Hip Precautions After Hip Operation (HippityHop):

A Before and After Study Evaluating Hip Precautions Following Total Hip Replacement

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BSc. MSc.

Thesis submitted to the University of Nottingham
for the degree of Doctor of Philosophy

2018

Abstract

Background

Total hip replacement (THR) is a common surgical intervention for treating painful osteoarthritis, especially with end-stage joint deterioration. A well-recognised complication of THR surgery is hip dislocation. To reduce the risk of dislocation, patients are often asked to observe 'hip precautions' (that is to restrict certain movements) for several weeks post-surgery. Hip precautions are routinely used despite conflicting evidence regarding their efficacy in reducing dislocation, and divergent clinical opinions as to whether they are detrimental or beneficial to patient recovery.

Aim

The overarching aim of this study, therefore, was to evaluate the effectiveness of hip precautions following THR by comparing a regime of routine hip precautions with a regime of no routine precautions, in order to: 1. compare patient outcomes in functional performance, pain, sleep, mood, satisfaction, and quality of life; and 2. ascertain staff and patient perceptions and experiences of the two regimes.

Method

A before and after study was conducted. In the 'before' phase patients received education on hip precautions, while in the 'after' phase patients received no advice on routine precautions. Data were collected from participants at baseline, and at one week, six weeks, and three months postoperatively. The primary outcome was the Oxford Hip Score (OHS) at three months; other outcomes measures were the Nottingham Extended Activities of Daily Living Scale, the Pittsburgh Sleep Quality Index, the Hospital Anxiety and Depression Scale, EQ-5D-5L, and rate of hip dislocation at the different time points. Equivalence analysis was conducted to determine whether patients' OHSs were equivalent at three months postoperatively. Statistical analyses were conducted to determine any differences in the other patient outcomes.

Semi-structured interviews were conducted with staff and patients who participated in the before and in the after phases of the study. Interviews included experiences and opinions of the service provided, provision of information, equipment prescription, and the impact on patients' recovery. Thematic analysis was used to identify and report themes.

Results

In the before and after study, 367 participants were recruited, of these a total of 237 participants successfully underwent THR surgery during the study period and were followed-up. Outcome data were obtained for 221 participants at six weeks and 212 at three months. The results indicated that patients who received hip precautions had similar outcomes to those who did not at six weeks and three months postoperatively. In addition, patients who did not receive precautions had equivalent levels of pain and function at three months as patients who received precautions. The rate of dislocation observed was comparable for both groups.

Interviews were conducted with 19 members of staff and 22 patients across both phases of the study. Findings from the interviews suggested that diverging clinical opinions remained amongst staff about the use of hip precautions and their impact on patients' recovery. Whilst therapists were more willing to withdraw precautions from practice, surgeons were more concerned about the change. Even following the change in service, some surgeons remained sceptical about the potential benefits that the relaxed regime may have on the patients' recovery and were concerned about the effects on dislocation rates. Patients in the before phase also had mixed views about the use of hip precautions, with varying adherence and perceived impact upon their daily lives and recovery following THR. Some felt that they were restrictive whilst others believed that precautions provided reassurance and decreased their risk of dislocation. Following the withdrawal of precautions, some patients were less fearful about dislocating their hip but were unsure how to perform certain movements and progress their rehabilitation.

Conclusion

The principal conclusion was that patients who did not receive hip precautions had similar outcomes to those who did receive them, at six weeks and three months postoperatively, in terms of pain, function, mood, sleep quality and health-related quality of life. In addition, the rate of dislocation observed was similar for both groups. Although this study demonstrated that hip precautions provided no additional benefit, some surgeons interviewed believed that precautions should continue to be provided to patients. The study findings support the removal of precautions following primary THR but highlighted that mixed opinions about this remain.

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List of abbreviations

ADLs	Activities of Daily Living
ASA	American Society of Anaesthesiologists
BI	Barthel Index
CI	Confidence Intervals
CLAHRC	Collaboration for Leadership in Applied Health Research and Care
EES	Epworth Sleepiness Scale
EQ-5D	EuroQol- 5 Dimension
HADS	Hospital Anxiety and Depression Scale
HHS	Harris Hip Score
HOOS	Hip disability and osteoarthritis outcome score
HRA	Health Research Authority
HRQoL	Health-Related Quality of Life
ILAS	Iowa Level of Assistance Scale
MLST	Multiple Sleep Latency Test
MDT	Multidisciplinary team
MUA	Manipulation Under Anaesthesia
NEADL	Nottingham Extended Activities of Daily Living
NEOS	Nottingham Elective Orthopaedic Services
NHS	National Health Service
NICE	National Institute of Health and Care Excellence
NJR	National Joint Registry
OA	Osteoarthritis
OHS	Oxford Hip Score
PSQI	Pittsburgh Sleep Quality Index
QoL	Quality of Life
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
ROM	Range of Motion
SF-36	Short Form – 36
THA	Total Hip Arthroplasty
THR	Total Hip Replacement
WHO	World Health Organisation
WOMAC	Western Ontario and McMaster Universities Osteoarthritis Index
YLD	Years Lived with Disability

Impact and achievements

Publications

Lightfoot, C. J., Sehat, K., Drury, G., Brewin, C., Coole, C., and Drummond, A. (2018). Hip precautions after hip operation (HippityHop): Protocol for a before and after study evaluating hip precautions following total hip replacement. *British Journal of Occupational Therapy (BJOT)*, 81(6). DOI: 10.1177/0308022618757183
First protocol paper published in the British Journal of Occupational Therapy.

Invited talks and conference presentations

'Hip precautions after hip replacement (HippityHop study): a before and after study evaluating hip precautions after total hip replacement: preliminary results'. Royal College of Occupational Therapist (RCOT) Annual Conference, Belfast, June 2018.

'Hip precautions after hip replacement (HippityHop study): a before and after study evaluating hip precautions after total hip replacement: protocol'. Royal College of Occupational Therapist Special Section Trauma and Orthopaedics (RCOTSSTO) Annual Conference, London, October 2017.

'Hip precautions after hip replacement: a before and after study evaluating hip precautions after total hip replacement: study update'. Orthopaedic Divisional Day, Nottingham University Hospitals Trust, September 2017.

'Hip precautions after hip replacement: a before and after study evaluating hip precautions after total hip replacement'. Orthopaedic Divisional Day, Nottingham University Hospitals Trust, September 2016.

'Hip precautions after hip replacement: a before and after study evaluating hip precautions after total hip replacement'. Enhanced Recovery After Surgery (ERAS) programme meeting, Nottingham University Hospitals Trust, July 2016.

Awards

National Institute of Health Research (NIHR) Collaboration for Leadership in Applied Health Research and Care (CLAHRC) East Midlands PhD Travel/Research prize. £500 awarded January 2017.

Acknowledgements

I would like to express my appreciation to all those who have helped me complete my PhD. It has been a challenging but rewarding experience, which has tested my resilience on numerous occasions.

Firstly, I would like to thank my supervisors Prof Avril Drummond and Dr Carol Coole for their supervision and guidance throughout the duration of my PhD. Thank you for giving me the opportunity to undertake my PhD and open my world to research. I am our truly grateful for your constant support, encouragement, and advice throughout this whole process. Thank you for all the time and effort you have invested in me.

I would also like to thank the School of Health Sciences for funding this research. Thank you to Dr Andrea Venn for her advice on statistics, especially on equivalence analysis. Thank you to Dr Joanne Ablewhite for her assistance with scoring and inputting the data, posting questionnaires, and proof reading my thesis.

Thank you to all the participants who took part in the study, without whom this research would not have been possible. Thank you for your time and sharing your experiences with me. Also thank you to the orthopaedic staff, particularly the hip champions for your assistance with the study. Thank you to project steering group for their advice and guidance throughout the study. I truly appreciate the input and support from Mr Kos Sehat, Gary Drury and Cathy Brewin who went the extra mile to help me with the research.

I would like to say a big thank you to my wonderful PhD friends – Jess, Jacqui, Olga, Snigdha, Matt, Muhammad, Becca, and Liz – whom I have shared the highs and lows of my PhD journey with. Special thanks to Matt for becoming my first PhD friend, and to Jess for introducing herself to me at our first stats lecture and becoming the best tea-drinking, cake-baking/eating friend!

Finally, the biggest thanks of all goes to my amazing family and partner: Mum, Dad, Colette, Ellice and Tom. It has been an eventful three years and I could not have done it without you. Thank you for continuous support and funding to help me achieve everything that I have wanted to do. Thank you for your unconditional love, encouragement, and for always believing in me.

1

Background and Review of Literature

1.1. Introduction

This research examines the use of hip precautions following total hip replacement (THR), which is a frequently performed procedure for advanced osteoarthritis (OA). The study comprised two interconnected but discrete elements that were conducted simultaneously: a before and after study, and an interview study. This chapter details an overview of OA and its current treatment strategies, which include THR surgery. It also summarises the main research evidence and associated literature related to the use of hip precautions following THR that was available when the study was conceived. The chapter concludes by identifying the limitations of this literature and presenting a rationale for the study.

1.2. Osteoarthritis

1.2.1. Definition

Osteoarthritis (OA) is 'a degenerative joint disease characterised by joint pain and a progressive loss of articular cartilage' (Rosenberg, 1999). The name is derived from the Greek word *osteon* meaning 'of the bone', *arthron* meaning 'joint', and *itis* meaning 'inflammation' (Iannitti et al., 2011). Osteoarthritis, commonly referred to as 'wear and tear' arthritis and 'degenerative joint disease', is one of the most common chronic diseases leading to pain and disability. The cartilage within the joints is metabolically active and goes through a continuous cycle of deterioration and subsequent repair; an imbalance in this relationship can lead to inexorable joint damage (Lim et al., 2007).

1.2.2. Incidence and Prevalence

Osteoarthritis occurs in all races and is found in all geographical locations. Precise estimates of the prevalence and incidence of OA are problematic due to issues associated with the definition and diagnosis of the disease. The prevalence varies according to the definition of OA, the specific joint(s) under study, and the characteristics of the study population (Zhang and Jordan, 2010). However, the most recent update of the Global Burden of Disease (GBD Study 2016) estimates that over 300 million people worldwide are living with OA (Institute for Health Metrics and Evaluation (IHME), 2017). Currently, over 30 million Americans are affected by OA (Arthritis Foundation, 2018). In the United Kingdom (UK) there are approximately 8.8 million people diagnosed with OA; of these a third are aged 45 years and over, and almost half are aged 75 years and over (Arthritis Research UK, 2018). It is estimated

that 9.6% men and 18.0% of women aged over 60 years worldwide have symptomatic OA (World Health Organisation (WHO), 2018), with even greater rates based on radiographic definitions (Pereira et al., 2011).

Osteoarthritis accounts for 2.4% of all years lived with disability (YLD) and has been ranked as the 10th leading contributor to global YLDs (Osteoarthritis Research Society International, 2016). The YLDs attributable to OA have increased by 75% from 1990 to 2013 and it is the third most rapidly rising condition associated with disability, accounting for 13 million YLDs (GBD Collaborators, 2013). The increase in OA prevalence is primarily due to an increasing elderly population and rising levels of obesity (Arthritis Research UK, 2013). The increase in the ageing population has been predicted to make OA the fourth leading cause of disability by 2020 (Woolf and Pfleger, 2003). The cost to the UK National Health Service (NHS) of OA exceeds £1 billion a year (Chen et al., 2012), and the rising prevalence in OA is expected to further increase the socio-economic burden to both individuals and to health care. Osteoarthritis is estimated to cost the UK economy over £3.2 billion in lost production annually, with almost £300 million spent on social service and community services for OA-related problems (Chen et al., 2012). The costs associated with OA include costs for adaptive aids and devices, medicines, surgery, and time off work (Maetzel et al., 2004).

1.2.3. Aetiology

Osteoarthritis is a complex musculoskeletal disorder with a multifactorial aetiology, which includes factors such as increased mechanical stress, ligament derangement, cartilage degradation, subchondral bone change and muscular impairment. It occurs when there is an imbalance between the destructive forces and repair mechanisms of the joint (Egloff et al., 2012). Until recently, the pathophysiology of OA was considered to be cartilage driven, however, recent evidence has shown an additional and integrated role of bone and synovial tissue, with patchy chronic synovitis evident in the disease (Sellam and Berenbaum, 2010). Bone changes, including osteophyte formation, bone remodelling, and subchondral sclerosis, occur not only during the final stages of the disease but also at its onset, possibly before cartilage degradation (Interma et al., 2010a; Interma et al., 2010b). Recent experimental data have shown that subchondral bone may have a substantial role in the OA process, as a mechanical damper, as well as a source of inflammatory mediators that are implicated in the degradation, and structural changes, of the deep layer of cartilage (Berenbaum, 2013). Failure of the repair process of damaged cartilage results from the

biomechanical and biochemical changes that occur within the joint. The biomechanical failure has been hypothesised to occur as a result of: (1) degradation and loss of collagen and proteoglycan matrix components; (2) abnormal collagen remodelling; (3) consequences of decreased cellularity; and (4) mechanical wear (Temple-Wong et al., 2009). However, it is unclear whether these proposed mechanisms individually or collectively contribute to the deterioration of cartilage biomechanical function and the progression of OA. Thus, OA is a complex disease.

Joint inflammation is a well-recognised symptom of OA, particularly in the early stages (Sellam and Berenbaum, 2010). The swelling can be attributed to inflammation and reflects the presence of synovitis due to thickening of the synovium or to effusion (i.e. an accumulation, or abnormal amount, of fluid within the joint capsule) (Berenbaum, 2013). Recent evidence has shown that inflammatory mediators are released by the cartilage, bone, and synovium (Goldring and Otero, 2011; Kapoor et al., 2011; Loeser et al., 2012). Inflammation of the synovium corresponds to clinical symptoms, such as joint swelling and inflammatory pain, which can occur in both early and late phases of OA. Why the synovium becomes inflamed in OA remains a controversial topic (Sellam and Berenbaum, 2010). The most accepted hypothesis is that once degraded, cartilage fragments fall into the joint and contact the synovium, which releases inflammatory mediators and in turn increases cartilage degradation; alterations in the cartilage increases synovial inflammation, creating a vicious self-perpetuating cycle (Berenbaum, 2013).

1.2.4. Risk factors

Whilst the exact cause of OA is unknown, there are a number of risk factors, systemic and local, that are associated with it, including age, gender, genetics, being overweight/obese, having joint injuries/trauma, and occupation (Lemmey, 2013). The relative importance of the risk factors may vary for different joints, different stages of the disease, and the development as opposed to the progression of the disease (Zhang and Jordan, 2010). The impact of different risk factors can also vary among men and women (March and Bagga, 2004), with women more likely to suffer (O'Conner, 2007). Whilst, men are affected more often than women among those aged <45 years, women are affected more frequently among those aged >55 years (Woolf and Pfleger, 2003).

Modifying risk factors, such as injury, occupation, and obesity, may reduce the risk of OA and prevent subsequent pain and disability. Prevention strategies recommended

for patients with OA are education, elimination of unhealthy behaviours and promotion of healthy habits, weight reduction, preservation of function (of the affect joint(s)), and encouraging appropriate physical activity with a focus on increasing muscle strength. Other strategies include treatment of comorbidities, appropriate rehabilitation, reducing the discomforts with self-medication (pharmacological interventions), and appropriately timed referral to surgery (Bijlsma and Knahr, 2007).

1.2.5. Signs and Symptoms

Osteoarthritis is most common in weight-bearing joints where altered load mechanisms, increased mechanical forces, and changed biomechanics are significant contributing factors (Egloff et al., 2012). Changes within the joints can lead to a number of symptoms, which can differ amongst individuals with the disease. Pain is the first symptom of OA, with nearly three-quarters of people with OA reporting some form of constant pain, and one in eight describing the pain as 'unbearable' (Arthritis Care, 2012). The onset of pain is closely followed by loss of movement and function (Bijlsma et al., 2011), causing difficulty in performing everyday activities, resulting in functional dependence, and in turn reducing quality of life (QoL) (March and Bagga, 2004). It has been reported that 80% of those with OA have limitations in movement, with 25% unable to perform their major daily activities (WHO, 2018).

As OA generally develops progressively over a period of several years, symptoms may remain stable for long periods (Arden and Nevitt, 2006). Other symptoms include grating/grinding sensations (crepitus), stiffness, and swelling of the joints. The symptoms of OA often diminish patients' QoL and can be associated with depression and disturbed sleep (Bijlsma et al., 2011). The relationship between sleep and pain is considered to be cyclical, whereby disrupted sleep can exacerbate the effects of pain, which then may perpetuate sleep disturbances, triggering increased risks of depression (Smith et al., 2009). Around 1 in 5 people with OA experience symptoms of depression and anxiety (Stubbs et al., 2016), with depressive symptoms found to be greatest amongst those with sleep problems and higher-than-average pain (Parmelee et al., 2015).

The diagnosis of OA relies on clinical and radiological features (Altman, 1991). Individuals can present either symptomatically or radiographically; nearly half of patients with radiological features of OA have no symptoms and vice versa (Bijslsma et al., 2011). Radiographical OA is traditionally considered the reference standard, and with multiple methods to define radiographic disease. The Kellgren-Lawrence

(K/L) radiographic grading scheme is the most commonly used diagnostic tool (Zhang and Jordan, 2010). The classification focuses on a sequence of osteophyte formation, joint-space narrowing, and bone sclerosis.

When the pain and loss of function associated with OA impact upon an individual's daily life, a decision can be made to seek medical attention for treatment to help relieve the symptoms of OA and improve the ability to move.

1.3. Treatment for osteoarthritis

Currently, there is no cure for OA as the mechanisms by which it arises, and progresses are not fully understood (Michael et al., 2010). However, a number of treatments are available to help alleviate the symptoms (e.g. pain, loss of function). There are three treatment modalities, of which two (non-pharmacological and pharmacological) are non-surgical and the third is surgery. In many patients, these modalities are combined and tailored to individual needs and risk factors. Treatment depends on the intensity of the symptoms, range of motion (ROM) limitation, and the degree of disability (Zhang and Jordan, 2010).

1.3.1. Non-surgical

The use of non-surgical treatments is always indicated in the initial stages of the disease, where pain and stiffness are the predominant symptoms (Wesseling et al., 2009). Treatment focuses on reducing symptoms and on the maintenance and/or improvement of functional abilities. Prevention of the progression of the disease and the improvement of QoL are long-term goals (Bijlsma et al., 2011).

Generally, self-help measures, including weight loss or maintenance, and regular exercise, are enough to help people manage their symptoms (Arthritis Research UK, 2013). Adjunctively, pain and anti-inflammatory medications (e.g. analgesics agents, non-steroidal anti-inflammatory drugs (NSAIDS), corticosteroids, and hyaluronic acid) can be prescribed in the form of pills, syrups, creams or lotions, or are injected into the affected joint, to alleviate pain (Arthritis Foundation, 2014). Physiotherapy, including exercise and physical measures (e.g. muscle or nerve stimulation, ultrasound application, and acupuncture) can be employed to relieve pain, increase mobility, and delay the progression of OA (Michael et al., 2010). In particular, manual

therapy (i.e. manipulative mobilisation) can significantly reduce pain and improve function in patients (Pollard et al., 2008).

1.3.2. Surgical

In advanced stages of the disease, when patients are suffering from unbearable joint pain and disability, with a continuing decline in QoL and conservative treatments have failed, surgical treatments are considered (Millis et al., 1992; Brady et al., 2000). Joint replacement is considered a cost-effective method of treatment (Zhang et al., 2008), especially in patients with end-stage joint deterioration (Ethgen et al., 2004), to relieve pain, restore function, and improve health-related quality of life (HRQoL). The most commonly performed joint replacements are total knee replacement (TKR) and THR, which is the focus of this research.

1.4. Total hip replacement

1.4.1. Definition

Total hip replacements (also called total hip arthroplasties (THA)) were first introduced in the 1960s by Sir John Charnley and have since developed into one of the most successful treatments in modern medicine (Murray et al., 1995; Learmonth et al., 2007). The operation generally involves replacing the femoral head and acetabular components of the arthritic or diseased joint with a prosthesis (i.e. artificial joint). The prosthetic hip is usually constructed from metal, plastic (polyethene), or ceramic components, or a combination of materials. Cementless metal-on-polyethene prostheses are the most common type used for THR in England and Wales (National Joint Registry (NJR), 2017).

1.4.2. Prevalence

Total hip replacement is one of the most widely performed orthopaedic procedures, and although THR surgery can occur for a number of reasons, including inflammatory conditions (e.g. rheumatoid arthritis), problems with development during childhood, trauma or infection, most THR surgery (>90%) is performed due to OA (NJR, 2017), and is therefore usually planned in advance; this is termed ‘elective’ surgery.

Elective THRs are considered to be one of the most successful surgical procedures (Learmonth et al., 2007), with more than 87,000 operations performed in England, Wales, and Northern Ireland in 2016 (NJR, 2017), and success rates of over 90%

reported at 10 years (Allami et al., 2006). It is, therefore, expected that the number of THRs will continue to rise, with the number of procedures expected to double in the next 20 years (Kurtz et al., 2007; Learmonth et al., 2007). It has been predicted that, by the year 2030, the demand for primary THRs will have increased by 134% in England and Wales (Patel et al., 2015); that is, an estimate of 120,000 primary THRs a year. The principal reason for the increase is that several population groups, who would not have previously been considered (e.g. younger individuals, the very elderly, and those with multiple comorbidities), are now receiving THR. However, there are concerns about performing THR procedures on patients too early, as the longevity of the prosthesis is limited and outcomes after revision THR are generally worse compared to primary THR (Hofstede et al., 2016).

Whilst THR is a very successful surgical procedure, enabling patients to return to a high level of function (Harris and Sledge, 1990), it does come at a substantial cost. At an average cost of £6000, primary THRs cost the NHS approximately £64 million per annum (Clarke et al., 2015). In the USA, the cost of a primary THR is greater, at an estimated cost of over $12,000 (~£8500) (Orthopaedic Network News, 2014). The total hospital cost in America has nearly tripled during a 12-year period, with the mean hospital cost for THR increased by $7,858 (49.8%) between 2002 and 2013 (Molloy et al., 2017). However, this was attenuated by reducing inpatient length of stay (mean time) from 4.06 to 2.75 days; if the length of stay remained at the 2002 mean, the growth cost for THR would have been 67.4% instead of 49.8% that was observed (Molloy et al., 2017). In America, the price for an elective THR can also vary enormously with estimated costs of between $12,500 to $105,00 at top-ranked hospitals (Paddock, 2013). The associated annual hospital costs are estimated to cost $25.1 billion (Lavernia and Villa, 2015). Due to the increasing demand for THR, more attention is being paid to cost-effectiveness, and in particular to evaluating rapid recovery programmes, and to reducing patients' length of stay.

1.4.3. Surgical approaches

The type of surgical approach used in THR is considered to play an important role in hip stability and there are several surgical approaches utilised for THR, which are defined by their relation to the gluteus medius. The most commonly used approaches are direct anterior, direct lateral, anterolateral, or posterior (Petis et al., 2015).

The ***direct anterior*** approach was first described by Smith-Peterson in the 1940s, and later modified by Heuter in the 1950s (Light and Keggi, 1980). The anterior

approach uses a gap between the sartorius muscle and tensor fascia latae. Advocates of this approach consider its advantages to be the muscle-sparing nature of its internervous intervals, earlier restoration of gait kinematics, and low dislocation rates (Petis et al., 2015).

The ***direct lateral*** approach was first described by McFarland and Osborne in 1954, and was modified by Hardinge in 1982 (Hardinge, 1982). This approach requires elevation of the hip abductors (gluteus medius and gluteus minimus), providing adequate exposure of both the proximal femur and acetabulum (Hoppenfeld et al., 2009). This allows for the preservation of the tendinous insertion of the gluteus medius and minimus proximally and vastus lateralis distally (Hardinge, 1982). Low dislocation rates have also been reported when using this surgical approach (Masonis and Bourne, 2002; Kwon et al., 2006).

The ***anterolateral*** approach was first described by Watson-Jones in 1936 (Watson-Jones, 1936), and was later modified by Harris (1967), Müller (1970), and (Charnley, 1979). The anterolateral approach utilizes the intermuscular plane between the tensor fascia latae and the gluteus medius (Hoppenfeld and Buckley, 2012), which are supplied by the superior gluteal nerve (Palan et al., 2009). Patients who are at high risk for dislocation may benefit from anterolateral approaches since there is no posterior soft tissue damage.

The ***posterior*** approach was first described by von Langenbeck in 1874. The Langenbeck approach was then modified by Kocher in 1907. However, it was popularized by Moore in the 1950s as ‘The Southern Approach’ (Hoppenfeld et al., 2009; Petis et al., 2015), and is believed to be the most commonly used surgical approach internationally for THRs (Chechik et al., 2013). Access to the joint and capsule is through the back of the hip, detaching (and later reattaching) the piriformis muscle and the short external rotators from the femur. This provides adequate visualization of both the acetabulum and femur during the reconstructive procedures, whilst sparing the abductor muscles (Petis et al., 2015).

The ***posterolateral*** approach resulted from the combination of Langenbeck’s and Kocher's approaches (Hoppenfeld and De Boer, 1984). In 1950 Gibson modified the Langenbeck-Kocher approach by making a lateral decision, which was further modified by Marcy and Fletcher in 1954. This approach is widely used as it enables dislocation of the hip without the osteotomy (i.e. bone cutting) of the great trochanter

and gluteal musculature injuries; however, weakening the hips posterior structures may lead to higher dislocation rates (Afonso et al., 2008).

1.4.3.1. Surgical techniques

Recent advances in prosthesis materials and improvements in surgical techniques have improved hip stability and decreased the risk of dislocation (Berry et al., 2005; Garbuz et al., 2012). There are several factors, including surgical experience and variations in surgical approach, which are considered the most controversial factors that influence hip stability (D'Angelo et al., 2008). Early dislocation often occurs in the same direction of surgical approach (e.g. anterolateral approach renders the hip most susceptible to anterior dislocation) as the soft tissues, which are divided during surgery to provide access to the hip, have not healed (Talbot et al., 2002). The posterolateral approach has one of the highest incidences of hip dislocation, with the prevalence two times greater than that of the anterolateral approach (Sariali et al., 2008). There is also an increase in the dislocation rates in surgeons who perform less than ten THRs a year (Meek et al., 2006), which can be up to three times greater than those who regularly perform THRs (Hedlundh et al., 1996).

Implant designs (e.g. femoral head size, femoral offset, head-to-neck ratio, and socket depth) also play an important role in hip stability, with an inadequate femoral offset and length proven to be a cause of instability, thus increasing the risk of dislocation (Callaghan et al., 2001). A larger femoral head has been associated with a lower risk of dislocation (Sariali et al., 2008; Bistolfi et al., 2011), and is effective in all operative approaches, with the greatest effect found in the posterolateral approach (Berry et al., 2005). Despite variations in techniques and implant selection, studies have demonstrated over 90% implant survival at 15 to 20 years (Burnett, 2010).

1.4.4. Complications of surgery

As with all procedures, THR can be complicated by adverse events leading to prolonged hospitalization, rehabilitation, and reoperation (Talbot et al., 2002), resulting in inferior outcomes and increased costs (de Vries et al., 2011). There are a number of risk factors, such as age, gender, and patient-related factors or comorbidities (e.g. obesity, cardiovascular disease, and diabetes) which are associated with complications following surgery (Lubbeke et al., 2009; Schairer et al., 2013). Common early complications include: mortality, significant blood loss, postoperative infection, deep vein thrombosis, instability, and dislocation of the

prosthesis (de Vries et al., 2011). The most common complication following THR is aseptic loosening, and the second most common is hip dislocation which is the basis of this research.

1.4.4.1. Hip dislocation

Hip dislocation is a major, multifactorial complication which can be defined as the complete loss of articulation contact between two artificial joint components (Dargel et al., 2014). Hip dislocation can be physically and mentally disabling to the patient (Woo and Morrey, 1982; Dorr and Wan, 1998; Bourne and Mehin, 2004), with reported incidence rates from <1% to >15% (Restrepo et al., 2011). In international literature and registries, data on the annual rate of THR dislocations can vary between 0.2% and 10% (Berry et al., 2005; Parvizi et al., 2008). Current dislocation rates are much lower than previously documented which could be due to modern implant technologies and biomechanical designs (Meek et al., 2006).

Hip dislocation is a major reason for revision surgery following THR (Bozic et al., 2009), with approximately 17% of revision surgery performed for dislocation (NJR, 2017). Revision surgery is expensive (Vanhegan et al., 2012; Singh and Lewallen, 2013) and is not as successful as primary THR, with reported dislocation rates of up to 28% following revision and implant exchange surgeries (Berend et al., 2010; Wetters et al., 2013). Hip dislocation can be single or recurrent (Meek et al., 2006), with the risk of recurrence after a single episode of approximately 33% (Huten and Langlais, 2012). Most dislocations (60 to 70%) occur within the first six weeks after surgery, with the risk of dislocation decreasing hereafter (Brooks, 2013).

The aetiology of hip dislocation is often due to a number of factors, including patient factors (e.g. gender, weak hip musculature, age), surgical factors (e.g. surgical approach, positioning of implant, previous hip surgery, surgeon experience), and implant factors (e.g. femoral neck length, offset, head diameter) (Blom et al., 2008). Surgical experience and variations in surgical approach are considered the most controversial factors that influence the risk of dislocation (D'Angelo et al., 2008). Anterior and lateral approaches are considered to have lower dislocation rates than the posterior approach. A large meta-analysis (>13,000 THR, with follow-up period of at least 12 months) evaluated surgical approaches and dislocation and calculated a dislocation rate of 3.23% for a posterior approach (2.03% when the posterior capsule is repaired), 0.55% for a lateral approach, and 2.18% for an anterolateral approach (Masonis and Bourne, 2002). The low dislocation rate has been attributed to verifying

both acetabular and femoral component positioning via fluoroscopy and preserving static stabilizers, such as the posterior joint capsule (Siguier et al., 2004; Matta et al., 2005). Careful reconstruction of the capsule and short external rotators may decrease the risk of postoperative dislocation for posterior approaches (Kwon et al., 2006; Hoppenfeld et al., 2009; Pellicci et al., 2009). A more recent study concluded that there were no differences in dislocation rates for either anterior (0.84%) and posterior (0.79%) approaches, and that neither has a compelling advantage at reducing the dislocation rate over the other (Maratt et al., 2016).

Activities associated with hip dislocation

Over half the dislocations that occur following THR surgery are believed to be due to undesirable movements (e.g. falling, unexpected twisting), which cannot be avoided even with movement restrictions and using assistive aids (Gromov et al., 2015). However, activities including getting into or out of bed, twisting or turning in bed, getting up from the toilet or a chair, and putting on shoes have also been frequently identified as causes of dislocation (Restrepo et al., 2011; Smith et al., 2012). Excessive bending over, e.g. to put shoes on or pick an item up from the floor, is often considered an 'avoidable' movement which can lead to patients dislocating their hip (Gromov et al., 2015).

A study that retrospectively reviewed 100 patients (Smith et al., 2012) found the most commonly reported activities resulting in hip dislocation were those that involved some degree of flexion, adduction and femoral rotation, such as bed or chair transfers and putting on shoes, socks or stockings. The authors recommended the long-term routine restriction of hip ranges of movement, specifically counselling patients to avoid picking objects up from the floor, to be vigilant when getting in or out of bed, and when getting off the toilet. However, as this study was based on self-report of patients who had dislocated and used unclear terms (e.g. bed transfer could mean moving in bed, moving on or out of bed), these results need to be viewed with caution. Furthermore, this was a highly selected sample of patients who had dislocated, and no contextual data was presented on overall numbers of procedures completed, differences in surgical technique, or other important factors (e.g. radiological positioning on prosthetic components).

1.4.5. Recovery following total hip replacement surgery

1.4.5.1. Rehabilitation

Following THR there is a convalescent period during which the loss of muscle strength and function is considerable, especially during the initial stages (Bandholm and Kehlet, 2012). Significant muscle atrophy and weakness of the quadriceps, hip flexors, and extensor muscles have been reported post-surgery (Bertocci et al., 2004; Readon et al., 2001; Holm et al., 2013). To help patients recover more quickly from major surgery, many hospitals have rapid recovery programmes (RRPs), which aim to improve patient education and expectations, and encourage early mobilisation and rehabilitation.

Rapid recovery programmes are usually standardised programmes with clear clinical pathways, which include education classes, or 'joint school'. Common complaints of patients who elect to have THR are pain and loss of mobility (Felsen et al., 2000; Trudelle-Jackson and Smith, 2004). Preoperative pain and function are important predictors of physical disability postoperatively (Fortin et al., 1999; Holtzman et al., 2002). Thus, RRPs are designed to enhance physical function, ROM, and muscle strength, which allow earlier return to ambulatory function following surgery (Wang et al., 2002; Gilbey et al., 2003).

Prolonged recovery after THR can adversely affect short-term outcomes (Kagan and Bar-Tal, 2008). Therefore, it is desirable to implement rehabilitation programmes immediately following surgery. Early rehabilitation programmes decrease postoperative pain, and improve function and self-efficacy (Munin et al., 1998; Dohnke et al., 2005). However, postoperative pain needs to be carefully managed as pain may increase with rehabilitation, thus limiting patient participation (Ranawat and Ranawat, 2007). If postoperative pain is well-controlled, it can improve patients' compliance in immediate postoperative rehabilitation, which subsequently improves pain control and hastens functional recovery (Sharma et al., 2009). As RRPs encourage early mobilisation, weight bearing and transfers, patients have better outcomes with respect to postoperative mental health, performing activities of daily living (ADLs), and QoL, can walk independently and for longer distances at discharge (Pour et al., 2007). Rapid recovery programmes can also lead to shorter hospital stay. There has been a reduction in mean length of stay over the last decade from three weeks (Epstein et al., 1987) to four days (Husted et al., 2008), and in a select group of patients, discharge can occur at two days post-surgery (Gulotta et al., 2011).

Following discharge, routine physiotherapy is not offered unless patients are considered to be in clinical need of additional support (Artz et al., 2013), as patients can still achieve excellent short-term recovery without it (Hunt et al., 2009). Patients are often satisfied with their immediate postoperative pain relief compared with their severe limitations prior to THR, and most patients report an improvement in the HRQoL during their first year after surgery (Jones et al., 2001; Nilsdotter and Isaksson, 2010; Rat et al., 2010). Pain reduction and mobility restoration are evident three to six months after THR, although during the initial postoperative phase patients are considerably limited in their normal function and mobility (Sicard-Rosenbaum et al., 2002; Judd et al., 2014). Postoperative protocols designed to prevent dislocation following THR surgery may play a role in this.

1.4.5.2. Hip precautions

In addition to the number of surgical strategies used to decrease the risk of dislocation post THR, such as prosthesis design and selection, choice of surgical approach, and technical intraoperative factors (Khatod et al., 2006), other key postoperative strategies include behavioural and biomechanical restrictions known as 'hip precautions'.

Definition

Hip precautions (sometimes referred to as movement restrictions) is the name given to a number of recommendations given to patients following THR, and specifically involve advising patients to avoid specific movements, including hip flexion, rotation, and adduction. Hip precautions thus limit movements that place the hip in positions of risk (i.e. dislocation) following surgery, to allow the capsular and other tissue elements around the replaced hip joint to heal (Barnsley et al., 2015).

Provision

In most cases, information and advice on hip movements are provided both preoperatively and postoperatively (McMurray et al., 2000). Patients are instructed to avoid three key movements and are advised not to: 1) flex beyond 90°, 2) adduct beyond the midline, and 3) medially or laterally rotate the hip. In addition, specific activities instructed to be avoided include driving a car, and side-sleeping (on the operated and/or non-operated side). These restrictions can impact upon daily activities such as getting dressed, using the toilet, getting in and out of a car, and sleeping; thus, occupational therapists and physiotherapists advise patients on how

to carry out everyday activities as safely and independently as possible, within the prescribed movement restrictions (Moores, 2009). Alongside promoting 'safe' movement patterns for positioning the hip, therapists routinely provide equipment (i.e. assistive aids) to prevent patients from over-flexing and twisting at their hip (Orpen and Harris, 2010), such as bed or chair raisers, and raised toilet seats. Most UK hospitals provide patients with adaptive equipment and assistive aids prior to hospital admission; this is most commonly prescribed by occupational therapists (McMurray et al., 2000; Drummond et al., 2012; Smith and Sackley, 2016). The recommended length of time for observing precautions varies from a minimum of six weeks to over 12 weeks (Drummond et al., 2012).

Variations in practice

Hip precaution protocols have commonly been implemented in UK hospitals, however, there remains variation in practice nationally and locally. This inconsistency has been highlighted not only by occupational therapists (Drummond et al., 2012) but also by physiotherapists (Smith and Sackley, 2016). The duration for which patients are currently advised to follow precautions varies nationally. More than half of hospitals recommend patients to follow precautions for the first six weeks post THR. Others recommend patients to follow them for up to three months, whilst some instruct patients to follow them for the initial 12 months after surgery, with a small number report instructing patients to continue with these precautions indefinitely (Smith and Sackley, 2016). The most commonly provided reason for following hip precautions is surgical protocol, including surgical opinion (Drummond et al., 2012; Smith and Sackley, 2016). Other reasons included occupational therapy policy and therapy protocol, clinical assessment of the patient, and team decision (Drummond et al., 2012; Smith and Sackley, 2016). However, less than a quarter of occupational therapists believe that the prescription of hip precautions is evidence-based (Drummond et al., 2012).

One of the widest variations in rehabilitation practice in the UK is the provision of, and charges for, adaptive equipment post THR (McMurray et al., 2000). The majority of hospitals recommend patients use the equipment for between six weeks and three months (Drummond et al., 2012; Smith and Sackley, 2016), whilst a small number recommend using the equipment for up to 12 months post-surgery (Smith and Sackley, 2016). Three-quarters of hospitals routinely provide all their patients with equipment following primary THR, however, there are inconsistencies in the routine provision of equipment for younger, very 'fit' patients and patients with a cognitive

impairment (Smith and Sackley, 2016). The most commonly provided equipment includes raised toilet seats, toilet frames and rails, chair raisers, perching stools and bed raisers (Drummond et al., 2012; Smith and Sackley, 2016). Despite some hospitals providing smaller aids, such as long-handled reachers, long-handled washing and dressing aids, others recommend that patients purchase these items themselves. As adaptive equipment is provided alongside hip precautions, reasons for prescribing equipment are similar to those given for prescribing hip precautions.

Hip precautions are widespread, with national guidelines differing not just within the UK but also in other countries across the world. Similar to UK national guidelines, Dutch guidelines on total hip prostheses do not provide any advice on the type or duration of patient restrictions (hip precautions) following THR (Swierstra et al., 2011). In a recent survey on national practice in the Netherlands (Peters et al., 2017), the majority of the orthopaedic departments reported using some type of restrictions after THR for six weeks, with fewer restrictions used for the anterior approach compared to other surgical approaches (e.g. anterolateral and posterolateral). The type of restrictions applied have previously been categorised into *the use of movement restrictions (e.g. no flexion beyond 90 degrees), the use of assistive devices (e.g. toilet seat, abduction pillow), and the use of daily life functional restrictions (e.g. sleep position, driving)* (Peters et al., 2017). The use of assistive devices also varied with the surgical approach, with lower use for the anterior approach. Hospitals surveyed also advised patients to use adaptive equipment at home following discharge, however, the time period advised was not reported (Peters et al., 2017). It has been suggested that although the results of the survey are only applicable to Dutch settings, they may correspond with the rest of Western Europe, as the Dutch guideline THA (THR) is internationally accepted and peer-reviewed (Swierstra et al., 2011).

In the USA, almost all hospitals reported using hip precautions as part of their patients' postoperative management after discharge (Youm et al., 2005). Patients are routinely advised to use a high toilet seat, a reacher, an abduction pillow, a high chair and to restrict hip flexion in ADLs. The average prescribed duration of use of each of these was five weeks for an abduction or regular pillow, eight weeks for a high chair, nine weeks for a reacher, and nine weeks for high toilet seats, and restricted hip flexion in ADLs was maintained for 12 weeks. The median duration of use for all listed precautions/devices was six weeks, with the exception of restricted hip flexion in ADLs (eight weeks) (Youm et al., 2005).

Despite patients being routinely prescribed hip precautions, a standardised, common postoperative protocol to optimise functional recovery following THR does not exist (Youm et al. 2005). The practice of hip precautions is guided by local policies and protocols and can vary greatly between hospitals (College of Occupational Therapists (COT), 2012). The variations in the practice across the UK has led therapists to question the evidence supporting the use of precautions (McQuaid et al., 2014). Thus, there is a need to evaluate the effectiveness of hip precautions following THR.

A review of the current literature was conducted to explore the effect that removing hip precautions has on dislocation rates and patient outcomes following THR.

1.5. Review of current literature

Although hip precautions are provided nationally in the UK (Drummond et al, 2012; Smith and Sackley, 2016), America and Europe, there is little evidence for their effectiveness in preventing dislocation or indeed other complications post THR. The findings from research to data are unclear and there are opposing opinions about using precautions (Coole et al, 2013). Advancements in surgical techniques (including approaches) and prosthesis design have reduced soft tissue damage and increased the stability of the hip, thereby increasing the speed of recovery and minimizing the risk of dislocation; this has questioned the need and rationale for hip precautions.

1.5.1. Removal of hip precautions in anterior/anterolateral surgical approach

A Cochrane review (Smith et al., 2016), two systematic reviews (Barnsley et al., 2015; Sharma et al., 2009), a literature review (Tejwani and Immerman, 2008), and four studies (Talbot et al., 2002; Restrepo et al., 2011; Peak et al., 2005; Ververeli et al., 2009) have all concluded that hip precautions are not needed when an anterior or anterolateral surgical approach is used.

In the Cochrane review by Smith et al. (2016), it was concluded that there is no difference in complications, such as hip dislocation, between patients who are provided with “functional limitations” (i.e. hip precautions) and postoperative equipment, and those who are not. However, the evidence supporting whether the provision of hip precautions and equipment are effective in preventing dislocation and improving functional outcomes following THR was considered ‘low-quality’ by the authors; this was attributed to the limitations in the study design and inconsistencies

in the results. The authors suggested that the studies were underpowered, poorly reported, and possessed a high risk of bias. They concluded that there is insufficient evidence to support the provision of equipment and hip precautions in the initial six weeks post THR, to reduce dislocation rates and associated adverse events.

Barnsley et al. (2015) in their systematic review drew similar conclusions and found no evidence to support the use of hip precautions in reducing rates of dislocations. Hip precautions were also found to be associated with a slower return to ADLs, significant expense, and decreased patient satisfaction. Sharma et al. (2009) supported the justification of the removal of postoperative hip precautions for THR following an anterolateral approach, deeming them unnecessary. Tejwani and Immerman's (2008) review into the routine use of hip precautions, failed to find high-quality evidence supporting hip precautions to decrease the rate of dislocation.

Talbot et al. (2002) followed up a prospective cohort of 499 patients who had been operated on using an anterolateral approach and who were not taught precautions postoperatively. Patients were encouraged to move in any way they found comfortable and to adopt any position they chose for sleeping and sitting. Only three dislocations were reported (rate of 0.6%) within six weeks of surgery. The authors concluded that a low early dislocation rate can be achieved using an anterolateral approach without the need of precautions. However, there was no control group and, moreover, the authors did not determine whether staff had adhered to the no precautions programme in practice.

These concerns also apply to research by Restrepo et al (2011). In a prospective cohort study of 2386 patients, who were followed up for six months after hip precautions were withdrawn from service, only four dislocations were reported (rate of 0.15%). The authors concluded that that the removal of hip precautions does not increase the incidence of early dislocation using an anterolateral approach. However, again there was no comparison control group and no attempts were made to check the fidelity of treatment; it is therefore not clear whether staff did actually adhere to giving no precautions advice to patients. None of these studies collected data on the patient perspectives of the regimes.

Peak et al (2005) conducted a prospective randomised controlled trial (RCT) comparing 265 patients randomised preoperatively into either a 'restricted' or 'unrestricted' precautions groups. The designation of patients was double-blinded

until the completion of wound closure. Both groups were limited to certain movements (e.g. less than (<) 90° flexion, <45° external/internal rotation, and avoid adduction) in the first six weeks after surgery but, thereafter, while the restricted group had to adhere to a number of precautions (including not to sleep on their side, not drive, use raised toilet seats), the unrestricted group did not. In addition, the restricted group used an abduction pillow in bed, and were provided with elevated toilet seats and elevated chairs to use in hospital and at home. The unrestricted group could choose to use equipment if they wished for comfort. Interestingly people in both groups followed restrictions even after the six week mandatory period. Only one dislocation was reported (in the restricted group). The study was not sufficiently powered to reach the conclusion that precautions could be removed. Overall the unrestricted group had higher levels of satisfaction as they achieved a quicker return to daily activities. They also had lower equipment costs than the restricted group. There are some methodological issues regarding the overlap of the intervention and control groups as the study did not strictly compare precautions to no precautions and so results cannot be fully generalised, and thus concerns about the applicability of the findings remain.

A smaller, open-label (unblinded) RCT (Ververeli et al., 2009) involving 81 patients examined outcomes of a group receiving hip precautions and an early rehabilitation group (relaxed precautions with the only restriction of not crossing their legs at the thighs). However, the early rehabilitation group were permitted to use a regular toilet, sit on a standard chair and sleep in any comfortable position without a pillow between their legs. The early rehabilitation group were faster to ambulate both with and without a walking stick and walk without a limp earlier. The authors concluded that the early rehabilitation protocol increased the rate of recovery compared to a protocol with hip precautions and did not increase postoperative complications. They suggested that hip precautions limit patients from activities that they are capable of doing, and that removal of restrictions allows a faster return to ADLs. The study had no incidents of dislocation; thus, the authors were unable to conclude if precautions are a necessary preventative measure. Yet, a limitation of the study was the small sample size (81 patients) which may not have been powered to detect any differences between the groups in terms of dislocation and raises questions about the generalisability of the results.

1.5.2. Removal of hip precautions in posterior/posterolateral surgical approach

Gromov et al. (2015) investigated the rate of early dislocation following primary THR, using a posterolateral approach, in an unselected retrospective cohort of 2275 patients at a single institution. Patients were identified from the Danish National Health Registry over a period of ten years and were classified into two consecutive cohorts: patients who received a primary THR from 2004 to 2008 (n = 946), and from 2010 through 2014 (n = 1329). The first group (2004-2008 patients) were mobilised with restrictions following primary THR, and the second group (2010-2014 patients) were mobilised without restrictions. Patients who were mobilised without restrictions had a comparably low dislocation rate of around 3% (within 90 days postoperatively), to those within the restricted group. However, the unrestricted group had a lower risk of dislocation within 30 days, of multiple dislocations, and of revision surgery due to dislocation. Results showed around 1 in 7 of all dislocations in both groups were classified as 'avoidable' and occurred due to excessive bending over (e.g. to tie shoelaces or to reach the floor), crossing of legs, and using the toilet without a raised seat. However, the study only examined the prevalence of dislocations from the joint registry, and no patient-reported outcomes (e.g. pain, function, and QoL) were collected. A period of two years separated the two cohorts, and it is unclear, to the reader, what occurred during this time period. Furthermore, there was no documentation regarding a washout period between the two cohorts, which is a recognised method of reducing potential contamination. Although the same posterolateral approach was used throughout the study period, subtle changes to the surgical technique may have occurred during the study period which could have potentially affect the dislocation rate.

Mikkelsen et al. (2014) conducted a non-RCT evaluating the influence of movement restrictions and assistive devices on rehabilitation outcomes after THR using the posterior approach. Patients (n = 365) were compared before ('restricted') and after ('unrestricted') a change in rehabilitation regime over a period of six months at a hospital in Denmark. During the change of procedures, a pre-defined intermediate period of 20 patients were excluded from the study (period of five days). Patients in the restricted group underwent 'traditional' rehabilitation, including movement restrictions and provision of assistive devices for six weeks. The unrestricted group had no movement restrictions but were instructed to avoid the combination of full hip flexion, internal rotation and adduction. The study reported that the restricted group had the fastest functional improvement, but this difference was eliminated at six weeks postoperatively. However, three weeks postoperatively, the unrestricted group

was capable of performing the four different ADL functions (stair climbing, getting dressed, bath/shower, and house cleaning) independently. The authors concluded that there were no beneficial, nor harmful, effects of rehabilitation with no movement restrictions. Patient-reported outcomes such as function, pain, and QoL were not affected. However, there was a relatively short follow-up of only six weeks, which neglected to evaluate the effects long-term.

A prospective, comparative safety study (Kornuijt et al., 2016) monitored a group of unselected patients managed with standard precautions (n = 109) and a group who were managed with fewer precautions (n = 108). Minimal precautions (avoid combining full flexion, internal rotation and adduction of the hip, and not to sit cross-legged) were provided from a safety perspective, but the authors were unsure whether minimal precautions were effective based on patient feedback. The minimal precautions applied in this study are similar to advice prescribed to unrestricted groups in other studies. There were no differences in the number of dislocations between the two groups, supporting the use of minimal precautions in patients after THR. Thus, the authors concluded that it 'appears' safe to manage patients in the immediate postoperative period with minimal precautions to protect against dislocation using a posterolateral approach. The small sample size of the study was acknowledged as a limitation, but the authors defend this by stating that the study was designed in this way to avoid placing large numbers of patients at risk of dislocation. In addition, the study did not assess compliance of the protocol and so it is unknown whether patients followed all the precautions prescribed. A strength of the study is a six week washout period which was applied after changing the protocol (standard precautions to minimal precautions) to ensure that the patient education and staff adherence to the new protocol were fully established.

1.5.3. Removal of hip precautions in mixed surgical approaches

A systematic review and meta-analysis by van der Weegen et al. (2016) aimed to evaluate whether lifestyle restrictions and precautions effectively prevented hip dislocation after THR surgery, using a variety of surgical approaches, including standard posterior and anterolateral approaches. The review determined that a more liberal lifestyle restrictions and precautions protocol led to earlier and better resumption of activities and higher patient satisfaction and suggested that postoperative precautions imposed intrusive limitations and sometimes discomfort for the patient in the initial postoperative period. The authors advocated that a less restrictive protocol, or a protocol without any restrictions or precautions after THR,

would not lead to increased dislocation rates. Potential reasons for lower dislocation rates in the unrestricted group were not identified but it was suggested that as the unrestricted group resume activities faster this could have resulted in earlier recovery of soft tissue around the joint which provided additional stability. The review made bold claims in stating that the results appear to 'hold up' for various surgical approaches, however, there were issues regarding methodology as three of the studies included had changed the surgical approach used during the study. In addition, half of the studies managed their patients with a less restrictive protocol rather than an unrestricted protocol (no precautions), which included precautions preventing hip flexion beyond 90°, and sitting crossed-legged.

1.5.4. Impact of hip precautions on daily life

Hip precautions can represent a major lifestyle modification for many patients and can hinder a number of functional activities. The prohibition of hip flexion greater than 90°, external rotation, and adduction of the hip can have a significant impact on the manner in which a person is able to complete everyday tasks, such as dressing, bathing, and chair and toilet transfers (Neville-Smith et al., 2000). However, there is also some suggestion that hip precautions may impede full functional recovery and result in a slower return to activities, such as mobility, shopping, and driving (Ververeli et al., 2009). Withdrawing hip precautions has been associated with a quicker and better return to daily functions, and has been reported to increase patient satisfaction, along with reducing hospital stay, and lower costs (Duwelius et al., 2007).

A cohort study of 64 consecutive patients assessed the impact of sleep deprivation on patients' recovery and QoL following THR (O'Grady et al., 2002). The authors concluded that sleep deprivation due to supine sleeping precautions led to increased anxiety and an increase in night sedation and analgesia. A study investigating compliance and effects of supine sleeping on sleep quality after primary THR, followed up 55 patients at 12 weeks post-surgery (Modi et al., 2012). Over two-thirds of patients report significant difficulties in maintaining a supine position for the full restricted period following THR, with many finding the position uncomfortable, thus preventing them from sleeping. Modi et al. (2012) suggest that limiting or disregarding this restriction may reduce the discomfort and poor sleep quality experienced by many patients after THR, which could lead to a more positive experience and greater satisfaction.

An interview study of 56 hip replacement patients found that almost a quarter of the sample did not engage in leisure activities one year after surgery, despite a vast majority of leisure activities rated as very important preoperatively (Wylde et al., 2012). Although participation in the majority of leisure activities was unproblematic after surgery, approximately a quarter of these were difficult to perform, with sporting activities causing the most difficulty. The participants in this study were considered to be very physically active, and so might not be representative of the general population. The study highlights that not all patients will be able to return to their preoperative leisure activities due to participation restrictions, which may lead to dissatisfaction with the outcome of surgery and contribute to depression. Although these studies are small, they contribute to the view that hip precautions adversely affect patient QoL and this has had relatively little attention. Currently, there are no studies of patients' opinions regarding precautions.

Generally, 'non-restriction' or 'no precautions' protocols tend to be related to the use of movement restrictions and assistive devices (Mikkelsen et al., 2014). Very few studies discuss whether functional restrictions (e.g. sleeping) are discontinued, whilst these probably have the highest impact on patients' daily lives. Peak et al. (2005) showed that over two-thirds of THR patients who were restricted to sleeping in a supine position reported it to be highly uncomfortable and suggested that this restriction can safely be abandoned.

1.5.5. Clinical perceptions of hip precautions

A qualitative study conducted by Coole et al. (2013) explored clinicians' perspectives and experiences of hip precautions, their use of precautions, and views of the evidence base. Sixteen semi-structured telephone interviews were conducted with occupational therapists, physiotherapists, surgeons, and nurses from six NHS hospitals. Clinicians' views regarding hip precautions varied due to differences in surgical opinion (e.g. surgical technique) and lack of evidence as to whether hip precautions affect the risk of dislocation. Barriers to moving away from routine hip precaution recommendations included perceived risk of dislocation and impairment of tissue healing, fear of litigation, tradition, and lack of evidence that precautions should not be used. Relaxing the routine provisions of precautions was perceived as having a potential impact on patient recovery and satisfaction, the role and skill of mixed therapy services, length of hospital stay, and resource use. Despite variations in clinicians' perceptions of hip precautions, there was a shared view that current practice lacks a robust evidence base. The authors supported the need for a definitive

trial to evaluate hip precautions and their effect on patient and surgical outcomes. Whilst the study considered staff attitudes towards potentially removing precautions from practice, the study did not explore staff perceptions following their removal.

A recent survey of therapists' (occupational therapists and physiotherapists) experiences and attitudes towards hip replacement precautions and equipment found a vast majority (97%) of UK hospitals still routinely provide hip precautions to patients following THR (Smith and Sackley, 2016). Despite this, a quarter of therapists felt that the prescription of hip precautions should not be routine practice. Although equipment was routinely provided in 87% of hospitals, only 54% of staff felt that it should be. The survey results provide evidence that the practice is widespread, particularly in occupational therapy, although uncertainty exists nationwide about hip precautions amongst therapists. Almost 90% of therapists advocated the need for research to be conducted on the provision of hip precautions, and two-thirds recommended further research on the provision of equipment following THR (Smith and Sackley, 2016). The authors propose that further research is warranted to determine whether and to whom hip precautions and equipment should be prescribed post THR as opposed to the current 'blanket' provision of equipment and movement restriction provided in UK practice.

1.5.6. Cost of hip precautions

The provision of equipment and hip precautions are associated with a substantial economic and environmental burden (Restrepo et al., 2011). Removing equipment and devices has been associated with a cost-saving of US $655 per patient, including the cost of raised toilet seat ($65), and an elevated chair ($15/day to rent); this does not account for transport costs, or loss of wages whilst not working (Peak et al., 2005). Fox et al. (2011) reported a mean cost reduction for equipment provision of £12 per patient in a local hospital; if the figures were extrapolated to patients across the UK, the use of no hip precautions could translate to a cost-saving of 3,400 beds days, and £165,000 worth of equipment per year. Although these results only apply to hemiarthroplasty for hip fractures, i.e. for non-elective surgery, they illustrate the potential cost savings of a no hip precautions regime following THR.

