it was also a weakness for this current study as patients will be undergoing treatment in a hospital in East Anglia which has a 'moderate' socioeconomic status (*Region and Country Profiles - Directory of Tables*, 2013). No attempt was made to sample across the socioeconomic spectrum. This was neither practical nor possible to stratify participants by socioeconomic status because the recruiting hospitals treat participants from the same area. This would have also impacted on the time constraints of this PhD. Although socioeconomic status does affect the level physical activity undertaken, it is important to consider this as a relative weakness of the OHS (Saelens et al., 2003).

To conclude this feasibility RCT demonstrated that it would be feasible, with adaption, to evaluate the effectiveness of a pedometer-prescribed walking intervention for people following THR.

7.4 Discussion on Physical Activity Measures

This study showed that there was no obvious pattern in respect to physical activity when comparing both groups. The following sub-sections will discuss each measure of physical activity separately and draw conclusions from their findings.

7.4.1 PASE

The lack of any noticeable difference between the control and intervention groups in respect to PASE score may be attributed to one of four reasons.

(1) The intervention does not work in the THR cohort in respect to increasing the amount of physical activity undertaken.

(2) The target number of steps were too low for the participants to engage fully in the intervention.

(3) The poor adherence to the intervention, as discussed above, resulted in the lack of significant difference.

(4) The sample size was under-powered to detect a statistically significant difference.

It is important to take into consideration the poor measurement properties of the PASE with patients with osteoarthritis (Svege et al., 2012). Svege et al. (2012) reported that using the Norwegian version of the PASE in a group of patients with hip osteoarthritis, that although the PASE showed moderate test-retest reliability (ICC = 0.61, p<0.01) there was however a large standard error of measurement (31), minimal detectable change (87) and limits of agreement would be at the lower level (-65) and upper level (100). This should be considered given that the primary presentation for THR is hip osteoarthritis (NJR, 2015) and therefore in essence this population pre-surgery comprise of those with hip osteoarthritis.

An additional consideration was that not all of the participants recruited to this study were over 65 years old. The mean for both groups was above 65 years (71±10 and 68±11 years for the control and intervention groups respectively). As it has been previously shown that not using an age-specific physical activity questionnaire results in biased results, the PASE use in this study was validated for the largest proportion of the population but not those under 65 years of age (Shephard, 2003).

7.4.2 Accelerometery

It would be futile to attempt to draw any conclusions from the acclerometery data that is presented in respect to change or between-group difference. This was justified due to the large proportion of missing accelerometer data (70%). Although the initial *a prori* assumption was that this was due to participants not wearing them, this turned out not to be the case. Analysis of the data indicated that there was no data recorded from when the accelerometer was in the post, which would be expected as the accelerometer is always on. It was therefore concluded that the reason for the lack of data was not because participants were not wearing the accelerometers but because there was a technical issue with the accelerometers itself. The company that provided the accelerometers (Technogym) were unable to find a solution to this technical problems that appeared to affect the majority of the accelerometers. Unfortunately, it was not possible to change the accelerometer to a different model due to the time and financial constraints of the project.

7.5 Discussion on Adverse Event

Participation in the trial was not considered to have played a part in any of the adverse events recorded. However, this section will discuss what could be learnt from the adverse events that did occur during this study.

7.5.1 Hip Re-Dislocation

One participant suffered multiple dislocations post-surgery. This resulted in the need for revision surgery. This provided a revision rate of 3% (95% CI: 0.05 to 6%) which was higher than the one year revision rate of 1% (95% CI: 0.7 to 0.9%) reported by in the NJR (NJR, 2015). However, given the small number of participants, further monitoring would be warranted to explore whether this rate was representative when a larger cohort was recruited.

7.5.2 Minor Adverse Events

The minor adverse events, detailed in section 6.6, were not attributed to study participation. It was suggested however that all of the adverse events, minor and major, were likely to reduce the amount of physical activity undertaken by the participants (Boyd et al., 2008). Boyd et al. (2008) showed that in older adults (aged 70 years or over), following acute hospital admission for medical illness, 41% died and 29% did not return to their baseline activity of daily living level. It was suggested that the effect on this study population is likely to be less as none of the minor events recorded required an in-patient hospital stay. It was suggested that the minor adverse events may have had an effect on physical activity. However due to the small number of participants and the small number of adverse events which occurred, it was not possible to make firm conclusions. As the number of adverse events was too small to be able to perform a meaningful sub-analysis.

7.5.3 Major Adverse Events

With the exception of the participant who underwent revision surgery, as discussed in Section 7.5.1, there was no other major adverse event.

7.6 Quality of Life Measures

The significant improvement in EQ-5D from pre-operatively to post-operatively has been previous demonstrated in studies of the THR population (Jansson & Granath, 2011). *A priori* this is also what one would expect as the THR is likely to increase the range of movement of the joint, with decreased pain (Davis, Ritter, Berend, & Meding, 2007). There were no noticeable differences between the control and intervention group which is suggestive that the pedometer-prescribed walking intervention had no effect on participant's quality of life. This is not surprising considering that physical activity was not significantly different between the groups. As it is suggested, any increase in physical activity would be a driver to improved quality of life in this sense.

Gill et al. (2013) showed, in an open-ended questionnaire study, that in older people (n=142, mean = 62.5 years; range 24 to 89 years) leading a physically active lifestyle had perceived 'social and emotional' benefits which in turn ensured a good quality of life. It is reasonable to expect that a beneficial physical activity intervention could also result in an improved in quality of life. The lack of difference therefore is additional evidence to suggest that the pedometer-prescribed walking intervention did not work in this instance due the lack of difference in quality of life from an under-powered cohort.

The general nature of the EQ-5D could be considered its main weaknesses. As a non-disease specific instrument, the EQ-5D would not assess the specific characteristics of THR hence why a global rating of change scale (GRCS) was also included posing the question 'with respect to your hip that you had replaced with an artificial one mark on the scale how you feel that particular hips health status has changed comparing now to immediately before your operation.' The GRCS therefore provided a specific perspective of the THR issues. However it is important to consider that if a patient is asked to self-rate their experience, they will provide answers based on their personal values. Through this, it

is suggested that the GRCS is actually of great benefit. It is beneficial as the participant only takes into consideration the parameters that he or she thinks are important when assessing change in a condition or illness. However this is also the GRCS greatest weaknesses as the change that is reported is based on different parameters for each participant as the participant decides what parameters to base the change on. This can be controlled if the question and scale are constructed in the correct manner.

To conclude there was no evidence to suggest that a pedometer-prescribed walking intervention has a significant benefit on quality of life. However the under-powered cohort should be remembered when interpreting these findings.

7.7 Clinical Implications

There are two broad clinical implications from this study:

(1) the use of pedometer-prescribed walking interventions within the THR populations
(2) the unique challenges of physical activity interventions within this population.

These findings suggest that a pedometer-prescribed walking programme has limited benefit to patients in respect to both hip health, physical activity and quality of life. However the relatively small sample size that is presented within this study, and low fidelity to the experimental intervention, should be noted and this would affect the interpretation of the results.

A pedometer-prescribed walking intervention has however worked in other clinical populations. Bravata et al. (2007) systematic review of the use of pedometer-prescribed walking intervention in a clinical population, concluded that the use of a pedometer was associated with a significant increase in physical activity. However of the 15 studies which

were included in this systematic review only one investigated an orthopaedic population (osteoarthritis of the knee) Talbot, Gaines, Huynh, & Metter (2003). This study compared an arthritis self-management programme compared to an arthritis self-management programme along with a pedometer-prescribed walking intervention. Talbot et al. (2003) concluded that a pedometer-prescribed walking intervention warranted further investigation as there were indications that it may have been of benefit in their small sample (n=17, both groups) due to a better functional performance however there was no improvement in step count, in agreement with this research.

To conclude, this study suggests that a pedometer-prescribed walking intervention has no clinical benefit. However the poor fidelity and small size should be considered before drawing any conclusions.

7.8 Issues on Implications of Findings

More research is needed to better understand the barriers to physical activity interventions in the THR population. Considering the findings from previous research highlighted above, and the findings from this study, the results should be used to further test a pedometer-prescribed walking intervention or a different physical activity intervention which is discussed in more detail in the proceeding section below.

7.9 Priorities for Future Research

As shown throughout this thesis, there remains a need to identify an intervention that increases physical activity following THR. The results suggest that is it feasible to investigate a pedometer-prescribed walking intervention within a definitive trial. It is proposed that the mean research question that arises from this feasibility study should be:

1. What is the clinical and cost-effectiveness of a pedometer-prescribed walking intervention for people following THR.

7.10 Summary

In summary this pedometer-prescribed walking interventions appear to have limited clinical benefit in the THR population. However these results should be treated with caution due to the feasibility nature of the RCT and the small sample size. There is still a need to better understand the THR population and therefore be able to develop a suitable physical activity intervention for this population. After revising the key trial design features such as recruitment, intervention fidelity and outcome measure data collection, a definitive trial assessing the clinical and cost-effectiveness of a pedometer-prescribed walking intervention is warranted.

The next and final chapter will summarise the findings from this whole thesis and draw appropriate conclusions.

Chapter 8 Conclusions

This thesis was formed of three studies: a systematic review, a secondary dataset analysis and a feasibility RCT. The three studies will now be briefly concluded and the appropriate conclusions made in respect to the whole thesis. It is also important to note the change of focus from the first two studies on physical activity to the functional measure of the Oxford Hip Score. This was done as it was felt that healthcare professionals would be able to relate to the measure better that one of physical activity. Secondly, it was felt that in a clinical population, a functional measure would be more relevant measure.

8.1 Systematic Review

The systematic review examined the change in physical activity pre- compared to up to one year post-THR. With the following research questions:

1. Is there a significant difference in physical activity pre- and post-THR operation?

2. Is the level of physical activity undertaken following THR associated with improved quality of life?

The conclusion of the systematic review was that there was no significant change in physical activity pre- compared to up to one year post-THR. Future research was recommended with better external validity to better understand the potential reasons behind this finding and whether this was a process of natural aging or something which occurs in the THR population.

8.2 Secondary Data Analysis

To begin to answer some uncertainties arising from the systematic review, a secondary data analysis was undertaken analysing data of 226 THR participant's pre- versus post-surgery compared 452 non-THR participants who had data collected at the same time points. Unlike the systematic review where all of the post-operative data included was collected within a year, in this analysis the majority (95%, n=214) of the physical activity data were collected more than one-year post-surgery. The research questions for this study were:

1. Is there a significant change in physical activity pre- compared to post-THR?
2. Does having a THR significantly predict physical activity post-surgery?

The conclusion of the secondary data analysis was that physical activity significantly decreased from pre- compared to post-THR. Having a THR was not a significant predictor of physical level. Therefore more research was recommended to identify a physical activity intervention which could potentially increase physical activity in the THR population, to address this clinical need.

8.3 Feasibility Randomised Controlled Trial

The aim of the feasibility RCT was to examine the use of a pedometer-prescribed walking intervention in the THR population. The conclusion of the study was that the adherence to the intervention was poor (29%). Recruitment to the study was challenging. However participants reported the intervention to have potential value. Therefore a greater understanding of the barriers to physical activity in the THR population was recommended so that either this intervention or another can be appropriate developed to take these barriers into consideration when tested within a definitive trial design.

8.4 Clinical Conclusions

This thesis has contributed to the clinical body of evidence on THR rehabilitation and recovery in a number of ways both clarifying previous debates and adding new evidence. Previous evidence has supported the theory that a specific area of physical activity; physiotherapy-led exercise (Minns-Lowe et al., 2015), physical activity and hip pain (Gill & McBurney, 2013), building an exercise programme (DiMonaco & Castiglioni, 2013) and when considering THR and total knee replacement together (Arnold et al., 2016), physical activity does not increase. However this thesis has provided evidence to suggest that this is not the case when considering physical activity as a whole. In addition to this, the thesis has presented evidence to suggest that this may in part be due to an age-related decline in physical activity.

These findings are useful in the clinical sense as it allows healthcare professionals to appreciate the likelihood of the patient achieving their physical activity goals post-surgery. It is also important to note that as of yet there is no evidence to conclusively support or rebuke the use of pedometer-prescribed walking interventions in the THR population, due to the feasibility nature of this RCT. This research also shows that currently there is no known intervention that increases physical activity within the THR population.

8.5 Research Conclusions

Considering the finding of this thesis, there are a number of important research question to consider for the future research. Further research is needed to better understand the lack of significance difference in pre- versus post-THR and the reasons behind this. This additional research should focus on whether this lack of difference is related to the age-related decline in physical activity or a different factor.

Further research should also stem from the feasibility RCT, which is discussed in detail in Section 7.9. In short, this research should focus on identifying barriers to physical activity in the THR population, and identifying a suitable intervention to increase physical activity.

8.6 Overall Conclusions

To conclude, this thesis has two main findings. Firstly that physical activity does not change pre- to post-THR. However over a longer time span, more than one year post-operatively, this may be a result of natural aging. Secondarily, there were a number of challenges that need to be overcome before a pedometer walking intervention can be taken to a full definitive trial. However, a definitive trial to assess the clinical and cost-effectiveness of this intervention is maybe warranted in the future.

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Washburn, R. A., Smith, K. W., Jette, A. M., & Janney, C. A. (1993). The Physical Activity Scale for the Elderly (PASE): development and evaluation. *J Clin Epidemiol, 46*(2), 153-162.

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White, D. K., Tudor-Locke, C., Felson, D. T., Gross, K. D., Niu, J., Nevitt, M., . . . Neogi, T. (2013). Walking to meet physical activity guidelines in knee osteoarthritis: is 10,000 steps enough? *Archives of Physical Medicine and Rehabilitation, 94*(4), 711-717.

Whitney, J. A. P., S. (2002). Preoperative physical activity, anesthesia, and analgesia: effects on early postoperative walking after total hip replacement. *Applied Nursing Research, 15*(1), 19-27.

Williams, S., & French, D. (2011). What are the most effective intervention techniques for changing physical activity self-efficacy and physical activity behaviour—and are they the same? *Health Education Research*, cyr005.

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APPENDICES

Appendix 1 PROSPERO registration

UNIVERSITY of York
Centre for Reviews and Dissemination

NHS
National Institute for Health Research

PROSPERO International prospective register of systematic reviews

Review title and timescale

1 Review title
Give the working title of the review. This must be in English. Ideally it should state succinctly the interventions or exposures being reviewed and the associated health or social problem being addressed in the review.
Is there a significant difference in total physical activity levels before and after elective unilateral total hip replacement? A systematic review

2 Original language title
For reviews in languages other than English, this field should be used to enter the title in the language of the review. This will be displayed together with the English language title.

3 Anticipated or actual start date
Give the date when the systematic review commenced, or is expected to commence.
30/06/2014

4 Anticipated completion date
Give the date by which the review is expected to be completed.
29/05/2015

5 Stage of review at time of this submission
Indicate the stage of progress of the review by ticking the relevant boxes. Reviews that have progressed beyond the point of completing data extraction at the time of initial registration are not eligible for inclusion in PROSPERO. This field should be updated when any amendments are made to a published record.

The review has not yet started ×

Review stage	Started	Completed
Preliminary searches	Yes	Yes
Piloting of the study selection process	Yes	No
Formal screening of search results against eligibility criteria	Yes	No
Data extraction	Yes	No
Risk of bias (quality) assessment	No	No
Data analysis	No	No

Provide any other relevant information about the stage of the review here.

Review team details

6 Named contact
The named contact acts as the guarantor for the accuracy of the information presented in the register record.
Mr Withers

7 Named contact email
Enter the electronic mail address of the named contact.
t.withers@uea.ac.uk

8 Named contact address
Enter the full postal address for the named contact.
Room 1.23, School of Health Sciences, Queen's Building, University of East Anglia, Norwich, NR4 7TJ

9 Named contact phone number
Enter the telephone number for the named contact, including international dialing code.
+44 (0)1603 593093

10 Organisational affiliation of the review
Full title of the organisational affiliations for this review, and website address if available. This field may be completed as 'None' if the review is not affiliated to any organisation.

University of East Anglia

Website address:
uea.ac.uk/health-sciences

11 Review team members and their organisational affiliations
Give the title, first name and last name of all members of the team working directly on the review. Give the organisational affiliations of each member of the review team.

