TITLE

Hip Precautions After Hip Operation (HippityHop): Protocol for a Before and After Study Evaluating Hip Precautions Following Total Hip Replacement

SHORT TITLE

Hip Precautions After Hip Operation (HippityHop)

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ABSTRACT

Introduction

Hip precautions are routinely used despite inconclusive evidence that they reduce dislocations, and concern that they impede activities of daily living. HippityHop compares a change in practice locally from implementing routine hip precautions to no routine precautions, in order to: 1. Compare patient outcomes in quality of life, functional performance, pain, sleep, mood and satisfaction. 2. Ascertain staff and patient perceptions of the two regimes. 3. Determine the cost of precautions.

Methods

Before and after study: phase one patients will receive hip precautions, while phase two patients will receive no routine precautions. We propose to collect data from 342 participants at baseline, and at one week, six weeks, and three months postoperatively. Interviews will be conducted with 20 staff and 20 patients, and data collected relating to costs.

Results

Statistical analysis will be conducted to compare the two groups to determine any differences in patient outcomes. Thematic analysis will be used to identify and report themes within the interview data.

Conclusion

If there are no additional advantages to hip precautions, patients could resume everyday activities more quickly, potentially improving their quality of life. Conversely, if withdrawing hip precautions is detrimental, evidence for precautions will be provided.

Key words: total hip replacement, hip precautions, quality of life

BACKGROUND

Elective total hip replacement (THR) is a common surgical procedure with more than 83,000 operations performed in England, Wales and Northern Ireland in 2015 (National Joint Registry (NJR), 2016). Dislocation of the hip is one of the most recognised complications following THR, with incidence rates reported ranging from less than 1% to greater than 15% (Restrepo et al., 2011). The reasons for hip dislocation after surgery are multifactorial, with contributing factors from the patient, the implant, and the surgeon (Brooks, 2013). Patient factors include age, gender, medical comorbidities, weak musculature, and ligament laxity (Blom et al., 2008; Brooks, 2013). The prosthesis design and selection of head diameter can influence the risk of dislocation (Blom et al., 2008), alongside the positioning of the prosthesis components (Patel et al., 2007). Surgical experience and variations in surgical approach, are considered the most controversial factors that influence the risk of dislocation (D'Angelo et al., 2008).

To reduce the risk of hip dislocation following surgery, staff routinely advise patients to follow certain postoperative restrictions which are commonly known as hip precautions (Reed, 2001; Turner, 2002). These precautions usually involve advising patients not to flex their hip beyond 90%, adduct, or rotate (medially or laterally) e.g. when getting dressed, reaching to the floor and getting into a car. Staff, particularly occupational therapists, spend a great deal of time pre- and postoperatively providing advice and equipment in regard to hip precautions (Drummond et al., 2012).

Four systematic reviews (Barnsley et al., 2015; Sharma et al., 2009; Smith et al., 2016; van der Weegan et al., 2016), and a literature review (Tejwani and Immerman, 2008) have all concluded that hip precautions are not needed when an anterolateral surgical approach is used. The reviews support the suggestion that hip precautions provide no additional benefit with regard to reducing dislocation rates and, moreover, are associated with slower return to activities, significant expense, and decreased patient satisfaction. Studies have examined the mobilisation restrictions (hip precautions) in posterior (Mikkelsen et al., 2014) and posterolateral approaches (Gromov et al., 2015); the studies concluded that the removal of restrictions following primary THR does not lead to an increased risk of dislocation (Gromov et al., 2015), nor affects the outcome of patient-reported outcomes, i.e. function, pain, and quality of life (Mikkelsen et al., 2014). However, overall the results are confusing and there remain strong opposing clinical opinions about whether precautions are effective or detrimental (Coole et al, 2013).

Although the evidence available suggests hip precautions are not needed, the trials to date have a number of issues: First a lack of robust methodology, such as not including an acceptable control or comparison group, changing surgical approaches during study period, no fidelity checks, and not completely removing hip precautions from the unrestricted group. Secondly, studies are underpowered with the rate of dislocation as the primary outcome measure (the incidence of dislocation is low nationally because of surgical advances and the numbers of patients needed to demonstrate any difference would be difficult to recruit with length of follow up prolonged). Thirdly, the focus is on dislocation, with other outcome data such as patient satisfaction, independence, and quality of life often ignored.