1.5.7. Concerns about hip precautions

Adduction, flexion, and rotation of the hip joint are associated with dislocation, lending theoretical credence to support the use of hip precautions (Nadzadi et al., 2003; Tejwani and Immerman, 2008). However, there is increasing concern at the lack of robust evidence to support the use of hip precautions which have not changed in the last few decades in line with developments in surgical technique and prosthesis development (Duwelius et al., 2007; Handoll and Sherrington, 2007; Tejwani and Immerman, 2008). There is also concern that hip precautions can lead to discontent for patients, as it may slow down their return to daily activities (Restrepo et al., 2011), and moreover undermine their recovery. It may be that surgical improvements and controlling for important surgical factors (e.g. technique of the procedure and implant designs), may alleviate the need for such restrictions postoperatively (Restrepo et al., 2011).

There are four key concerns about the provision of hip precautions:

1) **Lack of evidence:** There are concerns about the lack of robust evidence to support the use of precautions in preventing the risk of dislocation, and uncertainty whether the provision of precautions and equipment is beneficial to functional recovery and social reintegration of patients following THR (Smith et al., 2016).

2) **Lack of consistency:** There is a lack of consistency in the provision and variation in the duration to which patients are advised to follow precautions and use the provided equipment post THR. The length of time patients are advised to follow precautions can range from six weeks to three months, with some hospitals recommending more long-term (e.g. first 12 months) (Smith and Sackley, 2016).

3) **Costs:** There are increasing concerns about the cost of therapists' time to teach precautions and the cost of providing equipment in routine practice (Drummond et al., 2012). Moreover, precautions and equipment may be associated with a substantial economic burden in the provision, returning and cleaning of equipment such as raised toilet seats or furniture raisers (NHS, 2017).

4) **Time:** Providing advice and equipment requires staff, particularly therapists and nurses, to spend a large amount of time treating patients pre and post THR surgery (Drummond et al., 2012). Although this differs among clinicians and hospitals (McQueen et al., 2009), there is on average a reported average of two

hours face-to-face contact time per patient (McMurray et al., 2000; Drummond et al., 2012).

1.5.8. Literature review summary

The review of the literature suggests that, although routinely provided, current evidence does not support the effectiveness of hip precautions in preventing dislocation or indeed other complications post hip replacement. The majority of the studies conclude that a less restrictive protocol, or a protocol without any hip precautions, in the postoperative phase after THR does not lead to an increase in dislocation. Although the number of studies is small, the removal of hip precautions has been associated with quicker and better return to ADLs, earlier return to work, shorter length of stay, lower costs, and higher patient satisfaction.

Overall, current research is equivocal, and there are conflicting opinions about whether precautions are effective or detrimental to recovery (Coole et al., 2013). There are three main difficulties in evaluating the key literature:

1) **Lack of robust methodology** – studies not including an acceptable control or comparison group, changing surgical approaches during the study period, no fidelity checks, and not completely withdrawing hip precautions from the unrestricted group.

2) **Underpowered studies** (with the rate of dislocation as the primary outcome measure) – studies with small sample sizes would not be able to detect a statistically significant difference in the rate of dislocation. Results that show a lack of significant differences between groups, with regard to the rate of dislocation, could be the result of a statistical error (the difference between the measured value and true value). As the incidence of dislocation is low nationally, because of surgical advances, the numbers of patients needed to demonstrate any difference would be difficult to recruit and length of follow-up prolonged.

3) **A focus on dislocation** - other outcome data such as patient satisfaction, independence, and QoL are often ignored, thus little is known about the impact of precautions on patients' day-to-day life. Patient-reported outcomes, including the perceived burden in terms of psychological distress (e.g. anxiety) and functional limitations of hip precautions during the rehabilitation process,

are considered equally important outcomes measures as dislocation (Peters et al., 2015).

1.6. Justification for the present study

Hip precautions are routinely prescribed to patients following THR surgery to reduce the risk of dislocation. Although, the risk of dislocation has decreased in recent years with improvements in surgical techniques and developments in prosthesis design, hip precautions are still routinely advised.

Practice guidelines for adults undergoing THR (Royal College of Occupational Therapists (RCOT), 2017) have also concluded that the evidence supporting the use of hip precautions is inconclusive and that variations in the practice of hip precautions exist. The RCOT report that practitioners providing precautions have identified a need for more high-quality research on the impact of relaxing or removing precautions on dislocations and rehabilitation outcomes.

Despite current evidence suggesting that hip precautions provide no additional benefit and may impede patients' recovery, the majority of Trusts in the UK are still routinely providing hip precautions to patients (Drummond et al., 2012; Smith and Sackley, 2016). This is possibly due to perceived flaws in the evidence base and variations in clinical opinions, which may impact on the confidence to change established practice. Whilst clinical perceptions and experiences of the use of hip precautions have previously been reported and their views on withdrawing precautions hypothesised by Coole et al. (2013), no study to date has explored clinical perspectives following the discontinuation of precautions in routine practice. In addition, no study has explored patient perceptions and experiences of hip precautions. The uncertainty about the effectiveness of hip precautions, and mixed clinical opinions provided an opportunity to develop a research study to address this.

1.7. Overarching research aim

1.7.1. Aim and objectives

The aim was to assess the effectiveness of hip precautions following THR by comparing outcomes in patients who had an elective THR and received hip precautions with those who did not, in a pragmatic, comparison study.

There were four specific objectives:

1) To pragmatically compare outcomes (pain and function) in patients who were prescribed hip precautions with those who were not at three months postoperatively.

2) To evaluate the effects of both hip precautions and no hip precautions on patients' quality of life, functional performance, pain, sleep, mood, satisfaction, and dislocation rates following THR.

3) To explore patients' perceptions and experiences of their recovery and the service they received following THR (in both regimes) to ascertain the impact hip precautions may have on their recovery following THR surgery.

4) To explore staff perceptions and experiences on the service provided to patients (in both regimes) to identify the facilitators and barriers to the change in the regime, and their attitudes towards changing the regime of hip precautions.

The research objectives were addressed in two related but discrete studies. The principal study was the before and after study that was conducted to evaluate the use of hip precautions, and no precautions, on patient outcomes. The second study was a qualitative study designed to ascertain staff and patients' views about the service provided during the before and after study (provision of hip precautions and no hip precautions). Information gained from this study will provide an additional perspective on the before and after study and identify any potential barriers or facilitators to changing the service provided to patients following THR.

1.7.2. Philosophical perspective

It is important to understand the philosophical assumptions that underpin this research, as they have informed the study design, data analysis, and interpretation of results. This section discusses the philosophical perspective that informed the research process, beginning with an explanation of ontology and epistemology, followed by details of the perspectives adopted for this research.

Ontology is the science or theory of being; it relates to the nature of reality, and questions what things, if any, have existence or whether they are the product of one's mind (Burrell and Morgan, 1979). In health research, this relates to whether the phenomena can be deemed to be 'real' whereby they exist independently of our ideas, or where they cannot be deemed to exist independently and are comprised in their entirety in our ideas (Giacomini, 2010). These contrasting perspectives are termed 'realism' and 'idealism'. Epistemology is the study of knowledge and its basis; specifically, the nature and justification of knowledge, and its potential scope and limitations (Hall, 1990; Hughes and Sharrock, 1997; Hartmann and Lange, 2000). Epistemology raises the question of how reality can be known, relating it to ontology. Epistemological assumptions can influence research methodology by producing and shaping the theory and analysis of the research data, providing justification of the methods used (Carter and Little, 2007). An individual's epistemological position reflects their "view of what we can know about the world and how we can know it" (Marsh and Furlong, 2002). Researchers are often encouraged to position their research within a chosen paradigm (Doyle et al., 2009), which guides the practices and beliefs of a specific field (Morgan, 2007).

This research is based upon the ontological premise of realism, adopting a realist perspective in which the existence of the universal reality that can be studied, researched, and represented through a variety of observations and measurements. Observing, measuring, and quantifying the phenomena which can be subject to statistical tests, repeated, and replicated under the same conditions (Handcock, 2002; Hamilton and Clare, 2003) can be seen as a strong point of the quantitative research approach (Caldwell et al., 2005; Curry et al., 2006; Nicholls, 2011), as quantified findings provide objectivity and reliability (Castro et al., 2010). However, quantitative findings cannot answer questions of 'why' or 'how' and are unable to provide the full picture of the phenomena (Mahoney and Goertz, 2006). Thus, qualitative methods can be used to support and further explore quantitative results. The use of multiple, integrated approaches may be particularly useful in the evaluation of health

interventions as they involve social or behavioural processes that are difficult to explore or capture using quantitative methods alone (Lewin et al., 2009). Mixed methods research is guided by philosophical assumptions that enable the mixing of quantitative and qualitative approaches (Hanson et al., 2005), to provide a better understanding of research issues. Therefore, this study uses a mixed method approach, incorporating both qualitative and quantitative methods to gain a greater understanding of the research.

The before and after study is informed by 'post-positivism' (Holt, 2009). Positivism is based on the premise that knowledge is acquired by direct observation, measurement and experiment and these will result in an objective 'truth' (Chalmers, 1999). This position has been altered in 'post-positivism' to acknowledge that observation and measurement are fallible, and that all theory has the potential to change (Trochim, 2000). Whilst the measurements and observations can be used from an experimental sample to draw inferences about the population of interest (Holt, 2009), findings are often not treated as objective 'facts' but as evidence to that is put forward to be subject to further scrutiny (Trochim, 2000). For the qualitative study, a post-positivist approach was also adopted. It was not intended to problematise whether the interviews could be considered as a true reflection of an individual's perceptions and experience (Silverman, 2006), but rather to accept what the interviewees said as reasonably representing reality. Post-positivists believe that all observations are theory-laden and that all individuals are inherently biased by their cultural experiences and worldviews: that our understanding of the 'real world' is shaped by the particular perspective or 'lens' that we bring to the research (Trochim, 2006).

The methodological and philosophical perspectives of this study are largely determined by pragmatic rather than ideological factors, which is becoming increasingly common in health research (O'Cathain et al., 2007). Thus, the epistemological assumptions which underpin the research are based on those of pragmatism. This perspective has been identified as the most appropriate epistemology for mixed methods (Tashakkori and Teddlie, 2003) as it enables researchers to draw from both positivist and interpretivist paradigms (Creswell, 2009) to answer the research questions. Pragmatists believe that the research question should determine the choice of research design and not the method or paradigm (Muncey, 2009). This approach to research allows the application of any method that will assist with the understanding and solving of the problem. It has been argued that mixed methods research can help answer research questions that cannot be

answered by qualitative or quantitative methods alone and can provide a greater range of tools to meet the aims and objectives of the study (Creswell and Plano Clark, 2007). The combination of qualitative and quantitative methods draws upon their strengths and improves the validity of theoretical propositions providing a more complete and comprehensive picture of the study phenomena (Doyle et al., 2009; Ihantola and Kihn, 2011). The pragmatic approach to research is informed by the belief that the research is not driven exclusively by theory or by data, but a process which enables the researcher to move back and forth between induction and deduction through a process of inquiry (Morgan, 2007).

Pragmatism places high regard for the reality of and influence of the inner world of human experience in action, and views knowledge as both being constructed and based on the realist of the world we experience and live in (Johnson and Onwuegbuzie, 2004). Pragmatism does acknowledge that researchers are limited in being able to establish certain knowledge of an ultimate 'truth', and they constrained by the research tools available, their assumptions, and they accept that knowledge is fallible (Holt, 2009; Maxwell, 2012). Researchers adopting a pragmatic philosophy view knowledge as constructed and real but only within the context that it was generated (Hooper and Wood, 2002). Current truth, meaning and knowledge are viewed as tentative and changing over time, and the knowledge obtained is a provisional truth (Johnson and Onwuegbuzie, 2004). The philosophical tenets of pragmatism are consistent with the aims and objectives of this research study and are inherent within this thesis.

1.8. Summary

In addition to this opening chapter, this thesis has five more chapters. In chapter two, the methodology and methods for the before and after study are described. Chapter three presents the results of this study and discusses the principal findings, and the strengths and limitations of the study. Chapter four describes the methodology and methods of the qualitative study. Chapter five presents the qualitative study findings and discusses the main findings. In the final chapter, chapter six, the principal findings of the research presented in this thesis are discussed, as well as the strengths and limitations of the methodology. In addition, it considers the implications for the practice of hip precautions and areas that need further exploration.

2

Before and After Study Methodology

2.1. Introduction

The previous chapter highlighted the lack of evidence to support the routine use of hip precautions and the variations that exist in practice nationally. It also presented the strong opposing clinical opinions about whether hip precautions are beneficial or detrimental to patients' recovery. Thus, the first stage of the research was to evaluate the use of hip precautions in routine practice. The results could have important implications for the service provided to patients, and would make a significant contribution to the debate around hip precautions and help determine their value in routine clinical practice. A study comparing patient outcomes of those who reived hip precautions after THR surgery with those who do not was considered an appropriate starting point. This chapter describes the design considerations and methods used, with the results and discussion presented in the subsequent chapter (Chapter 3).

2.1.1. Potential changes to local routine clinical practice

In light of the weak evidence base for hip precautions and the belief of key staff that precautions were not necessary, Nottingham Elective Orthopaedic Services (NEOS) at Nottingham City Hospital were keen to revise their practice of treating patients post THR; this would involve a change in the delivery of the treatment service provided to patients, from a regime of routine prescription of hip precautions to a regime of no routine hip precautions. The decision to change practice was made over several years and involved the removal of routine hip precautions en masse, with a more individualised approach to the prescription of hip precautions. The focus was on a more 'natural' or instinctive precaution, encouraging patients to move as is comfortable within their own limitations; in other words, patients' movements should be guided by their pain.

This change in clinical practice provided an opportunity for researchers to collect patient outcome data to evaluate hip precautions, with respect to the change in the delivery of service to patients following THR.

2.1.2. Study aim and objectives

The aim of the before and after study was to determine the effectiveness of hip precautions in routine clinical practice following THR.

There were two specific objectives:

1) To pragmatically compare outcomes (pain and function) in patients who were prescribed hip precautions with those who were not at three months postoperatively.

2) To evaluate the effects of both hip precautions and no hip precautions on patients' QoL, functional performance, pain, sleep, mood, satisfaction, and dislocation rates following THR.

2.2. Methodology and methods

As discussed earlier in this thesis (Chapter 1, section 1.7.), the overarching methodological and philosophical perspectives of this study were largely determined by pragmatic factors. A quantitative method was selected because the aim was to evaluate the use of hip precautions by comparing the outcomes of two patient groups. Thus, the design of this study was based upon the selection of particular methods for their suitability and appropriateness to address the research question.

2.2.1. Design considerations

When designing a study, there are two types of basic research approaches to consider when assessing whether a specific treatment condition is associated with a particular outcome: experimental and observational. In an experimental study, the investigator assigns a treatment to the subjects and proceeds to observe the effect of the treatment. In an observational study, the investigator observes and measures variables of interest without assigning treatments to the subjects. The types of design considered for this study will now be discussed.

2.2.1.1. Randomised controlled trial

Definition

When appropriately designed and conducted randomised controlled trials (RCTs) are considered the 'gold standard' for testing interventions (Schulz et al., 2010). In healthcare, RCTs are the most robust and optimal study design for evaluating the efficacy and effectiveness of an intervention (Concato et al., 2000; Craig et al., 2008). Efficacy can be defined as the ability of an intervention to produce the desired beneficial effect under ideal circumstances (Dorland, 2007), whereas effectiveness can be defined as a test of how successful an intervention is when delivered 'under real-world conditions' (Glasgow et al., 2003).

Procedure

In an RCT, participants are randomised to either an 'intervention' or a 'control' (non-intervention) group; this randomisation minimises any differences between the groups prior to the intervention, and that observed changes can be attributed to the treatment(s) under study.

Although RCTs have a high level of internal validity (i.e. confidence that the treatment caused the change in outcome), they may have less external validity or applicability to the real world (i.e. the extent to which the outcome can be generalised to other populations, settings, or treatments). The benefits of some interventions can be generalised to most patients and settings; however, the effects of other interventions can be dependent upon factors such as patient characteristics, method of intervention application, and the treatment setting (Rothwell, 2006). Thus, to be clinically useful, the results must be relevant to a definable group of patients, in a particular clinical setting.

Randomised controlled trials are typically the first choice of design when assessing the effectiveness of treatment interventions and are predominant in medical research. Randomising participants to treatment groups can protect against bias and minimise the effects of confounding variables (known and unknown), thus increasing the probability that any differences observed are the result of the intervention (Akobeng, 2005). Whilst RCTs are a well-established method for assessing the efficacy of treatments with pharmaceutical and surgical research (Bothwell et al., 2016), RCTs in therapy interventions are less common. It can be difficult to plan and implement RCTs in clinical settings, and the outcomes that result from the extra effort required may be an unrealistic guide as to what can be achieved in routine practice (Tones

and Tilford, 1994). Thus, therapeutic interventions can often be implemented in routine practice before efficacy is demonstrated; it is possible that this is reflected within the other hospital trusts that have removed the prescription of hip precautions from routine practice.

In RCTs participants are often 'blinded' to the treatment provided in order to increase rigour, however, it is not always possible to blind participants to therapeutic treatments. The purpose of blinding is to eliminate bias that might result from the expectations of the patient or the provider (Medical Research Council, 2000). These expectations may arise if the patient or the provider has a treatment preference; if they believe that they have received their preferred intervention they are likely to expect and achieve more positive outcomes, and thus compliance is likely to be improved. In a drugs trial, participants may receive a placebo drug, which does not differ from the active drug in appearance, so individuals within the research, including researchers and participants, often do not know whether the placebo or drug has been given. When delivering a therapy intervention, it is not always possible to blind participants or therapists to the treatment given. This may result in increases in bias and could impact upon the robustness of the study. Despite this, it is possible to blind assessors to the treatment given to participants; thus, RCTs are still believed to be a robust method for testing the efficacy of therapeutic interventions.

However, whilst an RCT would have been the preferred method to evaluate hip precautions following THR, an RCT would have been impractical in this research for several reasons:

1. **Variations in practice**

   In an RCT, patients could be randomised by their consultant; however, at Nottingham City Hospital each consultant has a varying caseload of THRs, with some consultants performing fewer than 100 THRs a year, and others performing almost 300 a year. There may have also been variations in the surgical technique between surgeons and among a surgeon's caseload. As surgical factors are associated with the risk of dislocation (Blom et al., 2008), there could have been a performance bias which could have potentially confounded the results. As surgery is rarely standardised, due to individual differences, it would have been very difficult to control for this potential bias. It was also not practical as therapists continued to work across wards, and there was potential for protocol infringement and contamination.

2. Service provision and implementation

Education about hip precautions, and the supply of adaptive equipment for THR patients are usually service based and extend from preoperative assessment clinics to provision of equipment in the community. Nottingham City Hospital has a large catchment area, and the community provision of equipment and additional resources can vary between counties. At the time the study was designed, hip precautions and equipment were prescribed preoperatively by the hospital occupational therapists, and postoperatively by all members of the orthopaedic multidisciplinary team (MDT). With numerous individuals from the MDT involved within the patients' care across a long pathway, it would have been unrealistic to provide hip precautions for half the sample and not for others across the whole treatment/care pathway. This could have caused confusion about the advice patients should receive and consequently have led to widespread contamination and protocol infringement by both patients and staff members.

Discussions with ward staff suggested that in practice they would find an RCT impossible to administer as they worked across three wards. It would potentially have been very difficult for nurses to ensure that the patient was receiving the correct advice according to the treatment group they had been recruited to. There could have been confusion about which group the patient was assigned to, with staff unlikely to remember which regime to deliver to each patient. Also, the close proximities of the ward beds would have enabled patients to talk amongst themselves about the treatment they were receiving. If patients were unhappy with the treatment they received or favoured the alternative treatment, then it is possible that they could have adhered to that treatment rather than the one they were prescribed; this could have caused further contamination and protocol infringement. In addition, at the design stage of the study, the hospital had separate female and male wards that meant that randomisation at ward level would not be possible. The variation in characteristics in between male and females may influence the results, whereby differences seen between the groups may be due to factors other than the removal of hip precautions. Following the commencement of the study the wards were changed to mixed-sex wards, however, despite this, it would not have been possible to randomise patients, as it was not possible to predict which ward the patient would be admitted to following surgery.

Adaptive equipment was routinely provided preoperatively to patients undergoing THR, including a raised toilet seat, perching stool, and furniture raisers, to assist with adherence to the precautions. Additionally, patients were assessed on the ward postoperatively as to their need for a leg-lifter and Buckingham caddy (walking frame with combined tray/bucket attached). Whilst it would have been possible to control/monitor the provision of equipment at the hospital, it would have been difficult to dictate the provision of equipment within the community. Social care services are provided by local councils, and the criteria to determine whether patients can receive social care may vary between councils (NHS, 2014). The hospital provides a service, not only for patients in the city or county where it is situated but also in neighbouring counties, and thus it would not have been feasible to control for the provision of equipment within such a large catchment area. There was the possibility that occupational therapy staff could have provided equipment to all patients because they believed it was unfair to provide items of equipment to some patients and not others and could also have led to potential widespread contamination and protocol infringement.

Cluster RCT

When it is not feasible to randomise at the level of an individual patient or specific groups of patients, another option is to randomise trusts or units instead; this approach is known as cluster randomisation (Medical Research Council, 2000). Cluster RCTs can be used when comparing alternative strategies, such as routine practice and a new treatment, and involves allocating clusters of patients to the intervention rather than allocating each individual patient to the intervention.

Discussion with THR services suggested that many services treating patients during their THR were not willing to consider the option of a no precautions regime in a cluster randomisation trial. This may be because of the fear or reluctance to make radical changes without robust supporting evidence, and the practicality of changing practice within a service. Concerns were also raised about the ethical implications of withholding hip precautions from some patients, as this approach could potentially be considered a less effective method of treatment by some sites (Coole et al., 2013). As there was a lack of agreement from multiple sites, it was more appropriate to start with a single site.

As an RCT (or cluster RCT) was not feasible, other research designs had to be considered. A quasi-experimental design was believed to be an appropriate design for this study.

2.2.1.2. Quasi-experimental

Definition

A quasi-experimental design by definition lacks random assignment of participants and is often used when random assignment is not possible or practical. However, assignment to conditions (treatment vs. no treatment) is either by systematic allocation or convenience, including self-selection (participant chooses the treatment themselves) or administrator selection (e.g. policy makers, officials, clinicians, etc.) (Shadish et al., 2002). Like RCTs, quasi-experimental designs involve comparing the changes in one group that receives an intervention with a group that does not (comparison control group). Therefore, it is desirable for the comparison group to be as similar as possible to the intervention group in terms of baseline characteristics. The purpose of the comparison group is to capture outcomes that may occur if the intervention had not been implemented (White and Sabarwal, 2014). The context and delivery of the intervention in quasi-experimental designs often reflects 'usual practice' more closely than in an RCT, meaning that the results can be more generalisable to other settings. As quasi-experimental designs typically have broader inclusion criteria and limited exclusion criteria than RCTs, they can produce a study population which is more representative of the target population (e.g. patients with multiple co-morbidities, elderly patients), allowing the results to be more generalisable (Velengtas et al., 2012).

Following discussions with clinical staff at Nottingham City Hospital about THR services, it was proposed that a quasi-experimental study design would be the most appropriate design to study the effect that withdrawing routine hip precautions has on patients' recovery.

Types of design

There are a number of quasi-experimental designs that were considered for this study, such as cross-sectional design, time series design, and pre-test post-test design. These are discussed below:

○ Cross-sectional design

Cross-sectional designs can be employed to examine the relationship between the treatment and outcomes of interest. In a cross-sectional study, all measurements of one participant are obtained at a single point in time, although recruitment may occur over a longer period of time (Sedgwick, 2014). It would be possible to measure patient outcomes at six weeks and compare those who were prescribed hip precautions with those who were not. However, it may not be possible to determine whether a difference between the groups' outcomes was because of the treatment itself, or if they were due to unmeasured confounding variables between the groups. Cross-sectional designs sometimes make it difficult to determine what is 'cause' and what is 'effect' (Coggon et al., 2009), thus using a cross-sectional design for this study would not be appropriate as it might not be possible to determine whether hip precautions are effective or not when compared to no hip precautions. Therefore, a design that assesses participants prior to the intervention would be more appropriate.

○ Time series design

Time series designs attempt to determine whether an intervention has an effect significantly greater than the underlying secular (general changes over time) trend (Cook and Campbell, 1979). In a time series design, there is a single group of participants who are tested at multiple intervals before and after the intervention to determine the long-term effects of treatment. Time series designs are useful when it is difficult to randomise or identify a control group (Eccles et al., 2003). Although this design would address the inability to randomise patients to treatment groups, the design would not be possible to conduct in the context of the study. Due to the nature of the study setting, it would be impossible to evaluate the effects of the change in the delivery of rehabilitation services to patients following THR surgery in one group of patients; in order to determine the effect of the intervention two groups were required to compare outcomes of those who follow hip precautions and those who do not following THR.

- Pre-test post-test design (before and after design)

In a pre-test post-test (before and after) design, there are two groups: treatment group and comparison group, which are compared using pre-test and post-test scores. The comparison group is a control population which has been identified by the researcher as having similar characteristics to the treatment group. Data are collected before and after the intervention from both groups to allow comparisons between the changes in the scores in each group, and observed differences are assumed to be due to the intervention (Eccles et al., 2003); it is possible to have multiple pre-tests and/or post-tests to control for potentially different time-varying confounding effects in the treatment and comparison group, and/or either assessing the effects of the intervention over time (Harris et al., 2006). As the groups are not randomised, differences between the groups at baseline are assessed and any demographic and behavioural differences are accounted for in the analysis, allowing for a more accurate assessment of how effective the treatment was. If there are differences between baseline scores between the groups, this type of design allows for comparisons within the groups, for example, when assessing changes from baseline to post-intervention scores, the assumption is made that if the change in the treatment group is significant and the change in the control group is not, then the intervention has had an effect (Eccles et al., 2003). However, assessing for comparisons *within* the groups can lead to a lack of direct comparison *between* the groups and may suggest that the control group is not truly comparable. Statistical methods (e.g. analysis of covariance) may be used to control differences between groups and minimise bias (Wludyka, 2011).

2.2.2. Study design

A before and after design was considered to be the most appropriate for this study. This study design would enable groups of patients to be assessed before (control/comparison group) and after (intervention group) the change in the delivery of service (removal of hip precautions), to determine whether there were comparable effects on patient outcomes following THR. In this thesis, the study will be described as a before and after study to reflect the change in treatment.

The study was conducted in two phases, with two consecutive groups (before group and after group), reflecting a change in the delivery of the orthopaedic services to patients listed for a primary THR. The study will refer to the ‘before’ group as phase one and the ‘after’ group as phase two. Depending on the timing of their THR in relation to the service change, participants were recruited to either receive hip

precautions (phase one - before) or no hip precautions (phase two - after). Figure 2.1. shows the study design.

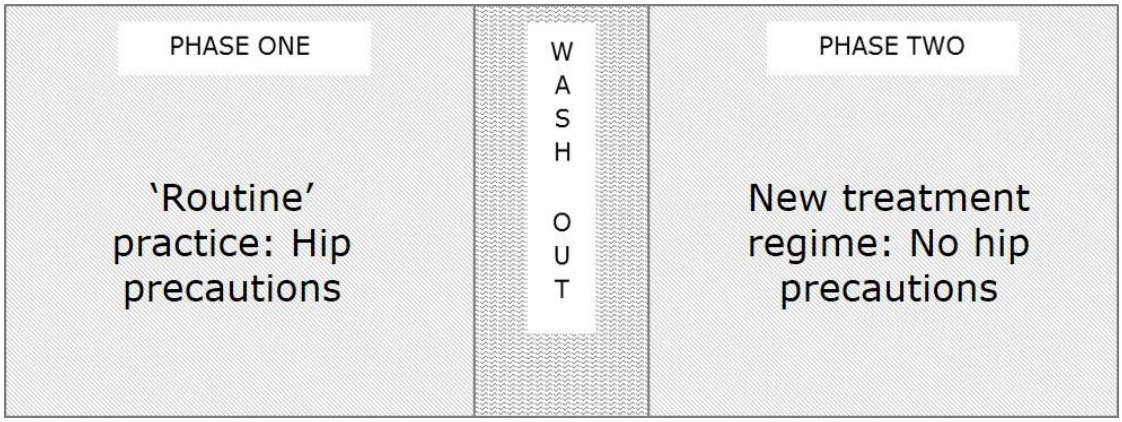


Figure 2.1. Study design

As the study aimed to test whether a new treatment intervention had comparable effects, in terms of patient outcomes, to an established standard of care, an equivalence design was adopted. The aim is to show that the new treatment is neither inferior nor superior than the standard treatment (i.e. having no hip precautions was no better or worse to using hip precautions).

Demonstrating the superiority of new treatments is increasingly difficult; however, new treatments may still be desirable even when they do not have superior effects, if they are safe, cheaper, or more convenient (Ewald, 2013). Claims of equivalence cannot be justified from a non-significant test for superiority, as negative results may simply result from a lack of power (Type II error) in the presence of a truly nontrivial population (Mascha and Sessler, 2011), therefore an equivalence design must be implemented. An equivalence design can be used to assess whether the outcomes of the two treatment groups do not differ, by a pre-specified amount known as the margin of equivalence.

In an equivalence designed study, the null hypothesis states that the difference between the two means is outside an a priori specified equivalence region (-δ to +δ). The equivalence region is often defined as the minimum important difference between the treatments (Ewald, 2013). If the difference lies within the prescribed equivalence region, then the null hypothesis is rejected, and the two treatments can be deemed 'equivalent'. It was hypothesised that hip precautions were neither inferior nor superior

to no hip precautions in terms of patient outcomes; in other words, using hip precautions was no better or no worse than using no hip precautions following THR, and the two treatments would be found to have 'equal' effects.

2.2.2.1. Washout period

A washout, or run-in, period to the new regime of no hip precautions was considered appropriate to ensure that hip precautions had been discontinued from practice before recruiting participants to phase two of the study.

A washout period occurs between two treatments and is included in research studies when carryover effects are a potential concern (Polit and Beck, 2012). Washout periods are common in clinical drugs trials to ensure that there is time for the drugs previously administered to the participants to be eliminated; this is to prevent them having an effect on the next stage of the study. In this study the same clinical staff would be providing treatment to both patient groups; it was, therefore, important that any potential carryover effects from the change in the delivery of service (from hip precautions to no hip precautions) were eradicated. Thus, a washout period was implemented to ensure that staff were not prescribing hip precautions to patients during the no hip precautions phase. During this time, the new treatment regime was administered to all patients, but no outcome data were collected. This was to enable staff time to adjust to the new regime of no hip precautions, and to eliminate any potential intervention contamination bias (e.g. prescribing hip precautions during the new treatment service). The delivery of the service was only evaluated when it had reached a certain standard.

In clinical drugs trials, the duration of the washout period is usually based upon the drug's half-life (D'Angelo et al., 2001); however, in non-drug trials there is very little literature suggesting how to determine the length of the washout period. It is not possible to 'wash out' a change in advice or behaviour intervention in the same way that a drug-free period would guarantee no active component (Sheldon et al., 2012). Therefore, as the study involved clinical staff changing the treatment and learning the new service provision, a pragmatic decision was made that the washout period should last approximately two months. It was believed that this length of time was sufficiently long enough to avoid any carry-over effects from the hip precautions service to the no hip precautions service (Fitzgerald et al., 2015).

2.2.3. Study setting

The study was a single-centre study, conducted at Nottingham City Hospital campus, Nottingham University Hospitals (NUH) NHS Trust, between January 2017 and August 2018.

Nottingham City Hospital had a specialist clinical unit, NEOS, situated within it, which undertook the highest volume of orthopaedic surgery within the region, including hip replacements (NUH NHS Trust, 2016). The NOES provide a service to patients in Nottingham, the East Midlands and the UK (NUH NHS Trust, 2016). At the time of commencement of this study, this hospital had three postoperative wards where patients who were undergoing THR surgery may have been treated: one male, one female, and one mixed ward (single sexed, 2-bed cubicles). Ten orthopaedic consultants treated patients who were admitted to these wards following their surgery, and Allied Health Professionals (e.g. physiotherapists and occupational therapist) treated patients across the three wards. During the study, the hospital closed the mixed ward, and the male and female wards became mixed wards.

2.2.4. Ethics

The study was approved by Nottingham 2 Research Ethics Committee (REC) - East Midlands (16/EM/0283), the Research and Innovation department of Nottingham University Hospitals NHS Trust (16HC005), and the Health Research Authority (HRA).

A study steering committee was set up and included a senior physiotherapist, two senior occupational therapists, a consultant surgeon, and a patient representative.

2.2.5. Sampling

2.2.5.1. Sample size calculation

A formal sample size calculation was conducted using the statistical program nQuery + nTerim 4.0 (Statistical Solutions, Ltd., 2015). As the study aimed to test whether a new treatment intervention (no hip precautions) had comparable effects in terms of patient outcomes with an established standard of care (hip precautions), a sample size calculation for an equivalence design was used.

To calculate the sample size in an equivalence design trial, a pre-defined margin of equivalence must be determined. The Oxford Hip Score (OHS), a nationally accepted

clinical instrument validated to measure disability pre- and post-surgery (Field et al., 2005), was believed to be the most appropriate measure to evaluate the efficacy of hip precautions. As the OHS had not been used in previous research of hip precautions, the minimum clinical important difference (MCID) remains unknown. Therefore, an a-priori power calculation using Cohen's (1998) generic MCID for clinical outcomes in the standard deviation was (SD) was applied (i.e. any difference more than 50% of the SD of the outcome measure in the study would be considered as clinically significant).

With a pre-defined margin for equivalence (i.e. 0.5SD), the a-priori power calculation indicated that 128 participants (64 per group) would be required to be 80% sure that the limits of a two-sided 95% confidence interval would exclude a difference in means of more than 0.5SD of the OHS. As this was a quasi-experimental study, and not an RCT, it could not be guaranteed that the two groups would be equivalent with respect to all factors other than the treatment provided. Age and gender, for example, might confound the difference between the groups. As confounding variables (known and unknown) may not be equally distributed between the two groups, the study was powered to take into account the adjustment for the baseline characteristics of patients recruited for the two phases to minimise bias. It was assumed that there were two covariates (age and gender) which would be different between the two groups at baseline, and thus the sample size was increased to approximately two times the original size, 128 participants per group (256 participants in total) to enable the test for interaction. To allow for dropouts (25%) we aimed to recruit 171 participants per group (342 in total).

Based on data (from the previous 5 years) obtained from Nottingham University Hospital Trust's Trauma and Orthopaedic Audit Office, Nottingham City Hospital was expected to perform 650-700 primary THRs per year during the study time frame. Therefore, it was believed that it was feasible to recruit the required sample size from this hospital.

2.2.6. Study population – eligibility criteria

Patients who were scheduled to receive an elective primary THR from NEOS were asked to participate in the study.

2.2.6.1. Inclusion criteria

To be included in the study, participants had to be:

(a) listed for elective primary hip replacement surgery

(b) able to provide informed consent

(c) aged ≥18 years; in the UK, individuals who are 18 and older are assumed to be a competent adult capable of consenting to treatment (Medical Protection Society, 2014). Hip replacements performed in children require a different surgical technique than those performed in adults.

2.2.6.2. Exclusion criteria

Patients were excluded from the study if they:

(a) did not speak and read English; individuals who could not understand English would not be able to complete the questionnaires, and the questionnaires used in the study are not validated in other languages. It was not feasible to hire an interpreter or translator due to financial costs, and the use of an interpreter could invalidate the questionnaires as the translation of the question may change the original context.

(b) were listed for revision surgery (including immediate, short-term, and long-term); revision hip surgery is required when the initial prosthesis becomes worn, loose, broken or has dislocated. It requires different surgical technique and approach to primary THR, and increases the risks of dislocation and other complications associated with hip surgery (i.e. infection, aseptic loosening).

(c) were listed for 'complex' hip surgery (as defined by the surgeon and documented in the medical notes). This often requires modular implants and/or bone grafting which also increase the risk of complications, particularly dislocation. It differs from revision surgery as it can be a primary procedure performed on patients with muscular problems, history of neurological disease, or associated morphological bone deformities.

(d) had a diagnosis of dementia documented in their medical notes. There were three considerations for this. Firstly, the individual may not be able to provide informed consent, secondly because potential short-term memory loss could impact the learning of hip precautions, and thirdly, the individual would not be able to complete the questionnaires.

2.2.7. Procedure

2.2.7.1. Recruitment

Prior to the commencement of the study, the researcher (CJL) presented at consultant team meetings and enhanced recovery after surgery (ERAS) group meetings to explain the purpose of the study. Posters were also displayed in key staff areas to facilitate the identification and recruitment of potential participants.

Invitation to participate in the study

Potential participants were identified from patients listed for elective primary THR, prior to their attendance at the preoperative assessment clinic. Preoperative clinic staff assisted with the identification of potential participants by screening patient clinical notes to determine whether they were eligible to participate. All eligible participants were sent a participant information sheet (PIS) (see Appendix A), along with their preoperative appointment letter inviting them to attend the preoperative clinic. This allowed participants a minimum of 48 hours to consider participating in the study.

Recruitment to the study

Patients were recruited from their preoperative assessment appointment and enrolled in the study following their attendance at the joint education session, known as ‘hip school’, which formed part of the preoperative appointment. Patients’ preoperative appointment took place approximately six weeks prior to their surgery to ensure that they were fit for surgery. At the preoperative assessment clinic, staff approached potential participants and asked whether they had considered participating in the study. The clinicians informed the patient that the researcher would discuss the study in more detail at the hip school. At the beginning of each hip school presentation, a slide detailing the study was displayed and the study was explained briefly by the clinician giving the session and the researcher was identified. Individuals who expressed an interest in the study were invited to discuss it further with the researcher at the end of the session. The researcher explained the study to the potential

participants and answered any questions or queries that they had. It was explained to the potential participant that entry into the study was entirely voluntary and that their treatment and care would not be affected by their decision. It was also explained that they could withdraw at any time, however it was explained that data collected so far could not be erased.

2.2.7.2. Consent

If the patient met the study criteria and wished to participate in the study, written informed consent was obtained (Appendix B). No personal information or medical notes were examined until the participant had given their consent. Consent was for the collection of data and applied to the entire duration of the study, including all the follow-up assessments. The participant received a copy of the signed and dated consent forms and the original was retained in the Study records. A second copy was filed in the participant's hospital medical notes.

If the patient wanted more time to decide whether to take part or not, they were given another PIS (identical to the one posted with their preoperative letter) to take home. Potential participants were asked to contact the researcher if they then decided they would like to take part in the study or wanted to discuss it further. Those wishing to take part were sent a consent form and a pre-paid return envelope and asked to return the completed form at their earliest convenience.

2.2.7.3. Allocation to group

The allocation of participants to the groups was dependent on the time point of their THR surgery. Patients who were listed for elective primary THR and attended the preoperative assessment between January 2017 and June 2017 (phase one) were allocated to receive hip precautions. Patients who were listed between September 2017 and January 2018 (phase two) were allocated to the no hip precautions group.

During phase one, hip precautions were provided as routine (traditional) practice; whereas, during phase two, patients were assessed and advised on a case-by-case basis by occupational therapists, with adaptive/assistive equipment only issued if required. A washout phase was implemented between the two phases to allow staff to adjust to the new regime of no hip precautions, and to ensure that there was no contamination between the two phases (see section 2.2.10.).

Prior to the commencement of phase two, patients who were listed for a THR at Nottingham City Hospital were informed that the service, relating to hip precautions, following THR was changing. Patients were notified about the change in service so that they could make an informed decision as to whether to continue to have their hip replacement at NCH, or whether to choose another hospital.

2.2.8. Phase one (Before) procedure

During phase one, hip precautions were administered as routine practice. This included the prescription of three key movement restrictions (no flexion beyond 90°, no rotation, no adduction across midline) and provision of adaptive equipment to assist with adherence to hip precautions. Patients were instructed to follow hip precautions for six weeks following their surgery to reduce the risk of dislocation.

2.2.8.1. Preoperative assessment for equipment provision

At the preoperative assessment clinic, occupational therapists carried out an assessment with each participant to determine the prescription of equipment. The assessment involved discussing home situations with each patient; this included living arrangements (e.g. type of house, social situation), functional activities (e.g. mobility, access, driving, personal and domestic ADLs, and transfers), and social support (e.g. family/friends to assist, social services). Patients were asked to provide measurements for the height of their toilets, bed, and chairs at home. Occupational therapists measured participants' popliteal height ("sitting height"): the distance from the anatomical landmark of the popliteal fossa (i.e. behind the patient's knee) to the ground, whilst wearing flat footwear (Moores, 2009). 5cm (2inches) was added to the participants' popliteal height to produce a 'safe height' for the patient. For example, if the distance between the popliteal fossa and the floor was 45cm (18"), the addition of 5cm (2") would result in a 'safe height' of 50cm (20"). Participants were informed of their safe height and were advised not to sit on any surfaces below this height. This prevented patients from flexing their hip beyond 90°.

A standard package of adaptive equipment was issued to patients, to enable them to adhere to their recommended safe height, which included:

- furniture raisers (for chairs and bed)
- additional furniture, if their furniture could not be raised (e.g. high back chair)
- perching stools, for use in the kitchen and bathroom
- raised toilet seats and frames (or combined).

The occupational therapists also advised participants to purchase small items of adaptive equipment to assist with ADL:

- 'helping hand' (i.e. easy reacher/long handled grabber)
- long handled shoe horn
- sock/stocking aids.

2.2.8.2. Hip school and hip precautions

Participants also attended hip school where hip precautions were discussed in greater detail. Participants were instructed 'do not bend more than 90 degrees, which includes both bending down to pick something up off the floor and sitting in a chair that is too low', 'do not twist or pivot, this includes turning to look at your scar', and 'do not cross your legs, which includes sleeping on your back'. Clinicians informed participants that hip precautions were to be followed for six weeks, in order to protect the new hip whilst the soft tissues heal, and to reduce the risk of dislocation. Demonstrations of the restricted movements were performed, showing participants that sitting on a chair set to the clinician's safe height was acceptable, however squatting or sitting on the low furniture was not, and neither was bending down to touch their toes.

The clinicians also discussed other daily activities in more detail and participants were shown examples of how to perform everyday activities within the restricted and recommended ROM; these activities included getting on/off a bed, walking with aids (e.g. walking frame, crutches), going up/down the stairs, and getting in/out of a car. Patients were shown various pieces of equipment that they would be issued with, including a raised toilet seat, furniture raisers, and perching stools. Participants were also shown smaller aids that they could purchase themselves (e.g. long handled shoe horn, easy reacher), if they wished, to assist them with completing everyday activities within the movement restrictions. Participants were taught recovery exercises, and demonstrations were provided to show participants how to perform them within the

movement restrictions. The clinicians also provided advice about long-term considerations, such as driving and flying abroad.

2.2.9. Phase two (After) procedure

In phase two hip precautions were not provided. Participants were encouraged to move as they were able, within a comfortable ROM. Standard packages of adaptive equipment were not routinely provided to participants. However, if, in the clinical opinion of the occupational therapists, the participant required adaptive equipment, then this was provided, e.g. if the patient was very frail or had other medical problems. Participants were assessed on a case-by-case basis by the clinical team to determine a more individualised approach to rehabilitation.

2.2.9.1. Preoperative appointment for equipment provision

In this phase, at their preoperative assessment appointment, participants were assessed by occupational therapists as to their home situation and equipment needs. Living arrangements (e.g. type of house, social situation), functional activities (e.g. mobility, access, driving, personal and domestic ADLs, and transfers), and social support (e.g. family/friends to assist, social services) were also discussed with the participant. Although participants were still required to measure their furniture at home, this was only used to determine those with extremely low furniture whom may struggle after their surgery. The occupational therapist then provided these participants with relevant adaptive equipment, such as a standing toilet frame. Occupational therapists also discussed purchasing small aids that participants may find beneficial for ADLs and for independence, especially if living alone.

2.2.9.2. Hip school and alternative advice to hip precautions

Participants also attended hip school, however, hip precautions were no longer taught. Information and demonstrations regarding hip precautions were removed from the session. Instead, clinicians encouraged participants to move as they were able within a comfortable ROM and to be guided by their pain. The clinicians provided examples of how to perform everyday activities and suggested techniques to do these depending on what was most comfortable or easier for the participant (e.g. log roll out of bed). Participants were advised to adopt a position of choice for sitting and sleeping, and the clinician demonstrated a number of sleeping positions, including side sleeping with pillows.

Participants were also encouraged to resume daily activities, and return to leisure activities and work, when they felt they able to do so. Driving (both manual and automatic transmission) was the only activity that the therapists did not encourage people to return to within the first six weeks; this was primarily due to restrictions from insurance companies (if driving right-hand drive automatic with left THR, there was potential to return earlier). The therapists advised patients to consult their General Practitioner (GP) or Consultant (orthopaedic surgeon) if they felt ready to return to driving within six weeks post-surgery; the patient's return was their GP's or consultant's clinical decision.

2.2.9.3. Hip champions

Each team of healthcare professionals within the MDT was assigned a 'Hip Champion' who could be contacted about the study by other staff. Hip champions were clinicians who assisted with the study (e.g. screening of potential participants, participant recruitment, providing training to staff about new regime) and provided an immediate point of contact for other clinicians when queries or questions arose regarding the study, for example, the eligibility of a patient. If the hip champions were unable to answer any queries, they then referred it to the research team to respond. Posters displaying key information about the study (e.g. inclusion and exclusion criteria) and the allocated hip champion for each team were displayed in relevant staff areas. The posters were targeted at clinicians (e.g. consultant surgeons, specialist preoperative nurses, occupational therapists) assessing patients for THR surgery and were displayed to serve as a reminder of the research study.

A small number of clinicians were recruited from each clinical team, consisting of senior physiotherapists, senior occupational therapists, nurse practitioners, and ward sisters to be hip champions. The role of the hip champions was to assist with the monitoring of treatment fidelity, ensuring that all staff were adhering to the delivery of the new treatment (no hip precautions) in phase two. Hip champions played an important role in identifying any deviations from the new protocol, both written in medical notes and advice given to patients. Hip champions approached and challenged members of staff who were providing incorrect advice to patients, such as prescribing hip precautions to routine primary hip replacements. The hip champions notified the researcher of the process of change, any issues raised or identified, and the methods in which they used to deal with hindrances.

2.2.10. Washout phase

During the two phases, there was a washout period. Recruitment to phase one ceased in June 2017, approximately one month prior to the commencement of the washout phase in July 2017 to minimise patient cross-over (i.e. patients recruited into phase one receiving the no precautions treatment). The washout period occurred following the removal of hip precautions and was expected to last two months. During this time, patients who were listed for THR surgery were not approached or invited to participate in the study and no data were collected.

2.2.11. Outcome measures and assessment

2.2.11.1. Potential outcome measures considered

A number of outcome measures are widely used to assess patients following THR, particularly those measuring pain and function. This section discusses the outcome measures that were considered when designing the before and after study and the reasons why the outcome measures were chosen.

This study uses self-reported measures, such as questionnaires, which are commonly used in rehabilitation as an alternative approach to direct observations. Whilst direct observations remove issues of recall and response bias, they require a great amount of clinicians' time, making them impractical and costly, and in some case unfeasible (Sohlberg and Mateer, 2001). For this study, it would not have been practical to perform objective physical function tests in the clinical setting, nor feasible to train staff to conduct the tests within the available time and resources.

Pain and function measures

Pain and functional restrictions are the main reasons as to why patients undergo THR surgery and are therefore important clinical outcome measures to assess patients' recovery following THR. A number of hip-specific pain and function measures were considered as the primary outcome, including The Western Ontario and McMaster University Osteoarthritis Index (WOMAC), Harris Hip Score (HHS), Hip disability and Osteoarthritis Outcome Score (HOOS), and Oxford Hip Score (OHS).

- *Western Ontario and McMaster University Osteoarthritis Index (WOMAC)*

The WOMAC Index (Bellamy et al., 1988) consists of 24 items which measures pain, stiffness and physical function in patients with hip (and/or knee) OA. The WOMAC has been validated for OA in the lower extremities and for evaluating outcomes after

THR; however, it has been shown that the WOMAC results are influenced by other factors than lower extremity disease, including fatigue, depression, back pain, and psychological status (Wolfe, 1999). The WOMAC was deemed inapplicable for the study as the remit of the questionnaire was too large.

- *Harris Hip Score (HHS)*

The HHS (Harris, 1969) was developed to assess outcomes following THR, in particular, pain, function, deformity, and ROM. The HHS is an observational assessment, making it less sensitive to the patient's subjective bias. Despite this, the HHS fails to account for individual differences (e.g. age, health, and/or personal issues) which may influence the score. A limitation to the HHS is the frequently identified ceiling effects (~20%), which severely limit its validity (Wamper et al., 2010). The large ceiling effects raised concerns as the questionnaire was to be repeated over four time points; in this study, therefore, the HHS was considered to be unacceptable.

- *Hip disability and Osteoarthritis Outcome Score (HOOS)*

The HOOS (Nilsdotter et al., 2003) measures patient-relevant outcomes such as pain, symptoms, ADLs ADL, sport and recreation function, and hip related QoL. As the HOOS is an extension of the WOMAC, it has been suggested that the added subscales make it valuable for younger and more active patients, in particular, those younger than 66 years of age (Nilsdotter et al., 2003). This could potentially be a limitation as the median age of female and male patients receiving THR in the UK are 69 and 70 years respectively (National Joint Registry, 2015). The HOOS is a 40-item questionnaire that takes approximately 10-15 minutes to complete, which was a potential burden for patients especially if they are being asked to complete several questionnaires. Thus, the HOOS was not a suitable measure to assess patients' pain and function in this study.

- *Oxford Hip Score (OHS)*

The OHS (Dawson et al., 1996a) assess joint-specific pain and functional ability. The OHS has been shown to have a high response rate, as it is easy to use and can be completed by patients independently (Ahmad et al., 2011). The OHS has been shown to be consistent, reproducible and valid (Dawson et al., 1996a; Fitzpatrick et al., 2000); it has also been demonstrated to be highly sensitive to change in patients undergoing primary THR (Dawson et al., 1996a; Dawson et al., 1996b; Ostendorf et al., 2004; Fitzpatrick et al., 2000; Dawson et al., 1996c). However, some questions

are believed to lack clarity which may provide some difficulties to respondents (Wylde et al., 2005). As a researcher would be present during the completion of the initial questionnaires, this was not a concern in this study. Most importantly, the OHS is the most commonly used outcome measure following THR in the UK and is routinely collected from patients following THR nationally for both the National Joint Registry and the UK Government patient-reported outcome measures (PROM's) (Arden et al., 2011). It is joint specific and has been extensively tested for reliability and validity (Field et al., 2005; Murray et al., 2007). Since the OHS was well recognised, and routinely collected, by orthopaedic consultants and other clinicians, it was determined that the OHS would be the most appropriate measure to use as the study's primary outcome measure to assess pain and function.

The OHS is a joint-specific 12 item questionnaire, designed to assess pain and function in relation to different ADLs from the patient's perspective. In the original version (Dawson et al., 1996a), the individual had to rate each response between 1 and 5, where 1 represented the best outcome and 5 the worst. The scores for each question were added together to formulate a score between 12 and 60 (12 = best outcome; 60 = worst outcome). However, in 2007 a new scoring system was suggested by Murray et al., which Dawson et al. supported, as many surgeons found the original scoring unintuitive. For the new scoring, participants must score each question from 0 to 4, with 0 representing the worst outcome and 4 representing the best outcome. As before, the scores from each question are summed producing an overall score, this score ranges from 0 to 48 (0 = worst outcome or the most severe symptoms; 48 = best outcome or least symptoms). To convert the score of the 'old' OHS system (60-12) to the new scoring system (0-48), and vice versa, the OHS score is subtracted from 60.

Activities of daily living measures

Following THR patients expect to return to their activities of daily living (ADLs), with some aiming to return to recreational activities, such as tennis, golf, and hiking, and maintain active lifestyles without pain and difficulty (Fischer et al., 2009). As there are great expectations placed on the outcomes of THR surgery, there is a need to monitor patients return to ADLs in the short-term recovery period. A number of measures have been considered to assess patients return to ADLs, including Barthel Index (BI), Iowa Level of Assistance Scale (ILAS), Frenchay Activities Index (FAI), and Nottingham Extended Activities of Daily Living Scale (NEADL).

- *Barthel Index (BI)*

The BI was originally developed by Mahoney and Barthel (1965) as a measure to assess disability in patients with neuromuscular and musculoskeletal conditions receiving inpatient rehabilitation. The index is a 10-item ordinal scale that comprises ten ADLs (e.g. feeding, bathing, dressing, walking, ascending/descending stairs), to measure functional independence in the domains of personal care and mobility. The index has been further modified by Collin et al. (1988), and Shah et al. (1989). Although the BI is widely used, there are some concerns as a number of modifications have been made to the original index, so determining which items should be included and how to score them (there is no definitive scoring system) often provides some challenges and confusion (Lewis and Shaw, 2006). The BI can be used to determine baseline functioning and monitor improvements over time; however, ceiling effects have been identified when the questionnaire is administered at hospital admission and discharge (de Morton et al., 2008). Confusion around the scoring and potential ceiling effects of the BI raised concerns about employing the measure in this study, and therefore it was disregarded.

- *Iowa Level of Assistance Scale (ILAS)*

The ILAS (Shields et al., 1995) measures patients' independence in functional activities, including the patient's ability to get out of bed, stand from the bed, ambulate 4.57m (15 ft), and climb up and down three steps. The ILAS appears to be valid and responsive in evaluating changes on patients' functional status following THR, in particular, the acute phase of the rehabilitation (within the first week) (Shields et al., 1995). However, these functional activities are often used in hospitals specialising in THR, as the criteria for discharge. As the ILAS is often used to determine whether a patient is ready to be discharged from hospital, it raises questions about whether these functional measures are responsive to change once the patient returns home. Also, there are no activities included in the measure that patients would be expecting to complete following discharge, such as dressing, bathing, preparing meals. Therefore, the ILAS was not considered a suitable measure to assess ADLs for this study.

- *Frenchay Activities Index (FAI)*

The FAI (Holbrook and Skilbeck, 1983) assesses a broad range of ADLs in areas of domestic chores, leisure/work, and outdoor activities. The responses measure the frequency of engaging in an activity over the past three or six months. Whilst the FAI includes items which go beyond the scope of many ADL scales, which tend to focus

on self-care and mobility, the length of time to which the activities are evaluated is too great (six months) and would not allow for patients to be monitored over the timescale of this project. Therefore, the FAI was not an appropriate measure to use for this study.

- *Nottingham Extended Activities of Daily Living Scale (NEADL)*

The NEADL (Nouri and Lincoln, 1987) was originally developed to assess the level of independence of particular activities that may be important to stroke patients following discharge from hospital. The NEADL has also been found to be valid and reliable in assessing the level of activities actually performed by patients with arthritis of the hip undergoing THR (Harwood and Ebrahim, 2002). The scale is symmetrical with no floor or ceiling effects (Sarker et al., 2012), and conforms to Guttman scaling properties allowing performance on individual items to be established from the total score, and changes in the score representing equivalent changes in ability (Nicholl et al., 2002). The NEADL has been designed to be suitable for telephone and postal administration, which provides a more cost- and time-effective method of ascertaining patients' functional abilities than a formal assessment. Thus, it was determined that the NEADL scale was the most appropriate measure to assess patients' ADLs in the study.

The NEADL comprises of 22 items divided into four subscales: mobility, kitchen, domestic, and leisure activities. The participants must rate their level of independence when completing specific activities, such as using public transport, washing their clothes, and making a hot drink, according to what they have actually done (as opposed to what they think they can do). Each item is rated as one of four responses (not at all = 0, with help = 1, on my own with difficulty = 2, and on my own = 3). Response items from each subscale are combined to give a score, with higher scores indicative of greater independence. For analysis in this study, response options 0 and 1 were coded as 0, and response options 2 and 3 were coded as 1. Response scores from each item were combined to give a total score of 22.

Measures of mood

Patients' mental health plays an important role in their recovery, and those who have preoperative anxiety and depressive symptoms (lower mental health score) have been found to be more often dissatisfied with the results following joint replacement surgery (Vissers et al., 2010; Duivenvoorden et al., 2013). As anxiety and depression are prevalent in individuals with OA (Memel et al., 2000; Rosemann et al., 2007), with

symptoms decreasing following THR (Duivenvoorden et al., 2013), it was determined that these specific mood states should be assessed using the Hospital Anxiety and Depression Scale (HADS).