Title	First name	Last name	Affiliation
Mr	Thomas	Withers	School of Health Sciences, University of East Anglia
Dr	Toby	Smith	School of Health Sciences, University of East Anglia
Professor	Catherine	Sackley	School of Health Sciences, University of East Anglia
Ms	Sarah	Lister	Norfolk and Norwich University Hospitals

12 Funding sources/sponsors
Give details of the individuals, organizations, groups or other legal entities who take responsibility for initiating, managing, sponsoring and/or financing the review. Any unique identification numbers assigned to the review by the individuals or bodies listed should be included.
None

13 Conflicts of interest
List any conditions that could lead to actual or perceived undue influence on judgements concerning the main topic investigated in the review.
Are there any actual or potential conflicts of interest?
None known

14 Collaborators
Give the name, affiliation and role of any individuals or organisations who are working on the review but who are not listed as review team members.

Title	First name	Last name	Organisation details

Review methods

15 Review question(s)
State the question(s) to be addressed / review objectives. Please complete a separate box for each question.
There is a significant difference in physical activity pre and post total hip replacement operation.

The more physical activity undertaken, the higher the quality of life.

16 Searches
Give details of the sources to be searched, and any restrictions (e.g. language or publication period). The full search strategy is not required, but may be supplied as a link or attachment.
Initially relevant databases will be searched; databases that contain both published and unpublished research shall be used to ensure that the maximum volume of relevant literature is used. The reference list of appropriate grey literature including 'Occupational therapy for adults undergoing total hip replacement: Practice guideline' (College of Occupational Therapists & Sainty) will be scanned to assess for any other research that could potentially be included in the systematic review.

17 URL to search strategy
If you have one, give the link to your search strategy here. Alternatively you can e-mail this to PROSPERO and we will store and link to it.

I give permission for this file to be made publicly available
No

18 Condition or domain being studied
Give a short description of the disease, condition or healthcare domain being studied. This could include health and wellbeing outcomes.
Primary unilateral total hip replacement.

19 Participants/population
Give summary criteria for the participants or populations being studied by the review. The preferred format includes details of both inclusion and exclusion criteria.
The inclusion criteria for this review are: 1. Adult participants (18 years old or greater). 2. Participants had or are about to have a unilateral total hip replacement and no other procedure at the time. 3. Participants had a total unilateral hip replacement.

20 Intervention(s), exposure(s)
Give full and clear descriptions of the nature of the interventions or the exposures to be reviewed
The inclusion criteria for this review are: Physical activity data was collected both post and pre operatively.

21 Comparator(s)/control
Where relevant, give details of the alternatives against which the main subject/topic of the review will be compared (e.g. another intervention or a non-exposed control group).
This systematic review will compare physical activity between pre and post total hip replacement.

22 Types of study to be included
Give details of the study designs to be included in the review. If there are no restrictions on the types of study design eligible for inclusion, this should be stated.
Observational, longitudinal or randomised control trials.

23 Context
Give summary details of the setting and other relevant characteristics which help define the inclusion or exclusion criteria.

24 Primary outcome(s)
Give the most important outcomes.
Change in physical activity.

Give information on timing and effect measures, as appropriate.

25 Secondary outcomes
List any additional outcomes that will be addressed. If there are no secondary outcomes enter None.
Quality of life and hip dislocation rate.

Give information on timing and effect measures, as appropriate.

26 Data extraction (selection and coding)
Give the procedure for selecting studies for the review and extracting data, including the number of researchers involved and how discrepancies will be resolved. List the data to be extracted.
Data from all suitable eligible papers will be extracted using the data extraction table; the table will be trialled before the full systematic review is undertaken. If there are missing data or hip and knee replacement data is combined which is common practice by some research groups in the field the author will be emailed and asked for clarification. Both reviewers will screen and identify studies independently and extract the data. After both reviewers have screened and extracted data from all studies that they believe confirm to the inclusion criteria, the reviewers will meet and discuss any difference of opinion which they may have. If need be a third reviewer will be used to settle any disagreements.

27 Risk of bias (quality) assessment
State whether and how risk of bias will be assessed, how the quality of individual studies will be assessed, and whether and how this will influence the planned synthesis.
All papers included in this study will be critically appraised and assessed for bias by using one of the appropriate tool listed below: • For RCTs: Critical appraisal tool developed by the Cochrane collaboration (Higgins & Green, 2008). • For Case control trials CASP Case Control Checklist • For Cohort Studies: CASP Cohort Study Checklist

28 Strategy for data synthesis
Give the planned general approach to be used, for example whether the data to be used will be aggregate or at the level of individual participants, and whether a quantitative or narrative (descriptive) synthesis is planned. Where appropriate a brief outline of analytic approach should be given.
After the data from all included papers has been collected heterogeneity will be assessed if appropriate the data will be synthesised and a single or multiple meta-analysis will be undertaken. Heterogeneity examines the null hypothesis that all studies are evaluating the same effect (Higgins, Thompson, Deeks, & Altman, 2003). The Cochrane recommended interpretation of I-squared, as shown below, will be used for this study (Higgins & Green, 2008). I-squared range 0% to 40%: Might not be important. I-squared range 30% to 60%: May represent moderate heterogeneity. I-squared range 50% to 90%: May represent substantial heterogeneity. I-squared range 75% to 100%: Considerable heterogeneity. If there are not enough data for individual measure analysis the measure will be converted into the standardised mean differences. The standardised mean difference is the difference in mean outcome between groups divided by the standard deviation of outcome among participants, as shown in the following equation. Standardised Mean Difference = (Difference in mean outcome between groups)/(Standard deviation of outcome among participants)

29 Analysis of subgroups or subsets
Give any planned exploration of subgroups or subsets within the review. 'None planned' is a valid response if no subgroup analyses are planned.
None planned

Review general information

30 Type and method of review
Select the type of review and the review method from the drop down list.
Epidemiologic, Systematic review

31 Language
Select the language(s) in which the review is being written and will be made available, from the drop down list. Use the control key to select more than one language.
English

Will a summary/abstract be made available in English?
Yes

32 Country
Select the country in which the review is being carried out from the drop down list. For multi-national collaborations select all the countries involved. Use the control key to select more than one country.
England

33 Other registration details
Give the name of any organisation where the systematic review title or protocol is registered together with any unique identification number assigned. If extracted data will be stored and made available through a repository such as the Systematic Review Data Repository (SRDR), details and a link should be included here.

34 Reference and/or URL for published protocol
Give the citation for the published protocol, if there is one.
Give the link to the published protocol, if there is one. This may be to an external site or to a protocol deposited with CRD in pdf format.

I give permission for this file to be made publicly available
Yes

35 Dissemination plans
Give brief details of plans for communicating essential messages from the review to the appropriate audiences.
The results of this systematic review will be disseminated at appropriate conferences and a paper will be submitted for publication to an appropriate peer reviewed journal, to ensure that the review is as widely received in the academic sphere as possible. A lay summary of the results and a copy of the paper will also be sent to relevant

charities for example Arthritis Research UK to ensure that the results are also disseminated to the non-academic community.

Do you intend to publish the review on completion?
Yes

36 Keywords
Give words or phrases that best describe the review. (One word per box, create a new box for each term)
Total hip arthroplasty

Total hip replacement

Physical activity

37 Details of any existing review of the same topic by the same authors
Give details of earlier versions of the systematic review if an update of an existing review is being registered, including full bibliographic reference if possible.

38 Current review status
Review status should be updated when the review is completed and when it is published.
Completed and published

39 Any additional information
Provide any further information the review team consider relevant to the registration of the review.

40 Details of final report/publication(s)
This field should be left empty until details of the completed review are available.
Give the full citation for the final report or publication of the systematic review.
Thomas M Withers, Sarah Lister, Catherine Sackley, Allan Clark, and Toby O Smith Is there a difference in physical activity levels in patients before and up to one year after unilateral total hip replacement? A systematic review and meta-analysis Clin Rehabil 0269215516673884, first published on October 23, 2016 as doi:10.1177/0269215516673884

Give the URL where available.
http://cre.sagepub.com/content/early/2016/10/20/0269215516673884.full.pdf+html

Appendix 2: Systematic Review Protocol

Title

Is there a significant difference in total physical activity levels before and after elective unilateral total hip replacement? A systematic review.

Aims of investigation

The aim of this systematic review is to synthesise the evidence in relationship to how, if at all, physical activity levels change pre and post total hip replacement. For this review, a measure of physical activity shall be considered anything that can be used to measure physical activity this could include a questionnaire, a lab-based test or a field-based test. This systematic review will also additionally collect data on quality of life and hip dislocation.

For this systematic review total hip replacement (THR) shall be defined as complete removal of the femoral head and neck along with the acetabulum; along with any other bone the surgeon views as appropriate to remove followed by fixation of at least an artificial femoral head and acetabulum into the remaining femur and pelvis. Exercise shall be defined as any structured activity that involves a sustained period of movement of at least 10 minutes that may be considered beneficial for cardiorespiratory fitness (Department of Health, 2011). In this research proposal exercise will be considered a form of physical activity. Physical activity shall be defined as any activity that involves a sustained period of movement that exceeds 10 minutes in duration, activities of daily living will be considered a form of physical activity assuming that they last more than 10 minutes. The minimum bout of 10 minutes for activities to count towards the recommended minimum weekly duration of physical activity is in line with current guidelines (Department of Health, 2011). Physical activity level shall be defined as the volume of physical activity undertaken over a given time frame.

Background and rationale

Total hip replacement is one of the most common operations performed in the United Kingdom (UK). A total of 94,044 THR were performed in England, Wales and Northern Ireland in 2012 (*National Joint Registry 10th Annual Report 2013*, 2013).

There are currently three published systematic reviews in the area of THR and physical activity. A recent systematic review of physiotherapist lead exercise post THR (Minns Lowe, Barker, Dewey, & Sackley, 2009) highlighted a lack of clarity in the field by concluding that there is insufficient evidence to disprove or prove any benefit. The findings cannot be generalised to THR as a whole as only examined patients who were having THR due osteoarthritis. However, osteoarthritis is by far the most common reason for a THR to be performed, 92% of THR performed in 2012 were due to a primary diagnosis of osteoarthritis (*National Joint Registry 10th Annual Report 2013*, 2013). A later systematic review concluded that increasing physical activity before THR reduces hip pain (standardised mean difference = 0.45, 95% confidence interval 0.15-0.75) (S. D. Gill & McBurney, 2013). A large number of studies included in the review group hip and knee replacement together (Barbay, 2009; S. D. Gill & McBurney, 2013), therefore potentially confusing the picture in relationship to the benefits of physical activity in THR specifically. The final systematic review in the area (Di Monaco & Castiglioni, 2013) concluded that there is insufficient evidence to build an 'ideal' exercise programme following THR.

In general previous systematic reviews have looked at the effect of a physical activity intervention on physical activity or quality of life measures. However no previous systematic review has examined the change in physical activity pre and post THR and the effect it has if any on quality of life, it is therefore proposed that this will form the basis of the rationale for this study.

Research hypotheses

The hypotheses for this systematic review are listed below:

1. There is a significant difference in physical activity pre and post THR operation.
2. The more physical activity undertaken the higher the quality of life.

Study design

This systematic review will be of randomised and non-randomised trials. The aim of this systematic review is to gather and synthesise all of the data in the area so that a more statically powerful conclusion can be reached in relationship to the change if any in relationship to the physical activity pre and post THR.

An initial scoping search of the literature in line with guidelines proposed by Arksey and O'Malley (2005) shall be undertaken. This scoping exercise will refine the search criteria and further refine the inclusion and exclusion criteria of the study.

Search Strategy

Initially relevant databases will be searched a list of which are shown in Table 9 and an example search strategy is shown in Appendix 1. Databases that contain both published and unpublished research shall be searched to ensure that the maximum volume of relevant literature is used. The reference list of appropriate grey literature including *'Occupational therapy for adults undergoing total hip replacement: Practice guideline'* (a. p. College of Occupational Therapists & Sainty) will be scanned to assess for any other potentially research that could be included in the systematic review. For this systematic review grey literature will be considered literature that has not been formally published this could include conference abstracts and artificial hip company experiments where the data was realised but a formal paper was never written. Grey literature will be included because it has been shown that excluding the grey literature can change the outcome of a systematic review and that it has previously made up to 10% of studies referenced in a review (Hopewell, McDonald, Clarke, & Egger, 2007; Mallett & Clarke, 2002).

Table 9: List of databases that will be used in the search and their purpose.

Database	Purpose of database
AMED	Database of allied and complementary medicine.
MEDLINE	Database of published biomedical research.
EMBASE	Database of published biomedical research.
CENTRAL	Cochrane central register of controlled trials.

AMED	Database of published allied and complementary medicine research.
CINHAL	Database of nursing and allied health journals.
OpenSIGLE	Database of grey literature.
ClinicalTrials.gov	Registry for privately and publically funded clinical studies of human participants around the world.
UK Clinical Trials Gateway	Database of clinical research trials currently running in the United Kingdom.

The reference list for any included paper will also be scanned for any additional papers that may be suitable to be included in the study.

There will be three reviewers for this study a primary and secondary reviewer and a third reviewer to resolve any disputes. The primary reviewer will undertake the database searches and from this compile a list of papers that meet and do not meet the inclusion criteria. The secondary reviewer will check and validate the list, the third reviewer will resolve any disputes that the primary and secondary reviewer cannot resolve themselves through discussion. This process will be repeated for both data extraction and risk of bias assessment.

Eligibility Criteria

The inclusion and exclusion criteria for this review are defined below. There will not be a date of publication restriction placed on this review. Only English language papers will be included in this review as no appropriate facilities to translate papers in other languages are available.

The inclusion criteria for this review are:

- Adult participants (18 years old or greater), to ensure the effects of skeletal maturation do not affect study outcome.
- Participants had or are about to have a unilateral THR and no other procedure at the time, to ensure that the study is purely examining the effects of the THR and no other procedures.
- Physical activity data was collected both post and pre operatively, so that a pre/post-operative comparison can be made.
- Participants had a total unilateral hip replacement; this is to ensure that the same broad group of hip replacements are compared as different types of hip replacements are given for different reasons.
- At least one measure of physical activity is taken before and one measure after the total hip replacement operation is performed.

The exclusion criteria for this review are:

- Drug trial, to ensure drugs do not affect the outcome.

- Participants had multiple procedures in the same operation, to ensure that the results from this systematic review are not complicated by other operations.

Outcomes measures

The primary outcome measure for this systematic review will be change in physical activity. For this systematic review measures that are considered suitable to measure the change in physical activity are: questionnaires, lab and field based tests, a non-exhaustive list of example measurement methods are shown in Table 3.3, measure of strength or power such as strength dynamometry shall not be considered measure of physical activity. Similarly biomechanical measures such as walking speed and peak impact force will not be considered measures of physical activity. All measures of physical activity will be included in this study to ensure that the maximum amount of data can be synthesised when producing the outcome for this systematic review.

Table 10: Examples of measures that can be used to measure physical activity.

Questionnaire	Lab based test	Field based test
Physical Activity Scale for the Elderly (PASE) (Washburn et al., 1993)	Cardiopulmonary exercise test (CPEX)	6 minute walk
General Practice Physical Activity Questionnaire (GPAQ) (Pearson & Grace, 2013)	Sub-maximal exercise test	12 minute walk
International Physical Activity Questionnaire (IPAQ) (Booth et al., 2003)		Up and go test

The secondary outcomes measure for this systematic review shall be: quality of life and hip dislocation. Quality of life will be used as an outcome measure for this systematic review as it has been shown that increased physical activity improves quality of life in other conditions and this may be considered an important potential benefit of an increase in physical activity following THR (Mereles et al., 2006; Tsai et al., 2004). Quality of life measures are likely to be through the form of a questionnaire all forms of administration of the measure will be acceptable and noted (i.e. self-administered, with or without a researcher presents, over the telephone). Hip dislocation will also be a secondary outcome variable as it is the most common major complication following THR surgery (*National Joint Registry 10th Annual Report 2013*, 2013), the displacement of the femur will also be noted.

Table 11: Example quality of life questionnaires.

Quality of life questionnaires
SF-36
SF-12
EQ-5D
Global rating of change scale
Quality of life scale

Study Identification and Data Extraction

The titles of the papers will initially be screened for suitability, if unclear the abstract will be read and then if unclear from both the title and abstract the whole paper will be read. If it is still unclear if the paper fulfils the inclusion criteria the author shall be contacted.

Data from all suitable eligible papers will be extracted using the data extraction table (Appendix 2); the table will be trialled before the full systematic review is undertaken. If there is missing data or hip and knee replacement data is combined which is common practice by some research groups in the field the author will be emailed and asked for clarification. Both reviewers will screen and identify studies independently and extract the data. After both reviewers have screened and extracted data from all studies that they believe confirm to the inclusion criteria, the reviewers will meet and discuss any difference of opinion which they may have. If need be a third reviewer will be used to settle any disagreements.