Aside from whether precautions are effective in reducing dislocation or not, there is some suggestion that they impede full functional recovery and slow return to activities such as mobility, shopping and driving (Ververeli et al., 2009). A cohort study of 64 consecutive patients (O'Grady, 2003) concluded that sleep deprivation due to supine sleeping precautions led to increased anxiety and increase in night sedation and analgesia. An interview study of 56 hip replacement patients found that almost a quarter of patients did not engage in leisure activities one year after surgery (Wylde et al., 2012). Although both studies were small, they contribute to the view that hip precautions adversely affect patient quality of life and this topic has had relatively little attention. Pain and function are important predictors in outcomes postoperatively (Sharma et al., 2009) and patient's recovery (McHugh et al., 2013). Despite this, studies have focused on hip dislocation as their primary outcome, and have made little reference to pain and functional measures. There is a lack of studies of patients' opinions regarding precautions.

In addition, there are concerns about the cost of providing assistive equipment during routine practice (Drummond et al., 2012), which is associated with associated with a substantial economic and environmental burden (Restrepo et al., 2011). Removing the routine use of equipment and devices has been associated with a cost-saving of US $655 (~£448) per patient, including the cost of raised toilet seat ($65), and an elevated chair ($15/day to rent); this calculation does not account for transport costs, or loss of wages whilst not working (Peak et al., 2005). However, although some studies report a cost saving when removing traditional hip precautions and equipment (Duwelius et al., 2007; Peak et al., 2005), no studies, to our knowledge, have evaluated the costs of a no hip precautions regime following THR in the UK.

A Randomised Control Trial (RCT) would be the preferred method to evaluate hip precautions. However, this design is impractical as education and supply of equipment is usually service based, and extends from preoperative assessment clinics to provision of equipment in the community. It would, therefore, be unrealistic to provide hip precautions for half the sample and not for others across the whole pathway, as there would be the potential for widespread contamination and protocol infringement. Moreover, the number of participants required to demonstrate a difference between hip precautions and no hip precautions would be very large; previous studies that have focused on the rate of dislocation as the primary outcome have been underpowered (Coole et al., 2013; Smith et al., 2016). An RCT in our current setting is not feasible due to the way in which the service is based. The education of precautions and supply of equipment extends from preoperative assessment clinics to provision in the community. It would, therefore, be unrealistic to provide hip precautions for half the sample and not for others across the whole pathway; there would be the potential for widespread contamination and protocol infringement. Moreover, extensive discussions with staff suggest that, in practice, they would find an RCT impossible to administer as they work across wards. A multicentre clustered RCT is not currently feasible; we have previously discussed conducting a multicentre RCT with several hospitals, but they were not willing to participate.

We are fortunate that our local hospital is moving to a no precautions model of care and are modelling a before and after study around this service change. The decision to change practice was made over several years, and was on the basis of the lack of evidence to support the use of hip precautions. Protocols for interventions were developed with the MDT clinical leads, focussing on encouraging patients to move as comfortable, within their own pain limitations. This study will enable us to determine the value of hip precautions in routine clinical practice following elective THR.

METHODS/DESIGN

East Midlands - Nottingham 2 Research Ethics Committee has granted ethical approval for this study (Ref: 16/EM/0318).

Objectives
The primary objective is to determine the influence of routine hip precautions and no routine hip precautions following elective THR on patients' quality of life, functional performance, pain, sleep, mood, and satisfaction. The secondary objectives are to ascertain staff and patient perceptions of these two regimes, and to assess the cost of providing routine hip precautions and no routine hip precautions in the context of the current NHS service.