- *Hospital Anxiety and Depression Scale (HADS)*

The HADS (Zigmond and Snaith, 1983) is a self-assessment questionnaire designed to determine levels of anxiety, depression and emotional distress in general hospital settings. The scale was not designed to be a clinically diagnostic tool (Whelan-Goodinson et al., 2009); however, it is a valid and reliable screening instrument for detecting mood disorder, specifically anxiety and depressive symptoms (Axford et al., 2010). The HADS contains 14 items, which are divided into an anxiety subscale and a depression subscale (each subscale has seven questions), with responses being scored on a scale of 0-3 (3 indicates higher symptom frequencies). Each subscale is scored between 0 and 21, with scores ≤8 deemed to be diagnostic of anxiety or depression. Scores for the entire scale (emotional distress) range from 0 to 42, with higher scores indicative of higher distress.

Health-related quality of life measures

The pain of OA has negative effects on HRQoL, including mood, sleep, and ability to participate in social and/or recreational activities (Hawker et al., 2008). With reductions in pain and improvements in functional ability following THR, patients experience better HRQoL (Judge et al., 2010). Therefore, it was considered important to assess the effect that THR has on patients' HRQoL during the recovery period.

- *Short Form – 36 (SF-36)*

The SF-36 (Ware and Sherbourne, 1992) was designed to survey health status in clinical practice and research. The SF-36 is a 36-item questionnaire that assesses eight health concepts, including functional status, well-being, and overall evaluation of health. The SF-36 is easy to use, reliable and valid (Brazier et al., 1992), and has been previously used in follow-up studies of THR (Bombardier et al., 1995; Nilsdotter et al., 2001). Whilst, the administration of the SF-36 can be conducted in person or by telephone, the response rate via post is significantly less than those seen in person (Dawson et al., 1996b); this could have been problematic for the study as participants were sent the questionnaires to complete by post. In addition, the SF-36 takes approximately 10 minutes to complete (Hayes et al., 1995) which was a potential burden to participants, especially when asked to complete several questionnaires.

- *European Quality of Life - 5D (EQ-5D)*

The EQ-5D questionnaire is an instrument designed to measure generic health outcomes, specifically HRQoL (EuroQoL Group, 1990). The EQ-5D is based on a descriptive system that defines health in terms of five dimensions: mobility, self-care, pain, usual activities, and psychological status. The 3-level EQ-5D (-3L) has been widely used and tested in various population groups, including patients having total joint replacement (TJR) (Conner-Spady et al., 2015); however, it has been found to contain ceiling effects for patient post-TJR (Giesinger et al., 2014), therefore limiting its effectiveness as an outcome measure for TJR. The 5-level EQ-5D (-5L) has less apparent ceiling effects than the 3L as it contains additional responses to reflect patients' HRQoL, which is believed to be severely affected by their pain and disability whilst waiting for TJR (Giesinger et al., 2014). The EQ-5D-5L has stronger validity that the EQ-5D-3L, especially for patients with OA waiting for TJR (Conner-Spady et al., 2015). The EQ-5D has been designed to be used in postal surveys, clinics, and face-to-face interviews, and therefore would be a suitable measure to be used in the study.

Participants' HRQOL was measured using EQ-5D-5L (Herdman et al., 2011), which evaluates and classifies respondents' health status into five domains (mobility, self-care, usual activities, pain/discomfort and anxiety/depression). The 5L was chosen as the 3L limits the description of the participants' restrictions and their range of responses. Each dimension has five levels of severity: no problems, slight problems, moderate problems, severe problems and extreme problems/unable to complete. The EQ-5D-5L was administered with a visual analogue scale (VAS) on which participants had rate their own health state from 0 (the worst imaginable) to 100 (the best imaginable), by marking the VAS with an 'X' between the two endpoints. Participants were required to write the number they marked on the scale in a box.

Sleep measures

Achieving good quality sleep is an important aspect of good physical and mental functioning, especially when recovering from surgery (Modi et al., 2012). In their postoperative protocols for THR, many hospitals instruct patients to sleep in a supine position for a period of time as part of hip precautions (Fielden et al., 2003; Youm et al., 2005). However, it has been implied that sleeping in a supine position can lead to sleep deprivation and is associated with increased anxiety and decreased satisfaction (O'Grady et al., 2003). Despite the relief of osteoarthritic pain and expected improvement in sleep quality (Fielden et al., 2003), there is an increased demand for

night sedation and analgesia (O'Grady et al., 2003). Patients frequently report discomfort and inability to sleep following THR, but little research has been conducted, and so sleep was believed to be an important outcome measure to assess for this study.

- *Epworth Sleepiness Scale (ESS)*

The ESS (Johns, 1991) is widely used as a measure of sleep disorders, in particular, excessive sleepiness in the daytime. The ESS has a significant correlation with the Multiple Sleep Latency Test and is widely used clinically (Chervin et al., 1997). In the ESS patients are asked to indicate the likelihood of falling asleep in eight common situations. The ESS was not a suitable measure to capture the aspects of sleep that the researcher was interested in.

- *Sleep diaries*

Sleep diaries are frequently used to monitor sleep quality as they provide an account of an individual's sleep schedule over a number of consecutive nights, including time going to bed, attempting to fall asleep, waking up, getting out of bed, nocturnal awakenings, and daytime napping. There are standardised sleep dairies available, such as the Consensus Sleep Diary (Carney et al., 2012) and the Pittsburgh Sleep Diary (Monk et al., 1994). Sleep diaries are validated and valuable tools in sleep research to quantify subjective sleep disturbances (Smith and Wegner, 2003). However, sleep diaries are not frequently used in pain research studies. It was determined that the use of sleep diaries for this study could be burdensome for the participants to complete sleep diaries for a number of consecutive nights, at several time points (baseline and follow-ups).

- *Pittsburgh Sleep Quality Index (PSQI)*

The PSQI (Buysse et al., 1989) assess sleep quality, primarily nighttime sleep quality and sleep disturbances. The PSQI is an internally consistent and valid measure of self-reported sleep in older men (Spira et al., 2011) and older women (Beaudreau et al., 2012). Therefore, the index is commonly used in clinical research studies and is considered the 'de facto gold standard' subjective measure of sleep quality (Landry et al., 2015). The PSQI is quick and easy to administer, with a process of scoring that can distinguish 'good' and 'poor' sleepers (Landry et al., 2015) Thus, the PSQI was selected as the sleep measure for this study.

The PSQI was used to examine the participants' quality of sleep over a one-month period. The original index consists of 10 questions; of these 10 questions, only questions 1 to 9 are used in the actual scoring of the PSQI, with question 10 used for clinical information only. Therefore, as question 10 is not tabulated in the scoring of the PSQI, it was not included in the questionnaire booklet for the research study. The nine question PSQI assesses seven sleep quality domains: sleep latency, sleep duration, sleep disturbances, habitual sleep efficiency, daytime dysfunction, subject sleep quality, and use of sleep medication. Each domain is scored from 0-3, where 0 = no symptoms or difficulty and 3 = severe symptoms or difficulty. The scores from each domain are summed to produce a Global PSQI Score, whereby a greater score (>5) is indicative of poor sleep quality.

Additional sleep questions

Previous research (Fielden et al., 2003; Peak et al., 2005; Modi et al., 2012) has shown the importance of sleep quality to patients following THR, and it was felt that the PSQI did not ask particular questions about sleep that the researcher was interested in. Thus, additional sleep questions were developed in conjunction with clinical staff and patient representatives, based on questions compiled by Modi et al. (2012) about compliance with sleep instructions following THR and from feedback obtained from patients. These questions included asking participants 'what position are you currently sleeping in?', 'have you received any advice regarding sleep?'.

Patient Satisfaction

Patient satisfaction is a well-recognised indicator for measuring health care quality and is often used by hospitals to monitor and improve service quality (Schaal et al., 2016). Overall patient satisfaction provides a gauge for self-perceived health after surgery (Baumann et al., 2009; Mancuso and Salvati, 2003; Lau et al., 2012). Following THR, there is predominately high patient satisfaction; despite this, there are between 7 and 16% patients who are dissatisfied (Jones et al., 2007; Mancuso and Salvati, 2003; Anakwe et al., 2011; Shan et al., 2014). Postoperative outcomes (symptoms and function) have been found to be strongly associated with patient satisfaction, regardless of prior expectations (Palazzo et al., 2014). Thus, it was important to determine patients' levels of satisfaction following THR with respect to the other outcome measures. However, no measures have been standardised to measure patients' satisfaction regarding rehabilitation and recovery to the researcher's knowledge.

Questions related to patient satisfaction were developed in consultation with a patient representative on the study steering committee and were discussed with the patients who piloted the questionnaires (see section 2.2.12.2.). Participants were asked, at six weeks and three months after their THR surgery, if they were satisfied with the outcome of their surgery, the rehabilitation programme they received, and the information they received relating to their recovery. Patient satisfaction questions had yes/no response options and there was space for participants to include reasons as to why they were satisfied or dissatisfied.

Other follow-up questions

In addition to above outcome measures, the follow-up questionnaires (six weeks and three months after THR surgery) also asked detailed questions on whether participants were currently taking any pain relief/painkillers or had been admitted and/or readmitted to hospital. Participants were also asked 'Is there anything about your hip or your recovery which we haven't asked you that you would like to tell us?', inviting them to disclose anything that was important to them in terms of their hip and recovery. This was to enable participants to further discuss their satisfaction (or dissatisfaction) about aspects of their care and treatment during their THR journey.

2.2.11.2. Data collected from medical notes

Demographic details

Data on gender, date of birth, living arrangements, place of residence on admission, and occupation were collected through participants' completion of the baseline questionnaire, and from patients' medical notes (including occupational therapy assessment notes) following their appointment at preoperative assessment clinic.

Medical information

Key medical conditions and/or comorbidities (e.g. rheumatoid arthritis, osteoporosis, diabetes, obesity (measured by body mass index: BMI)) were obtained via patients' medical notes. Patients' current key medication (e.g. for sleep, pain relief) was also obtained from their medical notes.

Surgical information

Relevant surgical information (e.g. side of the operation, surgical approach) was recorded from patients' medical notes.

Follow-up information

Information relating to deaths, falls, and hip dislocations was recorded at follow-up time points (six weeks and three months) and was obtained from the questionnaires and patients' medical notes. The audit office also assisted with the collection of information relating to hip dislocations (see section 2.2.14.).

2.2.11.3. Participant procedure

Following initial screening and recruitment into the study, participants completed the study questionnaire booklets at baseline, which occurred between their preoperative assessment appointment and their scheduled THR surgery. Participants who received a THR completed questionnaire booklets at three follow-up time points: 1) one week postoperatively (via telephone call), 2) six weeks (via post), and 3) three months post-surgery (via post). The outcome measures conducted at each assessment time point are displayed in Table 2.1, and the flow of the participant progress through the study is highlighted in Figure 2.2.

Baseline

Baseline questionnaires (see Appendix C.) were completed at the preoperative assessment clinic, following the participant's appointment with the clinicians or following hip school. Participants who were unable to complete the questionnaires due to time commitments were given the questionnaire booklet to take away to complete at home, along with a free post return envelope. Those who took the questionnaire booklets away were asked to return it at their earliest convenience, preferably within the next two weeks. The researcher was present at the clinic to assist participants who required help in completing the questionnaire booklet if necessary.

Relevant participant information (e.g. demographic and medical details) was collected from the medical notes, following the preoperative assessment clinic by the researcher. Surgical information was collected following patients' discharge from hospital (after THR surgery).

One week follow-up

At Nottingham City Hospital the clinical staff aim to discharge patients following a three-night stay post THR. Therefore, at one week postoperatively, participants were contacted via telephone by the researcher, using the contact details provided at their preoperative appointment relating to where they would be staying following discharge from hospital (e.g. own home, with relatives etc.). The researcher completed

measures of pain and function (OHS) with the participant over the phone and asked the participant if they had any specific difficulties relating to their hip or recovery. Details provided by the participants with regards to how they were coping with their recovery were noted at the end of the questionnaire booklet. Participants who had not been discharged were asked by the clinicians if they would be willing to complete the questionnaire booklet whilst still in hospital. Participants who were discharged to another hospital for rehabilitation, or to a care facility were contacted via their mobile phone number or an answer machine message was left asking them to return the call at their earliest convenience.

Six weeks follow-up

At six weeks postoperatively, participants were posted a covering letter inviting them to complete the follow-up questionnaire booklet enclosed (the same questionnaire measures as at baseline, with additional questions relating to recovery and satisfaction (Appendix D)); a free post envelope was also enclosed. If participants had not responded within two weeks of the postal date, the researcher contacted them via telephone, offering assistance to complete the questionnaire or to re-send the questionnaire booklet.

Three months follow-up

Three months post-surgery, covering letters were posted to all participants inviting them to complete the final follow-up questionnaire booklet (same measures and questions as the six weeks questionnaire (Appendix D)); a free post return envelope was also enclosed. Two weeks after the date of sending the questionnaire booklet, phone calls were made to those participants who had not responded, and a further copy of the questionnaire booklet was posted if required.

Table 2.1. Outcome measures conducted at four study time points

Measures	Preoperatively	Postoperatively		
	Baseline	One week	Six weeks	Three months
Demographic details	✓			
Medical information	✓			
Surgical information		✓		
Follow-up information			✓	✓
Oxford Hip Score	✓	✓	✓	✓
Nottingham Extended Activities of Daily Living Scale	✓		✓	✓
Hospital Anxiety and Depression Scale	✓		✓	✓
European Quality of Life – 5 dimensional	✓		✓	✓
Pittsburgh Sleep Quality Index (and additional sleep questions)	✓		✓	✓
Patient satisfaction			✓	✓
Rate of dislocation and revision surgery			✓	✓
Additional follow-up questions (e.g. pain relief, admitted to hospital)			✓	✓

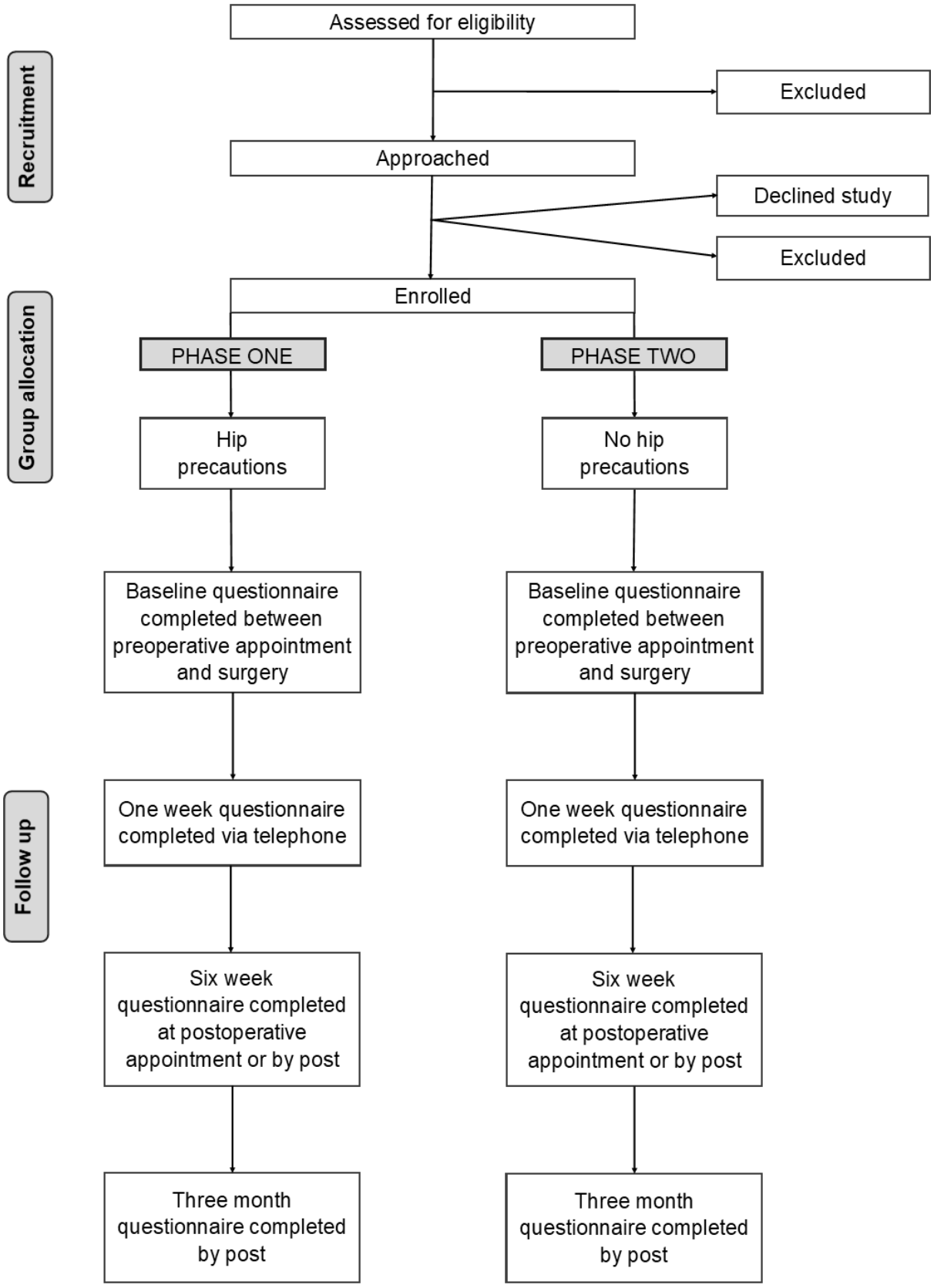


Figure 2.2. Flow diagram of the study

2.2.12. Questionnaire booklets

2.2.12.1. Preparation of questionnaire booklets

The outcome measures used in this study were presented in a questionnaire booklet (see Appendix C (preoperative) and D (postoperative)). Using a questionnaire booklet rather than several separate questionnaires made it easier for participants to progress through the document and increased their likelihood of completing all the questionnaires. The booklet was designed to be simple and with a layout that had a meaningful order and format.

The layout of the questionnaire booklet and the sequence of the questions was important in order to engage the participant. Following discussions with the steering group (including the patient representative), more patient-friendly headings for the standardised questionnaires were adopted. For example, the HADS was entitled 'mood and feelings', as it was believed that the words anxiety and depression might discourage a participant from completing the questionnaire. Also, the EQ-5D-5L was entitled 'Wellbeing'. However, the official titles of the measures and their references were included in smaller-sized, grey font as requested by the ethics committee.

The flow of questions was considered to be important as participants may have felt disconcerted if there was a difficult or unnatural flow from one question to the next, or if there were constant shifts from one topic to another. The questions were chosen to follow a particular order to keep the participant engaged. The initial questions asked the participant for basic information about themselves (e.g. date of birth, gender, and living arrangements) and therefore easy to answer. The second section of questions asked about the participant's hip; as the OHS relates to function it was logical for the 'activities of daily living' (NEADL) to follow. The longest questionnaire regarding sleep (PSQI) was placed in the middle of the questionnaire booklet, to prevent it from being too taxing on the participant and discouraging them to continue. Following the sleep questions, participants were asked about their 'mood and feelings' (HADS). Asking sensitive questions early on may have unsettled participants and discouraged them from completing the rest of the questionnaire booklet. Including the 'well-being' (EQ-5D-5L) questions after the HADS may have lifted the participant's mood as these questions were easier to answer. The questionnaire booklet concluded with an open-ended question (section for comments) inviting participants to include information relating to their hip, or recovery, that they felt was important. In the postoperative follow-up questionnaire booklets, the patient satisfaction questions were also situated

at the end. Although these questions were closed-ended, there was a designated space below each question inviting participants to discuss their answers in detail.

In addition to consideration of the order of the questionnaires within the booklet, it was also important that the standardised questionnaires were formatted into the same style for visual appearance. This was to ensure that there was flow between the separate questionnaires and that it was easy for participants to read, follow, and complete the questions within the booklet. The reformatting of the questionnaire did not change the content or the response format.

2.2.12.2. Piloting of questionnaire booklets

The questionnaire booklets were checked by two clinical staff (an occupational therapist and a physiotherapist) and a patient representative to assess their appropriateness. Following this, the questionnaire booklets were pilot tested with THR patients. The pilot testing was conducted to evaluate the acceptability of the questionnaire booklets, determine the time taken to complete them, and evaluate the extent to which instructions were followed. At the time of pilot testing, the researcher attended a hip school session to invite patients to complete the questionnaire booklets and provide feedback. Patients were initially screened against the study's eligibility criteria (see section 2.2.6.) before being recruited. Nine patients agreed to participate, completed the questionnaires and provided feedback. A range of coloured paper was also presented to the participants to determine which colours they preferred, to increase response rates. The time taken for each participant to complete the questionnaire was recorded by the researcher.

Feedback from the pilot tests was very positive in terms of the instructions, questions asked, and the layout of the questions and booklet. Minor alterations were made to the questionnaires based on comments from the participants, such as changing the question 'are you currently taking any medication to help you sleep' in the baseline questionnaire to 'have you taken pain relief medicine (prescribed or 'over the counter')?' and moving the question to the section on 'hip related problems' (OHS). Other changes included adding the phrase 'for your hip' to the question 'are you currently taking pain relief or painkillers' in the follow-up questionnaire, and changing the question 'have you been admitted to hospital since hip replacement surgery for either hip related or other problems' to include 'was it your hip?' or 'was it for other problems', if the participant had answered in the affirmative.

The time taken for the participants to complete the questionnaires ranged from 10-20 minutes. None of the participants who participated in the pilot test required assistance from the researcher to complete the questionnaires. Questionnaire booklets in bright pink, blue, green, red, and orange were rejected. Thus, purple, pale green, pale blue, and yellow coloured paper were chosen for the questionnaire booklets. Each questionnaire booklet was assigned a different colour in order to easily identify the time point of the booklet. The baseline questionnaire booklet was printed on pale blue paper, one week on yellow, the six weeks on purple, and the three months on pale green.

In addition to pilot-testing the questionnaires, participants were invited to assist with developing of the patient satisfaction questions (see 2.2.11.1. – patient satisfaction). Potential questions had already been deliberated with clinicians and the patient representative, but it was important to discuss these with current THR patients. Participants highlighted that the information received about THR, the surgical outcome, and the rehabilitation they received were aspects that they considered important and would greatly influence their levels of satisfaction with their THR. Thus, these were incorporated into the questionnaire booklet.

2.2.13. Data management

Throughout the study, steps were taken to minimise missing data by maintaining personal contact during the study period with the researcher. If any of the questionnaires returned were incomplete, the researcher contacted the participant by telephone to obtain the missing information where possible. This was in order to minimise the amount of missing data and to maximise full completion of individual outcome measures. A personalised approach is believed to increase response rates (Sahlqvist et al., 2011), and postal responses are known for much lower response rates than other data collection methods (Edelman et al., 2013).

All completed copies of the questionnaire booklets were stored in a locked filing cabinet at the University of Nottingham. Data were stored securely on a University of Nottingham computer, encrypted on a password protected folder and drive. Data were transferred from the questionnaire booklets to a Microsoft Excel spreadsheet for storage and then exported into SPSS for analysis.

All questionnaires were scored and entered by either a research assistant or the researcher. Following the completion of data collection, prior to analysis, a data quality check was carried out by the researcher and the research assistant. This involved checking a random 10% sample of each of the databases (10% for phase one data, and 10% for phase two), against the original paper questionnaire booklets for baseline and follow-ups.

2.2.14. Monitoring of adverse events/major complications

Hip dislocation is a well-documented complication following THR, which predominantly results in revision surgery. Hospitals within the UK, including Nottingham University Hospitals Trust (NUH), routinely collect hip dislocations in a rolling observational audit of all THR patients and publish the data on the National Joint Registry. The Trauma and Orthopaedic Audit Office at NUH are responsible for collecting a dataset of information regarding hip dislocations, including the mechanism and treatment of the dislocation.

> *"The case ascertainment at NUH for hip dislocations is high. All patients are audited on discharge, allowing the capture of major complications during their initial inpatient stay. For those readmitted as an emergency, the data is captured by the Trauma Audit Team, which has stringent processes in place to ensure attainment of all admissions. The audit data is routinely discussed in local Morbidity and Mortality (MandM) meetings, and occasionally passed as a report to the clinical lead".* [Information obtained from the Trauma and Orthopaedic Audit office at NUH].

During the study, the researcher had regular contact with NUH's Trauma and Orthopaedic Audit Office, who agreed to assist with the safety surveillance of the study by contacting the research team about identified study participants whose hip had dislocated.

Participants were asked in the follow-up questionnaires (six weeks and three months) if they had dislocated their hip and/or had received revision surgery. Patient medical records were also referred to, as well as contact with the Trauma and Orthopaedic Audit Office, to verify and identify the aetiology of the dislocation, treatment of dislocation, and revision surgery. A member of the research team (KRS, Consultant

Orthopaedic Surgeon) specifically monitored dislocation rates, in order to detect any obvious increase.

The occurrence of a serious adverse event (e.g. death, life-threatening adverse event, inpatient hospitalisation or prolongation of existing hospitalisation) as a result of participation in this study was not expected. However, deaths, falls, and hip dislocations were recorded at follow-up. This information was obtained from the questionnaire booklets and patients' medical notes. All serious adverse events were recorded and closely monitored. The principal investigator was informed immediately of any adverse events and determined the seriousness and causality.

If a patient scored highly on the HADS (scores ≥ 8), the researchers discussed the concerns with the chief investigator and the clinicians responsible for the care of the patient. Participants were also contacted by the researcher to discuss high scores on the HADS, and recommended to contact their GP to discuss this further as required.

2.2.15. Treatment fidelity

Treatment fidelity refers to the ongoing assessment, monitoring an enhancement of the reliability and internal validity of the study (Borrelli, 2011). It aims to increase the confidence that the changes in the targeted outcomes are due to the intervention under investigation (Robb et al., 2011), and includes methodological strategies that enhance the reliable and consistent behavioural intervention delivery during clinical trials (Bellg et al., 2004; Borrelli et al., 2005). Treatment fidelity consists of two components: 1) "treatment integrity", the degree to which the intervention (or treatment) was implemented as intended, and 2) "treatment differentiation", the degree to which study conditions (or two or more study arms) differed from one another in the intended manner, along critical dimensions (Moncher and Prinz, 1991; Kazdin, 1986; Yeaton and Sechrest, 1981; Lichstein et al., 1994). The benefit of treatment fidelity is that it allows for early detection of errors to prevent protocol deviations from becoming widespread and long-lasting, which could potentially affect the study's ultimate conclusion (Borrelli, 2011). Monitoring treatment fidelity early in study implementation increases the fidelity of implementation (DuFrene et al., 2005). High levels of treatment fidelity improve treatment retention and reduce attrition (Noel, 2006). Without the assessment of treatment fidelity, conclusive statements about the treatment effects cannot be made, as significant results may be the function of either an effective intervention or the influence of other unknown factors added into (or omitted from) the intervention (Borrelli, 2011).

As there was a change in service delivery, it was important to assess the fidelity of the treatment throughout the study, something which previous studies have failed to examine (see section 1.5.8.). The process evaluation to assess the fidelity of the treatment involved observing a sample of staff interactions with patients, in particular discussions about the therapy treatment and functional assessments. Two domains from Borrelli's (2011) guidelines for treatment fidelity were the main focus of evaluation: treatment delivery and treatment receipt. It was important to ensure that the clinicians were delivering the specified treatment during each phase, and that the patients understood the treatment they were receiving from the clinicians.

Treatment fidelity was measured during the washout phase to ensure the delivery of the treatment of no hip precautions was implemented, and that staff were adhering to the new regime of treatment. The delivery of treatment was not monitored prior to the change in the orthopaedic services as this has been routine practice for a number of years. During the washout phase, and phase two, there was an ongoing assessment and monitoring of the treatment delivery. The researcher conducted random observations on the orthopaedic wards, at preoperative assessment clinics, and hip school sessions, documenting interactions between clinical staff and patients. Field notes were completed detailing any errors observed of staff informing patients of hip precautions in the no precautions phase.

2.2.15.1. Role of hip champions

Hip champions assisted with the monitoring of the treatment fidelity throughout the study, ensuring that all clinicians were adhering to the delivery of the correct treatment for the relevant phase. The focus of the treatment fidelity assessments were mainly on the preoperative clinics and postsurgical wards, as these were the main contact points where clinicians educated patients about hip precautions. The evaluation provided a basis for staff education and supported them in the implementation of the new treatment programme. Hip champions informed the researcher of any errors that occurred and their actions in dealing with them. All protocol infringements, by both patients and staff, were recorded.

2.2.16. Proposed data analysis

The primary outcome of the study was the OHS (pain and function) at three months, and secondary outcomes included OHS, measures of ADLs (NEADL), mood (HADS), sleep (PQSI), QoL (EQ-5D), rate of dislocation, and patient satisfaction. Although measures were taken to reduce potential effects from confounding variables between the two groups, by the extrapolation of sample size, demographic and clinical characteristics were comparatively analysed.

When randomised trials cannot be implemented, approaches for inferences with comparative studies are required, including historical controls (comparing new treatment in a current series of patients with the old treatment in a previous set of patients). In order to make a valid inference, a number of assumptions are required, including the assumption of stable care (there were no systematic changes in care, unrelated to the intervention) and stable population (there were no changes between the two time periods in characteristics of the population) (Baker and Linderman, 2001). In other words, it can be assumed that patients in both groups received the same standard of THR care and treatment, with the exception of hip precautions; it can also be assumed that the patients who received the 'traditional' treatment in phase one (hip precautions) had the same distribution of unknown covariates as the patients who received the 'new' treatment in phase two (no hip precaution).

2.2.16.1. Equivalence testing

Statistical analysis typically involves testing for differences between two groups with Student's t-test and ANOVA often employed to compare the two sets of results. This usually tests for a 'zero-difference' hypothesis: "is it likely that no difference exists between two sets of results?". In these traditional comparative studies, the burden of proof rests on the research hypothesis to determine differences between the efficacies; however, if the evidence is not strong enough in favour of a difference then equality cannot be ruled out (Walker and Nowacki, 2011). Unlike traditional comparative studies, equivalence testing is often used to validate the fact that a difference is given in a different interval, using special statistical approaches that test the hypothesis that the difference between the groups falls within the a-priori specified region of equivalence. Previous research evaluating hip precautions has determined that there is no significant difference between the use of hip precautions and no hip precautions. Despite this, these studies cannot claim equivalence, as the negative results may simply be due to a lack of power. Thus, equivalence tests must be

employed to validate the equivalence between hip precautions and no hip precautions.

Schuirmann's (1987) Two One-Sided test (TOST) is the simplest and most widely used approach to assess for equivalence, thus was considered the most appropriate statistical test to determine equivalence between 'hip precautions' and 'no hip precautions'. The TOST is based on the classical t-test used to test the hypothesis of equality between two means. To put simply, the null and research hypothesis testing of equivalence are the reverse of those in traditional comparative studies. The null hypothesis in equivalence testing is that there is a true effect larger than the Smallest Effect Size of Interest (SESOI; Lakens, 2014). In other words, the null hypothesis states that there is an effect. For example, the null hypothesis of this study was:

> *There is a difference in the outcomes between patients who are prescribed hip precautions and patients who are not.*

Alternatively, the research hypothesis is that the effect is smaller than the SESOI and lies within the pre-determined equivalence range: an effect that is considered too small to matter or feasibly measure. Thus, the research hypothesis for this study was:

> The outcomes are equivalent (neither better nor worse) between patients who are prescribed hip precautions and patients who are not.

An upper and lower equivalence bound must be specified based on the SESOI. The TOST performs two tests: one to test if the effect is smaller than the upper bound limit of equivalence range (Δ_U), and one to test if the effect is larger than the lower bound equivalence range (Δ_L). When both these one-sided tests can be statistically rejected, we can conclude that the observed effect falls within the equivalence bounds and is close enough to zero to be practically equivalent (Seaman and Serlin, 1998).

For this study, the specified equivalence region, was set between -δ and +δ, where δ = 0.5 SD. To conclude that hip precautions and no hip precautions are equivalent, the observed effect must fall between -0.5 SD and +0.5 SD. If the effect lies outside this region, then it can be concluded that they are not equivalent. Figure 2.3 demonstrates the observed effect and the equivalence region; the blue line indicates that the confidence intervals (CI) fall within the equivalence bounds and can be deemed

equivalent, and the red line indicates that the CIs fall outside of the equivalence region thus non-equivalent.

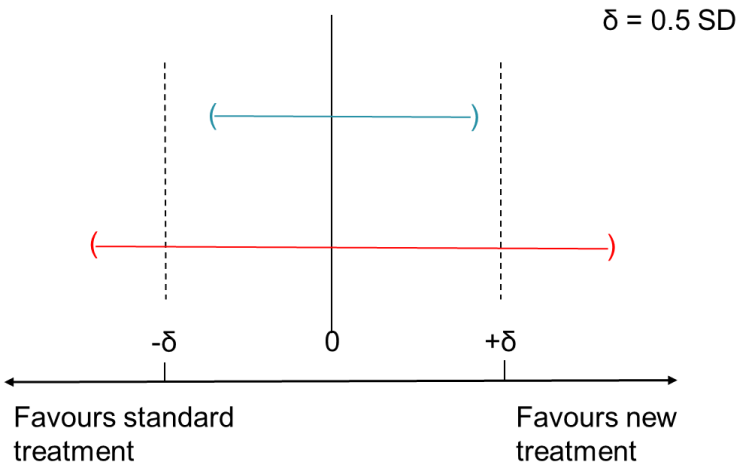


Figure 2.3. Confidence intervals from the two one-sided test. Adapted from Walker and Nowacki, 2011.

When equivalence tests are used, there are four possible outcomes of a study, illustrated in Figure 2.4:

1) the effect can be statistically equivalent (larger than Δ_L, smaller than Δ_U) and not statistically different from zero,
2) statistically different from zero but not statistically equivalent
3) statistically different from zero and statistically equivalent
4) undetermined (neither statistically different from zero or statistically equivalent)

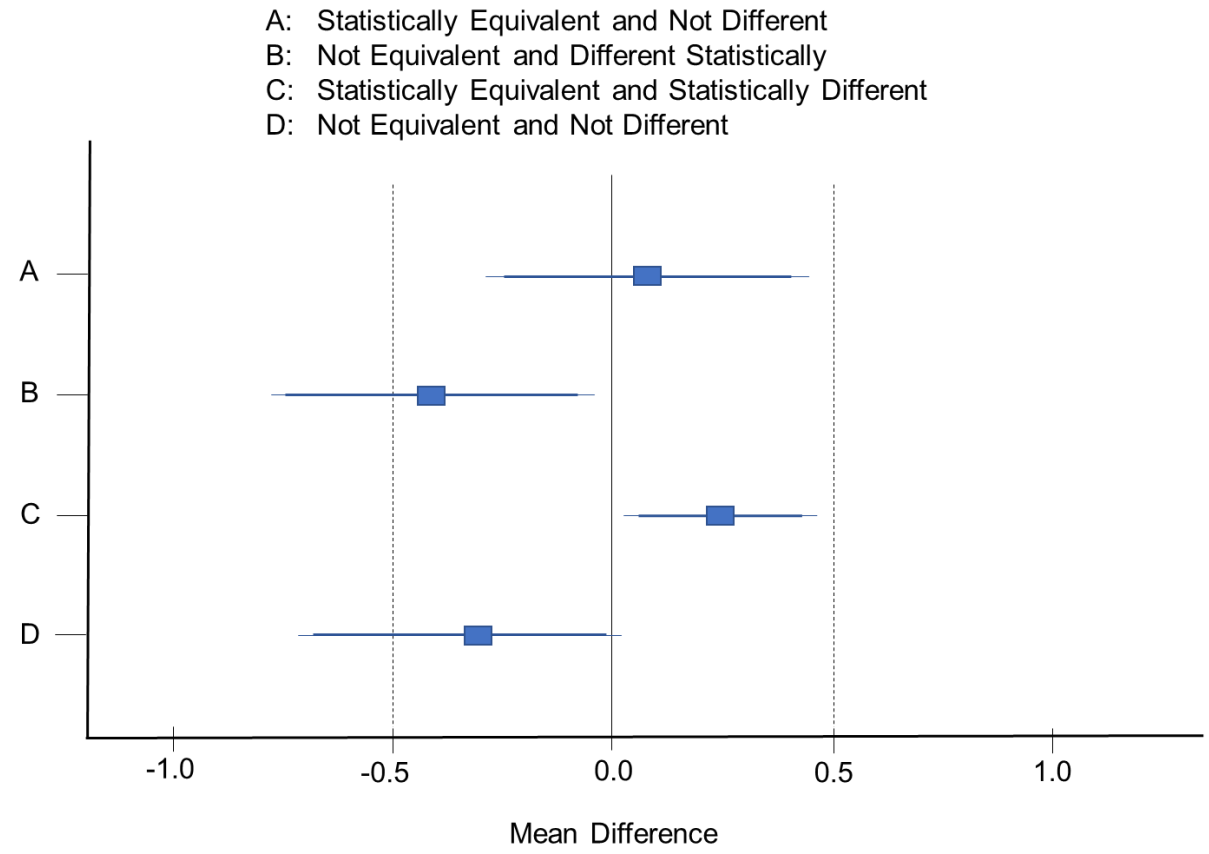


Figure 2.4. Illustration of four possible outcomes of a study when equivalence tests are used. Adapted from Lakens, 2017.

Figure 2.4. shows the mean differences (squares) and 90% confidence intervals (CI; thick horizontal lines) and 95% CIs (thin horizontal lines) with equivalence bounds Δ_L = -0.5 and Δ_U = 0.5 for four combinations of test results that are statistically equivalent or not and statistically different from zero or not. To conclude equivalence (scenario A), the 90% confidence interval (CI) around the observed mean difference should exclude the Δ_L and Δ_U values of -0.5 and 0.5.

The traditional two-sided null hypothesis significance test is rejected (scenario B) when the CI around the mean difference does not include 0 (vertical black line). Effects can be statistically different from zero and statistically equivalent (scenario C) when the 90% CI excludes the equivalence bounds and the 95% CI excludes zero. Finally, an effect can be undetermined, not statistically different from zero and not statistically equivalent (scenario D) when the 90% CI includes on one of the equivalence bounds and the 95% CI includes zero.

Generally a 90% CI (1 – 2 α) is used instead of a 95% CI (1 – α) because two one-sided tests (each with α of 5%) are performed. The two tests performed are completely dependently of each other. Using a 90% CI yields a 0.05 significant level for testing equivalence (Walker and Nowacki, 2011).

Primary analysis included testing for equivalence between the OHSs of the 'hip precautions' group and the 'no hip precautions' group at three months, using a TOST procedure. STATA has a TOST package to perform t-tests of mean equivalence. This package was used to test for equivalence between the OHSs of the two groups at three months (i.e. having no hip precautions is neither superior nor inferior to having hip precautions). In order to conclude equivalence, a difference small enough to reject that closeness is not due to sampling error from distributions centred on large effects must be observed. In other words, the efficacy of hip precautions and no hip precautions are close enough that, so that one is not considered superior, nor inferior, to the other. If the OHS of patients who do not follow hip precautions is within ±0.5 SD from that of the OHS of patients who follow hip precautions, then equivalence can be concluded.

Equivalence analysis was conducted in STATA 14 (Texas, USA), using the TOST program package (Dinno, 2017). Analysis was also conducted in a package for equivalence analysis developed by Lakens (2017) to corroborate the STATA output. The specified range of the equivalence margin was set between - δ and + δ, where δ = 0.5SD.

2.2.16.2. Secondary analysis

Secondary analysis included comparison of the hip precautions group and the no hip precautions group.

Prior to analysis, variables were checked for outliers and normal distribution via visual assessment of the frequency distribution and detecting marked departures from normality (stem-and-leaf plots and histograms). Where necessary, data were transformed (depending on the nature of distribution) to obtain normally distributed data, and to assess its relative effect on associated significance values. As parametric tests are robust and can allow for moderate departures from normality (Kirkwood and Sterne, 2003), the relevant statistical tests were performed using the raw data. Following this, the tests were performed using the transformed data to check the

findings. If the transformed data did not have a similar result to the raw data, then the relevant non-parametric tests were performed.

Secondary statistical analyses were performed using the statistical package IBM Statistical Package for Social Sciences (SPSS) Statistics for Windows, Version 24.0. (IBM Corp, 2016: Armonk, N.Y., USA). All data will be presented as mean (±SD) unless otherwise stated. Data analyses to compare two groups (e.g. hip precautions versus no hip precautions) involved univariate of analysis (ANOVA). A mixed-model (2 x 3 (2 x 4 for OHS) repeated measures) ANOVA was used to detect an effect of treatment (hip precautions versus no hip precautions) (treatment x time interaction). If an interaction or main effect of time was identified, post-hoc tests were used to identify within-group differences, and between-group differences at each time point. Significance was set at $P < .05$ for the analysis conducted, a trend was recognised as $P = .05–.10$. An effect size (ES) (η^2: small ≥.01; medium ≥.08; large ≥.26; very large ≥.50) was calculated to support the interpretation of differences.

Data were analysed using descriptive statistics for demographic, medical and surgical information. Text data from the comments sections were entered into a word document. These were then categorised.

Participants with missing data (e.g. did not complete a particular questionnaire) were included in the subsequent analysis of other measures. No data imputations were performed, and the number included in each analysis is reported. Analysis involved the intention-to-treat concept (ITT), and included all patients in the groups to which they were assigned, regardless of their adherence with the criteria, treatment they received, and subsequent withdrawal from treatment or deviation from the protocol (Fisher et al., 1990). Intention-to-treat analyses are often used to assess the clinical effectiveness of treatments as they mirror actual practice, when not everyone adheres to the treatment, and the treatment people have may be changed according to how their condition responds to it (National Institute for Health and Care Excellence (NICE), 2018). The analysis ignores noncompliance and protocol deviations after allocation and accepts that they are likely to occur in clinical practice. It limits inferences based on arbitrary or ad hoc subgroups of patients and emphasizes greater accountability for all patients enrolled in the study, and also minimises type 1 error due to cautious approach and allows greatest generalisability (Gupta, 2011).

A protocol paper was published for the HippityHop study (Lightfoot et al., 2018).

3

Before and After Study Results

3.1. Introduction

This chapter presents the results of the before and after study. It presents the flow of participants in the study, baseline data, primary and secondary outcome measures, patient satisfaction levels, and dislocation rates.

3.2. Study sample

3.2.1. Participant recruitment

The study opened for recruitment on 9th January 2017 and closed on 12th January 2018. Recruitment for phase one began on 9th January 2017 and finished 20th June 2017. The washout phase commenced on 24th July 2017. Recruitment for phase two began on 4th September and finished on 12th January 2018. The final surgery was completed on 25th April 2018, and follow-up questionnaires were returned by 24th August 2018.

A total of 569 patients who were scheduled to receive a THR during the study recruitment period, and had received an invitation to participate in the study, were approached at their preoperative assessment appointment (302 patients in phase one, and 267 patients in phase two). Across both phases of the study 367 (64.5%) of the patients, who were approached, enrolled to participate in the study: 182 patients in phase one, and 185 patients in phase two. Of these patients, 332 (90.5%) returned their baseline questionnaires before their THR surgery, with 173 questionnaires returned in phase one and 159 in phase two. Figure 3.1. shows the recruitment figures and the flow of participants through phase one and phase two of the study.

The follow-up period for the study started in February 2017 and ended in August 2018. A cancellation in elective surgery during January and February 2018, due to winter pressures, delayed patients' surgeries and thus their follow-up questionnaires (see section 3.7.9.2.). The washout period was reduced from two months and lasted six weeks.

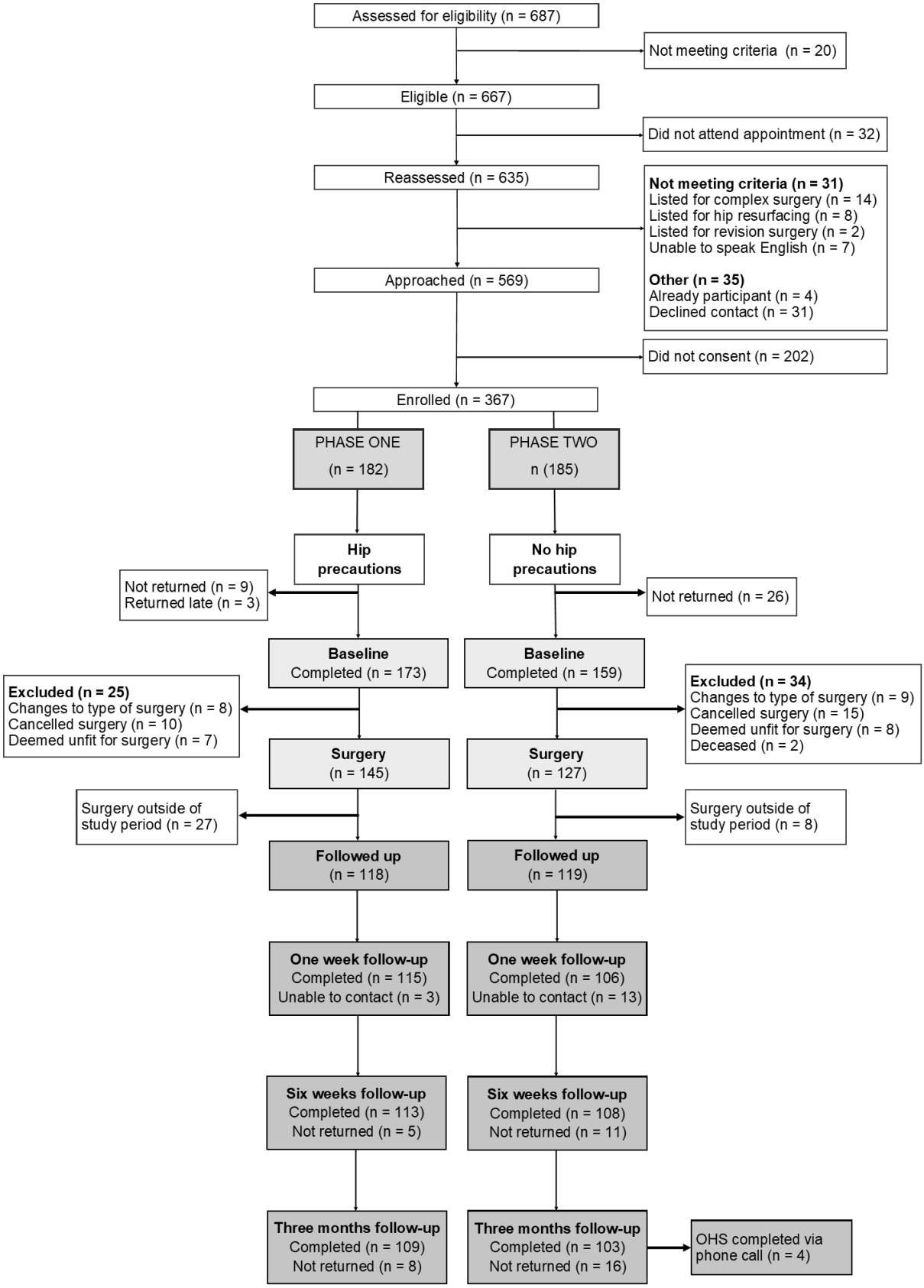


Figure 3.1. Recruitment and flow of participants

Phase one

In phase one, a total of 52 participants were excluded from the analysis:

Twenty-five participants were excluded following receipt of their baseline questionnaire. Eight were excluded to a change in the type of surgery received; participants were originally listed as primary THR but the type of surgery they received was changed to either a hip resurfacing or complex surgery prior to, or during, the surgical procedure. Ten participants' surgery was cancelled either by themselves or by the surgeon, as they no longer required surgery or wished to receive alternative treatment (e.g. steroid injections). Seven participants were deemed unfit for surgery following referrals to specialists (e.g. anaesthetist, cardiologist, pulmonologist, etc.).

Of the 145 phase one participants who returned their questionnaire and underwent a primary THR, a further 27 of these participants were excluded from the study as they received their THR following the change in service (after 24th July 2017). These participants had been recruited to phase one, and thus were educated about hip precautions preoperatively, however, they received their surgery during the washout phase when hip precautions had been withdrawn from practice, and therefore, these participants were not taught hip precautions postoperatively. As the participants received conflicting information relating to hip precautions, these participants were removed from the main group to avoid any potential contamination. These participants were not included in the main analysis, and the results will not be reported in this thesis.

Thus, data analysis was conducted for a total of 118 participants in the phase one (hip precautions) group.

Phase two

In phase two, a total of 42 participants were excluded from the analysis:

Thirty-four participants were excluded following receipt of their baseline questionnaire. Nine participants were withdrawn from the study due to the type of surgery they of received. Eight were considered to be medically unfit for surgery. Fifteen participants' surgeries were cancelled; a small number of surgeries (seven participants) were cancelled due to no beds being available as a result of winter pressures, and the new surgery dates for these participants were not within the study period (see section 3.7.9. for more detail/information). Two participants died following the return of their questionnaire and prior to their surgery. Of the 127 participants who returned their questionnaires and had surgery dates, a further eight were excluded as

these participants had surgery dates outside of the PhD data collection period (after 25th April 2017).

Thus, data analysis was conducted for a total of 119 patients in phase two (no hip precautions) group.

3.3. Demographics/patient characteristics

Table 3.1. shows the demographic and clinical characteristics of the 118 phase one (before) participants and 119 phase two (after) participants. Despite not being randomised, the groups were visually well matched on all variables.

The mean age overall was 67.5 years (SD = ±10.6), and two-thirds of participants were female (66.5%). Across the study, the majority of participants were retired (66%) and lived with family members, including spouse, partner, parent(s), and children (72%). Only 66 (28%) participants lived alone, and 64 (27.5%) were employed.

In regard to pain relief for their hip, over 90% of participants in both groups took some form of pain relief, with over half taking pain relief every day. Over half the participants (54%) were taking prescribed non-opioid analgesics (e.g. paracetamol, co-codamol), a fifth (19%) were taking opioid analgesics (e.g. codeine, morphine, tramadol), and a quarter (26%) were taking non-steroidal anti-inflammatory (NSAIDS) drugs (e.g. ibuprofen, naproxen). All participants had OA, with this listed as the main reason for surgery in almost all the patients; a small number of participants also had secondary causes, including dysplasia (abnormality of hip joint, usually results from development in childhood), rheumatoid arthritis (RA: an autoimmune disease that causes inflammation in your joints), and avascular necrosis (AVN: cellular death of the components of bone as a result of blood loss to the bone).

There was a preponderance of THR performed using the posterior approach compared to other surgical approaches and there were also more right-sided THR performed in both groups. The after group had a small number of participants (3%) who received a THR using the posterolateral approach, but this approach was not used in phase one. Both groups were otherwise well-matched in terms of surgical factors.

Table 3.1. Participant demographic, medical and surgical details

	Hip precautions (n = 118)	**No hip precautions (n = 119)**
Age (years)	67.0 (±11.1)	68.3 (±9.9)
Sex (*n* female) (%)	73 (62)	85 (71)
Height (cm)	166.8 (±10.1)	165.6 (±9.3)
Weight (kg)	81.2 (±17.3)	80.2 (±19.0)
BMI (kg/m2)	29.1 (±5.34)	29.1 (±8.85)
Lives alone (Y) (%)	38 (32)	28 (24)
Employment, *n* (%)		
- Employed (inc. self-employed)	36 (31)	28 (24)
- Retired	72 (61)	85 (71)
- Unemployed	6 (5)	6 (5)
- Other (e.g. housewife)	4 (3)	-
Pain relief (Y) (%)	107 (91)	112 (94)
Frequency pain relief, *n (%)*		
- Only 1 or 2 days	10 (8)	4 (3)
- Some days	20 (17)	25 (21)
- Most days	13 (11)	17 (14)
- Everyday	64 (54)	66 (55)
Medications, *n (%)*		
- Non-opioid analgesics	62 (53)	64 (54)
- Opioid analgesics	28 (24)	18 (15)
- NSAIDS	28 (24)	33 (28)
- DMARD	3 (3)	1 (1)
- OA supplements*	4 (3)	6 (5)
- Corticosteroid	2 (2)	12 (10)
- Osteoporosis treatment	13 (11)	16 (13)
Reason for surgery, *n (%)*		
- OA	114 (97)	115 (97)
- OA and dysplasia	3 (3)	2 (2)
- OA and RA	1 (<1)	1 (<1)
- OA and AVN	-	1 (<1)
Surgical approach, *n (%)*		
- Lateral	33 (28)	32 (27)
- Posterior	83 (70)	78 (66)
- Posterolateral	-	4 (3)
- Anterior	-	-
- Anterolateral	2 (2)	5 (4)
Side of THR surgery, *n (%)*		
- Left	45 (38)	51 (43)
- Right	73 (62)	68 (57)

NSAIDS = Non-steroidal anti-inflammatory drugs; DMARD = Disease modifying anti-rheumatic drugs; OA = Osteoarthritis; RA = Rheumatoid arthritis; AVN = Avascular necrosis;

3.4. Baseline data

Table 3.2. shows the results of the measures completed at baseline for both groups. Higher scores indicate better outcomes for the OHS, NEADL and EQ-5D, with higher scores signifying poorer outcomes for PSQI and HADS.

The means of all measures for both groups are similar, indicating that despite not being randomised or matched, the groups have similar levels of perceived pain and function, ability to perform ADL, sleep quality, mood, and HRQoL.

Table 3.2. Participant baseline measures

Measure	Hip precautions (n = 118)	No hip precautions (n = 119)
OHS	19.31 (±8.52)	20.33 (±7.47)
NEADL	18.15 (±3.82)	18.22 (±3.79)
PSQI	9.25 (±4.05)	9.95 (±4.13)
HADS - Anxiety - Depression	 6.01 (±4.04) 5.70 (±3.68)	 6.00 (±4.01) 5.70 (±3.82)
EQ-5D - Index - VAS (%)	 .43 (±.24) 63.1 (±19.3)	 .47 (±.21) 63.8 (±19.2)

Data presented as mean (±SD).

Table 3.3. shows participants' preferred sleep positions at the baseline time point. Over three-quarters of participants preferred sleeping on their sides, with just under a sixth of participants preferring to combine side sleeping with another position (e.g. front or back). The majority of participants (78-79%) reported that they were currently sleeping in their preferred position before surgery. The most commonly listed reason for participants who were not sleeping in their preferred position was pain and discomfort. A small number of participants, approximately 6% (13/236), who had stated that they were sleeping in their preferred position, also reported experiencing pain and discomfort whilst sleeping.

Table 3.3. Participants preferred sleeping position before surgery

Sleep position	Preoperative	
	Hip precautions (n = 118)	No hip precautions (n = 118*)
Side, n (%)	88 (75%)	87 (74%)
Back, n (%)	5 (4%)	7 (6%)
Front, n (%)	4 (3%)	8 (7%)
Combination**, n (%)	20 (17%)	16 (14%)
Seated, n (%)	1 (1%)	0
Sleeping in preferred position, y (%)	93 (79%)†	92 (78%)†

* missing data. ** combination of either front, back, and/or side. † one participant stated Y/N.

3.5. Primary outcome results at three months

A TOST was conducted to assess for equivalence between the two groups OHS at three months post-surgery. As the raw data was not normally distributed (negatively skewed) there were concerns that the results may be false (positive or negative) and invalid conclusions drawn (Type I or Type II error). Although Schuirmann's TOST is fairly robust to slightly skewed data (Zhou, He and Yuan, 2004), a power transformation was applied to the data to normalise the distribution.

The TOST analysis was conducted on the raw data and the transformed data (squared, cubed, and to the power of four) to determine if there were differences in the results obtained. When the TOST procedure was performed on the transformed data, the results were significantly equivalent, and were, in fact, more significant ($p < .001$). The test was performed on three power transformations (squared, cubed, and power of four) and was still highly significant, so the same conclusions could be drawn as for the raw data. As the raw data is easier to interpret, and the results are very similar to the transformed data, this will be presented. The mean OHS at three months of each group is shown in Table 3.4.

Table 3.4. Participants Oxford Hip Scores at three months post-surgery

Measure	Hip precautions (n = 109)	No hip precautions (n = 107)
OHS	40.32 (±7.03)	41.14 (±6.46)

Data presented as mean (±SD).