Critical Analysis

All papers included in this study will be critically appraised using the appropriate tool this will either be:

- For RCTs: Critical appraisal tool developed by the Cochrane collaboration (J. P. Higgins & S. Green, 2008).
- For Case control trials CASP Case Control Checklist
- For Cohort Studies: CASP Cohort Study Checklist

Plan of analysis

After the data from all included papers has been collected heterogeneity will be assessed if appropriate the data will be synthesised and a single or multiple meta-analysis will be undertaken. Heterogeneity examines the null hypothesis that all studies are evaluating the same effect (Higgins, Thompson, Deeks, & Altman, 2003). The Cochrane recommended interpretation of I^2 will be used for this study as shown in Table 3.5 (J. P. Higgins & S. Green, 2008).

Table 12: Cochrane suggested interpretation of I^2 values (J. P. Higgins & S. Green, 2008).

I^2 range	Interpretation
0% to 40%	Might not be important.
30% to 60%	May represent moderate heterogeneity.
50% to 90%	May represent substantial heterogeneity.
75% to 100%	Considerable heterogeneity.

If there is not enough data for individual measure analysis the measure will be converted into the standardised mean differences. The standardised mean difference is the difference in mean outcome between groups divided by the standard deviation of outcome among participants, as shown in equation 1.

$$Standerdised\ Mean\ Difference = \frac{Difference\ in\ mean\ outcome\ between\ groups}{Standard\ deviation\ of\ outcome\ among\ participants} \quad equation\ 1$$

Plan of Dissemination

The results of this systematic review will be disseminated at appropriate conferences and a paper will be submitted for publication to an appropriate peer reviewed journal, to ensure that the review is as widely received in the academic sphere as possible. A lay summary of the results and a copy of the paper will also be sent to relevant charities for example Arthritis Research UK to ensure that the results are also disseminated to the non-academic community.

Timetable and Cost

It is proposed that from start to finish this systematic review will take 12 months to complete the timetable for the systematic review is shown below.

Date	Target
May 2014	Complete systematic review protocol
July 2014	Complete literature search
September 2014	Complete data extraction
October 2014	Complete data analysis
December 2014	Complete paper write up
January 2015 and onwards	Disseminate findings

The proposed costs of this study are shown below.

Item	Cost
Inter library loan (50 loans at £8 each)	£400
Second reviewer time	30 days

Conclusion

To conclude the aim of this systematic review is to synthesise the evidence in relationship to the change if any in physical activity following total hip replacement. This shall be achieved by searching and synthesising the literature in a systematic manner and disseminating the findings at conferences, as a paper in a peer reviewed academic journal and to relevant charities. It is hoped that this systematic review will for the first time show how physical activity changes from pre to post total hip replacement.

Appendix 3 Selection of Non-Arthroplasty Cohort for the EPIC Physical Activity Arthroplasty Analysis (January 2016)

It is a nested case control study (or the case-control in a cohort study). In the nested case-control study, cases of a disease that occur in a defined cohort are identified and, for each, a specified number of matched controls is selected from among those in the cohort who have not developed the disease by the time of disease occurrence in the case.

1 Eligibility:

Cases and controls can only be part of the study if they have returned the first **EPIC Physical Activity Questionaire (EPAQ1)**.

2 Sources of cases:

Cases are primary EPIC participants who have undergone either hip or knee replacement in the period between six months after the EPAQ1 (January 1998 – January 2001) and six months prior to the Follow-up National Prevention Research Initiative (NPRI) postal questionnaire (September 2006 – September 2007).

3 Selection of the controls:

Controls **must not have either hip or knee replacement** before the completion of the NPRI postal questionnaire.

4 Matching criteria:

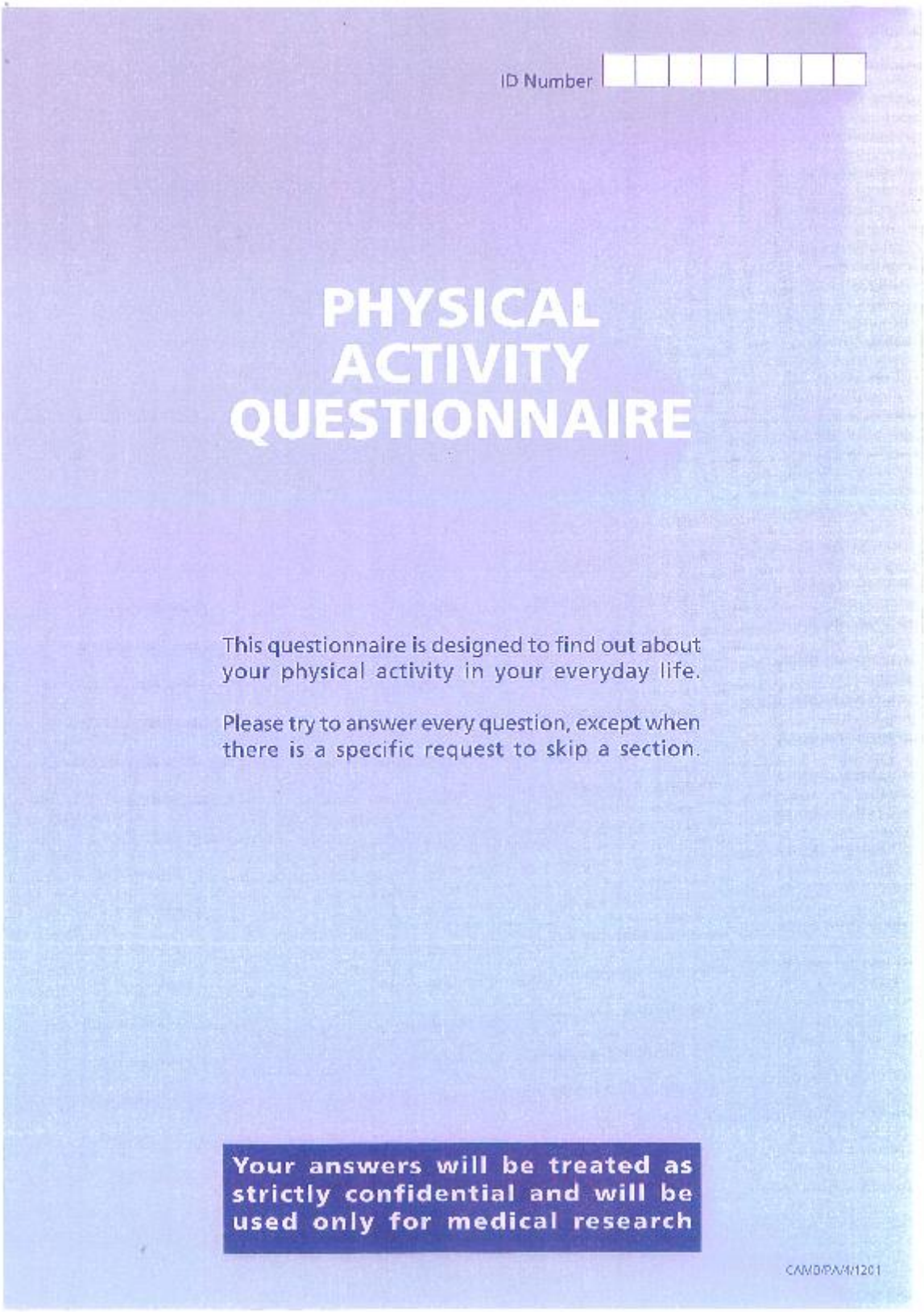
Two controls have to be matched to each case. A control can be matched to only one case. If the constraints on controls reduce the number of potential controls below the required two, then the only available controls is to be used. Controls are matched to cases on: ***sex***, ***date of birth (± 3 years)*** and ***the day of baseline health check (± 3 months)***.

In the dataset, each individual case can be identified with its matched two controls from variables “cc” and “tsid_match”. The cases are assigned with cc=1 while the controls are cc=0. Also, individual case with its two matched controls have the same “tsid_match” values.

Checklist for the physical activity arthroplasty study:	**Cases**	**Controls**
❑ EPAQ1 (with one or more missing entries may be included)	Yes	Yes
❑ self-reported hip or knee replacement	Yes. The participants required to have self-reported hip or knee replacement six months after the EPAQ1 and six months prior to the NPRI.	No. The participants required not to have self-reported hip or knee replacement before the NPRI.
❑ no control is matched to more than one case		No
❑ each case has two controls	Two controls	One case
❑ dates of birth		± 3 years compared to the case

Checklist for the physical activity arthroplasty study:	**Cases**	**Controls**
❑ sex		Same sex to the case
❑ dates of the baseline health check		± 3 months compared to the case
❑ variables and values in the dataset	Variables “cc” = 1; “tsid_match” = same value as controls	Variables “cc” = 0; “tsid_match” = same value as case

Appendix 4: EPIC Physical Activity Questionnaire



ID Number

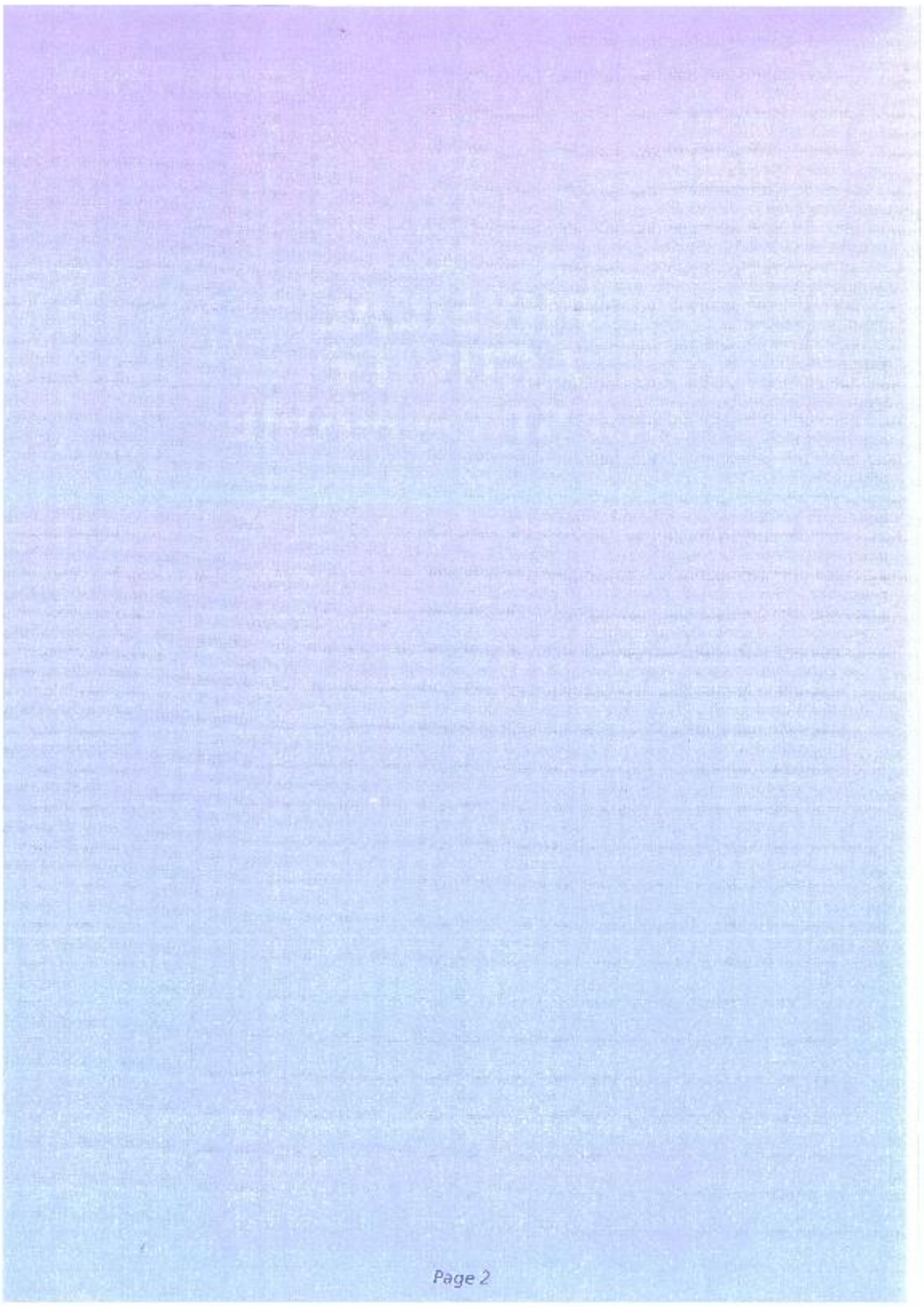
PHYSICAL ACTIVITY QUESTIONNAIRE

This questionnaire is designed to find out about your physical activity in your everyday life.

Please try to answer every question, except when there is a specific request to skip a section.

Your answers will be treated as strictly confidential and will be used only for medical research

CAMDPAN/4/1201


Page 2

THE QUESTIONNAIRE IS DIVIDED INTO 3 SECTIONS

- **Section A** asks about your physical activity patterns in and around the house.
- **Section B** is about travel to work and your activity at work. It may be skipped by people who have not worked at any stage during the last 12 months.
- **Section C** asks about recreations that you may have engaged in during the last 12 months.

What is your date of birth? day / month / year

What is today's date? day / month / year

Your sex *(Please tick (✓) appropriate box)*? Male ☐ Female ☐

Section A HOME ACTIVITIES

GETTING UP AND GOING TO BED

Please put a time in ***each*** *box*

	Average over the past year	
	At what time do you normally get up?	At what time do you normally go to bed?
On a weekday		
On a weekend day		

GETTING ABOUT — Apart from going to work

Which form of transport do you use **most often** apart from your journey to and from work?

Please tick (✓) one box ***ONLY*** *per line*

Distance of journeys	Usual mode of transport			
	Car	Walk	Public transport	Cycle
less than one mile				
1–5 mile(s)				
More than 5 miles				

TV OR VIDEO VIEWING

*Please put a tick (✓) on **every** line*

Hours of TV or Video watched per day	Average over the last 12 months					
	None	less than 1 hour a day	1 to 2 hours a day	2 to 3 hours a day	3 to 4 hours a day	More than 4 hours a day
On a weekday before 6 pm						
On a weekday after 6 pm						
On a weekend day before 6 pm						
On a weekend day after 6 pm						

STAIR CLIMBING AT HOME

*Please put a tick (✓) on **every** line*

Number of times you climbed up a flight of stairs (approx 10 steps) each day at home	Average over the last 12 months					
	None	1 to 5 times a day	6 to 10 times a day	11 to 15 times a day	16 to 20 times a day	More than 20 times a day
On a weekday						
On a weekend day						

ACTIVITIES IN AND AROUND THE HOME

*Please put a tick (✓) on **every** line*

Approximate number of hours each week	Average over the last 12 months						
	None	Less than 1 hour a week	1 to 3 hours a week	3 to 6 hours a week	6 to 10 hours a week	10 to 15 hours a week	More than 15 hours a week
Preparing food, cooking and washing up							
Shopping for food and groceries							
Shopping and browsing in shops for other items (e.g. clothes,toys)							
Cleaning the house							
Doing the laundry and ironing							
Caring for pre-school children or babies at home (not as paid employment)							
Caring for handicapped, elderly or disabled people at home (not as paid employment)							

Section B ACTIVITY AT WORK

Please answer this section **only** if you have been in paid employment at any time during the last 12 months or you have done regular, organised voluntary work.

If not please go to page 9

TYPES OF WORK DURING THE LAST TWELVE MONTHS

- We would like to know what full or part-time jobs you have done in the last 12 months.
- You may have held a single job or have held two jobs at once.
- If you have changed jobs with the same employer, you should enter it as a change of job **only** if it entailed a substantial change in physical effort.

EXAMPLE

Someone who worked full-time for 6 months, then retired, rested for 3 months and then started a voluntary job for 6 hours a week, would complete the questions as follows.

	Job 1	Job 2
Name of occupation	nurse	shop work
How many hours per week did you usually work?	38	6
For how many months in the last 12 months did you do this work?	6	3

EXAMPLE

ACTIVITY LEVELS AT YOUR WORK

Now we would like you to take the total number of hours you worked per week in each job and divide them up according to your activity level.