Design
Single-centre before and after study, with two consecutive cohorts of patients, reflecting a change in the delivery of the orthopaedic services to people having a THR. Before the change in service (phase one), patients will receive current 'routine' practice which involves the prescription of hip precautions. After the change in service (phase two), patients will be advised to move as they are able (i.e. no routine prescription of hip precautions). Questionnaire booklets will be completed at baseline, and one week, six weeks, and three months post-surgery to assess patient outcomes. There will be a 'washout' phase, of one to two months, between the two study phases to allow staff time to adjust to the new regime of treatment (no routine hip precautions) and eliminate any intervention contamination bias (i.e. prescribing routine hip precautions during the no routine hip precautions regime). Data will not be collected during this period. (See Fig 1.).

Interviews will commence part way through each phase to allow staff and patients to share their perceptions and experiences of the treatment provided during each phase.

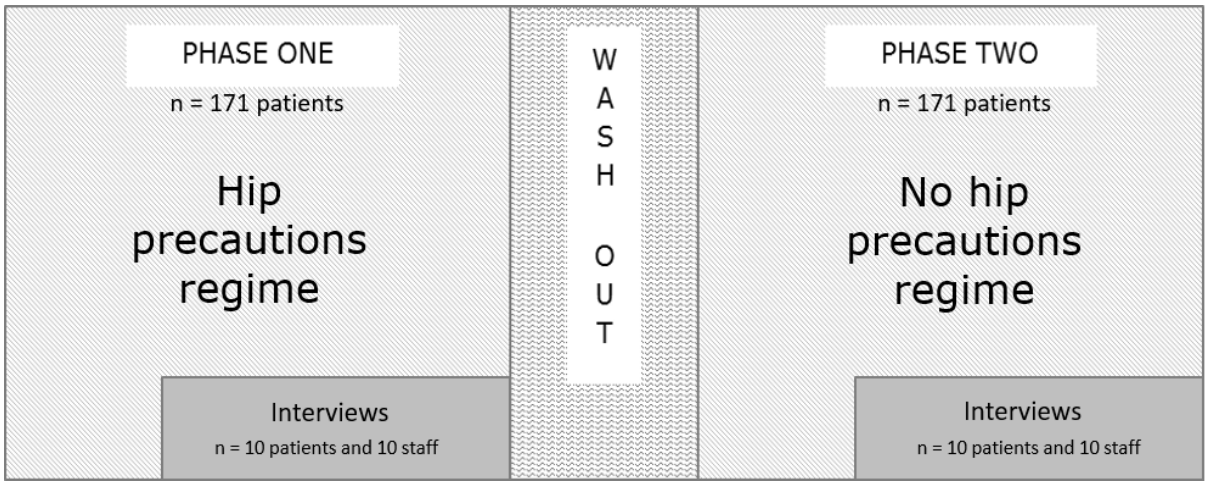

Figure 1. HippityHop study design

Recruitment
Prior to preoperative assessment clinics at Nottingham University Hospitals NHS Trust – Nottingham City Hospital, preoperative nurses and clinical teams will identify potential participants from lists of those awaiting elective THR. Participant information sheets will be sent to all eligible participants with their pre-operative assessment appointment letter. This will allow the participants at least 48 hours to consider participating in the study.

At their preoperative assessment appointment, clinicians will initially approach potential participants and ask them whether they have considered participating in the study. If a

potential participant is considering taking part in the research a member of the research team will approach them and answer any questions or queries that they may have.

Inclusion criteria

Participants will be eligible if they: i) are 18 years or over ii) are scheduled for an elective primary THR iii) provide written informed consent.

Exclusion criteria

Potential participants will be excluded if they: i) do not speak or read English ii) have previous history of revision surgery on either hip iii) are admitted for 'complex' (as defined by the surgeon, but typically involves bone grafting) or revision surgery iv) have dementia documented in their medical notes.

Participant Withdrawal

Participants may be withdrawn from the study either at their own request or at the discretion of the Investigator. The participants will be made aware that this will not affect their future care. Participants will be made aware that should they withdraw the data collected to date cannot be erased and may still be used in the final analysis.

Informed consent

All participants will provide written informed consent for the collection of their data including access to medical notes and for follow up assessment. Additional consent will be collected from participants recruited for the interviews.