The TOST procedure showed that the observed effect size (d = -.12) was significantly within the equivalent bound of Cohen's d: -.5 and .5, t (214) = 2.93, p = .002. Figure 3.2 shows the mean difference and the 90% CI with the equivalence bounds for the test results. The results show that the groups are statistically equivalent and not different.

Excluding the three participants whose hip had dislocated, the TOST procedure showed that the observed effect size (d = -.12) was significantly within the equivalent bound of Cohen's d: -.5 and .5, t (211) = 2.82, p = .003. Including participants whose hip had dislocated only increased the strength of the significance.

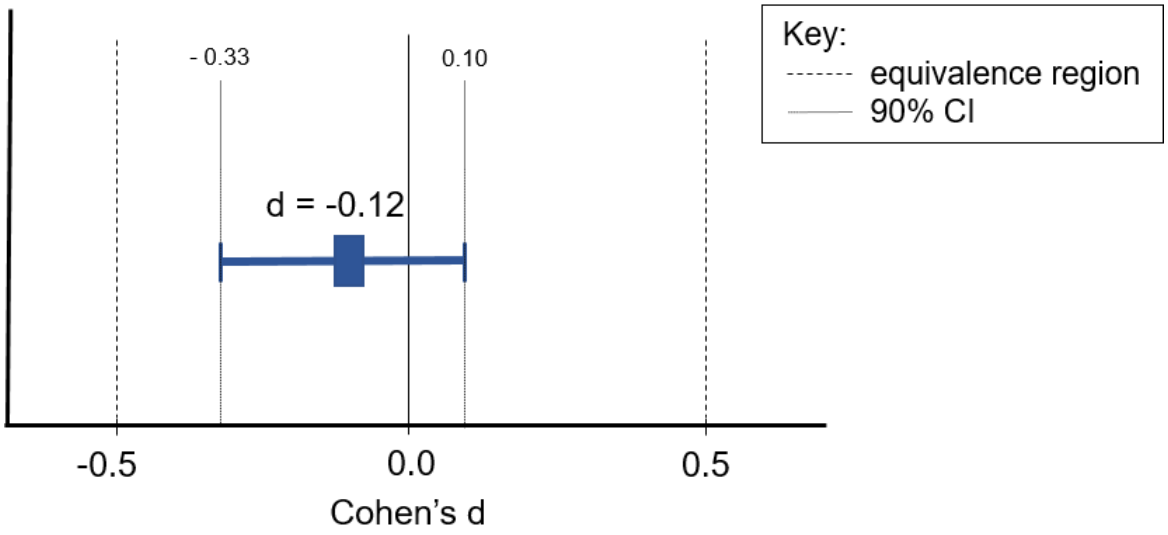


Figure 3.2. Differences of the Oxford Hip Score at three months post-surgery

3.6. Secondary outcome results

The data for the secondary analysis was also skewed. The raw data were transformed using power transformations (either squared or cubed) to determine if there were any differences in the results obtained. Again, the analysis with the transformed data produced similar results to the raw data, suggesting that the data had not departed significantly from normality, and that the parametric tests were robust enough for the departures from normality that were observed in the raw data. Thus, the results of the raw data will be presented and interpreted.

3.6.1. Self-reported pain and physical function (OHS)

To assess the effects of hip precautions and no hip precautions on participants' pain and function (OHS) over time, following surgery, a mixed-model ANOVA was conducted. Results showed a trending effect for the group (hip precautions vs no hip precautions) ($p = 0.098$, $\eta^2 = .014$, small), and showed a significant effect of time ($F [2.296, 440.783] = 454.348$, $p < .001$, $\eta^2 = .703$, very large) and a significant group x time interaction ($F [2.296, 440.783] = 7.570$, $p < .001$, $\eta^2 = .038$, small) (Table 3.5. Post-hoc tests identified significant improvements in OHSs between preoperative scores and postoperative scores (all three-time points), and between each of the postoperative time points, for both groups ($p < .001$). A significant difference was found between the groups at 1-week post-surgery ($F [1, 219] = 15.219$, $p < .001$). No significant differences were noted between the groups at the other time points. Both groups experienced similar improvements in self-report levels of pain and physical function following surgery and during their recovery. At one week post-surgery, the no hip precautions group had significantly greater OHSs than the hip precautions group, meaning the no precautions group had significantly greater function and lower pain levels at one week compared to the precautions group. However, at the other time points, both groups had comparable OHSs.

Table 3.5. Preoperative and postoperative Oxford Hip Scores of patients advised on hip precautions and patients who were not

OHS	Hip precautions (n = 106)	No hip precautions (n = 88)	P (η^2)	
			Group x time	Time
Baseline	19.72 (±8.24)	21.11 (±7.58)	<.001* (.038)	<.001* (.703)
One week	25.00 (±6.56)	29.20 (±7.26)		
Six weeks	35.64 (±6.67)	34.90 (±7.44)		
Three months	40.32 (±6.90)	41.05 (±7.00)		

Data presented as mean (±SD). Higher scores = better outcomes, greater function and less pain.

3.6.2. Activities of daily living (NEADL)

A moderate main effect of time for participants' ability to perform ADLs (NEADL) was observed (F [1.963, 394.568] = 58.986, p <.001, η^2 = .225, medium) (Table 3.6. Follow-up tests showing a significant decrease from baseline scores to six weeks post-surgery (p =.001), and a significant increase in scores from six weeks to three months (p <.001); there were also significant differences between pre-surgery and 3 months post-surgery scores (p <.001). However, there was no significant difference between hip precautions and no hip precautions (p = .683, η^2 = .001), or a significant group x time interaction (p = .559, η^2 = .003). Both groups experienced similar improvements in their ability to perform ADLs following surgery and during their recovery.

Table 3.6. Preoperative and postoperative Nottingham Extended Activities of Daily Living scores of patients advised on hip precautions and patients who were not

NEADL	Hip precautions (n = 107)	No hip precautions (n = 96)	P (η^2)	
			Group x time	Time
Baseline	18.38 (±3.71)	18.35 (±3.72)	.562 (.003)	<.001* (.225)
Six weeks	17.50 (±4.19)	16.99 (±3.71)		
Three months	20.17 (±2.47)	20.20 (±3.38)		

Data presented as mean (±SD). Higher scores = better outcomes, able to perform a greater number of ADLs.

3.6.3. Sleep quality

3.6.3.1. PSQI

A large significant effect of time for sleep quality was observed (F [1.917, 385.321] = 77.282, p <.001, η^2 = .278, large) (Table 3.7.), with follow-up tests showing significant decrease from baseline scores to six weeks post-surgery (p <.001) and from six weeks to three months (p <.001); there were also significant differences between pre-surgery and 3 months post-surgery scores (p <.001). There was no significant difference between participants who received hip precautions and those who did not (p = .563, η^2 = .002), or a significant group x time interaction (p = .396, η^2 = .005). Both groups experienced similar improvements in their quality of sleep following surgery and during their recovery.

Table 3.7. Preoperative and postoperative Pittsburgh Sleep Quality Index scores of patients advised on hip precautions and patients who were not

PSQI	Hip precautions (n = 107)	No hip precautions (n = 96)	P (η^2)	
			Group x time	Time
Baseline	9.03 (±4.03)	9.73 (±4.09)	.396 (.005)	<.001* (.278)
Six weeks	7.79 (±4.59)	7.93 (±4.19)		
Three months	6.15 (±4.30)	6.18 (±4.30)		

Data presented as mean (±SD). Higher scores = worse outcomes.

3.6.3.2. Additional sleep questions

Sleep positions

Participants preferred sleeping position are shown in Table 3.8. Before surgery, approximately three-quarters of participants preferred to sleep on their side (175/236), with a small number preferring to sleep on their back (12/236, 5%) or front (12/236, 5%), and almost a seventh of participants (15%) sleeping in a combination of these positions. Participants preferred sleeping position was similar postoperatively, although approximately 5% participants who preferred sleeping on their side preoperatively, preferred sleeping in a combination of positions postoperatively.

Table 3.8. Participants preferred sleeping positions

Sleep position	Baseline		Six weeks		Three months	
	Hip precautions (n = 118)	No hip precautions (n = 118*)	Hip precautions (n = 113)	No hip precautions (n = 108)	Hip precautions (n = 108*)	No hip precautions (n = 103)
Side	88 (75%)	87 (74%)	87 (77%)	74 (69%)	81 (75%)	72 (70%)
Back	5 (4%)	7 (6%)	4 (4%)	7 (6%)	4 (4%)	5 (5%)
Front	4 (3%)	8 (7%)	4 (4%)	6 (6%)	5 (4%)	6 (6%)
Combination**	20 (17%)	16 (13%)	17 (15%)	21 (19%)	18 (17%)	20 (19%)
Seated	1 (1%)	0	1 (<1%)	0	0	0

Data presented as n, (%). * missing data for participants. ** combination of either front, back, and/or side

Table 3.9. The length of time that participants were advised to sleep on their back

Length of time	Six weeks postoperatively		Three months postoperatively	
	Hip precautions (n = 111)	No Hip precautions (n = 70*)	Hip precautions (n = 104)	No Hip precautions (n = 66*)
< 6 weeks	7 (6%)	11 (16%)	4 (4%)	5 (8%)
6 weeks	78 (70%)	33 (47%)	76 (73%)	36 (55%)
> 6 weeks	14 (13%)	-	16 (16%)	3 (4%)
Not specified	4 (4%)	6 (1%)	-	3 (4%)
Unable to recall	3 (3%)	-	3 (3%)	5 (8%)
Until comfortable	-	7 (10%)	-	9 (14%)
Conflicting information	-	7 (10%)	-	2 (3%)
Other	4 (4%)	1 (1%)	1 (<1%)	1 (1%)
Missing data	1 (<1%)	5 (7%)	4 (4%)	2 (3%)

Data presented as n, (%). * participants who reported Y/N on the questionnaire and were initially advised to sleep on their back

Supine sleeping

- Advised length of time

The length of time that participants were advised to sleep on their back is shown in Table 3.9.

Six weeks

At six weeks post-surgery, 98% (111/113) participants in phase one reported being advised to sleep on their back. Of those, 70% (78/111) were advised to sleep on their back for six weeks, 9% (10/111) for six to eight weeks or until their outpatient follow-up appointment (usually six to eight weeks following surgery). Four participants stated that they were not given a time limit, and three did not know how long they were supposed to sleep on their back for. Four commented “all night”, which we assumed inferred they were advised to sleep on their back. The other participants’ answers ranged from one week to ten weeks.

In the no precautions group, 64% (69/108) participants reported that they were advised to sleep on their back and 35% (38/108) were not. One participant in this group (1/108, 1%) commented that they received mixed advice about whether to sleep on their back or not, initially being advised to sleep on their back before being told that they could sleep in the most comfortable position. Of those advised to sleep on their back (including the participant who was initially advised to), almost half the participant (33/70, 47%) were advised to do this for six weeks (Table 10). Ten participants (10/70, 14%) were advised to sleep on their back for three to four weeks, one participant for two weeks, and seven (7/70, 10%) until they felt comfortable to change position or sleep on their side. Seven (7/70, 10%) participants stated that they received mixed information either from staff members or between written and verbal information, and six (6/70, 9%) participants commented that they were unsure or could not remember. One participant reported that they were advised to sleep on their back all the time, and four participants did not comment.

Of the participants who were advised to sleep on their back (including the participant who was initially advised), 71% (79/111) in the hip precautions group and 70% (49/70) participants in the no precautions group found it difficult to sleep on their back. The most common reasons listed were ‘uncomfortable’, ‘not their usual sleeping position’, ‘back and/or hip pain’, ‘unable to get to sleep’, and ‘dry mouth’.

Three months

At three months postoperatively, 95% (104/109) stated that they were advised to sleep on their back, two participants did not respond, and one participant commented 'can't remember'. Of the participants who were asked to sleep on their back, almost three-quarters (76/104, 73%) were advised to sleep on their back for six weeks. Sixteen participants (16/104, 16%) reported that they were advised to sleep on their back for more than six weeks, and four participants (4/104, 4%) for less than six weeks. One participant stated that they were advised to sleep on their back 'all the time'. Three participants could not recall the length of time advised, four participants did not comment.

In the no precautions group, 62% (64/103) reported that they were advised to sleep on their back and 36% (37/103) were not. Two participants in this group (2%) commented that they received mixed advice about sleeping on their back. Of those advised to sleep on their back, over half (56%, 36/64) were advised to do this for six weeks, with just under a fifth (17%, 11/64) advised to do so until they felt comfortable to sleep in another position or were given no specific timeframe (Table 10). Three participants (5%) were asked to sleep on their back for more than six weeks, and four (6%) for less than six weeks. One participant stated that they were advised to sleep in their back 'all night', five participants (8%) could not recall on the length of time they were advised to sleep on their back for, and two participants did not comment.

Of those participants who were advised to sleep on their back, 73% (76/104) participants in hip precautions group and 80% (51/64) participants in the no precautions group found it difficult to sleep on their back following surgery.

- Reported length of time

The length of time that participants reported that they slept on their back is displayed in Table 3.10.

Six weeks

In the hip precautions group, 40% (44/111) participants reported sleeping on their back for six weeks following surgery, 20% (22/111) for less than six weeks, and 18% (21/111) for more than six weeks. Another 20% (22/111) of participants in this group reported other lengths of time, including reporting the number of hours (or minutes) they slept on their back per night, and stating 'all night' or 'all the time'.

For the participants who were not advised hip precautions, 11% (8/70) reported sleeping on their back for six weeks. Only 4% (3/70) of participants reported sleeping on their back for longer than six weeks before returning to their preferred sleep position, and 6% (4/70) participants were still sleeping on their back at the time of completion of the questionnaire. Over half the participants (38/70, 55%) reported sleeping on their back for less than six weeks.

Three months

In the hip precautions group, 33% (34/104) participants reported sleeping on their back for six weeks following surgery, 25% (26/104) for less than six weeks, and 29% (30/104) for more than six weeks. Six (6/104, 6%) participants continued to sleep on their back after six weeks. Six (6/104, 6%) participants were still sleeping on their back at the time of the three-month follow-up questionnaire.

For the participants who were not advised hip precautions, just over a quarter of participants (18/66, 27%) reported sleeping on their back for six weeks, and 14% (9/66) participants reported sleeping on their back for longer than six weeks but resuming other positions prior to the competition of the three-month questionnaire. Six (6/66, 9%) participants were still sleeping on their back at the time of completion of the three-month questionnaire. Less than half the participants (28/66, 42%) reported sleeping on their back for less than six weeks.

Table 1. Length of time that participants reported having slept on their back

Length of time after surgery (weeks)	Six weeks		Three months	
	Hip precautions (n = 111)	No Hip precautions (n = 70*)	Hip precautions (n = 104)	No Hip precautions (n = 66*)
≤2	4 (4%)	11 (16%)	4 (4%)	8 (12%)
2-4	11 (10%)	23 (33%)	14 (13%)	14 (21%)
4-6	7 (6%)	4 (6%)	8 (8%)	6 (9%)
6	44 (40%)	8 (11%)	34 (33%)	18 (27%)
6-8	20 (18%)	2 (3%)	14 (13%)	7 (11%)
8+	1 (<1%)	1 (1%)	10 (10%)	2 (3%)
Still on back	-	4 (6%)	6 (6%)	6 (9%)
Not a full night†	14 (13%)	10 (14%)	7 (7%)	3 (5%)
Usual position	1 (<1%)	-	2 (2%)	-
Other	7 (6%)	4 (6%)	4 (4%)	2 (3%)
Missing data	2 (2%)	3 (3%)	1 (<1%)	-

* includes participants who reported Y/N on the questionnaire and were initially advised to sleep on their back. † reported the number of minutes or number of hours

3.6.4. Mood and feelings – anxiety and depression (HADS)

Both groups had a similar number of participants that reported symptoms of anxiety and depression preoperatively and postoperatively (Table 3.11.). Although the mean anxiety and depression scores fell within the normative range (Tables 3.12. and 3.13.) (subscale score ≤ 7), 27% (65/237) of participants had mild symptoms of depression and 31% (73/237) had mild symptoms of anxiety preoperatively (score ≥8). Approximately half of the participants in the study who reported symptoms, experienced severe levels of anxiety (55%, 40/73) and depression (46%, 30/65) symptoms (score ≤ 11) preoperatively. Symptoms of anxiety and depression decreased across both groups at six weeks and three months following surgery.

Table 3.11. Number of participants reporting mild (≥8) and severe (≥11) levels of depression and anxiety symptoms

	Preoperatively		Postoperatively			
			Six weeks		Three months	
	Hip precautions (n = 118)	No hip precautions (n = 119)	Hip precautions (n = 113)	No hip precautions (n = 108)	Hip precautions (n = 108)	No hip precautions (n = 103)
Depression (≥8), n (%)	34 (29%)	31 (26%)	16 (14%)	16 (15%)	11 (10%)	8 (8%)
Anxiety (≥8), n (%)	34 (29%)	39 (33%)	18 (16%)	19 (18%)	12 (11%)	15 (15%)
Depression (≥11), n (%)	17 (14%)	13 (11%)	6 (5%)	6 (6%)	4 (4%)	2 (2%)
Anxiety (≥11), n (%)	16 (14%)	24 (20%)	5 (4%)	8 (7%)	5 (4%)	5 (5%)

Data presented as n, (%). Higher scores = worse outcomes, a greater number of symptoms

3.6.4.1. Depression

A significant effect of time was observed for participants' feelings of depression (HADS-D) ($F [1.690, 337.919] = 89.157$, $p < .001$, $\eta^2 = .308$, large) (Table 3.12.), with follow-up tests showing significant decrease in depression scores between preoperative scores and six weeks postoperative scores ($p < .001$), and six weeks and three months scores ($p = .001$). There was no significant difference between patients who received hip precautions and those who did not ($p = .868$, $\eta^2 = .000$), or a significant group x time interaction ($p = .711$). Both groups experienced similar reductions in symptoms of depressive following surgery and during their recovery.

Table 3.12. Preoperative and postoperative Hospital Anxiety and Depression Scale - Depression scores of patients advised on hip precautions and patients who were not

HADS - D	Hip precautions (n = 106)	No hip precautions (n = 96)	P (η^2)	
			Group x time	Time
Baseline	5.53 (±3.58)	5.31 (±3.58)	.711 (.001)	<.001* (.308)
Six weeks	3.19 (±3.32)	3.30 (±3.14)		
Three months	2.69 (±3.32)	2.59 (±3.02)		

Data presented as mean (±SD). Higher scores = worse outcomes, greater levels of depression.

3.6.4.2. Anxiety

Results of the mixed model ANOVA showed a significant effect of time for participants' levels of anxiety (HADS-A) (F [1.676, 335.202] = 99.078, p <.001, η^2 = .331, large) (Table 3.13.), with follow-up tests showing a significant decrease in anxiety scores between preoperative scores and six weeks postoperative scores (p <.001), and six weeks and three months scores (p = .011). There was no significant difference between hip precautions and no hip precautions (p = .994, η^2 = .000), or a significant group x time interaction (p = .703, η^2 = .001). Both groups experienced similar reductions in symptoms of anxiety following surgery and during their recovery.

Table 3.13. Preoperative and postoperative Hospital Anxiety and Depression Scale - Anxiety scores of patients advised on hip precautions and patients who were not

HADS - A	Hip precautions (n = 106)	No hip precautions (n = 96)	P (η^2)	
			Group x time	Time
Baseline	6.00 (±4.04)	5.99 (±4.00)	.703 (.001)	<.001* (.331)
Six weeks	3.82 (±3.79)	3.81 (±3.71)		
Three months	3.13 (±3.58)	3.19 (±3.44)		

Data presented as mean (±SD). Higher scores = worse outcomes, greater levels of anxiety.

3.6.5. Health-related quality of life – EQ-5D-5L Index (health state) and VAS (health status)

Results of a mixed-model ANOVA showed a significant effect of time for participants' health state (EQ-5D index) (F [1.575, 316.560] = 239.971, p <.001, η^2 = .544, very large) (Table 3.14), with follow-up tests showing a significant increase in scores between preoperative scores and six weeks postoperative scores (p <.001), and six weeks and three months scores (p <.001). There was no significant difference between patients who received hip precautions and those who did not (p = .621, η^2 = .001), or a significant group x time interaction (p = .297, η^2 = .006). Both groups experienced similar improvements in their health state following surgery and during their recovery.

Table 3.14. Preoperative and postoperative EQ-5D Index (health state) scores of patients advised on hip precautions and patients who were not

EQ-5D Index	Hip precautions (n = 107)	No hip precautions (n = 96)	P (η^2)	
			Group x time	Time
Baseline	.43 (±.24)	.48 (±.21)	.297 (.006)	<.001* (.544)
Six weeks	.71 (±.17)	.70 (±.17)		
Three months	.78 (±.17)	.79 (±.18)		

Data presented as mean (±SD). Higher scores = better outcomes, greater health state

A significant large effect of time for participants' health status (EQ-5D VAS) was observed (F [1.643, 328.502] = 106.837, p <.001, η^2 = .348, large), and a trending group x time interaction (F [1.643, 328.502] = 2.696, p = .080, η^2 = .013, small) (Table 3.15.). Post Hoc tests showed no significant differences between the groups (hip precautions and no hip precautions) at any of the time points. The follow-up test showed a significant increase in scores between preoperative scores and six weeks postoperative scores (p <.001), and six weeks and three months scores (p = .004). There was no significant difference between hip precautions and no hip precautions (p = .568, η^2 = .002). Both groups experienced similar improvements in their health status following surgery and during their recovery.

Table 3.15. Preoperative and postoperative EQ-5D VAS (health status) scores of patients advised on hip precautions and patients who were not

EQ-5D VAS	Hip precautions (n = 106)	No hip precautions (n = 96)	P (η^2)	
			Group x time	Time
Baseline	63.10 (±19.27)	63.83 (±19.16)	.080 (.013)	<.001* (.348)
Six weeks	77.71 (±15.44)	75.81 (±14.22)		
Three months	81.53 (±13.59)	79.23 (±15.82)		

Data presented as mean (±SD). Higher scores = better outcomes, greater health status

3.6.6. Patient satisfaction

At the time of the six-week follow-up, participants in the precautions group (n = 113) reported a similar levels of satisfaction to those in the no precautions group (n = 108), with regard to their surgery (109, 96% vs. 105, 97%), rehabilitation program (101, 89% vs. 96, 89%), and the information that they received (107, 95% vs. 102, 94%).

Three months postoperatively, the precautions group (n = 109) still had greater levels of satisfaction than the no hip precautions group (n = 103) for surgery (106, 97% vs. 98, 95%), and the information provided (105, 96% vs. 94, 91%). However, the no precautions group had greater levels of satisfaction for the rehabilitation program (91, 88%) than the hip precautions group (92, 84%). (n, % respectively)

3.6.7. Follow-up questions

Table 17. shows the number of participants who reported taking pain relief, experiencing a dislocation, or other significant complication, and readmissions to hospital. These data were collected from returned questionnaires.

3.6.7.1. Pain relief

At six weeks postoperatively, a greater number of participants in the no hip precautions group were still taking pain relief (60/108, 56%) compared to those in the hip precautions group (47/113, 42%). At three months, the number of participants in each group taking pain relief was similar, 26% in no precautions and 30% in precautions group.

Table 3.16. Additional information obtained at six weeks and three months follow-up

	Hip precautions		No hip precautions	
	Six weeks (n = 113)	Three months (n =109)	Six weeks (n = 108)	Three months (n = 103)
Pain relief, n (%)	47 (42%)	33 (30%)	60 (56%)	27 (26%)
Dislocation*, n (%)	1 (<1%)	1 (<1%)	1 (<1%)	2 (2%)
Significant complication, n (%)	26 (23%)	26 (24%)	19 (17%)	14 (14%)
Hospital readmission, n (%)	3 (3%)	4(4%)	10 (9%)	8 (8%)

* dislocations reported. No other dislocations occurred within the two groups.

3.6.7.2. Dislocations

In the follow-up questionnaires, three participants reported suffering from a dislocation following their surgery (Table 3.16.). Other than the dislocations reported in the follow-up questionnaires, no other dislocations occurred during the study period. Of the three dislocations that occurred, two dislocations were in the no precautions group (2/119, 1.7%) and one in the precautions group (1/118, 0.8%). Two of the participants whose hips had dislocated received a THR using a posterior approach, and one using the anterolateral approach. The participants were each under the care of a different surgeon.

The dislocation in phase one occurred two weeks postoperatively, whilst the participant was travelling as a passenger in a car. One of the dislocations in phase two occurred three days postoperatively, following discharge home, while the patient was sitting on the sofa; the other dislocation occurred eight weeks postoperatively when the patient bent down to dry their feet, this participant experienced another dislocation six weeks after their first dislocation whilst bending down to pick something up off the floor. All patients initially underwent manipulation under anaesthesia (MUA) and received a Derby brace (hip abduction brace that prevents adduction and limits flexion of hip joint). This was successful for one of the participants. For one of the participants they remained unstable after the reduction and experienced a second dislocation while lying in a hospital bed wearing a Derby brace; consequently, this participant underwent revision surgery. The final participant who dislocated their hip successfully underwent MUA for the first dislocation; they experienced a second dislocation six weeks after their first, and subsequently received revision surgery.

The Trauma and Orthopaedic Audit Office at NUH recorded a total of 15 primary THR dislocations during the study period. Four of those patients received an MUA, and nine patients underwent revision surgery. Of the patients who underwent revision surgery, four occurred during phase one and three occurred during phase two. Two revisions were performed during the follow-up of phase two. No revision surgeries were performed during the washout period. Patients who dislocated and subsequently underwent revision surgery during the study period did not necessarily receive their THR during this time period.

3.6.7.3. Other complications relating to surgery

Six weeks

At six weeks postoperatively, 26 (of 113, 23%) participants who were prescribed hip precautions reported significant complications following their THR surgery. Nine participants (9/26, 35%) listed pain as a significant complication, and five participants (5/26, 19%) listed pain with either swelling, numbness, or nerve damage as a complication experienced following surgery. Four participants (4/26, 15%) reported wound problems following surgery, with three of those reporting wound infection. One participant (1/26, 4%) stated unitary tract infection (UTI) as a complication of surgery, and another listed deep vein thrombosis (DVT) as a significant complication experienced following surgery. Five participants (5/26, 19%) reported other complications, including muscle related problems (e.g. pulled muscle, muscle cramps/spasms) (2/26, 8%), nausea (1/26, 4%), low blood pressure (1/26, 4%), and other hospital-related (e.g. mental and physical injuries received in hospital) (1/26, 4%). One participant indicated that they suffered a complication but did not state what it was.

Of those participants who were not prescribed precautions, 26 (of 108, 24%) of those reported significant complications at six weeks after surgery. Seven participants (7/26, 27%) reported pain as a significant complication, and two (2/26, 8%) participants listed pain and swelling as a complication experienced following surgery. Five participants (5/26, 19%) reported wound problems, with two of those participants detailing the wound problem as a wound infection. Two participants (2/26, 8%) experienced a UTI, and one participant experienced a DVT. Seven participants (7/26, 27%) reported other complications including haematoma (2/26, 19%), allergic reaction to dressing (1/26, 4%), muscle-related problems (e.g. pulled muscle, muscle cramps/spasms) (3/26, 12%), and inability to fully weight-bear due to previous stroke (1/26, 4%).

Three months

At three months, 19 (19/109, 17 %) participants who were prescribed precautions reported complications. Of those, half (10/19, 53%) participants had previously documented their complication on the six weeks questionnaire. Of the additional nine participants, one of the participants had not returned their six-week questionnaire as they were staying on a rehabilitation ward at another hospital; they stayed on the orthopaedic ward for five weeks before being transferred to the rehabilitation facility. Two of the participants had fallen, one of the participants suffered a fractured finger, and the other had suffered broken ribs. Four participants listed pain as a complication experienced, and one had stated swelling as a significant complication. Another participant reported arthritis in their lower spine and knee as a significant complication experienced following their surgery.

Of the participants who were not prescribed precautions, 14 (14/103, 14%) reported significant complications. Eight (8/14, 57%) of these had previously reported complications at the six-week follow-up. Of the other six participants, two reported pain, two reported wound problems with one a wound infection, one reported sepsis and pneumonia, and the final participant did not specify.

3.6.7.4. Hospital admission

At six weeks follow-up, three participants in the hip precautions group (3/113, 3%) had been readmitted to hospital, following their surgery. One participant was readmitted due to dislocation of the hip. Another participant was readmitted due to an infection of the hip joint, which required a debridement operation (removal of damaged tissue or debris from a wound). The final participant was admitted due to chest and upper abdominal pain. At three months, another two participants had been readmitted to hospital, one for a THR on their other hip, and the other was for gallbladder surgery.

In the no hip precautions group, ten participants (10/108, 9%) had been readmitted to hospital within six weeks of their surgery. One participant was readmitted following the dislocation of their hip, two following a fall, and two resulting from DVT. One participant was readmitted due to their wound bleeding, one for suspected infection, one for a bladder problem (related to previous surgery), and another for pneumonia. At three months, a further two participants were readmitted, one for a dislocated hip, and another due to dizziness which resulted in collapse.

3.7 Discussion

The purpose of this before and after study was to pragmatically compare outcomes of patients who were prescribed hip precautions with those who were not and to determine the effects prescribing hip precautions, or not prescribing them, had on other patient outcomes following THR surgery.

3.7.1. Summary of main results

The main finding from the study is that participants who were not prescribed hip precautions following surgery had equivalent outcomes in regard to levels of pain and function (i.e. OHS, the main outcome measure), to those who were not. Patients also had similar outcomes for other measures: ability to perform daily activities, perceived HRQoL, sleep quality, and mood.

3.7.2. Pain and function (primary outcome)

Participants' levels of pain and function were equivalent at three months and were similar (i.e. not significantly different) at six weeks (equivalence analysis was not performed for six-week outcomes). These results suggest that both groups recovered at a similar rate following THR, and that patient outcomes were comparable at six weeks and three months after surgery whether they received precautions or not. The results reflect those reported by Ververeli et al. (2009), who found that hip pain and function (measured using Harris Hip Score, discussed in section 2.2.11.1.) of patients who received precautions was 'equivalent' (but note they did not conduct equivalence analysis) to those who did not at one month, and one year postoperatively. However, Ververeli et al. (2009) observed a small effect size at three months, albeit non-significant. Despite this, Ververeli et al. concluded that, on average patients, regained their full ROM and functions at the same rate. However, they also found that the removal of precautions resulted in a significant improvement (and a strong effect size (ES)) in the speed of recovery, in terms of the ability to walk without a stick (ES = 0.89) and walk without a limp (ES = 0.70). As the HippityHop study did not collect information relating to walking ability outcomes, these results cannot be compared.

A significant difference was found between the two groups only at one week post-surgery, whereby the no precautions group had significantly a greater OHS score. The higher the OHS score, the better the outcome in relation to pain and function. This might have been due to patients not being prescribed movement restrictions and thus they perceived that they had greater function. There was a mean score difference

of 4 points between the two groups at one week post-surgery. It was possible that this difference could be related to the questions asked. For example, one of the questions was 'have you been able to put on a pair of socks, stockings or tights?', where the action or movement to put a pair of socks on breaches using hip precautions unless an aid is used. Participants might not have attempted to put a pair of socks on as they were adhering to the precautions and at the time in which they were contacted, or they might not have mastered the technique to use an aid to assist with putting socks on. Alternatively, the patients who were in the no precautions group might have felt more confident about performing certain tasks as they had not been warned against or advised to restrict these movements. Previous research conducted by Jepson et al. (2016) assessing the feasibility of a preoperative occupational therapy intervention for patients undergoing THR reported a large proportion of missing data on some of their outcome measures (i.e. WOMAC and NEADL) at four weeks post-surgery. The authors suggested that participants may not have completed some of the four week questions as they contradicted with the routine hip precautions patients had to comply with following THR. This might have also been the reason for the differences observed at one week in this study. If the participants in the HippityHop study were expected to self-complete the one week questionnaire via the post, the response rate or amount of missing data might have been considerably greater than it was.

3.7.3. Return to activities of daily living

The results suggest that there was no difference in the number of ADLs participants were able to perform at each of the time points. These results did not reflect those from other previous studies that assessed the use of hip precautions and return to ADLs. Peak et al. (2005) noted that patients in the unrestricted (no precautions) group were able to perform a significantly greater number of ADLs compared to the patients in the restricted group (precautions) at six months postoperatively, 106% compared to 97% of preoperative daily activities. Unrestricted participants in Peak et al.'s study returned to driving and work significantly earlier, by approximately two weeks and three weeks earlier respectively, than those in the restricted group. Half of the participants in the unrestricted group returned to work within six weeks of surgery, whereas less than a fifth of the restricted group had returned in the same length of time. By six months post-surgery, all the working patients in the unrestricted group had returned to work compared with 95% patients in the restricted group. Peak et al. assessed ADLs at six months, and in relation to the number of ADLs that patients were able to perform preoperatively. HippityHop did not follow up participants for long

enough to assess ADLs at six months and did not assess the length of time taken to resume driving or returning to work; thus, comparisons cannot be drawn between the ADLs results of the two studies.

Interestingly, Mikkelsen et al. (2014) reported a significant difference between the groups in their study in the change in HOOS ADL score, with patients in the restricted (precautions) group having the fastest increase. The study found a difference between the groups with greater scores in the restricted group at three weeks. Despite this, a higher proportion of the unrestricted (no precautions) group was capable of performing the four different ADL functions (stair climbing, getting dressed, bath/shower, and house cleaning) independently, when functional capacity was assessed by a physiotherapist, at three weeks postoperatively. The authors suggested that differences between the groups concerning functional capacity could be influenced by both fewer movement restrictions and fewer use of assistive devices. There were no differences observed in the HOOS ADL scores between the groups at six weeks; this is similar to the results in the HippityHop study. However, Mikkelsen did not follow up participants for longer than six weeks so it is unknown whether no differences remained between the groups long-term.

3.7.4. Sleep quality

In HippityHop, sleep quality was found to significantly improve from preoperatively to six weeks and three months postoperatively, with similar improvements in both groups. Almost all of the participants in the hip precautions group and two-thirds of participants in the no precautions group reported that they were advised to sleep on their back. Over 80% in the precautions group were advised to sleep on their back for at least six weeks, whereas only ~35% of the no precautions group were advised of this. Even though two-thirds of the no precautions group were advised to sleep on their back, the length of time they were advised to varied, and the duration did not appear to be as rigid as in the precautions group. Discrepancies were noted in the verbal and written information provided to participants, in the no precautions group, about the length of time they should sleep on their back. Recovery information provided to participants stated that participants should sleep on their back for six weeks, but clinicians advised participants to do this until it was comfortable to change position, or for the first couple of weeks.

Despite over a third of participants in the no precautions group being advised to sleep how they wished; only half of them began sleeping in their position of choice within two weeks of their surgery, and only three participants reported not sleeping a full night in the supine position following surgery. This suggests that supine sleeping may have been the preferred sleep position for participants during the initial phase of their recovery. However, supine sleeping was considered difficult by 70% of participants across both groups. Participants might have found this difficult because it was not their usual sleeping position and may have struggled to fall asleep, nevertheless, supine sleeping may have been more comfortable than side sleeping. These results were similar to the findings of Peak et al. (2005) who showed that over two-thirds of THR patients reported supine sleeping to be highly uncomfortable. Patients in their study began side sleeping at an average of three weeks in the unrestricted group, compared to six weeks in the restricted group. However, Peak and colleagues reported that 14% of the patients in the unrestricted group began sleeping on their side on the night of surgery, which was a greater proportion than in this current study. Modi and colleagues (2012) have also highlighted difficulties with supine sleeping. In their study, over two-thirds of their participants reported significant difficulties in maintaining a supine position, with many of them finding the position uncomfortable and led to sleep deprivation. This is similar to the results from O'Grady et al. (2003) who suggested that the supine sleeping precautions resulted in sleep deprivation, which in turn increased night sedation and analgesia.

3.7.5. Mood

All participants' mood was significantly worse preoperatively compared to postoperatively, with a decrease in anxiety and depression symptoms after surgery. The decrease in anxiety and depression scores was similar in both groups. The decrease in anxiety and depression symptoms was not surprising given that over one-fifth of people with OA experience symptoms of depression and anxiety (Stubbs et al., 2006), and that there is a high prevalence in THR patients preoperatively which significantly decreases following surgery (Duivenvoorden et al., 2013). The high prevalence of depressive symptoms has been suggested to be the result of an inability to perform their ADLs preoperatively; when pain and disability experienced decreases after THR, the prevalence of psychological (e.g. anxiety, depression) symptoms also decreases (Duivenvoorden et al., 2013).

The high prevalence of depression and anxiety symptoms in THR patients observed by Duivenvoorden et al. supports the results of this study; where although the mean anxiety and depression scores were within the normative range, over a fifth of participants in this study indicated mild symptoms of depression and anxiety preoperatively. Mikkelsen et al (2014) reported that 38% of participants were categorised with anxiety preoperatively, but this decreased to 4% at three weeks and 8% at six weeks postoperative. The HADS depression scores showed the same tendency but the data was not reported in the paper. Although participants in Mikkelsen et al.'s study had higher scores in the HADS preoperatively compared to this current study (38% for restricted group, and 30% unrestricted group), the number of participants with symptoms of anxiety and depression at six weeks were similar (8% restricted group and 4% unrestricted group): there were also no differences in the HADS scores between the two groups. Duivenvoorden et al. (2013) reported similar findings with regard to the prevalence of anxiety and depression symptoms at three months postoperatively. The authors followed up participants 12 months postoperatively and found no further increase in symptoms and suggest that the significant improvement seen within the first three months after surgery is maintained until at least one year post-surgery.

3.7.6. Health-related quality of life

Both groups were found to recover at a similar rate and had a 17% increase in perceived health status from preoperatively to three months postoperatively. This suggests that regardless of the treatment provided patients had the same perceived HRQoL. This could be due to the effects of surgery, which has been found to be effective in terms of improving HRQoL (Ethgen et al., 2004). This was perhaps unsurprising considering the surgery is typically performed to decrease pain and improve function, ultimately resulting in improved QoL. This finding reflects the results of Verevereli et al. (2009) who found that their groups recovered with the same levels of physical function and mental stamina. They suggested that patients in their early rehabilitation (no precautions) groups were equally likely to feel limited from performing housework or social activities and suffer emotional strain due to a decreased sense of accomplishment in the months following surgery. Interestingly, the authors cited one patient who was randomly assigned to the standard group for a THR for one hip and then a year later into the early rehabilitation group for the other hip. In the diary that participants completed about their recovery, the participant

reported “depression was a real issue to contend with in the control group. I was so much happier and the QoL was so much better in the accelerate group”.

3.7.7. Patient satisfaction

The findings of this study suggest that participants were satisfied with their surgery, with the rehabilitation program they were provided, and the information they received relating to their surgery and recovery. At six weeks postoperative, the levels of satisfaction were very similar, however, at three months the no precautions group had greater levels of satisfaction with their recovery than the precautions group. This mirrors results found by Peak et al. (2005) and Mikkelsen et al. (2014) who both reported high levels of patient satisfaction. Peak et al. (2005) found that patients in the unrestricted group had significantly greater levels of satisfaction than the restricted group. The authors highlighted that some participants in the restricted group of the study were dissatisfied with the additional restrictions they were prescribed as they were aware of the unrestricted protocol. Patients in their (Peak et al.) study also reported that they had ‘planned to recover at their own pace’. These were the main reasons to which Peak et al. attributed the high noncompliance rate (26%). In the HippityHop study, as the participants were not randomised, all participants recruited at the same time point received the same treatment. It was possible that participants in the no precautions group were aware of precautions, however, this was advice was not provided to patients. Had the study been an RCT it is possible that there could have been greater levels of noncompliance reported.

It has also been suggested that patients with preoperative anxiety or depressive symptoms were less satisfied postoperatively, and preoperative anxiety had the greatest influence on patient-reported outcomes (Duivenvoorden et al., 2013). Preoperative uncertainty and anxiety have been found to be negatively related to postoperative well-being and mental health, and positively associated with the level of postoperative physical symptoms (Kagan and Bar-Tal, 2008). As both groups in HippityHop exhibited similar levels of preoperative anxiety, it was not possible to draw conclusions about the relationship between the use of hip precautions, levels of anxiety, and their influence on patients’ recovery.

3.7.8. Other patient outcomes

Hip dislocation is a significant complication following THR, however, the dislocation rate in HippityHop was low (1.2%), as anticipated given the overall sample size. Despite the removal of precautions, the number of dislocations that occurred in each group was comparable. The participants whose hip had dislocated were under the care of different surgeons who used either an anterolateral or posterior approach. In addition, two of the dislocations occurred whilst seated within in the first two weeks of surgery, and the other occurred eight weeks postoperatively. The participants who dislocated were all female and approximately 70 years old. The factors attributing to their dislocation were unknown, as data was not collected with regards to American Society of Anesthesiologists (ASA) score and component malposition, which are recognised risk factors for dislocation (Gromov et al., 2015).

There might have been some discrepancies and confusion with regard to the reporting of complications following surgery. It was possible that participants were not fully aware of what a complication was. A number of participants had listed swelling and/or bruising as a complication, which is quite common but can vary from patient to patient. The number of complications had decreased from six weeks to three months, which suggests that participants spoke to the clinician at their outpatient follow-up appointment (~6-8 weeks postoperative) about the side effects they had been experiencing and been reassured that these symptoms were not complications, or that the symptoms had resolved.

3.7.9. Practical considerations/delays experienced during the study

3.7.9.1. Research ethics and approvals

The process of obtaining ethical approval for this study was very complex and time-consuming. Following the phone consultation with the Central Booking Service, it was advised that the study should be submitted for a Proportionate Review. However, the study received an unfavourable opinion from the REC committee as the ethics committee believed that “due to the standard care change [it] will require discussion at full REC because of the ethical issues this will raise”. Thus, the study was resubmitted for a full REC review. Before issuing their approval, the REC committee raised several queries. Queries included; 1) requesting each of the individual questionnaires (originally included in one booklet), 2) the scoring methods/system for each of the validated questionnaires, 3) reassurance that copyright for the questionnaires had been obtained.

The time taken to obtain REC ethical approval took approximately three months (REC approval obtained 14th September 2016). There were further delays experienced in obtaining Health Research Authority (HRA) approval. Whilst there were no issues raised by the HRA, the approval was requested when the system was undergoing substantial change. It took two months to obtain HRA approval following REC approval (HRA approval obtained on 16th November 2016). The time taken to obtain the relevant approvals impacted upon the timing of the study as recruitment could not begin until all approvals were obtained.

3.7.9.2. Winter pressures

Delays to the study were also experienced as a result of the winter pressures placed on the NHS. The 'winter crisis' of 2017/2018 was nationally well-documented in the media, on NHS Trust websites, The Health Foundation, and in the British Medical Journal (BMJ). The pressure that NUH were under was also documented in the TV programme 'Hospital' on BBC Two (BBC, 2018).

In January 2018, following recommendations from National Emergency Pressures Panel, NUH cancelled 346 routine operations to free up capacity in its hospitals; with pressures on services continuing into March, NUH opted to cancel more operations (NUH, 2018). As a result of winter pressures and lack of available beds, 27 participants had their surgery cancelled during this time. Of those, 15 participants successful underwent THR after their surgery was rearranged; five participants had their scheduled surgery cancelled twice before undergoing THR surgery. In addition, a further seven patients were excluded from the study as a result of winter pressures: three participants had surgery rescheduled for a date which outside of the PhD study time period (after 25th April 2018), and the other four participants did not have a new surgery date by the end of the PhD study time period.

Prior to the cancellation of elective surgeries at NUH, the last participant received surgery on the 2nd January 2018. Surgeries ceased after this time and the next participant did not undergo surgery until 6th February 2018. This delayed the study by five weeks. The researcher was in regular contact with the orthopaedic team, in particular, the hip champions, to keep informed of updates with regard to the recommencement of surgery. Despite surgery commencing in early February, the number of surgeries performed was significantly less than the number performed on average.

3.7.10. Strengths and limitations of the study

The principal limitation of the study is that the study design was not an RCT, which is considered the 'gold standard' in clinical research and are the first choice when assessing for the effectiveness of treatment interventions. Methodologically, it would have been ideal to use an RCT design, however, this approach was not an option as previously discussed (section 2.2.1.1.). However, a non-randomised design was chosen to avoid potential contamination of the prescription of hip precautions between the two groups. Using an RCT design would have minimised the risk of bias attributable to the unequal distribution of participant characteristics and confounding factors between the groups, which would have increased the level of internal and external validity of the study, and the generalisability of the results. However, the baseline characteristics indicate an equal distribution of the variables measured. There is a risk that unknown factors (e.g. changes in surgical technique, ASA scores) may have influenced the results, but there were no other changes in the treatment of THR patients, other than the removal of hip precautions, that could reasonably have had an impact on the results.

Aside from the fact that this was not an RCT, the use of equivalence analysis performed on the primary outcome was a strength of the study. No previous studies in this area have performed equivalence analysis to compare outcomes of patients who were prescribed hip precautions with those who were not. The authors of one study (Ververeli et al., 2009) incorrectly concluded that their results were equivalent across the two groups, but the study was not powered to determine equivalence. Thus, HippityHop is the first study to validate equivalence between hip precautions and no hip precautions, and to demonstrate that patients who receive hip precautions have neither better, nor worse, outcomes than those who do not.

The use of self-report rather than objective measures was a potential limitation to the study; although it was possible to obtain a large number of outcomes from patients through self-report, this method can be subjected to recall and social desirability biases leading to potential exaggeration or under-reporting of pain and physical function. In addition, the questions had closed response options, which limited the participant to a set of fixed set of responses. Whilst these enabled ease of competition, they limited the degree to which definitive conclusions could be drawn, particularly for the follow-up questions and patient satisfaction questions. A weakness

of structured questionnaires is that the response options might 'force' some respondents to select an answer that does not fully represent their view. However, the questionnaires used in this study were standardised and are valid and reliable in this population (see section 2.2.11.1.). In addition, there was space available for participants to write reasons as to why they chose a particular answer to gain a greater understanding of their perspectives.

The wording of questions might have also influenced participants' response to certain questions. For example, in the additional sleep questions section of the questionnaire, participants were asked if they were instructed to sleep on their back after surgery. Participants in the no precautions group might have wondered why they had not been asked to do so and that they should respond in the affirmative. This question may have also led participants to start sleeping on their back despite not having been advised to. However, the questionnaires were developed with assistance from the steering group and were piloted by a group of THR patients, prior to the commencement of the study.

The focus on patient outcomes rather than dislocation was considered a strength of the study. Whilst dislocation is a significant complication following surgery, the goal of the surgery is to decrease pain and improvement function. The incidence of hip dislocation is low for primary THR surgery. The assessment of outcomes focuses on the perceived health of the participants rather than adverse events and complications associated with surgery.

Despite the time constraints of the study, the inclusion of a washout phase between the two groups was considered a strength of the study; to the researcher's knowledge, this was the first prospective study with this design to evaluate the use of hip precautions. The study also used an intention-to-treat analysis; it was not feasible to perform per-protocol analysis as it was not possible to determine whether participants actually followed the advice they were provided. The use of intention-to-treat analysis reflects actual clinical practice and was relevant to this study as patient compliance with hip precautions might be flawed; participants might have forgotten them or chosen to ignore them. Patient noncompliance with precautions is supported by findings from Peak et al. (2005) and Lee et al. (2017), which is discussed in more detail later in the thesis (section 5.4.5.).

Another strength of this study was the sample size and homogeneity of the participants. It was fortunate that given that the participants were not randomised, they were well-matched on key characteristics. The study participants reflect the characteristics of the population that undergo THR nationally (patients included in the NJR report). Age and sex were considered potential confounders and the sample size was doubled from 64 participants in each group to 128 participants to help control for this. As the participant characteristics were similar, it is believed that the study was sufficiently powered to strongly conclude equivalence.

3.8. Conclusion

Patients in the study who did not receive hip precautions had equivalent levels of pain and function (OHSs) at three months post-surgery to those patients who received precautions. In addition, patients who received hip precautions had similar outcomes for all other measures, (ADLs, mood, sleep, and HRQoL) to those who did not, at six weeks and three months following THR surgery. However, at one week post-surgery, patients who did not receive precautions had significantly greater function and less pain than those who received precautions.

All patient outcomes improved significantly from preoperatively to six weeks and three months postoperatively, and the overall change in scores was similar for both groups. However, improvements in patient outcomes were expected given the nature of the surgery performed. Despite this, the before and after study results demonstrate that hip precautions provide no additional benefits to patients following THR surgery, and that patients recover at a similar pace regardless of whether they receive precautions or not.

This chapter has evaluated the use of hip precautions and no precautions on patient outcomes following surgery. In the next two chapters, patient and staff perceptions of both regimes will be explored. The findings of both studies will be further discussed in the final chapter of this thesis.

4

Interview Study Methodology

4.1. Introduction

This chapter explores the perceptions and experiences of hip precautions through interviews conducted with both patients and orthopaedic staff. Previous literature relating to hip precautions has largely focused on dislocation rates in relation to hip precautions, whilst other patient outcomes, and their views and experiences of hip precautions have largely been ignored. Qualitative research conducted in this area has focused on clinicians' perceptions of hip precautions and on more hypothetical issues rather than pragmatic change.

There is a paucity of qualitative research studies on staff perceptions of hip precautions. Previous research by Coole et al. (2013) explored clinicians' perceptions and experiences of hip precautions, their use of precautions, and views of the evidence base. The authors concluded that there were variations in orthopaedic staff views regarding hip precautions, due to the lack of evidence for their use, and differences in surgical opinion. Whilst Coole et al. enquired about staff attitudes towards potentially removing precautions from practice, the study did not explore staff perceptions and experiences following their actual removal. Ascertaining staff perceptions of hip precautions and their experiences of the change in practice could help identify the factors (e.g. barriers and facilitators) influencing the implementation of a new practice in orthopaedic services. Additionally, no research has been conducted to explore patients' perspectives of hip precautions and the THR service, particularly in terms of the perceived impact they have on recovery and daily lives. Exploring patient perspectives of hip precautions will provide an insight into their experiences of hip precautions following THR and may help provide a greater understanding of the before and after results.

Given the limited evidence, exploratory research was conducted to investigate perceptions and experiences of staff and patients of hip precautions before and after a change in service. It was considered that qualitative data would supplement and extend the understanding of the results from the before and after study (see 3.7.1. for a summary). The findings could assist with implementing a new service regime locally, and potentially nationally if the results are positive.

4.1.1. Study aim and objectives

The aim of the study was to explore perceptions and experiences of THR in relation to the prescription of hip precautions and no hip precautions.

There were two specific objectives:

1) To explore patients' perceptions and experiences of their recovery and the service they received following THR (in both regimes) to ascertain the impact hip precautions may have on their recovery following THR surgery.

2) To explore staff perceptions and experiences on the service provided to patients (in both regimes) to identify the facilitators and barriers to the change in the regime, and their attitudes towards changing the regime of hip precautions.

4.2. Method

4.2.1. Ethics

The study was approved by Nottingham 2 Research Ethics Committee (REC) - East Midlands (16/EM/0283), the Research and Innovation department of NUH Trust (16HC005), and the HRA. Written informed consent was obtained from all participants. All data were anonymised and stored in accordance with the Data Protection Act (1998).

4.2.2. Study design

4.2.2.1. Rationale

Qualitative research involves the study of phenomena in their natural settings (Creswell et al., 2003), attempting to understand the phenomena by describing and analysing the culture and behaviour of humans and their groups, from the view of those being studied (Bryman, 2003). The primary focus of qualitative research is to understand human beings' 'richly textured experiences', and reflections about those experiences (Jackson et al., 2007). Qualitative methodology is often used when there is little known about a certain topic, the research context is poorly understood, or the nature of the problem is not clear (Morse, 2003). The research strategy usually emphasises words rather than quantification in the collection and analysis of data (Bryman, 2008), and enables the participants to offer in-depth responses to questions about their experiences, which cannot be obtained from quantitative research

(Jackson et al., 2007). Thus, qualitative methods are frequently employed to answer open questions that begin with ‘what’, ‘how’ and ‘why’, rather than ‘how many’ or ‘how much’, to ensure sufficient depth and detail is obtained through the questions.

4.2.2.2. Research method

It was decided that interviews were the most appropriate method to adopt for this study based on the aims of the study, the study setting, and the resources available.

Interviews

Interviews are a flexible tool for research and can be used at any stage during the research process, either as the primary (or only) approach in the study or in combination with other data collection procedures in a mixed method approach (Robson, 2002; Breakwell, 2006). Interviews are a conversational practice where knowledge is produced and have been defined as a conversation with “the purpose of obtaining descriptions of the lifeworld of the interviewee in order to interpret the meaning of the described phenomena” (Kvale and Brinkmann, 2008). They provide greater detail and depth than the standard survey, allowing insight into how individuals understand and narrate aspects of their lives. There were several possible interview methods that needed to be considered, which will be discussed below:

- Focus groups

A focus group is a group of individuals who have been selected, because they are homogeneous in some respect, to discuss a specific topic (i.e. focus) chosen by the researcher (Hydén and Bülow, 2003). The group discussions allow peoples’ views or perceptions of, attitudes towards, and experiences of particular aspects to be explored (Morgan, 1988; Kitzinger and Barbour, 1999). Collecting information from a number of people at the same time can stimulate discussions and initiate the production of new ideas and information within the group, as participants share their own thoughts and beliefs with each other. As a result, this can generate novel ideas leading the research into new and unexpected directions (Kitzinger, 2006). However, an important issue to consider when drawing conclusions about the participants’ views and experiences is that participants may talk and interact differently within the group session, altering their representative and position. Although focus groups may empower participants to express their views more than they may feel that they are able to in one-to-one interviews (Green, 2007), there is a disadvantage in this as participants’ attitudes may be more extreme within the group discussions, leading to

a ‘polarization’ effect (Sussman et al., 1991). A consequence of sharing these individual experiences within a group is that participants may be influenced by the perceptions of other participants, and thus if their viewpoint differs from the majority of the group they may not be willing to express this. Furthermore, in a group interview, all members are unlikely to contribute equally, especially if there are one or two group members who dominate the discussion (Goering and Streiner, 2013). Consequently, a consensus of opinion may emerge which may not accurately represent the views of all group members. However, sharing perceptions and experiences within a group represents a more natural environment and reflects real life (Krueger and Casey, 2014). Despite this, group interviews may not be suitable for research which aims to explore different experiences and perceptions, rather than an agreed focus. In addition, they would be difficult to organise in a busy orthopaedic setting or in the community. Also, focus groups would have been impractical given the time and financial constraints of the study.

- Individual interviews

Whilst a group interview can collect a wide range of experiences, an individual interview can delve deeper into an individual’s experience. Interviews are one of the most recognised methods for collecting a detailed account of an individual’s experiences, beliefs, and understanding of a particular phenomenon (Britten, 2006; Sliverman, 2010). They are also considered to be convenient to conduct, resource efficient, and enable the researcher to focus directly and specifically on the topic of interest (Green and Thorogood, 2014), further exploring any issues which arise during the course of discussion (Merriam, 2009). In-depth interviews involve a personal and intimate encounter in which open, direct, verbal questions are used to elicit detailed narratives and stories (DiCicco-Bloom and Crabtree, 2006). Individual interviews are the most commonly used method in qualitative health research (Britten, 2006; Green and Thorogood, 2014) and are widely used by healthcare researchers to establish individuals’ meanings, perceptions, and experiences of events related to their health and healthcare delivery (DiCicco-Bloom and Crabtree, 2006). From a practical point of view, individual interviews are easier to organise and more flexible than group interviews.

The emphasis of the interview can be the perspectives, understandings, and meanings constructed by participants regarding an event they experienced in their life (Al-Busaidi, 2008). Interviews require researchers to be flexible in their response, drawing upon their skills and knowledge to explore interesting ideas that emerge

during the course of the interview (Jackson et al., 2007). However, responses from interview participants only provide an account of their own experience and behaviours, which may not be a true representation of the participants' actual behaviours and practices. As interviews elicit participants' perceptions, questions can be raised as to whether it is appropriate for researchers to think that individuals attach a single meaning to their experience, or that there are multiple meanings of a situation or activity, which are represented by what people say (Silverman, 2015). Questions have also been raised as to whether the interview responses are to be considered as direct access to experiences, or as actively constructed narratives involving activities (Gubrium and Holstein, 2009; Riessman, 2011; Silverman 2011). However, because the data generated can be represented in different ways developing from different epistemological positions (e.g. positivism, constructionism) (Breakwell, 2006), it is important that the position taken by the researcher is justified and explained (Silverman, 2015). The researcher's epistemological position for this study is discussed in chapter one of this thesis (section 1.7.2.).