Please complete EACH line

	Job 1			Job 2		
	No	Yes	Hours per week	No	Yes	Hours per week
Sitting — light work e.g. desk work, or driving a car or truck		✓	6	✓		
Sitting — moderate work e.g. working heavy levers or riding a mower or forklift truck	✓				✓	2
Standing — light work e.g. lab technician work or working at a checkout		✓	30		✓	4
Standing — light/moderate work e.g. light welding or stocking shelves		✓	2	✓		

EXAMPLE

The number of hours in each activity should add up to the number of hours that you worked in each job e.g. 6+30+2=38 (nurse)

What jobs have you held in the last 12 months, and how many months in the year did you do them?

Please complete EACH line

	Job 1	Job 2
Name of occupation		
How many hours **per week** did you usually work?		
For how many months in the last 12 months did you do this work?		

ACTIVITY LEVELS AT YOUR WORK

Now we would like you to take the total number of hours you worked per week in each job and divide them up according to your activity level.

Please complete EACH line

	Job 1			Job 2		
	No	Yes	Hours per week	No	Yes	Hours per week
Sitting — light work e.g. desk work, or driving a car or truck						
Sitting — moderate work e.g. working heavy levers or riding a mower or forklift truck						
Standing — light work e.g. lab technician work or working at a shop counter						
Standing — light/moderate work e.g. light welding or stocking shelves						
Standing — moderate work e.g. fast rate assembly line work or lifting up to 50 lbs every 5 minutes for a few seconds at a time						
Standing — moderate/heavy work e.g. masonry/painting or lifting more than 50 lbs every 5 minutes for a few seconds at a time						
Walking at work — carrying nothing heavier than a briefcase e.g. moving about a shop						
Walking — carrying something heavy						
Moving, pushing heavy objects objects weighing over 75lbs						

STAIR OR STEP CLIMBING AT WORK

Please put a tick (✓) on EACH line where appropriate

Number of times you climbed up a flight of stairs (10 steps) at work	AVERAGE OVER THE LAST 12 MONTHS					
	None	1 to 5 times a day	6 to 10 times a day	11 to 15 times a day	16 to 20 times a day	More than 20 times a day
Job 1						
Job 2						

Please put a tick (✓) on EACH line where appropriate

Number of times you climbed up a ladder at work	AVERAGE OVER THE LAST 12 MONTHS					
	None	1 to 5 times a day	6 to 10 times a day	11 to 15 times a day	16 to 20 times a day	More than 20 times a day
Job 1						
Job 2						

KNEELING AND SQUATTING AT WORK IN JOB 1

In an average working day in Job 1 did you

kneel for more than one hour in total? No ☐ Yes ☐ Don't know ☐

squat for more than one hour in total? No ☐ Yes ☐ Don't know ☐

get up from kneeling or squatting more than 30 times? No ☐ Yes ☐ Don't know ☐

KNEELING AND SQUATTING AT WORK IN JOB 2

In an average working day in Job 2 did you

kneel for more than one hour in total? No ☐ Yes ☐ Don't know ☐

squat for more than one hour in total? No ☐ Yes ☐ Don't know ☐

get up from kneeling or squatting more than 30 times? No ☐ Yes ☐ Don't know ☐

TRAVEL TO AND FROM WORK

JOB 1

Please complete EVERY line

Roughly how many miles was it from home to Job 1?	
How many times a week did you travel from home to Job 1?	

Please tick (✓) one box ONLY per line

How did you normally travel to Job 1?	Always	Usually	Occasionally	Never or rarely
By car				
By works or public transport				
By bicycle				
Walking				

JOB 2 *(if appropriate)*

Please complete EVERY line

Roughly how many miles was it from home to Job 2?	
How many times a week did you travel from home to Job 2?	

Please tick (✓) one box ONLY per line

How did you normally travel to Job 2?	Always	Usually	Occasionally	Never or rarely
By car				
By works or public transport				
By bicycle				
Walking				

Section C RECREATION

The following questions ask about how you spent your leisure time.

Please indicate how often you did each activity on average over the last 12 months.

For activities that are seasonal, e.g. cricket or mowing the lawn, please put the average frequency during the season when you did the activity.

Please indicate the average length of time that you spent doing the activity on each occasion.

EXAMPLE

If you had mowed the lawn every fortnight in the grass cutting season and took 1 hour and 10 minutes on each occasion.

If you went walking for pleasure for 40 minutes once a week.

You would complete the table below as follows:

Please give an answer for the AVERAGE TIME you spent on each activity and the NUMBER OF TIMES you did that activity in the past year.

	Number of times you did the activity in the last 12 months								Average time per episode	
	None	Less than once a month	Once a month	2 to 3 times a month	Once a week	2 to 3 times a week	4 to 5 times a week	Every day	Hours	Mins
Mowing the lawn				✓					1	10
Walking for pleasure					✓					40

Now please complete the table on pages 10 and 11

Please give an answer for the NUMBER OF TIMES you did the following activities in the last 12 months and the AVERAGE TIME you spent on each activity.

Please complete EACH line

	Number of times you did the activity in the last 12 months								Average time per episode	
	None	Less than once a month	Once a month	2 to 3 times a month	Once a week	2 to 3 times a week	4 to 5 times a week	6 times a week or more	Hours	Mins
Swimming — competitive										
Swimming — leisurely										
Backpacking or mountain climbing										
Walking for pleasure — you should not include walking as a means of transportation as this was included in Sections A & B										
Racing or rough terrain cycling										
Cycling for pleasure — you should not include cycling as a means of transportation										
Mowing the lawn — during the grass cutting season										
Watering the lawn or garden in the summer										
Digging, shovelling or chopping wood										
Weeding or pruning										
DIY e.g. carpentry, home or car maintenance										
High impact aerobics or step aerobics										
Other types of aerobics										
Exercises with weights										
Conditioning exercises e.g. using an exercise bike or rowing machine										

Please continue on the next page

Please complete EACH line

	Number of times you did the activity in the last 12 months								Average time per episode	
	None	Less than once a month	Once a month	2 to 3 times a month	Once a week	2 to 3 times a week	4 to 5 times a week	6 times a week or more	Hours	Mins
Floor exercises e.g. stretching, bending, keep fit or yoga										
Dancing e.g. ballroom or disco										
Competitive running										
Jogging										
Bowling — indoor, lawn or 10 pin										
Tennis or badminton										
Squash										
Table tennis										
Golf										
Football, rugby or hockey (during the season)										
Cricket (during the season)										
Rowing										
Netball, volleyball or basketball										
Fishing										
Horse-riding										
Snooker, billiards or darts										
Musical instrument playing or singing										
Ice-skating										
Sailing, wind-surfing or boating										
Martial arts, boxing or wrestling										

You have finished the questionnaire — *Thank you*

Appendix 5: Feasibility Randomised Control Trial Protocol.

PhD Research Proposal: What is the effect on independent recovery of using pedometers as a tool to prescribe exercise following total hip replacement?

Study Acronym: HPA
Protocol Version **3; 24/09/15**

Contents

Abstract

Objective: This study will examine if pedometer based exercise prescription decreases independent recovery time following total hip replacement.
Design: The proposed design for this study is a 2 arm randomised control trial; the control arm will receive normal care, the intervention group will receive normal care and a pedometer-based exercise programme.
Subjects: Patients on the waiting list for elective unilateral total hip replacement.
Outcomes measures: The primary outcome measure will be the Oxford Hip Score. Secondary outcome measures will be hip dislocation, quality of life measured by self-completed questionnaire and physical activity level through accelerometry.

Study definitions of total hip replacement, physical activity and exercise

In this research proposal the following terms will be defined as:

- Exercise shall be defined as any structured activity that involves a sustained period of movement of at least 10 minutes that may be considered beneficial for cardiorespiratory fitness (Department of Health, 2011). In this research proposal exercise will be considered a form of physical activity (PA).
- PA shall be defined as any activity that involves a sustained period of movement that exceeds 10 minutes in duration, activities of daily living will be considered a form of PA assuming that they last more than 10 minutes. The minimum bout of 10 minutes for activities to count towards the recommended minimum weekly duration of PA is in line with current guidelines (Department of Health, 2011).
- Total hip replacement (THR) shall be defined as complete removal of the femoral head and neck along with the acetabulum; along with any other bone the surgeon views as appropriate to remove followed by fixation of at least an artificial femoral head and acetabulum into the remaining femur and pelvis.
- Hip precautions (HPs) shall be defined as any object that is given or restriction placed on a patient to reduce hip movement these can include raised toilet seats, not being permitted to drive or be a passenger in a motor vehicle along with avoiding any activity that involves excessive medial or lateral rotation, flexion or adduction of the hip. Rotation being when a bone revolves around its own longitudinal axis either towards the midline of the body (medial) or away (lateral), flexion being a decrease in the angle between articulating bones and adduction is the movement of a bone towards the midline of the body (Tortora & Derrickson, 2009).

Section 1: The Study

Current research in brief: Is there a change in physical activity following total hip replacement?

THR is one of the most common operations performed in the UK, a total of 94044 THR were performed in England, Wales and Northern Ireland in 2012 (*National Joint Registry 10th Annual Report 2013*, 2013). The care for a patient who is about to undergo THR can be split into 4 distinct time periods:

(1) Preoperative the care before the operation.
(2) Operative the care during the operation.
(3) Perioperative the care immediately following the operation.

(4) Postoperative the care after the operation.

For this research the perioperative period will be from when the surgery has finished to when the patient is transferred to the ward bed. This research summary will focus on how the use of hip precautions and physical activity pre and post operation affects the outcome of the surgery.

Current best practice indicates that PA should play an important part in THR care though how to do this optimally is currently unclear (a. p. College of Occupational Therapists & Sainty). In a recent systematic review it has been shown that PA before THR reduces hip pain (S. D. Gill & McBurney, 2013). Though a large number of studies group hip and knee replacement together (Barbay, 2009; S. D. Gill & McBurney, 2013), therefore potentially confusing the picture in relationship to the benefits of PA in THR specifically. Minns Lowe et al. (2009) systematic review also highlighted the lack of clarity in the field by concluding that there is insufficient evidence to disprove or prove the benefits of physiotherapist lead exercise post THR. Though this finding cannot be generalised to THR as a hole as it only examined patients who were having THR due osteoarthritis. Though admittedly osteoarthritis is by far the most common reason for a THR to be performed, 92% THR were performed due to a primary diagnosis of osteoarthritis in 2012 (*National Joint Registry 10th Annual Report 2013*, 2013).

It has also been shown that quality of life improves post THR and that the increase is strongly correlated with an increase in physical activity (Fujita et al., 2013). However what is currently not known is the effect of physical activity pre surgery on the effect of quality of life post-surgery.

Current research as of yet has not examined the potential benefits of prescribed exercise following THR. Therefore there is a need for research to examine the potential benefits if any that prescribed exercise following THR may have on outcome following THR.

Rationale for undertaking the study

Both gaps in current literature and the current financial strain the National Health Service (NHS) is under (Morse, 2012) can be used to justify undertaking studies that examine the potential health saving and financial benefits of prescribed exercise following THR. The research hypothesis are listed below:

Research Hypotheses

1. Prescribed PA will significantly increase the overall amount of PA undertaken.
2. Prescribed PA will significantly improve quality of life.

Focus group

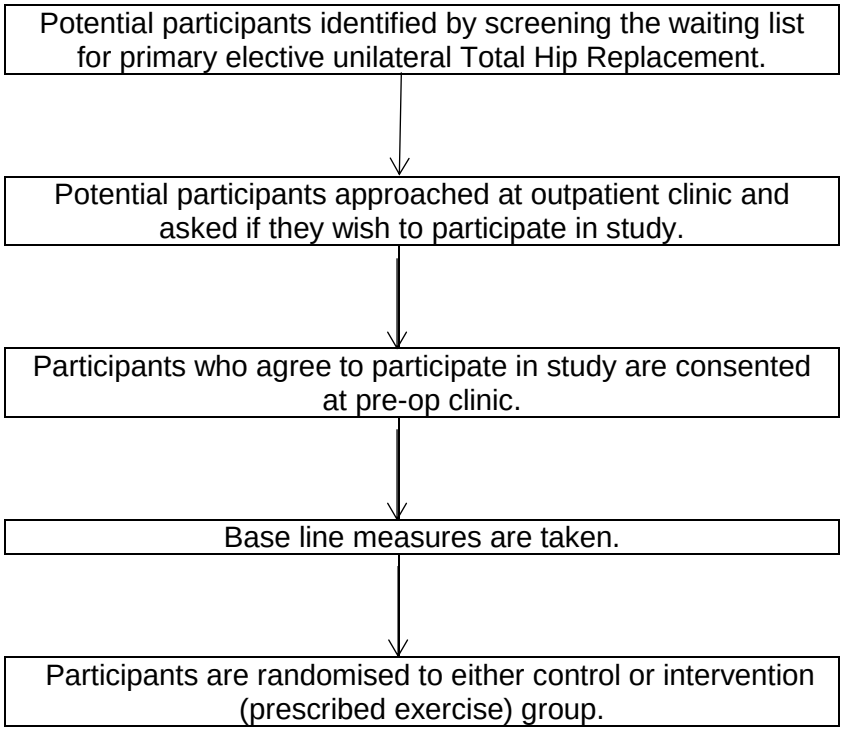
In line with guidelines set down by the Medical Research Council for complex interventions (P. Craig et al., 2008) a proposed protocol was taken to a patient focus group at an early stage (11th December 2013) to seek patient and public opinions. This protocol aimed to compare normal care to no HP, examining the affect on PA levels. The patient focus group consisted of members of the public who had a general interest in orthopaedic research, have had or are on the waiting list for a hip replacement or a close relative or friend has had a hip replacement. The focus groups overall opinion of the research was that it was a worthwhile research project but they felt it may be particularly

challenging to recruit participants for this study as the intervention involves taking something away opposed to evaluating an intervention which is an addition to normal care. The focus group suggested ways in which in their opinion this affect could be mitigated and aired other questions about the research which are listed below:

- Ensure that the potential health economics benefit of the study are mentioned but it is made clear that they are not the main reason why the study is taking place.
- Will not giving HPs result in the patients modifying their behaviour to avoid excessive pain for example will this result in patients not going to the toilet as perhaps they would regularly?
- Stress the lack of the information in regard to the use of HPs and that the point of this study is to clarify their use.
- Consider the burden that this study will put on the close family and friends of the participant and how this can be mitigated.
- How is the study going to control getting HPs through other means?
- Consider the effect waiting list time may have on physical activity.
- Would it be appropriate for there to be a pilot study initially to assess the appropriateness of the study?

Study

Taking into consideration the feedback from the focus group on the proposed study, the original research protocol was adjusted revised. The main study adjustment being that the element of the study that examined the relevance of HP was removed with a principle focus on THR and PA. The primary outcomes for this study did however remain the same, that being Oxford Hip Score, and secondary outcomes being hip dislocation, quality of life and PA. The study is described in brief in Figure 11 and in full in the text that follows **Figure 11.** The revised study was therefore be a randomised control trial examining the effectiveness of exercise prescription following THR.