Intervention

Participants will be recruited into either phase one or phase two, depending on the timing of their operation; in the first phase, they will have routine hip precautions, in the second these will have been withdrawn from service.

During phase one, patients will receive the treatment currently available, 'routine practice'. Routine practice will involve teaching patients about routine hip precautions and advise them about which movements they should avoid (e.g. flexion >90°, adduction, rotation). Patients will also be given opportunities to practice activities of daily living e.g. getting on and off chairs. Patients will be issued with a standard package of equipment including a raised toilet seat.

During phase two, patients receiving a THR will receive the new regime and will be encouraged to move as they are able, within a comfortable range of motion (ROM). Specialist equipment will only be given to those patients who require it.

Baseline Assessment

Participants will be asked to complete a questionnaire booklet following their preoperative assessment appointment; a researcher will assist those requiring help. Participants who do not have time will be given a questionnaire booklet to complete at home, along with a free post return envelope. The researchers' contact details will be displayed on the front of the questionnaire booklet for participants if they require any help completing the questionnaire booklet at home. Data will be collected on the following;

Demographic factors

Age, gender, living arrangements, place of residence on admission, and employment status.

Oxford Hip Score (Dawson, 1996)

Participants will be assessed on their level of pain and function, using the Oxford Hip Score (OHS). The OHS is also the most commonly used outcome following THR in the UK, and is routinely collected from patients following THR nationally. This is the primary outcome measure.

Nottingham Extended Activities of Daily Living Scale (NEADL) (Nouri and Lincoln, 1987)
Participants' functional performance of activities of daily living will be assessed using NEADL.

Hospital Anxiety and Depression Scale (HADS) (Zigmond and Snaith, 1983)
Mood and feelings will be assessed using the HADS. If a participant has a high anxiety score or a high depression score, one of the research team will contact them to discuss this, and may suggest they contact their G.P. However, it is the participants' choice whether they do this or not.

European Quality of Life questionnaire (EuroQol Group, 1990)
Health-related quality of life will be evaluated using European Quality of Life - 5 dimensional questionnaire (EQ-5D 5L) to assess function in social domains (mobility, self-care, usual activities, pain/ discomfort and anxiety/ depression).

Pittsburgh Sleep Quality Index (PSQI) (Buysse et al., 1989)
Quality of sleep will be examined using this scale which assesses sleep quality, latency, duration, and sleep disturbances. Participants will also be asked supplementary questions regarding sleep, such as 'what position do you normally prefer to sleep in?' and 'are you currently sleeping in your preferred position? If no, why not?'.

Pain relief medication
Participants will be asked about whether they are currently taking pain relief medication (prescribed or over the counter) and how often they are taking it.

In addition, we will collect medical information through assessment and from the medical notes or, if missing, will obtain the information from the medical staff.

- Side of operation (right or left) – recorded from medical notes
- Type of surgical approach – recorded from medical notes
- Current key medication – recorded from medical notes (e.g. for sleep, pain relief)
- Other key medical conditions or comorbidities (e.g. rheumatoid arthritis, osteoporosis, diabetes, obesity (measured by body mass index: BMI)) – recorded from medical notes.

Follow up Assessments
At one-week post-surgery, participants will be contacted by phone to complete the Oxford Hip Score questionnaire, and asked about any specific difficulties.

At six weeks and three months post-surgery, participants will be asked to complete final follow up questionnaire booklets. At six weeks, they will be asked to complete the questionnaire booklet at their outpatient surgery appointment. If a researcher is unable to attend the outpatient appointment, then the booklet will be sent to the participant via post with a free post return envelope. At three months, the booklet will be sent by post and participants will be asked to complete it and return it in the free post return envelope provided.

The follow-up questionnaire booklets include the baseline measures (quality of life, functional performance, pain, sleep, and mood) and additional questions relating to their recovery. These questions relate to whether they; have dislocated their hip; have had revision surgery; are currently taking any pain relief/ painkillers or sleeping medication; have been admitted and/ or readmitted to hospital. They will be asked supplementary questionnaires regarding sleep, such as 'what position are you currently sleeping in?', and about their satisfaction or otherwise with their treatment. Assistance with the questionnaire booklets can be provided to those participants who require it.