The objectives of this research were to explore patient and orthopaedic staff perceptions and experiences of the treatment service provided to patients following THR, in particular, the prescription of hip precautions. Patients who receive a THR choose to have elective surgery for a number of reasons (e.g. to decrease pain, increase function, improve QoL), and are a diverse population encompassing the young and active, the old and frail, and those with multiple comorbidities. Therefore, it was considered important to explore a range of experiences of the treatment service received following their THR, and how people felt this impacted upon their recovery. In addition, there were a number of orthopaedic staff from different disciplines working within the same team to provide care to patients at various time points of their THR journey (e.g. occupational therapists, physiotherapists, consultant surgeonsm, nurses), whose perceptions and experiences of the service provided to patients were considered important to explore. Staff may have diverse perceptions and experiences of the service depending upon on their interaction with patients, and potential changes to the service may impact upon their practice differently. Using one-to-one interviews with the diverse range of orthopaedic staff and patients would allow an exploration and probing of these perceptions and experiences further than would be able in a focus group, which may not be feasible or appropriate with such a broad population. Thus, individual interviews were selected as the preferred method in order to explore the patients' experiences, and also the staff members' perceptions of the treatment service provided to those following THR.

○ Types of interviews

It was important to determine the type of interview that was most appropriate. There are three main types of interviews: structured, semi-structured, and open-ended interviews (Noaks and Wincup, 2004). Open-ended (unstructured) interviews have a general area of interest and attempt to understand the complex phenomena without imposing an a priori categorization that may limit the field of enquiry (Denzin and Lincoln, 2000). The interview involves 'active listening' in which the interviewer allows the participant the freedom to speak and ascribe meanings, but bears in mind the overall aims of the project (Noaks and Wincup, 2004). Semi-structured interviews have a pre-prepared schedule of the topics which neede to be covered in the interview (usually include a series of additional questions and prompts), but the researcher has the freedom to deviate from the schedule and further explore areas of interest (Robson, 2011), for example if an individual raises a new issue. As semi-structured interviews are based on a flexible topic guide that provides a loose structure of open-ended questions that enable exploration of attitudes and experiences, they are commonly used in healthcare-related qualitative research (Al-Busaidi, 2008). Structured interviews require the researcher to follow a specified set of questions, in a specified order and do not allow for deviations from the pre-prepared schedule (Green and Thorogood, 2014). Structured interviews are 'standardised' with a tightly structured schedule of questions which are phrased in such a way that a limited range of responses is elicited, thus can be very limiting in terms of the exploration of areas of interest.

The type of interview chosen should depend upon the research aims, research questions, and the design of the study. Unstructured interviews would not have been appropriate for this study as there would not be enough focus on the key topics in which the study aims to explore, and without a pre-prepared schedule, there was a potential risk that important themes could be missed. Structured interviews would also not have been appropriate for this study as a fully prepared rigid schedule would not have allowed participants the freedom to express and expand on information that was important to them; it would have also prevented being able to probe the participants to further explore topics raised by them.

Therefore, semi-structured interviews were chosen to ensure that a number of aspects of the service regime provided to patients following THR were covered, whilst being flexible and adaptable in the flow of the conversation. In a semi-structured interview, the researcher pre-designs the schedule and selects the topics to be

covered, and possible key questions (or prompts) to ask in relation to the topics of interest. The researcher chooses the ordering and wording of the questions, which may be adapted to suit the characteristics of each participant.

4.2.3. Interview schedules

4.2.3.1. Development of interview schedules

An interview schedule should enable the researcher to remain focused on the agreed topic and not be distracted by irrelevant information. The interview topic guides were based on a review of the literature and the research aims and were developed with input from orthopaedic staff and the patient representative. Two separate interview schedules were developed simultaneously, one for staff and one for patients, and were designed to be adaptable for each phase (before and after). Areas of interest included information and advice provided, provision of adaptive equipment, challenges/difficulties of the service, and the impact of the service (treatment) upon patients' recovery. Each area within the topic guides had a series of prompts to assist the interviewer, if necessary, to add more context and depth to the interview. This partly deductive method has been suggested to enable the researcher to be more sensitive to subtleties within the data (Tuckett, 2005), whilst providing adaptability to allow exploration of unanticipated themes and amendments or additions to be made to the schedule in response to new topics arising as the study progressed.

Interview schedules were designed to encompass a range of potential issues from the before and after study, in terms of the orthopaedic treatment services provided. The focus of the interviews was to determine patients and orthopaedic staff members' perceptions and experiences of hip precautions. Rather than asking patients and staff directly about hip precautions, questions were framed in relation to the treatment service provided and patients' recovery. Topic guides began by asking the participant background information about themselves (e.g. 'what is your professional background?', 'how do you feel that your recovery has gone?'). Asking questions which the interviewee feels comfortable with and are easy to answer, allows the participants to settle into the interview, before proceeding on to more difficult questions (Britten, 2006). The topic guides were developed so that the interviews would last no longer than 30 minutes. The researchers believed that this was a reasonable amount of time to capture sufficient detailed information without overburdening the interviewees.

4.2.3.2. Piloting of interview schedules

Prior to the commencement of the interviews, pilot interviews were conducted. The purpose of the pilot interviews was to ensure that the topic guidelines were suitable, easily understood, and functional. The pilot interviews provided valuable feedback on the relevance and ease of understanding of the topic areas within the interview schedule. Data obtained in the pilot interviews was not included in the analysis.

Staff pilot interviews

Staff pilot interviews were conducted with colleagues, an academic occupational therapist, and a clinical occupational therapist employed in another hospital's orthopaedic team.

Minor revisions were made to the staff interview schedules following the pilot interviews. The revisions included adding additional prompts to the individual questions, in particular, the question relating to the information that they provided to patients, and also the question about their thoughts on the service provided. These prompts were regarding the development of information, information materials, hip precautions, and the timings of THR stages (e.g. timings between various appointments and length of time of each appointment).

Patient pilot interviews

A patient representative and other colleagues participated in patient pilot interviews. Following the pilot patient interviews, minor revisions were made to the interview schedule. Revisions including adding additional prompts about patient expectations, potential complications of surgery specifically dislocation, and return to work. The prompts regarding dislocation included asking patients if they were informed about the risk, their thoughts and feelings regarding this, and what advice they would give to future patients.

4.2.3.3. Final interview schedules

Staff

Clinicians were asked about their professional background and their role within the multidisciplinary team (MDT). Subsequent questions included asking about their perceptions of hip precautions, and their experiences of assisting with patients' recovery following either hip precautions or no hip precautions.

The staff interview schedule covered the following topic areas (see Appendix H for staff schedule):

- Provision of information
- Equipment prescription and recommendations
- Service provision currently provided
- Changes in service involving the withdrawal of hip precautions

Patients

Patients were first asked 'How do you feel that your recovery has gone?'; following this initial question to help the patient relax into the interview, they were asked questions about their perceptions and experiences of recovery following surgery.

The patient schedule covered the following topic areas (see Appendix I for patient schedule):

- Information received about treatment and recovery
- Equipment provided or recommended
- Experiences and impact of treatment regime on daily life
- Expectations of and satisfaction with postoperative outcomes

The final interview schedules can be seen in Appendices H and I.

4.2.4. Sampling

4.2.4.1. Sample size

Determining sample sizes for qualitative research does not require any statistical calculations, instead, they are generally determined by the aim of the research and other aspects, such as the depth and duration of each interview, and the feasibility of conducting the interviews (Britten, 2006). Semi-structured interviews are commonly conducted once with an individual and generally last between 30 minutes to several hours (DiCicco-Bloom and Crabtree, 2006), thus it was important to consider the time and resources available in determining the sample size. For this study, it would not have been as informative to have held in-depth interviews with a small number of participants, this might not have provided a sufficient range of perceptions and experiences. The range, type, number of participants, and the basis on which participants are selected, also had to be taken into consideration.

The aim was to recruit a total of 40 participants: 20 orthopaedic staff who provided care and treatment to patients during the study period, and 20 patients who participated in the before and after study (see chapters 2 and 3). The target sample size was 10 staff and 10 patient participants from the hip precautions regime (before), and 10 staff and 10 patients from the no precautions regime (after). The proposed number of participants was based on practical considerations of time and resources available to collect and analyse the data. It was believed that these sample sizes, would reflect sufficient diversity and address the research question within the time and resources available. This decision was based on previous research by Francis et al. (2010), who provide a set of recommendations for justifying an appropriate sample size as a result.

4.2.4.2. Sampling strategy

The aim of a sampling strategy is to maximise the opportunity of producing data that captures a range of views on the topic (Green and Thorogood, 2010). In qualitative studies, information-rich cases or informants are often identified as those from which one can learn a great deal about issues that are of central importance to the purpose of the research (Hardon et al., 2004). It has been observed that sampling methods are intended to maximise efficiency and validity (Morse and Niehaus, 2009), and must, therefore, be consistent with the aims and assumptions inherent in the use of the strategy chosen. Whilst some strategies (e.g. maximum variation sampling) can be used to identify and expand the range of variation or differences, others (e.g. snowball sampling) can be used to narrow the range of variation and focus on similarities (Palinkas et al., 2015). There were several strategies for sampling that were considered and are discussed below:

- Convenience sampling

Convenience sampling is a ‘non-probability’ method in which population members who are conveniently available at the time of data collection are selected to participate in the study. In convenience sampling, there are no inclusion criteria to identify potential participants, as all subjects are invited to participate. Whilst this method often simplifies the sampling and facilitates data collection, it is vulnerable to selection bias and a high level of sampling error. For example, in this study, a clinician who plays an important role in prescribing hip precautions and adaptive equipment (e.g. occupational therapist) may be missed because they are not available at the time. Thus, convenience sampling was not an appropriate method for this study.

- Snowball sampling

Snowball sampling is one of the most common sampling methods used in qualitative research, particularly when selecting respondents for semi-structured interviews (Hardon et al., 2004). The aim is to identify cases of interest from sampling people who know people with generally similar characteristics, who in turn know people who also have similar characteristics (Palinkas et al., 2015). The process typically begins by asking key informants or well-situated people "who know a lot about ... [phenomena]…" (Patton, 2001). Snowball sampling offers practical advantages and is primarily explorative, qualitative, and descriptive (Hendricks et al., 1992), particularly when members of the population are hard to locate and there are limited resources. Despite this, there is often a lack of variation within the sample, as it consists of informants who belong to the same network of index cases. As the study aimed to gain a broad perspective of individuals' perceptions and experiences at a single location, snowball sampling was not a suitable method to select participants for this study.

- Purposive sampling

Purposive sampling is a method used for the identification and selection of information-rich cases to study in depth (Patton, 2002). This involves identifying and selecting individuals or groups of individuals who are knowledgeable about or have experience with the phenomenon of interest (Creswell and Plano Clark, 2011). In addition to the knowledge and experiences of the phenomenon, the importance of the ability to communicate experiences and opinions in an articulate, expressive, and reflective manner has been noted (Spradley, 1979; Bernard, 2002). Studying information-rich cases enables the researchers to gain an insight and in-depth understanding about issues that are of central importance to the purpose of inquiry, rather than empirical generalizations (Patton, 2002).

As the intention was to gain a broad range of participants to maximise the potential richness of the data and to gain a more in-depth understanding of individual perceptions and experiences, purposive sampling was considered the most appropriate method. Purposive sampling techniques that could have been employed are discussed below:

- Stratified purposeful sampling

Stratified purposeful sampling aims to capture the major variations rather than identify a common core, although the latter may emerge later in the analysis (Patton, 2002).

Purposive samples are stratified by selecting particular units or cases that vary according to a key dimension or characteristic (Patton, 2001). The researcher divides the representative population with specific characteristics into subgroups (strata) and each unit belongs to a single stratum (e.g. nurse, occupational therapist, physiotherapist) and then selects units from those strata. Each of the strata constitutes a fairly homogeneous sample. An advantage of stratified purposive sampling is that it is possible to take a larger sample of individuals from a small specific group within the study population, enabling researchers to draw valid conclusions about a relatively small group without having to collect an unnecessarily large sample of other, larger groups (Hardon et al., 2004). However, it represents a less diverse range of variation than the full maximum variation sample, which may be a more appropriate method for this study.

- Maximum variation sampling

This sampling method aims to select study units which represent a wide range of variation in the topic area of interest. Maximum variation sampling ensures representativeness and diversity of cases, with important shared patterns that cut across cases and derive their significance from having emerged out of heterogeneity (Palinkas et al., 2015). It can be used to document diverse variations that have emerged in adapting to different conditions (units) (Patton, 2002), ranging from those that are viewed to be typical through to those that are more extreme. These units may exhibit a wide range of attributes, behaviours, experiences, incidents, qualities, and situations. The basic principle is to gain greater insights into a phenomenon by examining it from multiple angles. Thus, maximum variation sampling was used in this study as this was believed to be the most appropriate method to capture a diverse range of perspectives of service delivery following THR.

4.2.4.3. Selection of participants

Maximum variation purposive sampling was used to select participants, in order to gain a broad and diverse range of perceptions and experiences. This type of sampling enables the selection of participants with characteristics of interest, such as age, gender, and speciality training (Creswell, 1998; Kuzel, 1999; Patton, 2002). A sample of both staff and patients were selected from each of the study phases: phase one (before the service change, i.e. hip precautions) and phase two (after the service change, i.e. no hip precautions).

Staff

The sample of orthopaedic staff was purposively selected from the team that provided care to THR patients during the time period of the before and/or after study. Orthopaedic staff were selected according to their discipline (surgeon, physiotherapist, occupational therapist, nurse), years of experience, and the type of care they provided (preoperative, postoperative). It was important to consider the different disciplines as their perspectives may differ depending upon their profession. The experience of staff may also influence their perceptions and practices.

Patients

Patients were purposively selected from the participants who participated in the before and after study. In order to ensure a wide range of characteristics were sampled, the selection process involved selecting patients according to their age, gender, living arrangements, and employment status. Due to the small sample size, it was not possible to purposively select participants to encompass a wider range of characteristics than those listed above, such as the side of operation, surgeon listed, and surgical approach. However, it was important to consider the age and gender of the patients as there may have been differences between their experiences. Whether patients lived alone and/or worked were considered important as these factors may have influenced recovery at home and return to activities.

4.2.5. Study participants

Interview study participants included both patients from the before and after study, and orthopaedic staff who provided treatment to patients following THR either before or after, or both.

4.2.5.1. Staff participants

Staff criteria

Orthopaedic staff members were interviewed during each phase of the before and after study.

- Inclusion

Staff had to: (a) provide care to patients undergoing THR during the before and after study; (b) provide informed consent.

- Exclusion

Participants were excluded if they could not read or speak English sufficiently, as all of the study documentation and the interviews were in English.

Staff recruitment procedure

Staff participants who were selected for interview were contacted via their NHS email address inviting them to take part. Attached to the email invitation was the PIS (Appendix E), which provided more detail about the study. Staff participants were asked to reply to the researcher if they wished to take part or to decline the invitation. The researcher answered any questions that the participant had, and a time and place was arranged for the interview if the participant was still in agreement.

4.2.5.2. Patient participants

Patient criteria

Patient participants were interviewed between six weeks and three months following their THR surgery. This was to ensure that the patients had followed the relevant treatment regime (hip precautions or no hip precautions) for the expected duration (6 weeks), and the experiences were still relatively fresh.

- Inclusion

Patients had to: (a) have participated in the before and after study; and (b) provide additional informed consent.

- Exclusion

Participants were excluded if they could not read or speak English sufficiently, as all of the study documentation and the interviews were in English.

Patient recruitment procedure

Those patients who were selected to be interviewed were contacted via a letter inviting them to take part. The letter of invitation was enclosed with the patients' 6-week questionnaire (for the before and after study), along with a PIS (Appendix F) detailing the study and a reply slip. Participants were asked to either contact the researcher or return their reply slip, if they wished to take part or not, with their 6-week questionnaire. Participants who replied stating that they would like to participate were contacted by a researcher to answer any questions they had and to arrange a suitable method (face-to-face, via telephone), time and place (patient's home, University of Nottingham, hospital) for the interview if the participant was still in agreement.

4.2.6. Consent

For participants who wished to have a telephone interview, consent forms (Appendix G) were sent via post at least 48 hours prior to the interview, and verbal consent was audio recorded at the time of the interview. For face-to-face interviews, written consent was obtained before the start of the interview. Consent forms were completed by all participants and were signed by the researcher and participant.

4.2.7. Interview procedures

Interviews were completed by the researcher who had undergone training in interview techniques. Participants were offered a choice of a telephone, video call, or face-to-face interview, at a choice of location, and a convenient time to suit them. Interviews were audio recorded, using a digital voice recorder. Field notes and a reflexive diary were kept by the researcher to provide context of the interview.

Prior to the commencement of the interview, the researcher explained the purpose of the interview study to the participant and gave the participant an opportunity to ask questions. It was also explained that the interview was strictly confidential and any information regarding personal details was anonymised, thus any opinions that they shared would not be attributed back to them. The researcher informed the participant that the interviews would be audio recorded, and the information collected would be transcribed. Participants were also informed that anonymised direct quotations may be taken from the interview and used in study reports. Interviews lasted approximately 30 minutes and were concluded by the researcher thanking the participant for their time and participation in the interview. Participants who wished to receive a copy of the findings were told that they would be sent a summary at the end of the study.

4.3. Data analysis

The staff interviews were conducted prior to the patient interviews, for both phases of the study.

4.3.1. Transcription

Following each interview, the digital audio recording was transcribed verbatim by the researcher. Paralinguistic features were not included as this level of detail was not required. The researcher then checked each transcript for accuracy against the audio recording. Any inaccuracies were identified and corrected by the researcher, as

inaccuracies affect the reliability of the analysis and findings (Stuckey, 2014). All transcripts were anonymised by removing identifiable details of the participant and coded with a study ID number. The anonymised transcripts were then used in the analysis.

Close observation of data through careful listening has been suggested to be an important step in the data analysis (Bailey, 2008). Thus, interview recordings were listened to several times in full and in conjunction with reading the written transcripts in order to gain a clear overview of the specific emphasis and meanings that were attributed by the interviewees in their interviews.

4.3.2. Methods of analysis considered

The method of data analysis was decided prior to data collection, and thus data was obtained to be analysed using the process that was pre-determined. Data analysis occurred concurrently with data collection, to generate an emerging understanding of the research question, informing the sampling and questions asked. As this was a qualitative study, an appropriate method of analysis must be employed in order to answer the research questions: “What are patients’ perceptions and experiences of the treatment service they are provided following THR?” and “What are orthopaedic staff members’ perceptions and experiences of the treatment service delivered to patients following THR?”.

A fundamental task in qualitative research and a key part in analysing the data is theme identification (Ryan and Bernard, 2003). A theme can be described as a patterned response within the data set, which captures something important about the data in relation to the research question. However, Luborsky (1994) suggested that the term ‘pattern’ may be best used to describe findings from the researcher’s frame of reference and proposed that themes should be defined as “the manifest generalised statements by informants about beliefs, attitudes, values, or sentiments”. On the other hand, Boyatzis (1998) proposed that a theme can refer to the manifest (semantic) content of the data or the latent meaning and can be identified at either ‘level’. According to Luborsky (1994), there are two basic approaches to identifying themes: 1) seek statements that occur most frequently or are repeated, 2) look for statements that are marked in some way as being of great meaning to a person or persons. In the first approach, statements are counted to determine the most frequently occurring ones; this can be done by counting the occurrence of the theme across each data set or counting the number of participants who articulated the theme

across the data set (Braun and Clarke, 2006). Whilst in the second approach, the researcher can identify statements within the data set which are deemed important to the respondent or are important in relation to the research question. There is some concern that only using quantifiable measures, such as counting the frequency of indexes, may mean that something important in relation to the overall research question may be missed (Braun and Clarke, 2006). However, a number of authors suggest that providing an indication of how often themes occur, commonly or rarely, may be helpful for the reader (Joffe and Yardley, 2004; Braun and Clarke, 2006).

In addition to these two approaches, the researcher must decide whether the theme is identified in an inductive ('bottom-up') or deductive ('top-down') manner (Braun and Clarke, 2006). The inductive approach is not driven by the researcher, but from the data itself; themes identified are strongly linked to the data rather than the research question (Patton, 1990). In the deductive or theoretical approach, themes are informed by the researcher's theoretical and analytical interests which they bring to the data, providing a more detailed analysis of aspects related to the research question. Theoretically derived themes allow the researcher to replicate, extend, or refute previous findings (Boyatzis, 1998), whilst more inductive themes are often used in novel areas of research. It should be noted that both approaches may begin with a theory about the target phenomenon or framework for collecting and analysing data, but that does not mean that there is a commitment to stay within this theory or framework (Sandleowski, 2010). The choice about which approach framework to work within can map onto how and why coding the data. A specific research question can be coded for, or it can evolve through the coding process. The method required can be determined by matching the specific research purpose and the state of science in the area of interest to the appropriate analysis technique (Hsieh and Shannon, 2005). For the process of analysis, a number of methods were considered:

4.3.2.1. Types of analysis

Interpretative phenomenological analysis (IPA) is linked to a phenomenological epistemology (Smith et al., 1999; Smith and Osborn 2003), which gives experience primacy (Holloway and Todres, 2003). It is concerned with understanding lived experiences and how participants make sense of their experiences, in great detail, so as to gain an understanding of the phenomena in question (McLeod, 2001). The aim of IPA is to develop a description of the essence of a concept or phenomena for all individuals (Creswell, 2007). Narrative analysis is also tied to a theory and is best for capturing detailed stories or life experiences of one or a small number of individuals

(Creswell, 2007). Whilst both IPA and narrative experiences can provide very detailed in-depth experiences of a particular phenomenon, it was determined that neither would be a suitable method of analysis as the study aimed to gain a broad range of perspectives and experiences.

Another theoretically bound analytic method that seeks to describe patterns across data is grounded theory. Grounded theory is unlike most other research methods in that it merges the processes of data collection and analysis; this involves moving back and forth between the two in an attempt to 'ground' the analysis within the data (Willig, 2013). A grounded theory is one that is inductively derived from the study of the phenomena it represents (Strauss and Corbin, 1990). Thus, theoretical sampling is a central tenet of grounded theory (Breckenridge and Jones, 2009), and it is essential that new respondents or settings are selected to assess the emerging theories. Although grounded theory can provide rich and detailed interpretations, the need for continuous sampling and analysis can be very time consuming and potentially overrun the resources of the study (Pope and Mays, 2006). Therefore, grounded theory was not a suitable method of analysis given the limited time and resources available for the study.

Another method of analysis to be considered for this study was thematic analysis. Whilst, grounded theory, IPA, and narrative analysis are theoretically orientated, thematic analysis is epistemologically orientated and can function independently of epistemological approaches (Braun and Clarke, 2006). As thematic analysis does not require the detailed theoretical knowledge of approaches, such as IPA and grounded theory, it offers a more accessible form of analysis, in particular for researchers who have little or no experiences in the field of qualitative research. Thematic analysis is also an appropriate method that can be used when the aim of the research is exploratory and inductive (Pope et al., 2006), and can be used to encode in a systematic manner (Burman, 1994). Thematic analysis is not connected to any pre-existing theoretical framework, and so can be used within different theoretical frameworks. Thematic analysis can be conducted within both realist/essentialist and constructionist paradigms, although the outcome of focus is different for each (Braun and Clarke, 2006). When used within the essentialist or realist method, thematic analysis reports experiences, meanings and the reality of participants; however, when a constructionist method is used, it examines the ways in which events, realities, meanings and experiences are the effects of a range of discourse within society. Thematic analysis can also be a 'contextualist' method, sitting in between the

essentialist and constructionist poles; it is characterised by theories such as critical realism (Willig, 1999), which acknowledge the ways individuals make meaning of their experience. Whilst, thematic analysis is independent of theoretical assumption and does not require the researcher to adopt a particular philosophical perspective, it is important that the theoretical position is made clear as it can carry a number of assumptions about the nature of the data, and what they represent. As this study was driven by the method, rather than being based on a particular philosophical paradigm, thematic analysis was considered to be the most appropriate method of analysis for this study.

Thematic analysis relies on an analytic strategy called 'constant comparative analysis' (Thorne, 2000), which involves taking an extract of data (e.g. them, statement, interview), and comparing it with others in the dataset to understand the relationship between them. Identifying similarities and differences between the constructed concepts can assist the reader to obtain a global view of the participants' perspectives of the phenomena (Joffe and Yardley, 2004; Blacker 2009). Whilst constant comparative analysis can be used in thematic analysis, it was originally developed for grounded theory (Glaser and Strauss, 1967). Although the process of analysis in thematic analysis is similar to that in grounded theory, possibly because thematic analysis is an analytical tool that can be used across different methodologies and analytic traditions rather than a specific method (Boyatzis, 1998), there are a number of differences between the methodologies. Thematic analysis aims to describe the data without necessarily building a theory, whereas grounded theory seeks to construct and develop a theory to explain the findings within the data (Burman, 1994).

Thematic analysis can be used to analyse, interpret, and report themes within the data, in order to organise and describe datasets in rich details (Braun and Clarke, 2006). Whilst thematic analysis often draws on both semantic and latent themes, and even when the manifest (i.e. semantic) theme is the focus, the aim is to understand the latent meaning of the manifest themes observable within the data (Joffe and Yardley, 2004). Thematic analysis typically focuses exclusively or primarily on one level (Braun and Clarke, 2006). An advantage of using thematic analysis is that it provides flexibility and allows for both approaches, detailed by Luborsky (1994), to be used in combination to determine themes (Luborsky, 1994; Braun and Clarke, 2006), provided that the researcher remains consistent in how they conduct their analysis on the dataset. This enables information on the frequency of themes to be provided, whilst keeping their meaning in context, and facilitates the emergences of

respondents' beliefs, perceptions, and experiences. In health research, this is particularly important as it enables the patient's voice to be heard, alongside the views of medical staff (Luborsky, 1994), allowing valuable information to be obtained regarding experiences of medical services and interventions.

Thematic analysis can summarise sections of narrative data into key themes that reflect the salient concepts and meanings, which can then be compared with other parts of the narrative of the same or different speakers. By highlighting the similarities and differences across the data set, it allows for the range of opinions to be represented in the results (Braun and Clarke, 2006), and provides an opportunity to understand potential issues more widely, as relationships between concepts can be determined (Marks and Yardley, 2004). It is possible to link and compare data gathered in different situations and at different times during the project. Therefore, thematic analysis was the most appropriate method to analyse data collected at the two different phases for this study. This allowed the researchers to observe differences and similarities between the participants' experiences and perceptions in the phase before and the phase after the change in the delivery of treatment services to patients following THR.

4.3.2.2. Thematic analysis

The thematic analysis used in the study was the approach described by Braun and Clarke (2006) involving six-stages of analysis. The authors note that the process of thematic analysis is non-linear, and is recursive, allowing researchers to move back and forth between the phases as required. Thematic analysis began with the identification of themes and patterns and ended with the content and meanings of patterns being reported.

Stage one: *Familiarisation with the data*. The first stage began with the researcher acquainting herself with the data, by checking the transcripts against the original recording. The audio recordings were listened to repeatedly, with the scripts being read and re-read. Initial analytical observations were noted.

Stage two: *Generating initial codes*. The second stage involved coding the entire dataset line-by-line and generating codes for important features of data relevant to the research question. The data sets were analysed using an inductive approach, whereby the codes were 'data-driven', in other

words, they were produced from the data. Each script was read through with each segment of text that was of some interest was assigned a code, that could potentially form the base of a theme. The coded text segments were highlighted and a brief description was written next to it. Text segments that were assigned the same, or similar, code were then grouped together in a separate document.

Stage three: *Searching for themes*. In the third stage, the coded text segments were coded in order to identify similarities and differences amongst them. Codes were combined and sorted into potential overarching themes and sub-themes. These themes were identified at sematic or latent level. At the end of stage three, all coded data was collated into the relevant theme.

Stage four: *Reviewing themes*. During this stage, the contending themes were checked and refined. Themes were reviewed and examined against the data to ensure that they were valid and represented the data as a whole. Themes were checked to ensure that they captured the ideas contained within the codes and that the meanings were coherent. The nature and the relationships between the themes were defined. Codes that did not fit within the identified themes were discarded.

Stage five: *Defining and naming themes*. In stage five, a detailed analysis of each theme was conducted, and the 'essence' of each theme was identified. Definitions of the themes were determined by identifying the narrative of each theme and its significance.

Stage six: *Writing up*. The final stage of the analysis involves constructing the analytic narrative and data extracts together. Representative quotations were selected to illustrate particular themes from a variety of participants. The aim was to tell the reader a coherent and persuasive story about the data, and to contextualise it in relation to existing literature.

4.3.2. Data management

Transcripts were assigned a unique identification code, which corresponded to the relevant code of the audio recording. The data was stored and managed in a qualitative software package (QSR International's NVivo 11), which was used to help systematically code each transcript and incorporate relevant information from the researcher's field notes.

Initial codes were identified by the researcher, then a sample of scripts were read and coded independently by a second researcher, one of the researcher's supervisors (CC). The two researchers reviewed, revised and agreed on the sample of coded scripts. Following this, the researcher coded the remaining scripts. Potential main themes and subthemes were identified by the researcher, which were then reviewed and refined with the second researcher. Definitions of the themes were agreed with the second researcher.

4.3.3. Presentation of themes

Patient and staff interviews were initially treated as separate datasets for analysis purposes. Staff interviews were analysed first. During the analysis of the patient data, similar themes to the staff interviews emerged. Amalgamating the findings from the staff and patient interviews and presenting them simultaneously was considered. However, the decision was made to present the findings separately, as this was felt to be the most appropriate way to synthesise and present the data in order to understand the findings. Presenting the findings from each group concurrently would not have allowed for such a clear presentation of the themes for both the staff and patients and may have lost some of the detailed descriptions. The next chapter reports on participants' perceptions and experiences of hip precautions and the withdrawal of hip precautions.

5

Interview Study Findings

5.1. Introduction

This chapter presents the perceptions and experiences of the interview participants. The findings of the study have been organised into themes and sub-themes. Each theme is presented as a narrative description and explanation of the focus and content. Quotations from interviewees have been selected to illustrate and support the themes and sub-themes. The chosen quotations were included as they represented clear and concise examples of the main content and were selected to include a range of the interviewees. Interview schedules can be seen in appendix X and Y.

5.2. Findings from phase one (before) – *hip precautions*

5.2.1. Phase one staff interview findings

A total of 18 orthopaedic staff members were invited to be interviewed, including four nurses, four occupational therapists (including one assistant), five physiotherapists (including one assistant), and five surgeons. Of these 12 replied, two (occupational therapists) declined to be interviewed and one (surgeon) agreed to be interviewed but did not attend. Thus, a total of nine orthopaedic staff members participated. Eight interviews were conducted face-to-face and one via telephone. Interviews ranged in duration from 20 minutes to 33 minutes, with a mean of 27 minutes. Participants comprised two senior occupational therapists, three senior physiotherapists, one surgeon, and three senior nurses (Table 5.1.). To report individual characteristics, such as whether the therapist treated patients pre- or post-surgery, would have identified the participants. Interview participants were either Band 6 or Band 7 (NHS pay scale), with the exception of the surgeon. The mean duration that interview participants had worked in their current role was 8.9 years.

There were four main themes identified through analysis of the interview scripts. Each theme was further categorised into sub-themes which can be seen in Table 5.2. These will be described in the relevant sections and are reported with quotations to illustrate the findings.

Table 5.1. Phase one staff participant characteristics

Participant	Occupation/discipline
101	Occupational therapist
102	Occupational therapist
103	Physiotherapist
104	Physiotherapist
105	Physiotherapist
106	Surgeon (consultant)
107	Nurse (postoperative)
108	Nurse (preoperative)
109	Nurse (practitioner)

Table 5.2. Themes and subthemes staff interviews phase one

THEME 1	**Rationale for hip precautions**
i	Historical
ii	Habitual or ingrained practice
iii	Protection against dislocation
iv	Accountability
v	Consultant surgeon - driven
THEME 2	**Provision of adaptive equipment**
i	Rationale for providing equipment
ii	Resources impacting upon provision of equipment
iii	Potential impact of equipment or furniture that cannot be adapted
THEME 3	**Perceptions of hip precautions**
i	Anxiety provoking
ii	Lack of evidence
iii	Inconsistencies in practices and differences in opinions
iv	Patient compliance
v	Impact on patients' recovery
THEME 4	**Discontinuing the use of hip precautions**
i	Willingness to change
ii	Resistance to change
iii	Potential impact on practice
iv	Potential cost and resource savings
v	Potential impact on patients
vi	Comfort as a guideline

5.2.1.1. Theme 1: Rationale for hip precautions

All participants discussed the rationale for routinely providing hip precautions to patients following a THR, reporting a number of reasons for their use, which have been summarised into five sub-themes: historical, habitual or ingrained practice, protection against dislocation, accountability, consultant-driven.

1. i. Historical

Participants reported that hip precautions were used for historical reasons and that it was something staff had 'always done'. Participants described the origin of hip precautions, which they believed to have been introduced when Sir John Charnley (a British orthopaedic surgeon who pioneered the modern THR) was practising in the 1960s when the risk of dislocation was much higher than the present day. The reasons why hip precautions were originally enforced were considered to be no longer valid, and staff expressed concerns that the application of hip precautions had not changed in line with developments in surgical technique and prostheses and improved surgical training. The rate of dislocation was considered by staff to be much lower now than when hip precautions were introduced.

> *"It's historical, there is no good common-sense grounding for it ... the things that enforced hip precautions in the first place no longer happen anymore … in the modern world, better prostheses with better training the risk has significantly decreased" - Physio, 105*

1. ii. Habitual or ingrained practice

The practice of prescribing hip precautions was described as ingrained and was considered to form part of clinicians' educational training. Staff described how precautions were 'consultant led' and were learnt from peers, with other surgeons and clinicians advocating the use of hip precautions as a 'sensible idea'. The practice of hip precautions was often passed down from the more experienced orthopaedic staff to the newly qualified, in particular, orthopaedic surgeons.

> *"A lot of what we do is habitual and it's what we've always been taught" - Nurse, 107*

1. iii. Protection against dislocation

Participants reported that the main rationale for hip precautions was to reduce the risk of dislocation by avoiding certain movements that might have placed the joint in vulnerable positions, whilst the soft tissues healed. The first six weeks following surgery was believed to be the most vulnerable period for dislocation, thus hip precautions were disseminated to patients as a means of protecting against the risk of dislocation.

> *"If you hyperflex the joint you have a tendency to dislocate and therefore to avoid putting it into vulnerable positions … dislocations tend to happen in those first six weeks so that would be the target to prevent it and usually, by then the soft tissues are starting to get a good reattachment" - Surgeon 106*

Participants explained their justification for the rationale of hip precautions to patients, by informing them of positions that may have increased their risk of dislocation.

> *"The way we rationalise this is we explain that the positions where the head of the femur is in the socket and positions where it is, more for want of a better word, out of the socket … and theoretically this raises the risk of dislocation" - OT, 102*

1. iv. Accountability

Participants described their fear of being held accountable for dislocations, in particular, early dislocations (within six weeks of surgery).

> *"I suppose if we didn't, there's the fear that if we weren't following them that someone might dislocate, and we wouldn't want that to be our fault" - OT, 101*

It was implied that the routine use of hip precautions could potentially divert therapists and clinical staff from identifying the aetiology of the dislocation and that dislocation might have been due to surgical error rather than patients not abiding by hip precautions.

> *"Hip precautions distract us from the fact that that is a surgical error … when therapists talk on the ward we say that the surgery has gone wrong but as long as we have this postoperative regime … we don't really clearly look at what has gone wrong" - OT, 102*

1. v. Consultant surgeon-driven

The decision to routinely use hip precautions was reported to be determined by the surgeons, as they were ultimately responsible for the patients' care. Staff described how the consultant surgeons wanted to protect their patients from actions or movements that they believed were not safe. Other orthopaedic staff considered that surgeons had superior knowledge and were influenced by what they said.

> *"Currently our consultants want us to observe hip precautions, so we advise them obviously not to flex the operative side past 90 degrees, not to adduct across the midline, and not to essentially pivot on a fixed foot, so no twisting" - Physio, 104*

Despite staff reporting that surgeons required them to advise precautions to patients, some staff were unsure of the reasons for this.

> *"Surgeons, I don't know really … I suppose they must do it because they are protecting themselves or protecting the patient, they must have some view to make us follow them" - Nurse 107*

5.2.1.2. Theme 2: Provision of adaptive equipment

Interviewees, in particular, occupational therapists, described the provision of adaptive equipment, reporting the reasons for this, the equipment routinely provided, advice on smaller aids and the potential impact if equipment or furniture could not be adapted.

2. i. Rationale for providing equipment

Participants reported how equipment was provided and furniture raised in line with hip precautions, specifically to prevent patients from over flexing at the hip or bending beyond 90°. Patients were provided with a 'safe height' for seats, which was the

distance from the back of the knee to the floor plus two inches, which enabled them to adhere to precautions. Occupational therapists described more general items of equipment that they also provided, in addition to equipment for hip precautions.

> *"To comply with hip precautions … we measure from the back of the knee to the floor, so we get a height, what we call a safe height, and we add another 2 inches and then we raise essential bits of furniture" - OT, 102*

Staff reported that they might recommend patients to use equipment for longer than six weeks if they felt they needed to. Staff perceived that equipment could facilitate patient comfort.

> *"I always talk about the things that they need for the hip, which basically helps with the precautions … but also I think it must be more comfortable if you've had surgery on your hip" - Nurse, 109*

2. ii. Resources impacting upon provision of equipment

Staff described how they advised patients to purchase small aids, such as helping hands, long-handled shoe horns and sock aids, as they were unable to loan these due to financial restrictions. Patients were advised by staff where to purchase different small aids and could be issued with mail order catalogues if they did not have access to the internet. Staff believed that the use of small aids were helpful in enabling patients to be more independent with functional tasks, such as washing and dressing, particularly for those who lived alone.

> *"So we have to advise patients to purchase their own small aids … they have to buy them for themselves, we're not allowed to buy the small aids, to provide the small aids … but we do find that it helps patients to be independent, the small aids are successful, especially if they live alone and they have no one to help them" - OT, 101*

2. iii. Potential impact of equipment or furniture that cannot be adapted

Participants reported that furniture that could not be raised could delay discharge if the patient was unable to provide an alternative or did not want to purchase additional

equipment. If patients required further support, because they were struggling to complete ADLs whilst adhering to hip precautions, they might be transferred to rehabilitation beds or referred for care packages (i.e. community care service), which could also delay discharge.

> *"We have to do referrals sometimes just so that they can have their feet washed and socks put on because they just can't bend down enough to do that. It's not very good for the community for people to be having to go out just to wash someone's feet that could do that before they needed their hip doing" - Nurse, 107*

Staff reported that there were insufficient providers of care packages, and reductions in funding for community services. Staff described how patients could be waiting on the wards for long periods of time to receive a care package, which could impact their target length of stay.

> *"Care packages are simply not available and if somebody needs a care package they are going to sit and wait seven days, a bigger package 2 weeks maybe, on the wards and our current target for primary total hip replacements is three days … mainly the provision just isn't adequate" - OT, 102*

5.2.1.3. Theme 3: Perceptions of hip precautions

Participants expressed their opinions on hip precautions and the impact they believed they had, particularly on patients' confidence and physical functioning. These opinions have been summarised into four themes.

3. i. Anxiety provoking

Staff expressed a belief that hip precautions could distress patients following surgery. They perceived that patients could worry about putting themselves in a position which they believed may lead to dislocation and were over-cautious in their application of hip precautions. Staff described how already anxious patients could become even more worried about the prospect of dislocating their hip and would take precautions 'very much to heart'. Participants reported that patients were often unnecessarily

worried about dislocation. Despite staff advising patients to relax precautions six weeks post THR, some patients still remained anxious about dislocation. Staff raised concerns about the impact the advice they prescribed, in terms of hip precautions, might have had on a patient's well-being and QoL long-term.

> *"It can generate further anxiety … because patients are just anxious that they are going to do something wrong and end up with a dislocated prosthesis. There are patients that have been given the all clear by their consultants to start putting the precautions to one side but remain anxious at the prospect of dislocating if they put themselves in a position which they were previously warned against, so I think psychologically it can be quite challenging for patients" - Physio, 104*

Hip precautions were considered not only to provoke anxiety in patients but also in staff. They were thought to cause staff, particularly nursing staff, to worry about breaching the precautions when treating a patient in case they dislocate, for example when rolling a patient in bed.

> *"I think it makes people nervous … they are frightened to move the patient because I think people have got this assumption that the patient is going to dislocate straight away" - Nurse, 107*

3. ii. Lack of evidence

Despite the routine use of hip precautions, staff perceived a lack of evidence supporting their use. Therapists were aware of the available evidence and considered that there was a need to investigate the effects of precautions on patient function. Without more evidence, they believed the use of hip precautions would continue to be the norm. Staff expressed concerns about continuing to use hip precautions despite the lack of evidence to support them, and the potential impact they might have on patients.

> *"We know from some of the evidence that there doesn't appear to be a link between early dislocation and hip precautions, but we have no evidence that tells us how it limits patients functionally" - OT, 102*

"Most studies that I have read … reinforce the fact that there is no obvious need for these in routine primary hip replacements … the problem with the RCTs is that they are on fairly small groups of patients, so you can't say definitely by looking at them that this is clearly not advantageous to have hip precautions, so they have tended to stick to the norm" - Physio 105

3. iii. Inconsistencies in practice and differences in opinion

Participants reported that there were inconsistencies between hospitals in the prescription of hip precautions. Staff believed that other hospitals had discontinued the use of precautions without an increase in dislocation rates, and felt it unfair for patients to receive different postoperative regimes. Overall, most staff groups felt that hip precautions were out-dated and no longer needed, particularly for primary THRs.

"I am aware that a lot of other trusts don't observe hip precautions, I am aware that a recent sort of vote of chartered physios, the overwhelming majority of them felt that hip precautions didn't really guard against dislocation, which obviously is the overriding principle behind them, so perhaps they should be discontinued" - Physio, 104

The surgeon was the only interviewee to favour the routine use of precautions.

"I favour them, in that at least some basic advice because if the patient has no idea what to do and you don't advise them … there is a chance it would pop out. I would be concerned" - Surgeon, 106

3. iv. Patient compliance

Staff reported variations in their perception of patients' compliance with hip precautions. On the whole, staff thought patients were completely compliant with hip precautions in the initial first few weeks but believed that as the pain decreased, and it became easier to move, that patients became less compliant. Staff described how some patients had 'confessed' to performing manoeuvres that they should have been avoiding.

> *"One of the questions I routinely ask at six weeks is 'can you reach to touch your feet yet?' … in theory nobody should have tried but majority answer 'yes I can' because you're supposed to be telling them at six weeks that they can finally get rid of the precautions. I think probably for the first one, two, three weeks you might get reasonable compliance, but I think after a while it stops hurting so much and it's easier to move, then the compliance level will start to fall" - Physio, 105*

Staff reported that some patients continued to follow precautions on a long-term basis, as they remained concerned about the prospect of dislocation.

> *"I know there are some patients who will follow hip precautions for the rest of their life … those are the ones that worry me the most because they are the ones that you get a phone call when they are asking about heights of furniture two, three years down the line" - OT, 102*

However, some felt that certain groups of patients (e.g. those who are elderly and/or forgetful) did not apply hip precautions to every situation. One participant described how patients might not have understood the application of hip precautions and the implications of them, particularly when combining the restricted movements together.

> *"I'm not sure how rigidly that they actually stick to them and they don't always apply them to every situation … so if they have got swollen legs they will put their legs up they won't necessarily realise that when they reach forward they are going over their 90 degrees … I do think, there are sometimes, that patients don't realise … we had a couple of dislocations whilst inspecting wounds … so those sorts of things you don't think about, as combining all those movements together" - Physio, 103*

On the other hand, some participants believed that patients misused hip precautions in order to request staff to do things for them, such as pour them a glass of water.

"I think they're almost, they want to use that as reasons why they need help with things when it suits them" - Nurse, 109

"They are quite happy for you to do everything for them. They will ask you to pour the jug of water for them because they don't want to lean forward too much to do things" - Nurse, 107

3. v. Impact of hip precautions on patients' recovery

Staff described how they believed that some patients were under the impression that there would be a period of convalescence after surgery, and often had an expectation of postoperative help following discharge (e.g. from carers and/or healthcare workers). The prescription of hip precautions was considered by staff to encourage the patient to believe that they might be incapacitated and unable to function independently at home. Staff also described how precautions could impact on various aspects of daily living, which provided greater challenges for patients who were older and deconditioned.

"Something like a restriction in adduction has to be considered when thinking about which way to move on and off the bed and if that doesn't necessarily mimic how someone's bedroom is set up at home, if they are used to getting on and off a bed a certain way at home and we then turn around and say well you can't do that anymore because of your hip precautions, that can be quite sort of disabling" - Physio, 104

Some staff felt that precautions contradicted the functional outcomes they were trying to achieve with patients, which could limit their ability to perform preoperative daily activities, leisure activities and hobbies.

"I know there are some patients who will follow hip precautions for the rest of their life and that is terrible because we're seeking for them to have surgery that makes them functionally better and instead by the advice we offer them, we limit them functionally and we can functionally make them worse forever" - OT, 102

Supine sleeping was reported to be difficult for patients, which often led to sleep deprivation and in turn distress. One participant believed that precautions potentially impeded a holistic approach to treating patients and that staff should have been able to provide alternative solutions for patients whose QoL is suffering as a result of precautions.

> *"Things have got so bad when they've got home, they've phoned us up to say 'I've now been home three nights, I haven't slept, I'm exhausted, I don't know what to do with myself, I can't sleep on my back' … The precautions shouldn't exclude everything about that person. If she can't sleep on her back, what is the point, what good are we doing if she can't sleep? So, we need to think of something else. Another solution, if there is another solution, then we should use it." - Nurse, 109*

5.2.1.4. Theme 4: Discontinuing the use of hip precautions

Staff discussed their readiness to withdraw hip precautions from routine practice and the potential impact that this could have.

4.i. Willingness to change

Therapists, on the whole, were willing to consider removing precautions from routine practice and to shift from a didactic approach to a more flexible approach which focuses on a patient's individual needs. Occupational therapists described how this would allow them to less rigid in ordering equipment and facilitate a more individualised approach to assessing patients, to enable them to be functionally independent at home. However, a small number of staff members were uncertain whether removing precautions was a good idea or not. Hip precautions were considered to be an outdated practice, particularly by therapists.

> *"Within the physio department, I think the opinion is largely the same as me, I do think there are one or two staff who are not absolutely certain… but they are willing to try … I think they (Occupational Therapists) would like to get away from a didactic approach on having to look at every single patient to give every*

single patient the same piece of equipment and actually look at patients individually and prescribe to the people who actually really need it" - Physio, 105

4.ii. Resistance to change

Surgeons appeared to be the most resistant about discontinuing precautions, despite colleagues encouraging them to abandon precautions. One surgeon described how they were hesitant to change the advice regarding hip precautions as recurrent dislocations was a complication that he experienced.

"I didn't seem to think there was an issue with giving precautions, but I am aware that some centres have let them go … one surgeon at a recent conference encouraged people to abandon them but they still seem to hang on to them" - Surgeon, 106

The lack of information and evidence available were considered the main reasons why some staff were reticent to change and develop new clinical protocols.

"The nursing and medical cohorts, where there has been less information about this, I think they probably would be more reticent to change than we would be, I don't think comes from a lack of desire to change, I think it's a lack of information … I think there will be certain consultants who will be resistant to change but that's natural whenever you make a change, there's always going to be someone who finds it difficult to accept or difficult to take the plunge … people are not keen to change without good evidence to the contrary" - Physio, 105

4.iii. Potential impact on practice

Removing precautions might have provided a more flexible service in terms of assessing patients' need for equipment. However, as the current protocol for assessment was quite prescriptive, it would have involved retraining staff to acquire greater skill and clinical reasoning in the assessment and prescriptive of adaptive equipment.

"The difficulty I'm going to have as a team leader is [to] almost train staff to do the assessments differently because … it's quite prescriptive knowing what that person needs … If we're not following that protocol … you've got to use more clinical reasoning and it is more individual based assessments" - OT, 101

4. iv. Potential cost and resource savings

There were potential cost-savings that could be considered if hip precautions were withdrawn from practice. Providing adaptive equipment to those patients who were needed it on an individual basis, rather than supplying a standard package to all patients, was considered a financial incentive. Individualised assessments for adaptive furniture was considered to have the potential to improve efficiency and decrease the amount of time spent ordering equipment.

"There are obviously financial incentives to do that (assess patients individually for equipment) as well in the current situation of the healthcare trust is not exactly flushed for cash, so if we can save money by doing that, there are significant advantages" - Physio, 105

Although some staff thought that there would be little time saved in treating patients, they did feel that the time they spent teaching precautions could have been used to practice rehabilitation techniques with patients, such as in self-care activities, and functional transfers. This would also have enabled them to spend more time treating elderly frail patients, or patients with delirium. Staff believed that by spending more time teaching patients different techniques and not restricting them, fewer care packages would be needed, which would save money and potentially decrease the length of stay.

"I think the time reduction would be minimal to us. If we did have more time we could spend it practising rehab techniques on the ward, for example, more washing and dressing assessments more functional assessments" - OT, 101

Staff described how manual handling risks could be reduced and that they would not have to spend large amounts of time altering furniture to adhere to patients' safe heights.

"When getting a patient out of bed immediately postoperatively we do have to perform a 2 man procedure … if we remove precautions we could actually log roll a patient out of bed which actually decreases the amount of effort that a staff member is having to put in and in theory decreases the manual handling risk … as long as the patient is capable of physically getting on and off the bed, chair and toilet without any problem we won't have to spend hours and hours running around changing the chair to the right height" - Physio, 105

4. v. Potential impact on patients

Discontinuing precautions was believed to be advantageous to patients' recovery and their anxiety levels. Staff believed that the patients would be functionally improved, less anxious, and able to resume normal activities sooner.

"I think patients will do functionally better. I think they will be less anxious, will sleep better, walk sooner … I think on many fronts that it would be really positive" - OT, 102

Participants discussed how they would also not have to worry about ensuring that the patients were adhering to precautions which would enable them to spend more time rehabilitating them. Physiotherapists described how they would be able to amend their treatment and hopefully expedite patients' rehabilitation to achieve greater function earlier, which would potentially enable them to resume their usual activities sooner.

"You are not limited to the exercises that you can do and can work into a deeper range of flexion without any significant risks, you can work harder into abduction and external rotation … which means you would stop a patient limping sooner and decrease their reliance on crutches and sticks … you can think about returning to certain activities faster than you do at the moment the possibilities are limitless really, it's those three simple things that do limit what you can do from an exercise perspective quite significantly" - Physio, 105

There were concerns expressed by some staff that withdrawing precautions might put patients at greater risk of dislocation which might not have been the case if they had received precautions. One participant questioned what they would say to a patient who dislocated and whether hip precautions should then be advised; they were fearful that this could result in recurrent dislocations. Staff were concerned that not providing any advice following surgery would be a disservice to patients.

> *"The worry is that some might be exposed to dislocation that wouldn't have had if they had precautions … the concern would be that some might put their hip in a provocative dislocating position and go on to dislocate … the concern would be to actively not recommend them, I would be concerned that it would be a disservice" - Surgeon, 106*

4. vi. Comfort as a guideline

Staff expressed that it would be difficult to not to provide any advice at all; they felt a more 'natural precaution' was appropriate, in which patients are guided by comfort and pain. Staff described how patients should be encouraged to 'take it easy', 'listen to their body' and not to move or force themselves into positions that were not comfortable. They believed that patients would be sensible, and that swelling, pain and stiffness would prevent them from moving into potentially 'vulnerable' positions or movements (e.g. getting down onto the floor) during the early stages of recovery.

> *"We need to put the emphasis on letting your body tell you when its limited generally patients bodies tell them if they are overdoing it and going beyond what they are capable of because it will be painful and feel very stiff, so therefore, we're looking towards a natural end feel for range of movement exercises and we're looking towards a natural precaution … rather than you can't do that, you can't do that, you can't do that, which just stops everybody from trying things, experimenting and pushing themselves a little bit" - Physio, 105*

5.2.2. Phase one patient interview findings

A total of 17 THR patients (8 males and 9 females) were invited to be interviewed. Of these, 12 responded and agreed to be interviewed. One interview was conducted face-to-face and 11 were conducted via telephone. Interviews ranged in duration from 20 minutes to 57 minutes, with a mean duration of 37 minutes. Interviewees comprised a range of patients: five were female and seven were male, with a mean age of 64 years and age range of 41-88 years. Three interviewees were employed, one was self-employed, one unemployed, and seven were retired. Nine participants lived with relatives whilst three lived alone. Participants' characteristics are listed in Table 5.3.

Table 5.3. Phase one patient participant characteristics

Participant	Gender	Age	Lives alone	Employment status
201	M	48	N	Self-employed
202	M	58	N	Employed
203	F	53	Y	Employed
204	F	41	N	Unemployed
205	M	58	N	Employed
206	M	66	N	Retired
207	F	76	N	Retired
208	F	88	Y	Retired
209	M	84	N	Retired
210	M	66	N	Retired
211	M	70	N	Retired
212	F	65	Y	Retired

There were five main themes identified through analysis of the interview scripts. Each theme was further categorised into sub-themes which can be seen in Table 5.4. These will be described in the relevant sections and are reported with quotations to illustrate the findings.

Table 5.4. Themes and subthemes patient interviews phase one

THEME 1	**Perceptions of hip precautions**
i	Rationale for prescription
ii	Perceived risk of dislocation
iii	Fear of dislocation
iv	Discontinuing the use of hip precautions
v	Consultant surgeon - driven
THEME 2	**Compliance with hip precautions**
i	Risk-averse/cautious
ii	Varying adherence
THEME 3	**Perceived impact on recovery**
i	Psychologically challenging
ii	Sleep deprivation
iii	Activity restriction
THEME 4	**Provision of adaptive equipment**
i	Equipment prescribed
ii	Usefulness
iii	Suitability
iv	Additional care and support needs

5.2.2.1. Theme 1: Perceptions of hip precautions

All participants discussed their perceptions of hip precautions, the rationale for them, and their perception of the risk of dislocation.

1. i. Rationale for hip precautions

Patients were able to recall the hip precautions, describing them as 'rules'. They explained their understanding of them and how they were advised to follow them for six weeks to reduce the risk of dislocation. Patients described how the risk of dislocation was greatest in the first six weeks whilst soft tissue around the new joint healed, and the muscles regained strength.

> *"You needed to grow more tissue to firm up the hip because as I understand it, it is perfectly possible for the hip to dislocate in the early stages, so you need to build up the tissue around the hip to keep it in place" - 209*

1. ii. Perceived risk of dislocation

When discussing the perceived risk of dislocation, patients described how they were very careful about following hip precautions to ensure that they did not dislocate. There were mixed opinions amongst patients about the possibility of dislocation. Some patients perceived that there would always a risk of dislocation, so they should remain careful long-term. However, the risk of dislocation was considered quite unlikely by other patients. One patient described how their surgeon informed them that the rate of dislocation was 1%. However, despite discussing the risk of dislocation with their surgeon, patients were still concerned about the possibility.

> *"I wasn't going to take any chances. I don't want to dislocate, it must be really horrible. People have gone to all this trouble to put a new hip in me and I've gone through all this, the last thing I want to do is go through a dislocation, so I just thought I am going to do as I am told" - 205*

One patient described how their surgeon tried to reassure them by demonstrating positions that were likely to lead to dislocation. Despite this, the patient still remained anxious at the prospect of dislocation.

> *"The only position and he actually demonstrated the position which is not a position that I would probably get into in normal circumstances. So, in fact, he reassured me, but it is that nagging doubt in your mind" – 212*

1. iii. Fear of dislocation

The majority of the patients reported that they were concerned about the possibility of dislocation. Patients described how they were initially very fearful about dislocation, but following hip precautions helped to reduce their anxieties and enabled them to focus on the exercises to strengthen their muscles. The exercise programme was considered to provide a structure and routine during their recovery period.