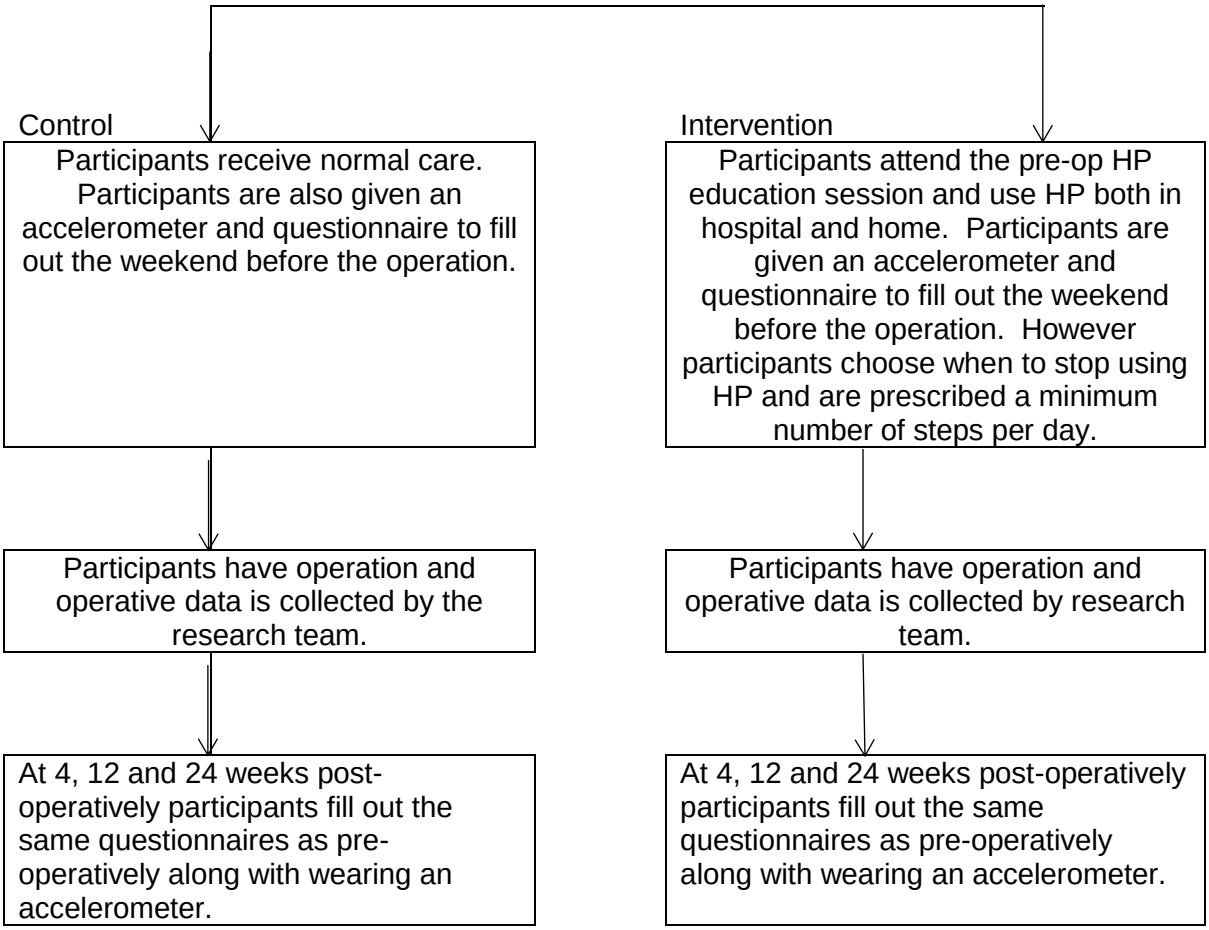


Figure 11: Flow chart representing study stages for study participants.

Study Design

The optimum study design for this study would be a randomised control trial (RCT) where participants are randomly allocated to normal care or intervention arm(s). For this study patients will be individually randomised to study arms opposed to cluster randomised as the risk of group contamination is low. Although no viable placebo can be given to the control group for this study the contamination risk is low as the intervention does not begin until the participant has returned home following the surgery.

Inclusion and Exclusion Criteria

Detailed below are the inclusion and exclusion criteria for this study. Potential participants must fulfil all of the inclusion criteria but if they fulfil any of the exclusion criteria they will not be eligible to take part.

Inclusion criteria:

- Patient is on the waiting list for primary elective unilateral THR.

- Patient is 18 years of age or older, to ensure that the study outcomes are not influenced by the process of skeletal maturation.
- Patient is able to walk at least 10m pre-operation without walking aids, if the patient is unable to walk pre-operation it is believed that the patient will be able to walk post-THR, as this study is only assessing change in ambulatory patients.
- Patients operation is scheduled to be at least 2 weeks away, to ensure that there is enough time for the participants to complete the pre-operative part of the study before the operation.
- Patients have no other prosthetic implants to ensure that the participants do not have any preconceptions about prosthetic limbs or joints.
- The surgeon that is performing the operation performs operations in both the independent and NHS hospital, this is to control for the potential influence of surgical skill on patient outcome.

Exclusion criteria:

- Patient is unable to give informed consent, to ensure that the patient can understand what the study involves.
- Patient is having two different procedures combined together in one operation for example THR followed by total knee replacement. This is to ensure that the other procedure does not influence the outcome of this study.
- Patients cannot comprehend English and do not have a friend, relative or care giver who is willing to translate for them; this is to ensure that the patient understands the study.
- Patient is currently undertaking a custodial sentence, the considerably different social environment that are found in prisons may bias the results of this study.
- Patient already has a prosthetic hip in the other femur or patient is undergoing replacement of a previously implanted prosthetic hip. This study is purely interested in outcome following primary THR the most common form of THR (*National Joint Registry 10th Annual Report 2013*, 2013).
- If the participants suffer an operative or perioperative complication they will be excluded from the study at this stage, this excludes complications that do not have a bearing on the participants ability to move following the operation for example unexpected bleeding during surgery. Participants will be excluded as this study is designed to assess the effects of a more structured pedometer-based exerciseprogramme following surgery therefore participants will need to be able to move to take part in the study.
- Participants who suffer from any absolute or relative contraindication to exercise (**Error! Reference source not found.**) will also be excluded from the study. lthough this study is not assessing a patients groups particular exercise response it is suggested that it is reasonable to assume that a patient who has a contraindication to exercise may have a modified intentionally or unintentionally there physical activity behaviour.
- For this this study partial proximal femur resection (PFR) will not be considered a form of THR. Patients who are undergoing PFR will be excluded from this study as the presenting symptoms to undergo PFR surgery are normally quite different to that of THR.
- Patient lives in a care home this is to ensure that housing where there is outside assistance does not affect the outcome of the study.

- A reason for the patients to undergo THR is due to a form of cancer, this is because the pathophysiology of cancer is considerably different to the vast majority of other reasons to undergo THR.

Table 13: Absolute and relative contraindications to exercise testing modified from: (Gibbons et al., 2002).

Contraindications to Exercise
Absolute
A recent significant change in the resting ECG suggesting significant ischemia, recent myocardial infarction (within 2 days) or other acute cardiac event.
Unstable angina.
Uncontrolled cardiac dysrhythmias causing symptoms or haemodynamic compromise.
Symptomatic severe aortic stenosis.
Uncontrolled symptomatic heart failure.
Acute pulmonary embolus or pulmonary infarction.
Acute myocarditis or pericarditis.
Suspected of known dissecting aneurysm.
Acute systemic infection, accompanied by fever, body aches or swollen lymph glands.
Relative
Left main coronary artery stenosis.
Moderate stenotic valvular heart disease.
Electrolyte abnormalities.
Severe arterial hypertension (systolic blood pressure >200 mmHg and or diastolic blood pressure of >110 mmHg) at rest.
Tachydysrhythmia or bradydysrhythmia.
Hypertrophic cardiomyopathy and other forms if outflow tract obstruction.
Neuromuscular, musculoskletal or rheumatoid disorders that are exacerbated by exercise.
High-degree atrioventricular block.
Ventricular aneurysm.
Uncontrolled metabolic disease.
Chronic infectious disease.

Sample Size

Using the method detailed by S. R. Jones et al. (2003) and the data presented by Restrepo et al. (2011) and N. J. Talbot et al. (2002) for the Oxford Hip Score, 5 and 10 are computed for difference between the means and standard deviation respectively. This therefore gives a standardised difference of 0.5 if power level is set at 0.8 this gives a group sample size of 64 and therefore a study sample size of 128. It will be assumed that this study will have a 20% dropout rate due to there being relatively little participant commitment therefore the aim will be to recruit 160 participants into this study.

Participant Recruitment and Consent

In Norfolk, the Norfolk and Norwich University Hospitals (NNUH) NHS Foundation Trust fund operations that are performed both in NNUH and Spire hospitals. For the purpose of this study, all participants from both NNUH and Spire will be NHS patients. No privately or independently funded patients will be considered for this trial. Initially the waiting list for primary elective unilateral THR will be screened for potential participants. The Norfolk and Norwich University Hospital (NNUH) and Spire Norwich have both been approached and agreed to participate in the study, the hospitals performed 744 and 540 THR in 2012 respectively. It will be assumed that 50% of participants are willing to take part in the

study and 30% of these participants will be lost during the study. Therefore currently it is predicted that it will be possible to recruit 449 participants a year from these two hospitals.

Potential participants will be sent along with their normal appointment letter for the pre-operation clinic a copy of the participant information sheet (Appendix 1), invitation to participate letter (appendix 2) and a prepaid envelope. Patients who are interested in participating in the study will then be asked to return the second page of the invitation to participate letter in the prepaid envelope.

All participants who return the second page of the invitation to participate letter will be met at their pre-operation clinic by a member of the research team and consent will be obtained, the participant consent form is shown in appendix 3.

At the pre-operation clinic (approximately 2 weeks before surgery) the eligibility of the participants to take part in the study will be checked again if the participants are still eligible and are willing to participate they will then be asked to sign the informed consent form (appendix 3).

Randomisation of participants

Participants will be block randomised in blocks of 8 after they have been consented using a 8 point integer random number table the integers that will be used are 1 to 8 inclusive. Participants with an even random number will be in the control group and participants with an odd number will be in the exercise prescription group. An example of how the random number table will be used is shown in **Error! Reference source not found.**. andomisation will be pre-prepared but participants will not be told their block number.

Table 14: Example of how the random number table will be used to randomise participants.

Participant	Random Number	Group participant is in
1	1	Exercise group
2	9	Exercise group
3	8	Control group
4	6	Control group
5	4	Control group
6	3	Exercise group
7	5	Exercise group
8	2	Control group

Intervention

This study will be a 2 arm RCT, both the intervention and control arm will receive standard care, with the intervention arm additionally receiving a pedometer based exercise programme. A summary in the differences in care post-surgery between both groups is shown in Table 15.

Table 15: The differences between the care in the 2 study groups following surgery.

Group	Gait re-education programme	At least daily in hospital physiotherapist	Hip Precautions	Pedometer based exercise

		session		programme
Control	Yes	Yes	Yes	No
Pedometer-based exercise programme	Yes	Yes	Yes	Yes

Intervention:

Control Group

The control group will follow standard care throughout and receive no additional intervention. Therefore following surgery standard care will involve the patient sitting on the edge of the bed and attempting to stand and walk using the appropriate walking aid from the first post-operative day. This treatment will then be repeated at least once daily for the duration of the patients hospital stay. The patient would then be progressed in walking distance and aid dependency from one frame, to two elbow crutches or two sticks. Step and stair practice was also performed. Progression will be determined by ward physiotherapist, dependent on patient performance. Patients will be encouraged to mobilise throughout the day, either independently or with the assistance of nursing staff. Assistance in standing and mobilising will be given by the ward physiotherapist and an appropriately qualified assistant if necessary.

Experimental Walking Group

The Experimental Group will receive the same intervention as the Control Group. However, in addition to this, patients randomised to this group will receive a pedometer based exercise programme. This will be prescribed through the use of pedometers where two days a week participants will be asked to achieve a target number of steps. The target number of steps participants will be asked to achieve are shown in Table 5.2. If a participant is unable to achieve the target number of steps, the number of will be revised down. The target number of steps will be revised down by no more than 15% to ensure that there is still a physiological benefit to the walking programme. For the number of steps to be revised down, the participants must have; failed to reach the target number of steps for at least 3 weeks and wish to be asked to achieve a lower target.

Active recovery will also form part of the study to ensure that participants receive the full benefit of the exercise programme (Garrett & Kirkendall, 2000). Although the idea of active recovery or periodisation of exercise is not common place in clinical exercise, it has been used in performance exercise since at least 1974 (Krüger, 1974). The benefits of active recovery are that it reduce the risk of overtraining, ensures that the participants have enough time to recover from the exercise to ensure that they gain optimum physiological benefit from the exercise (Fry et al., 1992).

Table 16: Exercise prescription for patients in intervention arm.

Week post-surgery	Target Steps (per day)	Per cent increase compared to previous non-rest week
1	300	
2	330	10
3	363	10
4	399	10
5	363	Active recovery
6	459	15
7	528	15

8	607		15
9	698		15
10	607	Active recovery	
11	838		20
12	1006		20
13	1207		20
14	1448		20
15	1207	Active recovery	
16	1810		25
17	2263		25
18	2828		25
19	3536		25
20	2828	Active recovery	
21	4596		30
22	5975		30
23	7768		30
24	10098		30

Admittedly the weakness of only prescribing activity on two days a week is that participants may conform to sedentary behaviours for the rest of the week. It is however suggested *a priori* that it is unlikely that a participant will be active for 2 days a week and then inactive for the rest. Participants in the intervention arm will be asked to record how many steps they actually took on a given day (Appendix 13), participants will also be reminded that these are the target number of steps and therefore is their exceed this step count it does not matter.

Measures to be taken

For this study 5 measures will be used 4 questionnaires and an accelerometer, the questionnaires that will be used are shown in Table 5.3.

Table 17: Questionnaires to be used in the study.

Questionnaire	What the questionnaire measures
Oxford Hip Score **(Dawson et al., 1996)**	Outcome measure following THR.
EQ-5D-5L	Provides a single value for health status.
Global rating of change scale (GRCS)	Patients based opinion in change in health.
Physical Activity Scale for the Elderly (PASE)	Estimate of physical activity for the elderly.

1. The Oxford Hip Score (OHS) was chosen over the more detailed WOMAC as this is the questionnaire that patients answer for the National Joint Registry (NJR) therefore it is likely to be easier to disseminate the findings of this research if the OHS is used, the OHS is also validated for use in THR whereas the WOMAC is not (Dawson et al., 1996).
2. The EQ-5D-5L (Herdman et al., 2011)is the preferred way to measure global health status as this questionnaire used in the NJR.
3. The GRCS will be used to assess the patient's opinion of health change. Copies of the questionnaires that will be used are in appendix 6, the GRCS will only be used for the post-operative measures as it asks the patient to compare current to pre-operation. Appendix 5 will also contains a form asking if the patient had dislocated their hip.
4. Participants will be asked to wear the accelerometer for seven consecutive days. Currently there is no research that validates the use of accelerometer in hip

replacement. Only one previous study (de Groot et al., 2008) has used accelerometer in THR they did however combine THR with total knee replacement in their research. This study will also act as a method of indirect validation of accelerometers in THR as the PASE questionnaire will also be used. The participants will be asked to wear the accelerometer for 7 days. Participants will be asked to keep an activity log whilst wearing the accelerometer, this is so any substantial change in PA can be quantified for example the participant went out for a bike ride. Participants will be asked to fill out the questionnaires during the seven days period when they are wearing the accelerometer, participants will also receive a reminder phone call or email if they wish to remind them about filling out the questionnaires and wearing the accelerometer. All questionnaires and the accelerometer will be returned to the research group in a pre-paid recorded delivery envelope that will be provided.

5. PASE is preferred over the International Physical Activity Questionnaire (IPAQ) as it is a PA questionnaire designed for the elder population opposed to the IPAQ which is validated on 18-65 year olds (C. L. Craig et al., 2003). Admittedly this is a compromise as it is quite unlikely that all of the participants who take part in this study will be over the age of 65, though it is likely that the vast majority of participants will be 65 or over (*National Joint Registry 10th Annual Report 2013*, 2013). The PASE questionnaire will also be used as a validation tool for the accelerometer.

6. Hip dislocation of the prosthetic hip will be self-reported. Participants will be asked: 'Since your hip replacement has your prosthetic hip dislocated?' If participants answer yes they will then be asked further information about the dislocation. The form that participants will be asked to fill out is shown in appendix 5.

Data Collection

The participants will then be shown how to wear the accelerometer, they will then be given an accelerometer, the how to affix the accelerometer and questionnaire instructions letter (appendix 4), and a pre-paid recorded delivery envelope to return the accelerometer, the questionnaires (appendix 5) and activity log (appendix 6) will also be given to the participants. Demographic and anthropometric measurements of the participant will also be taken (appendix 7) the participants will also be informed what group they are in. A letter will also be sent to the participant's general practitioner GP (appendix 12).

After the operation has been performed a copy of the data submitted to the NJR will be taken key measures on the NJR form are shown in Table 5 the overall length of hospital stay from admission to discharge will also be noted. Appendix 8 contains a copy of the NJR data capture form and the hospital stay data capture form. The operative data will be captured in case anything that occurs during the operation has an effect on physical activity following the operation.

Table 18: Key measure taken from the NJR data capture form.

Measures to be captured
Patient ASA grade
Anaesthetic type
Operation funding
Surgical approach
Untoward intraoperative event
Type and make of prosthesis used

Following the surgery the participants will be sent the same questionnaires (Table 5.3) as pre surgery along with an accelerometer, and a letter informing the participants about what they are being asked to do (appendix 9). **An additional questionnaire will be added at the final data point, week 24 to seek study feedback (appendix 14).** The participants will be asked to fill in the survey and wear the accelerometer on either a Friday and Saturday or Sunday and Monday at 3-5, 11-13 and 23-25 weeks post-surgery. At the same time the patients NHS record will be checked for additional entries and noted using the additional medical and or surgical interventions form (appendix 10). This data collection will be performed by a member of the research team.