Qualitative Study

For the qualitative study, semi-structured individual interviews will be conducted during each phase of the before and after study. A sample of 20 patients, who participated in the before and after section of the study, and 20 members of staff will be interviewed across the whole study.

Patients will be selected using maximum variation purposive sampling, 10 participants from phase one and 10 from phase two of the before and after section of the study, to gain a greater, more in-depth understanding of patients' recovery. Following each phase, letters will be sent by post to those patients selected inviting them to be interviewed. Written consent will be obtained from the patient prior to commencement of the interview. Interviews will be conducted via telephone, video call (Skype, FaceTime), or face-to-face, according to participant preference, and will last no longer than 30 minutes. Face-to-face interviews with the patients will take place in their own home, at the University of Nottingham, or at Nottingham University Hospitals NHS Trust, whichever they prefer.

The patient interviews will include questions about experiences of recovery following surgery in either the routine hip precautions regime (phase one) or no routine hip precautions regime (phase two), and the facilitators and barriers to recovery. Patients will also be asked about their experiences of their rehabilitation, how they feel about the service that they received in terms of hip precautions, and their levels of satisfaction with aspects of their recovery. They will also be asked about their discussion of recovery regarding hip precautions with staff members.

Staff members, including nurses, surgeons, physiotherapists, and occupational therapists and their assistants, will also be purposively selected in each phase. Following completion of each phase, selected staff members will be contacted by letters distributed via the hospital mail, inviting them to be interviewed. Written consent will be obtained prior to commencement of the interviews, which will take place at the hospital. Interviews will last a maximum of 30 minutes.

The staff interviews will include questions about their experiences of assisting with patients' recovery following routine hip precautions (phase one) or no routine hip precautions (phase two). The interview aims to identify the facilitators and barriers to the change in the regime, and their attitudes towards changing the regime of routine hip precautions. They will also be asked about the discussions they have with patients in terms of recovery and routine hip precautions. Staff will be asked what advice and recommendations they give to patients following THR surgery, and what questions they receive from patients. Staff members will also be invited to discuss their perceptions of routine hip precautions and the service they provide to patients post-surgery.

The interviews will be digitally recorded and transcribed verbatim. Thematic analysis (Braun and Clarke, 2006) will be used to interpret the data. The data will be stored and managed with QSR International's NVivo qualitative data analysis software.

Cost Evaluation

Cost analysis will be used to evaluate the costs of a regime of no routine hip precautions compared to usual care (current practice) following THR. As part of the cost evaluation, a sample of 20 participants from each group will be randomly selected in order to assess the use of resources. Occupational therapists and physiotherapists, who provide treatment and care to THR patients, will be asked to monitor the number of times they visit the patient from admission to discharge, and the amount of time spent per visit. In addition, a record of the cost of equipment and minor adaptations provided or recommended to the selected participants will be kept. The cost of the time spent organising, ordering and teaching patients how to use the equipment will also be recorded.

Adverse Events

The occurrence of an adverse event as a result of participation within this study is not expected. However, we will record deaths, falls and hip dislocations at follow-up. This information will be obtained from the questionnaire booklets and patients' medical notes. We will have regular contact with the Trauma and Orthopaedic Audit Office, Nottingham University Hospitals NHS Trust, who will assist with identifying any dislocations during this study.

Criteria for terminating the study

The study will not be stopped. However, if the no routine hip precautions regime increases dislocation rates, then the service will be reviewed and this may affect the study.

ANALYSES

Sample size and justification

The total proposed sample will be 362 participants; 342 participants in the before and after study, and 40 participants in the qualitative study (this includes 20 participants from before and after study, and 20 members of staff).

The proposed sample for the before and after study, of 342 participants, was calculated using an equivalence design, i.e. having no routine hip precautions is neither inferior nor superior to using routine hip precautions, that is, that the difference between the means of routine hip precautions and no routine hip precautions falls within an a priori specified equivalence region.