> *"It gave me something to work on, something to go with. Without it, without knowing what exercises what I can and can't do I'd have really struggled. I perhaps wouldn't have done anything because I'd*

have been fearful, just of dislocation ... that was one of my biggest fears. I was absolutely terrified of it, but knowing what I could and couldn't do, you know, put my mind at rest hugely" – 204

Some patients explained how they were still fearful about dislocation and were scared about moving into certain positions. One patient discussed the concerns they had about the consequences of dislocation and the potentially 'excruciating' pain they might experience as a result. The lack of information regarding the treatment and management of a hip dislocation was considered to further exacerbate their anxiety of dislocation.

"I was scared about dislocating it and I still am … the biggest worry I have is about how to move without dislocating it … I don't know what would occur and how would they put that back together again … I don't know whether I would have to have an operation to put it back in or whether they would just do it under a mild anaesthetic, or local anaesthetic or gas and air … I think maybe for me the lack of knowing is fearful" – 212

One patient considered that a patient support group would have been beneficial to discuss their progress, concerns and fears about their new hip joint.

"It would have been nice to have gone to a support group where people because if you don't know anything about it, it's frightening. You don't know if you are doing right or wrong, or if you have something like oh what was that, there is no one to ask … I know you can always phone the nurse. But you can't ring the nurse and talk generally, so it would have been nice to have a support group" - 207

1. iv. Discontinuing the use of hip precautions

The potential removal of hip precautions was discussed with patients who expressed a range of opinions. Some patients described that they would have preferred to sleep on their side if it had been possible.

"I think most people do tend to go on their side. I suppose they have a favourite side. I still haven't slept on the operated side, I've always gone on the other side" - 207

One patient had mixed views about the potential removal of hip precautions from routine practice.

"I think that is good and bad because obviously … [it's] such a huge operation … [it] is really fundamental, you do need to know what you can and can't do to some extent. However … it was almost like it was too frightening, it was too much warning. But I do need to know what to do and what I can't do" – 212

5.2.2.2. Theme 2: Compliance with hip precautions

The majority of patients described how they adhered to hip precautions as instructed. Some patients reporting that they applied them to all situations.

2. i. Risk-averse/cautious

Patients explained how, due to their fear of dislocation, they were cautious about moving themselves into certain positions, and having hip precautions enabled them to avoid certain 'at risk' positions. Hip precautions were considered to provide guidance about what they could and could not do, preventing patients from moving into positions that could potentially lead to dislocation. Patients reported that they were careful because they did not want to damage the new joint. One patient described how, whilst they were in the hospital, two patients were readmitted and had revision surgery as a result of dislocation, and that this had influenced her compliance with hip precautions.

"When you have seen them being readmitted, it makes you think. I was very careful, I did as I was told. … obviously, you take note of things in hospital. They have a bearing, it certainly had a bearing on what I did and how I did it. - 207

2. ii. Varying adherence

Patients described how they were advised to follow precautions for six weeks, but the majority of patients adhered to them until they saw their surgeon again – for some patients this was eight weeks after their surgery.

> *"As I understood it was six weeks, but my appointment at the hospital was actually after eight weeks, so I continued sticking to the rules until then. I was then told it was fine to start breaking the rules" - 209*

Patients described how they strictly followed hip precautions and did not try to 'push the boundaries' of the restricted positions. Whilst some patients stated that they constantly abided by precautions, others reported forgetting on occasion.

> *"I followed them religiously, I was very careful to follow all the things religiously … I think I forgot once, I dropped something and picked it up without thinking, but mostly I just followed religiously" - 205*

Two patients reported riding a bicycle during the time period in which they were supposed to be following precautions. One patient believed that the benefits of cycling outweighed the potential risks, despite the advice given by clinicians.

> *"I asked the physio and he said you're not allowed on your bike until after you have seen the doctor. I said is that because cycling is bad, and he said no actually cycling is good it's just that you will break the 90-degree rule" - 205*

Both patients reported that they knew they were not supposed to be riding a bicycle but believed that this would not lead to dislocation and that cycling would be beneficial for strengthening the muscles in their legs. The patients believed that they could mount the bicycle whilst adhering to hip precautions.

> *"I went on a pushbike after three weeks … I did raise the seat high enough so, you know, it was high enough. I managed to just pull the bike over, like lay it on its side to make a little bit and then just get it*

up and used my good leg to get the power down on the pedal first and sit on the seat so I was OK from that point of view" – 201

Some patients reported that they had stopped sleeping on their back before the end of the six-week precaution period, mostly at approximately four weeks post-surgery. Patients described how they felt comfortable to change their sleep position and used pillows to help support their leg in bed.

"I did go against the instructions and stopped sleeping on my back earlier than I should have done but it doesn't have seemed to cause any problems … I didn't feel that there was a risk, I didn't think that I would be doing anything by changing the position that would risk dislocation. It just didn't feel that it was a risk really. If I had felt that I wouldn't have done it obviously. It was just based on a hunch" - 205

"For about the first four weeks I tried to sleep exclusively on my back … but after about four or five weeks I put a pillow towards my right leg, so I didn't bring my left leg over or anything like that" - 211

5.2.2.3. Theme 3: Perceived impact on recovery

Patients described the impact that they believed hip precautions had on their recovery.

3. i. Psychologically challenging

Hip precautions were perceived to create anxiety amongst patients and potentially prevent them from progressing and returning to activities. Participants described how even though they no longer had to follow precautions they still remained anxious at the prospect of certain activities that could lead to injury or a fall (such as walking over uneven terrain), and consequently result in dislocation.

"I think to begin with, because I was quite scared about the restrictions, I think I held myself back … I think I am still a little

scared of what I could do or couldn't do with it. There is just a little bit, there's a little bit of fear of how I could hurt myself" - 212

3. ii. Sleep deprivation

Patients described supine sleeping as the most difficult hip precaution to follow. All patients reported poor quality sleep during the night and napping during the daytime as a result. Patients discussed how supine sleeping was unnatural for them and not their position of choice, and that they had been sleeping in a certain position for several decades. Patients described how they found it difficult and uncomfortable to sleep on their backs, with many reporting lower back pain and sore heels as a result.

"I found it really difficult staying on my back … I just didn't like it and I didn't get used to it either … I had lots of broken sleep for a long time … it was just real discomfort at night, that got to me and made me feel very tired and a bit fed up" - 204

Patients discussed how other medical conditions made supine sleeping extremely difficult and patients often resorted to using a number of different methods, including pillows and medication in order to help them sleep.

"I have other medical conditions … so lying on my back is not pleasant. It is quite painful … I did resort to the painkillers" – 207

3. iv. Activity restriction

Patients described how hip precautions restricted their daily activities, hobbies and leisure activities.

"I have always been a busy man outside like cutting hedges, skimming the dykes. All things that you can't do, as you can't twist your body … there are lots of things at the moment that I can't do" – 206

Patients described how once they stopped following precautions, and were able to perform the previously restricted movements, they felt their recovery progress had slowed or declined.

"Now I've got to the point when I'm allowed to break the rules … it sort of feels a bit as though I have gone backwards. I'm suffering more pain and I feel I can't walk as well as I was used to. I guess it is probably to be expected that things will be different when you start twisting and bending and so on. I am putting more strain on it" - 209

Some patients discussed how hip precautions were affecting them longer-term as they were still concerned about the risk of dislocation. One patient described how they were unsure how to perform certain movement patterns of everyday activities, such as picking something up off the floor.

"I am a bit tentative … there is a restriction on bending down so I'm not sure about bending … I bend at a really awkward angle because I'm not sure how I'm supposed to bend, or how I can bend, so that's a slight problem. …. I find bending quite difficult, at the moment, I sort of bend as you do when you bend to touch your toes … now I am not sure if that is good, or bad, or indifferent … these are all the things that are a problem not knowing what you can do afterwards, to dislocate" – 212

5.2.2.4. Theme 4: Provision of adaptive equipment

Patients described their perceptions and experiences of the adaptive equipment that had been prescribed by the occupational therapists.

4. i. Equipment prescribed

Patients explained how their furniture had been raised, and that they had been provided with adaptive equipment. All reported that they had been issued with raised toilet seats, perching stools and sofa raisers. Some patients had also been provided with a high-backed chair. On the whole, patients were positive about the equipment provided, however, a small number believed that they received pieces of equipment which they did not necessarily need.

"Raised toilet seat, a perching stool for the kitchen, one for the bathroom, a commode, just in case my, say, in case I had to sleep

downstairs or something which I didn't, so I've not used the commode – so yeah that's what I was given. And that was all set to height when it was delivered which was fantastic" - 204

One patient received additional equipment to assist with washing.

"I had superb support from the support team OT who sorted out extra hand grips and different equipment. Extra was the 2 grab rails in the shower unit itself. Sponge on a stick and a smaller sponge on stick because I have to clean my whole body" - 207

One patient who had previously had a hip replacement explained that at the time of their first hip replacement small aids were provided but now patients had to purchase their own.

"The grabbers and stuff like that, eight years ago the National Health gave you the lot; whereas now it's like you've got to buy that, you've got to buy this" - 201

4. ii. Usefulness

Patients described raised toilet seats and toilet frames as the most practical pieces of equipment provided, helping to support them when transferring to and from the toilet.

"The best thing I ever had are the toilet seats, to be honest with, I used to sort of crash down onto the toilet, because if your muscles are not working and your legs are in pain it is really hard to sit down onto the toilet and it is quite hard. I have actually found those quite wonderful … they have been really helpful, really comfortable" - 212

Some patients reported that their use of equipment had extended beyond six weeks, due to concerns about their ability to transfer.

"Yeah, that's been a frame and a toilet raise yeah. That's been quite useful. I haven't sent them back yet because I think I just need to

make sure I can get off the loo without that frame being there. I'm fairly sure I can" - 203

The majority of patients found the perching stool beneficial for its intended use, however, one patient explained how they found an alternative use for theirs.

"The perch stool for the kitchen, I didn't really use it much. It was quite nice when the weather was good … I could use that to just perch one outside, sit in the sun. I managed to use it as a walking frame to get out the door" - 203

Small aids had been purchased by nearly all the patients, with long-handled shoe horns and helping hands/grabbers the most commonly reported. Some of these patients had purchased them before their THR as they were struggling to put their shoes on or pick items up off the floor. Whilst some patients purchased sock aids, most patients explained that their spouse, partner or another relative assisted with this task.

"I purchased a long-handled shoehorn, very very useful that was …. And one of these handle things for when you drop something on the floor ... I found that useful for the first four weeks because you worry about your hip so I found that quite useful this long-handled lifting equipment … I found those two very useful, I didn't bother with sock aid which they suggested to help me put my socks on, I got my wife to do that" - 211

One patient described how a leg lifter issued by the hospital was very helpful in providing support when getting in/out of bed.

"The only thing that the hospital gave me which I did find extremely helpful, again perhaps it is to do with the muscles in my leg, if I wanted to put both of my legs onto the settee, the nurse at the hospital gave me a double loop thing ... that was wonderful because … I couldn't manage to lift my operated leg up at all, it just didn't

seem to work. I used that for about two to three weeks, as soon as it became ok to lift it suddenly I could lift it" - 212

4. iii. Suitability

Some patients found that the adaptive equipment was unsuitable for them and their home situation.

"I had perch stools which in all honesty, I had one for the bathroom and my bathroom's just too small. I couldn't get the toilet frame and the perching stool in, so I never use it" – 203

One patient explained how they had to be provided with additional equipment because the original equipment provided was not appropriate.

"Extra was the 2 grab rails in the shower unit itself. They did bring shower stools, different ones they tried but they didn't really work … they were either too big or very uncomfortable for me" - 207

Some patients described how the equipment they were provided was not appropriate, and it had to be either altered or exchanged.

"Unfortunately, they measured me up for all the bits of equipment and worked out what height I should have. But everything I sat on I couldn't put my feet on the floor … everything was too high" - 206

One patient expressed their concerns when they were informed that their furniture could not be altered.

"They were going to come and raise the sofa. That was a bit of an issue actually. When they got in they said we can't raise that sofa and so that was a bit of a worry … to be told then they couldn't raise the sofa was a huge concern about what I was going to do when I came home" - 203

4. iv. Additional care and support needs

Two patients received additional care and support following discharge, to assist with washing, dressing and meal preparations. Both patients reported cancelling the care by the end of their first week at home.

> *"Occupational therapy were very good. They set up for me to have city care come in after one day I asked for the lunchtime call to be removed. After five days, no three days I asked for the nighttime call to be cancelled so I only had the morning ones come in" - 208*

One patient described their feelings of panic about trying to purchase small aids when they realised that they were not supplied on the ward.

> *"I was thinking, oh god, I need to get one of those and I was flapping about that, and in the end I didn't get one. I don't know why … I didn't realise, I thought they'd have them on the ward" - 203*

4. v. Additional help/support

Two patients received additional care in the form of support packages, from suppliers, to assist them with meals and personal care. Other patients described how they received assistance from relatives for tasks/activities they were unable to do, such as cooking and cleaning. Family members were reported to not only provide practical support but also emotional support, and motivation to progress recovery/rehabilitation. Friends were also reported to provide emotional support.

> *"All my family and my wife in particular. General day-to-day life I suppose, you would have to put that down to encouraging me to proceed. When I didn't feel like getting up in the morning, they made me get up" - 210*

5.3. Findings from phase two (after) – *no hip precautions*

5.3.1. Phase two staff interview findings

A total of 20 orthopaedic staff members were invited to be interviewed, including four nurses, four occupational therapists (including one assistant), five physiotherapists (including one assistant), and seven surgeons. Thirteen of these responded, one of whom declined to be interviewed. Three members of staff agreed to participate but were unable to attend. A total of 10 orthopaedic staff participated in the interviews. Of these, nine were conducted face-to-face and one by telephone. Interviews ranged in duration from 11 minutes to 40 minutes, with a mean duration of 24 minutes. Interviewees comprised two senior occupational therapists, one occupational therapist support worker (assistant), three senior physiotherapists, two surgeons, and two senior nurses (Table 5.5.). To report individual characteristics, such as whether the therapist treated patients pre- or post-surgery, would have clearly identified who the participant was. Interview participants were either Band 6 or Band 7 (NHS pay scale), with the exception of the surgeons, and the therapy support worker (non-professionally qualified staff, NHS Band 3). The mean duration that interview participants had worked in their current role was 9.8 years. Two of the participants interviewed were also interviewed in phase one of the study.

Table 5.5. Phase two staff participant characteristics

Participant	Occupation/discipline
301	Physiotherapist
302	Occupational therapist
303	Occupational therapy support worker
304	Physiotherapist
305	Occupational therapist
306	Nurse (preoperative)
307	Nurse (postoperative)
308	Surgeon (consultant)
309	Surgeon (consultant)
310	Physiotherapist

There were four main themes identified through analysis of the interview scripts, which were further categorised into sub-themes (Table 5.6.). These will be described in the relevant sections and are reported with quotations to illustrate the findings.

Table 5.6. Themes and subthemes staff interviews phase two

THEME 1	**Changes to practice/removal of routine hip precautions**
i	Rationale for withdrawing hip precautions
ii	Information and training provided
iii	Alternative advice provided
iv	Challenges experienced
THEME 2	**Staff perceptions of the new regime**
i	Adapting to the new regime
ii	Consultants remain conservative
iii	Patient responses and educating patients
iv	Impact on treatment practice
THEME 3	**Perceived impact on patients**
i	Ambiguous instructions/mixed messages
ii	Sleep positions
iii	Decreased anxiety
iv	Improved recovery or progress rehabilitation
THEME 4	**Adaptive equipment provision**
i	Individualised assessments
ii	Reduction in the prescription of adaptive equipment
iii	Overprescribing equipment to patients 'out of area'
iv	Equipment supplied on the ward
v	Referrals for patients who require additional help and support

5.3.1.1. Theme 1: Changes to practice/removal of routine hip precautions

All participants discussed the recent changes to clinical practice, the rationale for withdrawing precautions from routine practice, staff training provision, and alternative information and advice provided to THR patients.

1. i. Rationale for withdrawing hip precautions

Staff described the reasons why hip precautions had been removed from routine practice. The majority of staff reported that the lack of evidence to support precautions was the main justification for withdrawing precautions. Some staff believed other hospitals no longer advised precautions to patients following hip replacement surgery. Consultants were believed to have had an important role in the decision to withdraw precautions from routine practice.

"[There's] research to say that there was no benefit to having hip precautions to the majority of people and if they were going to dislocate that was going to happen in the very early stages, whereas hip precautions were not going to prevent that. So that is why I think they decided not to issue the hip precautions" – Nurse, 306

1. ii. Information and training provided

Information and training to support the transition and change in routine practice were discussed. Therapy team leaders recognised that they were key to ensuring that all their staff understood the new treatment regime, and they provided training sessions to assist with this. The team leaders reported that most staff attended the sessions and staff informed them that they had received and read the relevant documentation detailing the changes. Staff were perceived to have engaged with training sessions and information provided. The training was considered to be time-consuming but worthwhile to support staff through the transitional period. Team leaders believed that staff lacked confidence about the removal of precautions and in their ability to answer patients' questions relating to the change. There appeared to be a need for reassurance for the more junior staff about how to discuss the topic with patients. Team meetings were considered to provide opportunities to discuss and coach staff through questions raised by patients.

"As a leader I felt my responsibility [was] to manage the staff through the change we did spend quite a lot of time investing before the study into kind of reassuring, and explaining what the study was, and explaining the reasons, talking about ways in which we might do our assessments differently, providing training for the support workers … I think a good investment in the time, but it has taken time to go through that with staff [to] make sure everyone feels confident leading up to the change, then through the change. We've discussed it a lot of at team meetings… reassurance in the wording I think has been the main thing staff have asked" - OT, 302

However, some nursing staff felt that not enough information or training had been provided to them, and that they were not fully aware of what the changes to practice were and when they were supposed to occur. Nursing staff reported receiving informal

training from other professions and believed that there was a need for a team approach in terms of training. They also felt that information regarding alternative advice for patients was not considered. Nursing staff suggested that their ingrained practices regarding hip precautions were difficult to change and felt that they required more reassurance and knowledge about the new regime.

> *"Whether we could have done with more [information], I don't know …. I think, not just the fact that we not doing hip precautions anymore, it is what do you say to them instead then. I probably would have felt more comfortable having a bit more information on that I think [they] should have got us all together and go through it and said right we are not doing that, so advise them to do this, tell them that and if they ask this, tell them that sort of thing … it has been instilled in me for so many years, it felt quite alien almost to be not saying all this" – Nurse, 306*

1. iii. Alternative advice provided

Staff described the advice they provided to patients instead of hip precautions. The focus of this advice was considered to be tailored to the individual, encouraging patients to move as they felt able within their own functional ability and as pain allows, rather than the 'blanket approach' of precautions. The emphasis of the new advice was on encouraging patients to 'listen to their body' and not to fear dislocation. Staff felt that the new advice was more progressive following surgery, instead of repeating the message of hip precautions to patients. Patients were advised to not force any movements if they felt they were 'pushing into pain', and to choose a position (for sleeping, sitting etc.) that was comfortable.

> *"It's kind of been more what we don't say rather than what we do say, so essentially before the operation, we advise people to move as is comfortable, which is a simple message and very easy to replicate. After surgery, … we are reinforcing the message that was given preoperatively that you can move, don't be frightened to bend, don't be frightened to reach down and touch your toes, don't be frightened to try and make the bed if you want to, don't be frightened to go outside and have a run around, a run [laughs], a walk around. Don't be frightened to progress onto one crutch, those are the sort*

of messages, that you can do things, you don't have to hold back, you are free to move as you wish" – Physio, 301

Staff reported discussing the current evidence available, and the advancements in surgical techniques and prosthesis development (e.g. bigger head sizes) with patients to reduce their anxiety. Patients were considered to be reassured by staff, particularly patients who were anxious at the potential risk of dislocating their hip, accepting their explanations as to why hip precautions were no longer enforced.

"Reassuring them about resuming function, getting back to normal for that patient … reassuring patients that its ok to move and exercise within their own limitations of comfort, and that pain doesn't mean harm and that they aren't going to do any damage. A lot of reassurance along the way" – Physio, 304

1. v. Challenges experienced in withdrawing precautions

Issues that arose during and following the removal of routine precautions were discussed by staff. Staff reported that some patients, those who had previously been taught precautions, were unsure about the new regime and found the change in advice quite daunting. Staff described how they had found it quite challenging to reassure patients.

"One problem that has been highlighted to me is patients who have had their other side done are very wary of it still. Because obviously when they had their other side done we were very much involved in hip precautions so they're a bit wary about how they've suddenly disappeared" – Physio, 310

Staff also reported that some staff members had continued to advise patients to follow precautions. One staff member described their experience of managing patients who had been instructed to following hip precautions by their consultant and discussed the difficulties they encountered when they provided opposing information. They discussed the challenges they experienced in trying to explain the potential benefits of not following precautions, and reassured the patient that the new regime could

potentially aid their recovery. However, despite their attempts, the patient was insistent on adhering to the advice provided by the consultant.

> *"I am aware of two incidents with a particular consultant where the consultant said preoperatively that the patient must follow hip precautions, whereas obviously as a trust we have agreed that is not the case so unfortunately, I think they are harder perhaps to control … it's been difficult actually because in theory, you can't go against what the consultant says but nothing had been documented about that. It was very much his word against ours … [but] you can't really say to the patient ignore what the consultant said because unfortunately, the consultant is God is you like, they have this {power} …" – Physio, 304*

5.3.1.2. Theme 2: Staff perceptions of the new regime

Staff described their perceptions of the new regime of no precautions.

2. i. Adapting to the new regime

Staff discussed their experiences of adjusting to the new regime, and how they perceived other disciplines had responded to the changes. It was believed that some long-term staff had 'adapted very quickly' and were willing to confront other members of staff who continued to advise patients to follow precautions. Nursing staff reported how hip precautions were 'drilled into them' and that during the initial period following the withdrawal of precautions they were having to 'bite their tongue', as the new advice was 'very much against the grain'. Some staff explained how they sometimes found it difficult not to advise patients about hip precautions, and so tended to provide little or no alternative advice in terms of movement.

> *"I think we in terms of physio team have been brilliant, we can really progress people a lot quicker and people will recover a lot better. Occupational therapists, interestingly I think they weren't sure initially because of their role in preop and the provisions that they provide in terms of equipment. I think there was a little bit uncertainty about whether we are giving the equipment to everyone*

or are we assessing people individually. I think staff on the ward, personally I have noticed that things haven't really changed, and unfortunately, nurses are still telling patients the wrong information, the phase of us getting rid of precautions is still perhaps ongoing on the wards with certain staff" – Physio, 304

"Hip precautions I think are still instilled in us, even though we try not to … I think we still have it in us that if we someone bending over I sometimes forget and automatically try and stop someone …. it's just periodically sometimes" – Nurse, 307

Doctors and nursing staff were considered to be the most difficult to convert to the new regimes and appeared to therapists as 'forgetful', as they were reported to revert back to hip precautions. Therapists suggested that another reason some staff returned to prescribing hip precautions might have been their lack of understanding of the justifications for the removal of precautions. Some staff described how they were anxious at the change because surgeons and consultants were also anxious about the removal of hip precautions. Support staff were thought to have found it challenging to adjust to a less prescriptive approach.

"I think the support workers have probably found it more of a challenge because they have to use clinical judgement more. Before it was very prescriptive, taking the safe height, it was very prescriptive how high to make furniture … I think staff are really thinking about taking each individual patient's circumstances on board because the staff that do the preop are band 3 and 4s, they are not qualified OTs, so they have not had OT training, so I think it has made it more of a challenge for them. Although I think they are pretty experienced and they are coping really well" – OT, 302

Staff explained that they have had to challenge other members of staff in regard to the advice and information provided to patients. Nurses were reported to be the staff group who required the most prompting about not prescribing precautions to patients.

"Every time we see it we challenge it, so if you see a nurse telling someone to lie on their back, generally we will have words and say no it is ok to lie on your side, it is ok to move as you want to … it is challenged repeatedly" – Physio, 301

"I think the biggest observation of mine is sleeping positions, so staff still telling people that they have to sleep on their back for six weeks. I think because the nurses are involved with patients at night, positioning them in bed, it's sort of just become roll of the tongue well you will be on your back for six weeks this is how you must sleep, whereas we need to change that way of thinking really … just reminding them nicely that's not as important anymore and not necessarily that they are on their backs for six weeks and to show alternative ... very defensively some of them … some just generally yes, of course, I keep forgetting. It's just that constant reminder I think" - Physio, 304

2. ii. Consultants remain conservative

Surgeons were considered to be the most resistant group to the removal of precautions. Staff described how they had to follow different protocols for individual consultants, and that they had to check the patient's notes to determine if the patient was required to follow a different protocol. Concerns about dislocations raised by the consultants were discussed by other members of staff, with some staff reporting that consultants had considered changing other areas of their practice, such as partially weight bear, and preventing external rotation.

"Yes, the consultants seem to do what they like. Issues with ensuring that they are documenting clearly for us, so the routine protocols are met. Unfortunately, I think consultants say what they want to say and that can be interpreted in different ways by patients. I am aware of two incidents with a particular consultant where the consultant said preoperatively that the patient must follow hip precautions, whereas obviously as a trust we have agreed that is not the case … it's been difficult actually because in theory, you can't go against what the consultant says but nothing had been documented about that" – Physio, 304

The surgeons also expressed their concerns about dislocation and the consequences that could occur when such an event takes place. Hip precautions appeared to still be advised by some surgeons, as they strongly believed that they protected against dislocation. The surgeons tried to provide some justification for their conservative outlook. They discussed the effects that a dislocation might have had on a patient, in particular, psychological effects.

> *"If you have one dislocation, they are never as good, they lose the confidence and they are just not the same … I don't think I've seen a patient return back to the original confidence as before. The first dislocation, especially immediately after an operation, is quite a catastrophic episode I think" – Surgeon 309*

One surgeon described how they encouraged patients to use crutches for six weeks, as it served as a reminder to the patient that they were still recovering from surgery. Another surgeon discussed how they advised patients to avoid excessive movements of those previous warned against (i.e. hip precautions); the surgeon described how the risk was less than 1% but the patients still needed to be careful in the first six weeks, as their range of movement had improved as a result of the surgery. Surgeons explained that they were solely held accountable if the surgery did not go as planned, and they had to deal with the consequences. There were concerns as the surgeons' performance data and surgical statistics were publicly available online with no justification provided as to why these adverse events occurred. Surgeons described how they were not acknowledged for their successes but were recognised for their failures, with little or no consideration taken into account regarding the complexity of the case.

> *"I'm very conservative and I believe that the dos and don'ts should be followed. … there is a lot of evidence to show that after the first dislocation the hip is never as good as it was before that dislocation happened. So, I'm very slow with rehabilitating patients. I would rather that they slow down, take it easy and then go on to work … I'm conservative because of the risk of dislocation. … for the surgeon, it is a problem, but for the patient, he has to live with that fear: oh, it's happened once, it might happen again, that fear … I don't know why, I believe in my mind that if you use crutches for the*

first six weeks then they know that something is not quite correct and then they will, they're less likely to dislocate the hip. So, my post-op instructions mention use crutches strictly for six weeks" – Surgeon, 309

2. iii. Patient responses and educating patients

Staff described the discussions they had had with patients about the removal of precautions. Patients who had previously had a THR were considered to quite 'wary' and 'cautious' at the prospect of no longer having to follow hip precautions. Younger, more able patients were more accepting of the change than older patients, happy that they did not have to follow a restrictive and rigid postoperative protocol. Whilst some of those patients accepted the new advice following discussions with staff, others wished to continue following them as a result of their previously successful THR. Staff discussed the explanations that they provided to patients regarding the removal of precautions and the rationale behind the change in advice. Patients were believed to respond well to the relaxation of precautions, and the increased flexibility of the service, which enabled them to be more mobile and independent.

"It's been positive when I have explained that there is not evidence either way that you should or shouldn't. With the primary hips, we have taken them away and it gives them more flexibility and I think they like that idea that they are not as restricted … If say they have had their other hip done under precautions and now you have removed precautions, they might be a bit more cautious because you are saying something slightly different now" – OT, 305

2. iv. Perceived impact on treatment practice

The removal of hip precautions was considered to be beneficial to other aspects of clinical practice, enabling staff to use a greater variety of techniques to mobilise a patient, and helping reduce patient handling and the strain on the therapist. The amount of time spent teaching precautions was considered to have provided some time-saving in certain areas, that has enabled staff to spend more time teaching different functional techniques and conduct functional assessments.

"Getting them out of bed is easier because you don't have to worry about the occasional cross-leg or occasional flexion beyond 90

degrees. You can also use a log roll technique to get patients out of bed if they are willing to try a different alternative, so instead of doing a pivot turn, you roll the patient onto their side and sit them up similar to someone who's just had back surgery which is less of a strain to the therapist" – Physio, 301

"It's a lot easier from our point of view … in the speed of seeing patients that come through to the clinics that has helped an awful lot. A lot as a lot of time was spent going through precautions and now with having the hip school doing that as well that has eased off the time spent with patients in clinics" – OT, 303

5.3.1.3. Theme 3: Perceived impact on patients

Staff discussed their perception of the impact that the removal of precautions had on patients and their recovery.

3. i. Ambiguous instructions/mixed messages

Staff described how 'not everybody had sung from the same hymn sheet' and that there was some frustration as patients were receiving different information from different members of staff. It was reported that some consultants were still advising patients to observe hip precautions, whilst therapists were advising them to move as is comfortable. Nursing staff were also suggested to advise patients about sleeping on their back, with some even advising against bending. Some staff, particularly therapists, were concerned about the potential confusion this might have created for patients. There were also concerns about external therapists (therapists from local hospitals or within the community) who might not have been aware of the removal of precautions which might have potentially further confused patients. Staff felt that external therapists should have been provided with more education about the recent changes to the hospital's practice to ensure patients were receiving consistent information.

"I suppose one of the things that would be ideal would be for there to be a bit more education out there for all the physios who aren't related directly to this acute hospital. You know, because I think there will be physios out there who have no idea this project's going

on and have no idea that we've done away with precautions. And maybe confusing the patients a bit more" – Physio, 310

3. ii. Sleep positions

Staff described how patients were no longer restricted to supine sleeping but were now able to sleep in any position in which they chose. The increased variety in sleep position was considered by staff to be beneficial to patients as many had previously stated that they did not like sleeping on their back or were unable to sleep in this position. The sleeping positions, alternative to supine, were reported to be discussed and demonstrated with patients preoperatively. Staff explained how they advised patients to use pillows to help support them in bed.

"Most people still report some sleep disturbance. They say they have some nights where they have not slept well … The number reporting heel soreness has decreased, which is definitely an advantage of being able to sleep on your side. Some patients were developing sore areas and were having to use alternative ways of sleeping to get around that. The number of reported sleep disturbance has not massively changed, but the amount that complain about sleeping positions generally has definitely gone down … We do tell them they can sleep in any positions they like, but the majority will sleep on their good side and some still sleep on their back" – Physio, 301

3. iii. Decreased anxiety

Staff described how patients appeared to be less anxious about the risk of dislocation than when hip precautions were enforced. Patients who were not prescribed hip precautions were believed to be more confident in mobilising and returning to functional activities than those who were. Staff discussed how the risk of dislocation was no longer considered pivotal in preoperative education and, as a result, patients were not acutely aware of dislocation and the potential risks.

"I do think a lot of it is the fright of having to adhere by precautions has now been relieved. They feel a bit more at ease with that, but they still have discomfort when you do mobilise patients with hip replacements still, so I don't think that changes … If you just had a

big surgery on your hip you are going to be in discomfort so that won't change but I think the aspect of worrying about having to adhere by all these precautions like they were having to do before has now been lifted from them they feel a lot more at ease with having surgery and worrying about things as much … they don't feel as anxious about getting up and mobilising like when they were having to adhere by a lot of these precautions" – OT, 303

"Yes, I think probably more confidence, because before by stressing the hip precautions and as I say they are almost frightened, well some of them, some didn't care, but some of them are almost frightened to do anything in case it comes out. I think it gives them more confidence" – Nurse, 306

3. iv. Impact on recovery/progress rehabilitation

The less restrictive protocol of no precautions was considered to provide staff with more options to help progress patients' rehabilitation. Therapy staff discussed how they were able to encourage patients to perform more movement specific exercises, which could enable them to perform daily activities more easily. Therapy staff perceived that hip precautions limited patients' recovery, not only physically but also psychologically.

"In terms of confidence of patients and their ability to do things, who can see a change in terms of their willingness to go home a try a move and progress their exercise … we have removed a barrier to progress. So, from a physiotherapy perspective that can mean only one thing, it should be earlier return of function, better recovery of strength, power, mobility, and decrease anxiety" – Physio, 301

"I think day-to-day practice we can do more with the patients, not necessarily straight away because postoperatively you are limited by their pain anyway so actually they are not moving and are probably staying within the precautions if you like, purely from a pain comfort point of view … I think it was very restrictive before, whereas I feel now that recovery is definitely aided because of it.

For the right patient, I do think recovery is quicker, more effective, they are probably benefiting a lot earlier from surgery than before … In terms of movement and progressive exercises so you can do more bending, more squatting, forms of exercise functionally I think that transfers over, so they can get themselves dressed and up and about so just generally their recovery is aided by that" – Physio, 304

However, surgeons believed that the use of hip precautions helped manage patients' expectations about their recovery and what they could achieve. The surgeons discussed how precautions ensured that patients did not push themselves beyond their limits during the early stages of their recovery. They described how, following surgery, patients could 'subconsciously lose the feeling' that they had had a THR, as the pain decreased and the hip eventually became painless. Surgeons were concerned that without precautions patients would return to activities more quickly than the surgeons believed they perhaps should following surgery. Surgeons were also worried that this might have increased the patients' risk of dislocation.

"I think it manages their expectations well. They need precautions because if someone dislocates, for instance, they're in a brace for six weeks and it puts them right back. So, yeah, the precautions shouldn't limit [patients' recovery] at all" – Surgeon, 308

5.3.1.4. Theme 4: Adaptive equipment provision

The provision of adaptive equipment was described as a personalised assessment that was conducted on an individual basis, following the removal of precautions.

4. i. Individualised assessments

The removal of precautions, and with safe heights no longer required, the provision of adaptive equipment required occupational therapists to provide a 'bespoke' assessment for each individual patient. Staff described how they adapted equipment and furniture to suit individual needs rather than supplying a standard package of equipment to each patient.

"We look at an assessment which is individual to them, so we look at how they are going to manage at home from a social point of view, have they got support, how are they physically. We take their individual needs into account as to how they are going to function at home. Some people still need equipment to help them get on and off things, especially if they are tall or if their furniture is particularly low so we still give out a furniture heights form, but we are not as rigid, we might say something like you might want to put a cushion on that chair to make it slightly higher because that will mean you can get on and off a bit easier. We don't work to rigid heights anymore like we used to" – OT, 302

Staff discussed how patients with other health issues or mobility difficulties that struggled with functional daily activities might still need adaptive equipment, despite the removal of precautions, and these patients needed a bespoke assessment to identify the required items.

"I still think you have to assess the individual, which is where it is tricky, its not just a blanket referral. I think there are individuals that are going to have other issues so it's not necessarily because of the precautions or not that they need the equipment, its actually because they have got a dodgy other hip or dodgy knees. I still think equipment has its place but not routinely given like it used to be" – Physio, 304

Staff also described the assessments which could be conducted on the ward for patients to receive additional equipment to aid their independence.

"Things like the leg lifter and caddy [Buckingham caddy – a tray that attaches to the walking frame to transport everyday items] we don't assess at preop … We only assess [if a patient is] having difficulty with bed transfers … then we would try them with a leg lifter … Similarly, with the caddy, unless someone is going home who lives alone they usually take crutches and a Zimmer frame [walking frame], so we can fit a caddy, so they have got more independence between carers for transporting food and drink"– OT, 305

4. ii. Reduction in the prescription of adaptive equipment

Staff described a reduction in equipment following the removal of precautions, particularly within the county (Nottinghamshire). However, staff reported prescribing equipment to patients who had low furniture and struggled to get on and off furniture safely or comfortably. One staff member perceived that occupational therapists were ordering fewer furniture raisers and toilet raisers, however, they explained that this was based on discussions at team meetings, rather than from an audit. Toilet aids and perching stools were considered by staff to be the most beneficial pieces of equipment for patients.

> *"We are still finding that people are struggling to get on and off the toilet, so we do provide a lot of toilet aids, raisers and frames. Not necessarily raisers but definitely the frames, so they can really use their arms and push up from that equipment. We also provide perch stools, again not for everybody but for anybody we think is going to struggle with fatigue in standing for long periods … a perch stool is really good to help pace that activity, they can perch a bit, stand a bit to help manage their energy levels" – OT, 302*

Despite occupational therapy staff discussing the decrease in the provision of adaptive equipment, surgeons believed that patients still required toilet and chair raisers following THR surgery.

> *"I think the occupational therapist does give them a cushion to keep their seats raised. Toilet seats are raised up. So, the OT input is quite significant after a hip replacement … I think that's all they need: a cushion to raise the seat whenever they are sitting down; a toilet seat that is raised up. That should be more than enough I think" – Surgeon, 309*

4. iii. Overprescribing equipment to 'out of area' patients

Staff explained that they were concerned about increasing the length of stay and delaying discharges, thus continued to pre-order equipment to patients that lived outside the Nottingham area (patients that live in Leicester, Lincoln, Derby) as equipment was not as readily available, if required for discharge. Occupational therapists considered that they were providing more equipment than perhaps

necessary to those patients, as it was believed to be more cost-effective than an extra night in hospital, and they did not want to be responsible for delays in discharge.

> *"We might over prescribe a bit more to those people out of area as it is more difficult to get the equipment in quickly and so at least if they have got it in, it's cheaper having it in and not necessarily need it than them staying overnight in hospital if they are ready for discharge, if they didn't have equipment and needed it … we couldn't send them, we wouldn't send them if we thought they were going to struggle" - OT, 305*

4. iv. Equipment supplied on the ward

Despite staff reporting reductions in the prescription in adaptive equipment, staff described how adaptive equipment was still in place on the wards. There were mixed views among staff as to whether the equipment should remain or be removed.

> *"There hasn't been any change particularly in terms of equipment on the ward, so every toilet still has a raiser on it. To be honest, in the early stages of the recovery it is probably beneficial to be able to move on and off the loo. You will still have patients that need that degree of support because of the fact they are otherwise frail and not particularly mobile" – Physio, 301*

> *"We still use everything on the ward, so the toilets still have the toilet frames over them, and again I still think they are being issued at home I believe. I think there is work to be done around that, if we're going to remove it then we should, in theory, we should completely remove all equipment, and shouldn't be raising furniture but I'm not entirely sure in preop now if the OTs have made many changes" – Physio, 304*

4. v. Referrals for patients who require additional help and support

Staff described the additional help and support patients could receive through Social Services. Staff discussed the barriers and difficulties in referring patients for additional support and the impact that this could have on the length of stay, due to delayed

discharges. Staff explained how the removal of precautions had enabled patients to be more independent, which had resulted in a decrease in larger, more long-term care packages but an increase in smaller, short-term care packages.

> *"One of the issues with needing care is the fact that you can't dress yourself, so actually now patients can, but they are not necessarily going to be doing that on day three. It's quite early on even without the precautions to be bending down to put your shoes and socks on, so I guess the initial care might not necessarily change but how long they need the care for might have reduced" – Physio, 304*

5.3.2. Phase two patient interview findings

A total of 19 THR patients (9 males and 10 females) were invited to be interviewed. Of these 16 responded, four of whom declined to be interviewed. All interviews were conducted via telephone. Interviews ranged in duration from 18 minutes to 57 minutes, with a mean of 33 minutes. Interviews comprised a range of patients, seven were male and five were female, with a mean age of 63 years and age range of 51-78 years. Six interviewees were employed and six were retired. Two participants lived alone whilst ten lived with relatives. Participants' characteristics are listed in Table 5.7.

Table 5.7. Phase two patient participant characteristics

Participant	Gender	Age	Lives alone	Employment status
401	F	65	N	Employed
402	M	51	N	Employed
403	M	72	N	Retired
404	M	75	N	Retired
405	F	78	N	Retired
406	M	63	N	Retired
407	F	58	Y	Employed
408	M	51	N	Employed
409	M	52	N	Employed
410	M	55	N	Retired
411	F	73	N	Retired
412	F	61	Y	Employed

There were three main themes identified through analysis of the interview scripts. Each theme was further categorised into sub-themes which can be seen in Table 5.8. These will be described in the relevant sections and are reported with quotations to illustrate the findings.

Table 5.8. Themes and subthemes staff interviews phase two

THEME 1	**Removal of hip precautions**
i	Knowledge of hip precautions
ii	Inconsistent information
iii	Perceptions of the risk of dislocation
iv	Other restrictions
v	Uncertainty without restrictions
vi	Need for reassurance
THEME 2	**Perceived impact on recovery**
i	Sleep disturbances
ii	Return to side sleeping
iii	Improved quality of life
THEME 3	**Provision of adaptive equipment**
i	Equipment prescribed
ii	Usage
iii	Managing without adaptive equipment
iv	Usefulness
v	Suitability
vi	Perceived need/requirement
vii	Additional help/support
viii	Collection of equipment

5.3.2.1. Theme 1: Removal of hip precautions

Patients discussed the removal of precautions from routine practice which have been summarised into the following themes.

1. i. Knowledge of hip precautions

A number of patients were aware of hip precautions and the restrictions they imposed on specific movements. The change in advice was seen to be an improvement or an advancement in terms of aiding and progressing their recovery.

> *"There were a lot of stipulations that had previously been made that were no longer made, but it's a more relaxed regime now… the more you can do the quicker the better" - 403*

Patients reported discussing precautions with members of staff, mainly physiotherapists. This was to provide confirmation regarding information received from friends who had previously had hip replacements, and clarification about what they could and couldn't do.

> *"I've got friends that have had the operation … there were things that they couldn't do … I did ask the physiotherapist while I was in hospital about that, and she said no you don't need to do that. You know, so things have moved on a lot since then." - 404*

Some patients were relieved that hip precautions were no longer in place and that they were free to move and sleep in any position that they felt comfortable. One patient felt that hip precautions, in particular, supine sleeping, would have hindered her recovery and would have had a detrimental effect on her psychological well-being.

> *"You can sleep in different positions …. if I'd been told I had to sleep on my back for six weeks, I'd be in even more of a psychological mess than I was … if I had to be restricted in anything else, I'd have, you know, I'd have been sectioned I think" - 412*

1. ii. Inconsistent information

There were inconsistencies reported by patients in terms of the information regarding hip precautions. The majority of patients were advised to "do what is comfortable for you" and "whatever you can do within reason". One patient described movements that might have been particularly difficult during the 'early days' and that they were using their common sense to perform movement activities within a ROM that they felt comfortable. However, a small number of patients recalled being advised to avoid specific movements to reduce the risk of dislocation.

> *"They [the surgeon] advised against them … by turning incorrectly with weight on the leg, by crossing the legs, by exceeding or by squatting less than 90 degrees at an angle best 90 degrees and just to be very, very careful of it" – 410*

Patients identified discrepancies between written and verbal information provided. The written information was provided by the hospital, however, information was also freely available online. Clarification in terms of which instructions and information patients should follow was sought from clinicians.

> *"Well, I was told that initially yes sleep on your back. But as soon as you felt it was comfortable for you, you could sleep on your side if you wanted to. I think in the early days, I mean the booklet that we got, it did actually say in there you must sleep on your back for six weeks or something. But when I first saw the, you know, we went to the physio class, she said ignore that, she said cross that out of there. You can sleep on your side or whatever as soon as you feel it's comfortable and you feel able to do it" - 401*

> *"If you look at the information on the internet, particularly from American sites, they say there's all sorts of things you should and shouldn't do, but the physios told me it's all rubbish and to just ignore it all. Things like crossing your legs and sleeping on one side and making sure you sleep on your back for six weeks, he said it's all rubbish and there's no evidence that any of it's of any utility" - 406*

1. iii. Perceptions of the risk of dislocation

Dislocation was a major complication following THR surgery and patients described discussions they had had with members of staff about the risks of dislocation. Some patients reported that staff had discussed that the risk of dislocation was small due to advances in surgery and prosthesis development.

> *"There is a chance but it's very rare these days because it's a well-honed operation" - 412*

Whilst almost all the patients reported being informed about the chances of dislocation, one participant reported that they were unaware of this.

"Nobody's mentioned that. I suppose, I don't know if they don't want to scare you or what I don't know" – 408

For many participants, there was little concern about dislocation and a belief that it was unlikely to happen to them. Justifications and explanations were provided by patients as to why they believed it would not happen to them. These included their age, cautiousness, unlikely to be in at-risk position, and avoiding thinking about it.

"To be honest again I didn't think that I was going to really do anything that was going to put myself in the position" - 402

"I thought well plenty of people have had it done, they can't be that, you know, they're not likely to happen is what I was thinking. I tried not to let it concern me. I tried to block everything out if I'm honest until I went in" - 407

However, there were a small number of patients who expressed worries during the initial period post-surgery.

"I was concerned about the possibility of dislocation, but it seems that it's quite uncommon with the modern procedures. Physios told me not to worry about it; they said it's not going to happen" - 406

One patient admitted to following hip precautions following surgery, despite being informed of the new regime, as they were very worried about dislocating their hip based on previous experiences.

"I knew I wasn't to twist or, because my mum's popped out so. I was very careful not to dislocate it if you like … I was concerned, and I was very careful not to sit, she was sitting in the chair and just twisted because she dropped something, and she twisted in her chair to reach down and they had to call the ambulance. And she was in a lot of pain with it" - 411

1. iv. Other restrictions

Participants described activities that staff members had advised them against (e.g. showering, driving), during the early stages of their recovery. Strip washing was advised for all patients for a minimum of two weeks, and for some, those with a shower over the bath, for up to six weeks. Patients discussed how getting in/out of the bath could be challenging, and expressed concerns about the potential risks of trying to get in and out of the bath, particularly the risk of falling/slipping and risk of dislocation as a result. Despite this, some patients devised methods which enabled them to get into the bath to shower. One patient described how they used a small step to stand on to reduce the distance required to get themselves over the side of the bath. Another patient explained how they sat on the edge of the bath and pivoted over the rim, instead of trying to step in and out. Several patients report that they were advised to avoid deep squats, high impact jumping activities and contact sports (e.g. rugby, football) long-term.

> *"I was told I should, for example, avoid squatting and so on, and avoid doing exercises which caused pressure on the joints, so not jogging for example" - 402*

Driving was reported as the greatest restriction for all patients. Some patients described how not being able to drive had not only restricted or impacted upon themselves but also other family members. A small number of participants lived in rural communities and had become reliant on neighbours and friends to assist them or transport them to the shops.

> *"I couldn't drive, and I was the only one in the family that does drive … I've had a friend help us out with the shopping and taking us here, there and everywhere" – 404*

Patients described how they felt 'trapped' and 'restricted to being at home' during the period in which they were unable to drive. One participant felt that they would have been able to drive before the restricted period was up.

"Obviously when I wasn't driving it was a problem … I was gated, stuck at home and that's frustrating but, you know, there's nothing you can do about it" - 406

"I couldn't drive, that was the biggest restriction actually. …. I think I could have been driving three weeks after the op but I understand that they have to be cautious with these matters" - 410

1. v. Uncertainty without restrictions

Without hip precautions to guide patients, there was some uncertainty about what they were able to do. Patients felt reassured by having support from their relatives when performing movements for the first time. Patients reported that they were conscious of the risk of dislocation when moving into positions.

"I think probably for me the thing that, it was the afterwards, things like how do I know whether I can do something. I know you can feel it in yourself, but like they were saying, you know, they obviously said be careful because there's a risk of dislocation, which I was aware of. But then you're conscious of that and you're sort of thinking well should I be doing this and should I be doing that or not? And it's all about how far to push yourself, you know, to try and get the mobility back. And, you know, if you do it too soon will you be doing too much, and that sort of thing really more than anything … I didn't know how to push myself if you know what I mean" - 401

1. vi. Need for reassurance

Several participants described how they were fearful of dislocation and were wary of performing certain movements or activities. Appointments with physiotherapists were seen as an opportunity to encourage patients to progress. Physiotherapists were considered to provide reassurance to patients about resuming their preoperative activities and returning to 'normal' life.

"You've been used to doing certain stuff your own way, you know, I guess it's like if you think like now, the replacement is probably stronger than my good hip as regards the strength-wise. And it's

having the confidence to believe that things like it will take your weight, you know, you're not going to stand on it and you're just going to end up in a heap on the floor. And I guess the sooner you can get your head around that confidence thing, the easier it is to then get on with doing what you've got to do" - 402

One patient who lived alone reported that 'there was just very long days', they felt 'vulnerable' and 'lonely', and 'needed somebody' to be there with them. Another patient explained how friends provided moral support.

"I felt I was really behind. And they encouraged me and said no for what you've got and how you're doing, you're progressing fine. So it was their practical help and their support" - 405

5.3.2.2. Theme 2: Perceived impact on recovery

Patients described the impact of the new regime (no precautions) on their recovery.

2. i. Sleep disturbances

Despite patients no longer being required to sleep in a supine position, many still reported some sleep disturbances. The majority of patients struggled to find a comfortable position in bed and resorted to using pillows to help them get into a more comfortable position.

"My sleep was very disturbed, but I mean your sleep can be disturbed anyway … I just couldn't get to sleep. Basically being uncomfortable, I just couldn't get into a comfortable position to drop off … [I felt] very restless, couldn't sort of settle down" – 406

One patient described continued sleep disturbances beyond the early stages of recovery.

"I still find, I struggle to sleep … sleep's my main problem at the moment. I sleep on my non-operated side. I find I do get an ache in my operated side and in my knee on the operated leg. I can't do

anything lying on my side because it's uncomfortable. I've tried with a pillow between my legs, that's doesn't work" - 407

However, despite occasional sleep disturbances, mainly to use the bathroom during the night, most patients reported good sleep quality.

"Beyond that first two weeks, I started to get my sleep patterns back. And like now I'm sleeping as well as I can remember for years. Made such a difference, it really has" – 409

2. ii. Return to side sleeping

The majority of patients reported sleeping on their back for the first couple of weeks and described it as the most comfortable position. They also expressed concerns about sleeping on the operated side, predominantly due to the tenderness of the wound/scar. Several patients described how they had tried to return to side sleeping around two or three weeks post-surgery. Despite returning to side sleeping, patients were only able to tolerate it for short periods of time.

"I probably had three weeks at least of sleeping on my back, and then I did then start to try sleeping on the non-operated side. Which was OK for short periods, I did put a pillow, which is one of the things they told us at the hospital, you know, put a pillow between your knees when you turned over so your operated leg is supported a bit, you know. So I could do that but it was only for a short while and then I'd have to turn back onto my back again" – 401

"I could only manage a brief period of time and then I moved back. So I tried it and it was sort of, again because the scar was very tender to begin with, I couldn't last very long, so again it would be about six weeks before properly" - 408

2. iii. Improved quality of life

Participants described how their THR and the recovery process had given them a 'new lease of life', 'second chance at life' and as a result, they were a much 'happier person'. Some reported that they often forgot which hip was their 'good' and 'bad' one and that they were going to live a 'full active life'.

> *"I think it's been a huge positive change … the biggest difference to me is my sleep. It's just allowed me to function much better and I think I'm a much, I nearly said happier that would be wrong because that would suggest being unhappy, but a much more, I'm just much more functional" - 409*

> *"I'm happier because I can get out and about independently. Do my own shopping, you know, go off and swim if I want to. It's that sort of thing that makes me feel happy that I can do those sort of simple things" - 412*

5.3.2.3. Theme 3: Provision of adaptive equipment

Patients described their perceptions and experiences of the adaptive equipment that they had been prescribed by the occupational therapists.

3. i. Equipment prescribed

Despite the removal of hip precautions, all patients described receiving adaptive equipment, with toilet aids and perching stools being the most commonly reported.

> *"I've got two toilets, so I was given two toilet risers, and then I was also given like a stool, a high stool in the kitchen to sit on" - 412*

3. ii. Usage

On the whole, most patients appeared to use to use the adaptive equipment for approximately three to four weeks.

"If I'm honest I stopped using [the raised toilet seat] probably after two or three weeks because I could manage to get down to a normal seat and it just felt more normal. I used one of the perching stools a little bit for washing and shaving but fortunately, I didn't really require a lot of it" – 409

Perching stools were reported to be used for a longer period of time to assist with domestic activities.

"*I suppose probably up until I came for my six weeks, I was using the perching stool to sit and do the ironing" - 411*

3. iii. Managing without adaptive equipment

A small number of patients expressed that they might have been able to manage without some pieces of adaptive equipment; however, the majority of patients believed that they were essential during the initial period.

"I think I could have done. I think initially in those early days, it was a bit of a stretch sometimes to get down, but I think I would have managed if I'd had to. So it wasn't, like I say, it got ditched pretty soon actually. So could probably have survived quite comfortably without it" - 409

"I would have struggled to get off the toilet, well, I just, you're not quite at the right height at the beginning. It's better not to be as low on the toilet seat and it was easier to get up and down from" - 412

3. iv. Usefulness

Mowbray toilet frames were considered to be a vital piece of equipment in the early days, in particular, providing assistance and support when standing.

"I think it was better because obviously on a toilet seat, you don't have arms on a normal toilet seat, or at least I don't, and therefore I think I needed the support of the arms to push myself up with my

arms to a standing position or a squat, a reasonably bent sort of standing position. It was useful in that respect" – 404

Nearly all participants described the perching stools as 'wonderful', 'handy', and 'invaluable'. One participant who was initially reluctant to use one found it beneficial.

"Yeah I was a bit sceptical about that initially and I thought well I'm never going to use that. And then, of course, one thing I didn't really appreciate was that I wasn't going to be showering for two weeks and it was just going to be kind of having flannel washes. So it did actually come in quite handy in that respect. So I think it was a useful thing to have in the end" - 409

Perching stools were reported to be more useful in the bathroom rather than the kitchen, with the kitchen ones often not used. They were considered to be essential for washing and bathing, particularly for those who were unable to or were worried about showering.

"I did have a perching stool. And so I was able to perch on that and have a good strip wash and things yeah. It was OK. I mean I did have it for use in the kitchen and then in the bathroom. I didn't use it so much in the kitchen because I found I didn't have too much of a problem in standing up. I, maybe, used it a couple of times in the early days" – 401

Small aids were described to be beneficial by most patients. Socks aids and helping hands were acquired or purchased by a number of patients, who found them to be very effective.

"I'd already got [a helping hand]. I was using that in any event and that sort of thing, that's been a godsend really because I'm always dropping things" – 405

"The simple sock tool for pulling a sock on over a foot…. I probably only used it about a dozen times but it was effective and it inexpensive" - 410

However, for some patients, they were considered a waste of money.

"I got a shoehorn, the first time I used it, it broke so that went in the bin. So that was rubbish. And the grabber thing, I did have it by my side, but I never actually used it" - 401

3. v. Suitability

A few patients reported that the toilet seats provided were unsuitable, and that they could not adjust to using one. One patient purchased a toilet seat privately, which he considered was a better fit and more comfortable than the one provided by the hospital.

"The toilet seat I actually bought my own because it fitted more effectively … I didn't particularly like [the one provided] and I found that an inexpensive plastic seat raiser, you know the ones where it's sort of oval in shape, about four inches high, they fit multiple units, multiple size toilets. I found that was more comfortable because it was wider" - 410

3. vi. Perceived need/requirement

One patient, who had previously had a stroke, believed that not enough consideration was taken, in terms of the difficulties that she had with weight bearing on her right side. The patient was uncertain about who should have assessed them for equipment and the process of obtaining the required equipment.

"Well certainly on a practical level I needed more equipment … eventually, when I came out of the ward, I was provided with lots of stuff, you know, gutter frames, raised toilet seats, which had never been an issue before … they asked the height of my toilets and I did that and it wasn't even considered that I might need them… I just generally feel that not enough consideration was given to the

difficulties I was going to have weight bearing. I always knew it was going to be a difficulty, but I hadn't appreciated just how much of a difficulty it was going to be" – 405

Despite advice on purchasing smaller aids, some patients did not perceive a need for them, in particular, those who did not live alone.