If a participant does not return the questionnaire and or pedometer and or accelerometer they will initially be contacted to check that they are still willing to participate in the study, this will occur a maximum of 3 times. On the third occasion the participants will be asked if they prefer to answer the Oxford Hip Score over the phone, and if so, this will be undertaken.

All participants who take part in the whole study will be sent a letter with a lay summary of the results (appendix 11).

Study costs

The estimated costs for this study are given below in of this study are given below in Table 19. It is approximated that 4200 hours of time approximately 2 working years will be needed for this study to undertaken.

Table 19: Estimated study costs.

Item	Reason needed	Cost
Printing costs (6p per sheet, approximately 7 998 sheets needed)	To print letters and questionnaires.	£479.88
Photo copying costs (4p a sheet including paper, approximately 854 needed)	To make copies of informed consent and NJR data capture form.	£34.16
Small parcel stamp (£2.80 each, approximately 320 needed)	To send parcel to participants containing accelerometer and questionnaires.	£896.00
Recorded deliver small parcel stamp (£3.60 each, approximately 427 needed)	So participants can return questionnaires and accelerometers.	£1537.20
Large Envelope (15p each, approximately 747 needed)	To post questionnaires and accelerometer to participants and so that they can post them back.	£112.05

Small envelope (12p each, approximately 154 needed)	To post participant study summary to participants.	£18.48
Normal stamp (53p each, approximately 154 needed)	To post participant study summary to participants.	£81.62
Pedometer (£5.40 each, approximately 64 needed)	To use in intervention.	£345.60
Accelerometer (£150 each, approximately 52 needed)	To use to collect data.	£7800.00
	Financial Total	£11304.99

Section 3: Data analysis

Statistical analysis

The data collected will be analysed for differences and correlations, exploratory analysis will also be conducted. Two separate analysis will be undertaken the first will be done by intention-to-treat that is including individuals in the group to which they were allocated regardless of treatment received. The secondary subgroup analysis will also be undertaken, which is detailed below.

Primary analysis
Chapter 8 Is there a significant difference in the Oxford Hip Score between the control and intervention group.

Secondary Analysis
Chapter 9 Is there a significant difference in PA between …

a. Between the experimental and control group?
b. ASA score in the control and intervention group?
c. Male and females in the control and intervention group?
d. Age in the intervention and control group separately?

Chapter 10 Is there a significant difference in dislocation between …

e. Control and Intervention groups?
f. ASA score in the control and intervention group separately?
g. Male and females in the control and intervention group separately?
h. Age in the control and intervention group separately?

Chapter 11 Is there a significant difference in quality of life between …

i. Control and intervention groups?
j. ASA score in the control and intervention group separately?
k. Male and females in the control and intervention group separately?
l. Age in the control and intervention group separately?

Additional statistical analysis

If the time constraints of the PhD permit the validity of using an accelerometer as an alternative to questionnaire based measurement will be assessed. This will be done by assessing the correlation between the accelerometer and questionnaire data. However there is no previous evidence to support the analysis of data in this manner but it is however proposed to examine the data in this manner as the data has been collected and if it can be shown that a single measure can be used to measure PA change in THR it would aid further research.

Economic Analysis

The aim of the economic analysis of this intervention is to assess the relative cost of the use of pedometers in relationship to a reduction and or gain in quality adjusted life years (QALYs), to achieve the cost utility ration will be calculated (Equation 1).

$$Cost\ utility\ ratio = \frac{Cost\ of\ Intervention\ A - Cost\ of\ Intervention\ B}{Number\ of\ QALYS\ produced\ by\ intervention\ A - \ Number\ of\ QALYS\ produced\ by\ Intervention}$$

Equation 1

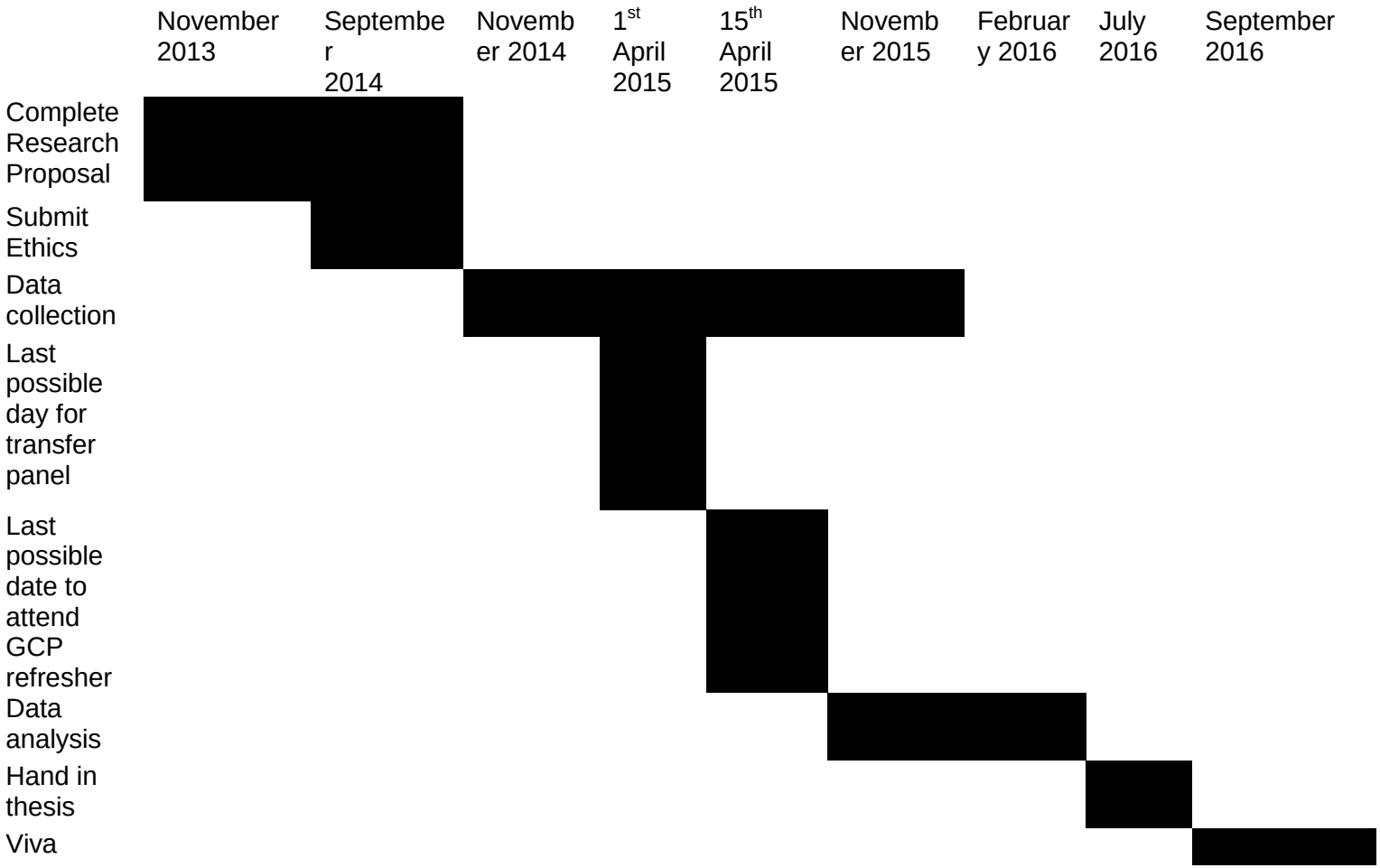
For this study the cost utility ratio equation can be rephrased to be more relevant for this study (Equation 2).

$$Cost\ utility\ ratio = \frac{Cost\ of\ Normal\ Care - Cost\ of\ Intervention}{Number\ of\ QALYS\ produced\ by\ normal\ care - \ Number\ of\ QALYS\ produced\ by\ intervention}$$

Equation 2

The cost of care shall be calculated in the same manner for both groups. As the intervention for this study only begins from when the participant is discharged from hospital the cost of care will be calculated from discharge and not from the beginning of care. The unit cost will be calculated using the information complied by (Curtis, 2012). Patients treated in independent hospitals will not be included in this analysis as no itemised information is currently available to assess the itemised cost of healthcare in independent hospitals. QALYS will be calculated using the information gathered from EQ-5D.

Timeline


November 2013
September 2014
November 2014
1st April 2015
15th April 2015
November 2015
February 2016
July 2016
September 2016
Complete Research Proposal
Submit Ethics
Data collection
Last possible day for transfer panel
Last possible date to attend GCP refresher
Data analysis
Hand in thesis
Viva

Continuation of research post PhD

To ensure that it is possible to continue the research after the PhD the informed consent for the study will ask the participants to consent for their contact details to be kept so that they can be contacted in the future about any other relevant research that is related to THR that they could potentially be participants in. The participants contact details will be kept on a password protected computer and in accordance with the data protection act. Any further studies will also seek the appropriate additional ethical approval.

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*Appendix 1: Participant Information Sheet Version **3; 24/09/2015***

Participant Information Sheet

What is the effect on independent recovery of using pedometers as a tool to prescribe exercise following total hip replacement?

Study title

The title of this study is: 'What is the effect on independent recovery of using pedometers as a tool to prescribe exercise following total hip replacement?

Invitation Paragraph

We would like to invite you to take part in our research study, before you decide to take part or not we would like you to understand why the research is being done and what it would involve for you. When you come into hospital for your pre-operation clinic a member of the research team will be able to answer any questions that you have about the study and if you wish to take part you will be asked to sign the consent form this will take approximately 40 minutes. The information sheet is split into two sections part 1 gives the general details of the study and part 2 provides some additional information.

Part 1: General Information

What is the purpose of this study?

The purpose of this research project is to examine if recovery time is improved following total hip replacement when a more structured exercise programme is used following surgery compared to normal care.

Why have I been invited to take part?

You have been invited to take part in this study as you are due to have a primary (first time) elective (planned) unilateral (one sided) total hip replacement.

Do I have to take part?

It is up to you to decide to join the study. Taking part in the study is completely voluntary and if you choose to take part you are free to withdraw from the study at any time without giving a reason. This will not affect your care.

What will happen to me if I take part?

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If you agree to take part in this study you will first of all be asked to sign the participant consent form on your visit to the hospital for your pre-operation clinic after any question that you may have about the study have been answered by a member of the research team. You will then be shown how to wear an accelerometer a small device that measures your activity levels, this will take no more than 30 minutes. At the pre-operation clinic you will also be told what study group you are in. You will either be in the normal care group in which case your care will be no different from normal; alternatively you will be in the intervention group. The intervention group will in addition to normal care be asked to wear a pedometer for two days a week for 24 weeks following the operation. A pedometer is a device that clips to your clothes and tells you how many steps your have done.

<Insert photo of a pedometer.>

Also at your pre-operation clinic you will be given an accelerometer, 3 questionnaires and a prepaid envelope. You will be asked to wear the accelerometer for seven consecutive days following your pre-operation clinic. During these seven days you will also be asked to fill out the questionnaires. All four questionnaires take no more 30 minutes to fill out in total. After the seven days are up you will be asked to post the questionnaires and accelerometer back using a pre-paid envelope that will be provided.

You will then have your operation and spend some time in hospital if your operation does not go to plan you will have to leave the study. Following your operation your surgeon will fill out a form detailing the surgical technicalities of your operation. On discharge if you are in the intervention group you will be given a target step count for 2 days of the week that you wear the pedometer it will increase every week following the operation. If you are in the normal care group you will not be given anything additional when leaving hospital.

At 4, 12 and 24 weeks following your operation you will be asked to fill out the same questionnaires and wear an accelerometer in the same way as you did before the operation. There will be an additional fourth questionnaire that will take approximately 2 minutes to answer for the post-operative measures. **To gain feedback your feedback from the study a fifth study feedback questionnaire will be added at week 24.** The 4 questionnaires and accelerometer will be posted to your home address and in the pack you will receive there will be a pre-paid envelope so that you can send the questionnaires and accelerometers and back. Also at 4, 12 and 24 weeks following surgery your NHS records will be checked for any treatment that you have had since the last set of questionnaires you answered (for week 12 and 24) or operation (for week 4).
The consent form will also ask permission for us to keep your contact details for 3 years following completion of the study. This is so that we can contact you if there is any other relevant research in the future that you may be eligible to participate in. For the research group to do this the group would first of all have to seek additional approvals from the

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ethics committee. This is an optional addition to the research project that you do not need to take part in.

Can I do any other additional Exercise or Physical Activity during the duration of this study?

You are encouraged to do as much exercise or physical activity as possible following your operation along as it is within the guidelines that your surgeon will tell you before your operation.

Expenses and Payment

You will not receive any payment or expenses for participating in this study.

What are the possible disadvantages and risk of taking part?

The additional risks on taking part in this study is that there is a slight increase in the risk of suffering a 'sports injury' as it is likely that participation in this study will result in you being more physically active following surgery than you would be otherwise.

What are the possible benefits of taking part?

By taking part in this study you are helping us understand if physical activity aids recovery following hip replacement. Currently there is suggestive evidence that physical activity aids recovery following hip replacement however there is no conclusive evidence something that this study hopes to rectify.

What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm you might have suffered will be addressed. More detail is given in part 2.

Will my taking part in the study be kept confidential?

Your participation in this study will be kept confidential and all ethical and legal guidelines will be followed. More detail is given in part 2.

If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making your decision.

Part 2: General Information

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What if relevant new information becomes available?

Sometimes we get new information about the treatment being studied. If this happens during the study your surgeon will inform you of these new findings and discuss with you whether it is appropriate for you to continue in this study.

What will happen if I don't want to carry on with the study?

You can withdraw from the study at any time without giving a reason. This will not affect your care. If you withdraw from the study no additional data will be collected but we will need to use the data collected up to your withdrawal.

What if there is a problem?

If you have a complaint about the research please contact a member of the research team, details are at the bottom of the information sheet. If you do not think it is appropriate to contact a member of the research team to complain please contact the Patient Advise and Liaison Services (PALS).

The PALS manager
Norfolk and Norwich University Hospital
East Block Level 2
Colney Lane
Norwich
NR4 7UY
Email: pals@nnuh.nhs.uk
Telephone: 0300 456 2370

Will my taking part in this study be kept confidential?

If you join the study, some parts of your medical records and the data collected for the study will be looked at by authorised persons from the University of East Anglia and the Norfolk and Norwich University Hospital (NHS funded patients) or Spire Norwich (privately funded patients). They may also be looked at by authorised people to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

Involvement of the General Practitioner/Family Doctor (GP)?

Your GP will be informed that you are taking part in this study. They will be told what group you have been randomised to, the length of the study and the measures being taken (questionnaires and accelerometer) they will also be given a copy of the participant information sheet.

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What will happen to the results of the research study?

It is planned that the anonymised data from this study will be published in a peer reviewed research journal(s) and the finding presented at a conference(s). All participants who take part in the whole study will be sent a letter detailing the general findings of the study.

Who is organising and funding the research?

This research project will form part of a PhD and is funded and sponsored by the University of East Anglia.

Who has reviewed the study?

This research has been looked by an independent group of people known as a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable opinion by <insert ethics committee name> Research Ethics Committee.

Further information contact details?

If you require and further information about this study or have any questions please contact Tom Withers on the details below.

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Thank you for taking your time to read this Participant Information Sheet.

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Appendix 2: Invitation to participate letter Version 1; 20/01/2014.

Dear <Insert Potential Participants Name>,

We are a research team based at the University of East Anglia currently researching if structured physical activity are beneficial to patients who have undergone total hip replacement. We are asking you to consider being a participant in this study as you are on the waiting list for primary (first time) elective (planned) unilateral (one sided) total hip replacement, not taking part in the study will not affect your care, this research will also form part of my PhD research. The title of the study is 'What is the effect on independent recovery of using pedometers as a tool to prescribe exercise following total hip replacement?'

Please find enclosed the participant information sheet which gives more detail about the study, please feel free to contact me using the details above if you have any questions.

If you are interested in taking part in this study please return the enclosed expression of interest form and a member of the research team will meet you at your pre-operation clinic. This will be an opportunity for any of your questions to be answered and sign the consent form if you still wish to take part.

Thank you for taking an interest in this study.

Kind regards,

Tom Withers
PhD Student

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Email: t.withers@uea.ac.uk

I am interested in taking part in the study entitled: What is the effect on independent recovery of using pedometers as a tool to prescribe exercise following total hip replacement?

Name: _____

Date: _____

Please return this page in the enclosed envelope and we look forward to meeting at your pre-operation clinic.

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Appendix 3: Participant Consent, Version 1 ; 27/01/2014

Participant Consent form

NHS number (write private if privately funded patient): _____

Participant number: _____

Title of research: What is the effect on independent recovery of using pedometers as a tool to prescribe exercise following total hip replacement?