The primary outcome, Oxford Hip Score, is the nationally accepted clinical instrument validated to measure disability pre- and post-surgery (Field et al., 2005), and will, therefore, be more sensitive than other disability measures for hip precaution therapy. As the OHS has not been used in previous research of hip precautions, the minimum clinical important difference (MCID) remains unknown. Therefore, Cohen's generic MCID for clinical outcomes in the standard deviation unit (SD) was applied, i.e. any difference more than 50% of SD of the continuous measure in the study will be considered as clinically significant (Cohen, 1988). With a pre-defined margin for equivalence (i.e. 0.5SD), 128 participants (64 per group) would be required to be 80% sure that the limits of a two-sided 95% confidence interval will exclude a difference in means of more than 0.5SD of the OHS.

As this is a before and after study, the difference may be confounded by factors other than hip precautions, e.g. age, gender, BMI, and femoral head size. Assuming there are four covariates which are different between the groups at baseline, the sample size would need to be increased by approximately 2 times the original size (256 participants: 128 per group) to enable the test for interaction. It is estimated that there will be a 25% attrition rate, so with this in mind, 342 participants (171 per group) will need to be recruited.

In the qualitative study, the sample size was based on the assumption that 20 patients and 20 members of staff across the two phases would reflect sufficient diversity within the time and resources available.

Methods

All statistical analyses will be conducted using SPSS or STATA. Statistical analysis will be conducted to test for equivalence between the Oxford Hip Score of the two groups. Additional

analyses will be conducted to identify factors that are associated with recovery, and to assess the changes in outcome variables over time.

Interview data will be stored in NVivo, and will be analysed using thematic analysis to identify and report themes within the data.

Cost evaluation data will be analysed using basic cost-effectiveness tools.

A full statistical plan will be written before the completion of the study.

Trial Management and Service User Involvement

The Chief Investigator (AD) has overall responsibility for the study and will oversee all study management. KS is the clinical lead for the study in Nottingham University Hospitals NHS Trust. CL has day to day responsibility for conducting recruitment, data collection, and data analysis

We have one patient representative, who has assisted us with specific tasks such as commenting on the layout of patient information sheets and with questionnaire booklet design and layout. In addition, we have had input from a patient group at the hospital and a number of clinical staff and previous THR patients have informed the study design.

DISCUSSION

The study will have important implications for the service provided locally and potentially nationally with regard to the use of routine hip precautions. The study will make significant contributions to the debate around hip precautions and will help determine the value of hip precautions in routine clinical practice following THR. The impact of the non-routine use of hip precautions on patients' recovery will also be determined.

Irrespective of the results, the study findings will be important. If there are no additional advantages to routine hip precautions, patients could resume everyday activities more quickly, potentially improving their quality of life earlier. This could also have significant potential savings to the NHS, and could free staff to work with more complex cases. Conversely, if withdrawing routine hip precautions is detrimental, then the need to adhere to strict precautions will be reinforced. The results will also contribute to the weak evidence base as outcomes which have been generally neglected, such as satisfaction and quality of life will be addressed.

Study limitations

A limitation to the study design is that, as participants are not randomised, there is potential for confounders within the study. Although we have doubled our sample size and included a comparison group, associations between the intervention and outcomes are still at risk of confounding variables or bias. We are using self-reported measures which have recognised limitations, such as participants not understanding or misinterpreting the question, participants providing a 'socially acceptable or desirable' answer, and participants providing extreme answers (e.g. exaggerating symptoms or abilities to perform tasks). However, all the measures we are using are well established in the area.

Study Status

This is an ongoing study. The first participant was recruited on 10th January 2017. At the time of preparing this manuscript, 182 participants had been consented and 164 have had data recorded. The study is due to finish July 2018.

Study Status

Ethical approval was obtained from the East Midlands – Nottingham 2 Research Ethics Committee on 14th September 2016 (Ref: 16/EM/0318). All participants provided written informed consent.

Declaration of Conflicting Interests

The authors confirm that there is no conflict of interest.

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