"We were advised about various other contraptions about putting socks on and this that and the other. Shoehorns, extra-long shoe horns, things like that. Didn't bother with any of those because living with my wife, my son, if there was ever a problem then they could obviously help me" - 409

3. v. Additional help/support

The majority of patients described how their partners/family members helped them with everyday tasks. They discussed how without them things would have been very difficult, and they had an appreciation for those who live alone. Some patients expressed a loss of independence during the initial couple of weeks post-surgery, with some relatives reported to have taken time off work, as they were concerned about the patient being alone.

"You feel a bit helpless to begin with. Like I said the initial couple of weeks when you can't do a lot, you're getting people to do everything for you" - 408

One patient explained that they received additional support from community allied health professionals.

"My husband's here. Without him, I doubt I would have been able to be at home actually. I've had an occupational therapist, the community nurse and the physiotherapist coming in. The occupational therapist came a couple of times. The community nurse came a couple of times; the physiotherapist has been several times" - 405

3. vi. Collection of equipment

Participants expressed issues with the collection of equipment following their required use. In some cases, equipment had been stored in sheds and garages, whilst waiting for collection. Some participants described how they had tried contacting the supplier without success.

> *"I tried to phone them and sometimes you don't get an answer and you get a machine. And I left a message on a machine about three weeks ago to get in touch with me to arrange a collection, but I've not heard anything. So, I don't know what happens there" - 404*

> *"I don't understand why but nobody's ever wanted any of this stuff, they don't want it back … We've actually only just got rid of it yesterday. We've given it to a charity shop. Because I just can't understand why, there must be some expense, a hell of a lot of expense there that they didn't want back. I don't have an understanding of that" - 402*

5.4. Discussion

This section of the chapter discusses the findings from the qualitative aspect of the study. It begins by summarising and interpreting the findings, which are then discussed in relation to previous research. Finally, the limitations and strengths of the study are presented.

The aim of this study was to ascertain patient and staff perceptions and experiences of the two regimes (hip precautions or no hip precautions). A total of 24 patients (14 males and 10 females) and 19 members of staff (six physiotherapists, four occupational therapists, one occupational therapy assistant, five nurses, and three surgeons) were interviewed across both phases. The interview findings demonstrated that there were mixed clinical opinions about whether precautions were beneficial or detrimental to patients' recovery. Whilst therapists were willing to withdraw precautions from practice, surgeons were more resistant to the change. Even following the change in service, surgeons were more sceptical about the potential benefits that the relaxed regime might have had on the patients' recovery (e.g. quicker

return to ADLs) and were more concerned about the effects on dislocation rates. These anxieties were underpinned by fear of litigation and accountability for potential consequences of the surgery. Patients also had mixed opinions of hip precautions; some felt that they were restrictive whilst others believed that precautions provided reassurance and decreased the risk of dislocation. The possibility of dislocation was a concern for patients, particularly in phase one when precautions were being prescribed. The fear of dislocation appeared to decrease following the removal of precautions, however, there was uncertainty about when to return to specific activities. On the whole, adaptive equipment was useful to patients, particularly during the early days following surgery, but some equipment was considered unsuitable or not necessary.

Team discussions about withdrawing precautions and the provision of training to assist with the implementation of the more relaxed regime were considered to be important facilitators to the change in service. Despite training sessions requiring substantial amounts of preparatory time to deliver, this was believed to be a good investment in ensuring a smooth transition. However, adjusting to the new regime was difficult for some staff, particularly those who were less experienced, as they struggled with providing alternative advice to patients. Nurses, in particular, seemed to struggle the most with providing alternative advice to patients. These issues might have been due to the lack of training and information provided, as some felt that they were not provided with enough information or sufficient training about the withdrawal of precautions. Whilst other professions, particularly physiotherapists, discussed the changes with individual nurses, some nurses felt that they needed a more discipline-specific training session. It might have been that senior nursing staff were not confident enough to deliver training sessions, and multi-discipline training sessions could have alleviated some of the issues. Resistance from surgeons and some medical staff (doctors and nurses) were perceived as significant barriers to treating patients without using precautions. In addition, patients who had previously undergone THR surgery and had followed precautions were a challenge for staff, as they had to educate the patients on the reasons for the change in advice and provide reassurance about the new regime.

5.4.1. Perceptions of hip precautions

The main rationale for the use of hip precautions was to reduce the risk of dislocation by avoiding certain movements or positions that were believed to place the joint at high-risk of dislocation. Hip precautions were perceived to be historical, ingrained within practice, and consultant-driven. The orthopaedic research evidence base was itself considered to be historical, which supports previous findings that suggest it is generally underdeveloped compared to other types of surgical-research (e.g. cardiac surgery), with orthopaedic surgery regarded as much of a 'learnt craft' as it was a science (Ferlie et al., 1999). The practice of hip precautions originated in the 1960s and there was perceived to have been very little change in the advice since then, despite surgical advances. Surgeons appeared reluctant to alter their practices, especially those which they deemed effective in reducing surgical complications. Protecting the patient from dislocation was considered by surgeons to be one of the most important aspects of THR surgery. Hip precautions were generally perceived positively by surgeons who were interviewed, who believed that they helped manage patient expectations after surgery.

Conversely, most other staff perceived precautions to have a negative influence on the patients' recovery, delaying patients return to preoperative functional activities and desired QoL. In addition to impeding recovery and restricting independence, staff described how precautions could provoke anxiety and exacerbate patients' worries. Clinicians' perceptions of hip precautions have previously been reported in a qualitative study conducted by Coole et al. (2013), who similarly identified variations in opinions regarding hip precautions and whether they affect the risk of dislocation. The 'blanket' provision of adaptive equipment and education regarding hip precautions was perceived to be an easier and safer option for both patients and staff, but conversely, staff viewed the lack of evidence, alongside the developments in surgical technique and prosthesis design, as a justification for relaxing precautions. Although HippityHop findings were consistent with Coole et al. (2013), the authors only interviewed clinicians who prescribed hip precautions to patients.

A recent qualitative study explored the rationale behind the continuation and discontinuation of hip precautions in 12 UK hospitals (Mandel et al., 2017). The authors conducted semi-structured interviews with clinicians (18 therapists and 15 surgeons) at centres who used precautions and centres that no longer used hip precautions following THR. Participants were recruited from 12 centres in the UK: six centres who still used precautions and six centres that did not. Clinicians

acknowledged that the avoidance of dislocation was paramount, and precautions were used to avoid dislocation by creating a rigid boundary of movement, which is important when dealing with patients who 'push' these boundaries. Centres that had stopped using precautions cited their reasons for the removal of precautions being the negative impact on patients and the lack of evidence, along with advances in surgical technique. The small number of centres that had discontinued precautions did not observe an increase in dislocation rates. The authors concluded that whilst the orthopaedic community might raise questions about the role of precautions, the widespread clinical practice of teaching precautions was unlikely to change without robust evidence. However, whilst, Mandel et al. explored the rationale for both the continuation and discontinuation of precautions, they did not examine staff views and experiences of withdrawing precautions from practice.

5.4.2. Willingness to discontinue hip precautions

The majority of staff participants, particularly therapists, felt that precautions should be withdrawn and were willing to change routine practice. Surgeons were considered, by other staff members interviewed, to be the more sceptical and resistant to the removal of hip precautions from routine practice. Reasons that staff provided suggest that these groups might have been more reticent to change due to the lack of information or their knowledge of research evidence available. A number of potential barriers and facilitators to relaxing hip precautions have previously been identified and discussed (Coole et al., 2013). Coole et al. highlighted that staff were resistant to withdraw precautions as accepting these new clinical procedures was considered to be difficult for them. Staff perceived withdrawing precautions as 'risky', as this could consequently result in increased dislocation rates. The staff interviewed by Coole et al. believed that more robust evidence was needed to support the discontinuation of hip precautions before they would consider withdrawing precautions from routine practice. Despite this, some staff interviewed by Coole et al. considered that this change in service could be facilitated by other changes, such as enhanced recovery programmes. Similarly to staff interviewed by Coole et al., staff in the HippityHop study believed that relaxation of precautions would benefit patients through earlier mobilisation and independence, and in turn greater satisfaction and QoL. The removal of precautions and relaxation of routine provision of adaptive equipment were considered to be cost saving, which could potentially reduce length of stay, which reflects Coole et al.'s findings. The patient participants in HippityHop had mixed opinions about the relaxation of hip precautions. For patients, the option of side

sleeping was perceived to be the greatest benefit from the removal of precautions. Alternatively, some patients believed that knowing what movements they should avoid following their surgery was important, even though they considered hip precautions to be frightening.

Despite the routine application of precautions, staff perceived that there was a lack of evidence to support their use and believed that there was a need for more research to explore the effects on patient outcomes. Whilst some staff, mainly therapists, were knowledgeable of the available evidence, they were concerned about continuing to routinely prescribe precautions. These concerns were also identified in a recent survey on occupational therapists' and physiotherapists' opinions and experiences of hip precautions and equipment provided by Smith and Sackley (2016). The authors suggested that whilst the practice of hip precautions was widespread, they were not evidence-based given the previous evidence which suggests that they do not decrease dislocation risks. The staff surveyed recognised that there was a need for more research to be conducted as to which specific subgroups of patients require precautions and adaptive equipment, rather than continuing the current provision of 'blanket' precautions and equipment.

Surgeons interviewed in the HippityHop study believed that patients should be provided with precautions and considered them to be an effective method of reducing the risk of dislocation. They expressed some concerns about the alternative information or advice they would have to provide to patients instead of precautions, following their withdrawal from routine practice. The resistance to the change could have been due to the fear of litigation, as surgeons were ultimately held accountable for any dislocations that might have occurred. The fear of litigation has previously been noted by Coole et al. (2013). Surgeons might have favoured the use of precautions as there was lack of evidence to support the withdrawal of them, and they were not perceived to be harmful. There was also the belief that dislocation rates might have been low as a result of the use of precautions. Orthopaedic surgeons were considered 'apathetic' towards academic papers and implementing research results into clinical practice (Ferlie et al., 1999), and thus have been adverse about changing practices which they believed successful. The potential risks and consequences might have been perceived to outweigh the potential benefits, and therefore, surgeons were perhaps more cautious about changing practice given the lack of robust evidence supporting the withdrawal of precautions. Studies are yet to evaluate the use of precautions following revision surgery, particularly as a result of a dislocation.

5.4.3. Accountability

The HippityHop findings also suggested that a hierarchy existed, whereby the surgeon was the key decision maker and the allied health professionals (AHPs) had to abide by their 'rules'. Each surgeon had their own postoperative protocol for their patients which AHPs were expected to follow. Hierarchies are believed to exist among other MDTs, where surgeons, consultants or doctors have the greatest authority and all staff are expected to follow their instructions. In a survey comparing attitudes, concerning teamwork, of medical staff and aviation staff (Sexton et al., 2000) concluded that surgeons favour 'steep' hierarchies in which junior staff did not question more senior staff, whereas aviation staff advocated 'flat' hierarchies (i.e. organisational structures with few or no management layers a 'short chain of command'). The authors also suggested that surgeons perceived teamwork and communication in their team to be of a higher quality than other staff (e.g. nurses, anaesthetists) within the team perceived it to be. Surgeons might have believed that they worked as part of a team, however, the rest of the team (AHPs and nurses) might not have perceived surgeons to be a team member but as more of a dominant figure.

This perceived hierarchy might have prevented staff in the HippityHop study from discussing new evidence regarding their practice with the surgeons. Although a hierarchy might have existed, surgeons were ultimately responsible for the patients in their care and were liable if the surgery did not go as planned. The surgeons' performance data were publicly available online (on the National Joint Registry), and so there might have been concerns should dislocation rates appear to increase following the withdrawal of precautions. The surgeons in the study did express fear of litigation and being held accountable for any complications, including dislocations, that might have occurred following the removal of precautions.

5.4.4. Adaptive equipment provision

Equipment was considered to be routinely provided to ensure that patients adhered to hip precautions. Equipment was provided as a standard package which was in line with precautions to assist with daily activities, such as bathing and toileting, as patients were unable to perform certain movements for a period of time after surgery. The patients believed that the majority of equipment was beneficial, particularly toileting aids, however, some considered the equipment they received to be unnecessary or unsuitable for their home circumstances. The provision of inappropriate equipment was consistent with a previous study which determined the

home-use of equipment from the perspective of older adults and home care therapists (Gitlin et al., 1993). This study showed that 20-50% of patients who were prescribed adaptive equipment did not use it consistently at home. At the time of the HippityHop study, adaptive equipment was supplied by the NHS and community services to patients, with patients playing a minor role in the decision about the pieces of equipment they might require following their surgery. Patients were not necessarily using the equipment that was provided to them, which suggested that there was a need for an assessment in which patients played a greater role in the decision process to ensure that they received the required equipment and were not provided with any unnecessary equipment. As a result, there could potentially have been a reduction in the provision of equipment that was often redundant. Research has shown that when patients are involved in the decision-making process for adaptive equipment, this positively impacts their compliance with the equipment (Wielandt and Strong, 2000). Patients' perceptions of the benefit of adaptive equipment are also believed to influence their compliance (Wielandt et al., 2001).

Smaller aids were considered to be useful by the patients, although many received support with daily activities, such as help from a relative to put their socks on. Both staff and patients believed that small aids enabled patients to be more independent in functional activities, although staff were unable to provide equipment that they judged to be effective and useful for patients, particularly those who lived alone. Contracts with suppliers might have influenced the provision of adaptive equipment in certain hospitals or areas, although, the reasons for this were not clear. It was suggested that staff were unable to purchase items below a certain value from suppliers. This was not consistent with practices nationally, whereby approximately three-quarters of Trusts provided helping hands and long-handled shoe horns (Smith and Sackley, 2016). A previous study conducted by Thomas et al. (2010) interviewed nine patients about their use of adaptive equipment, in particular, smaller aids, and the reasons for non-use of equipment after their THR. All nine patients purchased a reacher, eight purchased a long-handled shoehorn, and seven purchased a raised toilet seat. This suggests that patients might consider smaller aids just as important to assist with daily life as larger pieces of adaptive equipment and should be more freely available.

Elective orthopaedic patients functionally improve over time and they only require equipment for short periods of time (Neville-Jan et al., 1992). As the patients in this study recovered from surgery and their function ability improved, they no longer

required the equipment prescribed, yet some patients continued to use it on a long-term basis. Some patients in the first phase of the study continued to use the equipment after the recommended time, which might have been due to patients becoming reliant on the use of aids to assist them with daily activities or due to 'fear avoidance'. Patients might have developed avoidance behaviours and entered into a vicious cycle where fears of increased pain or reinjury contributed to the avoidance of many activities, leading to inactivity and, ultimately, to greater disability (Gatchel et al., 2016). Patients in the Gatchel et al. study believed that they would have benefitted from adaptive equipment prior to the surgery. This highlighted that patients struggled with daily activities, such as getting on and off the toilet, before surgery and raised the question as to whether there was any difference in patients' functional abilities immediately prior to and following surgery. Patients' characteristics such as the level of pain experienced, and HRQoL prior to surgery have been suggested to influence patients' service use (e.g. physiotherapy), equipment use, and ability to manage at home after surgery (Montin et al., 2009).

An audit to determine the cost-effectiveness of providing 'hip packs' (packages containing all pieces of adaptive equipment that a THR patient might possibly need), concluded that packs were not cost effective as they did not consider what was needed at home (Davidson, 1999). It was believed that packages of equipment did not take into account the patient's home environment, help or support available, and patient needs and values (Neville-Jan et al., 1993). This reflected the findings of the HippityHop study, as patients reported not using certain items because their home environment was suitable for their needs, for example having a spouse who helped them. In some cases, adaptive equipment was considered to be inconvenient and impractical by other members of the family. In their study, Thomas et al. (2010) reported that over three-quarters of patients were not involved in the decision-making process of adaptive equipment. The authors suggested that the lack of patient involvement might have been a contributing factor as to why patients did not use equipment recommended by occupational therapists. The lack of involvement in deciding which adaptive equipment was required following THR surgery was identified as the main reason for noncompliance. The authors stated that this was "an alarming result within a profession that strives to remain client-centred" and suggested that occupational therapists must obtain an understanding of the patients' home environment when recommending adaptive equipment. It was believed that occupational therapists did not always consider the needs of each patient when recommending equipment (Gitlin et al., 1993). In the HippityHop study, despite

patients ostensibly receiving a more individualised approach in phase two, one of the participants felt that their other medical conditions were not taken into consideration when they were prescribed with adaptive equipment. These findings indicate that there is a need for more detailed individualised assessment for prescription of adaptive equipment. There is a lack of research in the field to support clinical decision making with regard to equipment provision, which may provide some justification for the inconsistencies that exist between practices.

In phase two, staff perceived that they were prescribing less equipment to patients on the whole but were possibly over-prescribing to patients who did not live in Nottingham. Patients considered adaptive equipment as essential in the first few days at home following discharge but stopped using it approximately 3-4 weeks post-surgery. This was at least two weeks earlier than recommended to patients in phase one. Whilst waiting for equipment that was no longer needed to be collected, patients stored it in garages or sheds, with one taking it to a charity shop after unsuccessful attempts at returning it. Although, this was not considered cost-effective, supplying patients with equipment they might need was perceived to be more cost-effective than an extra night's stay in the hospital. In addition, occupational therapists did not want to be held responsible for delayed discharges due to equipment not being in place. The reduction in equipment required following the relaxation of precautions has previously been associated with a substantial cost saving of $655 per patient, and the economic burden associated with discarding equipment (for hygiene uses) was reduced (Peak et al., 2005). It has also been suggested that the removal of precautions could potentially save over 3000 bed days and approximately £165,000 worth of equipment (Fox et al., 2011). Delays in patient discharge due to equipment provision were eradicated following the removal of hip precautions (Fox et al., 2011).

5.4.5. Patient compliance with hip precautions

The findings of the patient interviews in phase one indicated that patients were able to recall hip precautions and perceived them as a 'set of rules' to follow after surgery. Most patients understood the potential risks of dislocation following surgery and the reasons why they were advised to adhere to precautions. It appeared that surgeons and/or staff discussed the rationale for hip precautions with patients prior to their surgery. To date, there has been very little research on patients' perceptions and understanding of hip precautions. A study assessed patients' recall and perceptions of precautions six weeks postoperatively, via a postal questionnaire. (Lee et al., 2017)

The authors stated that 86% of patients were able to recall hip precautions, and 91% of patients reported the lesson ('hip class') to be quite or very useful. Joint schools or 'hip classes' were common practice in the UK, to help prepare patients for their upcoming surgery and their postoperative needs.

In the HippityHop study, there was varying adherence reported by the patients. Whilst most patients believed that they complied with precautions, some suggested that they were not applying precautions to all situations. This reflected the staffs' perceptions of patient compliance. Staff were concerned that some patients continued to follow precautions long-term, and that they did not understand the application of hip precautions. The findings suggest that patients, on the whole, were compliant with hip precautions and some continued to abide by them after the required period. These findings were similar to those of Peak et al. (2005) who reported that 96% of patients who were prescribed precautions, complied with them for the required six weeks, and over half (54%) of patients were still following them six months after surgery.

However, this contradicted research by Lee and colleagues (2017) who stated that less than a quarter (23%) of patients followed all precautions for six weeks. It was possible that patients might have believed that they were complying with all precautions but might not have understood how they applied to different situations; for example, patients might not have bent down to put on their sock on as they recognise that this was against the 'no bending past 90 degrees' precaution, however, they might have brought their foot up towards them to put their sock on, not realising that this also was a breach of precautions. Patients might have possibly complied with precautions long term as they might have been fearful of dislocation and damaging their new joint even after the precautions period, and might not have felt psychologically that they were physically able to perform previously restricted movements. This might have also been due to a lack of patient education about how to protect their joint long term. At the time of HippityHop, little was known about the impact that long-term compliance with precautions might have on patients' overall QoL and participation in activities. Patient noncompliance with hip precautions was perceived to be a contributing factor to dislocation but there is very little evidence to support this (Soong et al., 2004).

5.4.6. Impact of hip precautions on patients' recovery

The patients in the study reported supine sleeping to be the hardest precaution to comply with, describing it as 'difficult' and 'uncomfortable'. Poor sleep quality and daytime napping were believed to be due to sleep deprivation, as a result of supine sleeping. Difficulties with supine sleeping following THR have been reported elsewhere. Peak et al. (2005) determined that over two-thirds of patients found supine sleeping uncomfortable and did not return to side sleeping until the end of the required period of precautions. This reflected the experiences of patients in phase two, who although they were allowed to sleep in any position of choice, slept on their back for the first couple of weeks. Patients seemed to find it difficult to sleep on their side initially, due to the scar being tender, and only slept on their side for short periods of time before lying on their back. Sleep disturbances were identified by patients in both groups, with some still having difficulties after six weeks.

Sleep deprivation has also been previously reported by O'Grady et al. (2003), who assessed the impact of sleep deprivation has on patients' recovery and QoL following THR using the Epworth Sleep Scale (ESS), SF-36, and HADS. The ESS increased following surgery and did not return to 'normal' until three months post-surgery. The results also suggested that sleeping in a supine position may lead to sleep apnoea in patients at greater risk. Sleep deprivation has been linked to increased levels of anxiety and decreased patient satisfaction (O'Grady et al., 2003). A study evaluating patients' perceptions of hip precautions determined that patients adhering to precautions have sleep disturbances, with nine-tenths of patients affected during the first six weeks and a fifth of patients affected every night (Lee et al., 2017). The authors did not ask the specific cause of sleep disturbances but suggested that lying supine was problematic for patients based on previous research by van Egmond et al. (2015). Van Egmond and colleagues (2015) interviewed patients following total joint replacement to explore their views six weeks after surgery and reported that all patients complained about their inability to sleep, stating supine sleeping instructions as the cause.

Continuous periods of sleep in the short term have been found to be important for both healing and patient well-being (Krenk et al., 2012; Myoji et al., 2015), whilst sleep disturbances in the first month following surgery are believed to be an independent predictor of three-month functional limitations (Cremeans-Smith et al., 2006). The findings from this study suggested that supine sleeping could lead to other problems for patients, including lower back pain, and could be troublesome for those with

existing conditions. Severe arthritis has been reported to cause spine alignment abnormalities and lower back pain, which has been reported to improve following THR (Eguchi et al., 2018). However, improvements might not have been seen in these patients immediately following surgery.

Following the removal of precautions, alternative restrictions were implemented by the surgeons to help control patients that they believed might 'push' themselves too far. Some patients were advised to use crutches for six weeks following surgery to serve as a reminder that their soft tissues had not fully healed. It was suggested that consultants were more fearful of dislocation in younger, more active patients. This could possibly be due to patients having a greater expectation of returning to their normal life including activities and work. Previous research reported that THR patients did not return to preoperative leisure activities even though they considered their participation as important (Wylde et al., 2012). The authors suggested that joint replacement surgery does not enable all patients to return to their previous activities and that these restrictions can lead to dissatisfaction with the outcome of surgery and contribute to depression.

A prospective comparison safety study (Kornuijt et al, 2016) concluded that experienced orthopaedic surgeons should not fear increased dislocation rates and that it is safe to manage patients with minimal precautions during the immediate postoperative period. The authors suggested that the reason that precautions might not have been effective was that as they originated from the conception of THR during the 1960s before capsular and muscle repair were common in THR surgery, and patients were first mobilised several days after surgery. The authors determined that, with the advancements in surgery and the adoption of fast-track principles, precautions might not provide extra security against dislocation and will delay resumption of daily activities. These findings also support those reported by previous studies (Peak et al., 2005; Duwelius et al., 2007; Ververeli et al., 2009; Mikkelsen et al., 2014).

5.4.7. Inconsistencies and variations in practice in the provision of hip precautions

In this study, staff reported that although hip precautions were provided, the advice surrounding them has changed slightly over recent years. Staff also reported inconsistencies in the prescription of hip precautions at different hospitals. With

hospitals changing their practices in terms of observing hip precautions, there has been recent interest in this area of practice at discipline-specific conferences. At the Association of Trauma and Orthopaedic Chartered Physiotherapists (ATOCP) annual conference in 2016, there was a debate on the 'abolishment of hip precautions after surgery'. Votes were taken prior to and following the debate, which both favoured the removal of hip precautions following THR (Chartered Society of Physiotherapists, 2016). These discussions suggested that clinicians across the UK favoured the removal of precautions, even though the majority of hospitals still routinely prescribed them (Drummond et al., 2012; Smith and Sackley, 2016). Despite this, variations existed in practice and had previously been reported (McMurray et al., 2000; Drummond et al., 2012; Coole et al., 2013; Smith and Sackley, 2016). Two national surveys encompassing occupational therapists (Drummond et al., 2012) and physiotherapists (Smith and Sackley, 2016) concluded that there were large discrepancies that existed nationally in the provision of hip precautions, relating to: the movements to avoid, the length of time to follow them, the reasons for teaching them, and the equipment provided. Variation had also been found to exist in hip-related literature provided to patients undergoing elective THR (Drummond et al., 2013). A national survey evaluating occupational therapy practice collected copies of booklets and leaflets provided to THR patients and found that the presentation and content of the information varied and ranged from covering surgery and possible complications to those including hip exercises and diet. Of the documents provided, 98% of them included generic advice on hip precautions.

Following the removal of precautions, staff reported that they were uncertain about the advice that should be provided to patients. In comparison to the prescription of hip precautions, staff perceived that they were not providing enough information to patients about how they should move and could potentially be considered to be a disservice to patients. Staff reported that it was difficult to adjust to the new regime and change their own established practices. It was possible that staff found it difficult to adapt to change as the practices were ingrained, described as habitual and almost second nature. Staff described how they had to consciously remind themselves to not discuss hip precautions with patients. Established behaviours are considered to be automatically activated when exposed to specific stimuli (Ouellette and Wood, 1998; Bargh and Chartrand, 1999; Bargh et al., 2001). The behaviour of prescribing precautions was routine and was probably initiated with minimal conscious effort or attention. Some individuals might have found the transition easier because they believed in withdrawing precautions and were more engaged with the process of

change. Those who were not convinced or unsure of the change might have found it more difficult to convey the new treatment information to patients. The theory of planned behaviour (Ajzen, 1991) could have been applied to gain a greater understanding of staffs' attitudes towards specific behaviours (not prescribing precautions to patients), their subjective norms (beliefs about precautions and viewpoints of other staff) and their perceived behavioural control (perceptions on their ability to provide new information to patients). If staff favoured the new regime, had stronger beliefs about not prescribing precautions to patients, and perceived that they had the ability to discuss the new regime in detail with patients, the stronger their intention was to provide the new regime. Conversely, staff could have favoured precautions and provided them to patients based on their beliefs. However, as behaviour change was not the focus of the research, staff behavioural intentions were unknown and might need to be investigated further to gain a greater understanding of the beliefs underlying their behaviour.

5.4.8. Training provided for the change in service and removal of hip precautions

Staff participants reported that they had received some form of training to assist them with the change in service, although, it appeared that some groups received more training than others. This could have been due to the fact that healthcare professionals typically train within their own discipline, and learnt in isolation from other professionals, even though their clinical practice may position them side by side at the same site of care (Mezey et al., 2008). The interview findings suggest that this approach might not have been very effective, as different disciplines had varying levels of confidence regarding the change and in their ability to adjust and adapt to change. Training appeared to either be conducted as a whole team or as sub-teams; with therapists having had training as a whole team, and nursing staff either received training from their ward manager or from members of other disciplines. It perhaps would have been more beneficial for staff to receive additional training about how each disciplines practice may have differed as a result of the change in service. Providing more training and education might have alleviated some confusion about the alternative advice. Empowering staff, particularly nursing staff, could have helped increase their self-efficacy and confidence in providing and discussing the new advice to patients.

Each discipline within healthcare is believed to have evolved independently, with each having their own tradition, culture, and regulatory requirements (Reuben et al., 2004). However, practising in isolation is considered to be undesirable in health care as it might put the patient at risk (Grumbach and Bodenheimer, 2004). The common aims which teams share, particularly in terms of the patient, are considered to be the driving force behind the evolution of modern healthcare (Mitchell et al., 2012). A study evaluating clinicians' participation in training programmes as a means of promoting evidence-based practice determined that these opportunities could provide a promising strategy for point-of-care clinicians (Black et al., 2015). The training programmes increased the motivation and commitment of clinicians to promote practice change and implement evidence-based practice, in healthcare organisations. They have also been reported to successfully increase clinicians' research knowledge and abilities, alongside increased confidence in their clinical practice. In this current study, implementing a training program for all disciplines to engage in would possibly have encouraged teams to work together through changes, rather than in isolation.

5.4.9. Limitations and strengths

The main limitation of the study was the potential bias of participants who were recruited. Both staff and patients who participated in the interviews may have had stronger opinions or felt more confident that they could contribute, and so were willing to spend time sharing their experiences. Whilst the sample was selected using maximum variation technique to obtain a broad and diverse range of views, there was self-selection bias as a number of patients who were invited to be interviewed declined. Male participants were more likely to participate in the interview than their female counterparts, with approximately 25% males declining and 50% of females declining. Participants who declined the invitation to be interviewed were not required to provide a reason, thus the reasons for non-participation are unknown. The most frequent reasons reported for non-participation in health studies are personal reason/disinterest, time constraints, and the inability to cope with the study (Markanday et al., 2013). For the staff interviews, a wide range of experience and grades (bands – pay levels) were invited to participate, however, all except one staff member were senior staff. Junior therapy staff, despite being invited, were not willing to take part in an interview. Some privately expressed their concerns that they may say something 'wrong', or may not be knowledgeable enough, and the potential consequences or repercussions of their responses. It may be that they were worried

about the implications of their perceptions and experiences could have on their job if they disagreed with more senior members of staff.

Secondly, the number of surgeons that were interviewed was smaller than intended. The study planned to interview an equal number of staff from each profession and aimed to interview at least three or four surgeons in each phase. The researcher contacted 12 surgeons, across both phases (five in phase one and seven in phase two), inviting them to participate, and if they did not respond repeat invitations were sent up to three times. Of those surgeons contacted, only five responded, with four willing to participate. The surgeon who was not willing to participate did not provide a reason. One surgeon's interview did not take place; their interview was rearranged three times prior to the surgeon stating that they were unable to participate due to prior engagements. This apparent lack of participation could have been due to the interviews being perceived as unimportant or not a topic of sufficient interest to the surgeons for them to give up their time to participate. It might also be that surgeons did not have strong opinions about the use of hip precautions and may have thought that sharing their neutral views was not a valuable use of their time.

The timing at which the surgeons and other clinicians were invited to be interviewed could have influenced the response rate. It may be that staff felt that they were unable to make judgements about the removal of precautions in the short time period of the study and needed more time to assess dislocation rates and patient outcomes. No other studies exploring clinicians' opinions of hip precautions have explicitly stated that they have had difficulties recruiting surgeons, but it can be assumed that some have also found it difficult. Coole et al. (2013) planned to interview clinicians from each profession at each of the six hospital sites, however, they were only able to interview surgeons at four of the hospital sites. However, in a recent study, Mandel et al. (2017) recruited a total of 15 surgeons from 12 hospitals, comprising nine surgeons from six hospitals that were still using precautions and six surgeons from six hospitals that were no longer using precautions. Although the authors did not report their intended sample size, it could be conjectured that this was an adequate sample.

The sample of participants recruited to interview in HippityHop was not as diverse as intended. No junior members of staff or therapy assistants were interviewed during phase one, and only one therapy assistant was interviewed during phase two. Despite a number of junior staff being invited to participate, they were reluctant to take part. This could be due to fear of having an opinion that may differ from more senior

members of staff, and that there could be repercussions as a result of this. One therapy assistant reported that the did not want to participate as they were worried about giving 'wrong answers'; they were still reluctant to participate following reassurance from the researcher that they were interested in their opinion and there were no right or wrong answers. As a result of the lack of junior staff members' perceptions and opinions, it is possible that data saturation was not achieved. They may have provided different opinions or experiences than more senior members of staff, and it would have been interesting to ascertain their views on hip precautions.

Data saturation may also not have been reached for surgeons, as they were also hesitant to participate. The surgeons in the study appeared to share the same opinion and it might be that these surgeons did not support the no precautions regime, and that those who had different opinions were not willing to participate. The clinical lead for the study, a consultant surgeon, was in favour of withdrawing precautions, but it was not possible to interview him due to his role in the study. There were other surgeons who were positive in promoting the discontinuation of precautions, but it was not possible to interview them; of the three invited, once declined and two did not respond to the invitation.

Finally, patients were interviewed at between six weeks and three months post-surgery. This ensured that participants in the precautions group were more likely to recall the advice given following the cessation of the six week hip precaution period and the effects that it had on their daily life. The no precautions group were interviewed at a similar time period to the precautions group after surgery to enable comparison between the groups' views. However, as patients were interviewed at their time of treatment, they were unable to make direct comparisons of the treatments provided during the study. The patients' views may be different if they had experienced both treatments, however, no patients in phase two had previously had a THR. Therefore, this could not be further explored during the scope of the study. Staff were interviewed during the before and after study period. Their views and opinions might have changed as they gained more confidence in delivering the new regimes and following the results of the before and after study. It would be interesting to interview these participants again in the future.

This study is the first to explore both staff perceptions and patients' experiences of hip precautions, the withdrawal from routine practice, and the implementation of a more relaxed regime. It has reported on a multi-disciplinary view and patient view of

hip precautions and has presented different opinions and experiences of their use. The sampling method used has enabled a range of perspectives to be captured which enhanced the richness of the data and provided a more in-depth understanding of participants' perceptions and experiences of hip precautions.

A strength of the study was that the interviews were conducted and analysed by a researcher with no clinical background. This enabled her to explore potential issues and obtain detailed explanations as she had no influence from prior knowledge, experience or assumptions relating to the practice of hip precautions in the setting. As a result, participants may have been more likely to provide criticisms or negative comments about the practice of hip precautions. The use of semi-structured interviews enabled the researcher to be flexible and adapt to the participants' responses that emerged during the interview. The use of semi-structured interviews also allowed exploration of topics raised by the participant which were of interest. The interview schedules were based on findings from previous research and included topic areas that were of interest to the research, including barriers and facilitators to the withdrawal of hip precautions from routine practice. The use of individual interviews encouraged each participant to share their own perceptions and experiences without being influenced by the presence of other participants and their views.

5.5 Conclusion

There were mixed opinions about the use of hip precautions held by both staff and patients in both phases of the study.

In phase one, the surgeon interviewed favoured the use of precautions, as they believed they prevented patients from placing their hip joint in a vulnerable position for dislocation and helped provide patients with realistic expectations. The surgeon was hesitant to change their practice and considered their methods to be effective in ensuring patients' safety. Conversely, other staff members interviewed felt that precautions limited patients' functional ability and exacerbated patients' anxiety unnecessarily. Therapists were receptive to withdrawing precautions from routine practice; they believed that patients benefited from earlier mobilisation and increased independence, enabling them to return to their desired quality of life earlier. Patients who were interviewed felt that precautions provided guidance on what they were able

to do following surgery, although they did consider them frightening and were cautious about performing movements that could put them at risk of dislocation.

Following the removal of precautions, staff believed that patients were more confident about mobilising and performing functional activities, and that they could spend more time teaching a greater range of functional techniques to patients. However, some staff were uncertain about the alternative information they should provide. Patients in phase two were less anxious at the prospect of dislocating their hip and appeared to be more confident in returning to activities, however, some required reassurance from staff. In addition, without more precise instructions, patients were unsure about when it was safe to return to more demanding ADLs and desired leisure activities.

This chapter has reported on and discussed staff and patient perceptions and experiences of a regime with hip precautions and a regime of no hip precautions. The findings from this study are synthesised with the findings of the before and after study and further discussed in the next chapter.

6

General Discussion

6.1. Introduction

This chapter draws together the findings of the before and after study and the interview study. It provides an overall summary and synthesis of the results and discusses the strengths and limitations of the research. Finally, the study is located within the context of other research, and the implications for academic knowledge, clinical practice, and future research are presented.

6.2. Synthesis of key findings

This section draws together the findings from the two parts of the research.

Impact on patients' daily lives

Findings were mixed about the impact of precautions on patient outcomes across the two studies. Interestingly, the results of the before and after study showed that patients had comparable outcomes in terms of functional ability, mood, sleep and QoL. For example, patients had equivalent levels of pain and function at three months postoperatively and their ability to perform ADLs, levels of mood, sleep quality and HRQoL were similar regardless of whether they received hip precautions or not. By comparison, in the interview study, the perceptions and experiences of hip precautions on patient outcomes varied. Hip precautions were perceived by some staff to increase patients' anxiety and to negatively impact upon their recovery, by impeding function and delaying the return to activities. On the other hand, some staff were concerned that by prescribing hip precautions they were thwarting the functional outcomes they were trying to achieve with patients, which could limit ability to perform ADLs. Interestingly, staff perceived that patients in phase two were more confident about mobilising and returning to functional activities than those in phase one. A less restrictive protocol seemed to provide staff with a greater range of options to progress patients' rehabilitation and to afford them more time to teach functional techniques. Staff worries about the negative impact of hip precautions on patients' recovery were not supported by the results of the before and after study.

Some patients in phase one perceived hip precautions negatively as they believed these impacted upon their lives, and frightened them about the risk of dislocation. Some patients remained frightened, even after the six-week period, about performing certain movements. However, there were some patients in phase one who liked precautions, as they provided reassurance about what movements they could do

without putting themselves at risk of dislocation. Although following the removal of precautions, some participants still had reservations, there were individual circumstances to the contrary. Some patients felt that hip precautions would have hindered their recovery and negatively impacted their psychological well-being. Patients in phase two believed that the new regime enabled them to progress their recovery and return to functional activities, resulting in increased independence and improved QoL. However, there were some patients who were unsure about when it was safe to return to more demanding ADLs and desired leisure activities, and required reassurance from staff.

Provision of information and equipment

The change in the provision of information and adaptive equipment was an important aspect of this study. Changing the service was challenging, as the practice of hip precautions had formed part of all the clinicians' training. Staff felt that hip precautions were a fundamental aspect of the treatment of patients undergoing THR, and many were unsure about the effect that the withdrawal of precautions would have on their role. Occupational therapists believed that the removal of hip precautions would enable them to use a more relaxed approach when assessing patients and to be less prescriptive when ordering equipment. However, there were concerns raised that a potentially more flexible service might require staff to retrain to acquire greater skill and clinical reasoning in assessing patients. In phase two of the study, a more individualised assessment was conducted with patients, with the aim of providing equipment to suit their individual needs rather than issuing a standard package of equipment. Despite this, some patients reported receiving unsuitable and unnecessary equipment. Equipment was considered, by both groups of patients, to be beneficial during the first few weeks after surgery and almost essential in the first few days after surgery. This suggests there is potential to evaluate the prescription of equipment further.

Following the withdrawal of hip precautions, many staff reported that they were uncertain about the advice that should be provided to patients; they believed that they were not providing enough information to patients as an alternative to precautions. Some staff found it difficult to adjust to the new regime. This theme was also reflected in the patient interviews, as some patients reported receiving inconsistent information from staff. They also reported some discrepancies in the written and verbal information they were provided with. Therapists in the staff interviews described that they had to challenge a small number of staff, mainly nursing staff, about advising

patients to sleep on their back when they did not need to. However, providing advice on other aspects of care was not raised as an issue in the interviews. In addition, staff raised concerns, in the interviews, that external services might not have been aware of the change in their practice and if patients were referred to them, they could have referred to precautions. This could have further contributed to the patients' confusion about which advice to follow.

Although there were some issues raised by staff in phase two of the study, around the alternative advice they should have provided instead of precautions, a washout phase was included in the study design to try and help staff adjust to the new regime, and to address and resolve any issues experienced during the change in practice. However, due to concerns with recruitment delays in the after phase of the study, a pragmatic decision was made to reduce the washout phase by approximately two weeks. On reflection, it might have been better to have used the full planned duration of the washout phase (two months). If the full duration of the original washout phase had been used, staff may have felt better prepared to deliver the alternative advice.

Staff engagement

The emphasis of the study was the withdrawal of hip precautions from routine clinical practice. In the before and after study, a small number of staff took a more active role as hip champions. These individuals were vital to the success of the study as they provided an important point of contact. Hip champions were key in the monitoring of treatment fidelity, to ensure that all staff were adhering to the correct treatment regime. Champions highlighted in the interviews that they had reminded some staff that they did not need to prescribe hip precautions to patients and reported any concerns or issues about the research to the researcher. In addition, hip champions provided training about the changes in the service.

Changing an established practice provided many challenges and there were divided opinions amongst staff. Although the overall research recruited the desired sample size, it was difficult to initially recruit staff to participate in the interviews. The pressures and time constraints that NHS staff experience may have contributed to this. The interviews were also difficult to organise, and whilst the researcher was flexible, she may not have accommodated some members of staff (interviews were generally conducted during normal working hours, 8am-6pm). In addition, some staff may have been reluctant to participate in the interviews for fear of having different views or opinions from their colleagues, and the potential consequences of this. On the other

hand, it could also be that staff did not have strong opinions about precautions and did not know how their views could contribute to the study.

It is possible that the sample of participants interviewed in the study may have had more negative opinions than other members of staff; the surgeons interviewed favoured the use of hip precautions and may have only agreed to participate in order to express their concerns about the withdrawal of precautions. However, there were some surgeons who were active in the study and were positive in promoting the discontinuation of precautions, but it was not possible to interview them. It may have been that the surgeons who were not interviewed prioritised supporting the withdrawal of precautions rather than sharing their perceptions and experiences of them.

Fear of dislocation

The original rationale for the use of hip precautions was to reduce the risk of dislocation. Concerns about the perceived risk of dislocation were evident in the literature reviewed and from the staff and patient interviews. Yet, there was no increase in the rate of dislocation following the withdrawal of hip precautions in the HippityHop study. The dislocation rates were comparable for both groups and very low (1.3% overall; 0.8% hip precautions group and 1.7% no hip precautions group) compared to those reported in the literature (1-15%). The study was not powered to determine if there was an increased risk of dislocation following the removal of precautions, and thus cannot conclude that the removal of hip precautions did not lead to increased dislocation rates. Nevertheless, if greater numbers of patients were experiencing a hip dislocation, this would have been noted and would have been a cause for concern.

Both staff and patients in phase one were anxious about the prospect of dislocation, and there were concerns about the impact that withdrawing precautions could have on dislocation rates. Surgeons were particularly concerned about the risk of litigation and the repercussions that could result from increased dislocation rates following the removal of precautions. Other staff members felt they should be cautious about mobilising patients, as they were worried about being held accountable if a patient dislocated whilst under their care. Patients were fearful of dislocating their hip, and the consequences this might have.

The findings from the interviews from phase two suggest that staff were less anxious about dislocation, and for some of the patients it was not an issue that they had really

considered or were particularly concerned about. The results of the HippityHop study suggest that the prescription of hip precautions may provoke anxiety and fear in patients about the risk of dislocation, and potentially caused unnecessary distress for some. It may be that less attention needs to be paid to the risk of dislocation, and more focus on patients' functional outcomes and QoL.

6.3. Research strengths and limitations

The principal limitations of this research were:

1. The study was not an RCT. Using an RCT design would have minimised the risk of bias attributable to unequal distribution of participant characteristics and confounding factors between the groups, which would have increased the level of internal and external validity of the study, and the generalisability of the results.

2. The study was conducted at one site only. Therefore, it is not possible to be certain the findings are transferable and generalisable to other sites nationally. However, despite this, there is no reason to assume the population receiving THR surgery at Nottingham City Hospital was significantly different to those undergoing THR at other hospitals; the study sample had similar characteristics to data reported in the NJR, so could be broadly viewed as being representative of the general primary THR population. Thus, it seems reasonable to speculate that the key findings relating to patient outcomes would be transferable to other hospitals across the UK.

3. Participants in the study might not have been a representative sample. Although the participants recruited into the interview were selected to provide a diverse range of views, the participants' views might not have reflected the full range of perspectives and experiences. The number of surgeons that were interviewed was smaller than intended; in addition, no junior members of staff were interviewed, and only one therapy assistant was interviewed. There was also potential bias in that the characteristics of those who participated in the before and after study may have differed to those who did not, which may have resulted in a sample that is not representative of the population (Sedgwick et al., 2014). In clinical trials, 'study non-participants' often have higher disease

and mortality rates, poorer health status, and lower levels of function than study participants (Gelea and Tracy, 2007). However, the characteristics of the participants in the before and after study were similar to those reported in the NJR. In addition, as the participants were not randomised, bias could have been introduced when allocating patients to groups. The allocation was dependent on the patients' surgery date and surgeons may compile their list in a certain way, which could have influenced the study.

4. Hip precautions were not completely eradicated from practice. It was highlighted that external services were not fully aware of the changes that the service had undergone and might have therefore encouraged precautions. In addition, THR is a common surgical procedure, and individuals participating in the study might have been told about precautions by people who had previously had a THR. Also, with access to online materials relating to THR freely available, there was the possibility that some participants followed them despite not being told to do this.

   There could have been participants in the hip precautions group who did not follow them, although this is unlikely. Hip champions were recruited to assist with the monitoring of the treatment fidelity and ensure that clinicians were adhering to the delivery of the correct treatment for the relevant phase of the study. In addition, those participants in the washout period who were likely to have received mixed messages around the use of hip precautions were excluded from the study to prevent any contamination.

The main strengths of this research were:

1. The study used a mixed-methods approach, across two consecutive phases. Findings were broadly consistent across both components of the study, which should increase the confidence in the reliability of the research findings. To the researcher's knowledge, this was the first study to evaluate hip precautions using both quantitative and qualitative methods simultaneously.

2. In contrast to the majority of studies in the field, the HippityHop study focused on a variety of other important patients' outcomes rather than dislocation rates. It has demonstrated that patients who did not receive hip precautions had

similar outcomes, in terms of pain, function, ADLs, mood, sleep, HRQoL, and dislocation as those patients who did following THR surgery.

3. Equivalence analysis was used to determine whether patients' who received hip precautions have similar outcomes to those who did not. The present study demonstrated that three months after surgery, both groups of patients had pain and function levels that could be considered equivalent.

4. This was also the first study, to the researcher's knowledge, that explored patients' perceptions and experiences of the use of hip precautions and their withdrawal. It also reported on a multidisciplinary view of hip precautions and presented different opinions and experiences of the use of hip precautions and their withdrawal from routine practice. The researcher was able to interview clinicians from each of the professions delivering care to patients who had undergone THR surgery before and after the change in the delivery of the service regarding hip precautions.

6.4. Contributions to knowledge and relevance to other research

As highlighted earlier, this was the first study to determine equivalence between patients who received hip precautions and those who did not, and there are, therefore, no other studies with which to directly compare the results. However, there are other studies that have compared hip precautions and no hip precautions. Previous studies (Peak et al., 2005; Ververeli et al., 2009) have suggested that hip precautions can impede patients' recovery, and that removing them will lead to earlier and better resumption of activities and higher patient satisfaction. However, this is not consistent with the results of the current study, which found that patients recovered at a similar rate regardless of whether they received precautions or not. It is possible that other factors contributed to the results of the HippityHop study. The hospital where the study was conducted had an enhanced recovery program for patients after surgery and provided extensive material and documents to patients to assist them with their recovery; therefore, as patients are encouraged to play a more active role in their recovery, any potential differences between using hip precautions or not may have been minimised.

However, the findings of the HippityHop study are similar to Mikkelsen et al. (2014) who found no differences between their groups (unrestricted and restricted) ability to perform ADLs at six weeks after surgery. Findings between the two studies were also similar for mood (anxiety and depression) and for patient satisfaction. However, Mikkelsen et al. (2014) did not follow up participants for longer than six weeks, so longer-term comparisons were not possible. The results of the HippityHop study are also similar to a more recent study (published after this research had commenced) by Allen et al. (2018), who retrospectively examined the impact of precautions on patient-reported satisfaction and OHS prior to and after a change in postoperative protocol. Results from their study showed no significant difference in patient satisfaction at six weeks, six months, and one year postoperatively. The authors suggested that patient satisfaction is not affected by the presence or absence of precautions. In addition, Allen et al. (2018) found no significant changes in the OHS, and no significant difference between the groups preoperatively or at one-year postoperatively. Although the authors did not collect OHS in the short-term recovery time, their results are similar to those observed in the HippityHop study. Despite some differences between the results of the HippityHop study and other studies (e.g. Peak et al., 2005; Ververeli et al., 2009) regarding the pace of recovery following THR, the conclusions are similar: that hip precautions provided no additional benefit following primary THR.

The results of the HippityHop study showed that the groups had comparable dislocation rates and found no increase in dislocation rates following the removal of precautions. The results could suggest that the removal of hip precautions does not lead to an increased risk of dislocation, however, the study was not powered to conclude this. The evidence available (Talbot et al., 2002; Restrepo et al., 2011; Gromov et al., 2015) suggests that hip precautions provide no additional benefit in reducing the risk of dislocation, as low dislocation rates can be achieved without the use of hip precautions. Although these studies have methodological weaknesses, such as not including an acceptable control or comparison group and not completely withdrawing precautions (see section 1.5.8.), the findings in relation to the removal or relaxation of hip precautions and reported dislocation rates were consistent.

Previous research exploring staff perceptions of hip precautions has yielded similar findings to the qualitative research of HippityHop. The findings from the qualitative interviews highlighted that mixed opinions about hip precautions remained in both phases. Whilst clinicians acknowledged that the use of hip precautions is historical, patient safety and the avoidance of dislocation was paramount. The lack of robust

evidence about whether hip precautions affect the risk of dislocation was a cause of concern for many staff. However, the perceived negative impact of hip precautions on patients and the lack of supporting evidence of the benefits of hip precautions were the main reasons for the willingness to discontinue precautions. Findings from research conducted by Coole et al. (2013) and Mandel et al. (2017) drew similar conclusions. Whilst, these two studies explored staff perceptions and experiences of the use of precautions, and the rationale for the continuation and discontinuation of hip precautions, the HippityHop study interviewed staff before and after the removal of hip precautions from routine practice. Staff perceptions and experiences of the removal of hip precautions supported those hypothesised in the study by Coole et al. (2013), in which the relaxation of hip precautions was perceived, by staff interviewed in their study, to have an impact of patient recovery and satisfaction, therapy services and resource use. The HippityHop study further explored this change in clinical practice to identify barriers and facilitators experienced with changing clinical practice.

The main barrier identified, in the HippityHop study, was the resistance to change. Some surgeons were reluctant to change practices they considered effective (e.g. hip precautions), due to fears of increased dislocation rates. The hesitancy of surgeons to change the advice regarding the use hip precautions seemed to lead other, less-experienced, staff members to become anxious about the removal of precautions from practice. This could also have been a result of their lack of knowledge or understanding of the evidence available around the use of hip precautions. It seemed that some staff needed more guidance about alternative advice to provide to patients, instead of precautions, and needed to be reminded by the hip champions about this. Therefore, the development of guidelines for staff on discontinuing hip precautions and determining alternative advice warrants further attention, including updating local clinical protocols. Allen et al. (2018) reported on new departmental guidelines for physiotherapists assessing and treating patients after THR surgery. Their guidelines were developed following the cessation of the routine prescription of hip precautions at their local orthopaedic centre. These could be further developed to produce departmental guidelines for all clinicians treating patients undergoing THR.

With regard to patient perceptions and experience of hip precautions, this was the first study to explore and compare patient perceptions and experiences of the same service providing hip precautions and not providing them. Lee et al. (2017) surveyed patients to assess the impact of precautions on ADLs and reported similar findings to the participants in phase one of this current study. Patients in both studies reported

that precautions stopped them from performing desired activities and affected their sleep. The perceptions and experiences of staff and patients about the discontinuation of hip precautions is an area which warrants further exploration.

Despite a change in clinical practice and the withdrawal of hip precautions, variation in opinions about the effectiveness of hip precautions still existed. Surgeons considered precautions as an effective method in maintaining realistic patient expectations, and to prevent patients from performing extreme movements or activities outside of their limitations (e.g. placing their joint at end of ROM or in a vulnerable position). Therapists believed that the removal of precautions was beneficial for patients' rehabilitation, as it enabled them to provide a wider range of techniques for mobilisation and spend more time conducting functional assessments.

Finally, it is important to consider research that is currently in progress. Three ongoing studies have been identified since this study was completed:

1. A RCT of posterior hip precautions after total hip arthroplasty (i.e. THR) (HIPPRECAU) is currently being led by researchers at West Virginia University (West Virginia, United States). In this trial, participants will undergo a THR via a posterolateral approach to receive either standard care post-surgery hip restrictions (hip precautions) or to receive no restrictions to assess the short-term dislocation rates three to six months and the one-year risk for dislocation. The study is estimated to finish in April 2020 (National Institutes of Health U.S. National Library of Medicine, 2018).

2. A study examining adherence to hip precautions after THR surgery is currently ongoing in Manchester (England, UK). The study aims to explore adherence levels of patients at six and twelve weeks following hip replacement surgery, using postal questionnaires (Health Research Authority, 2017a).

3. A study led by Glyndwr University (Wales, UK) is investigating service users' (i.e. patients) experience of implementing hip precautions following THR surgery. Semi-structured interviews will be conducted six weeks post-operatively to explore how current practice (i.e. hip precautions) is experienced by service users (Health Research Authority, 2017b).

Thus, there is continuing investigation of the effects of hip precautions on dislocation rates. In addition, there is a growing interest in research on the perceptions and experiences of hip precautions. The results of this study will be relevant within this context. A qualitative systematic review and meta-synthesis could be considered when the above studies have been completed and published.

6.5. Implications of the research

At the time of commencement of the study, the majority of hospitals in the UK routinely provided hip precautions to patients following THR, despite a quarter of therapists believing that they were not necessary (Drummond et al., 2012; Smith and Sackley, 2016). As the use of hip precautions was common practice, there were several aspects of the HippityHop study that could have implications for clinicians treating patients following THR surgery, which are discussed below.

The findings from this study suggested that following hip precautions provided no additional benefits to patients following primary THR. Comparable dislocation rates were observed for both groups, and patient outcomes were similar at six weeks and three months regardless of whether they follow precautions or not after surgery. However, patients who did not follow precautions had significantly greater hip function and less pain immediately after surgery (one week post-surgery). It may be that encouraging patients to move as they are able, using pain for guidance, increases their confidence in their ability to move and perform ADLs safely, but this warrants further investigation.

Clinicians could utilise the findings of the interviews to develop a plan to successfully implement the changes in practice, as the study provides a discussion of the perceived barriers and facilitators to the withdrawal of hip precautions from routine practice. The findings of the study could increase the confidence of clinicians to generate discussions within the MDT about the possibility of relaxing hip precautions following THR surgery and may be the catalyst in changing established practices relating to hip precautions. If services are interested in revising their practice and discontinuing the use of hip precautions, there needs to be appropriate training for all staff, particularly nursing staff, about the new regime and how to manage the change successfully. The training would need to focus on the alternative advice given to patients, as this was an area that staff struggled with when adjusting to the new

regime. Particular attention needs to be paid to surgeons and their engagement, as the practice of other clinicians is governed by the views of surgeons and their postoperative protocols regarding patient care. Updating current clinical protocols, particularly surgeon protocols, including recommendations for rehabilitation and the potential withdrawal of hip precautions from routine practice following primary THR is needed.

Patients interviewed in this study were less anxious without hip precautions and appeared to be more confident in returning to activities; however, they still required reassurance from clinicians due to concerns about the potential damage they could do to their new hip. Patients believed that goal setting and timescales about what they should be achieving within specific time frames are required to realistically manage their expectations; they were unsure about how to progress their rehabilitation and when they were safe to return to more demanding daily and leisure activities. This indicates that there could be a need for advice and recommendations about when patients should expect to be able to carry out certain activities and movements. For example, when hip precautions were enforced, patients were theoretically unable to touch their toes for six weeks, so there was an expectation that they probably would be able to touch their toes at least six weeks after their surgery; however, following the removal of precautions, theoretically patients could touch their toes straight away as there were no restrictions, but were probably unable to due to pain.

The findings from the HippityHop study showed that both groups of patients had similar levels of satisfaction at six weeks postoperatively, however, at three months patients who were prescribed hip precautions were more satisfied with the information they were provided but less satisfied with their rehabilitation compared to patients who were not advised about hip precautions. Although the new regime provided more individualised care that was tailored appropriately to the patients' needs during their recovery, feedback from patients suggests that there is a need for timescales about when they should expect to be able to complete specific activities. Further research could determine timescales in which the majority of patients were able to perform specific movements or perform certain activities without the use of hip precautions. This information could then be used to provide patients with realistic expectations and progressive exercises that would enable patients to set goals and achieve them within the desired timeframe.