	Please Initial Box
1. I confirm that I have read and understand the participant information sheet dated …….. (version ……) 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, without my medical care or legal rights being affected.	
3. I understand that relevant sections of my medical and therapeutic notes and data collected during the study may be looked at by individuals from the University of East Anglia, from regulatory authorities, from the NHS Trust or Spire Healthcare, where it 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 the study.	
5. I agree to my contact details being held for no more than 3 years following the completion of the study and to be contacted if any other relevant research projects are undertaken in this time frame (optional).	
6. I agree to take part in the above study.	

Name of participant	Date	Signature
Name of person taking consent	Date	Signature

For further information please contact Tom Withers (t.withers@uea.ac.uk/01603 593093).

When completed: 1 for participant; 1 for researcher site file; 1 (original) to be kept in medical notes.

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Appendix 4: How to use the accelerometer and questionnaire instructions Version 1; 20/01/2014.

Dear <Insert Name of Participant>,

Thank you for agreeing to participate in this study an important measure being taken in this study is accelerometery. An accelerometer measures how active you are and is worn on the arm/waist <delete as appropriate>. You would have been shown by a member of the research team how to wear the accelerometer at your pre-operation clinic. The photo below also shows you how to wear your accelerometer simply clip it around your waist/arm <delete as appropriate>.

<Insert picture of someone wearing the accelerometer>

Please wear the accelerometer on either <insert date> or <insert date> it is important that you put the accelerometer on when you wake up and take it off when you go to sleep. You do not need to wear your accelerometer when you have a shower or a bath and if you choose to go for a swim. Over the seven days that you are wearing your accelerometer please also fill out the enclosed questionnaires and activity log.

If you have any question please feel free to contact me using the details above.

Thank you,

Tom Withers
PhD student

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Appendix 5: EQ-5D- 5L, Oxford Hip Score, GRCS, PASE and Hip Dislocation Form

EQ-5D-5L

Participant number: _____

Under each heading, please tick the ONE box that best describes your health TODAY

MOBILITY
I have no problems in walking about ☐
I have slight problems in walking about ☐
I have moderate problems in walking about ☐
I have severe problems in walking about ☐
I am unable to walk about ☐

SELF-CARE
I have no problems washing or dressing myself ☐
I have slight problems washing or dressing myself ☐
I have moderate problems washing or dressing myself ☐
I have severe 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 doing my usual activities ☐
I have slight problems doing my usual activities ☐
I have moderate problems doing my usual activities ☐
I have severe problems doing my usual activities ☐
I am unable to do my usual activities ☐

PAIN / DISCOMFORT
I have no pain or discomfort ☐
I have slight pain or discomfort ☐
I have moderate pain or discomfort ☐
I have severe pain or discomfort ☐
I have extreme pain or discomfort ☐

ANXIETY / DEPRESSION
I am not anxious or depressed ☐
I am slightly anxious or depressed ☐
I am moderately anxious or depressed ☐
I am severely anxious or depressed ☐
I am extremely anxious or depressed ☐

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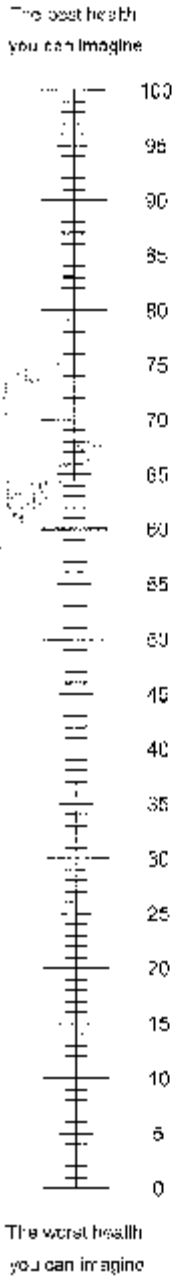
- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100
- 100 means the best health you can imagine
  0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY =



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Oxford Hip Score

Participant number: _____

Please answer the following 12 questions. Choose only one answer per question and indicate your answer by ticking the box next to your answer.

During the past 4 weeks.

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

1	None	☐
2	Very mild	☐
3	Mild	☐
4	Moderate	☐
5	Severe	☐

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

1	No trouble at all	☐
2	Very little trouble	☐
3	Moderate trouble	☐
4	Extreme difficulty	☐
5	Impossible to do	☐

3. Have you had any trouble getting in and out of a car or using public transport because of your hip? (whichever you tend to use)

1 No trouble at all ☐

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2	Very little trouble	
3	Moderate trouble	
4	Extreme difficulty	
5	Impossible to do	

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

1	Yes, easily	
2	With little difficulty	
3	With moderate difficulty	
4	With extreme difficulty	
5	No, impossible	

5. Could you do your household shopping on your own?

1	Yes, easily	
2	With little difficulty	
3	With moderate difficulty	
4	With extreme difficulty	
5	No, impossible	

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

1	No pain/>30 minutes	
2	16 to 30 minutes	
3	5 to 15 minutes	

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4	Around the house only	
5	Not at all	

7. Have you been able to climb a flight of stairs?

1	Yes, easily	
2	With little difficulty	
3	With moderate difficulty	
4	With extreme difficulty	
5	No, impossible	

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

1	Not at all painful	
2	Slightly painful	
3	Moderately painful	
4	Very painful	
5	Unbearable	

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

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1	Rarely/never	
2	Sometimes or just at first	
3	Often, not at first	
4	Most of the time	
5	All of the time	

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

1	No days	
2	Only 1 or 2 days	
3	Some days	
4	Most days	
5	Every day	

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

1	Not at all	
2	A little bit	
3	Moderately	
4	Greatly	
5	Totally	

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

1	No nights	

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2	Only 1 or 2 nights	
3	Some nights	
4	Most nights	
5	Every nights	

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Physical Activity Questionnaire in the Elderly (PASE)

Modified Physical Activity Scale for the elderly

I am interested in how much time you have spent doing the following activities over the last 7 days.

Leisure time activity

1. Walking outside the home

How much time was spent on the activity over the last 7 days (tick as appropriate)

Never (0 days)	Seldom (1 to 2 days)	Sometimes (3 to 4 days)	Often (5 to 7 days)

How many hours per day did you spend on this activity?

Less than 1hour	1 to 2 hours	2 to 4 hours	More than 4 hours

2. Light sport/recreation

Name the activity/activities_____

How much time was spent on the activity over the last 7 days (tick as appropriate)

Never (0 days)	Seldom (1 to 2 days)	Sometimes (3 to 4 days)	Often (5 to 7 days)

How many hours per day did you spend on this activity?

Less than 1hour	1 to 2 hours	2 to 4 hours	More than 4 hours

3. Moderate sport/recreation

Name the activity_____

How much time was spent on the activity over the last 7 days (tick as appropriate)

Never (0 days)	Seldom (1 to 2 days)	Sometimes (3 to 4 days)	Often (5 to 7 days)

How many hours per day did you spend on this activity?

Less than 1hour	1 to 2 hours	2 to 4 hours	More than 4 hours

4. Strenuous sport/recreation

Name the activity_____

How much time was spent on the activity over the last 7 days (tick as appropriate)

Never (0 days)	Seldom (1 to 2 days)	Sometimes (3 to 4 days)	Often (5 to 7 days)

How many hours per day did you spend on this activity?

Less than 1hour	1 to 2 hours	2 to 4 hours	More than 4 hours

5. Muscle strength/endurance exercises

Name the activity_____

How much time was spent on the activity over the last 7 days (tick as appropriate)

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Never (0 days)	Seldom (1 to 2 days)	Sometimes (3 to 4 days)	Often (5 to 7 days)

How many hours per day did you spend on this activity?

Less than 1hour	1 to 2 hours	2 to 4 hours	More than 4 hours

Chapter 13 Household Physical Activities

Have you performed the following activities over the last 7 days (tick appropriate box)

1. Light housework

No	Yes

2. Heavy housework and chores

No	Yes

3. Home repairs

No	Yes

4. Lawn work

No	Yes

5. Outdoor gardening

No	Yes

6. Caring for another person

No	Yes

Work related physical activity

In the last 7 days how many hours paid work have you done._____

Would you describe your work as mainly: (Please tick appropriate box)

1. Sitting with slight arm movements	
2. Sitting or standing with some walking	
3. Walking with some handling of materials generally weighing less than 50 pounds	
4. Walking and heavy manual work often requiring handling of materials weighing over 50 pounds.	

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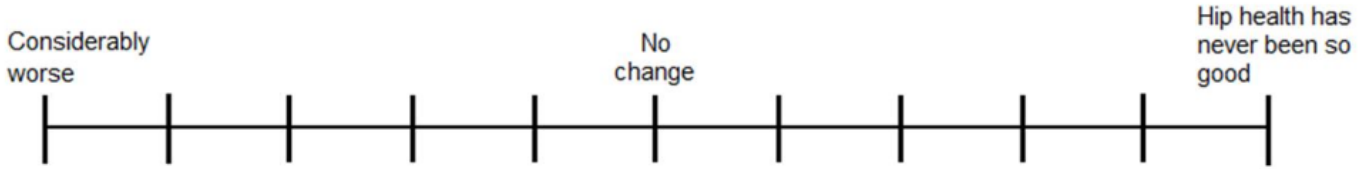
GRCS (Only give to participants for post-operative measures)

Participant Number: _____

With respect to your hip that you had replaced with an artificial one mark on the scale how you feel that particular hips health status has changed comparing now to immediately before your operation.



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Hip Dislocation Form

Since your hip replacement has your prosthetic hip dislocated? Yes/No (Circle answer)

If yes, what treatment was needed? (Please circle answer)

- No treatment was needed dislocation was only temporally.
- Went to hospital, no surgery was needed.
- Went to hospital, surgery was needed.

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Appendix 6: Activity log Version 1; 20/1/14

Participant number: _____

Please fill in the below activity log detailing what you did whilst you were wearing the accelerometer. You should include a general description of what you did in each time slot.

Time	Day 1date:	Day 2 date:
Before 7:00 am		
7:00am – 8:59 am		
9:00 am – 10:59 am		
11:00 am – 12:59 pm		
1:00 pm – 2:59 pm		
3:00 pm – 4:59 pm		
5:00 pm – 6:59 pm		
7:00 pm – 8:59 pm		
9:00 pm – 10:59 pm		
11:00 pm and later		

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Appendix 7: General participant characteristics Version 1; 26/01/2014.

General Participant Information

Participant Number: _____

GP address:

_____

_____

_____

_____

_____

Address to post correspondent to:

_____

_____

_____

_____

_____

Preferred contact method: email/phone/letter

Phone number: _____

Email address (optional): _____

Date of birth: _____

Hospital operation being performed at: _____

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Gender: M/F

Does the participant currently use assistive aids? Yes/No

If Yes what?

_____

_____

_____

_____

_____

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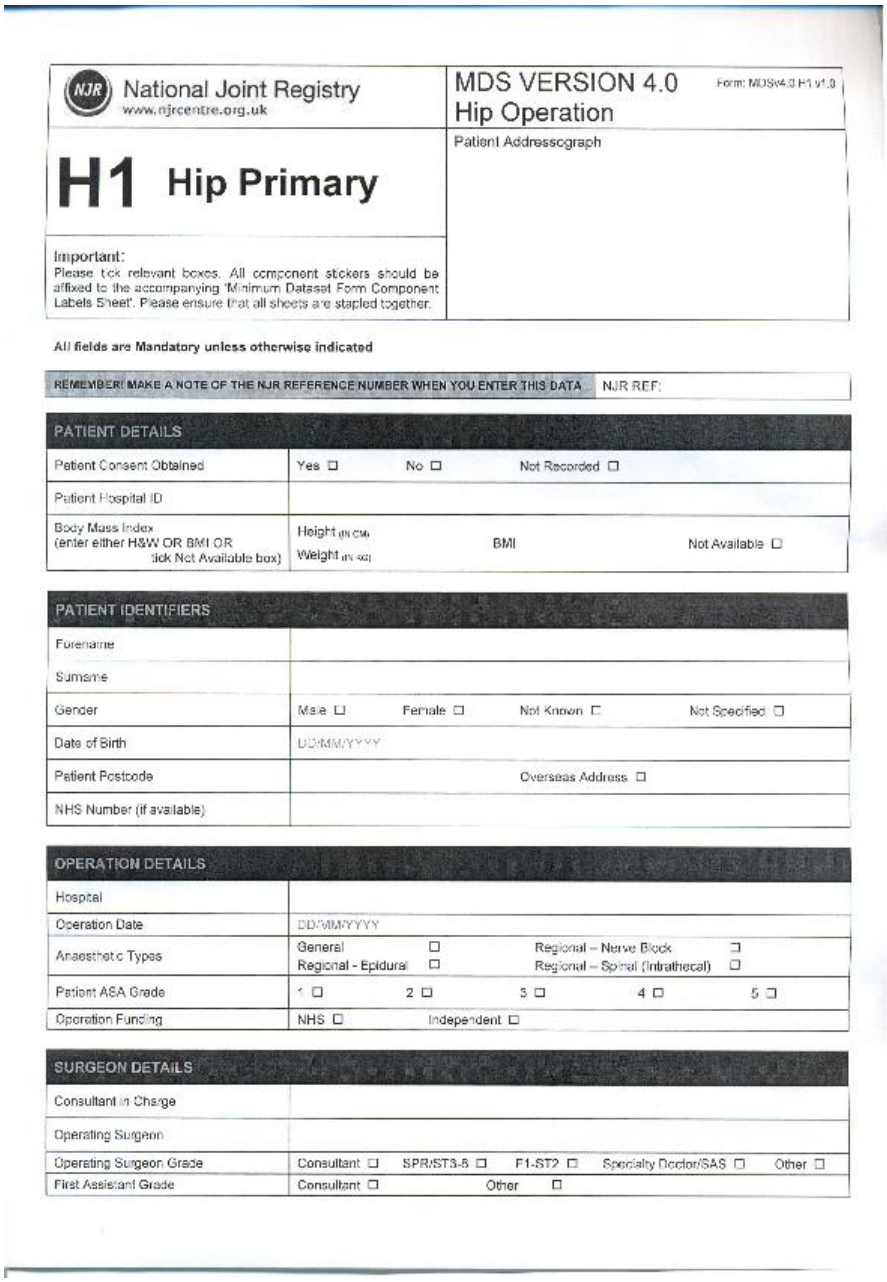
Appendix 8: Operative data capture form Version 1; 20/01/14.

The top box will be covered when a copy is taken to ensure that the patients identity remain anonymous.



National Joint Registry
www.njrcentre.org.uk

MDS VERSION 4.0 Form: MDSv4.0 H1 v1.0
Hip Operation

H1 Hip Primary

Patient Addressograph

Important:
Please tick relevant boxes. All component stickers should be affixed to the accompanying 'Minimum Dataset Form Component Labels Sheet'. Please ensure that all sheets are stapled together.