Implementation of a new practice is often variable, and there are numerous factors that influence clinicians' and healthcare workers' behaviour. Improving the implementation of changes in practice is dependent on changing the multiple behaviours of multiple types of people. Changing behaviours is difficult (Kelly and Barker, 2016) and it is often more effective if interventions are based on principles of appropriate behaviour change theory (Davies et al., 2015). Whilst this study involved an intervention which incorporated a change in clinical practice (i.e. removing the routine prescription and provision of hip precautions), the change in behaviour by clinical staff was not the focus of the research. However, incorporating a behaviour change theory may help to gain a greater understanding of the staff behaviours regarding the change in routine clinical practice.

Applying the theory of planned behaviour could provide an explanation for the reasons that staff were able to change from a practice of prescribing precautions routinely to only providing them to selected patients. The model claims that the behaviour is controlled by intentions, which can vary in strength. How strong an attempt the individual makes to engage in the behaviour, and how much control the individual has over the behaviour, are influential in whether he or she engages in the behaviour. Behaviour intention is produced from a combination of attitude towards the behaviour, subjective norm, and perceived behavioural control (Ajzen, 2002). The theory suggests that in order to change behaviours, individuals need to change their behavioural attitudes in which a different attitude towards the use of hip precautions can be created (e.g. suggestion that they are potentially not necessary, hinder patients' recovery, substantial resources required to provide them). In addition, individuals need to change their subjective norm, which can be achieved by providing actual data and evidence about the use of hip precautions and the impact of withdrawing them from routine practice (e.g. lack of evidence to support their use, more flexible approach to rehabilitation, potential cost-savings). By helping staff to focus on the effort required to change their behaviour (e.g. new local protocols, training sessions, information leaflets, team discussions) this can change perceived behavioural control. However, this theory may be more relevant to different staff members, depending upon their level of autonomy. For example, surgeons have greater autonomy in their choice of behaviour within orthopaedics, whereas nurses are expected to follow surgical protocols and may therefore have less autonomy.

In addition, changing the culture around hip precautions could make it difficult for an individual to continue to prescribe hip precautions if other members of staff are not prescribing them. Normalisation Process Theory (May et al., 2009) may help understand how the individualised approach to hip precautions can become routinely embedded within practice. The theory focuses on the work that people do and includes four generative practices: coherence (e.g. sense making, meaning), cognitive participation (e.g. commitment), collection action (e.g. effort) and reflexive monitoring (e.g. appraisal), that require continuous investment. In this study, the hip champions were key in driving forward the intervention and ensuring that other members of staff bought into and supported the new intervention. Educating staff about the research and evidence currently available and engaging staff with the change in the provision of hip precautions were also key mechanisms in enabling change in routine practice to be made. Hip champions ensured that staff were supported through the change in practice by providing training sessions, information leaflets, and team meetings for discussions. There were also a number of incentives for staff to change their clinical practice, including reducing the burden of prescribing hip precautions, ensuring that all the equipment on the ward was set to the patients' safe height, and also reducing the time spent ordering equipment. Reducing the time spent teaching precautions would have enabled staff to spend more time treating more complex patients (e.g. patients who were frail, had multiple comorbidities). It is believed that incorporating multiple strategies and hip champions to assist staff with the change in the routine practice of hip precautions facilitated the successful implementation of a new rehabilitation protocol in a local orthopaedic service.

In this thesis, the change in service has been described as a 'no precautions' phase for ease of expression and to provide distinction between the two phases of the research study. However, although participants in phase two of the study did not receive education about hip precautions, they received a more individualised approach to rehabilitation. The new treatment for primary THRs involved patients being encouraged to move within a comfortable ROM, as pain allowed, enabling them to take greater control over their rehabilitation. The therapists in this phase advised patients how to progress their rehabilitation and how to exercise and move in a safe but unrestricted ROM, focusing very much on the needs of the individual. Thus, no precautions should not be confused with no rehabilitation. It is also important to underline that there were patients who were excluded from this research (e.g. patients who underwent complex THR surgery, revision surgery, hip resurfacing) who

continued to receive standard hip precautions during the study period. This is also likely to continue for the foreseeable future until more research is undertaken with these patients.

6.6. Future direction

Despite the promising results from the before and after study, the qualitative study highlighted that some staff remained uncertain about the use of hip precautions and their removal from routine practice. It is clear that further research is required and a large multi-centred clustered RCT is warranted to determine whether hip precautions should be removed from routine practice nationally.

Participants should be followed up longer-term, to assess outcomes at six and twelve months postoperatively, to determine if there are any long-term effects as a result of not following precautions. Following patients up for longer would also determine the time point at which participants had returned to work, leisure activities, and physical activity. Further research is required to determine the effects of following hip precautions or not has on participants' return to work and resumption of leisure and physical activities.

There were some challenges experienced during the change in service that were highlighted by the staff in the interviews. They reported that they would have liked more MDT training and information relating to alternative advice, and that it was difficult to reassure patients about the new regime. Although the study focused on the experiences of staff, research could evaluate the training sessions and supplementary educational materials about the change in practice and withdrawal of precautions. Research could also include the application of the theory of planned behaviour to understanding staff behavioural beliefs and intentions towards withdrawing precautions from practice.

In addition, occupational therapists reported a reduction in the overall amount of equipment that they were providing to patients following the removal of precautions; however, they described how they tended to over-prescribe to patients who lived out of area and perhaps ordered more equipment than necessary to avoid delays with discharge. Patients across both phases considered adaptive equipment essential in the first couple of weeks, but reported that this might be stored in sheds and garages

when it was no longer required. It was perceived that there would have been much less adaptive equipment provided in phase two of the study, but the occupational therapists were in a difficult position clinically to significantly reduce the amount of equipment they prescribed to patients. Some occupational therapists were worried that patients may not be able to manage at home and complete ADLs safely without equipment; they also expressed concerns about delaying patients' discharge from hospital if the relevant equipment was not set-up at home. The withdrawal of hip precautions was perceived as cost-saving, but research needs to be conducted in order to determine if this was the case.

6.7. Final conclusion

In summary, the before and after study demonstrated equivalence between patients' hip pain and function at three months after THR surgery, however, hip precautions remain controversial. With the growing interest in the discontinuation of hip precautions from routine clinical practice for primary THRs, the findings provide support for individual trusts who are considering changing their clinical practice with patients following THR.

On the whole, staff were considered to have adapted well to the change in practice but the need for more in-depth training, particularly for nursing staff, was highlighted. The input that is required to change clinical practice and train staff is significant and needs engagement from all staff to be successful. Future studies in this area are likely to need to develop an implementation protocol that includes resources and extensive training for staff to ensure that the delivery of the intervention is standardised.

In conclusion, this thesis presented the evaluation of hip precautions before and after a change in clinical practice, using equivalence analysis. It also explored the perceptions and experiences of both staff and patients of the two regimes. The HippityHop study has shown that patients have similar outcomes regardless of whether they are prescribed hip precautions or not. Furthermore, the study has highlighted the barriers and facilitators to change clinical practice with regard to the removal of hip precautions (i.e. training, hip champions). Given that hip precautions are a controversial topic and the large variations that exist in clinical practices, the impact of a large multicentred cluster RCT study in this area is likely to be substantial.

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Appendices

Appendix A. Participant information sheet for the before and after study

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Participant Information Sheet
(Final version 1.3: 23rd August 2016)

IRAS Project ID: 194841

Title of Study: Recovery After Hip Operation - The "HippityHop" Study (Participant)

Name of Researcher(s): Courtney Lightfoot; Prof Avril Drummond; Mr Khosrow Sehat; Dr Carol Coole; Prof Brigitte Scammell

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through the information sheet with you and answer any questions you have. Talk to others about the study if you wish. Ask us if there is anything that is not clear.

What is the purpose of the study?

Nottingham City Hospital are changing the advice and equipment provided to patients following hip replacement. This is because advances in surgery mean that hip replacements are more stable, and the risks associated with surgery, such as dislocation, are much lower than in the past. Now, rather than giving all patients the same advice and equipment - which restricts movement following surgery - patients will receive more individualised advice and equipment provision. However, we need to evaluate this change in our service.

We are therefore carrying out a study to follow up patients after hip replacement surgery to monitor their recovery and progress. We are studying two groups of patients, one group of patients before the change in service, the other group after the new service has been introduced. We wish to compare how the change in service affects patients' recovery.

Why have I been invited?

You are being invited to take part because you are waiting for a total hip replacement from Nottingham City Hospital, which is the centre for this study, and you will be treated during the period in which the change in the delivery of service occurs. The staff from the orthopaedic team have identified you as being a suitable participant for the study. We are inviting 342 participants like you to take part.

Do I have to take part?

It is up to you to decide whether or not to take part in the study to collect information about your recovery. If you **do** decide to take part in the study, you will be given this information sheet to keep and asked to sign a consent form. If you do decide to take part, you are still **free** to withdraw at any time, and without giving a reason. This will not affect your legal rights, nor will this affect the treatment or standard of care that you receive.

What will happen to me if I take part?

If you agree to take part, you will be asked by a researcher to complete a questionnaire about your level of pain, level of physical activity, mood, sleep and other factors relating to your hip. Assistance with filling in the questionnaire will be provided if required. Completing the questionnaire should take 20-30 minutes. You will also be asked to complete a similar questionnaire again at 1 week, 6 weeks and 3 months after your total hip replacement surgery. The questionnaires can be completed at your organised hospital appointments or at home (we will give you a free post envelope to return to us).
We would also like to obtain background information from your hospital medical notes. Information such as your age, side affected, and any other medical conditions you have will help us to better understand your recovery. Only members of the research team will have access to your hospital medical notes.
A small number of patients will be invited to take part in an interview about their experiences during their recovery. The interview will last a maximum of 30 minutes.

Expenses and payments

Participants will not be paid to participate in the study. Information from you will be collected during your scheduled hospital visits, and return postage of questionnaires will be pre-paid for by us.

What are the possible disadvantages and risks of taking part?

There are no particular risks or disadvantages associated with this study. However, we appreciate that taking part may be inconvenient.

What are the possible benefits of taking part?

We cannot promise the study will help you but the information we get from this study may help us determine how best to organise and develop treatment services in the NHS, and could improve the recovery process for others who have a hip replacement in the future.

What happens when the research study stops?

You will continue to receive any care or treatment that has been arranged. A summary of the findings will be sent to you. A copy of the report can be requested from Courtney Lightfoot whose details are listed at the end of this information sheet.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. The researchers contact details are given at the end of this information sheet.
If you remain unhappy and wish to complain formally, you can do this by contacting PALS (Patient Advice and Liaison Service) for NHS Complaints as follows:

Queens Medical Centre
PALS is situated close to the Main Reception (Derby Road entrance), on the central corridor, opposite X-Ray.
Telephone QMC campus: 0800 183 0204
If using a mobile, please call QMC: 0115 924 9924 (ext 65412 or 62301)

City Hospital
PALS is on the South Corridor at Junction S6.
Freephone City Hospital campus: 0800 052 1195
If using a mobile, please call City Hospital: 0115 969 1169 (ext 59671)

Minicom: 0800 183 0204 (Fax: 0115 875 4655)
Email: pals@nuh.nhs.uk

Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence.

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 Nottingham who are organising the research. 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.

All information which is collected about you during the course of the research will be kept **strictly confidential**, stored in a secure and locked office, and on a password protected database. Any information about you which leaves the hospital will have your name and address removed (anonymised) and a unique code will be used so that you cannot be recognised from it.

Your personal data (address, telephone number) will be kept for a maximum of 12 months after the end of the study so that we are able to contact you about the findings of the study *and possible follow-up studies* (unless you advise us that you do not wish to be contacted). All other data (research data) will be kept securely for 7 years. After this time your data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team will have access to your personal data.

However, if you make a disclosure to a member of the research staff which makes them seriously concerned about you or someone else's safety or well-being as a result, then the researcher is obliged to break confidentiality in accordance with the Human Rights Act 1998. It is only in this case that we would discuss your information with anyone outside of the research team.

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

Your participation is voluntary and you are **free** to withdraw at any time, without giving any reason, and without your legal rights being affected. If you withdraw then the information collected so far cannot be erased and this information may still be used in the project analysis. You will continue to receive treatment as normal from the orthopaedic service and therapy team.

Involvement of the General Practitioner/Family doctor (GP)

Your GP will not be notified of your participation. However, your orthopaedic consultant and clinical members of staff will be informed of your participation.

If you record a high score on our anxiety and depression questionnaire, a member of the research team will contact you to discuss this and may recommend that you contact your GP. However, it is your choice as to whether you contact your GP or not.

What will happen to the results of the research study?

The results of the study may be presented to other researchers, at conferences, and through publication in scientific journals. The results of the study will also be written up as part of a doctoral thesis. We will ensure that it will not be possible for anyone to identify you from the published findings of the study. If you wish to know the results of the study, we will send you a summary of the findings.

Who is organising and funding the research?

This research is being organised by the University of Nottingham and is being funded by the University of Nottingham. The research is being conducted as part of a doctoral research project.

A steering group meets regularly to advise the research team. This group includes experienced researchers, service user representatives, and staff from Nottingham City Hospital and University of Nottingham.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by East Midlands – Nottingham 2 Research Ethics Committee.

Further information and contact details:

Courtney Lightfoot
Rehabilitation Research Office
A floor, Medical School
South Block Link
Queens Medical Centre
Nottingham
NG7 2UH
Tel: 0115 823 0890
E-mail: Courtney.Lightfoot@nottingham.ac.uk

Professor Avril Drummond
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Mr Khosrow Sehat
Consultant Orthopaedic Surgeon
Department of Orthopaedics
Nottingham City Hospital
Nottingham
NG5 1PB
Tel: 0115 969 1169 (ext. 55069)

Thank you for taking the time to read this information pack

Appendix B. Participant consent form for the before and after study

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The University of Nottingham
UNITED KINGDOM · CHINA · MALAYSIA

CONSENT FORM
(Final version 1.0: 16th June 2016)

Title of Study: Recovery After Hip Operation, The "HippityHop" Study

IRAS Project ID: 194841

Name of Researcher: Courtney Lightfoot

Name of Participant:

Please initial box

1. I confirm that I have read and understand the information sheet version number 1.3 dated 23rd August 2016 for the above study and have had the opportunity to ask questions. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my medical care or legal rights being affected. ☐
I understand that should I withdraw then the information collected so far cannot be erased and that this information may still be used in the project analysis.

3. I understand that relevant sections of my medical notes and data collected in the study may be looked at by authorised individuals from the University of Nottingham, the research group and regulatory authorities where it is relevant to my taking part in this study. I give permission for these individuals to have access to these records and to collect, store, analyse and publish information obtained from my participation in this study. I understand that my personal details will be kept confidential. ☐

4. **(Optional)** I agree that my contact details can be stored by the University of Nottingham at the School of Health Sciences, to contact me regarding possible future studies. I understand that some of these studies may be carried out by researchers, within the University of Nottingham, other than the current team who ran the first study. ☐

5. **(Optional)** I would like to receive a summary of the findings once the study is complete. ☐

6. I agree to take part in the above study. ☐

_____	_____	_____
Name of Participant	Date	Signature
_____	_____	_____
Name of Person taking consent	Date	Signature

3 copies: 1 for participant, 1 for the project notes and 1 for the medical notes

Appendix C. Baseline questionnaire for the before and after study

HippityHop Study

Initial Questionnaire

Thank you in advance for completing this questionnaire.

Please check that you answer all questions.

Study Number:		Participant Initials:	

Today's date : ☐☐ / ☐☐ / ☐☐☐☐ (D D / M M / Y Y Y Y)

Instructions

We very much appreciate your help in completing this questionnaire, as this will enable us to find out more about any problems patients have following their total hip replacement.

If you need help filling in this questionnaire, a researcher will be able to assist you following your pre-operative assessment.

For each question, please choose the answer that best applies. If you are unsure which answer to choose, select the one which seems most appropriate, rather than leaving the question blank. You may feel that some of the questions do not apply to you, but please attempt to answer them all so that we can have an overall picture.

We want to remind you that your answers will be kept completely confidential.

If you would like to discuss this questionnaire, or need any further information, please contact:

Name: Courtney Lightfoot

Tel: 0115 823 0890

Email: Courtney.Lightfoot@nottingham.ac.uk

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1. About you

1. **What is your date of birth?:** (dd/mm/yyyy) _____

2. **Are you:** (please circle) male / female

3. **Do you live alone?:** (please circle) yes / no

   If no, who do you live with? _____

4. **What is your current occupation?:** _____

   _____

2. Hip related problems (Oxford Hip Score)

© Oxford University Innovation Limited, 1996.

The following questions are about hip related problems. Please answer by ticking ☑ **ONE** (the most appropriate) box for each of the 12 questions.

During the past **FOUR** weeks……

1. **How would you describe the pain you <u>usually</u> have from your hip?**
   - None ☐
   - Very mild ☐
   - Mild ☐
   - Moderate ☐
   - Severe ☐

2. **Have you had any trouble with washing and drying yourself (all over) <u>because of your hip</u>?**
   - No trouble at all ☐
   - Very little trouble ☐
   - Moderate trouble ☐
   - Extreme difficulty ☐
   - Impossible to do ☐

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3. Have you had any trouble getting in and out of a car or using public transport <u>because of your hip</u>? (whichever you tend you use)

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

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

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

5. Could you do the household shopping <u>on your own</u>?

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

6. For how long have you been able to walk before the <u>pain from your hip</u> became severe? (with or without a stick)

- No pain/ greater than 30 minutes ☐
- 16 to 30 minutes ☐
- 5 to 15 minutes ☐
- Around the house only ☐
- Not at all ☐

7. Have you been able to climb a flight of stairs?

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

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

- Not painful at all ☐
- Slightly painful ☐
- Moderately painful ☐
- Very painful ☐
- Unbearable ☐

9. Have you been limping when walking, <u>because of your hip</u>?

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

10. Have you had any sudden, severe pain – 'shooting', 'stabbing' or 'spasms' – <u>from the affected hip</u>?

- No days ☐
- Only 1 or 2 days ☐
- Some days ☐
- Most days ☐
- Everyday ☐

11. How much has <u>pain from your hip</u> interfered with your usual work (including housework)?

- Not at all ☐
- A little bit ☐
- Moderately ☐
- Greatly ☐
- Totally ☐

12. Have you been troubled by <u>pain from your hip</u> in bed at night?

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

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Additonally...

1. **Have you taken pain relief medicine (prescribed or 'over the counter')?**
   (please circle) yes / no

   If yes, how often have you taken it in the past four weeks?

Only 1 or 2 days	☐
Some days	☐
Most days	☐
Everyday	☐

3. Daily activities (Nottingham Extended ADL Scale)

© University of Nottingham 2007

The following questions are about everyday activities. Please answer by ticking ☑ **ONE** box for each question. Please record what you have **ACTUALLY** done in the last **FOUR** weeks.

DID YOU…….	Not at all	With help	On your own with difficulty	On your own
1. Walk around outside?	☐	☐	☐	☐
2. Climb stairs?	☐	☐	☐	☐
3. Get in and out of a car?	☐	☐	☐	☐
4. Walk over uneven ground?	☐	☐	☐	☐
5. Cross roads?	☐	☐	☐	☐
6. Travel on public transport?	☐	☐	☐	☐

DID YOU…….	Not at all	With help	On your own with difficulty	On your own
7. Manage to feed yourself?	☐	☐	☐	☐
8. Manage to make yourself a hot drink?	☐	☐	☐	☐

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DID YOU…….	Not at all	With help	On your own with difficulty	On your own
9. Take hot drinks from one room to another?	☐	☐	☐	☐
10. Do the washing up?	☐	☐	☐	☐
11. Make yourself a hot Snack or hot meal?	☐	☐	☐	☐

DID YOU…….	Not at all	With help	On your own with difficulty	On your own
12. Manage your own money when you were out?	☐	☐	☐	☐
13. Wash small items of clothing?	☐	☐	☐	☐
14. Do your own housework?	☐	☐	☐	☐
15. Do your own shopping?	☐	☐	☐	☐
16. Do a full clothes wash?	☐	☐	☐	☐

DID YOU…….	Not at all	With help	On your own with difficulty	On your own
17. Read newspapers or books?	☐	☐	☐	☐
18. Use the telephone?	☐	☐	☐	☐
19. Write letters or email?	☐	☐	☐	☐
20. Go out socially?	☐	☐	☐	☐
21. Manage your own garden?	☐	☐	☐	☐
22. Drive a car?	☐	☐	☐	☐

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4. Sleep (Pittsburgh Sleep Quality Index)

© 1989, University of Pittsburgh.

The following questions are about your sleep habits during the **PAST MONTH ONLY**. Please answer each question by writing the most accurate reply for the **MAJORITY** of days and nights in the **PAST MONTH.**

During the **PAST MONTH**…..

1. What time did you usually go to bed at night?

USUAL BED TIME: _____

2. How long (in minutes) did it usually take for you to fall asleep at night?

NUMBER OF MINUTES: _____

3. What time did you usually get up in the morning?

USUAL GETTING UP TIME: _____

4. How many hours of <u>actual sleep</u> did you get at night? (This may be different than the number of hours you spend in bed)

HOURS OF SLEEP PER NIGHT: _____

For each of the remaining questions, please tick ☑ **ONE** (the best response) box for each question.

During the **PAST MONTH** ……

5. How often have you had trouble sleeping because you ….

	Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
a. …cannot get to sleep within 30 minutes	☐	☐	☐	☐
b. …wake up in the middle of the night or early morning	☐	☐	☐	☐
c. …have to get up to use the bathroom	☐	☐	☐	☐

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d. …cannot breathe comfortably ☐ ☐ ☐ ☐

e. …cough or snore loudly ☐ ☐ ☐ ☐

f. … feel too cold ☐ ☐ ☐ ☐

g. …feel too hot ☐ ☐ ☐ ☐

h. …had bad dreams ☐ ☐ ☐ ☐

i. …have pain ☐ ☐ ☐ ☐

j. Other reason(s), please describe

_____

_____

_____

	Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
How often in the last month have you had trouble sleeping because of this reason?	☐	☐	☐	☐

6. During the past month, how often have you taken medicine (prescribed or 'over the counter') to help you sleep?

Not during the past month ☐
Less than once a week ☐
Once or twice a week ☐
Three or more times a week ☐

7. During the past month, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity?

Not during the past month ☐
Less than once a week ☐
Once or twice a week ☐
Three or more times a week ☐

8. During the past month, how much of a problem has it been for you to keep up enough enthusiasm to get things done?

Not a problem at all ☐
Only a very slight problem ☐
Somewhat of a problem ☐
A very big problem ☐

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9. During the past month, how would you rate your sleep quality overall?

Very good	☐
Fairly good	☐
Fairly bad	☐
Very bad	☐

Additional sleep questions

The following questions are about your **USUAL** sleeping habits.

1. In what position do you normally prefer to sleep? (e.g. front, back, side, combination)

PREFERRED POSITION: _____

2. Are you currently sleeping in your preferred position? If not, what are the reasons for this?

Please circle: YES / NO

_____

_____

_____

5. Mood and feelings (Hospital Anxiety and Depression Scale)

© Zigmond and Snaith, 1983

The following questions are about your emotions. Please answer by ticking ☑ **ONE** box (most appropriate) that **BEST** describes how you have been feeling over the **PAST WEEK.** Don't take too long over your replies: your immediate reaction to each item will probably be more accurate than a long thought out response.

1. I feel tense or 'wound up':

Most of the time	☐
A lot of the time	☐
Time to time, occasionally	☐
Not at all	☐

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2. I still enjoy the things I used to enjoy:

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

3. I get sort of a frightened feeling like something awful is going to happen:

Very definitely and quite badly ☐
Yes, but no too badly ☐
A little, but it doesn't worry me ☐
Not at all ☐

4. I can laugh and see the funny side of things:

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

5. Worrying thoughts go through my mind:

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

6. I feel cheerful:

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

7. I can sit at ease and feel relaxed:

Definitely ☐
Usually ☐
Not often ☐
Not at all ☐

8. I feel as if I am slowed down:

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

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9. I get sort of frightened feeling like 'butterflies in the stomach':

Not at all ☐
Occasionally ☐
Quite often ☐
Very often ☐

10. I have lost interest in my appearance:

Definitely ☐
I don't take as much care as I should ☐
I may not take quite as much care ☐
I take just as much care as ever ☐

11. I feel restless as if I have to be on the move:

Very much indeed ☐
Quite a lot ☐
Not very much ☐
Not at all ☐

12. I look forward with enjoyment to things:

As much as I ever did ☐
Rather less than I used to ☐
Definitely less than I used to ☐
Hardly at all ☐

13. I get sudden feelings of panic:

Very often indeed ☐
Quite often ☐
Not very often ☐
Not at all ☐

14. I can enjoy a good book or radio or TV programme:

Often ☐
Sometimes ☐
Not often ☐
Very seldom ☐

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6. Wellbeing (EQ-5D-5L)

UK (English) © 2009 EuroQol Group EQ-5D™ is a trade mark of the EuroQol Group

The following questions are about your general wellbeing and quality of life. Under each heading, please tick ☑ the **ONE** box that **BEST** describes your own health state **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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Finally ....

How do you feel today?

We would like to know how **good or bad** your health is **TODAY**.

This scale is numbered from 0 to 100.

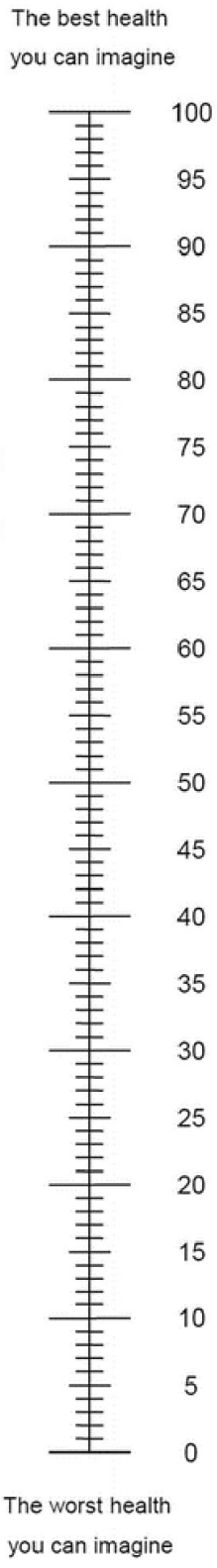
100 means the **best** health you can imagine.

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** =



©HippityHop Stu

Is there anything about your hip we haven't asked that you would like to tell us about?:

Thank you for taking the time to complete the questionnaire.

Please make sure that you have answered every single question, and then return the completed questionnaire in the stamped addressed envelope provided.

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If you would like to discuss this questionnaire, or any need any further information, please contact:

Name: Courtney Lightfoot

Tel: 0115 823 0890

Email: Courtney.Lightfoot@nottingham.ac.uk

Appendix D. Follow-up questionnaire for the before and after study

The University of Nottingham

HippityHop Study

Nottingham University Hospitals NHS Trust

Follow-Up Questionnaire 6 weeks/ 3 months

Thank you in advance for completing this questionnaire.

Please check that you answer all questions.

Study Number:		Participant Initials:	

Today's date : ☐☐ / ☐☐ / ☐☐☐☐ (D D / M M / Y Y Y Y)

©HippityHop Study

Instructions

We very much appreciate your help in completing this questionnaire, as this will enable us to find out more about any problems patients have following their total hip replacement.

If you need help filling in this questionnaire, we can arrange for a researcher to assist you over the phone or to visit you to help.

For each question, please choose the answer that best applies. If you are unsure which answer to choose, select the one which seems most appropriate, rather than leaving the question blank. You may feel that some of the questions do not apply to you, but please attempt to answer them all so that we can have an overall picture.

We want to remind you that your answers will be kept completely confidential.

If you would like to discuss this questionnaire, or any need any further information, please contact:

Name: Courtney Lightfoot

Tel: 0115 823 0890

Email: Courtney.Lightfoot@nottingham.ac.uk

1. Hip related problems (Oxford Hip Score)

© Oxford University Innovation Limited, 1996.

The following questions are about hip related problems. Please answer by ticking ☑ **ONE** (the most appropriate) box for each of the 12 questions.

During the past **FOUR** weeks……

1. How would you describe the pain you <u>usually</u> have from your hip?

- None ☐
- Very mild ☐
- Mild ☐
- Moderate ☐
- Severe ☐

2. Have you had any trouble with washing and drying yourself (all over) <u>because of your hip</u>?

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

3. Have you had any trouble getting in and out of a car or using public transport <u>because of your hip</u>? (whichever you tend you use)

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

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

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

5. Could you do the household shopping <u>on your own</u>?

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

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6. For how long have you been able to walk before the <u>pain from your hip</u> became severe? (with or without a stick)

- No pain/ greater than 30 minutes ☐
- 16 to 30 minutes ☐
- 5 to 15 minutes ☐
- Around the house only ☐
- Not at all ☐

7. Have you been able to climb a flight of stairs?

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

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

- Not painful at all ☐
- Slightly painful ☐
- Moderately painful ☐
- Very painful ☐
- Unbearable ☐

9. Have you been limping when walking, <u>because of your hip</u>?

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

10. Have you had any sudden, severe pain – 'shooting', 'stabbing' or 'spasms' – <u>from the affected hip</u>?

- No days ☐
- Only 1 or 2 days ☐
- Some days ☐
- Most days ☐
- Everyday ☐

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11. How much has <u>pain from your hip</u> interfered with your usual work (including housework)?

Not at all	☐
A little bit	☐
Moderately	☐
Greatly	☐
Totally	☐

12. Have you been troubled by <u>pain from your hip</u> in bed at night?

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

2. Daily activities (Nottingham Extended ADL Scale)

© University of Nottingham 2007

The following questions are about everyday activities. Please answer by ticking ☑ **ONE** box for each question. Please record what you have **ACTUALLY** done in the last **FOUR** weeks.

DID YOU…….	Not at all	With help	On your own with difficulty	On your own
1. Walk around outside?	☐	☐	☐	☐
2. Climb stairs?	☐	☐	☐	☐
3. Get in and out of a car?	☐	☐	☐	☐
4. Walk over uneven ground?	☐	☐	☐	☐
5. Cross roads?	☐	☐	☐	☐
6. Travel on public transport?	☐	☐	☐	☐

DID YOU…….	Not at all	With help	On your own with difficulty	On your own
7. Manage to feed yourself?	☐	☐	☐	☐
8. Manage to make yourself a hot drink?	☐	☐	☐	☐

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DID YOU…….	Not at all	With help	On your own with difficulty	On your own
9. Take hot drinks from one room to another?	☐	☐	☐	☐
10. Do the washing up?	☐	☐	☐	☐
11. Make yourself a hot Snack or hot meal?	☐	☐	☐	☐

DID YOU…….	Not at all	With help	On your own with difficulty	On your own
12. Manage your own money when you were out?	☐	☐	☐	☐
13. Wash small items of clothing?	☐	☐	☐	☐
14. Do your own housework?	☐	☐	☐	☐
15. Do your own shopping?	☐	☐	☐	☐
16. Do a full clothes wash?	☐	☐	☐	☐

DID YOU…….	Not at all	With help	On your own with difficulty	On your own
17. Read newspapers or books?	☐	☐	☐	☐
18. Use the telephone?	☐	☐	☐	☐
19. Write letters or email?	☐	☐	☐	☐
20. Go out socially?	☐	☐	☐	☐
21. Manage your own garden?	☐	☐	☐	☐
22. Drive a car?	☐	☐	☐	☐

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3. Sleep (Pittsburgh Sleep Quality Index)

© 1989, University of Pittsburgh.

The following questions are about your sleep habits during the **PAST MONTH ONLY**. Please answer each question by writing the **MOST ACCURATE** reply for the **MAJORITY** of days and nights in the **PAST MONTH**.

During the **PAST MONTH**…..

1. What time did you usually go to bed at night?

USUAL BED TIME: _____

2. How long (in minutes) did it usually take for you to fall asleep at night?

NUMBER OF MINUTES: _____

3. What time did you usually get up in the morning?

USUAL GETTING UP TIME: _____

4. How many hours of <u>actual sleep</u> did you get at night? (This may be different than the number of hours you spend in bed)

HOURS OF SLEEP PER NIGHT: _____

For each of the remaining questions, please tick ☑ **ONE** (the best response) box for each question.

During the **PAST MONTH** ……

5. How often have you had trouble sleeping because you ….

	Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
a. …cannot get to sleep within 30 minutes	☐	☐	☐	☐
b. …wake up in the middle of the night or early morning	☐	☐	☐	☐
c. …have to get up to use the bathroom	☐	☐	☐	☐

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	Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
d. …cannot breathe comfortably	☐	☐	☐	☐
e. …cough or snore loudly	☐	☐	☐	☐
f. … feel too cold	☐	☐	☐	☐
g. …feel too hot	☐	☐	☐	☐
h. …had bad dreams	☐	☐	☐	☐
i. …have pain	☐	☐	☐	☐

j. Other reason(s), please describe

_____

_____

_____

How often in the last month have you had trouble sleeping because of this?	☐	☐	☐	☐

6. During the past month, how often have you taken medicine (prescribed or 'over the counter') to help you sleep?

- Not during the past month ☐
- Less than once a week ☐
- Once or twice a week ☐
- Three or more times a week ☐

7. During the past month, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity?

- Not during the past month ☐
- Less than once a week ☐
- Once or twice a week ☐
- Three or more times a week ☐

8. During the past month, how much of a problem has it been for you to keep up enough enthusiasm to get things done?

- Not a problem at all ☐
- Only a very slight problem ☐
- Somewhat of a problem ☐
- A very big problem ☐

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9. During the past month, how would you rate your sleep quality overall?

Very good	☐
Fairly good	☐
Fairly bad	☐
Very bad	☐

Additional sleep questions

The following questions are about your **USUAL** sleeping habits

1. **What position do you normally prefer to sleep?** (e.g. front, back, side, combination)

   PREFERRED POSITION: _____

2. **Were you instructed to sleep on your back after your hip replacement? If so, for how long?**

   Please circle: YES / NO

   LENGTH OF TIME: _____

If you answered **YES** to **Question 2**, then please **answer the following questions**. If you answered **NO**, then please go to **Question 3**.

   i) How long did you actually sleep on your back for?

   LENGTH OF TIME: _____

   ii) Did you find it difficult to sleep on your back? If so, what were the reasons for this?

   Please circle: YES / NO

   _____

   _____

   _____

3. **Are you currently sleeping in your preferred position? If not, what are the reasons for this?**

   Please circle: YES / NO

   _____

   _____

   _____

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4. Mood and feelings (Hospital Anxiety and Depression Scale)

© Zigmond and Snaith, 1983

The following questions are about your emotions. Please answer by ticking ☑ **ONE** box (most appropriate) that **BEST** describes how you have been feeling over the **PAST WEEK.** Don't take too long over your replies: your immediate reaction to each item will probably be more accurate than a long thought out response.

1. I feel tense or 'wound up':

- Most of the time ☐
- A lot of the time ☐
- Time to time, occasionally ☐
- Not at all ☐

2. I still enjoy the things I used to enjoy:

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

3. I get sort of a frightened feeling like something awful is going to happen:

- Very definitely and quite badly ☐
- Yes, but no too badly ☐
- A little, but it doesn't worry me ☐
- Not at all ☐

4. I can laugh and see the funny side of things:

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

5. Worrying thoughts go through my mind:

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

6. I feel cheerful:

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

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7. I can sit at ease and feel relaxed:

Definitely ☐
Usually ☐
Not often ☐
Not at all ☐

8. I feel as if I am slowed down:

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

9. I get sort of frightened feeling like 'butterflies in the stomach':

Not at all ☐
Occasionally ☐
Quite often ☐
Very often ☐

10. I have lost interest in my appearance:

Definitely ☐
I don't take as much care as I should ☐
I may not take quite as much care ☐
I take just as much care as ever ☐

11. I feel restless as if I have to be on the move:

Very much indeed ☐
Quite a lot ☐
Not very much ☐
Not at all ☐

12. I look forward with enjoyment to things:

As much as I ever did ☐
Rather less than I used to ☐
Definitely less than I used to ☐
Hardly at all ☐

13. I get sudden feelings of panic:

Very often indeed ☐
Quite often ☐
Not very often ☐
Not at all ☐

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14. I can enjoy a good book or radio or TV programme:

- Often ☐
- Sometimes ☐
- Not often ☐
- Very seldom ☐

5. Wellbeing (EQ-5D-5L)

UK (English) © 2009 EuroQol Group EQ-5D™ is a trade mark of the EuroQol Group

The following questions are about your general wellbeing and quality of life. Under each heading, please tick ☑ **ONE** box that **BEST** describes your health state **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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How do you feel today?

We would like to know how **good or bad** your health is **TODAY**.

This scale is numbered from 0 to 100.

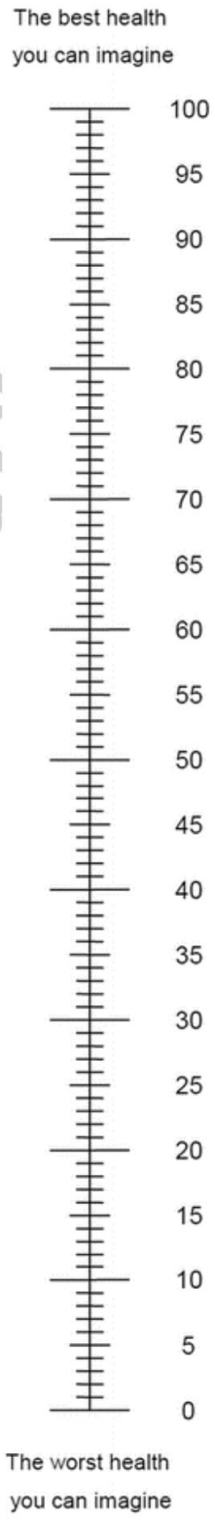
100 means the **best** health you can imagine.

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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Finally ...

1. **Are you currently (in the last week) taking any pain relief or pain killers for you hip?**

   Please circle: YES / NO

2. **Have you dislocated your hip since your hip replacement surgery?**

   Please circle: YES / NO

3. **Have you had any other significant complications following the operation such as wound healing, pain, infection?**

   Please circle: YES / NO
   If yes, please specify _____
   _____

4. **Have you been admitted to hospital since your hip replacement surgery for either your hip or other problems?**

   Please circle: YES / NO

   If yes,
   Was it your hip? (please tick the box ☑) ☐
   please specify _____
   _____

   Was it for other problems? (please tick the box ☑) ☐
   please specify _____
   _____

5. **Are you satisfied with the outcome of the surgery?**

   Please circle: YES / NO
   Reason(s): _____

6. **Are you satisfied with the rehabilitation program that you were given?**

   Please circle: YES / NO
   Reason(s): _____

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7. Are you satisfied with the information you received?

Please circle: YES / NO
Reason(s): _____

Is there anything about your hip or your recovery which we haven't asked you that you would like to tell us?:

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Thank you for taking the time to complete the questionnaire.

Please make sure that you have answered every single question, and then return the completed questionnaire in the stamped addressed envelope provided.

If you would like to discuss this questionnaire, or any need any further information, please contact:

Name: Courtney Lightfoot
Tel: 0115 823 0890
Email: Courtney.Lightfoot@nottingham.ac.uk

Appendix E. Staff participant information sheet for the interview study

The University of Nottingham
UNITED KINGDOM · CHINA · MALAYSIA

The University of Nottingham
UNITED KINGDOM · CHINA · MALAYSIA
Faculty of Medicine and Health Sciences
School of Health Sciences
The University of Nottingham
B Floor, South Block Link
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NG7 2HA

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Participant Information Sheet
(Final version 1.0: 16th June 2016)

IRAS Project ID: 194841

Title of Study: Recovery After Hip Operation - The "HippityHop" Study (Staff Interview)

Name of Researcher(s): Courtney Lightfoot; Prof Avril Drummond; Mr Khosrow Sehat; Dr Carol Coole; Prof Brigitte Scammell

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through the information sheet with you and answer any questions you have. Talk to others about the study if you wish. Ask us if there is anything that is not clear.

What is the purpose of the study?

We are carrying out research exploring patients' recovery, and the care and treatment they received after having a total hip replacement. As part of this research, we would like to talk to you about your perceptions and experiences of the service provided to patients after total hip replacement, to gain a more in-depth understanding of the support patients receive.

Why have I been invited?

You have been invited because you currently work within the orthopaedic team, and are involved in treating and caring for patients following total hip replacements at Nottingham City Hospital.

Do I have to take part?

It is up to you to decide whether or not to take part in an interview. You have some time to think about it. If you **do** decide to take part in an interview, you will be given this information sheet to keep and asked to sign a consent form. If you decide to take part you are still **free** to withdraw at any time, without giving a reason. Withdrawing from the study will not have a negative effect on your employment, nor will it affect your legal rights.

What will happen to me if I take part?

If you decide that you want to take part in an interview, please contact a member of the research team to discuss the interview further and to ask any questions you may have. If you still wish to take part, then they will arrange an interview to discuss the current care and treatment provided to patients to aid their recovery following total hip replacement. We are particularly interested in your perceptions, thoughts, and feelings about the service currently being provided.

The interview will be conducted by a researcher from the University of Nottingham and will last a maximum of 30 minutes. The interview can be completed face-to-face, via video call (e.g. Skype, FaceTime) or via telephone, depending on what you prefer, at a time that suits you. The face-to-face interview will be conducted at Nottingham City Hospital campus. The interview will be audio recorded, with your consent.

Expenses and payments

Participants will not be paid to participate in the study. Unfortunately, we are unable to reimburse travel/parking expenses.

What are the possible disadvantages and risks of taking part?

There are no particular risks or disadvantages associated with this study. However, we appreciate that taking part may be inconvenient.

What are the possible benefits of taking part?

There may be no direct benefit to you but we anticipate that the research will benefit patients requiring total hip replacements in the future. The information we collect from the study will help us understand staff perceptions of the treatment service provided. The information may also help us determine new ways, or improve the current practice, of providing recovery care and treatment to patients following total hip replacement.

What happens when the research study stops?

A summary of the findings will be sent to you. A copy of the report can be requested from Courtney Lightfoot whose details are listed at the end.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. The researchers contact details are given at the end of this information sheet. If you remain unhappy and wish to complain formally, you can contact the Research Ethics Committee Administrator as follows:

Mrs Louise Sabir,
Ethics Committee Secretary,
Division of Therapeutics and Molecular Medicine,
D Floor, South Block,
Queen's Medical Centre,
Nottingham, NG7 2UH.

Telephone 0115 823 1063
E-mail louise.sabir@nottingham.ac.uk

Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence.

If you join the study, some parts of the data collected for the study will be looked at by authorised persons from the University of Nottingham who are organising the research. 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.

All information which is collected about you during the course of the research will be kept **strictly confidential**, stored in a secure and locked office, and on a password protected database. Any information about you which leaves the hospital will have your name and address removed (anonymised) and a unique code will be used so that you cannot be recognised from it.

Your personal data (address, telephone number) will be kept for a maximum of 12 months after the end of the study so that we are able to contact you about the findings of the study *and possible follow-up studies* (unless you advise us that you do not wish to be contacted). All other data (research data including recordings) will be kept securely for 7 years. After this time your data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team will have access to your personal data.

Although what you say in the interview is confidential, if you make a disclosure to a member of the research staff which makes them seriously concerned about you or someone else's safety or well-being as a result, then the researcher is obliged to break confidentiality in accordance with the Human Rights Act 1998. It is only in this case that we would discuss your information with anyone outside of the research team.

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

Your participation is voluntary and you are **free** to withdraw at any time, without giving any reason. This will not affect the standard of care that you receive, and your legal rights will not be affected. If you withdraw, then the information collected so far cannot be erased and this information may still be used in the project analysis.

What will happen to the results of the research study?

The results of the study may be presented to other researchers, at conferences, and through publication in scientific journals. We will ensure that it will not be possible for anyone to identify you from the published findings of the study. If you wish to know the results of the study, we will send you a summary of the findings.

Who is organising and funding the research?

This research is being organised by the University of Nottingham and is being funded by the University of Nottingham. The research is being conducted as part of a doctoral research project.

A steering group meets regularly to advise the research team. This group includes experienced researchers, service user representatives, and staff from Nottingham City Hospital and University of Nottingham.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by East Midlands – Nottingham 2 Research Ethics Committee.

Further information and contact details

Courtney Lightfoot
Rehabilitation Research Office,
A floor, Medical School
South Block Link
Queens Medical Centre
Nottingham
NG7 2UH
Tel: 0115 823 0890
E-mail: Courtney.Lightfoot@nottingham.ac.uk

Professor Avril Drummond
Director of Research
A floor, Medical School
South Block Link
Queens Medical Centre
Nottingham
NG7 2UH
0115 823 0493
Avril.Drummond@nottingham.ac.uk

Mr Khosrow Sehat
Consultant Orthopaedic Surgeon
Department of Orthopaedics
Nottingham City Hospital
Nottingham
NG5 1PB
Tel: 0115 969 1169 (ext. 55069)

Thank you for taking the time to read this information pack

Appendix F. Patient participant information sheet for the interview study

The University of Nottingham
UNITED KINGDOM · CHINA · MALAYSIA

Faculty of Medicine and Health Sciences
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The University of Nottingham
UNITED KINGDOM · CHINA · MALAYSIA

Participant Information Sheet
(Final version 1.0: 16th June 2016)

IRAS Project ID: 194841

Title of Study: Recovery After Hip Operation - The "HippityHop" Study
(Participant Interview)

Name of Researcher(s): Courtney Lightfoot; Prof Avril Drummond; Mr Khosrow Sehat; Dr Carol Coole; Prof Brigitte Scammell

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through the information sheet with you and answer any questions you have. Talk to others about the study if you wish. Ask us if there is anything that is not clear.

What is the purpose of the study?

We are carrying out research exploring peoples' experiences of their recovery following a total hip replacement. As part of this research, we would like to talk to you about your treatment and recovery following surgery.

Why have I been invited?

You are being invited to take part because you have already taken part in the first stage of our research study. We are inviting a small sample of 20 participants who have had a total hip replacement like you to take part.

Do I have to take part?

It is up to you to decide whether or not to take part in an interview. You have some time to think about it. If you **do** decide to take part in an interview, you will be given this information sheet to keep and asked to sign a consent form. If you decide to take part you are still **free** to withdraw at any time, without giving a reason. This will not affect your legal rights. This will also not affect the treatment or standard of care that you receive.

What will happen to me if I take part?

If you decide that you want to take part in an interview, please return the letter enclosed or contact Courtney Lightfoot on 0115 823 0890. A member of the research team will then contact you to discuss the interview further and answer any questions you may have. If you still wish to take part, then they will arrange an interview with you to discuss your recovery experiences further. We are particularly interested in your experiences about how you felt your recovery progressed, any challenges you faced, and how it affected your daily life.

The interview will be conducted by a researcher from the University of Nottingham and will last a maximum of 30 minutes. The interview can be completed face-to-face, via video call (Skype, FaceTime) or via telephone, depending on what you prefer, at a time that suits you. The face-to-face interview can be conducted at your own home, Nottingham City Hospital campus or University of Nottingham, wherever you feel most comfortable. The interview will be audio recorded, with your consent.

Expenses and payments

Participants will not be paid to participate in the study. Unfortunately, we are also unable to reimburse travel, parking, or other related expenses.

What are the possible disadvantages and risks of taking part?

There are no particular risks or disadvantages associated with this study. However, we appreciate that taking part may be inconvenient.

What are the possible benefits of taking part?

We cannot promise the study will help you but the information we get from this study may help benefit patients following total hip replacement in the future. The information we collect from the study will help us understand recovery more, and may help us determine new ways, or improve current ways, of providing treatment.

What happens when the research study stops?

You will continue to receive any care or treatment that has been arranged. A summary of the findings can be requested from Courtney Lightfoot whose details are listed at the end.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. The researchers contact details are given at the end of this information sheet. If you remain unhappy and wish to complain formally, you can do this by contacting PALS (Patient Advice and Liaison Service) as follows:

Queens Medical Centre
PALS is situated close to the Main Reception (Derby Road entrance), on the central corridor, opposite X-Ray.
Telephone QMC campus: 0800 183 0204
If using a mobile, please call QMC: 0115 924 9924 (ext 65412 or 62301)

City Hospital
PALS is on the South Corridor at Junction S6.
Freephone City Hospital campus: 0800 052 1195
If using a mobile, please call City Hospital: 0115 969 1169 (ext 59671)

Minicom: 0800 183 0204 (Fax: 0115 875 4655)
Email: pals@nuh.nhs.uk

Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence.

If you join the study, some parts of the data collected for the study will be looked at by authorised persons from the University of Nottingham who are organising the research. 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.

All information which is collected about you during the course of the research will be kept **strictly confidential**, stored in a secure and locked office, and on a password protected database. Any information about you which leaves the hospital will have your name and address removed (anonymised) and a unique code will be used so that you cannot be recognised from it.

Your personal data (address, telephone number) will be kept for a maximum of 12 months after the end of the study so that we are able to contact you about the findings of the study *and possible follow-up studies* (unless you advise us that you do not wish to be contacted). All other data (research data including recordings) will be kept securely for 7 years. After this time your data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team will have access to your personal data.

Although what you say in the interview is confidential, if you make a disclosure to a member of the research staff which makes them seriously concerned about you or someone else's safety or well-being as a result, then the researcher is obliged to break confidentiality in accordance with the Human Rights Act 1998. It is only in this case that we would discuss your information with anyone outside of the research team.

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

Your participation is voluntary and you are **free** to withdraw at any time, without giving any reason. This will not affect the standard of care that you receive, and your legal rights will not be affected. If you withdraw, then the information collected so far cannot be erased and this information may still be used in the project analysis.

Involvement of the General Practitioner/Family doctor (GP)

Your GP will not be notified of your participation. However, your orthopaedic consultant and clinical members of staff will be informed of your participation.

What will happen to the results of the research study?

The results of the study may be presented to other researchers, at conferences, and through publication in scientific journals. We will ensure that it will not be possible for anyone to identify you from the published findings of the study. If you wish to know the results of the study, we will send you a summary of the findings.

Who is organising and funding the research?

This research is being organised by the University of Nottingham and is being funded by the University of Nottingham. The research is being conducted as part of a doctoral research project.

A steering group meets regularly to advise the research team. This group includes experienced researchers, service user representatives, and staff from Nottingham City Hospital and University of Nottingham.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by East Midlands – Nottingham 2 Research Ethics Committee.

Further information and contact details

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Thank you for taking the time to read this information pack

Appendix G. Consent form for the interview study

The University of Nottingham
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CONSENT FORM
(Final version 1.0: 16th June 2016)

Title of Study: Recovery After Hip Operation, The "HippityHop" Study (Interview)

IRAS Project ID: 194841

Name of Researcher: Courtney Lightfoot

Name of Participant:

Please initial box

1. I confirm that I have read and understand the information sheet version number 1.0 dated 16th June 2016 for the above study and have had the opportunity to ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my medical care or legal rights being affected. I understand that should I withdraw then the information collected so far cannot be erased and that this information may still be used in the project analysis. ☐
3. I understand that the interview will be recorded and that anonymous direct quotations from the interview may be used in the study reports. ☐
4. **(Optional)** I agree that my contact details can be stored by the University of Nottingham at the School of Health Sciences, to contact me regarding possible future studies. I understand that some of these studies may be carried out by researchers, within the University of Nottingham, other than the current team who ran the first study. ☐
5. I agree to take part in the above study. ☐

Name of Participant	Date	Signature
Name of Person taking consent	Date	Signature

3 copies: 1 for participant, 1 for the project notes and 1 for the medical notes

Appendix H. Staff interview schedule

Staff interview schedules

We are conducting research into recovery following a total hip replacement. As you are a member of staff working as part of the orthopaedic multidisciplinary team (MDT), we would like to talk to you about your perceptions of the service provided to patients following their total hip replacement. This interview will be recorded and the recording will be anonymised, so if you're happy to continue there are some forms to sign first.
Are you happy for me to start recording?

1. **Let us start by asking you what your professional background/ role in the MDT?**
   (Prompt: what does your job entail with THR patients? How long have you been in that role?)
   What do you mean by that? What does that mean? Can you explain a bit more/ give more information?

2. **What information and/ or advice do you give to patients?**
   (Prompt: what movements are/ are not recommended? Did you recommend them for a specific length of time? Do you prescribe exercises for the patients to do and what are they? Do you provide any information leaflets or attend any sessions?)
   What happens after operation? Timing of pre-op – thoughts/ why then? What is included? How was it developed? What does it look like? Where does this information come from? Why do you do that? How do you know? Why do people have HPs? Does everyone get given HPs? Evidence for HPs? Does everyone attend hip school? Why was this developed? What do the patients think/ feel about it? How do you know? Do you keep up to date with evidence? How often? Do you have access? Who decided to change the service? How was this decision made? How do you feel about the changes? What do you colleagues think? How has it changed practice? What impact has this had on patients? How was the transition? Did you have training of new regime? How are things different now? How have these changes affected your practice? What impact do you think it has had on dislocation rates/ patient outcomes?

3. **Did you give out or recommend any equipment/ aids for patients?**
   (Prompt: toilet raisers? Small aids such as easy reacher? How long did you recommend the equipment to be used for?)
   Why those? What for? Do patients use them? Benefit from them? How do you know? Who determines/ decides this? Does everyone get the same? Who assesses this? How do you assess this now? What equipment do patients get now?

4. **What do you think of the service that currently provided?**
   (Prompt: what do you think works/ doesn't work? Why do you think that? What impact do you think it has on patients' recovery?)
   Timings? – When see patients? For how long? Happy for assistants to be involved in that area? Conflicts between surgeons? Staff roles in post op?
   Opinions of HPs? Compliance with HPs – staff and patients? How long for? How do you know that? Why is that? How does it compare to the service before?

5. **What in the service would you like to change? Why?**
   (Prompt: what impact to you think that would have? How would it improve things?)
   What do you think of removing HPs? What would you do with time if HPs were removed? – Impact on service/ discharge planning/ rapid recovery? What is it like to challenge X (consultant)? What would you like to change about the service, and why?

6. **Is there anything else that you would like to add or ask me?**
   Is there anything that we haven't discussed that you would like to talk about?

Thank you very much for taking part in the interview.

Appendix I. Patient interview schedule

Patient interview schedules

We are conducting research into recovery following a total hip replacement. As you have received a hip replacement within the last few months, we would like to talk to you about your recovery. We are particularly interested in your experiences and opinions of the service provided to you by the hospital. This interview will be recorded and the recording will be anonymised, so if you're happy to continue there are some forms to sign first. Are you happy for me to start recording?

1. **Let us start by asking you how you feel your recovery has gone?**
   (Prompt: how has your recovery been so far? Are you getting back to normality? Has it been quicker/ slower than expected? What were you expecting? Have you had a hip replacement before? How does that compare?)

2. **What information and/ or advice were you given by the physiotherapists/ occupational therapists?**
   (Prompt: what movements were/ were not recommended? Were you told to follow them for a specific length of time? Did you receive any exercises and what were they? Did you receive any information leaflets or attend any sessions? What did you think/feel? Is there anything that you wished you were told about? Did the information cover what you expected? What advice would you give to future patients? Did staff talk to you about dislocation?)

3. **Were you given or recommended any equipment from the hospital or provided any support from friends/family? If so, what and how has it helped you?**
   (Prompt: toilet raisers? Small aids such as easy reacher? Help with cooking/cleaning/washing? How long did you need the equipment and/or help? Did you purchase any small aids/ equipment? Did you receive any community support? What support have you had? Who provided the support?)

4. **What challenges/difficulties have you experienced? How have they affected you?**
   (Prompt: how have you found the exercises? Walking? Crutches? Sleeping? Pain?)

5. **What effect has the rehabilitation treatment and advice you received had on your daily life?**
   (Prompt: when and what activities couldn't you do that you could do normally or wanted to do? Effect on ADL, work family, relationships and how have they responded? Have you gone back to work? How long following surgery? When you expecting to?)

6. **Are you satisfied with how your recovery has gone? If so/ not, why?**
   (Prompt: are you able to do more? How is the pain? Have you returned to all the activities you were able to do before or wanted to be able to do? Are you doing any new ones? How is your life different now? Is it how you expected it to be?)

7. **Is there anything else that you would like to add or ask me?**

Thank you very much for taking part in the interview.