All fields are Mandatory unless otherwise indicated

REMEMBER! MAKE A NOTE OF THE NJR REFERENCE NUMBER WHEN YOU ENTER THIS DATA | NJR REF:

PATIENT DETAILS				
Patient Consent Obtained	Yes ☐	No ☐	Not Recorded ☐	
Patient Hospital ID				
Body Mass Index (enter either H&W OR BMI OR tick Not Available box)	Height (in cm) Weight (in kg)	BMI	Not Available ☐	

PATIENT IDENTIFIERS				
Forename				
Surname				
Gender	Male ☐	Female ☐	Not Known ☐	Not Specified ☐
Date of Birth	DD/MM/YYYY			
Patient Postcode		Overseas Address ☐		
NHS Number (if available)				

OPERATION DETAILS				
Hospital				
Operation Date	DD/MM/YYYY			
Anaesthetic Types	General ☐ Regional - Epidural ☐		Regional – Nerve Block ☐ Regional – Spinal (Intrathecal) ☐	
Patient ASA Grade	1 ☐	2 ☐	3 ☐	4 ☐ 5 ☐
Operation Funding	NHS ☐	Independent ☐		

SURGEON DETAILS						
Consultant in Charge						
Operating Surgeon						
Operating Surgeon Grade	Consultant ☐	SPR/ST3-8 ☐	F1-ST2 ☐	Specialty Doctor/SAS ☐	Other ☐	
First Assistant Grade	Consultant ☐	Other ☐				

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HIP PRIMARY PROCEDURE DETAILS					
Side	Left ☐	Right ☐			
Indications for Implantation (select all that apply)	Osteoarthritis ☐ Inflammatory Arthropathy ☐ Congenital Dislocation / Dysplasia of the Hip ☐ Avascular Necrosis ☐ Trauma – Acute (Neck of Femur) ☐ Failed Hemi-Arthroplasty ☐		Trauma – Chronic ☐ Previous Hip Surgery – non Trauma related ☐ Previous Arthrodesis ☐ Previous Infection ☐ Other ☐		

SURGICAL APPROACH				
Patient Procedure	Primary Total Prosthetic Replacement Using Cement ☐ Primary Total Prosthetic Replacement Not Using Cement ☐ Primary Resurfacing Arthroplasty of Joint ☐ Primary Total Prosthetic Replacement Not Classified Elsewhere (eg Hybrid) ☐			
Consultant in Charge – Default Technique used?	Yes ☐ No ☐ If Yes, ensure the relevant Surgeon Default Technique is recorded on the Data Entry system. The Surgeon's Default Technique is made up of several data fields.			
Patient Position	Lateral ☐ Supine ☐			
Approach	Hardinge ☐ Posterior ☐		Trochanteric Osteotomy ☐ Other ☐	
Minimally Invasive Technique Used?	Yes ☐ No ☐			
Computer Guided Surgery Used?	Yes ☐ No ☐			
THROMBOPROPHYLAXIS REGIME (Intention to treat)				
Chemical	Aspirin ☐ LMWH ☐ Pentasaccharide ☐		Warfarin ☐ Direct Thrombin Inhibitor ☐ Other ☐	None ☐
Mechanical	Foot Pump ☐ Intermittent Calf Compression ☐ TED Stockings ☐		Other ☐ None ☐	
BONEGRAFT USED				
Femur	Yes ☐ No ☐			
Acetabulum	Yes ☐ No ☐			
SURGEON'S NOTES				

INTRA OPERATIVE EVENT					
Untoward Intra Operative Event	None ☐ Calcar Crack ☐ Pelvic Penetration ☐		Shaft Fracture ☐ Shaft Perforation ☐ Trochanteric Fracture ☐		Other ☐

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Minimum Dataset Form - COMPONENT LABELS

1. Please affix any component labels to this sheet and ensure any extra component label sheets are attached to the main Minimum Dataset Form.
2. Ensure all component details are provided, including cement.
3. The NJR DOES NOT record the following: wire, mesh, cables, plates, screws, surgical tools, endoprostheses or bipolar heads.

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Length of hospital stay data capture form

Participant number: _____

Length of hospital stay in days from admission to discharge:
_____

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Appendix 9: Letter that accompanies all questionnaires sent out at 4, 12 and 24 weeks post-surgery.

Dear <Insert Name of Participant>,

Please find enclosed 4 questionnaires, an accelerometer and an activity log. They are the same questionnaires that you filled in before your operation and you need to wear the accelerometer in the same way as you did before the operation. Please could you wear the accelerometer on either <insert date> or <insert dates>, instructions on how to wear the accelerometer are at the bottom of this letter.

Over the seven days that you are wearing your accelerometer please also fill out the questionnaires and activity log.

How to wear the accelerometer

Clip the accelerometer to your waist/arm <delete as appropriate> you should put the accelerometer on when you wake up in the morning and take it off when you go to bed. You do not need to wear your accelerometer when you have a shower or a bath and if you choose to go for a swim. The picture shows how to wear the accelerometer correctly.

<Insert picture of someone wearing the accelerometer>

If you have any question please feel free to contact me using the details above.

Thank you,

Tom Withers
PhD student

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Email: t.withers@uea.ac.uk

Appendix 10: Additional medical and or surgical intervention form from NHS record data Version 1, 27/01/2014.

Additional surgical and medical interventions

Participant number: _____

Study period that records searched for (circle one):

- operation to 4 weeks post operation (post-op)
- 4 weeks post-op to 12 weeks post-op
- 12 weeks post-op to 24 weeks post-op

Date records searched from: _____

Date records searched to: _____

Additional entries found: Yes/No (delete as appropriate).

If yes fill in table below.

Type of admission el = elective em = emergency	Reason for admission	Length of hospital stay (days)	Details of medical and or surgical interventions undertaken on admission (answer no if none were undertaken) and type of ward visited.

Use continuation sheet if necessary.

Continuation sheet additional surgical and medical interventions

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Participant number: _____

This is continuation sheet _____ of _____.

Study period that this continuation sheet relates to (circle one):

- operation to 4 weeks post operation (post-op)
- 4 weeks post-op to 12 weeks post-op
- 12 weeks post-op to 24 weeks post-op

Type of admission el = elective em = emergency	Reason for admission	Length of hospital stay (days)	Details of medical and or surgical interventions undertaken on admission (answer no if none were undertaken) and type of ward visited.

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Results for: What is the effect on independent recovery of using pedometers as a tool to prescribe exercise following total hip replacement?

Dear <insert name of participant>,

Thank you for participating in the 'What is the effect on independent recovery of using pedometers as a tool to prescribe exercise following total hip replacement?' study. We have not collected and analysed all of the data for this study and are writing to inform you of our findings.

<Insert lay summary of results>

Thank you once again for participating in this study.

Kind regards,

Tom Withers
PhD student

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Room 1.23 Queens Building
University of East Anglia
Norwich NR4 7TJ
Tel: 01603 593093
Email: t.withers@uea.ac.uk

Appendix 12: Letter to GP Version 1, 27/01/2014.

RE: <insert patient name and NHS number>

Dear <insert name of GP>/To whom it may concern <if participant does not have a named GP at the practice> <delete as appropriate>,

I am writing in relationship to your patient named above who has agreed to take part in a study looking at if prescribed exercise following total hip replacement (THR) reduces time to independent recovery. The research will form part of my PhD.

This study is a 2 arm randomised control trial, the control arm will receive normal care, the intervention arm in addition to normal care will be given a pedometer and will wear it two days a week for 24 weeks following the operation. On the day of the week that the participant is wearing the pedometer they will be given a target step count for that day the target step count increases week on week for the duration of the study. The patient named above is in the <insert arm that patient is in>.

At 2 weeks pre-operation your patient will be asked to fill in 3 questionnaire and 4 questionnaires at 4, 12 and 24 weeks post-operation, they will also wear an accelerometer for 2 days at all of the data collection points. The primary outcome measure for this study is the Oxford Hip Score the secondary outcome measures are: quality of life, hip dislocation rate and physical activity. It is hoped that the results from this study may show the potential benefits of a more structured approach to physical activity following THR.

I would appreciate it, if this letter could be filed in the patient's notes or being contacted if this patient is no longer under your care. The participant information sheet is also attached for information and if you have any questions please feel free to contact me using the details at the top of this letter.

The study received a favourable ethical opinion from <insert name of ethics committee> on <insert date>.

Yours Sincerely,

Tom Withers
PhD Student

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Norwich NR4 7TJ
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Email: t.withers@uea.ac.uk

Appendix 13: Pedometer Count Version 1; 20/6/14

Participant number: _____

Please fill in the below table detailing the number of steps you undertook for each day you wore your pedometer.

Week	Pedometer wearing day	Target number of steps	Actual number of steps	If not able to complete target steps, any reason why? E.g. bad weather, feeling unwell
1	First of the week	300		
	Second of the week	300		
2	First of the week	330		
	Second of the week	330		
3	First of the week	363		
	Second of the week	363		
4	First of the week	399		
	Second of the week	399		
5	First of the week	363		
	Second of the week	363		
6	First of the week	459		
	Second of the week	459		
7	First of the week	528		
	Second of the week	528		
8	First of the week	607		
	Second of the week	607		
9	First of the week	698		
	Second of the week	698		
10	First of the week	607		
	Second of the week	607		
11	First of the week	838		
	Second of the week	838		
12	First of the week	1006		
	Second of the week	1006		
13	First of the week	1207		
	Second of the week	1207		
14	First of the week	1448		

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	Second of the week	1448		
15	First of the week	1207		
	Second of the week	1207		
16	First of the week	1810		
	Second of the week	1810		
17	First of the week	2263		
	Second of the week	2263		
18	First of the week	2828		
	Second of the week	2828		
19	First of the week	3536		
	Second of the week	3536		
20	First of the week	2828		
	Second of the week	2828		
21	First of the week	4596		
	Second of the week	4596		
22	First of the week	5975		
	Second of the week	5975		
23	First of the week	7768		
	Second of the week	7768		
24	First of the week	10098		
	Second of the week	10098		

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Appendix 14 Study Feedback Questionnaire

Study Feedback Questionnaire – (22.09.2015: Version 1)

The following questions will help the study team understand better your thoughts about the study along with helping researchers improve similar studies in the future. It would be greatly appreciated if you could take a few minutes to answer these questions.

1. What were the main reasons that you decided to participate in this study?

Comments

2. Did you have any concerns about the study before agreeing to take part?

☐Yes ☐No

Comments

3. Were your worried that participating in the study would be an inconvenience?

☐Yes ☐No

Comments

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Email: t.withers@uea.ac.uk

4. Did any friends or family help you decide whether to take part in this study?

☐Yes ☐No

Comments

5. Did you have enough time to complete the questionnaires?

☐Yes ☐No

Comments

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University of East Anglia
Norwich NR4 7TJ
Tel: 01603 593093
Email: t.withers@uea.ac.uk

6. Did you receive a pedometer to wear?

☐Yes - go to Question 8 ☐No - go to Question 7

7. Were you disappointed not to be given a pedometer?

☐Yes ☐No

Comments

Please now go to Question 10

8. Did you have enough time to wear the pedometer and fill out the step log?

☐Yes ☐No

Comments

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Norwich NR4 7TJ
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Email: t.withers@uea.ac.uk

9. If you were not given a pedometer do you think that you would have been less active following your total hip replacement?

☐Yes ☐No

Comments

10. Were the questionnaires easy to understand?

☐Yes ☐No

Comments

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Norwich NR4 7TJ
Tel: 01603 593093
Email: t.withers@uea.ac.uk

11. Please use the box below to add any additional comment about the study which you may wish to share.

Comments

Thank you for your time

Appendix 6: Letter of Approval for Ethics Committee.

NHS
Health Research Authority
NRES Committee East of England - Cambridge Central
Royal Standard Place
Nottingham
NG1 6FS

Telephone: 0115 883 9309

20 October 2014

Mr Thomas Withers
Room 1.23 Queen's Building
University of East Anglia
Norwich
NR4 7TJ

Dear Mr Withers

Study title:	What is the effect on independent recovery of using pedometers as a tool to prescribe exercise following total hip replacement?
REC reference:	14/EE/1178
IRAS project ID:	143417

The Research Ethics Committee reviewed the above application at the meeting held on 10 October 2014. Thank you for attending to discuss the application.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details unless you express y w thhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to withhold permission to pu ish, please contact the REC Manager Tracy Leavesley, NRESCommitte.EastofEng!and-CambridgeCentra@nhs.net

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions be ng met prior to the start of the study.

Management permission or apuroval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on question 2 of the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non clinical trials this is not currently mandatory.

If a sponsor wishes to contest the need for registration they should contact Catherine Blewett (catherineblewett@nhs.net), the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

NHS Sites

The favourable opinion applies to all NHS sites taking part in the study taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non NHS sites

The Committee has not yet completed any site-specific assessment(s) (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. I will write to you again as soon as an SSA application(s) has been reviewed. In the meantime no study procedures should be initiated at non-NHS sites.

Summary of discussion at the meeting

Care and protection of research participants; respect for potential and enrolled participants' welfare and dignity

It was discussed the applicant is intending to access participant notes during the study and the Committee queried the rationale behind this with the applicant. *The applicant advised he is taking consent to access the participant's notes and is only using this information to compliment the economic data with medical evidence. The applicant went on to advise the Committee he is only accessing hospital information for relevant data and he had sought advice from the Health*

Economics Department at his University to check the validity of this approach and had been reassured they considered this to be the correct method to adopt.

Other general comments

The Committee discussed the reference to a participants' GP being asked to file the study letter in their patient's notes and considered many GPs would be too busy to do so. *The applicant advised he was following NRES guidelines when listing this procedure.*

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Covering letter on headed paper		18 September 2014
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only)		18 September 2014
GP/consultant information sheets or letters	1	27 January 2014
IRAS Checklist XML [Checklist_19092014]		19 September 2014
IRAS Checklist XML [Checklist_22092014]		22 September 2014
Letter from sponsor		18 September 2014
Letter from statistician		
Letters of invitation to participant	1	20 January 2014
Non-validated questionnaire		17 January 2014
Other [Toby Smith CV]		04 October 2013
Participant consent form	1	27 January 2014
Participant information sheet (PIS)	1	29 January 2014
REC Application Form [REC_Form_19092014]		19 September 2014
Research protocol or project proposal	1	07 August 2014
Summary CV for Chief Investigator (CI)		10 July 2014
Summary CV for student		10 July 2014
Summary CV for supervisor (student research)		17 September 2014
Summary, synopsis or diagram (flowchart) of protocol in non technical language		17 September 2014
Validated questionnaire		17 September 2014

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

After ethical review

Reporting requirements

The attached document 'After ethical review – guidance for researchers' gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol

- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

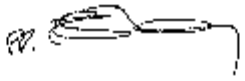
HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

14/EE/1178	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project.

Yours sincerely



Mrs Carolyn Read
Chair

E-mail: NRESCommittee.EastofEngland-CambridgeCentral@nhs.net

Enclosures. *List of names and professions of members who were present at the meeting and those who submitted written comments*

"After ethical review – guidance for researchers"

Copy to: *Mrs Sue Stool*

Ms Laura Harper, Norfolk and Norwich University Hospital

NRES Committee East of England - Cambridge Central

Attendance at Committee meeting on 10 October 2014

Committee Members:

Name	Profession	Present	Notes
Dr Joseph Cheriyan	Consultant Physician	No	
Ms Anita Chhabra	Clinical Trials Pharmacist	Yes	
Dr Lydia Drumright	Lecturer in Infectious Diseases and Epidemiology	No	
Revd Dr Derek Fraser	Chaplain	Yes	
Dr Adrian French	Retired General Practitioner	Yes	
Mr Stuart Kent	Retired Consultant Surgeon	Yes	
Miss Giselle Kerry	Data Access and Regulatory Support Officer	Yes	
Mr David Lewin	Retired Research Officer	Yes	
Ms Moira Maltroy	Retired Senior Research Nurse/Clinical Trial Manager	Yes	
Mrs Bath Midgley	Lay Member	Yes	
Dr Nothando Bukhabenkosi Ngwanya	Research Associate	Yes	
Dr Ian Nimmo-Smith	Statistician	Yes	
Ms Polly Page	Operations Director	No	
Dr Sumantra Ray	Senior Medical Advisor/Scientist	Yes	
Mrs Carolyn Read (Chair)	External liaison and Research Governance Officer	Yes	
Mrs Caroline Saunders	Nurse	No	
Dr Mary-Beth Sherwood	Clinical Researcher	Yes	

Also in attendance:

Name	Position (reason for attending)
Ms Tracy Learesley	REC Manager

Appendix 7: Major Amendment Approval

NHS
Health Research Authority

East of England - Cambridge Central Research Ethics Committee
Royal Standard Place
Nottingham
NG1 6FS

Tel: 0115 8839521

20 October 2015

Mr Thomas Withers
PhD Student
University of East Anglia
University of East Anglia
Queen's Building
Norwich
NR46TJ

Dear Mr Withers

Study title:	**What is the effect on independent recovery of using pedometers as a tool to prescribe exercise following total hip replacement?**
REC reference:	**14/EE/1178**
Amendment number:	**1**
Amendment date:	**24 September 2015**
IRAS project ID:	**143417**

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Notice of Substantial Amendment (non-CTIMP)	1	24 September 2015
Other [Study feedback questionnaire]	1	22 September 2015
Participant information sheet (PIS)	3	24 September 2015
Research protocol or project proposal	3	24 September 2015

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

14/EE/1178:	**Please quote this number on all correspondence**

Yours sincerely

pp. V. Sweet

Dr Joseph Cheriyan
Chair

E-mail: NRESCommittee.EastofEngland-CambridgeCentral@nhs.net

Enclosures: *List of names and professions of members who took part in the review*

Copy to: *Ms Laura Harper, Norfolk and Norwich University Hospital*
Mrs Sue Steel

East of England - Cambridge Central Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 08 October 2015

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr Joseph Cheriyan - Chair	Consultant Physician	Yes	
Ms Moira Malfroy	Retired Senior Research Nurse/Clinical Trial Manager	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Miss Rebecca Morledge	REC Manager